PENNSYLVANIA PATIENT SAFETY ADVISORY

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About the Pennsylvania Patient Safety Advisory

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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Editorial: None Is Perfect

In June, a series of problems with brachytherapy for prostate cancer at a Veterans Administration (VA) hospital in Philadelphia became front-page news in the *New York Times*,[1] as well as the *Philadelphia Inquirer*.[2] This series followed on the heels of congressional hearings on reports of widespread contamination of endoscopes alleged to have exposed thousands of patients to possible serious infections at VA medical centers in Tennessee, Georgia, and Florida.[3]

Ironically, the Veterans Health Administration (VHA) is renowned for its quality and safety programs. VHA developed strong, centralized, quality assurance programs, a patient safety center, and a detailed reporting system. If major problems can happen in a model system like VHA, is there any hope for facilities in Pennsylvania?

I propose that there are valuable lessons to be learned from the recent VA experiences for much smaller systems and facilities, as follows:

1. The potential for catastrophe is ever present and requires constant effort and vigilance for areas of weakness, even in the best healthcare delivery systems.
2. VHA is a highly centralized system with high levels of accountability to Congress for the healthcare of our veterans. When VHA detects a problem in the system and thoroughly investigates, the action plan has the potential to improve the care for a large number of patients. The Pennsylvania Patient Safety Authority has shown that reporting from a large number of small systems or facilities can also identify problems that, when investigated, can improve the care for large numbers of patients beyond a single experience at a single hospital.
3. Standardization across an entire system can produce a uniform, reliable result, but if not standardized around best practice, it can produce systematic, rather than sporadic, problems. Processes and outcomes need continued monitoring to make sure that the best practices are followed and result in the optimal outcomes.
4. Part of the problem with the brachytherapy, as reported in the papers, was the lack of compliance with existing protocols. For instance, it was reported that the program did not require the proceduralist to obtain radiographic images to confirm the location of the radioactive pellets and that the calculations were not done to determine the doses delivered.[2,4] Compliance with protocols needs to be verified and periodically monitored.

Patient safety is not a task. It is an integral part of the reliable delivery of quality healthcare and of quality improvement. Monitoring best practices, compliance with those practices, and outcomes is essential to quality improvement.

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Medication Monitoring Errors: Inappropriate Levofloxacin Doses

ABSTRACT

Measuring and monitoring a patient's clinical laboratory values is critical for diagnosing problems, gauging effectiveness of treatment, and selecting appropriate doses of many drugs. Breakdowns can occur when necessary monitoring of laboratory values is not ordered or performed or when abnormal levels occur and action is not taken by healthcare practitioners. More than 2,500 event reports submitted to the Pennsylvania Patient Safety Authority were specifically classified as errors involving drug-related clinical monitoring. Analysis reveals that 48% of the events reached the patient. The medication most frequently involved in these reports was levofloxacin (416 events), a drug that requires dosage adjustments based on renal function. Nearly 99% (345) of the 349 reports that included information regarding the node in which the error occurred identified the prescribing node. Almost 92% (382) of the event reports indicated that patients required dose adjustment due to renal function. Of the 416 events involving levofloxacin, 95.4% (397) occurred with patients who were 65 years of age or older, a population with naturally occurring age-related decreases in renal function. The majority (411) of these events was intercepted by practitioners before reaching the patient. Strategies to address these problems include obtaining baseline renal function information, ensuring that current laboratory and testing information is available to all practitioners, interfacing laboratory computer systems with order entry systems, and building computer-based clinical decision support to help guide medication dosing for patients with renal insufficiency. (Pa Patient Saf Advis 2009 Sep;6[3]:74-8.)

Introduction

Patient information helps practitioners select appropriate therapy. One set of critical patient-specific information is the patient's clinical laboratory values. Laboratory values provide information for a range of activities, including diagnosing problems and gauging effectiveness of treatment. Another area in which laboratory values play an important role is in medication and dose selection, especially for drugs that are dosed based on renal function, liver function, or drug levels. However, breakdowns can occur when necessary monitoring of laboratory values are not ordered and performed or when abnormal levels occur and are not acted upon by healthcare practitioners.

Pennsylvania facilities have submitted reports to the Pennsylvania Patient Safety Authority describing situations such as these, often involving antibiotics or anticoagulants. Clinical analysts reviewed 2,564 event reports submitted to the Authority from June 2004 through November 2008 that categorized the event type as "Medication Error, Monitoring Error, Clinical (lab value, vital sign)." Further breakdown of these events by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,[1] shows that 48% (1,227) of the events reached the patient (harm index = C to I), 0.7% (18) of the events resulted in harm significant enough to require additional treatment, and one event contributed to a patient death.

It was anticipated that medications that require intense, regular monitoring to ensure their safe and effective use, such as heparin, enoxaparin, warfarin, vancomycin, gentamicin, and insulin, would be predominant in the data. Some of these medications appear in the top five medications cited in the reports (see Table 1); however, levofloxacin (Levaquin®) is the medication most often cited. Therefore, the analysis focused on levofloxacin to determine why and where in the process these errors are occurring.

Levofloxacin Use and Dosing

Levofloxacin is classified as a fluoroquinolone antibiotic.[2] It has a broad spectrum of activity against gram positive, gram negative, and atypical organisms. A variety of infections, including lung, sinus, skin, and urinary tract infections, can be treated with levofloxacin, including hospital- and community-acquired pneumonia, acute bacterial sinusitis, complicated and uncomplicated skin infections, and acute pyelonephritis. Levofloxacin is available in oral solid, oral solution, and intravenous injectable formulations.

The dosing of levofloxacin is first based on indication. While the duration of treatment may vary, levofloxacin is typically administered in daily doses. For example, oral levofloxacin is administered every 24 hours, and levofloxacin injection is infused over 60 to 90 minutes every 24 hours (see Table 2).

The second critical piece of information needed to safely prescribe levofloxacin is the patient's renal function. Appropriate laboratory studies and clinical observation is indicated before and during therapy

Table 1. Top 5 Medications Involved in Therapeutic Monitoring Error Reports (n = 1,294)

MEDICATION	TOTAL
Levofloxacin	416
Heparin	387
Vancomycin	180
Insulin	170
Warfarin	141

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since elimination of levofloxacin may be reduced in patients with renal impairment. Patients with a creatinine clearance (CrCl) below 50 mL/min require dose adjustments.[2] These adjustments may be accomplished by administering the same dose less frequently (e.g., 750 mg every 48 hours versus 750 mg daily) and/or administering a lower dose. Table 3 provides more detailed information regarding dosing adjustments for adults with renal impairment. Failure to adjust a dose of levofloxacin based on renal function may place patients at greater risk of adverse reactions. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and renal function should be monitored. Potential adverse events with levofloxacin include neurotoxicity (e.g., confusion, dizziness, tremors, seizure), *Clostridium difficile*-associated colitis, prolongation of QTc interval, phototoxicity, and tendon rupture.[2,3]

Analysis of Levofloxacin Event Reports

The analysis of the levofloxacin-related event reports (416) submitted to the Authority included a review of the nodes—prescribing, transcription/order processing, preparation/dispensing, administration, and monitoring—of the medication-use process in which the event occurred, each report's description, and the age of the patient. Failure to use critical patient information during the various nodes, or stages, of the medication-use process, particularly during the prescribing phase, can lead to inappropriate dose selection.

Clinical analysts specifically reviewed the nodes in the medication-use process in which the error occurred, as reported by the facilities (see Table 4). Overwhelmingly, facilities indicated that errors involving levofloxacin originated in the prescribing phase. Nearly 99% (345) of the reports that included information regarding the node(s) identified the prescribing node. Even though these reports were classified as errors involving drug-related clinical monitoring, none of the reports indicated an error during the monitoring phase.

The reports indicate that pharmacists are intercepting a large number of the errors associated with levofloxacin. This may be a result of independent pharmacist

Table 2. Dosage in Adults with Normal Renal Function (Creatinine Clearance Greater Than or Equal to 50 mL/min)

TYPE OF INFECTION	DAILY DOSE (IN MG)	DAYS OF TREATMENT
Hospital-acquired pneumonia	750	7 to 14
Community-acquired pneumonia	500 750	7 to 14 5
Acute bacterial sinusitis	750 500	5 10 to 14
Acute bacterial exacerbation of chronic bronchitis	500	7
Complicated skin and skin structure infections	750	7 to 14
Uncomplicated skin and skin structure infections	500	7 to 10
Chronic bacterial prostatitis	500	28
Complicated urinary tract infection or acute pyelonephritis	750 250	5 10
Uncomplicated urinary tract infection	250	3
Inhalational anthrax (postexposure)	500	60

Source: Ortho-McNeil-Janssen Pharmaceuticals, Inc. Levaquin® (levofloxacin) [full prescribing information] [online]. 2008 Sep [cited 2009 Apr 15]. Available from Internet: http://www.levaquin.com/levaquin/shared/pi/levaquin.pdf.

Table 3. Dosage Adjustment in Adult Patients with Renal Impairment

CREATININE CLEARANCE (CRCL) GREATER THAN OR EQUAL TO 50 ML/MIN	CRCL 20 TO 49 ML/MIN	CRCL 10 TO 19 ML/MIN	HEMODIALYSIS OR CHRONIC AMBULATORY PERITONEAL DIALYSIS
750 mg daily	750 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours
500 mg daily	500 mg initial dose, then 250 mg daily	500 mg initial dose, then 250 mg every 48 hours	500 mg initial dose, then 250 mg every 48 hours
250 mg daily	No dosage adjustment required	250 mg every 48 hours (No dosage adjustment needed for uncomplicated urinary tract infection)	No dosing adjustment information available

Source: Ortho-McNeil-Janssen Pharmaceuticals, Inc. Levaquin® (levofloxacin) [full prescribing information] [online]. 2008 Sep [cited 2009 Apr 15]. Available from Internet: http://www.levaquin.com/levaquin/shared/pi/levaquin.pdf.

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review of a patient's CrCl or the pharmacy computer system alerting pharmacists to abnormal CrCl values. Analysts noted that pharmacists intercepted at least 48% (199) of the 416 levofloxacin-related events. Of the reports that indicated the error occurred in the prescribing node, pharmacists caught roughly 57% (198). Analysts identified these reports according to wording included in the event details, such as "PharmInt" (i.e., pharmacy intervention), "pharmacist recommend to change the dose," and "Doctor changed order after speaking with pharmacist."

It is likely that pharmacists intercepted more of the levofloxacin-related events. For example, analysts found an additional 95 reports attributed to the pharmacy that indicated that the dose had been "clarified" or the prescriber was "called," "contacted," or "notified," resulting in a change in dose. If these were actual pharmacist interventions, then the number of events that pharmacists intercepted would be 294 or roughly 70% of the levofloxacin-related events. Of the remaining 122 reports, 117 indicated the error had been caught before reaching the patient, but it was not possible to determine whether the error had been detected by a prescriber, pharmacist, nurse, or patient. This data shows that effective pharmacy and nursing intervention programs can intercept medication errors and generate data that can be analyzed to identify failure modes in the medication-use system.

The Authority does not require facilities to include specific laboratory information for this event type when submitting reports through its reporting system. However, for 62.3% (259) of the 416 levofloxacin-related reports, facilities included specific patient laboratory values in the event description field; all of these patients had below normal renal function (e.g., CrCl below 50 mg/mL) (see Table 5). This laboratory information appears to not have been referenced during the prescribing phase despite the need to adjust the levofloxacin dose when a patient's CrCl falls below 50 mg/mL to avoid drug accumulation and decrease risk of toxic reactions. Another 29.6% (123) of the event reports documented that the levofloxacin dose was reduced due to renal function but did not provide actual laboratory values.

Potential contributing factors to the prescribing and dispensing of inappropriate levofloxacin doses may include the following:

- Prescribers may not be aware of the need to assess renal function and adjust doses as necessary.
- Clinical laboratory values may not be readily available to practitioners at the time of prescribing, dispensing, and administering. Even in facilities with electronic systems, laboratory computer systems may not interface with computerized prescriber order-entry (CPOE) and pharmacy computer systems.[4] If the systems do interface, CPOE and pharmacy computer systems may not generate alerts to warn practitioners about high doses with respect to serum creatinine levels.[5]
- CPOE systems may not have effective computer-based clinical decision support to help guide appropriate dose selection for patients with renal insufficiency or advanced age.[4,6]
- The clinical status of the patient may require administration of a first dose of an antibiotic before an accurate assessment of renal function is available.

Another piece of patient information that should at least trigger investigation of the need for dose adjustments is the patient's age. Decreased muscle mass and a corresponding lower production of creatinine in the elderly patient may give the impression that the patient's serum creatinine level, and therefore renal function, is "normal."[7] However, it is well known that renal function decreases with age.[8] Cross-sectional studies have shown that renal function, specifically glomerular filtration rate as measured by CrCl, decreases as age increases.[9,10] Therefore, age-related changes in pharmacokinetics may be expected.

The event reports suggest that many prescribers are not using age as a signal to consider or investigate potential age-related decreases in renal function before prescribing levofloxacin. The age of the patient was disproportionally skewed toward the elderly population. Of the 416 events involving levofloxacin, 95.4% (397) occurred with patients who were 65 years of age or older. In fact, a vast majority (91.9% [365]) was 75 years of age or older (see Table 6).

Risk Reduction Strategies

Healthcare facilities should take steps to safeguard the prescribing, dispensing, and administering of

Table 4. Nodes of the Medication-Use Process in which Events Occurred (n = 349)*

NODE	TOTAL
Prescribing	345 (98.9%)
Transcription	1 (0.3%)
Preparation	1 (0.3%)
Administration	5 (1.4%)
Monitoring	0

* Facilities may select more than one node for a given report; therefore, percentages may be greater than 100%.

Table 5. Below Normal Creatinine Clearance Values Documented in Event Reports (n = 259)

CREATININE CLEARANCE (ML/MIN)	TOTAL
20 to 49	215 (83%)
10 to 19	32 (12.4%)
Less than 9	12 (4.6%)

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levofloxacin, as well as other medications that require routine monitoring of laboratory values to maintain appropriate dosing. Examination of the prescribing process for levofloxacin, in particular, should be reviewed as inappropriate doses are being prescribed to patients, especially elderly patients. Based on the review of reports submitted to the Authority, as well as observations at the Institute for Safe Medication Practices and in the literature, strategies include the following:

- Determine the microbiological indication for levofloxacin.
- Obtain baseline patient information such as age and renal function information (e.g., serum creatinine, CrCl). Continue to assess renal function throughout therapy and over time to obtain a true picture of the patient's renal function. Adjust the dose as necessary for patients with renal impairment.[2]
- In the event that CrCl data is not available, consider dosage adjustments based on age. It can be expected that elderly individuals may have lower CrCl values due to age-related reduction in renal function.[9,10]
- Use appropriate assessment techniques (and/or patient information such as age or laboratory values) before drug administration.
- Ensure that current laboratory and testing information is available to all practitioners. Work with physicians' offices to develop a process for communicating this essential patient information timely and efficiently.
- Work with vendors to interface the laboratory system with CPOE and pharmacy systems. During order entry, computer systems should warn practitioners when these agents are about to be used for patients with decreased renal function.[11] Computer-based clinical decision support to help guide medication dosing for patients with renal insufficiency can result in improved dose and frequency choices.[12]
- Expand organizational medication-use policies to include the provision that medications are not prescribed, dispensed, or administered unless relevant clinical information such as critical laboratory values for patients are available and considered by practitioners.[13]

Table 6. Patients 65 Years of Age or Older (n = 397)

AGE (YEARS)	TOTAL
65 to 69	6 (1.5%)
70 to 74	26 (6.6%)
75 to 79	64 (16.1%)
80 to 84	95 (23.9%)
85 or older	206 (51.9%)

- Provide essential patient information, including patient age, height (cm), weight (kg),[14,15] allergies with descriptions of the reactions, previous adverse drug reactions with manifestations, diagnosis, and comorbid conditions (e.g., renal impairment) at the *top* of all preprinted order sets, medication administration records, and pharmacy patient profiles, as well as screens within future CPOE systems.
- Create competency statements for the medical and pharmacy staff to use laboratory parameters when necessary to check on the proper dosing of drug therapy. Consider specific competency exercises on appropriate patient and dose selection for levofloxacin.
- Develop efficient methods for collecting and documenting information on prescribing errors through the tracking of pharmacy and nursing interventions. Once collected, refer to the following strategies:
  - Present quarterly aggregate information at the pharmacy and therapeutics committee meetings and to the medical board.
  - Gain insight into why such prescribing errors are occurring, and generate ideas for improvement.
  - Work with the medical staff to take action (e.g., establish prescribing/dosing guidelines, develop drug protocols, design preprinted order forms) on identified problems, and evaluate their effectiveness (e.g., perform medication-use reviews, monitor use of protocols).
  - Provide frontline, leadership, and medical staff with ongoing information on errors prevented by pharmacy and nursing interventions.

Notes

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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.

1. Which node of the medication-use process is associated with the highest number of levofloxacin-related events?
   a. Administration
   b. Monitoring
   c. Prescribing
   d. Preparation
2. Potential adverse events with levofloxacin include all of the following EXCEPT:
   a. Prolongation of the QTc interval
   b. Ototoxicity
   c. *Clostridium difficile*-associated colitis
   d. Tendon rupture
3. Potential contributing factors to the prescribing of inappropriate levofloxacin doses may include all of the following EXCEPT:
   a. The clinical status of the patient may require the immediate administration of a first dose of an antibiotic.
   b. Computerized prescriber order-entry (CPOE) systems may not have effective computer-based clinical decision support to help guide appropriate dose selection.
   c. Essential patient information is provided at the *top* of all preprinted order sets and medication administration records, as well as screens within CPOE systems.
   d. Clinical laboratory values may not be readily available to practitioners at the time of prescribing.
4. All of the following are risk reduction strategies to prevent errors with levofloxacin EXCEPT:
   a. Obtaining baseline patient information such as age and laboratory results
   b. Developing efficient methods for collecting and documenting information on prescribing errors
   c. Working with vendors to interface the laboratory system with CPOE systems
   d. Selecting a dose based on the patient's liver function
5. A 77-year-old female is diagnosed with acute bacterial exacerbation of bronchitis due to *H. influenzae*. The prescriber wants to order levofloxacin, which the patient used successfully about five years ago, to treat the infection.

   What would be the appropriate approach to dosing this patient to minimize the risk of adverse events?
   a. Check the patient's renal function.
   b. Order a normal dose for the given indication.
   c. Order the same dose the patient received in the past.
   d. Check the patient's liver function.

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Connecting Remote Cardiac Monitoring Issues with Care Areas

ABSTRACT

Patients in noncritical settings may have underlying cardiac conditions or demonstrate unexpected symptoms and condition changes that require continuous or physiologic cardiac monitoring or transfers to a higher level of care, for which appropriate treatment may be delayed due to bed unavailability. Many facilities implement remote cardiac monitoring to facilitate alarm notification. Remote cardiac monitoring of patients in noncritical care areas alerts healthcare providers about patient condition changes, which may avoid further deterioration of patient conditions and potential cardiac arrests. Remote cardiac monitoring alone does not ensure patient condition changes are successfully communicated to appropriate healthcare providers. Seventy-four percent of the 194 Incidents and Serious Events reported to the Pennsylvania Patient Safety Authority from June 2004 to December 2008 associated with remote cardiac monitoring were issues with communication or monitoring problems. Monitoring problems include the failure to monitor, the unavailability of monitors, or delay in monitoring. Healthcare providers may consider incorporating risk reduction strategies that include more effective communication between care areas, delineation of personnel responsibility, and standard protocols for alarm conditions. (Pa Patient Saf Advis 2009 Sep;6[3]:79-83.)

Patients in noncritical settings may demonstrate unexpected symptoms and condition changes that require cardiac monitoring or transfer to a higher level of care. Remote cardiac monitoring is one of many important telemedicine applications available in today's healthcare environment. Remote cardiac monitoring provides additional surveillance for patients, typically at locations outside the care areas.[1] This type of cardiac monitoring generates visual and audible alarm signals based upon condition changes that exceed established alarm limits for a specific patient.[2]

Remote cardiac monitoring of patients in noncritical settings provides the physiological monitoring and identification of potential cardiac arrhythmias by qualified staff in a centralized remote location away from the patient care area. For example, remote cardiac monitoring observation may be performed by intensive care unit (ICU) nurses who have the added responsibility of balancing the demands of a typical caseload of critically ill patients with responding to remote arrhythmia alarms for patients in other care areas.[3] Remote cardiac monitoring may also be performed by technicians or monitor watchers who may be responsible for as many as 50 monitors of patients in different care areas simultaneously.[1] More recently, technological advances have introduced new electronic telemonitoring methods such as the electronic ICU, the war room (a central command center for telemetry), and Tele-ICU.[1-5]

In remote cardiac monitoring, individuals who monitor surveillance are also responsible for capturing data and alerting staff in the appropriate care area about any changes in patient physiological conditions so that bedside assessments may be conducted and appropriate care is delivered.[6] Remote cardiac monitoring enhances patient safety by providing noncritical patient care areas with rapid cardiac data transmission, improves communication through use of real-time data, and reduces liability.[7,8] Late recognition of arrhythmias and symptoms may lead to potentially avoidable deaths.[9,10] Remote cardiac monitoring helps in the early identification of physiological changes, guides appropriate therapies, results in better clinical outcomes, and enhances operating efficiency.[9]

Remote Cardiac Monitoring Event Data Reported to the Authority

There were 194 Incidents and Serious Events, including 12 deaths, reported to the Pennsylvania Patient Safety Authority from June 2004 to December 2008 associated with remote cardiac monitoring. The most frequently cited types of failure in these reports were as follows:

- Communication issues
- Delayed or incorrect placement
- Power failures (including disconnection of devices from their power sources and failure to replace batteries)

Communication Issues

Of the 194 reports submitted to the Authority from June 2004 to December 2008, 74% of these events included issues with communication and delayed monitoring, or failure to place a patient on monitoring, or incorrect monitoring placement (see Table). The reports indicate breakdown in communication between the healthcare providers performing surveillance and those administering care to the monitored patients in the noncritical care areas. Seventy-three event reports indicated communication issues. The majority of the communication issues involve failures to implement remote cardiac monitoring orders and to identify arrhythmias. Examples of these events include the following:

> *Patient was seen in the postanesthesia care unit, and remote telemetry was ordered [after transfer to the floor]. Patient arrived on floor [one hour later]. [Remote telemetry] orders were not communicated to floor, so a remote telemetry monitor was not reserved.*

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Table. Remote Cardiac Monitoring Events Reported to Pennsylvania Patient Safety Authority, June 2004 to December 2008

REMOTE CARDIAC MONITORING ISSUES	NUMBER OF REPORTS	PERCENTAGE (%)
Communication	73	38%
Unavailable/delayed/ not placed	69	36%
Patient condition (e.g., arrhythmia, seizure, fall)	24	12%
Battery problem or disconnection	17	8%
Wrong patient	11	6%
Total	**194**	**100%**

After reviewing the patient's chart, it was discovered that the patient was transferred from the ICU to [a patient care area]. Staff did not notify the [monitoring] nurse or the monitor station that the patient was ordered remote monitoring.

Patient was to have remote telemetry once admitted to the floor. The emergency department (ED) handoff communication form did not [indicate remote telemetry was] needed for the patient. The patient [was] admitted to the floor and had been transported with a monitor in use. The ED nurse who transported the patient did not know if the patient was to have remote [telemonitoring], and there was no handoff [communication].

Remote telemonitoring was ordered on admission. The order was signed off, but a telemetry monitor was never [secured] for the patient.

A telemetry unit was transmitting [a heart rhythm] with a full signal but with[out] patient information. The unit [where the signal was transmitting from was called] and was not aware of any admission to telemetry. [The unit staff were notified that] the transmission was coming from their unit and the monitor was found on a patient in [that unit].

A telemetry monitor was placed on a medical surgical patient, but the monitoring ICU was not aware of the need to [remotely] monitor the patient until 10 hours later.

Delayed or Incorrect Placement

Sixty-nine of the remote cardiac monitoring reports indicated lack of monitor availability or delays in placing a patient on monitoring. The reports do not always convey why monitor placement was delayed, which may have been based on other factors unrelated to remote cardiac monitoring, such as workload. Examples include the following:

A physician ordered remote cardiac monitoring. The order was discovered [15 hours later]. The patient was placed on the monitor upon discovery of the event.

Orders to start remote telemetry were written [but not initiated for nearly 10 hours]. Intravenous Lopressor® had been administered [four hours after the remote telemetry orders were written], which was the reason for monitoring.

A physician ordered remote monitoring but [the monitoring] nurse was not notified, resulting in a delay. The patient was placed on the monitor [16 hours later].

The remote monitor assigned to [patient A] was sent to the ED but was placed on [patient B], whose assigned remote monitor was placed on [patient A]. [This] resulted in the wrong rhythm information for both patients; [patient A] was not in an [arrhythmia as the monitor indicated] and [patient B] was [experiencing an arrhythmia] and not in [a normal sinus heart] rhythm [as the monitor indicated].

A patient on a medical/surgical unit was placed on remote telemetry monitor and monitored by nurses in the cardiac care unit (CCU). A sticker with patient's name found on the desk–indicating telemetry #4 being used for this patient–was showing a monitor pattern. Nurses later found a discontinuation notice for this same telemetry [#4] on a different patient's [chart]. When investigated, the patient whose telemetry was discontinued was still on telemetry and the CCU nurses were monitoring [the patient's] pattern for [the patient] on telemetry #4, which was never turned on. [Nine hours after arriving on the medical/surgical unit], telemetry #4 was turned on and the correct patient was being monitored. Unable to check anything in telemetry memory since [the monitor] was not turned on.

Power Failures

Seventeen of the reports involved failures related to the remote cardiac monitors' power supplies. These included improper battery insertion or absent battery issues. Examples are as follows:

The monitoring telemetry unit called the [patient care] unit to say that they did not have a reading on a patient and [requested a battery change] because there was no signal. [The monitor was checked and it was] discovered that there were no batteries in the monitor.

A patient was admitted from the ED [to a patient care area] and ordered remote telemetry. Upon arrival to the [patient care area], the patient information was loaded into the monitor but the rhythm was not visible to the monitor technician. Upon checking the monitor, staff discovered the batteries were inserted backward.

Clinical Guidelines

In 2004, the American Heart Association (AHA) issued a scientific statement from the Councils on Cardiovascular Nursing, Clinical Cardiology, Cardiovascular Disease in the Young, and the International Society of Computerized Electrocardiology to update and expand the scope of the best practice standards for in-hospital electrocardiographic monitoring.[8] These comprehensive guidelines outline the need for 24-hour human surveillance of monitors, appropriate staff levels consisting of qualified physicians and nurses in critical and noncritical care areas, and the

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development of protocol and procedures for common arrhythmias for in-hospital hard-wire and telemetry cardiac rhythm monitoring systems for adults and children. A rating system was developed by the American College of Cardiology Emergency Cardiac Care Committee in 1991, which is still used today to classify common clinical conditions for cardiac monitoring. This rating system categorizes patient conditions into three classes, depending on the severity of medical indications. Class I signifies patients at significant risk of an immediate, life-threatening arrhythmia for which cardiac monitoring is indicated. Class II patients may benefit from cardiac monitoring, but it is not essential for all patients of this class type. Cardiac monitoring is not indicated in Class III patients because the risk of a serious arrhythmia or the therapeutic benefit is low with these patients.[8]

The AHA's scientific statement is based on expert opinions, supported by clinical experience, and indicates that regardless of the technologic advances over the last 40 years, the electrocardiogram (ECG) contains a wealth of diagnostic information and its interpretation continues to require human oversight.[8] Despite the more aggressive treatment methods for arrhythmias, the use of new drugs (which have the potential to cause certain arrhythmias), and the introduction of new technology, only humans can determine whether individual patients will require cardiac monitoring either remotely or in ICUs.[8]

Clinical Literature

Hodgett et al. conducted a retrospective review that examined the odds of potentially avoidable cardiac arrests in non-ICU patient care areas and found that they were 5.1 times greater for these patients than those in critical care areas. In 48% of 78 cases, personnel failed to act on the clinical signs of deterioration in the 24 hours preceding the cardiac arrest. The study cited system failures, which included errors and delays in diagnosis, (eight delays in diagnosis were due to incorrect ECG interpretation; of these, six were missed myocardial infarctions), inadequate interpretation of investigations, incomplete treatment or a failure to appreciate the severity of patient conditions, and personnel inexperience. The review indicated that the majority of the non-ICU cardiac arrests are potentially avoidable and are the result of multisystem failures.[10]

Billinghurst et al. conducted a prospective observational study of 420 hours of observation in a nine-bed coronary respiratory care unit to determine the frequency of rhythm disturbance events among patients being remotely monitored by telemetry nurses, as well as the number of detected cardiac events and the effect of the events on telemetry nurses' workload.[3] There were a high number of remote telemetry warning arrhythmias, though 80.2% were artifact. Warning alarms occurred every 2.1 to 6.2 minutes, and although no malignant arrhythmias were noted during this study, telemetry nurses detected 60% to 100% of valid warning alarms. This added surveillance contributes to the competing demands placed on telemetry nurses and has the potential to negatively affect patient safety and the nurses' caseloads. These demands may delay or impede communication between the telemetry staff and the patient care area staff. Upon detection of a potentially fatal arrhythmia by the telemetry nurse, its prompt communication to the appropriate nurse, and the quick response, assessment and treatment by the nurse in the non-ICU area may be delayed due to competing workload demands.[3]

A prospective observational study conducted by Tsien et al. looked at the accuracy in determining positive predictive value of routine monitoring alarms and causes for false-positive alarms.[5] This study assessed the effectiveness of ICU alarms in alerting personnel to significant changes in patient conditions. False alarm rates were found to be extremely high, while positive predictive values were very low. Of the 2,942 total alarms, 86% were found to be false positive, 6% were classified as clinically irrelevant true alarms, and only 8% were determined to be true alarms with clinical significance. High false-positive rates may lead to the disabling of alarms by ICU personnel, as they can be distracting and annoying. Other competing auditory sounds in the ICU may also be confusing for ICU personnel who must determine the source of the alarms, particularly if they have the added responsibility for the remote cardiac monitoring surveillance of patients in noncritical care areas.[5]

Risk Reduction Strategies

Healthcare providers may use a number of strategies to facilitate communication about remote cardiac monitoring. Consider addressing the following key elements for use of remote cardiac monitoring of patients in noncritical care areas.

Communication

Implementing effective alarm notification can provide organizations with a communication process that begins with the monitoring system and ends with appropriate assessment and care provided to the patient in the noncritical care area. This process would include developing communication protocols that identify backup coverage and ensure staff notification when the primary caregiver is unavailable.[11] Some communication methods include the use of smart phones, cell phones, or personal digital assistants, although there may be problems with limited memory and security concerns to consider.[7,12] Wireless technology may add more access points for remote cardiac monitoring, improve workflow, and decrease dead zones within the care areas, but it can be more expensive than other applications.[1,9,10-14] What is key in alarm notification is that the communication of the alarm signal is delivered to the surveillance person, who communicates this information to the nurse in the patient care area, not just to the device.[12]

Responsibility Delineation

Organizations may consider the development of surveillance protocols for the remote cardiac monitoring

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of noncritical patients and the assessment and care of the remote cardiac monitoring of noncritical patients. Consider including standing orders for placing patients on remote cardiac monitoring and verifying waveform and numerics at the monitoring station.[6] Ongoing education and competency skills of monitor surveillance staff may include the ability to recognize computer algorithms, to ensure proper skin preparation and accurately place monitoring electrodes, to ensure appropriate heart rate alarm settings, and to measure heart rate and intervals using ECG calipers. Ensure monitor surveillance staff are qualified to verify alarm conditions on cardiac monitors by providing regular refresher programs that include validation of arrhythmia interpretation skills and problem solving case-based scenarios.[6] Ensure noncritical care area nurses are qualified to respond to and assess arrhythmias by providing regular competency reviews that include the demonstration of patient care provided to simulated malignant arrhythmias.[1,5,8-10,14]

Standard Protocols for Alarm Conditions

Developing alarm setting protocols that are tailored for individual patient needs that are communicated during shift change and handoff communications may minimize nuisance alarms and remove excess alarm noise.[6] Monitor technicians may be better equipped to filter false alarms and thereby reduce the number of false alarms that reach the monitoring nurses.[1,9,12,15] Organizations may consider developing policies that address regular battery replacement of cardiac monitors, as well as training and implementing reminders about battery replacement to reduce improper battery insertion in remote cardiac monitoring devices.[6] Technological advances include the electronic ICU, the war room (a central command center for telemetry), and Tele-ICU that enable uninterrupted care to ICU patients across multiple hospitals using remote and often intensivist-led multidisciplinary teams. These advances augment on-site care and interventions, ensure continuous care, and can provide hospitals with the ability to track outcomes of performance improvement indicators.[1-5]

Conclusion

Remote cardiac monitoring enhances patient safety by providing noncritical patient care areas with rapid cardiac data interpretation, improves communication through use of real-time data, and reduces liability.[7,8] Remote cardiac monitoring assists in the early identification of physiological arrhythmia changes and directs appropriate assessment and treatment.[9] Remote cardiac monitoring results in better clinical outcomes and enhanced operating efficiency. Risk reduction strategies that healthcare providers may implement when using remote cardiac monitoring of patients in noncritical care areas include the key elements of clear communication protocols, responsibility delineation, and standard practices protocols for alarm conditions.

Supplementary Review

A March 2008 *Pennsylvania Patient Safety Advisory* supplementary review discussed the results of a failure mode and effects analysis (FMEA) about alarm interventions during medical telemetry monitoring. Healthcare facilities can use the published results of this FMEA to understand telemetry monitoring alarm response processes and similar process failures and as an aid to develop facility-specific risk reduction strategies. The complete review, "Alarm Interventions during Medical Telemetry Monitoring: A Failure Mode and Effects Analysis," is available on the Pennsylvania Patient Safety Authority's Web site at http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/mar5(suppl_rev)/Pages/mar5(supplrev).aspx.

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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.

1. Benefits of remote cardiac monitoring of patients in noncritical settings include all of the following EXCEPT:
   a. Early identification of potential cardiac arrhythmias
   b. Additional surveillance of patients typically at locations outside the patient care areas
   c. Improved communication between healthcare providers through the use of real-time data
   d. Assurance that remote cardiac monitoring alone provides successful communication of patient condition changes to appropriate healthcare providers
2. Problems identified with remote cardiac monitoring in the noncritical setting include all of the following EXCEPT:
   a. Communication problems
   b. Delayed or incorrect cardiac monitor placement
   c. Disconnection of cardiac monitoring device from power sources
   d. Scope of practice delineation problems
3. The American College of Cardiology Emergency Cardiac Care Committee's rating system provides which of the following guidance statements about cardiac monitoring in Class I patients?
   a. Cardiac monitoring may benefit these patients.
   b. Cardiac monitoring is not essential for these patients.
   c. Cardiac monitoring is indicated for these patients who are at significant risk of an immediately life-threatening arrhythmia.
   d. Cardiac monitoring is not indicated for these patients because the risk of serious arrhythmias is low.
4. The American College of Cardiology Emergency Cardiac Care Committee's rating system provides which of the following guidance statements about cardiac monitoring in Class III patients?
   a. Cardiac monitoring is not indicated for these patients because the risk of serious arrhythmias is low.
   b. Cardiac monitoring is not essential for these patients.
   c. Cardiac monitoring is indicated for these patients who are at risk of an immediate, life-threatening arrhythmia.
   d. Cardiac monitoring may benefit these patients.
5. Remote cardiac monitoring generates visual and audible alarm signals, based on condition changes that exceed established alarm limits for a specific patient.
   a. True
   b. False

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Epidural or Subarachnoid Catheter Shear

ABSTRACT

Epidural or subarachnoid catheters (sometimes called lumbar drainage catheters) are very small hollow tubes inserted into the epidural or subarachnoid space to administer medications or drain body fluids, respectively. Under certain conditions they can shear, leaving a fragment in the patient. Between June 2004 and December 2008, the Pennsylvania Patient Safety Authority received 13 reports related to epidural or subarachnoid catheter shear. However, most catheter procedures occur without complications. The predominant causes of catheter shear are applying excessive force while removing the catheter, withdrawing the catheter back through the needle, withdrawing the catheter over a deformed or damaged needle bevel, or damaging the catheter during or after placement in the patient. Defects in the catheter occuring during the manufacturing process can also be a cause of catheter shear. The position of the patient during insertion and withdrawal of the catheter can play an important part in reducing the likelihood of fracturing the catheter. For difficult-to-remove catheters, allowing the patient's back muscles to relax for a few days may facilitate the removal in some cases. Unless complications arise, surgery is unnecessary in most cases since catheters are constructed from inert materials.
(Pa Patient Saf Advis 2009 Sep;6[3]:84-6.)

At the request of a Patient Safety Officer at a Pennsylvania healthcare facility, Pennsylvania Patient Safety Authority analysts examined events of sheared spinal and epidural catheters reported between June 2004 and December 2008. During that time, 13 events were reported to the Authority relevant to spinal and epidural catheter shear, which corroborate reports in current literature. The following are examples of reports of spinal and epidural catheter shear submitted to the Authority:

> *A lumbar puncture was attempted to rule out meningitis. Noted 1.5 mm puncture or possible sheared area on soft catheter withdrawn from vertebral space. Apparently, reentering the trocar into the soft catheter while attempting entry in the cerebrospinal column punctured/sheared the catheter.*

> *While doing a lumbar drain, the moulding portion of the [brand omitted] lumbar drain was sheared off. According to the physician, it could not be retrieved as it is not radiopaque.*

> *The anesthesiologist inserted a spinal drain to maintain cerebrospinal pressure at <10 mm Hg. The catheter was placed at the lumbar area without trauma. The patient moved during removal of the needle introducer, severing the catheter. . . . Unable to remove the distal portion. Neurosurgery was consulted on whether or not to remove the severed catheter via laminectomy.*

> *A catheter insertion was attempted in the preoperative PACU [postanesthesia care unit]. . . While the catheter placement was checked by pulling back on the catheter, the catheter tip sheared off. A CT [computed tomography] scan confirmed that there was a piece of catheter present in the paraspinal musculature at the level of a lumbar facet. It is posterior to the spinal canal. No catheter fragments were identified in the spinal canal.*

Reasons for Catheter Shear

An epidural or subarachnoid catheter* is a very small flexible hollow tube that can be inserted into epidural space to administer fluids (e.g., pain medication) or into the subarachnoid space to drain body fluids (e.g., cerebral spinal fluid). On occasion, spinal catheters are placed in the subarachnoid space to administer medications as well. Depending on a patient's medical condition, a catheter may be placed on a short- or long-term basis. Under certain circumstances, catheters can break. The majority of catheter procedures occur without complications; however, catheters have been sheared in some cases.[1] Shearing typically occurs during insertion or removal of the catheter from patients.[1] Catheter fragments remaining in patients can result in serious complications due to the location or migration of the fragment or inflammation at the fragment site.[1] Reasons for catheter shearing include the following:†

- Applying excessive force while removing the catheter
- Withdrawing the catheter back through the insertion needle
- Withdrawing the catheter over a deformed or damaged needle bevel
- A flaw in the catheter from defects during the manufacturing process
- Damaging the catheter during or after placement in the patient

Applying Excessive Force

A user may use excessive force if he or she encounters resistance during catheter removal. Patient position during insertion or removal of the catheter may increase the resistance. For example, excessive

* For the remainder of this discussion, the term "catheter" will be used with the understanding that the discussion pertains to epidural and subarachnoid catheters.
† This list and the accompanying discussion represent some causes of catheter shear based on documented evidence, but neither the list nor discussion is comprehensive.

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force might be applied if the catheter is placed while the patient's back is arched but is removed with the patient in a different position (e.g., sitting position).[2] Boey et al. observed that the force required to remove an epidural catheter was 2.5 times more with a patient in the sitting position than in the lateral decubitus position.[3] Morris et al. recommend that the patient be placed in the same position for insertion and withdrawal of the catheter.[4]

Withdrawing through the Insertion Needle

A very sharp needle bevel may shear the catheter with minimal retraction or manipulation of the catheter during insertion. According to Olivar et al., when difficulty in advancing the catheter is encountered, users tend to partially withdraw (back through the needle) then reinsert the catheter.[2] The authors suggest that the catheter never be withdrawn from the needle once the catheter tip has passed through the needle;[2] rather, the needle and catheter should be withdrawn as a unit, or the needle should be withdrawn first.

Withdrawing the Catheter over a Deformed or Damaged Needle Bevel

Catheters may shear from snagging on imperfections such as barbs or nicks on the bevel of an unsharpened needle.[1]

Manufacturing Defects

Catheter fractures are rarely related to manufacturing defects.[5] However, defects such as a bubble or foreign material in the catheter wall can cause the catheter to break under less force than that required to break an intact catheter (i.e., without a defect).[5]

Damaging the Catheter during or after Placement

Manipulating the catheter within the patient can cause the catheter to become trapped.[1] A catheter can become looped or knotted from curling back on itself when deflected by anatomical structures.[1] Epidural catheters can also become entrapped in nerve roots, blood vessels, lumbar fascia, posterior vertebral arches, and facet joints.[1] The use of clamps or hemostats to remove catheters can result in fractures. In a 2001 study, Nishio et al. observed that the tensile strength of catheters decreased with the use of a stainless steel hemostat at the site grasped by the hemostat.[6]

Avoiding Catheter Shear during Removal

When encountering a catheter that is difficult to remove, the following methods are available to clinicians to reduce the risk of catheter shear:[1]

- Place the patient in a position that will exert the least amount of pressure during insertion and withdrawal of the catheter, such as the lateral decubitus position.
- To help identify any knots or entanglements, consider injecting sterile saline into the catheter. If a knot is encountered, gentle, firm traction may tighten the knot, making it smaller. Decreasing the size of the knot may ease catheter removal.
- Do not use metal forceps, hemostats, or clamps to remove catheters; their use may increase the likelihood of fracturing the catheter.
- Allow the patient's back muscles to relax for a few days to facilitate catheter removal.
- If pain or paresthesia develops during catheter removal in the intrathecal space, stop removal and consider performing a neurosurgical consultation with radiographic evaluation to help in determining the location of the retained catheter.
- Consider surgical removal of the catheter for patients who are symptomatic. Unless complications develop, surgery may be unwarranted since the catheter is inert.

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(See Self-Assessment Questions on next page.)

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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.

1. Which of the following factors is NOT a reason for catheter shear?
   a. Application of excessive force while removing the catheter
   b. Withdrawal of the catheter back through the insertion needle
   c. A flaw in the catheter caused by defects during the manufacturing process
   d. Placement of the patient in the lateral decubitus position during insertion and withdrawal of the catheter
   e. Withdrawal of the catheter over a deformed or damaged needle bevel
2. All of the following are methods for avoiding catheter shear EXCEPT:
   a. Using metal forceps, hemostats, or clamps to remove catheters
   b. Allowing the patient's back muscles to relax for a few days to facilitate catheter removal
   c. Injecting saline into the catheter to help identify any knots or entanglements
   d. Surgically removing the catheter from patients who are symptomatic
3. The following methods are likely to minimize resistance during withdrawal of the catheter EXCEPT:
   a. Placing the patient in the lateral decubitus position
   b. Placing the patient in the sitting position
   c. Placing the patient in the same position for insertion and withdrawal of the catheter
   d. Allowing the patient's back muscles to relax for a few days
4. A patient experiences pain and paresthesia during catheter removal in the intrathecal space.

   Select what to do when encountering this situation.
   a. Allow the patient's back muscles to relax for a few days to facilitate catheter removal.
   b. Stop the removal and consider performing a neurosurgical consultation with radiographic evaluation to help in determining the location of the retained catheter.
   c. Apply firm, steady traction when removing the retained catheter.
   d. Pull sharply on the retained catheter to facilitate withdrawal.
5. An obstetric patient underwent epidural anesthesia during labor. During removal, the catheter began to stretch. Injection of saline through the catheter showed that the catheter was obstructed, most likely due to a knot.

   Select the appropriate method to remove the knotted catheter.
   a. Pull on the catheter with gentle, firm traction to reduce the size of the knot.
   b. Surgically remove the catheter.
   c. Place the patient in the sitting position.
   d. Grasp the catheter with forceps and pull sharply to remove the catheter.

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Errors in Radiation Therapy

ABSTRACT

Radiation therapy is a highly regulated medical practice with historically low error and injury rates. Rare instances of radiation therapy errors resulting in severe injuries have been documented. These errors can result in devastating and sometimes fatal injuries, especially when the misadministration results in injury to vital organs or structures, such as the spinal cord, heart, lungs, or brain. Delivering radiation therapy is a team effort requiring collaboration and clear communication between the radiation oncologist, medical physicist, dosimetrist, and radiation therapist/technologist. As technology advances and computers are routinely used to plan, verify, and deliver radiation therapy, an information technologist may also be included on the team. Preventing errors in the delivery of radiation therapy involves not only understanding and appropriately utilizing new advances in technology, but also utilizing established patient safety procedures that optimize safe healthcare delivery. (Pa Patient Saf Advis 2009 Sep;6[3]:87-92.)

Introduction

Radiation therapy is used in the treatment of approximately 40% to 60% of patients who are diagnosed as having cancer.[1,2] Radiation therapy uses ionizing radiation delivered by external beam therapy or radioisotopes with either a palliative or curative goal.[1] These complex treatments are usually delivered daily during a period of five to seven weeks.[1,2] Radiation therapy is recognized as a high-risk procedure because of the number of steps and staff involved.[3] The radiation oncologist, medical physicist, dosimetrist, and radiation therapy technician work in concert to prescribe, plan, and deliver radiation therapy. The goal is to deliver a prescribed dose of radiation to the patient's tumor site, while restricting the dose to all surrounding healthy tissue and organs to that less than or equal to normal tissue tolerance.[4]

While errors in the delivery of radiation therapy are rare and usually result in little or no injury to a patient, the real danger is if an error in administration goes undetected.[5] This may result in healthy tissue being exposed to unnecessary levels of radiation or the tumor site not receiving a full effect of therapy. When radiation misadministrations are caught early, subsequent treatment doses can be adjusted so that the patient avoids receiving an under- or overdose. A severe misadministration may result in radiation necrosis to vital organs/structures and can be fatal. A highly publicized case of radiation misadministration resulting in a fatality occurred in Glasgow, Scotland, in 2005, in which a young patient, Lisa Norris, received a 58% higher dose than ordered to her craniospinal area. An autopsy revealed that her tumor was still present despite radiation therapy.[6] Another example of radiation misadministration involved the Therac-25 incidents, which occurred between 1985 and 1987. Two different computer software errors in a computerized linear accelerator resulted in massive radiation overdoses that injured six patients and caused two fatalities.[7]

Due to the low incidence of radiation therapy errors, many radiation therapy professionals may never encounter a significant misadministration during their career. This article focuses on types of external beam radiation therapy events reported in Pennsylvania and in the literature related to external beam radiation therapy. The most common errors reported include patients receiving the wrong dose of radiation, the wrong site being treated, and the wrong patient being treated. In a review of three decades of documented radiation therapy patient safety incidents, adverse events, near misses, and errors sponsored by the World Health Organization's World Alliance for Patient Safety, causal factors implicated in these adverse events were found to be errors in therapy planning, treatment delivery, and information transfer, as well as lack of knowledge and experience in using radiation therapy equipment and/or computer software.[8] Additionally, this article reviews strategies to reduce these errors, including discussion about how advances in technology may assist a radiation therapy provider in risk avoidance.

Regulation of Radiation Therapy

One reason cited for the low incidence of errors occurring in the delivery of radiation therapy is the strict regulatory environment surrounding this practice. Radiation therapy is regulated at both the federal and state level and is considered one of the most highly regulated medical practices. At the federal level, the Nuclear Regulatory Commission (NRC) regulates the use of radioactive materials.[9] On March 31, 2008, the Commonwealth of Pennsylvania entered into an agreement with NRC whereby the Department of Environmental Protection (DEP) took over regulatory authority for the possession and use of radiation materials and byproducts and other duties as authorized in section 274 of the Atomic Energy Act of 1954.[10,11]

In 1998, legislation was enacted in Pennsylvania requiring that all facilities with linear accelerators be licensed by the Commonwealth.[12] This licensing process allows DEP to evaluate and determine what requirements are necessary for the accelerator to be used safely in a medical facility. Pennsylvania has 126 facilities licensed with linear accelerators and is

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one of several states currently requiring a licensing process. The Pennsylvania Department of Health regulates all hospitals and free- standing cancer therapy centers; however, the department authorizes DEP to license and inspect these facilities.

The U.S. Food and Drug Administration regulates the manufacturers of medical devices and other products that emit radiation and has published regulatory standards for medical x-ray equipment safety and performance. It has no legislative authority to regulate users of these devices, with the exception of facilities that perform mammography.[13]

Although nonregulatory in nature, the Conference of Radiation Control Program Directors is a nonprofit agency that serves as a common forum for many government radiation protection agencies to communicate with each other and promote uniform radiation protection regulations and activities.[14] Finally, the Joint Commission now focuses on this issue and revised its definition of a sentinel event in 2006 to include the delivery of radiotherapy to the wrong body region or delivery of greater than 25% more than a planned dose.[15]

Errors in Radiation Therapy

In the Commonwealth of Pennsylvania, events related to errors in the administration of radiation therapy are reported to two statutory bodies: the Pennsylvania Patient Safety Authority and the Pennsylvania DEP. It was noted in review of both data sets that the overall number of reports is low. According to Joseph Melnic, radiation protection program supervisor, Pennsylvania DEP, Bureau of Radiation Protection, these low rates may be attributed to the safety measures and advances in computerized technology.[16] It is unclear whether events reported to the Authority were also reported to the Pennsylvania DEP, so similar events may have been reported to both organizations. Although little has been published regarding error rates in radiation therapy, a study conducted by Macklis et al. at the Cleveland Clinic in 1995 reviewed 1,925 patients who were treated with a total of 93,332 individual radiotherapy fields. The study revealed a crude radiation delivery error rate of 0.18%.[2]

Pennsylvania Patient Safety Authority Data

Act 13 of 2002 requires all hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities to report Serious Events and Incidents to the Authority. Table 1 shows the number of radiation oncology events reported to the Authority from June 2004 through January 2009. The Authority received 25 reports of radiation oncology events during this period. Of these reports, 24 involved external beam therapy and 1 involved brachytherapy. Six events were categorized as Serious Events (adverse events resulting in harm to the patient), and 19 events were categorized as Incidents (near misses). The majority of events reported to the Authority involved a patient receiving the wrong dose of radiation (40%), with a wrong patient (16%), wrong location (12%), wrong side (12%), and wrong setup (8%) being the most predominant treatment errors (see Table 2). The following examples further detail the types of errors reported to the Authority:

[Transcription error resulted in the wrong dose to the patient.] The dosimetrist transcribed the radiation oncologist's prescription incorrectly to the planning system and then to the recording system, which caused the patient to receive 2.5 times the recommended dose.

[Radiation therapy provided to the wrong patient.] The patient was given one treatment of the wrong patient's treatment plan in radiation oncology. The patient was called by name in the waiting room and answered to a similar sounding name; the patient identified herself with the incorrect patient's picture on the computer screen in the treatment room and the staff did not catch the error. The treatment given was for another patient with a similar type of cancer [with a similar physical appearance]. This patient received 1 Gray less than the prescribed dose to the intended area. There was no harm to the patient. There was no clinical significance.

Table 1. Radiation Oncology Events Reported to the Pennsylvania Patient Safety Authority, June 2004 through January 2009

YEAR	NUMBER OF REPORTS	% OF TOTAL
2004	6	24%
2005	4	16%
2006	6	24%
2007	1	4%
2008	6	24%
2009	2	8%
Total	**25**	**100%**

Table 2. Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, June 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Wrong dose	10	40%
Wrong patient	4	16%
Wrong location	3	12%
Wrong side	3	12%
Wrong setup	2	8%
Wrong treatment	1	4%
Wrong treatment device	1	4%
Equipment other	1	4%
Total	**25**	**100%**

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[Radiation therapy to the wrong location.] A non-English speaking patient with breast cancer was to have radiation treatments to the left breast. The patient received 15 treatments on the right breast before the error was recognized. The consent was signed for left breast. The prescription for treatments was written for the right breast.

Pennsylvania Department of Environmental Protection Data

In accordance with state code (25 Pa. Code § 219.3), facilities that are licensed or registered to deliver radiation therapy are also required to report a radiation therapy event to DEP when it meets the following definition:

Medical reportable event for radiation-producing machine therapy. The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual

(ii) An administration of a dose for therapy when the result is an increase in the total expected doses inside or outside the intended treatment volume for organs, tissue, or skin that exceeds 20% of the total prescribed dose for the intended target volume

(iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%[17]

From February 2004 through January 2009, 35 medical events were reported to DEP (see Table 3). An exact total number of radiation therapy procedures performed per year in Pennsylvania is not available; however, Melnic estimates that up to 1 million radiation therapy treatments are given each year in Pennsylvania. Melnic noted that the number of medical events reported to his department has been decreasing in recent years and attributes the reduction in medical events to increases in computerized technology in conjunction with the licensing program mentioned previously.[16] Analysis of the DEP data reveals the predominant type of medical event reported involved the patient receiving radiation therapy to an incorrect site (46%), followed by a wrong patient being treated (27%), and a patient being given the wrong dosage of radiation therapy (21%) (see Table 4), which is consistent with the Authority's data.

Radiation Oncology Safety Information System

The Radiation Oncology Safety Information System (ROSIS) maintains a database of radiation therapy events. This voluntary Web-based safety information database was established in 2001 and currently holds approximately 700 reports from 19 countries. In January 2007, a sample of the report generated by ROSIS included a spotlight on data transfer errors. At that time, 294 of 600 events reported (49%) were considered to have an element of data transfer that caused or contributed to the occurrence of a radiation therapy event. Of the events reported, 130 of the 294 resulted in the patient getting the incorrect treatment. Fifty-three percent of the errors were discovered during a chart check, with 34% being found at the time of patient treatment.[18]

Risk Reduction Strategies

As noted above, the most common radiation misadministrations have resulted in patients receiving a wrong dose of radiation therapy, delivery of radiation therapy to a wrong site, or patients receiving the wrong treatment plan. Risk reduction strategies discussed will address an advancing role of technology in preventing errors as well as utilization of other patient

Table 3. Medical Accelerator Events Reported to the Pennsylvania Department of Environmental Protection, Feburary 2004 through January 2009

YEAR	NUMBER OF REPORTS	% OF TOTAL
2004	6	17%
2005	9	26%
2006	7	20%
2007	6	17%
2008	6	17%
2009	1	3%
Total	**35**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

Table 4. Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, February 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

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safety protocols, such as patient identification processes, to ensure the patient receives the prescribed therapy.

Reducing Radiation Therapy Errors through Emerging Technology

Delivering the prescribed dose of radiation to the patient remains the top goal as deviations in prescribed dose by more than 5% may influence the outcome of treatment.[19,20] Technology associated with delivering radiation therapy has advanced greatly during the last decade.[5,21] The manual processes of planning and delivering radiation therapy are being replaced by computerized systems for electronic order entry, treatment plan development, and review and verification of coordinates at the time of treatment.

Most linear accelerators use a computerized record and verify (RV) system. RV systems have been used since the 1970s and are successful at reducing the number of misadministration errors while allowing for delivery of complex treatment plans.[22] RV systems verify that treatment parameters entered are the same that are set to be delivered to a patient. If these parameters do not match, then the external beam is inhibited from firing.[4] Though RV systems have been found to help reduce the errors in radiation delivery, they are not used in every facility. In Pennsylvania, all linear accelerators have computerized RV systems, with the exception of a few grandfathered devices, according to DEP.[16] While reducing overall errors in radiation therapy, use of RV systems has created some new types of errors.[5,7] A study conducted by Patton et al. from 1999 to 2000 at the University of Utah showed radiation therapy staff had an overreliance on RV systems. During that 1-year period, this study showed that of 22,542 external beam radiation therapy treatments administered, 38 treatment errors were identified (0.017%). Nine of these events involved errors related to the use of the RV system. Identified errors included a wrong patient being treated, an incorrect data file being used by means of a staff override of the system, an incorrect site being treated, and incorrect beam modification.[7] Another study conducted by Leunens et al. in 1990 reported that nearly half of all major deviations (more than 5% from prescribed treatment) were introduced during the manual input of data into the RV system. This study showed that these human errors would lead to greater systematic errors if not caught.[20]

Computer-controlled delivery systems have led to a decrease in errors while allowing for more complex treatment plans to be delivered, without increasing treatment time.[22] Fraass et al. explains that computer-controlled delivery systems have three main aims: (1) make treatment delivery more efficient, (2) improve accuracy of treatment, and (3) make new and more complex treatment modalities, such as intensity modulated radiation therapy, possible even as facilities continue to try to improve cost efficiency.[22] A 15-month study conducted between 1996 and 1997 by Fraass et al. found an error rate of 0.21% for all manually treated cases and an error rate of 0.085% for all computer-controlled cases.[22] While computer-controlled treatment plans reduce the rate of random treatment delivery errors, they may be susceptible to systematic errors, which may be hard to detect. New technology creates new types of errors when staff do not have proper knowledge or training regarding new equipment, resulting in the utilization of workarounds when encountering system errors.[23] In addition, quality assurance (QA) testing must be done to ensure that the computers are working appropriately.[23] Methods of performing QA as recommended by such groups as the American Association of Physicists in Medicine (AAPM) predate technologic advances such as image-guided radiation therapy, computer-controlled linear accelerators (linacs), RV systems, electronic medical records, and use of digital imaging.[23] The increasing complexity of modern radiation therapy planning and delivery techniques challenges traditional prescriptive QA programs as they are consuming more resources than facilities have available. In this current environment, the number and sophistication of possible tests and measurements have increased dramatically. Task Group 100 of the AAPM is developing a framework for designing QA activities and will provide guidelines on risk assessment approaches with emphasis on failure mode and effects analysis.[24]

Checking and Double Checking before Radiation Therapy Is Delivered

Ensuring that a patient receives the prescribed dose of radiation therapy occurs in several different ways. Performing independent checks of therapy treatment plans is considered an integral part of the therapy verification process. The American College of Radiology recommends all radiation therapy plans undergo an independent double check and be signed by a radiation oncologist within one week of treatment initiation.[1] An Australian study conducted by Duggan et al. examined the efficacy of performing an independent double check of radiation therapy treatment plans (check of prescription, choice of beam, and dose calculations) From 1993 to 1995, 1,579 patients were treated, 2,328 treatments plans were reviewed, and 235 interventions or changes were made. Of these 235, the majority of the interventions were minor in nature and only 6 fell into the category of major errors that would have resulted in the patient receiving a dose of greater than 10% of the intended dose. Although the checks were found effective, these study authors estimated that staff needs would increase by 0.3 full-time staff per 1,000 patients per year to provide these checks.[25]

Although not unique to radiation therapy, proper patient identification procedures need to be in place and strictly followed. In both the Authority and DEP reporting system databases, events involving patients receiving therapy prescribed for other patients were noted. Joint Commission's National Patient Safety Goals state that at least two patient identifiers will

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be used when providing care to a patient.[26] This information should be confirmed with information in a patient's medical record. Even though the Joint Commission excludes radiation oncology from the Universal Protocol standard,[27] radiation therapy staff should consider performing a final verification, which may include verification of patient's identity (two identifiers); verification of the site of treatment, including laterality as compared to the digitally reconstructed radiograph and port films; and comparison to the consent and treatment plan.

Lastly, in vivo dosimetry has been established as a reliable method for verification of external beam therapy. It is defined as dose measurements performed on patients during the delivery of radiation therapy. This process is accurate and may be effective in minimizing errors resulting in 5% or more being delivered but can be costly and time-consuming if used on every patient. Most departments select which group of patients on which they will use this process to ensure timely and efficient use of resources.[25] An in vivo dosimetry program should be considered for QA of machine calibration, planning dosimetry and dose calculation, patient setup, and influence of beam modifying components. [28]

Conclusion

Radiation therapy is a highly regulated, complex treatment modality that is performed on approximately half the patients diagnosed as having cancer. Error rates associated with delivery of radiation therapy are low, as are reports of injury to patients. This discipline of medicine is subject to strict regulatory and quality control standards. Safety in delivery of radiation therapy has been a result of advances in computerized technology, which reduces many errors associated with manual preparation and delivery of radiation therapy. Radiation therapy providers must be proficient when utilizing these new technologies. In addition, providers must perform effective independent double checks not only of treatment plans but also of patient identification and site verification.

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Safe Patient Outcomes Occur with Timely, Standardized Communication of Critical Values

ABSTRACT

A critical value is defined as an imminent life-threatening laboratory result requiring immediate physician notification. The concept was first introduced in 1972 and has been widely adopted as a standard of good laboratory practice. Regulatory agencies and federal legislation require that hospitals and laboratories establish a list of critical tests and values and have procedures in place for promptly conveying critical results to the responsible practitioner. Yet, despite the importance of critical values in patient care and requirements to identify and promptly communicate critical results to healthcare providers, there is little standardization of procedures. Communication of critical values has potential for failure, as illustrated in reports submitted to the Pennsylvania Patient Safety Authority and demonstrated in the medical literature. Standardization of processes related to critical tests, results, and values can positively affect quality of care and patient safety. First, facilities must develop a critical test list and identify critical values or results. Next, implementation of processes that identify critical values and mechanisms to quickly document and communicate critical values to healthcare providers caring for the patient may reduce harm to patients. (Pa Patient Saf Advis 2009 Sep;6[3]:93-7.)

From June 2004 through February 2009, the Pennsylvania Patient Safety Authority received nearly 1,000 reports involving critical tests and values. Failure of laboratory staff to communicate critical values to the responsible provider and failure to match results to the correct patient are the most common issues identified in the reports. Approximately 3% of these reports were identified as Serious Events that required additional interventions such as prolonged hospitalizations or increased lengths of stay in intensive care units (ICUs). Of the Serious Events, five patient deaths were reported. Almost 50% of the total reports were generated from the laboratory, with the remaining reports dispersed throughout care areas.

The issues associated with the critical values reports were poor communication, delays in treatment, and documentation issues. Analysis of current processes at a facility can determine what strategies (i.e., to identify, document, and communicate critical values) may be necessary to improve patient safety and quality of care, including strategies compliant with the Joint Commission 2009 National Patient Safety Goal (NPSG) related to critical values.

Background

The Joint Commission recognizes an explicit difference between critical tests and critical values. Facilities need to establish a critical test list and a critical values list, also known as critical results. Critical tests are tests that always require immediate communication of the results, even if the results are normal.[1] Critical values are test results that are significantly outside the normal range and may represent life-threatening values.[1] The concept of critical values was first introduced by Lundberg in 1972. A critical value is a pathophysiological state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action must be taken.[2,3,4] It is a life-threatening situation requiring immediate intervention.[2,3,5] In 1988, Congress enacted the Clinical Laboratory Improvement Act (CLIA), requiring laboratories to follow written procedures for reporting critical values.[4] The College of American Pathologists (CAP) and the Joint Commission are accrediting agencies that survey laboratories to assure CLIA compliance, which includes establishing a list of critical values and results. Moreover, laboratories must have procedures in place for promptly passing on critical results to the responsible practitioner.[2,6]

The critical values concept extends beyond laboratory tests, encompassing radiologic and other diagnostic tests and studies. The prompt communication of critical, life-threatening test results is crucial to reduce harm to patients. This article focuses on strategies to improve processes related to laboratory critical values. The same principles may be applied to radiology and other diagnostic departments. Specifically, development of a standardized list of critical radiology tests and results and methods to document and communicate the critical results promptly to healthcare providers may reduce harm to patients. The scope of this article will focus on laboratory tests.

Poor Communication Leads to Delays in Treatment

Although most clinical laboratory results have therapeutic implications that do not require urgent physician attention, some test results may indicate a potentially life-threatening situation. These critical results require immediate notification and action by the responsible licensed healthcare provider. This multifaceted process has potential for failure, as illustrated in reports submitted to the Authority. The most common errors identified are poor communication and delays in treatment related to critical values, which are consistent with themes in the literature of communication breakdown in reporting critical results. Specifically, 33% of reports related to critical lab values identified a failure of laboratory staff to report critical results to the responsible provider or a delay in reporting. In particular, the reports described

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healthcare providers who did not receive notification about critical results and discovered the critical results by calling the laboratory or referring to the medical record. In the majority of cases, the laboratory totally failed to report the result and in other reports there was a significant delay in communicating the result directly to the healthcare provider. In the latter cases of delay in communication, several issues were identified, including the laboratory calling the wrong physician or the wrong number or the physician not responding in a timely manner. Additionally, some reports indicated failure by the recipient of the critical value to verify correct patient and correct result by means of the read-back process. The following Authority reports illustrate how such errors can result in patient harm:

> *The patient had blood drawn the day prior to the patient going to the cardiac catheterization laboratory. The catheterization laboratory nurse checked the patient's lab work prior to patient arriving to the [cardiac catheterization] lab, but the laboratory results reviewed were from a previous blood draw. According to the supervisor, there was a delay in lab work being sent to laboratory. While the patient was on the [cardiac catheterization] table, the patient became unresponsive, pulseless, and stopped breathing. Cardiopulmonary resuscitation (CPR) was initiated. The nurse checked the computer for lab work again. The critical result had been called to the nursing unit but had not been passed on to the catheterization staff. The potassium level was 6.8.*

> *The critical hematocrit [laboratory value] was called to the wrong physician. An order for blood was obtained by the nurse. Blood transfusion started on patient who developed a reaction. The blood was stopped and the nurse called the physician, who at this point realized this was not his patient.*

> *Blood work was drawn in the morning. There was a critical ammonia level of 352. Laboratory did not notify the nursing unit about the result. The critical value was available via computer in the afternoon but was not noted by the nurse until the night shift. The patient was unresponsive and pulseless. CPR was initiated, and the patient was transferred to the ICU.*

Despite the importance of critical values in patient care and various regulatory agency requirements to identify and promptly communicate critical results to healthcare providers, there is little standardization of the process and procedures in organizations.[2] The development of a list of critical tests and results is established at individual organizations after discussion with representative groups of ordering providers. Establishment of communication processes is critical. For example, facilities may assign laboratory personnel to be responsible to communicate critical results. Likewise, facilities may determine the appropriate fixed time frame and the method of communicating the critical test result to the provider.

Barriers to Communication

Effective communication is defined by the Joint Commission as timely, accurate, complete, unambiguous, and understood by the recipient.[7] Standardization of communication and documentation of critical results by the responsible provider may improve patient safety and quality of care. In 2003, the Joint Commission implemented NPSG 2C to improve the effectiveness of communication among caregivers.[7] The goal includes implementation of a read-back process for taking verbal orders and standardization of abbreviations throughout the organization. Read-back helps to ensure that a message sent by a sender is understood by the receiver in the manner the sender intended. The sender sends a message, the receiver fully repeats the message as understood, and the sender acknowledges the message has been understood correctly.[6,8] Some facilities require the recipient of the critical value perform a read-back of the value. Laboratory staff document the patient name, critical value, date and time communicated to the provider, and the provider's name who received the critical value and confirmation of the read-back process. In 2009, the Joint Commission expanded NPSG 2 to include defining critical tests, critical results, and values as described previously. In addition, Joint Commission included a requirement for organizations to identify and communicate critical tests and values in a timely manner and to measure, assess, and if needed, take action to improve the timeliness of reporting and the timeliness of receipt of critical tests and critical test results and values by the responsible licensed caregiver. Data from the Joint Commission, which includes surveys conducted from 2003 through the third quarter of 2007, indicates that NPSG 2C has the lowest compliance rate (36%) compared to the other NPSGs.[9]

Delays and inaccuracies in reporting critical values place patients at risk of harm due to treatment delays, omissions, and errors. The following Authority reports illustrate the range of communication problems resulting in errors:

> *Patient labs were drawn in the morning; critical blood sugar of 18 was not reported until five hours later.*

> *Patient was admitted with fatigue. A laboratory test for a CBC [complete blood count] was drawn. [The results included] a white count of 0.7. This was not effectively communicated to the physician and went unnoticed until days later, at which point the patient was transferred to the hematology unit.*

> *A patient [with] CHF [congestive heart failure] had blood work drawn [on admission]. No results were obtained until the next day [when] a critical potassium result of 6.4 was noted. Patient had been receiving potassium daily. No call was received on admission [for this critical result] and no printed lab report [was received] until the next day.*

> *The unit clerk reported to the nurse and physician [a critical potassium level] of 2.2. The physician*

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wrote orders for potassium bolus and PO KCL [potassium chloride by mouth]. Both were given [promptly]. An hour later, the written lab results were received and the potassium was high and the phosphorus [level was] critically low at 2.1.

The report from the nurse included that the heparin 4,000 was titrated based on what was believed to be a partial thromboplastin time (PTT) [level of] 15. The patient was [given an intravenous] bolus of heparin and the heparin [drip] was increased. This titration was completed at [the end of the shift]. During report, we received a call from the lab with a critical high PTT of 180. The previous nurse had misread the PT (prothrombin time) as the PTT value. [The nurse] notified the on-call physician of the error and held the heparin [drip].

Patient evaluated with history of [cardiac and renal disease]. A critical potassium result of 8.5 was verbally communicated from nurse to the emergency department physician. Physician states he interpreted result as 5.8. [The lab reported the] specimen was slightly hemolyzed. No treatment was initiated. A repeat potassium level was 8.5. Treatment was ordered.

Identification of Critical Tests, Critical Results, and Values

There is little consensus or benchmark data about critical values in the clinical laboratory.[3] The definition of a critical value remains unspecified in the minds of many clinicians and laboratory professionals. For example, data from 623 institutions participating in a CAP Q-Probe study indicated that critical value lists vary widely for routine chemistry and hematology laboratory tests.[5] Facilities must establish a list of critical laboratory test values relevant to their daily operations and patient population. Ultimately, the medical director has the primary responsibility to establish a list that meets the needs of the organization it serves.[4]

Establish a List of Critical Tests, Critical Results, and Values

First, identify critical tests, critical results, and values that warrant prompt notification to a licensed healthcare professional at the facility level. Establish a multidisciplinary committee to develop the critical values test list.[4] The Massachusetts Coalition for the Prevention of Medical Errors has created a starter set of critical results.[7] According to Hanna, this list may stimulate discussion during the development of facility-specific lists.[7] The CAP Q-Probes Committee does not endorse a national standard critical values list.[4] However, improved safety and quality of care is enhanced with individualized lists. Consider the following components when establishing a facility-specific critical value list:

- Ensure committee representation from various departments, including the medical staff, laboratory staff, and nursing staff.[4]
- Customize the critical list as directed by the laboratory medical director, who has primary responsibility for the laboratory specimens list.[4]
- Consider the needs of special programs in the facility, such as cardiac surgery, bone marrow transplant, or high-risk obstetrics.[4]
- Post the critical laboratory test list in all areas of the laboratory.
- Review and revise the critical values list and related policies annually to maintain compliance with regulatory agencies.[4]
- Educate laboratory staff on the critical values list annually.[4]

Recognize and Notify of Critical Values

Next, develop and implement methods to guarantee that critical results from the approved list are recognized and communicated to the responsible provider and documented in the laboratory. Standardization of the process may promote the appropriate, prompt treatment of patients.

Recognition and notification of critical results begins in the laboratory. Laboratory staff should identify a critical value by strict semantic interpretation of the critical limits. For example, the upper limit for a potassium level is 5. If the result is 5.1, it is a critical value, but staff may not interpret one tenth of one point above as abnormal. Additionally, laboratory staff verifies that the sample of a critical lab value is satisfactory.[4] Laboratories should set clear, realistic time frames to initiate and complete a critical value notification to enhance patient care.[4] Healthcare facilities should implement processes of notification based on resources, technology, and personnel available.

Some facilities communicate critical results to the nurse caring for the patient, while others communicate critical results directly to medical staff by means of alphanumeric pagers.[4] If available, laboratory information system (LIS) software can identify critical values and be integrated with telecommunication systems to deliver critical values directly to the physician's pager.[4] Additionally, two-way pagers provide a method for physicians to acknowledge receipt of the critical value.[4] An automated system provides high reliability of critical value notification.[4] The use of LIS software may limit communication breakdowns such as those illustrated in Authority reports (e.g., unsuccessful attempts to notify responsible provider).

Furthermore, methods that identify a backup healthcare provider to be notified may improve notification of critical results.[4] Identification of failure modes and implementation of strategies to prevent communication breakdown is essential. Establishing a process for the communication of critical values to the responsible provider improves timely treatment to patients.[10]

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Additionally, implement policies and procedures that include the following strategies:

- Identify and assign staff to report critical results.[4]
- Establish a method for communicating the critical result. (The telephone and alphanumeric pager are reported to be the most effective methods to report critical values.)[4]
- Establish read-back policies appropriate to the communication method that require laboratory staff to ask and document the following elements from the recipient of the critical value: recipient first and last name, critical test and value, date and time, sender first and last name, and completion of read-back.
- Maintain an up-to-date directory of all relevant telephone and pager numbers in the laboratory.[4]
- Develop and implement backup systems to report critical test results for inpatients when the ordering provider is unavailable.[6,11]
- Establish procedures to implement when an attempt to report a critical value to the ordering provider or backup provider fails. Follow the chain of command.[4]
- Document all critical value notifications. The documentation includes patient identification, laboratory test and result, date and time of notification, identity of reporter, and the recipient of the critical value.[4]
- Require recipients of critical results to read back the message for affirmation.[6]
- Identify methods for improving processes in reporting critical values.[6]
- Analyze and collect data to determine efficacy of notification to healthcare providers.[6]

Establish Time Frames for Reporting Critical Results

Not every critical test result needs to be reported with the same urgency.[10] The Massachusetts Coalition for the Prevention of Medical Errors developed three categories (i.e., red, orange, yellow) with different time targets for communicating the result to the licensed healthcare worker. The goal is to ensure that results reach the provider and that treatment is initiated within an established appropriate time frame.[10] The definitions of the categories are as follows:[10]

- *Red* signifies all test results that represent a clinical emergency that places a patient in imminent danger of death, or a significant adverse event unless treatment is initiated immediately. Notification within an hour is an appropriate time frame.
- *Orange* represents test results that require immediate notification to the physician and may occur during change of shift within six to eight hours.
- *Yellow* represents test results with significant abnormalities but do not pose an immediate threat to life. Notification of the result within three days is an appropriate time frame.

Verify Critical Results and Patient Treatment

- Verification of the critical result is the next step in the process. Actions taken by the recipient of the critical result and subsequent steps taken to ensure timely intervention is the key focus. Ideally, the primary physician receives the critical result and determines the need for treatment. If treatment is needed, the physician promptly instructs the nurse or other care provider to treat the critical value. The care provider or nurse provides the treatment, and the process is complete. However, difficulty contacting the responsible physician directly has resulted in facilities adopting a policy that permits the laboratory to convey the critical result to the registered nurse caring for the patient.[12] In this situation, the nurse must communicate the result accurately and promptly to the primary care physician. Research and experience indicates that each handoff communication increases the chance for error and miscommunication.[12] Implementation of the following strategies may enhance communication of critical results and improve timeliness of patient treatments. Identify and assign staff to receive critical results. The Joint Commission requires that critical results be reported promptly to a licensed provider or the practitioner who ordered the test.[8]
- Confirm correct patient name and critical test result by means of a read-back.[6]
- Use a standardized form (part of the medical record) to document all communications and interventions related to the critical value and critical result that includes patient identification, test result, date and time of notification, identity of reporter, and the recipient of the critical value.[4,13]
- Also include in documentation the date and time the result was reported to the primary physician and time the patient received treatment, if indicated.[6,13]
- Establish procedures to implement when an attempt to report a critical value fails to reach the primary licensed provider.[4]
- Initiate treatment promptly, if ordered, and document the time that the patient received the intervention.[13]
- Assess patient response to the intervention, and document in the medical record.

The process is complete when the patient receives treatment for the critical test result. However, maintain attentiveness and continue to monitor and assess the patient's response to treatment and subsequent laboratory testing related to the intervention.

Conclusion

Identification and notification of critical tests, values, and results is a complex process with potential for communication breakdown at every step. Implementation of the protocols presented here may improve

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patient care and reduce harm. Ongoing evaluation and improvements in identifying and reporting critical tests, values, and results will lead to accurate notification from laboratory staff to the licensed professionals resulting in prompt treatment, if necessary, to patients.

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Barriers to Urinary Catheter Insertion and Management Practices

Despite evidence that catheter-associated urinary tract infections (CAUTIs) and accompanying adverse outcomes can often be prevented, these infections remain among the most predominant healthcare-acquired infections in the United States. In May 2009, hospital infection preventionists (IPs) across Pennsylvania participated in a detailed survey of implementation of urinary catheter insertion and management practices. The survey was designed to measure the level of adoption of practices and tools useful to overcome obstacles to uniform implementation of CAUTI-prevention practices. The following discussion highlights the survey results, which were also presented during the June 2009 Pennsylvania Patient Safety Authority Webinar "Getting Past the Policy: Overcoming Barriers to CAUTI Prevention Practices."

Clinical and Economic Consequences of CAUTIs

Between 12% and 25% of all hospitalized patients are catheterized during their hospital stay, and as many as 80% of all hospital-acquired urinary tract infections can be attributed to indwelling urinary catheters.[1] Use of an indwelling urethral catheter is an invasive intervention that carries a significant risk for patient harm leading to prolonged length of stay, secondary bacteremia, sepsis, and increased mortality.[1] In a catheter awareness survey, 288 physicians and medical students from 4 university-affiliated U.S. hospitals were asked whether patients under their care had a Foley catheter. The physicians surveyed were unaware of Foley catheterization in 28% of 117 patients, and subsequent patient observations indicated that 31% of catheter use was inappropriate.[2] Among the non-reimbursable hospital-acquired conditions selected by the U.S. Centers for Medicare & Medicaid Services, CAUTIs received a high priority due to the high cost and high volume and because prevention is reasonable through application of accepted evidence-based prevention guidelines.[3] A systematic review of evidence published between January 2001 and June 2004 found that the average cost of treating a CAUTI is $1,006 in 2002 U.S. dollars.[4] A cost study from the University of Michigan Health System found the minimum cost of treating a patient with catheter-related bacteremia is at least $2,836 in 1998 U.S. dollars.[5]

Authority Survey of CAUTI Prevention Practices

Methods and Limitations

The Authority surveyed IPs from Pennsylvania hospitals about obstacles to implementing CAUTI prevention guidelines. Sixty-five IPs completed the survey. The IPs were surveyed about implementation of 16 practice elements (see Table), which were defined according to guidelines from the Centers for Diseases Control and Prevention (CDC), the Society for Healthcare Epidemiology of America (SHEA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Institute for Healthcare Improvement (IHI). Limitations of the survey include that results represent about 26% of reporting hospitals in Pennsylvania at the time of the survey, and the results may not reflect statewide adoption practices.

Results

The majority of IPs indicated that their hospitals have fully implemented the requirement that a Foley catheter securement device be used on all patients, have a CAUTI prevention program in place with a designated physician champion, have a written plan that is communicated to clinical staff, and have adopted criteria for Foley catheter use. About 40% of the IPs indicated that their hospitals have fully implemented assessment of annual competency for clinical staff on CAUTI prevention practices and use of silver-coated Foley catheters on all catheterized patients. Forty-five percent of the IPs indicated that their hospitals have formally discussed and considered a hospital policy on standing orders allowing nurses to discontinue or remove catheters that no longer meet criteria.

Prevention practices that the majority of IPs indicated their hospitals have not implemented include changing of chronic Foley catheters on admission, a hospital policy to prohibit catheter insertion if criteria are not met, automatic reminders to nursing for routine maintenance activities, and use of a catheter-insertion checklist. IPs from these hospitals also indicated that there was no activity to implement the following practices: incorporate catheter criteria into the physician's order form, provide written Foley catheter education materials for patients, require physicians to document catheter necessity on a daily basis, and periodically educate physicians about CAUTI prevention strategies.

Responses on implementation of a monitoring system for documentation of Foley criteria on physician orders are spread across the categories of fully implemented, formally discussed but not yet implemented, and no activity to implement this item.

System Failures and Barriers

Many organizations have adopted the practices advocated in evidence-based guidelines but still struggle with implementation and lack methods for efficient and reliable performance of prevention practices. The Authority polled attendees of its June 2009 Webinar about the most significant barriers to implementation of CAUTI prevention practices (see Figure). Poll results indicate that the predominant barriers among the attendees are lack of accountability by members of the healthcare team for appropriate and safe practice and active resistance

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Table. Pennsylvania Patient Safety Authority Hospital Foley Catheter Practice Survey (N = 65)

SURVEY QUESTION	FULLY IMPLEMENTED THROUGHOUT THE ORGANIZATION	FULLY IMPLEMENTED IN SOME AREAS OF THE ORGANIZATION	PARTIALLY IMPLEMENTED IN SOME OR ALL AREAS	FORMALLY DISCUSSED AND CONSIDERED BUT NOT IMPLEMENTED	THERE HAS BEEN NO ACTIVITY TO IMPLEMENT THIS ITEM	NUMBER OF RESPONDENTS
Hospital policy requires that a Foley catheter (FC) securement device be used on all catheterized patients.	63.1%	10.8%	4.6%	9.2%	12.3%	65
A catheter-associated urinary tract infection (CAUTI) prevention program is in place with a designated physician champion.	51.6%	3.1%	17.2%	21.9%	6.3%	64
A written CAUTI prevention plan is in place that is communicated to clinical staff.	49.2%	9.2%	10.8%	24.6%	6.2%	65
The hospital has adopted written FC criteria.	49.2%	9.2%	13.8%	18.5%	9.2%	65
Clinical staff receives at least annual competency on CAUTI prevention strategies.	42.2%	7.8%	20.3%	17.2%	12.5%	64
Silver-coated FCs are used on catheterized patients.	39.1%	4.7%	1.6%	21.9%	32.8%	64
Hospital policy includes standing orders allowing nurses to discontinue/remove FCs that no longer meet criteria.	13.8%	6.2%	3.1%	44.6%	32.3%	65
Chronic FCs are changed on admission.	10.9%	4.7%	3.1%	15.6%	65.6%	64
Hospital policy prohibits FC insertion if criteria are not met.	4.7%	3.1%	7.8%	29.7%	54.7%	64
Routine maintenance activities (catheter securement, collection bag below bladder, emptying protocol) are prompted by automatic alerts or reminders to nursing staff.	16.9%	6.2%	7.7%	24.6%	44.6%	65
An FC insertion checklist is used to verify aseptic techniques and insertion criteria.	10.8%	3.1%	10.8%	33.8%	41.5%	65
FC-insertion criteria are incorporated into the physician's order form.	13.8%	6.2%	9.2%	27.7%	43.1%	65
Catheterized patients receive written education materials on FC and infection prevention.	13.8%	4.6%	15.4%	29.2%	36.9%	65
Physicians are required to document FC necessity on a daily basis.	20%	6.2%	6.2%	32.3%	35.4%	65
The CAUTI prevention program includes periodic physician education on CAUTI prevention strategies, including FC-insertion criteria.	20%	6.2%	7.7%	30.8%	35.4%	65
A monitoring system is in place for documentation of FC criteria on physician's orders.	24.6%	7.7%	10.8%	26.2%	30.8%	65

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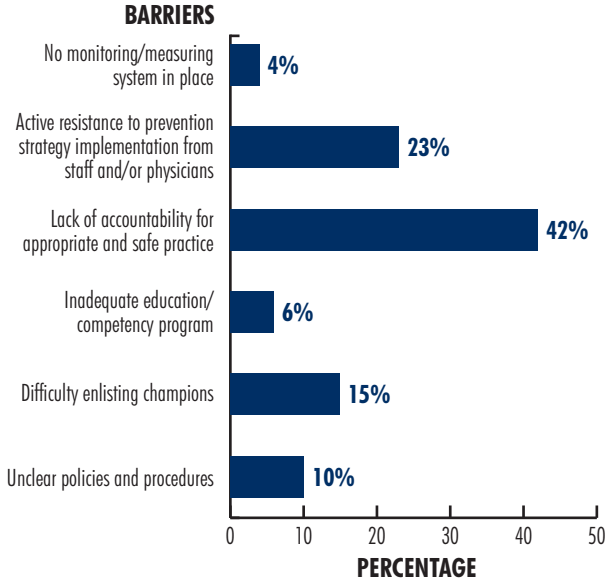
(continued from page 98)

Figure. Barriers to Prevention Practices (N = 48)



to prevention strategy implementation from staff and/or physicians. Less common barriers included unclear policies and protocols, difficulty enlisting physician and nursing champions, inadequate education and competency programs, and inadequate process or outcome monitoring/measuring systems.

Risk Reduction Strategies

Several evidence-based guidelines summarize the most up-to-date, significant prevention and implementation strategies and provide a road map for development of institutional policy and practices to address CAUTIs. The guidelines include the following:

"Compendium of Strategies to Prevent Catheter-Associated Urinary Tract Infections in Acute Care Hospitals." The intent of this 2008 compendium, published by SHEA and the Infectious Disease Society of America, is to assist hospitals to prioritize and implement practical strategies for CAUTI prevention. The compendium summarizes specific expert implementation and monitoring methods and addresses accountability as well as detailed process and outcome measures.[6] The compendium is available online at http://www.shea-online.org/compendium.cfm.

"Guide to the Elimination of Cather-Associated Urinary Tract Infections (CAUTIs)." This 2008 guide, published by APIC, outlines evidence-based practice guidance to CAUTI prevention in acute and long-term care facilities, including antimicrobial stewardship, surveillance, and data dissemination, as well as how to perform a CAUTI risk assessment.[7] The guide is available online at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/CAUTI_Guide1.htm.

"Getting Started Kit: Prevent Catheter-Associated Urinary Tract Infections: How-to Guide." This guide from IHI focuses on four components of patient care recommended for all patients and outlines specific methods to translate research into practice change at the bedside.[8] The guide is available online at http://www.ihi.org/IHI/Programs/ImprovementMap/PreventCatheterAssociatedUrinaryTractInfections.htm.

"Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2008." CDC revised its 1981 guideline on preventing CAUTIs and released a draft guideline for public comment in June 2009.The guideline emphasizes specific recommendations for all aspects of CAUTI prevention and implementation initiatives, updates surveillance definitions, and lists clear indications for Foley catheter use.[9] The draft guideline is available online at http://www.cdc.gov/ncidod/dhqp/pdf/pc/cauti_GuidelineApx_June09.pdf.

Additional Resources Available through the Authority

The Authority conducted its June 2009 Webinar to help hospital IPs identify practical strategies to overcome barriers, recall methods to enlist the support of physician and nursing champions, and recognize how to encourage and monitor staff compliance with CAUTI prevention practices at the bedside. The Webinar included discussion about results of the hospital survey and successful prevention efforts in Pennsylvania.

Presenters included representatives from hospitals in Pennsylvania that have successfully reduced CAUTI rates through implementation of specific strategies. For example, at Doylestown Hospital, the 2005 intensive care unit (ICU) CAUTI rate averaged 6.6 per 1,000 catheter days. A campaign initiated in 2006 helped reduce the rate to 0 by first quarter 2009. (A 22% decline in catheter utilization from 2006 to 2009 resulted in an accompanying decline in the housewide CAUTI rate from 9.5 in third quarter 2006 to 1.5 in first quarter 2009.) The initiative addressed approved criteria for removal of Foley catheters by a registered nurse without a physician order if criteria for use were not met. Analysis of hospitalwide catheter practices indicated that most ICU Foleys were inserted in the emergency department (ED). A Foley insertion checklist and bundle were initiated in the ED, straight catheters were used for emergency specimens, and Foleys were inserted only in controlled situations with time for proper preparation (i.e., not during a code or a rapid response). The ED coordinator monitors the checklists for orders, criteria, size of the catheters, pericare, and the use of an assistant during insertion. Physicians document the reason for continued Foley use on a Foley utilization chart sticker.

At Paoli Hospital, the IP identified 62 CAUTI cases in 2006, a rate of 5.39 CAUTIs per 1,000 catheter days. Failure modes and effects analysis helped identify opportunities for improvement and standardization, including a nurse-driven catheter-removal

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protocol, daily assessment of catheter care, and criteria on the nursing flowsheet and daily rounds. A Foley catheter bag label identifying the insertion date, time, location, inserter, and a hand hygiene reminder was developed. Voiding trials and bedside commode use increased, and bladder scanning was initiated. Unit and physician champions were identified, and registered nurses were reeducated about insertion, care, and catheter alternatives. Orders are required for Foley insertion, and daily physician reminders were instituted. Application of these strategies reduced the number of CAUTIs to 33 in 2008, a 47% reduction, or a rate of 3.59 infections per 1,000 catheter days, as well as a consistent decline in unnecessary catheter usage from 11,489 to 9,180 catheter days.

The Authority hosts an online collection of CAUTI resources, including the full Webinar presentations discussing efforts at Pennsylvania hospitals and additional patient safety tools from the Webinar presenters (a detailed nurse-driven Foley catheter-removal protocol; sample physician reminders; insertion, performance, and tracking checklists; and an infection prevention tip sheet). The collection is available online at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

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An Update on the "Epi"demic: Events Involving EPINEPHrine

Medication errors involving EPINEPHrine,* a high-alert drug,[1] are known to happen. An article in the September 2006 issue of the *Patient Safety Advisory* focused on two problems indicated in reports submitted through the Pennsylvania Patient Safety Authority's reporting system and elsewhere: (1) concentration expressed as a ratio strength rather than a metric per-volume concentration and (2) confusion between EPINEPHrine and ePHEDrine.[2] Since September 2006, Pennsylvania facilities have continued to report events involving EPINEPHrine. Ongoing individual case review and analysis indicated that a number of different types of errors were occurring with EPINEPHrine, many with a potential to cause patient harm. Authority analysts decided to look again into the nature of EPINEPHrine events and provide an updated picture of what is going wrong, beyond just name and concentration confusion.

Analysts examined all medication and medical error reports that included mention of EPINEPHrine (n = 648) that were submitted to the Authority from June 2004 to July 2009. Review of the cases found that 280 reports indicated some type of error occurred involving EPINEPHrine. The majority (268 of 280) were classified as some type of medication error. The other 12 EPINEPHrine-related events were classified as an error related to procedure/treatment/test, complication of procedure/treatment/test, or other/miscellaneous.

Analysis of the events filtered by "harm" showed that more than half the errors involving EPINEPHrine resulted in a need for monitoring, intervention, and/or treatment (see Table 1). Nearly 11% (30 of 280) of the reports indicated that some level of patient harm, including permanent harm or a near-death event, occurred. Patients required either monitoring to confirm that no harm occurred or intervention to prevent harm in 45% (126 of 280) of the reports.

The largest percentage of events (26.8%) occurred in the emergency department (ED) (see Table 2). The events in the ED also accounted for the highest number of harmful events. Thirteen of the 30 patients harmed as a result of an error involving EPINEPHrine were being treated in the ED at the time of the event.

More events were classified by facilities as wrong-route errors (59) than as any other error type (see Table 3). Typically, these events involved intravenous (IV) administration of EPINEPHrine, rather than subcutaneous or intramuscular administration, leading to cardiovascular sequelae (e.g., elevated blood pressure, increased heart rate, chest pain). However, analysis of the error descriptions in the reports identified 12 additional reports that described wrong-route events but were not classified as such. This increased the number of wrong-route errors to 71, or 25.4% of all EPINEPHrine-related events. This analysis also revealed that wrong-route errors accounted for 63.3% of the harmful events (19 of 30), more than any other type of error.

When looking specifically at reports from the ED, 41 of the events in the ED were classified by facilities as wrong-route errors. Analysis of error descriptions identified six additional cases of wrong-route events that had been classified using other error types. As a result, the number of wrong-route errors in the ED rose to 47 or 62.7% of the ED events.

Table 1. Harm Scores* of Reported Events

HARM SCORE	NUMBER OF EVENTS
No Harm (n = 250)	
A. Circumstances that could cause adverse events	11 (3.9%)
B1. An event occurred, but it did not reach the individual because of chance alone	0 (0%)
B2. An event occurred, but it did not reach the individual because of active recovery efforts by caregivers	31 (11.1%)
C. An event occurred that reached the individual but did not cause harm and did not require increased monitoring	82 (29.3%)
D. An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm	126 (45%)
Harm (n = 30)	
E. An event occurred that contributed to or resulted in temporary harm and required treatment or intervention	18 (6.4%)
F. An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization	9 (3.2%)
G. An event occurred that contributed to or resulted in permanent harm	2 (0.7%)
H. An event occurred that resulted in a near-death event (e.g., patient required ICU care or other intervention necessary to sustain life)	1 (0.4%)
I. An event occurred that contributed to or resulted in death	0 (0%)
Total	**280 (100%)**

*Adapted from: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). NCC MERP index for categorizing medication errors [online]. 2001 [cited 2009 Jul 20]. Available from Internet: http://www.nccmerp.org/medErrorCatIndex.html.

* The "TALLman" (or mixed case) lettering schemes suggested by the Institute for Safe Medication Practices[3] for the look-alike names EPINEPHrine and ePHEDrine are used in this article. TALLman letters, by drawing attention to the dissimilarities in the names, can help distinguish similar looking drug names[4] and make them less prone to mix-ups.[5,6]

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Table 2. Top 10 Cited Locations of Events as Reported by Pennsylvania Facilities (Total Reports N = 280)

LOCATION	NUMBER OF EVENTS
Emergency department	75 (26.8%)
Operating room	25 (8.9%)
Pharmacy	16 (5.7%)
Pediatric intensive care unit (ICU)	16 (5.7%)
Cardiac unit	14 (5%)
Cardiac ICU	11 (3.9%)
Cardio/thoracic ICU w/transplant	11 (3.9%)
Medical ICU	10 (3.6%)
Cardio/thoracic ICU w/o transplant	8 (2.9%)
Medical/surgical ICU	8 (2.9%)

Table 3. Top 10 Reported Error Types as Reported by Pennsylvania Facilities (Total Reports N = 280)

ERROR TYPE	NUMBER OF EVENTS
Wrong route	59 (21.1%)
Wrong drug	50 (17.9%)
Medication error other	34 (12.1%)
Wrong dose/over dosage	31 (11.1%)
Wrong strength/concentration	21 (7.5%)
Wrong rate	11 (3.9%)
Wrong dose/under dosage	10 (3.6%)
Dose omission	8 (2.9%)
Monitoring error—documented allergy	7 (2.5%)
Wrong technique	7 (2.5%)

Wrong drug was the second most commonly cited medication error type (17.9%). Analysis of the events not classified as a type of medication error uncovered one additional case, raising the total number of wrong-drug events to 51. These errors involved mix-ups of EPINEPHrine with medications such as ePHEDrine (n = 6), norepinephrine (n = 8), neosynephrine (n = 5), and Ethamolin® (n = 3). Wrong-drug errors accounted for only two cases of patient harm. However, the inadvertent IV administration of EPINEPHrine instead of ePHEDrine resulted in a near-death event for a patient on a labor/delivery/recovery unit.

Thirty-one events were classified as wrong dose/over dosage. While this event type was fourth among the most commonly cited event types, it accounted for the second most number of harm events (5). Many of these events involved pump-related errors (e.g., programming) or administration of more volume of drug than necessary.

Ratio-strength expressions have been known to create confusion and lead to errors.[2,7] Practitioners have not recognized or understood the difference between dose concentrations, such as 1:1,000 (or 1 mg/mL) and 1:10,000 (or 0.1 mg/mL). Also, numbers in the thousands are easy to confuse because there are so many zeros (i.e., 1,000 looks like 10,000). Given their error-prone nature, the Authority's reporting system database was examined specifically for cases of confusion related to the use of ratios to express concentration. For the majority of event reports, insufficient information was provided to determine the role, if any, the ratio expression played. However, eight cases were identified. The events were classified as either wrong dose/over dosage or wrong strength/concentration errors. Four of these events resulted in temporary harm that required either treatment/intervention or initial/prolonged hospitalization.

Given the potential harm associated with an error that occurs with the use of EPINEPHrine, facilities should examine how and where the drug is ordered, stored, and administered. Particular attention should be focused on practices in the ED as well as strategies to prevent wrong-route errors because these areas/errors are affecting the most patients and inflicting the most harm. For additional strategies, review the September 2006 *Patient Safety Advisory* article "Let's Stop This "Epi"demic!—Preventing Errors with Epinephrine."

Notes

1. Institute for Safe Medication Practices (ISMP). ISMP 2007 survey on high-alert medications: differences between nursing and pharmacy perspectives still prevalent. ISMP Med Saf Alert [online]. 2007 May 17 [cited 2009 Jul 20]. Available from Internet: http://www.ismp.org/Newsletters/acutecare/articles/20070517.asp.
2. Let's stop this "Epi"demic!—preventing errors with epinephrine. PA PSRS Patient Saf Advis [online] 2006 Sep [cited 2009 Jul 20]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Sep3(3)/Pages/16.aspx.
3. Institute for Safe Medication Practices. Use of tall man letters is gaining wide acceptance. ISMP Med Saf Alert [online]. 2008 Jul 31 [cited 2009 Jul 20]. Available from Internet: http://www.ismp.org/Newsletters/acutecare/articles/20080731.asp.
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6. Grasha A. Cognitive systems perspective on human performance in the pharmacy: implications for accuracy, effectiveness, and job satisfaction. Report No. 062100. Alexandria (VA): National Association of Chain Drug Stores (NACDS); 2000.
7. Institute for Safe Medication Practices. It doesn't pay to play the percentages. ISMP Med Saf Alert [online]. 2002 Oct 16 [cited 2009 Jul 20]. Available from Internet: http://www.ismp.org/Newsletters/acutecare/articles/20021016.asp.

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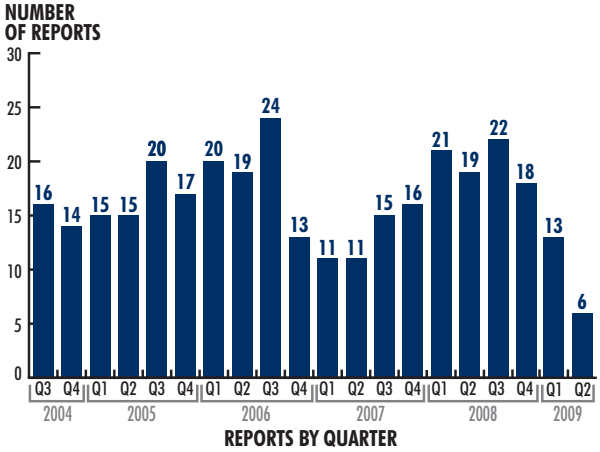
Improvement in Preventing Wrong-Site Surgery! Traction or Transient?

The latest update from the Pennsylvania Patient Safety Authority's reporting system database shows an encouraging decrease in the number of reports of wrong-site surgery for the third consecutive quarter (despite adjustments for late reports) to an all-time low of six reports (see Figure). This is the most sustained statewide decrease in wrong-site surgery events to date. Furthermore, a regional collaborative to prevent wrong-site surgery that began in March 2008 reported zero wrong-site surgeries during the second quarter of 2009, meaning facilities participating in the collaborative have reported only two events in more than seven months and none in more than four months. The collaborative's time without wrong-site surgery exceeds 95% of its previous event-free intervals. The Authority continues to monitor wrong-site surgeries and plans to replicate the collaborative in another region.

Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter



The six reports during the second quarter of 2009 all described problems previously addressed by the Authority:

- One report described a wrong-site surgery based on an incorrect side listed on the schedule. The Authority advocates checking the accuracy of the site on the schedule by reconciling the schedule with the history and physical, physician order, and consent.
- Three reports described wrong-site anesthesia blocks without referencing the site mark. Many wrong-site procedures are wrong-site anesthesia blocks that could be prevented by a formal time-out before such procedures.
- One report described doing the time-out before prepping the patient. The wrong site was then prepped. The Authority advises doing the time-out after prepping and draping, with the site mark visible in the field.
- One report, edited for contextual deidentification, is described in full because it includes many causes of wrong-site surgery. (The reader is encouraged to take a moment to list as many causes he or she can and then compare those causes with the causes that the Authority's analysts identified.)

  The patient arrived for ordered left YAG laser iridotomy for glaucoma. The patient was identified and prepped for this procedure. When the surgeon arrived, the nurse performed a time-out using the original physician order and the consent, both indicating that the patient was to undergo a left YAG laser iridotomy for glaucoma. The doctor informed the nurse that the nurse was wrong. The nurse showed the doctor the original order and consent signed by the patient in the office. The doctor insisted the patient was to have left YAG laser capsulotomy for posterior capsule opacification. The doctor overruled the information from the time-out and performed a left YAG laser capsulotomy for posterior capsule opacification. At the end of the procedure, the doctor realized an error had been made and then performed the correct procedure on the patient's left eye. Investigation of the event revealed that the surgeon had two patients scheduled back-to-back that afternoon: the first for a capsulotomy and the second for an iridotomy. The patients were taken to the [operating room (OR)] out of order due to their arrival time. Even though the nurse identified the patient correctly and performed a time-out correctly indicating a left iridotomy procedure, the surgeon "pulled rank" and insisted on doing a left capsulotomy, which was originally the first procedure on the schedule that day.

The facility identified two problems: (1) the lack of situational awareness about the change in the OR schedule and (2) the use of hierarchy to resolve a conflict. The Authority's analysts also identified the failure of the surgeon to see the patient before the patient entered the OR to verify the correct information, the failure to verify information with the patient, reliance on memory rather than documentation, the failure to reconcile conflicting information, the failure to have office records available for reference, the failure to empower the nurse, and the failure to satisfactorily address a concern raised by a member of the operating team.

Although Pennsylvania facilities are reporting fewer wrong-site surgeries, one of the above reports was from a facility that had never previously reported a wrong-site procedure in the five years of mandatory reporting to the Authority, despite a large volume of surgery. Its report is an example that facilities must always be aware of the possibility that the next case may involve wrong-site surgery.

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If surgical facilities are to hold their gains in consistently performing correct-site surgery, the following principles for reliable performance of correct-site surgery, identified by the Authority during its Preventing Wrong-Site Surgery Project, should be consistently followed:

1. The correct site of the operation should be specified when the procedure is scheduled.
2. The correct operation and site should be noted on the record of the history and physical examination.
3. The correct operation and site should be specified on the informed consent.
4. Anyone reviewing the schedule, consent, history and physical examination, or reports documenting the diagnosis, should check for discrepancies among all those parts of the patient's record and reconcile any discrepancies with the surgeon when noted.
5. The surgeon should bring copies of supporting information uniquely found in the office records to the surgical facility the day of surgery.
6. All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the nurse, anesthesia provider, and surgeon before the patient enters the OR.
7. All verbal verification should be done using questions that require an active response of specific information, rather than a passive agreement.
8. Patient identification should always require two unique patient identifiers.
9. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.
10. The site should be marked by a healthcare professional familiar with the facility's marking policy, with the accuracy confirmed both by all the relevant information and by an alert patient, or patient surrogate if the patient is a minor or mentally incapacitated.
11. All information that should be used to support the correct patient, operation, and site, including the patient's or family's verbal understanding, should be verified by the circulating nurse upon taking the patient to the OR.
12. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.
13. The site mark should be visible and referenced in the prepped and draped field during the time-out.
14. Verification of information during the time-out should require an active communication of specific information, rather than a passive agreement, and be verified against the relevant documents.
15. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.
16. The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.
17. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.
18. Any concerns should be resolved by the surgeon, based on primary sources of information, to the satisfaction of all members of the operating team before proceeding.
19. Verification of spinal or rib level should require radiological confirmation, using a stable marker and readings by both a radiologist and the surgeon.
20. All paperwork and labels for a patient in an OR should be cleared before the next patient arrives.
21. Information identifying surgical specimens should be verified with the surgeon via active communication of specific information, rather than a passive agreement.

Survey on Surgical Site Marking Pens and Techniques

In July 2009, the Authority's analysts distributed a survey, through Patient Safety Officers (PSOs), for OR managers in Pennsylvania hospitals and ambulatory surgical facilities to share their good and bad experiences using various marking pens with various skin preparation agents. OR managers were asked to report the visibility of their markers with their various skin preparations and to relay any complaints from patients.

Within three weeks, the Authority received 106 responses of facility experiences. The results of the survey are available in two tables on the Authority's Web site.* Table 1 lists experiences according to the markers, and Table 2 lists experiences according to the skin preparation agents. (Although respondents were not asked to list multiple products, some did; hence, the number of evaluations exceeded the actual number of survey responses.) Experiences are reported for visibility of the mark after skin preparation and for patient complaints about the marks. Cardinal Health markers were almost always reported to be visible with no patient complaints, although the specific Cardinal Health products were not listed in the reports. Viscot Medical Precision surgical skin markers received comparable reports, albeit with fewer

* The Pennsylvania Patient Safety Authority has a Web page devoted to educational tools for preventing wrong-site surgery (available at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx). Its resources include all the Authority's publications on the subject, including self-assessment tools, sample forms and checklists, educational posters and videos, illustrative figures and tables, patient-education brochures, and online information available from other Web sites.

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experiences and one comment that the ink needs adequate time to dry.

Only 3 of the 106 facilities reported surgeons' concerns about the sterility of marks in a prepped surgical field. In a prior review, the Authority reported no documented concerns in the medical literature regarding the sterility of single-use marking pens.[1]

The Time-Out Script Competition

The Authority has posted five entries for the Time-Out in the OR Script Competition online at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/scripts.aspx.

The first round of open-ended review and comment remains active for all who wish to participate. The *Pennsylvania Patient Safety Advisory* editors appreciate the review comments submitted to date. The editors may publish some of the critiques during the second round but will not identify any reviewers. The reviews may make a general comment on any script or comment on any parts of any scripts, positively or negatively, but should specifically consider at least three issues: (1) compliance with the time-out elements of the Universal Protocol intended to prevent wrong-site surgery, (2) active participation of all the important members of the operating team, and (3) efficiency. Efficiency will be defined as the length of time involved in performing the script. As mentioned in the March 2009 issue of the *Advisory*, the time should ideally be less than 90 seconds. Please note that the script competition includes only the parts of a time-out script that identify the patient, procedure, and side or site of the procedure. Implants availability, antibiotic administration, allergies, and other additions to the Universal Protocol not related to preventing wrong-site surgery have been eliminated from the time-out scripts. Elements of the time-out that involve confirmation or documentation not based on conversation have also been eliminated. Please send your reviews and comments on any or all components of any or all scripts electronically to the editor at jclarke@ecri.org. Please ensure comments are linked to specific scripts by their numbers. This is your chance to help shape robust scripts for time-outs.

The Authority remains committed to decreasing and eventually eliminating wrong-site surgery. The Authority welcomes any comments, suggestions, and specific inquiries from facilities with specific problems or questions concerning wrong-site surgery. For example, PSOs at facilities that experience wrong-site surgery could contact the Authority to assist in root-cause analysis. Communications should be directed to: John Clarke, MD, FACS, clinical director of the Pennsylvania Patient Safety Authority, at ECRI Institute, by telephone at (610) 825-6000 or by e-mail at jclarke@ecri.org.

Note

1. Surgical site markers: putting your mark on patient safety. Pa Patient Saf Advis [online] 2008 Dec [cited 2009 Aug 4]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Dec5(4)/Pages/130.aspx.

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Collaborative Patient Safety Effort: Addressing Phlebotomy Specimen Mislabeling

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Collaboration among healthcare facilities is an effective means to bring about positive change. Such collaboration is evident in Pennsylvania healthcare facilities. Event reports submitted through the Pennsylvania Patient Safety Authority's reporting system have prompted regional collaboratives and even a national response to a patient safety issue (i.e., standardization of color-coded patient wristbands).[1] In 2009, Pocono Medical Center, recognizing an opportunity in near-miss data, pursued a regional collaborative through the Authority to address the issue of mislabeled specimens.

Recognizing the Problem

During a January 2009 Authority presentation titled "Patient Safety Challenges in Pennsylvania" at Pocono Medical Center, participants noted that in 2007 "errors related to procedure/treatment/test" were the predominant type of event reported to the Authority (23%), of which "laboratory test problem" was the predominant subcategory (41%). This information coincided with findings at the medical center. Specifically, the medical center identified that it reported a large proportion of specimen mislabeling events under this subcategory.

Recognizing that other facilities likely had experienced mislabeled specimen near misses, the medical center contacted the Authority to facilitate—through the Authority's Patient Safety Liaison (PSL) Program—a regional improvement collaborative to address this problem.

In a typical hospital clinical laboratory, thousands of specimens are received and analyzed daily.[2] Specimen mislabeling can happen in any setting in the organization. Analysis of Authority data has shown that mislabeling events occur more often in the emergency department (ED) than other care areas, which is consistent with findings reported in the literature. In a study conducted at University Hospitals of Cleveland, Ohio, results indicated that laboratory samples drawn in the ED were 10 times more likely to be mislabeled.[3] Patient volume, emergent conditions of the patients, and demand for rapid turnaround on collection and analysis of specimens likely all affect the higher number of reported events in this setting. According to Wagar et al., these types of events would score high for severity and low for detectability using failure mode and effects analysis because the errors are not generally discovered until a clinician questions a result that is atypical for a given patient.[2] Lippi et al. discuss that errors are not detected or reported consistently because frontline healthcare staff may feel that it is not worth their time to report an event if no harm comes to the patient as a result of a misidentification error.[4]

Injuries associated with phlebotomy specimen mislabeling can have a significant clinical, financial, and emotional effect on all involved. Seventy percent of all information used by clinicians to diagnose conditions and treat patients comes from the laboratory setting.[5] Therefore, inaccurate test results could lead to serious adverse outcomes for the patient, financial costs for the institution, and high emotional tolls for patients, family, and healthcare workers who experience an adverse event.

Building the Collaborative

Preliminary work started with a team that included the medical center's patient safety officer, regulatory director, and medical chief of staff, as well as the Authority's director of education, a patient safety analyst, and myself as the PSL. The team reviewed the most recent data available (calendar year 2008 through April 2009) to identify the extent of the problem. Results indicated an enduring high proportion of reports related to mislabeled specimens. The Authority then facilitated several meetings to introduce interested medical facilities in the Northeast Region to the collaborative.

All Northeast medical facilities that provide laboratory services to patients were invited to participate in an introductory session about the problem of mislabeled phlebotomy specimens, the objectives of the proposed collaborative, the benefits of involvement, and commitment to a year-long project. Representatives attended from 10 acute care hospitals and 1 rehabilitation hospital, comprising patient safety officers, laboratory directors, other laboratory personnel, and leadership. When polled, the participants identified that this was their first exposure to an interhospital project of this scope.

"Accurate specimen identification is a challenge in all hospitals, and a mislabeled specimen can lead to devastating consequences for patients."[2] In order to emphasize this point, Authority Director of Education Fran Charney, RN, BS, MSHA, CPHRM, CPHQ, CPSO, FASHRM, provided a real-life case scenario in which a blood transfusion mix-up led to a patient's death. Through group discussion, it was evident that the case scenario was not an isolated situation and that it could happen elsewhere given the right set of circumstances and lack of forcing functions to prevent recurrence.

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An Authority patient safety analyst presented aggregated specimen mislabeling event data reported to the Authority, stratified according to event taxonomy, subcategories, care area, day of the week, and harm score. Analysis of the Authority data revealed that in the Northeast Region one mislabeling event was reported per facility per month. Participants recognized the high likelihood of underreporting of this event, especially for Incidents (near misses) that do not result in harm to the patient.

To ensure that the participating facilities will capture the appropriate events for analysis, they were encouraged to compare specimen mislabeling events submitted to the Authority to other data, such as the number of redraws per month, the number of specimens wasted per month, or other internal coding systems. The participants identified two key elements for this purpose: (1) the definition of phlebotomy specimen mislabeling and (2) the taxonomy under which these events will be reported to the Authority. Multi-institutional collaboration is an important aspect of this project, and while each facility may define a "correctly labeled specimen" differently, it was important that the definitions be shared across facilities and that each facility commit to capturing and reporting all specimens that were not correctly labeled according to their definition. These mislabeling events will be reported under standardized taxonomies so that data can be analyzed by region, as well as by individual facility.

At each facility, efforts will begin with coordinating resources and educating the leadership and staff about the issue. Participants expect an initial "spike" in the reporting of phlebotomy specimen mislabeling events after frontline staff are educated about the need to ensure complete capture of this data. Therefore, the participants anticipate a need for dedicated resources to collect and report the event data. The initiative is scheduled for completion in one year.

Providing Guidance

For this ongoing initiative, the Authority will provide education, technical assistance, tools, resources, and an interactive forum to facilitate participants' efforts to improve patient safety relative to phlebotomy specimen mislabeling prevention. Success in this effort depends on a high level of commitment from patient safety officers, laboratory directors, information technology personnel, nursing leaders, physician champions, senior leaders, and frontline staff. However, facilities throughout Pennsylvania stand to gain knowledge and insight from the work ahead.

The anticipated benefits of this collaboration include the following:

- A collaborative learning network in the Northeast Region of Pennsylvania that will foster success in reducing/eliminating phlebotomy specimen mislabeling
- Education built upon the "Reliable Design" process, including mapping the process, identifying barriers, and implementing change measures
- A business plan for patient safety related to phlebotomy specimen mislabeling
- Exploring human factors as a variable affecting laboratory specimen labeling processes
- Continuing nursing educational hours for attendance at Authority-sponsored educational events
- Aggregate and facility-specific baseline data (e.g., number of wasted specimens, number of patient redraws, number of deleted orders)
- A bibliography of medical literature related to laboratory specimen errors
- Ongoing Authority guidance, technical assistance, tools, and educational support
- Follow-up data collection and comparison reports to measure progress

Conclusion

As recognition has grown that errors are caused by failures in systems, interdisciplinary collaboration has become necessary to redesign complex systems of care. The collective goal of this collaborative is to identify steps and system redesigns to reduce and eventually eliminate opportunities for phlebotomy specimen mislabeling. Identified best practices will be shared in future updates in the *Pennsylvania Patient Safety Advisory*. As the Authority's PSLs further engage facilities in their regions, there will be more opportunities for similar collaboratives. Joint collaboratives are just one way that the Authority continues its work to improve patient safety in Pennsylvania healthcare facilities.

Notes

1. Color-coded patient wristbands create unnecessary risk. PA PSRS Patient Saf Advis [online] 2005 Dec 2 [cited 2009 Jul 29]. Available from Internet: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/dec14_2(suppl2)/Pages/dec14;2(suppl2).aspx.
2. Wagar EA, Tamishiro L, Yasin B, et al. Patient safety in the clinical laboratory. *Arch Pathol Lab Med* 2006 Nov;130(11):1662-8.
3. Sandhaus L, Michelson E, Sauder K. Relative frequencies of mislabeled laboratory samples from the emergency department (ED) versus other hospital areas [poster online]. 2005 Institute for Quality in Laboratory Medicine Conference: Recognizing Excellence in Practice; 2005 Apr 28-30 [cited 2009 Jul 9] Available from Internet: http://wwwn.cdc.gov/dls/IQLM/2005Posters/Sandhaus-39-Frequency%20of%20mislabeled%20lab%20samples%20fm%20ED%20comapred%20to%20other%20hosp%20areas.pdf.
4. Lippi G, Blanckaert N, Bonini P, et al. Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics. *Clin Chem Lab Med* 2009;47(2):143-52.
5. Dock B. Improving the accuracy of specimen labeling. *Clin Lab Sci* 2005 Fall;18(4):210-2.

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Online Resources Associated with Patient Safety Advisories

Patient Safety Officers have expressed their interest in distributing educational resources within their healthcare facilities. The Pennsylvania Patient Safety Authority provides a growing collection of resources related to *Pennsylvania Patient Safety Advisory* articles to help increase situational awareness and patient safety within healthcare facilities. Examples include sample policies, educational videos and posters, brochures, interactive learning graphics, and reference materials.

This collection of resources is available online at http://www.patientsafetyauthority.org. Topics addressed include the following:

- Preventing wrong-site surgery
- Verbal orders
- Contrast-induced nephropathy
- Expressed breast milk
- Hospital bed safety
- Skin tears
- Color-coded wristbands
- Common hazards in the behavioral health patient room

More improvement comes from improving a system than improving the performance of individuals within an existing system.

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Whether you would like to learn more about the topics described above, or you need tools to help you meet other challenges, these educational resources can help.

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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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.