PENNSYLVANIA PATIENT SAFETY ADVISORY

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OBJECTIVE

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

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Managing Drug Shortages

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During my visits to regional healthcare facilities, I often ask the facility patient safety officers what challenges they face. One common frustration they mention is managing drug shortages. Drug shortages affect patient care. Not only are there clinical implications to drug shortages, such as having to use a less optimal medication or rescheduling procedures, there is a financial impact, and resources are required to manage the shortage. The patient safety aspect of drug shortages is not to be underestimated, either, as evidenced by these events reported to the Pennsylvania Patient Safety Authority.

> *The pharmacist was working on an order for a brand new bag of D10/0.2%NS, as the premade bottles were on back order. The pharmacist had to start from scratch to prepare the solution. The pharmacist did his calculations and noted that he came up with something different than the pharmacist did the previous day. The pharmacist believed that the previous pharmacist had miscalculated and was low by a factor of ten of the sodium chloride. When the other pharmacist came into work on this day, this pharmacist discussed the miscalculation together. It was learned that the order from the previous day was correct, and the miscalculation for today resulted in the sodium chloride content of the IV [intravenous bag] to be ten times higher than what was ordered.*
>
> *A patient [presented] to the ED [emergency department] for rabies vaccine; the pharmacy informed the ED that the vaccine was not available due to back order.*
>
> *A patient required 71 mg tissue plasminogen activator (t-PA). [The patient] received 50 mg t-PA related to pharmacy shortage.*

DRUG SHORTAGES AND PATIENT SAFETY

Results of a 2010 Institute for Safe Medication Practices (ISMP) survey of pharmacists and other healthcare providers[1] indicated that drug shortages present a clear patient safety threat. More than 1,800 respondents from across the country participated in the survey. Thirty-five percent of respondents indicated they experienced a near-miss event because of a drug shortage. One in four reported an error occurred that reached a patient, and one in five reported an adverse patient outcome occurred due to a drug shortage.

Many error examples included in the ISMP article discussing the survey results involve high-alert medications, which are medications that are more likely to cause harm when used in error. In one case, propofol was unavailable, and an alternative medication was not prescribed, leaving a paralyzed and ventilated patient with no sedation. Another patient received 10 mg of morphine instead of the 1 mg that was ordered. Another report indicated that a shortage of prefilled EPINEPHrine syringes may have contributed to a patient death during a code situation because healthcare providers were unable to keep up with the demand for EPINEPHrine when each ampul had to be diluted.

WHY DRUG SHORTAGES OCCUR

Drug shortages occur for many reasons.[2] Raw materials used in manufacturing may be unavailable. Manufacturing disruptions could occur due to a change in formulation, manufacturer mergers, product discontinuation, or moving production to a new facility. Production line downtime due to maintenance, changes, or regulatory shutdowns will also adversely affect supply. A manufacturer may choose to eliminate a product due to small market size or unprofitability. Recalls may decrease a drug's availability. Natural disasters may disrupt production or increase demand. Drug demand may also increase because of a new indication, new guideline, a shift in clinical practice, or a disease outbreak. Hoarding of drugs can prematurely increase a shortage's impact or lead

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to secondary shortages; for example, if morphine is in short supply, more people may be purchasing HYDROmorphone, leading to shortage of HYDROmorphone as well.

MANAGING DRUG SHORTAGES

The American Society of Health-System Pharmacists (ASHP) identifies three main steps in managing a drug shortage in a healthcare facility:[2]

1. Identification and assessment
2. Preparation
3. Contingency

The first step in managing a drug shortage is to identify that there is a shortage. Often, a shortage is discovered when attempts are made to order a medication. How much medication is in stock will determine how much time a facility has to address the issue. ASHP and the U.S. Food and Drug Administration (FDA) have both created webpages to notify healthcare professionals when a drug shortage has been identified or is likely to occur. The FDA webpage (http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm) lists only medically necessary drugs, while the ASHP webpage (http://www.ashp.org/menu/PracticePolicy/ResourceCenters/DrugShortages.aspx) is more comprehensive, with 199 medications listed in September.

Once a drug shortage has been identified, facilities need to assess the impact of the shortage on their practice. For example, how much of the drug is currently in stock? How is the drug used and in what population? How long is the shortage expected to last?

After the impact has been assessed, facilities can begin to prepare to mitigate the effects of the shortage. This requires evaluating what concentrations, alternate packaging, or therapeutic alternatives are available. Therapeutic alternatives are rarely optimal choices, or they would be in use already. It is important to consider how the alternatives work. For example, are they appropriate for the population? Or, what are the dosing and prescribing parameters? There will likely be differences in the amount and frequency of dosing, side effects, and the onset and duration of the drug's effectiveness. Preparation, storage, and administration requirements are also important to examine. Certain populations may not be appropriate for use of these alternatives. Education and drug information about the alternatives is to be easily accessible to all staff. Facilities can also review the potential for look-alike or sound-alike confusion to arise whether utilizing an alternative drug or a different concentration of the drug in short supply.

The contingency step may involve the facility risk management or ethics departments if there is reason to believe that patient care could be delayed or compromised due to the shortage. Communication with staff and patients is also a component of this step.

EFFORTS TO DECREASE SHORTAGES

Increasing attention has been paid to the impact of drug shortages. In November 2010, ISMP, ASHP, the American Society of Anesthesiologists, the American Society of Clinical Oncology, and representatives from other professional organizations, manufacturers, and healthcare facilities convened a summit to discuss the impact of drug shortages and create recommendations.[3]

In February 2011, the Preserving Access to Life-Saving Medications Act was introduced to the U.S. Senate and referred to committee.[4] This bill would require a drug manufacturer to notify the Secretary of Health and Human Services of a "discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug" six months before a discontinuance or planned disruption, or "as soon as practicable" if the disruption is unplanned.

CONCLUSION

Drug shortages can affect patient care and patient safety. While they are not preventable, they can be managed in a way that will decrease the likelihood of negative outcomes. This management includes identifying which drugs are likely to be unavailable or in short supply, assessing the utilization of those drugs in the healthcare facility, preparing for the shortage, and having clear policies for controversies that may arise.

NOTES

1. Institute for Safe Medication Practices (ISMP). Drug shortages: national survey reveals high level of frustration, low level of safety. *ISMP Med Saf Alert* 2010 Sep 23;15(19):1-6.
2. Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. *Am J Health Syst Pharm* 2009 Aug 1;66(15):1399-406.
3. American Society of Health-System Pharmacists, American Society of Anesthesiologists, American Society of Clinical Oncology, et al. Drug shortages summit summary report, November 5, 2010 [online]. [cited 2011 Jul 27]. Available from Internet: http://www.ashp.org/drugshortages/summitreport.
4. S. 296—112th Congress: Preserving Access to Life-Saving Medications Act. (2011). In GovTrack.us [database of federal legislation]. [cited 2011 Jul 27]. Available from Internet: http://www.govtrack.us/congress/bill.xpd?bill=s112-296.

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Point-of-Care Technology: Glucose Meter's Role in Patient Care

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ABSTRACT

Glucose meters are a point-of-care device used in the management of blood glucose levels for hospitalized patients. Glucose meters provide results so quickly that, in some cases, health-care workers treat patients based on meter results before validating them. Events reported to the Pennsylvania Patient Safety Authority demonstrate unintended consequences that arose when patients were treated based solely on glucose meter results. Proper meter use, hospital policies and protocols, and a physical assessment coupled with effective communication are components of good patient care. The ability to think critically, balancing these components, can be the difference between the delivery of safe patient care and a serious or fatal adverse event. (Pa Patient Saf Advis 2011 Dec;8[4]:119-125.)

INTRODUCTION

Point-of-care (POC) glucose meters are an integral part of the typical approach to managing hospitalized patients' blood glucose levels[1,2] because they provide immediate results and are cost-effective. Used correctly, these devices are an invaluable aid; however, they are not infallible. Taking action solely on the basis of the glucose meter results without a patient assessment can lead to serious unintended consequences. The following event reported to the Pennsylvania Patient Safety Authority demonstrates this point:

> *A patient's [glucose meter result] read "RR HI." The patient was asymptomatic and previous [glucose meter results] were not running "HI." Insulin coverage was held until the result of the [laboratory] glucose [level] was obtained. The [laboratory] glucose result read 79. The patient was not given any insulin coverage and remained asymptomatic with low glucose [levels].*

The purpose of this review is to identify problems related to POC blood glucose testing in Pennsylvania hospitals and provide suggestions to prevent adverse events.

PROBLEMS WITH POC BLOOD GLUCOSE TESTING

A search of the Authority reporting system database, from June 28, 2004, through May 31, 2011, was conducted to identify glucose-meter-related event reports. The initial search, using the words "test strips," "glucose strips," and "accucheck," identified more than 3,200 event reports, which were refined to more than 1,300 reports by limiting the search to specific event types (e.g., procedure errors and complications, equipment use and device issues, miscellaneously identified glucose-meter-related reports). A review of the 1,300 reports identified 71 glucose meter near-miss and adverse event reports that composed the final data set. The detailed analysis identified four common themes, as follows:

— Equipment use
— Hospital policy and protocols
— Physical assessment of the patient
— Healthcare team communication

Seventy percent (n = 50) of the 71 reports document equipment use as the only issue, while the remaining 30% (n = 21) of the reports identified an equipment use issue in conjunction with 1 or more of the 3 other issues identified above, (e.g., equipment use and hospital policy; equipment use, hospital policy, and physical assessment). (See Table 1.)

Next, the analyst examined harm score event report categories.[3] Fifty-four percent (n = 38) of the reports were reported as harm scores A through C (an event did not reach the patient, or an event that reached the patient but did not cause harm or require increased monitoring). Forty-six percent (n = 33) of the reports were reported as harm scores D through I (the event reached the patient and required monitoring intervention or caused harm or death). Harm scores D through I were present whether there was only one issue (i.e., equipment use) or multiple issues reported.

Equipment Use

Results from blood glucose meters are not as accurate as lab-based blood glucose results.[4-6] The Authority data analysis identifies two types of glucose meter issues: questionable glucose meter results and test strip issues.

Standards set by the U.S. Food and Drug Administration (FDA) and the International Organization for Standardization require that 95% of glucose meter results vary no

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Table 1. Glucose-Meter-Related Events Reported to the Pennsylvania Patient Safety Authority, June 28, 2004, through May 31, 2011

EQUIPMENT USE	HOSPITAL POLICY AND PROTOCOL	PHYSICAL ASSESSMENT OF THE PATIENT	HEALTHCARE TEAM COMMUNICATION	TOTAL NUMBER OF REPORTS
✓				50
✓	✓			9
✓		✓		5
✓	✓		✓	3
✓	✓	✓		2
✓		✓	✓	1
✓	✓	✓	✓	1
				71

more than 20% (±20%) when glucose levels are greater than 75 mg/dl. This means that when a blood glucose level reads 100 mg/dl, 95 of 100 samples should read between 80 and 120 mg/dl.[4,5] The other 5% of results may fall just outside the 20% range or may be extreme outliers. The magnitude of this issue was presented at an FDA public meeting. A physician reported that at his hospital he had 600,000 glucose meter results per year; if 95% of the results fall within the 20% variability, the other 5% or 30,000 results fall outside the acceptable range.[5]

An analysis of the Authority data was conducted to determine the type of glucose meter variability within Pennsylvania hospitals. There are three types of variability: high-blood glucose results (72%, n = 51), unidentified questionable results (18%, n = 13), and low-blood glucose results (10%, n = 7). The analyst then evaluated whether the high-blood glucose results were validated, how they were validated, and where they occurred (see Table 2).

The following two Authority reports demonstrate the significance of high-blood glucose meter results:

> *The nightly [glucose meter] reading was 454. [Staff] obtained a stat blood glucose from the lab. The [lab result] was 152. A quality check was done to the machine and an out-of-order sign was placed on the machine.*

> *A patient's blood sugar was checked using a [glucose meter]. The lunchtime result was 517. A [blood glucose test] was [immediately] retaken to check for accuracy, and the result was greater than 600. A blood [laboratory] level check was conducted per protocol, and the [lab] glucose [result] was 136. The nurse used the serum glucose as the actual result and reported a malfunction in the machine to the lab and the [nurse manager]. The [nurse manager] was made aware of the situation and took the glucose meter out of use on the floor and notified the supervisor in the lab. The supervisor in lab removed the machine from service and replaced the machine with a new machine.*

Test strips are the second issue. Glucose meter test strips are layers of porous paper with enzyme reagents that react to substances, using whole blood to calculate a blood glucose result.[6,7] Test strips require careful handling because they can absorb and react to different types of nonblood substances (e.g., food, moisture, nonglucose sugars), leading to test strip contamination. Other commonly reported problems associated with test strips include improper use and patient physiologic conditions. The following is an Authority report example:

> *The nursing supervisor received a call from the community [outpatient] peritoneal dialysis [nurse] about a patient being directed to the ED. The peritoneal dialysis nurse called the ED nurse to report the patient was on extraneal/icodextran peritoneal dialysis solution, and that [certain] blood glucose machines cannot be used [on patients receiving certain types of peritoneal dialysis] or false readings will occur [because certain types of test strips cannot distinguish between glucose, maltose, galactose, and xylose]. The peritoneal dialysis nurse requested this information be placed on the patient chart and reported to the floor nurse. Only [lab] blood glucose [tests] can be performed on the patient. [Glucose meter results] were done [over a 24-hour period]. [On the second day,] ... [a glucose meter result] was done and results appeared normal. A serum blood was drawn ... and the [lab] blood glucose was 32. .... All unit managers involved were made aware. Orders were changed to reflect serum blood glucose [lab tests] only and a note was placed on the front of the chart.*

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Table 2. Validation Technique and Event Location (n = 51) of High Glucose Meter Result Events Reported to the Pennsylvania Patient Safety Authority, June 28, 2004, through May 31, 2011

AUTHORITY HIGH GLUCOSE METER RESULT REPORTS	NUMBER OF REPORTS	PERCENTAGE OF REPORTS
Validation Technique		
Compared to blood serum lab value	44	86.3%
Check result with same or different glucose meter	6	11.8
Not validated with glucose meter or serum lab	1	1.9
Location of Event		
Units other than intensive care units	36	70.6
Not specified	10	19.6
Intensive care units	5	9.8

Hospital Policy and Protocol Challenges

Hospital policies and procedures dictate how blood glucose meters are used. The Authority event descriptions that mention patient treatment delivered based on glucose meter results were a proxy for hospital policy and protocols. Twenty-one percent (n = 15) of the reports implicated hospital policy or protocols.

The following example demonstrates the impact of hospital policies on how blood glucose meters are used:

> *A [glucose meter] gave a reading of 468, and the physician was notified and ordered insulin, which was given. The morning [fasting blood sugar] from lab came back with result of 122. A [glucose meter test] was redone on a different machine with a reading of 135. [The second glucose meter] was calibrated [within normal limits] following the discrepancy. [The initial glucose meter] machine was taken out of service. The patient's [blood sugar] was checked [on the hour for six hours] and observed for hypoglycemia. No adverse outcome was observed.*

This report does not indicate whether the result was a new high glucose level or an existing condition. Before treating a patient's high glucose level, especially a new high glucose level, the result needs to be validated. Hospital policies and protocols can guide staff in the proper response to this situation.

Physical Assessment Symptoms

Hyperglycemia is more likely to occur when patients are experiencing a sympathetic response to physiologic stress. The challenge for healthcare workers is to distinguish actual hyperglycemic states from inaccurate meter results. When interpreting a high blood sugar reading, it is important to consider the clinical context. For example, has the patient been experiencing similar levels of hyperglycemia? Has he or she just eaten or taken sugar containing fluids? Has the patient just been started on steroids? Was a dose of insulin omitted? High glucose meter results accompanied with a physical assessment help validate the results and reduce the likelihood of patients developing hypoglycemia from inappropriate treatment. Nine of the 51 high glucose meter readings (13%) identified whether patients exhibited or were subsequently evaluated for symptoms of hypoglycemia. A separate analysis of high glucose meter results was conducted to determine the occurrence of insulin-induced hypoglycemia. Twenty-seven percent (n = 14 of 51) of patients with high meter results were administered insulin; four patients subsequently experienced hypoglycemic symptoms or were treated with dextrose 50%. See the following reported example:

> *Patient's glucose meter reading [prior to lunch] read "HI." Patient covered with 6 units Novolog insulin. A stat venous draw was done; [the result] was 62. The patient was lethargic at this time and was given orange juice with sugar. [Repeat glucose meter result] came up to 156.*

Healthcare Team Communication Delays

Miscommunications, lack of communication, or partial communication of information were reported in only 7% (n = 5 of 71) of the reports; see the following example:

> *A routine [glucose meter test] was performed with a result of 520. The lab was called to draw a blood glucose level. The patient was [treated] with 10 units of Novolog subcutaneous. The [blood glucose] result was 375. A [glucose meter test was performed] one hour later after administration of the insulin. The insulin coverage was given to the patient prior to lab verification, which could have been detrimental to the patient.*

This report demonstrates the importance of obtaining more detailed information, the lab glucose level, before any treatment decisions.

WAYS TO SAFELY INCORPORATE GLUCOSE METER USE INTO CLINICAL PRACTICE

Equipment Use

Questionable glucose meter results can occur because of meter variability, user variability (e.g., sample quality, timing),

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patient physiology, care of the meter, and test strips. The following measures (based on literature and analysis of reports) can reduce the chance of questionable glucose meter results:

— Perform quality checks at the beginning of every shift.
— Stay informed about the patient's blood glucose result history and activities.
— Use the same glucose meter for the same patient all day.[8]
— Place a clearly marked identification number on each glucose meter.
— Record the glucose meter identification number in the patient's chart to ensure that the same glucose meter is used on the same patient throughout the day.
— Perform a separate or additional glucose meter reading at the same time as the glucose serum blood draw each day to validate the blood glucose result with the serum lab value.
— If a glucose meter is dropped, check the manufacturer's protocol and run test strips with the appropriate control solution.[9]
— Clean meters at regular intervals and whenever visibly dirty, following the manufacturer's instructions and facility policy. Dirty optics and inappropriate cleaning products can produce invalid results.[9]
— Check the meter for check battery or replace battery messages.[9]
— Follow hospital policies for confirming questionable results.[9]
— Avoid squeezing the finger to obtain a drop of blood. Fluid from the surrounding tissue can mix with the blood sample and affect test results.[9]

Sources of test strip error come from the enzyme testing technology and the test strips. There are ways to avoid invalid glucose meter results that include knowing the limitations of certain types of enzyme testing glucose meters and ensuring the proper care and handling of test strips.

Glucose meters use enzymes (glucose oxidase, glucose hexokinase, or glucose dehydrogenase) and an indicator (pyrroloquinolinequinone or nicotine adenine dinucleotide) to calculate results.[10] Glucose meters that use the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) enzyme testing method cannot distinguish between glucose, maltose, galactose, or xylose.[10] GDH-PQQ devices used in the wrong patient population can lead to fatal results.[11] Patients susceptible to GDH-PQQ enzyme indicator problems include those receiving peritoneal dialysis solutions containing icodextrin, certain types of immunoglobulin therapy, or other drugs containing maltose, galactose, or xylose.[7,10,12] (See "GDH-PQQ Test Strip Implementation Strategies" exclusively available on the Authority website.)

The following are other physiologic conditions that can invalidate glucose meter results:

— Hematocrit (low levels can falsely elevate results; high levels can falsely lower results)[12]
— Dehydration, hypotension, and hyperosmolar states
— Oxygen levels (both low and high oxygen levels can affect results)
— Perfusion rates (changes in perfusion rates, such as a shock state or post exercise, can influence results)[4,9]

Two types of therapies can invalidate glucose meter results, as follows:

— Uric acid and vitamin C can interfere with blood glucose meter measurement.[9]
— High levels of drugs such as acetaminophen or salicylate acid can affect results.[4]

The second problem with meters is the test strips. Special care is required to maintain their precision. Many different actions can invalidate test strip accuracy, including the following:

— Incorrect entry of the test strip lot or calibration code[4,7,12]
— Improper storage of the test strips (e.g., exposure to heat, moisture, light)[4,12,13]
— Improper handling of test strips (e.g., sugary foods such as bananas or fruit juice on hands can contaminate the strips)[4,7]
— Use of outdated strips[7,9,12]
— Improper blood sample collection[4]
— Inadequate blood sample size[4]

The following strategies can help maintain test strip validity:

— Follow the Centers for Disease Control and Prevention clinical laboratory improvement advisory rules and regulations for assuring meter/testing accuracy.[14,15]
— Consider the presence of physiologic conditions (listed above) when assessing the validity of an unexpected result.
— Perform quality checks on the machine and test strips at the beginning of every shift, especially if the meter is used on multiple patients each day.
— Check that test strip and control lot numbers have been correctly entered into the meter.[9]
— Read and follow manufacturer instructions on proper use and storage of test strips.[9]
— Ensure proper storage of test strips; do not expose to heat, light, or humidity.[4,13]
— Wear gloves to prevent contamination due to food or sugar residue on hands.
— Use all test strips in a bottle before opening a new bottle.
— Do not combine old test strips in a bottle of newly opened strips.
— Use a permanent marker to label bottles of test strips and control solution with the date and time opened.

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— Document the control solution expiration date after opening.

— Check test strip and control solution expiration dates.[4]

Hospital Policy and Protocol Refinement

Blood glucose meter use in the hospital setting is an accepted practice.[1,2] What hospitals may not be aware of is an FDA recommendation regarding inpatient hospital glucose meter use clearance. In 2009, FDA wrote a letter to the president of the American Association of Clinical Endocrinologists[16] in response to concerns about blood glucose testing meter performance. The letter addresses hospital uses of self-monitoring blood glucose (SMBG) devices, stating:

> FDA has cleared laboratory-based and bench-top point-of-care devices that provide accurate glucose test results with a fast turnaround time. Meters such as the HemoCue Glucose 201 RT system and the i-Stat system, which are not test strip based technologies, have accuracies approaching those of laboratory methods. Nevertheless, many hospitals continue to use SMBG [test strip based] devices, cleared only as aids in the management of diabetic patients, in these settings, even though they are not FDA cleared to diagnose disease or to maintain tight glycemic control of diabetic and non-diabetic patients in the hospital environment. This practice can be problematic.

This FDA concern is underscored in this event reported to the Authority:

> *[Glucose meter] read high on patient mentioned before. I obtained a stat blood glucose reading before covering my patient with the highest dose of coverage with Novolog. The blood glucose reading came back only 91. This could have been detrimental to the patient if policy was followed.*

Rather than follow hospital policy and treat the patient based on the glucose meter result, the individual withheld treatment until a lab result invalidated the result. This decision was beneficial since the patient's serum lab glucose result was normal.

Another report demonstrates the importance of hospital policies:

> *A [patient's] blood sugar was reported as 480 from the machine. Per policy, a venipuncture blood sugar was drawn for a new high. The patient was treated with [sliding scale] coverage as ordered. The blood sugar came back at 158. The machine was removed from service to be checked. All follow-up [glucose meter results were within normal limits] for the patient.*

Hospital policies and protocols that anticipate alternative scenarios, such as withholding insulin until lab results are received, guide staff when questionable situations arise. Hospital policies can be written in ways that empower staff to consider alternative actions, when necessary. (See "Hospital Policy Measures to Ensure Appropriate Use of Blood Glucose Meters.")

Physical Assessment Evaluation

Patient care is not to be based on POC glucose meter results alone. Quality bedside patient care includes a physical and mental assessment. The following report demonstrates the value of a physical assessment to validate glucose meter results.

> *The patient's evening [glucose meter result] read "hi." A [second glucose meter result] was rechecked and read "hi." A stat [laboratory] glucose was drawn. The result was 58. The [staff] spoke with the lab, which ran the [test] twice and [received] the same results. A third [glucose meter test] was done using a [different glucose meter and received] a reading of 112. The physician was made aware [of the results]. The patient was asymptomatic. An order was received to give an evening snack and to use the result of 112 as the patient's [glucose level].*

A physical and mental assessment can validate hyperglycemic or hypoglycemic glucose meter results. Hyperglycemic patients can experience polydipsia (increased thirst), polyuria (increased urination), and sugar in the urine. In cases of extremely high blood glucose levels (i.e., greater than 240 mg/dl), urine needs to be checked for ketones to determine whether the patient is in diabetic ketoacidosis. Symptoms of ketoacidosis include shortness of breath, breath that smells fruity, nausea and vomiting, and very dry mouth.[17]

Hypoglycemia is a condition that requires immediate attention because it can be fatal if left untreated. Hypoglycemic symptoms include hunger, shakiness, nervousness, sweatiness, sleepiness, irritability, light-headedness, fainting, unresponsiveness, coma, and death. Hypoglycemia can also cause symptoms when sleeping, including crying out or having nightmares, finding pajamas or sheets damp from perspiration, and feeling tired, irritable, or confused after waking up.[18] Not all patients are symptomatic. Careful and close monitoring is necessary to accurately identify the patient's condition and respond appropriately.

Effective Healthcare Team Communication

Effective communication provides appropriate situational information, including any pertinent background information, a physical assessment, and any test results upon which to base care.[19]

The following general actions can improve communication:

— State the situation succinctly, including pertinent background and physical assessment information.[19]

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HOSPITAL POLICY MEASURES TO ENSURE APPROPRIATE USE OF BLOOD GLUCOSE METERS

The following 10 measures are suggestions to add to current hospital blood glucose meter policies and protocols:

1. Consider facility-wide use of one type of blood glucose meter. It will decrease staff confusion and increase learning as staff shares experiences, problems, and potential solutions.[1]
2. Consider certification and recertification of healthcare personnel to use blood glucose meters, especially those performing routine quality control.
3. Provide routine education in the appropriate care and use of blood glucose meters and test strips.
4. Blood glucose meters are cleared only as aids in the management of diabetic patients in hospital settings and should be used as an aid. Blood glucose meters are not cleared by the U.S. Food and Drug Administration to diagnose disease or to maintain tight glycemic control of diabetic and non-diabetic patients in the hospital environment.[2]
5. Perform a separate or additional blood glucose meter test daily at the same time as a lab serum glucose draw to compare and validate blood glucose meter results with lab results.
6. Perform a quality-control check for each blood glucose meter at the beginning of each shift. Increased use increases the likelihood of inaccurate results (e.g., dirty optics, dropping or bumping the machine, issues with the test strips).
7. Place a hard stop (forced function) in the meter, if possible, to prevent use until a quality check is completed.
8. Consider a hospital policy that requires staff to wear gloves when touching the test strips.
9. Consider a hospital policy that requires staff to draw a serum lab value when questionable results arise (i.e., newly unexpected high blood glucose meter results) or when glucose meters are used in settings that increase the likelihood of invalid results (i.e., specific physiological conditions as identified in the main article). The policy can address withholding treatment of questionable blood glucose meter results until the serum lab value results are known.
10. Consider a hospital policy that requires stat glucose lab value results should be completed and available in a clinically reasonable time frame, preferably 30 minutes to no longer than 1 hour.
11. When questionable results arise, take the following actions:
    a. Check the last time a quality check was done.
    b. Check the meter for cleanliness.[3]
    c. Check the meter batteries and test strips.[3]
    d. Obtain a different meter to compare results.
    e. Draw a serum lab value and withhold treatment until results are available.
    f. Perform a patient physical assessment.
    g. Communicate the situation with physician. Provide a comprehensive summary of the patient's physical and mental status, the glucometer reading, and any other meter-related issues, serum lab value, and past medicine and diet history.
12. When blood glucose meter results are in doubt, remove the meter from patient care, and send it for servicing.

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— Inform appropriate individuals and all team members when plans change.[19]

— Speak clearly and simply, and repeat back information to decrease communication errors.[20]

— Use correct terminology, and provide explanations of ambiguous terms.[20]

— Request and provide clarifications as needed.[20]

— Ensure statements are direct and unambiguous.[20]

— Allow the receiver to review the information.[20]

— Allow opportunity for questions and clarifications.[20]

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CONCLUSION

Blood glucose management in hospitalized patients is a multifaceted process that requires critical thinking. Test results are one important measure of a patient's condition but should never be used as the sole basis for treatment. Treating a patient based on measurements alone can lead to serious and fatal patient events. Blood glucose meter results provide a starting point of inquiry about a patient's health status. A physical and mental assessment, along with an evaluation of the patient's previous history, are needed. As deviations arise, communication with the physician is essential before any actions are taken. The amount of time required considering all aspects of the patient's condition and the usual way to respond can be the difference between the delivery of safe patient care and serious or fatal patient events.

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Survey of Emergency Department Practices in Pennsylvania Hospitals to Protect Patients and Staff

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ABSTRACT

The incidence of workplace violence experienced by emergency department (ED) staff is well documented. Protecting ED staff from violent individuals will enable staff to provide safe and optimal care to patients. Equally important are the safeguards that protect patients and visitors from violent acts from any source in the ED. In June 2011, the Pennsylvania Patient Safety Authority conducted a survey to study violence protection practices in Pennsylvania acute care hospitals. The survey also examined potential barriers to compliance. Survey findings showed potential gaps in violence protection practices. For example, mandatory violence prevention training for ED staff was reported by only 36% of respondents. Eighty-seven percent of respondents indicated that the ED did not have a designated area for holding prisoners. Thirty-four percent of respondents reported that hands-free personal communication devices and other communication equipment, such as walkie-talkies, were used in the ED. Ninety-three percent of respondents reported that ED staff did not wear a personal alarm. Gaps in violence protection practices identified through the survey suggest opportunities for improving violence protection practices to increase the safety of both ED staff and patients. At the facility level, awareness of knowledge gaps and/or compliance gaps as compared to best practices will also facilitate targeted allocation of resources. (Pa Patient Saf Advis 2011 Dec;8[4]:126-130.)

INTRODUCTION

The incidence of workplace violence experienced by emergency department (ED) staff is well documented. Reports indicate that nurses experience work-related crime at least twice as often as any other healthcare provider.[1] An Emergency Nurses Association 2009 ED violence surveillance study showed that of 2,907 emergency nurses who reported a violent experience, 54.8% reported having experienced physical violence or verbal abuse from a patient or visitor during a seven-day calendar period. More than half of those reported experiencing more than one incident of patient or visitor violence during this period.[2] Physicians also experience a high rate of violence in the ED. Behnam et al. estimated the rate of violence against ED physicians and residents by surveying residents and faculty ED physicians of 65 randomly selected residency programs nationwide.[3] More than 75% of respondents experienced a violent act while working in the ED. The most common violent acts were verbal threats (75%) followed by physical assaults (21%), confrontations outside the workplace (5%), and stalking (2%). One in 10 was threatened with a weapon (knives or guns). Full-time security was available in most settings (98%), but was least likely to be physically present in patient care areas. The majority of respondent EDs did not screen for weapons (60%) or have metal detectors (62%). Only 16% of programs provided violence workshops, and fewer than 10% offered self-defense training.

A considerable variability in ED security programs has been demonstrated in the literature. A cross-sectional survey of security programs conducted among New Jersey hospitals from 2003 through 2005 examined ED security programs and employee assault rates in EDs with different financial resources, sizes, and background community crime rates.[4] Small hospitals in towns with low community crime rates implemented the fewest security program elements and provided less funding for security programs, despite having the second highest rate of assault-related Occupation Safety and Health Administration (OSHA) recordable injures among ED staff. Large hospitals had lower employee assault rates irrespective of where they were located. The authors conclude that due to the highly stressful workplace characteristics of EDs, the risk of employee assault is likely to be universal among all hospital sizes in all types of communities; therefore, a comprehensive security program is needed in all hospital EDs.[4]

Not only is ED staff exposed to violence, but patients are at risk. A 2010 Joint Commission Sentinel Event Alert advises that patients are at risk from violence entering from outside the hospital.[5] According to security consultant Russell Colling, MS, CHPA, "The most important factor in protecting patients from harm is the caregiver . . . "[5] Accordingly, ED staff must be educated and enabled to protect themselves in order to help ensure a safe environment for patients.

REPORTS TO THE AUTHORITY

A search of the Pennsylvania Patient Safety Authority reporting system database for reports from the ED using words related to violence showed that from 2006 through 2010, Pennsylvania healthcare facilities reported 384 events of violent acts or verbal abuse. This is no doubt an underestimate of the number of relevant reports actually submitted by Pennsylvania hospitals, because most assaults and other potentially criminal events are reported as Infrastructure Failures and are accessible only to the Pennsylvania Department of Health. The 384 events reported as Serious Events and Incidents include 266 (69%) cases of verbal abuse or threats. The remaining 188 events were cases of physical violence in the ED. Of the total events, 3% were reported as a Serious Event. In 85% of the reported Serious Events, the patient sustained an injury.

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Both patient and staff were reported injured in three events. Respondents reported that the ED staff responded to these violent events in a number of ways, including summoning security staff or the police department to the ED or using methods to help subdue a violent patient to protect the patient, the staff, and other patients. The Table shows those reported responses to violent events in the ED.

The following are examples of reports submitted to the Authority related to ED violence.

> *A safety security officer responded to the ED for a disorderly patient. Upon arrival, contact was made with ED doctor and nurse practitioner, who reported the patient was at the ED seeking medications for his illness and was threatening staff verbally and yelling and screaming. The doctor reported that there was nothing else the doctor could do for the patient and requested that man be removed from the ED. The man was noted to be yelling, screaming, and using profanity while sitting in the treatment area. The man was asked several times by the undersigned to calm down; however, he refused to do so. The man refused any and all offers of assistance from ED staff and doctors. The man was then escorted from the ED as well as from hospital property.*

> *A patient became belligerent and loud with foul language after an offer of prescription for a non-steroidal medication. Security was called, and the patient demanded to leave with narcotics, while acting violent and swinging his arms at staff. [The patient was] escorted out of the ED by security while maintaining loud verbal abusive language toward staff in the waiting room.*

> *A patient kicked and punched an ED nurse while the patient was being restrained. The patient ripped off the four-point restraints on one side and also pulled out the [intravenous line] in an arm. Security, the nursing supervisor, and the police were called. Per the nurse, "I was kicked in the side and punched on side of the face by patient."*

> *Police officers brought a violent and aggressive patient to the ED. The patient was placed in the observation room of the ED. The patient became violent and punched the seclusion room door. Following this, there was a scuffle between police officers, security, and the patient. The patient was Tasered once. . .*

Table. Response to Violent Events in the Emergency Department (N = 384), Reported to the Pennsylvania Patient Safety Authority, 2006 through 2010

POLICE OFFICERS CALLED TO ED	SECURITY OFFICERS CALLED TO THE ED	USE OF RESTRAINTS	USE OF PEPPER SPRAY	USE OF A TASER®
34 (9%)	84 (22%)	32 (8%)	4 (1%)	2 (<1%)

AUTHORITY SURVEY OF ED VIOLENCE PROTECTION PRACTICES

After analysis of events reported to the Authority, the high incidence of violence against ED staff, and the potential variability of security programs and resources as reported in the literature, the Authority elected to study the implementation of ED violence protection best practices in Pennsylvania acute care hospitals. The Authority developed a survey based on the International Association for Healthcare Security and Safety (IAHSS) safety program in healthcare, OSHA guidelines, and other current literature.[3,4,6-8] Survey content was also developed and reviewed in collaboration with expert ED practitioners and security officers. To increase response rates, the survey was distributed online, accompanied by a letter of endorsement by the Pennsylvania Chapter of the American College of Emergency Physicians. All results are published anonymously in the aggregate.

Methods and Limitations

The Authority distributed online surveys to acute care hospital patient safety officers (PSOs) in June 2011. Of 157 surveys sent to Pennsylvania acute care hospitals, 94 (60%) surveys were returned; of these, 71 (76%) of respondents were identified by a facility-specific numeric code for purposes of analysis. The 71 identifiable individual respondents represent 65 hospitals, or 41% of all hospitals that received a survey. Not all respondents answered each survey question. Response rates are based on actual responses for each individual question.

RESULTS

ED Volume

Survey participants were asked about the annual volume of patients treated in the ED. Of the 65 hospitals represented in the survey, representatives of 58 responded to this question. The results are shown in Figure 1.

Individual Participants

Survey participants were asked to identify their job designation (e.g., title). Thirty-nine percent of respondents identified themselves as an ED physician director and 31% as the ED security director. The remaining 30% of respondents represented diverse job titles, such as ED nurse manager, director of nursing, PSO, risk manager, director of support services, or director of clinical operations.

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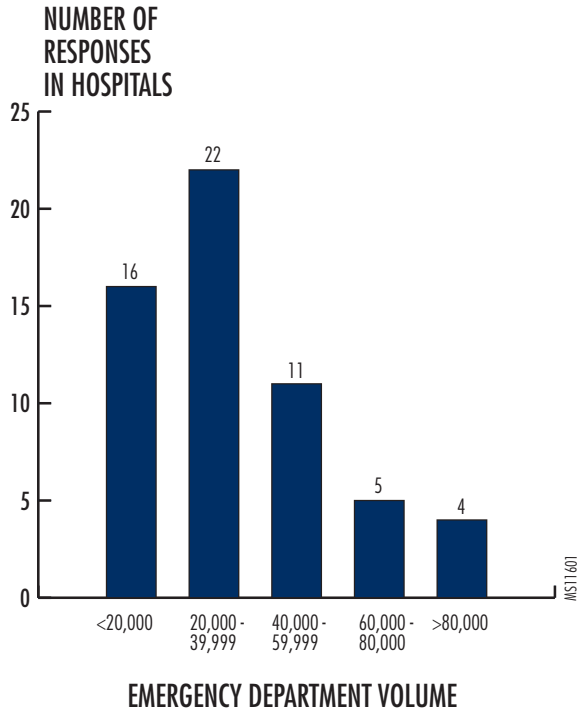
Figure 1. Average Annual Emergency Department Volume, According to Pennsylvania Patient Safety Authority Survey of Violence Prevention Practices, June 2011



ED Security

To ensure security of patients and visitors, hospitals employ security personnel or hire outside security services. Survey respondents were asked about the type, availability, and training of security services available in the ED. Sixty (71%) respondents have security officers that are hospital employees; of those, 31% have security officers that are hospital employees who are available in the ED 24 hours per day, 7 days per week, and more than half (59%) have security officer employees who are not stationed in the ED full time but are available to the ED full time. Fifty-one percent of all respondents reported that ED security officers were required to complete a national training program, such as Management of Aggressive Behavior or Crisis Prevention Institute programs. Survey participants were asked about the use of protective equipment by ED security officers. Ninety-three percent of respondents reported that security officers did not carry firearms. Protective devices used by security officers were pepper foam/spray (22%), batons (10%), conducted energy weapons (e.g., Taser®) (9%), and handcuffs (1%). The remainder of respondents (58%) reported either "unknown" or "none of the above," suggesting that more than half of security officers may not use protective equipment in the ED.

Survey participants were asked about screening practices in the ED for weapons or other potentially dangerous items. The majority of respondents reported that metal detectors (86%) or x-ray scanners (100%) were not used to screen patients, visitors, or belongings. However, 79% of respondents reported that the ED had a written policy and procedure to follow if a weapon or other potentially dangerous item was found in the possession of a patient or visitor. Almost half (48%) of respondents reported that the ED had a policy and procedure to follow if a weapon was fired in the ED.

ED Monitoring and Access

Survey participants were asked questions about monitoring of the ED, including identification of visitors, access to the ED, and the presence of security cameras. More than half of respondents reported that visitors were required to check into the ED (61%), and 23% required visitors to wear a visitor badge for identification. The majority of respondents indicated that access was restricted to the ED; 87% reported restricted access to the ED treatment area from the waiting room, and 74% reported restricted access from the hospital into the ED (e.g., badge required for entrance to the ED from the hospital). Of the respondents that reported the use of security cameras in the ED waiting room (87%), more than half (53%) reported the cameras were monitored 24 hours a day, 7 days a week. When security cameras are used in the ED treatment areas (31%), 40% of respondents reported that the cameras were monitored 24 hours a day, 7 days a week. The lower percentage of respondents that reported the presence and monitoring of security cameras in the ED treatment area compared to monitoring of the ED waiting room may be related to patient privacy concerns.

ED Designated Areas

EDs may have a designated area or separate room for certain patient populations to help ensure the safety of the patient, visitors, and staff. Of note, a majority of respondents (87%) indicated that the ED did not have a designated area for prisoners. The 2010 IAHSS survey describes the increasing number of forensic and psychiatric patients as a growing concern among security professionals because these patients are considered high risk in terms of potential violence and danger to staff.[8] Figure 2 depicts the availability

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of a designated area or separate room for categories of patients that may pose a risk to themselves or others.

ED Staff Communication Devices

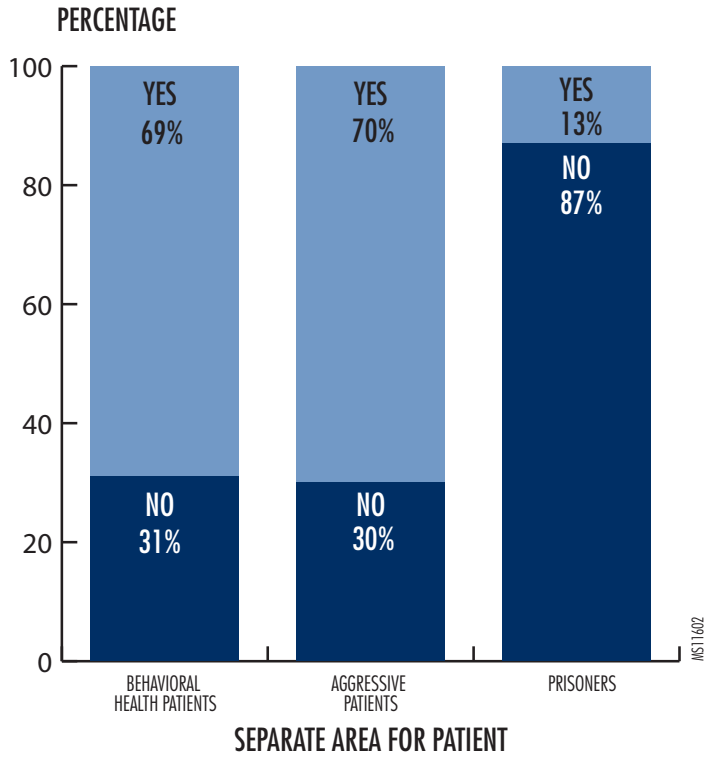
The survey included questions about the availability of personnel protection devices and alarms in the ED. Almost three-quarters of respondents (71%) reported that the ED had panic buttons placed throughout the ED. These devices may be used by ED staff to summon assistance in a situation in which violence is threatened or occurring. Personal communication devices and alarms were generally not available. Only 34% reported that hands-free personal communication devices and other communication equipment, such as walkie-talkies, were used in the ED. Ninety-three percent reported ED staff did not wear a personal alarm.

Self-Defense Training and ED Violence Prevention Programs

According to Blando et al., a significant degree of variability among hospital ED security programs is thought to be due in part to absence of federal legislation requiring baseline security features. Moreover, nationally, OSHA guidelines for the protection of healthcare workers are voluntary.[4] Similarly, results of a survey of workplace violence across 65 U.S. EDs showed that fewer than half the EDs had violence training programs for staff, although little data is available to prove that these programs actually reduce the number of events. The authors conclude that the efficacy of violence prevention programs needs further study.[9]

Authority survey participants were asked about self-defense and violence prevention training for hospital employees and ED staff. Similar to the aforementioned studies, fewer than half of respondents (32%) reported that their hospital offers self-defense training for employees, and 68% responded that their hospital offers violence prevention training to hospital employees. Violence prevention training was reported to be mandatory for ED staff by 36% of respondents.

Figure 2. Emergency Department Designated Patient Areas, According to Pennsylvania Patient Safety Authority Survey of Violence Prevention Practices, June 2011



Participants were asked to choose all barriers to compliance with a violence protection plan that applied. The respondents could choose more than one answer and identified insufficient staff training (70%) and that the time required to comply with the program was prohibitive (70%) as the major barriers, followed by cost factors (65%) and lack of a perceived need to comply due to low volume of violent acts in the ED (48%). Other barriers entered in free-text fields by participants included failure to identify acts of violence, high turnover of ED staff, and lack of approval for the use of metal detectors. More than half of respondents (64%) reported that their hospital has a zero tolerance policy for violence in the ED workplace (e.g., a defined approach to violent patient or visitor behavior, including steps to stop unacceptable behavior and removal of the individual from the ED if required). Fifty-five percent of participants reported that the ED performed a safety assessment within the past year.

RISK REDUCTION STRATEGIES

Survey findings show a number of potential areas for improvement:

— Sixty-nine percent of respondents do not have a security officer available in the ED 24 hours per day, 7 days per week.

— The majority of respondents reported that metal detectors (86%) or x-ray scanners (100%) were not used to screen patients, visitors, or belongings for weapons or other potentially dangerous items.

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— Personal communication devices and alarms are generally not available to ED staff. Sixty-six percent of respondents reported that hands-free personal communication devices and other communication equipment, such as walkie-talkies, were not used in the ED. Ninety-three percent reported ED staff did not wear a personal alarm.

— Eighty-seven percent of respondents indicated that the ED did not have a designated area for holding prisoners.

— Thirty-nine percent of respondents reported that violence prevention training was mandatory for ED staff.

The following resources can provide guidance and information on the development of policies and procedures to prevent violence in the ED:

— Emergency Nurses Association Institute for Emergency Nursing Research. Emergency department violence surveillance study [online]. 2010 Aug [cited 2011 Aug 18]. Available from Internet: http://www.ena.org/IENR/Documents/ENAEDVSReportAugust2010.pdf.

— Joint Commission. Preventing violence in the health care setting [online]. Sentinel Event Alert 2010 Jun 3 [cited 2010 Nov 15]. Available from Internet: http://www.jointcommission.org/sentinel_event_alert_issue_45_preventing_violence_in_the_health_care_setting_/.

— Occupational Safety and Health Administration (OSHA). Guidelines for preventing workplace violence for health care & social service workers [online]. [cited 2011 Aug 15]. Available from Internet: http://www.osha.gov/Publications/OSHA3148/osha3148.html .

— Occupational Safety and Health Administration (OSHA). Healthcare wide hazards: workplace violence [Hospital eTool online]. 2008 Mar 6 [cited 2011 Aug 18]. Available from Internet: http://www.osha.gov/SLTC/etools/hospital/hazards/workplaceviolence/viol.html.

— International Association for Healthcare Security and Safety. Healthcare security: basic industry guidelines [online]. [cited 2011 Aug 20]. Available from Internet: http://www.iahss.org/About/Guidelines-Preview.asp.

CONCLUSION

Analysis of events reported to the Authority reporting system database showed that from 2006 through 2010, Pennsylvania healthcare facilities reported 384 events of violent acts or verbal abuse. Although they represent an underestimated number of relevant events actually reported by Pennsylvania hospitals for reasons cited above, the event reports show that staff and patients have been harmed. The Authority's survey was intended to study violence protection practices in Pennsylvania acute care hospitals and has demonstrated a number of potential gaps in those practices that suggest opportunities for improving violence protection practices to increase the safety of both ED staff and patients. Identification of these gaps can also facilitate the development of training programs on a statewide level. The Authority will be publishing additional guidance on gaps in ED violence prevention practices identified by the survey in a future issue of the *Pennsylvania Patient Safety Advisory*.

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Strategies to Improve Outcomes in Nursing Home Residents with Modifiable Risk Factors for Respiratory Tract Infections

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ABSTRACT

Pneumonia and other lower respiratory tract infections (LRTIs) are the second most common infections among nursing home residents and the leading cause of death from infections in the long-term care setting. From January through June 2011, the monthly average number of reported LTRIs in Pennsylvania nursing homes increased by 6.4%, and the number of influenza-like Illnesses (ILIs) increased by 28.2%, compared to the first 6 months of 2010. Poor oral care, aspiration due to swallowing difficulty, and inadequate vaccination programs are modifiable risk factors for ILI and LRTI. Pennsylvania Patient Safety Authority analysis found that Pennsylvania nursing homes with mandatory programs in place showed 21.5% lower combined seasonal LRTI/ILI infection rates and 42% lower mortality rates than nursing homes without mandatory programs. Approaches to integrate evidence-based strategies into clinical practice include a structured prevention program that targets intensive oral hygiene, identification of dysphagia, implementation of aspiration prevention protocols, and a commitment to implement a universal influenza vaccination program. (Pa Patient Saf Advis 2011 Dec;8[4]:131-7.)

LOWER RESPIRATORY TRACT INFECTION IN LONG-TERM CARE FACILITIES

Pneumonia and lower respiratory tract infections (LRTIs) are the second most common infections among nursing home residents and the leading causes of death from infections in nursing homes. Smith et al. cite literature reviews describing the incidence of nursing home LRTIs ranging from 0.3 to 2.5 episodes per 1,000 resident-care days.[1] The burden of LRTI on healthcare facility operations includes the increased time and cost of additional resident care services, such as radiology and lab tests, antibiotics, multiple physician visits, nursing time, administration of medication and respiratory treatments, and hospital admissions. Residents affected by LRTI may be at additional risk for confusion, falls, and pressure ulcers.[2]

PENNSYLVANIA SNAPSHOT

Of the 9,929 respiratory tract infections reported by Pennsylvania nursing homes to the Pennsylvania Patient Safety Authority in 2010, 99.4% were LRTIs, a subcategory that includes pneumonia, bronchitis, and tracheobronchitis. The highest number of events was reported as occurring in skilled nursing/short-term rehabilitation units, which were also associated with the highest number of resident-care days. Overall rates of respiratory tract infection (combined LRTI and influenza-like illness [ILI]) were highest on the ventilator-dependent units (0.6 per 1,000 resident-care days).

The incidence of LRTIs and ILIs has increased in Pennsylvania nursing homes, specifically in the first three months of 2011 when compared to monthly LRTIs and ILIs reported to the Authority from June 2009 through December 2010 (see Figure). The incidence of respiratory tract infection is second only to catheter-associated urinary tract infections, except during norovirus season.

From January through June 2011, the monthly average number of reported LTRIs increased by 6.4%, and the number of ILIs significantly increased by 28.2% compared to the first 6 months of 2010 (see Table 1).

MODIFIABLE RISK FACTORS

Risk factors must be considered in the development of a framework for a targeted prevention strategy for pneumonia and other LRTIs in long-term care facilities. Elderly long-term care facility residents are predisposed to LRTI because of defects in host defenses and risk factors, including the following:[1,3]

- swallowing difficulty
- smoking
- lack of influenza and pneumococcal vaccination
- immobility
- decreased clearing of bacteria from the airway
- altered throat flora
- poor functional status
- presence of feeding tubes
- poor oral care
- underlying disease

The pathophysiology of LRTIs results from the combination of pathogen adherence to the oro- or nasopharynx, an immune system unable to eradicate the pathogen, as well

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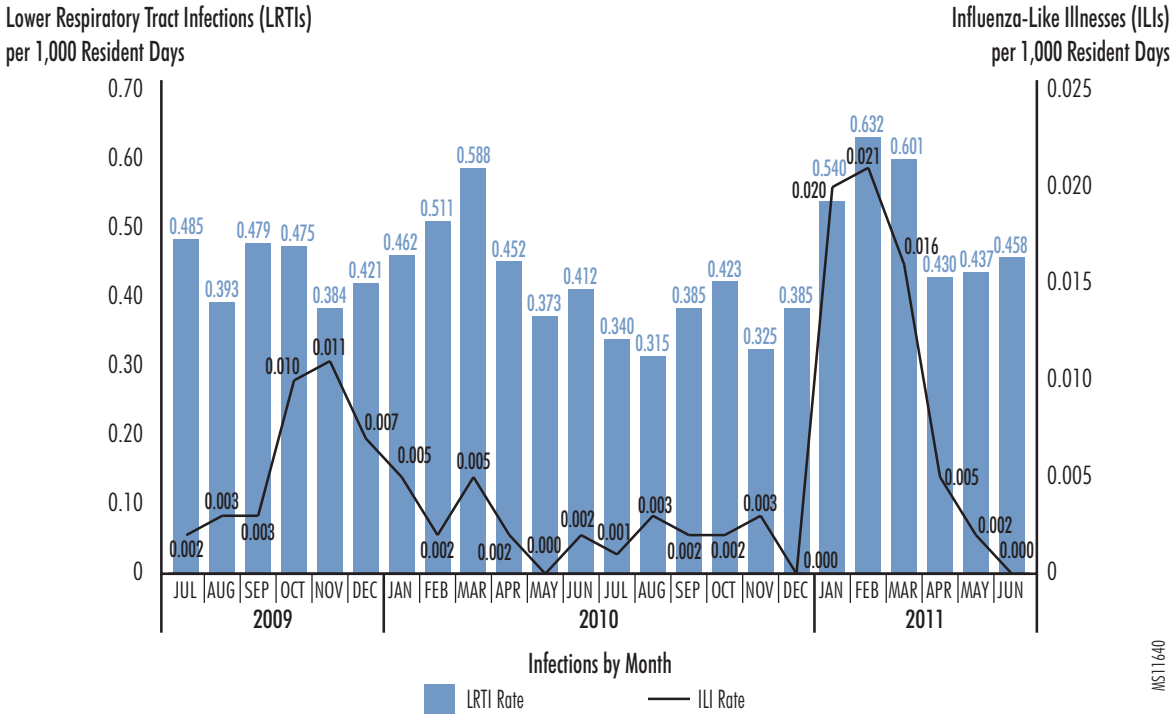
Figure. Respiratory Tract Infections in Pennsylvania Nursing Homes, by Month, July 2009 through June 2011



as an easy path to the lower respiratory tract in residents with a tendency to aspirate.[4] For example, in a 2-year cohort study of 613 residents from 5 nursing homes in Connecticut, Quagliarello et al. calculated that 21% of all cases of pneumonia could have been avoided with adequate oral care and swallowing difficulty interventions.[5] Loeb et al. and Quagliarello et al. describe major modifiable risk factors that predispose elderly nursing home residents in the United States and Canada to LRTIs, including (1) inadequate oral care, (2) difficulty swallowing, and (3) lack of influenza vaccination.[3,5]

Inadequate Oral Care

Residents at high risk for pulmonary infections associated with inadequate oral care include residents with natural teeth, swallowing disorders, poor ability to self-perform good oral hygiene, and diminished salivary flow, as well as mechanically ventilated residents with no ability to clear oral secretions by swallowing or by coughing.[6] A 2008 American Geriatric Society systematic review of the preventive effect of oral hygiene on pneumonia and LRTI concluded that daily attention to oral hygiene reduces the occurrence of nursing-home-acquired pneumonia and LRTIs among high-risk elderly people living in long-term care settings.[7] Nursing home residents often have difficulty accessing frequent professional dental care. The U.S. surgeon general's May 2000 report on oral healthcare specifically stated that older adults living in long-term care settings where dental care is problematic are among those individuals who suffer the worst oral healthcare and hygiene.[8]

Xerostomia, or dry mouth, is a common side effect experienced by the elderly who take multiple medications. The inhibition of salivary flow increases the risk for oral disease because saliva contains antimicrobial components as well as minerals that can help rebuild tooth enamel after attack by acidic, decay-causing bacteria.[8]

The oral cavity is a rich source of bacteria.[9] Higher plaque scores, bacterial presence in saliva, or colonization in the oropharynx seem to influence the incidence of pulmonary infections in elderly nursing home patients. Dental plaque is a tooth-borne biofilm that initiates infections of the oral cavity, such as periodontitis and dental caries. One cubic millimeter of dental plaque contains approximately 100 million bacteria. Teeth and gingival margins are places that favor bacterial colonization, and periodontal pockets may serve as persistent reservoirs for potential pathogens for pneumonia. It is likely that oral and respiratory bacteria in the dental plaque are shed into the saliva and then aspirated into the lower respiratory tract and the lungs causing infection.[8] Residents with natural teeth have been found to develop aspiration pneumonia more often than residents

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Table1. Lower Respiratory Tract Infections in Pennsylvania Nursing Homes, January through June 2010 and 2011

	YEARS	MONTHS January	February	March	April	May	June	MONTHLY AVERAGE	PERCENTAGE INCREASE
No. of lower respiratory tract infections	2010	1,119	1,137	1,434	1,060	903	968	1,103.5	NA
	2011	1,264	1,361	1,415	974	1,012	1,019	1,174.2	6.4%
No. of influenza-like illnesses	2010	13	5	11	4	1	5	6.5	NA
	2011	47	46	37	12	4	0	8.3	28.2

without teeth.[6] The protective extracellular slime matrix of oral biofilm makes bacteria extremely resistant to antibiotics, antimicrobial agents, and host defense mechanisms. Mechanical removal is the most effective treatment currently available for the control of dental plaque biofilms.[10]

Oral care may not always be implemented correctly or consistently in long-term care facilities. Staffing issues, absence of protocols and monitoring, as well as perceived time barriers, knowledge deficits, and uncooperative residents, may make oral care a low priority.[11] The 1987 Omnibus Reconciliation Act mandates long-term care facilities that receive Medicare or Medicaid funds to annually assess the oral health of residents using the Minimum Data Set (MDS) questionnaire and to provide or arrange for the provision of routine and emergency dental treatment to meet resident's needs.[12] A sample of the MDS 3.0 questionnaire can be accessed at http://www.geronet.ucla.edu/centers/borun/MDS%203.0%20Recommended%20Form.pdf.

Coleman and Watson describe a 2003 observational study in 5 New York State nursing homes that evaluated oral care provided by 47 nursing assistants to 67 residents. Oral care standards were developed and validated by an expert panel of dentists and clinicians. Observers noted that standards that were never met included brushing teeth for at least two minutes, flossing, oral assessment, rinsing with mouthwash, and wearing clean gloves during oral care.[11]

The oral care of older and disabled residents can be improved by incorporating the following strategies:

Leadership approaches. Long-term care facility administrators can promote oral health as an institutional value by standardizing methods to document daily oral care, monitoring practice, removing barriers, and ensuring provision of adequate oral hygiene supplies, including toothbrushes, fluoride toothpaste, mouthwashes, moisturizing gels, denture cleaning tablets, and storage containers. Resident care conferences can include planning for a diligent, documented, daily regimen of oral hygiene. Administrators can make expectations of oral care clear and hold staff accountable.[13]

Education and assessment. Recommendations for successful educational programs include providing instruction in small groups on oral diseases, oral assessment, the methods and importance of oral care, and hands-on training for delivery of oral care, particularly to care-resistant patients.[13] The Kayser-Jones Brief Oral Health Status Examination is a simple screening tool that can be used by nursing personnel in long-term care settings to rule out problems with the tongue, teeth, dentures, or oral mucosa and to establish criteria for referral for a dental evaluation, examination, and follow-up. It is available online at http://consultgerirn.org/uploads/File/trythis/try_this_18.pdf.[14]

Handling resistance to care. Resistance to receiving care is a significant barrier to good oral care among long-term care residents. Staff can communicate what is happening, use a pleasant facial expression, encourage self-care, pantomime appropriate actions, and provide distractions to promote cooperation.[13] The Southern Association of Institutional Dentists provides specific guidelines and self-study modules on oral hygiene in residents with mental and developmental disabilities on its website at http://www.saiddent.org/modules.asp.

Providing tooth brushing and alternatives. Mechanical removal of oral bacteria by tooth brushing is the gold standard of oral hygiene.[13] The Hartford Institute of Geriatric Nursing recommends morning and evening oral care, preceded by hand washing and donning gloves, then brushing teeth and tongue, and applying lip moisturizer.[15] A small minority of severely debilitated residents (e.g., residents with mouth ulcerations, clotting issues, gingival hemorrhages, or who are ventilator dependent) may require an alternative to tooth brushing. In these instances, swabbing all tooth surfaces for two minutes with a gently abrasive, disposable, soft-foam swab soaked in alcohol-free mouth rinse can be effective in reducing plaque.[13]

Managing dry mouth. An atomizer or spray bottle can be used to mist the oral tissues with water or a water-based hydrating rinse. In addition, a moisturizing gel may be applied periodically to oral mucosa. Mouth rinses that contain alcohol are to be avoided because alcohol is drying and can exacerbate xerostomia; similarly, lemon and glycerin swabs are to be avoided.[13]

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Difficulty Swallowing (Dysphagia)

Nursing-home-acquired aspiration pneumonia has the highest mortality rate of any healthcare-acquired infection. It is estimated that 30% of pneumonia in long-term care facilities is caused by aspiration.[16] Singh and Hamdy state that dysphagia carries a sevenfold increased risk of aspiration pneumonia.[9] Aspiration develops after the inhalation of colonized oropharyngeal material into the lower respiratory tract, often because of impaired swallowing (dysphagia) or ineffective cough. Infection occurs when the inhaled pathogenic secretions create an acute inflammatory reaction.[16]

The Quagliarello et al. study found that cough during swallowing represents the best bedside predictor of aspiration; however, residents may also aspirate oropharyngeal contents silently.[5] Oropharyngeal and esophageal dysphagia is often related to stroke, inadequate oral care, or multiple chronic illnesses.[16] Conditions predisposing the elderly for oropharyngeal and esophageal aspiration include dementia, inability to perform activities of daily living, neurologic dysphagia, medication-induced dysphagia, tracheostomy and tube feedings, and gastroesophageal reflux diseases. Feeding tubes offer no protection from colonized oral secretions.[17] Eisenstadt describes a correlation between the use of proton pump inhibitors (PPIs) used to treat residents with gastric reflux and associated aspiration pneumonitis. PPIs have been found to block gastric acid production, resulting in bacterial overgrowth and an increase in the number of bacteria in the oral cavity.[16]

It is important to identify and implement aspiration-prevention strategies because difficulty swallowing has been shown to be a modifiable risk factor.[5] Evidence-based preventive strategies can be outlined in feeding protocols, aspiration risk reduction algorithms, clinical triggers, care pathways, or checklists that contain the following elements:

Assessment. Residents admitted with pulmonary problems are to be assessed very carefully and monitored frequently for subtle changes in condition that can be addressed immediately. Being proactive instead of reactive is critical to avoiding unplanned discharges to the hospital from the nursing home. Implementing timely and individualized interventions is crucial to improved clinical outcomes. Identification of residents at risk for aspiration and the potential development of pneumonia requires awareness of early indications of swallowing difficulty.[18] Clinical indictors of swallowing difficulty include the following:[18]

- Food remaining on the resident's tongue after swallowing, or pocketing of food on side of mouth
- Coughing or choking while eating or drinking and gargled sounding voice changes after eating or drinking
- Excessive drooling

Relevant history and physical taking. Assess the resident for past and present eating habits, any history of aspiration pneumonia, poor appetite, fear of choking, broken or ill-fitting dentures, and neglected oral care.[18]

Comprehensive diagnostics. Evaluate the resident's medical and family history, surgical procedures, and lifestyle. Identify conditions that impair the ability to protect the airway.[16]

Pharmacology. Employ agents that facilitate gastric emptying or folic acid supplements that have been shown to improve swallowing reflex; avoid sedatives and hypnotics.[16]

Swallowing therapy. Supervise the resident's oral feeding with altered textures, such as nectar- and honey-thick liquids. Supervise positioning with a chin-tuck posture in an upright 90-degree-angle sitting position. Conduct a noninvasive bedside swallowing evaluation and speech/language pathology to strengthen and improve swallowing muscles. Provide rest periods for the resident.[16] Educate and monitor family members' participation in feeding the resident to ensure that they abide by the liquid thickness ordered for the resident.

Enteral feeding. Raise the head of the resident's bed up to 30 degrees. The angle can be marked with tape for visual assessment of correct positioning. Assess for signs of gastric stasis, such as nausea and bloating. Measure gastric residual volumes routinely and before feedings. Establish continuous pump feedings.[16] Ensure the use of proper feeding devices and the education of nurse aides on appropriate adaptive equipment.

Individualized patient care plan. Address the resident's specific problem; develop realistic and measurable goals, specific actions, and interventions. Review and assess the resident's progress, educating the resident and the family in approaches to prevent aspiration.[18]

Oral and dental hygiene. Intensive oral care may reduce the incidence of aspiration pneumonia in residents not only by reducing oropharyngeal colonization, but also by improving both swallowing and cough reflex sensitivities.[19] In a healthy individual, the respiratory tract is able to mount a defense against aspirated bacteria.[6] Daily gum and tooth brushing is known to stimulate sensory nerves in the oral cavity and enhance release of a salivary hormone believed to play a major role in both cough and swallowing sensory pathways.[20]

Lack of Influenza Vaccinations

Vaccination of healthcare workers against influenza has been shown to reduce illness and absenteeism and to reduce transmission of influenza to healthcare workers, their families, and their residents.[21] Vaccination of both residents and their contacts (e.g., visitors, clinicians) is the foundation of efforts to prevent influenza transmission. Vaccination of healthcare workers serves to prevent transmission to residents who have a lower

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Table 2. Seasonal LRTI/ILI rates in Pennsylvania Nursing Homes—Mandatory versus Nonmandatory Vaccination Programs—October 2010 through March 2011

LONG-TERM CARE PROGRAM	LRTI/ILI RATE
Voluntary (n = 203)	0.64 (95% CI = 0.62 - 0.66)
Mandatory (n = 18)	0.50 (95% CI = 0.44 - 0.57)

$p = 0.0001$ by z-test

likelihood of vaccination responses themselves and to create "herd immunity" that protects both the healthcare worker and residents who are unable to receive vaccine or who are unlikely to respond with a sufficient antibody response.[22]

A 2005 study in 301 long-term care facilities noted that high rates of both healthcare workers' and residents' vaccinations substantially altered the rate and impact of nosocomial influenza outbreaks.[23] Carman and Lemaitre cited several cluster randomized controlled trials that found that vaccination of healthcare workers in a long-term care setting was associated with significant reductions in patient mortality.[24,25] The results of a 2008 mathematical model to estimate the effects of healthcare worker vaccination found that approximately 60% of influenza virus infections in residents can be prevented when 100% of staff are vaccinated.[26]

The Society for Healthcare Epidemiology of America views influenza vaccination of healthcare workers as a "core patient and healthcare professional safety practice with which noncompliance should not be tolerated."[22] A Centers for Disease Control and Prevention survey of healthcare worker influenza vaccination coverage during the 2010-2011 seasons found that in facilities with mandatory healthcare worker vaccination programs, 98.1% of healthcare workers were vaccinated, compared to 58.9% in nonmandatory settings. Greater coverage in facilities without a vaccination requirement was associated with personal reminders and free vaccine available for more than one day.[21]

Authority analysts examined event report data and nursing home responses from the Authority's 2010 annual survey to assess the effect of healthcare worker vaccination on the reduction of LRTI and ILI in Pennsylvania nursing homes. Eighteen (8.1%) of the 221 nursing homes that responded to the survey reported having mandatory annual healthcare worker vaccination programs in place. This analysis found that mandatory healthcare worker influenza vaccination programs in Pennsylvania nursing homes have shown 21.5% lower combined seasonal LRTI/ILI infection rates from October 2010 through March 2011 (see Table 2). Extrapolating from the difference in rates between mandatory and nonmandatory facilities, a projection of 616 potential respiratory tract infections could have been prevented among the remaining 203 respondent facilities. Taken a step further, 1,991 RTIs could have been prevented among all Pennsylvania nursing homes.

Reducing transmission of influenza from healthcare workers to residents and patients is a top priority in Pennsylvania. During the summer of 2011, the Pennsylvania Department of Health, in collaboration with the Authority, the Center for Vaccine Ethics and Policy at the University of Pennsylvania, the Hospital and Health System Association of Pennsylvania, and the Pennsylvania Immunization Coalition, conducted an educational campaign across the state to encourage influenza vaccination among healthcare personnel in Pennsylvania hospitals and health systems including nursing homes to implement an influenza healthcare personnel vaccination program for the 2012-2013 influenza season. The campaign home page can be accessed at http://pahcwfluvax.org. Campaign materials include a commitment form due by the end of December 2011 and a best practices guide and toolkit. The pledge form is available at http://www.haponline.org/quality/resources/flu-campaign, and the toolkit can be accessed at http://www.haponline.org/downloads/Universal_Flu_Immunization_Programs_for_Health_Care_Personnel-HAP_Quality_Best_Practice_Series_Sept2011.pdf.

CONCLUSION

Recent evidence indicates that the morbidity and mortality associated with ILI and LRTI in nursing homes can be substantially improved with prevention programs that target modifiable risk factors, including inadequate oral care, aspiration due to swallowing difficulty, and inadequate employee vaccination programs. Several components are crucial to structuring a targeted prevention program. First, an effective oral hygiene program includes education and assessment, handling resistance to care, providing tooth brushing and alternatives, and managing dry mouth. Second, dysphagia and aspiration risk factors can be modified with a structured history and physical assessment; an individualized care plan; the use of comprehensive diagnostics, pharmacologic agents, swallowing therapy, and enteral feeding; and the stimulation of hormones that affect swallowing by daily gum and tooth brushing. Finally, research indicates that vaccination of healthcare workers can reduce the transmission of influenza to residents by 60%. Translation of these evidence-based interventions into actionable facility practices has been shown to have a significant impact on respiratory tract infection outcomes.

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LEARNING OBJECTIVES

— Identify strategies considered effective to improve the oral care of nursing home residents.

— Select the interventions necessary to modify risk factors for lower respiratory tract infections (LRTIs) and aspiration pneumonia.

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.

While making rounds to monitor compliance with resident oral hygiene practices, the nursing supervisor noticed multiple inadequacies with resident oral care, including presence of thick oral and tongue plaque, inadequate teeth brushing, no use of mouthwash rinse, and lack of gloves and hand hygiene. The nursing assistant reported a lack of oral care supplies, as well as caring for multiple dependent and combative residents. A family member was seen feeding a dysphasic resident in a semi-reclining position. Review of

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(continued)

— Recognize influenza vaccination program strategies most likely to reduce transmission of influenza to nursing home residents and their contacts.

the medical record and care on several of these residents indicated diagnoses of recurring aspiration pneumonia, inconsistencies in assessments and documentation of oral health and care, and use of medications inducing dry mouth. Surveillance for respiratory tract infection found that the facility's influenza-like illness infection rates have not decreased over several years. The resident influenza vaccination rate remains high, but employee vaccination rates are consistently below 50% acceptance.

1. Review the following strategies to improve the oral care of nursing home residents. Which strategy would be the *least* effective in improving the oral care of the combative and dependent residents discussed in the case scenario above?
   a. Monitor daily oral care practices and availability of supplies (toothbrushes/paste, foam swabs, mouthwash and moisture gel supplies).
   b. Discourage resistance to care with communication, modeling, expression, distraction, and interventions found in self-study modules.
   c. Manage dry mouth with hydrating spray or moisturizing gel.
   d. Provide web-based in-services as needed to all facility staff about the importance of oral care to residents.
2. All of the following practices exemplify adequate oral care EXCEPT:
   a. Wash hands and don clean gloves prior to giving oral care.
   b. Clean the oral cavity of ventilator-dependent residents with lemon-glycerin swabs.
   c. Complete oral care twice daily (i.e., once during the morning and once during the evening).
   d. Brush teeth and tongue for two minutes and, if needed, apply lip moisturizer.
3. Based on the case scenario above, which of the following risk factors for LRTIs would be modifiable?
   a. Inability to perform activities of daily living and neurologic- and medication-induced dysphagia
   b. Multiple chronic illnesses, dementia, and smoking
   c. Dysphagia, inadequate oral care, and inadequate vaccination compliance
   d. Tracheostomy, tube feedings, and gastroesophageal reflux diseases
4. All of the following actions are associated with evidence-based strategies to prevent aspiration in the above resident with dysphagia EXCEPT:
   a. Supervise oral feeding and position with a head-up posture in a 30-degree angle sitting position.
   b. Provide intensive oral care with daily tooth and gum brushing.
   c. Complete a proactive assessment to identify residents with clinical indicators of dysphagia aspiration.
   d. Measure gastric residual volumes routinely and before feedings.
5. Which of the following influenza vaccination program strategies is *most* likely to reduce transmission of influenza in the facility in the case scenario above?
   a. Vaccinate all consenting residents to increase herd immunity.
   b. Achieve high vaccination rates for all healthcare workers, residents, and contacts (i.e., family members, visitors).
   c. Mandate a vaccination program for all clinicians.
   d. Vaccinate all residents and family members.

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Gap Assessment of Hospitals' Adoption of the Just Culture Principles

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Pennsylvania Patient Safety Authority

BACKGROUND

Patient safety experts recognize that a healthcare organization's culture exerts a critical influence on staff response to patient safety issues, as well as on staff members involved in those events.[1,2] Willingness to report both actual and potential adverse events can be a strong indicator of the organization's attitude toward patient safety generally and a key to its perception and treatment of staff involved in adverse events. Organizations with strong safety cultures have robust reporting mechanisms to identify risks and effective systems for evaluating causes and taking action to address process weaknesses. They develop and reinforce the perception among staff that reporting is accepted, expected, and nonpunitive. In the alternative "blame and shame" environment, adverse events go unreported and process failures are not identified, causes go unaddressed, and the cycle of event-blame-punishment is often repeated to the detriment of patients and healthcare staff alike.

Many healthcare organizations have made the transition from the punitive culture that dominated thinking in the years before the Institute of Medicine's landmark report *To Err Is Human* to the nonpunitive stance that many hospitals now take toward reporting. Some hospitals, such as those in the Department of Veterans Affairs system, have evolved to a view that does not punish individuals for reporting or committing human errors and mistakes and instead choose to identify the reasons for the error and to change the underlying process that either caused or contributed to the error.[3] Recognizing the inevitability of human error while still holding staff accountable for individual actions is the cornerstone of the just culture approach that has been articulated by Outcome Engineering president David Marx. Outcome Engineering has developed an algorithm for assessing the role of human behavior in individual events, as well as a methodology for evaluating an organization's culture and commitment to a just culture that can be used by hospitals and other facilities.[4]

In the Pennsylvania Patient Safety Authority's 2007 survey of Pennsylvania healthcare organizations reported in the Authority's 2008 annual report, facilities were asked whether their internal policies and procedures related to adverse event reporting incorporated just culture principles.[1] Statewide, 118 hospitals and 82 other facilities (including ambulatory surgical facilities [ASFs] and birthing centers) responded to the survey. The majority of hospitals that responded (70%) reported some level of implementation of a just culture, and 59% reported that the just culture model was fully implemented hospital-wide. The remaining 30% of hospitals reported that the principles were not yet implemented. Similar results were found among responding ASFs and other facilities, with 72% reporting some or partial implementation and 28% having not adopted the just culture approach.

The Authority wanted to ensure that Pennsylvania facilities fully understood the tenets of a just culture and sought out Outcome Engineering to discuss the survey results. That discussion was the genesis for the Pennsylvania Just Culture Project. The project, which began in spring 2010 and concluded with a report of gap survey results in February 2011, tested whether Pennsylvania facilities have more verbal commitment to just culture than is codified in facility policies and reflected in facility handling of adverse events and staff error. Indeed, during the process of identifying hospitals interested in participating in the project, many shared the view that they might have overstated the extent of their implementation.

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METHODS

The Authority partnered with Outcome Engineering in early 2010 to assess the degree to which a just culture was implemented in Pennsylvania. The Authority challenged Outcome Engineering to devise a method that could be used on a larger scale and that would protect hospitals' confidentiality while assessing their adherence to a just culture's essential tenets. Meanwhile, the Authority invited all Pennsylvania hospitals to consider participating in the project and, ultimately, 10 hospitals volunteered. Hospital patient safety officers (PSOs) were engaged to lead the assessment effort in each facility and the gap analysis and be the conduit for communicating results. The hospitals represented different regions of the commonwealth and ranged from large urban hospitals to smaller community hospitals.

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Table 1. Part 1: Patient Safety Officer Assessment of Just Culture Principles Based on Document Review

JUST CULTURE ATTRIBUTE	QUESTION	HOSPITALS ANSWERING "YES"	HOSPITALS ANSWERING "NO"	QUESTION WEIGHT	SCORE ACROSS ALL 10 HOSPITALS
Policies					
A just culture organization avoids using certain terms that can be misunderstood or not aligned with the principles of the model.	Are the following terms used in your disciplinary policies: negligent, careless, criminal conduct, egregious? (Reverse worded: "No" preferred)	4	6	1	6
A just culture organization makes a distinction between values supportive discussions with employees to influence behavior and those conversations that are intended as steps in a disciplinary process.	Do your organization's human resource policies distinguish between coaching and counseling?	1	9	1	1
A just culture organization defines the three manageable behaviors: human error, at-risk behavior, and reckless behavior.*	Do your organization's policies define the following behaviors: human error, at-risk behavior, reckless behavior?	1	9	3	3
A just culture organization expects justifiable breaches of policies and procedures to occur and provides clear examples.	Do your organization's policies provide clear examples of justifiable violations of policies and procedures?	4	6	1	4
A just culture organization emphasizes the need to improve system design while simultaneously managing human behavior.	Do your organization's policies emphasize both system design and the management of employee behavior?	2	8	2	4
Event Investigations					
A just culture organization investigates and explains the causes of human errors.	Does your event reporting system require explanations for each human error identified?	1	9	2	2
A just culture organization investigates and explains the causes of at-risk behaviors and procedural deviations.	Does your event reporting system require explanations for each at-risk behavior and/or procedural deviation identified?	2	8	2	4

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(table continued)

JUST CULTURE ATTRIBUTE	QUESTION	HOSPITALS ANSWERING "YES"	HOSPITALS ANSWERING "NO"	QUESTION WEIGHT	SCORE ACROSS ALL 10 HOSPITALS
Human Resource Actions					
A just culture organization recognizes and avoids the severity bias.† It is the quality of the choice involved in the behavior that determines the level of response to an employee, not the actual harm that results.	Does your organization's disciplinary response to employees consistently depend on the quality of the choices involved in their behaviors, irrespective of actual harm that occurs?	3	7	3	9
	Does evidence suggest that your organization's employees have not been disciplined for human errors, unless reckless choices were contributory?	8	2	1	8
	Does evidence suggest that your organization consistently takes disciplinary action with employees who have made a reckless choice?	6	4	1	6
A just culture organization consoles an employee who makes a human error and examines both the quality of the choices involved in the behavior as well as the design of the system around the employee.	Do managers in your organization consistently console employees who make human errors and examine both the choices involved and the system designed around the employee?	3	7	1	3
A just culture organization coaches an employee who makes an at-risk behavioral choice and examines both the incentives for the employee's choice and the design of the system around the employee.	Do managers in your organization consistently coach employees who make an at-risk behavioral choice and also examine the incentives for the employee's choice and the design of the system around the employee?	2	8	3	6
A just culture organization places an employee on notice of disciplinary action when repetitive human errors or repetitive at-risk behaviors are present and not caused by system performance shaping factors and not correctable through changes in work choices, remedial education, or coaching.	Do managers in your organization consistently place employees on notice of disciplinary action when repetitive human errors or repetitive at-risk behaviors are present and not caused by system performance shaping factors and not correctable through changes in work choices, remedial education, or coaching?	6	4	1	6

* Human error—an inadvertent action; inadvertently doing other than what should have been done; a slip, lapse, or mistake
At-risk behavior—a behavioral choice that increases risk where risk is not recognized or that is mistakenly believed to be justified
Reckless behavior—a behavioral choice to consciously disregard a substantial and unjustifiable risk

† The severity bias is present when the severity of the actual outcome influences how we think about the person involved or how we respond to them if we have managerial authority over them. In other words, the level of actual harm determines whether discipline or punishment is used.

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The just culture self-assessment tool developed by Outcome Engineering was based on two existing survey tools: a gap analysis and a benchmarking survey. Outcome Engineering developed the tool specifically for this project to address concerns that traditional methods of assessing a hospital's culture might breach confidentiality and required a significant time commitment. The just culture self-assessment tool comprises two parts:

— Part 1 measures organizational culture through 13 questions about organizational policies, adverse event investigations, and human resources actions. This section is completed by the PSO after reviewing a representative sample of documents related to these three areas.

— Part 2 measures the perceptions of leaders about the organization's culture through 20 questions about critical behavioral markers, such as system design, coaching, reporting, responses to human error, responses to reckless behavior, severity bias, equity, and transparency. This section is completed by 10 to 15 leaders within each organization. Recommended respondents include the chief nursing and medical officers, PSOs, and directors or managers of human resources, quality assurance, and risk management departments. (No information identifying individuals by name, position, or title was collected.)

Participating hospitals received their survey forms in January 2011 and were given three weeks to complete the survey tasks. The surveys were then reviewed and scored by Outcome Engineering working with Authority staff. Results were tabulated and presented to the participating hospitals in late February 2011. After completing the self-assessment, each hospital received a confidential report presenting its results compared with the average results of the other deidentified participating facilities. This report explained the significance of each attribute examined in the tool and provided guidance on how to improve attributes on which the facility scored low.

The survey tool is available to Pennsylvania PSOs on the Authority's secure PassKey website. The Authority's regional patient safety liaisons can assist facilities in the use and scoring of the assessment.

RESULTS

The two parts of the tool were scored separately. Part 1, which evaluated the hospitals policies and practices, contained elements that could produce a maximum score of 22 points for each hospital. Only one of the participating hospitals scored well—it earned 20 points, indicating compliance with key just culture tenets in policies, human resources practices, and investigation documentation. Two hospitals met the required adherence on approximately 50% of the scored items, while the majority of hospitals (seven) met just culture expectations on fewer than 50% of the elements. Six hospitals scored below 5 of a possible 22 points. All 10 participating hospitals as a group scored 62 of a total 220 points (see Table 1).

While none of the just culture principles was consistently present across all 10 hospitals, elements most widely adopted included not disciplining employees for human errors in the absence of reckless choices, taking disciplinary action with employees who have made reckless choices, and placing employees on notice of disciplinary action when repetitive human errors or repetitive at-risk behaviors are present and not caused by system performance shaping factors and not correctable through changes in work choices, remedial education, or coaching. However, only one hospital reported that their policies define human error, at-risk behavior, or reckless behavior. If staff do not understand the distinctions between these types of errors—or the distinctions management makes among them—human resources actions may appear arbitrary. Other principles of the just culture model that were not widely adopted were distinguishing between discussions aimed at coaching versus counseling, requiring explanations in event reporting systems for human errors and at-risk behaviors, and emphasizing both system design and management of employee behavior.

Part 2 involved a series of 20 statements to be evaluated by key leaders in the organization to assess their perception of the organizational culture. For each statement, response categories were presented on a five-point Likert scale ranging from "strongly disagree" (-2) to "strongly agree" (2) with a neutral value (0) for "neither agree nor disagree." Most statements were worded positively, with "strongly agree" being the preferred response. Those statements worded negatively were scored in reverse. The maximum number of points available for each hospital was 40. Results of this section are presented in Table 2.

The maximum score achievable was 40. No participating hospital scored well on these elements of the survey. The average score for all participating hospitals was 9.56 or only 24% of the 40 possible points. Six of the 10 participating hospitals scored slightly higher than the project average; 4 had scores significantly lower than average. The highest score from any hospital was 15.41, while the lowest was 3.19 of the total 40 possible points.

Based on the average scores, the aspects of their organizational culture hospital leaders rated most positively were investigating "close calls" to understand the underlying causes, changing work practices to improve safety when concerns are reported, and disciplining employees who intentionally endanger safety regardless of whether harm resulted. The negative aspects of organizational culture included disciplining

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Table 2. Part 2: Survey of Hospital Leaders

EVALUATION STATEMENTS	LOWEST HOSPITAL SCORE	HIGHEST HOSPITAL SCORE	AVERAGE HOSPITAL SCORE
1. Managers in this organization discipline employees who make mistakes that might impact patient safety.*	-0.79	0.09	-0.43
2. When a safety concern is reported, the way we work is changed to make things safer.	0.72	1.76	1.20
3. If employees are doing something unsafe, their managers will talk to them and explain a safer way to behave or work.	0.7	1.38	1.06
4. If employees are doing something unsafe, their coworkers will talk to them and explain a safer way to behave or work.	-0.22	0.84	0.26
5. Managers in this organization treat all employees and staff, regardless of their position in the hospital, fairly after an event involving harm to a patient.	0.0	1.38	1.01
6. Over the past 12 months, this organization has reduced its number of safety events resulting in harm to patients.	0.0	1.6	0.90
7. Employees and staff at this organization are reporting things they see that could impact the safety of the patients.	0.0	1.3	0.96
8. This organization looks into "close calls"—things that could have harmed the patients but did not—to understand the underlying causes.	0.0	1.82	1.26
9. Physicians are less likely than other staff to be disciplined in similar circumstances.*	-1.11	0.69	-0.40
10. Managers in this organization talk to employees and staff about adverse events and lessons learned.	0.53	1.31	0.95
11. Managers in this organization discipline employees and staff who intentionally endanger safety, whether or not harm occurs.	0.8	1.43	1.16
12. Managers in this organization address safety events only if a patient is seriously harmed.*	-0.17	1.3	0.75
13. Employees will report their own mistakes that could have resulted in patient harm.	-0.11	0.71	0.31
14. Employees will report their own mistakes that did result in patient harm.	0.21	1.17	0.83
15. Occasionally our core organizational values will be in conflict.	-0.45	0.8	0.15
16. Some patient safety events are 100% preventable.*,†	-1.75	-0.5	-1.33
17. Our employees know they will be consoled if they make a human error.	-0.5	1	0.24
18. Our employees know they will be coached if they engage in at-risk behavior (e.g., taking shortcuts).	0.0	1	0.54
19. Our employees know they will be disciplined for reckless behavior regardless of whether harm results.	0.5	1.23	0.96
20. There is never an acceptable reason for an employee to violate patient safety policies and procedures.*	-1.54	0.17	-0.82
Score Sum (maximum possible = 40)			**9.56**

* Reverse worded and reverse scored, so that a higher score is always indicative of higher just culture alignment.

† The project team determined after survey administration that this question, on which hospitals scored the lowest, would have been better worded to read, "Some human errors are 100% preventable." The just culture model incorporates the notion that humans are fallible and will always make errors. Systems should be improved so that they are resistant to such errors without resulting in patient harm.

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employees for mistakes, treating physicians more leniently than other staff in similar circumstances, and believing there is never an acceptable reason for employees to violate safety policies and procedures.

This last item, while seeming to hold employees accountable for willful violations of procedure, is problematic because it encourages following the rules for their own sake even in situations in which the rules do not serve the greater good or when rules conflict with one another. For example, if a patient were falling, the correct action is to prevent the fall, even if this means ignoring normal hand hygiene protocols. The item on which participating hospitals scored lowest was the belief that some patient safety events are 100% preventable, which fails to acknowledge that human errors are inevitable.

CONCLUSION

The results supported the Authority's perception that Pennsylvania hospitals may have overestimated the degree to which the hospital is in alignment with core principles of the just culture approach. Some hospitals' scores revealed significant gaps in multiple just culture elements, while others can focus on a few key points to strengthen a solid foundation. The self-assessment results along with the suggested improvement strategies provided by Outcome Engineering can help participating hospitals' PSOs identify their organizations' weaknesses and set a plan for working with hospital leaders to improve their culture. Despite these gaps, the 10 hospitals in this project voluntarily chose to participate, in part because the PSOs recognized that their culture was not as aligned with the just culture principles as it could be. These hospitals are to be commended for their willingness to be self-critical and to focus on their shortcomings. These are among the defining characteristics of high-reliability organizations.

Overall, the results of this project suggest that work remains to be done to bring Pennsylvania hospitals and other healthcare facilities closer to achieving a just culture in healthcare. While this project focused on a small sample of the state's hospitals, the results suggest that facilities may overestimate their implementation of key principles of the just culture model. With reporting a crucial feature of a culture of patient safety and the need to focus on process design rather than human error to reduce adverse events for patients, the results suggests that there is room to improve staff awareness of the value of reporting, the need to focus on system process redesign, and the nature and cause of human error.

NOTES

1. Pennsylvania Patient Safety Authority. 2008 annual report [online]. 2009 Apr [cited 2011 Jul 5]. Available from Internet: http://patientsafetyauthority.org/PatientSafetyAuthority/Documents/annual_report_2008.pdf.
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FDA LAUNCHES SURGICAL FIRE PREVENTION INITIATIVE

In October 2011, the U. S. Food and Drug Administration (FDA) announced the launch of a surgical fire prevention initiative as part of its overall Safe Use Initiative. The Safe Use Initiative provides an avenue for FDA to establish partnerships and collaborations with appropriate stakeholders to identify risks and reduce harm associated with using medications. FDA regulates the drugs (e.g., oxygen, skin preparation solutions) and the devices (e.g., electrosurgical units, lasers) that, when combined in the right proportions and associated with the right conditions, contribute to surgical fires. However, according to FDA, regulations of drugs and devices alone cannot prevent surgical fires.

The surgical fire prevention initiative is a collaborative effort between the clinical community and patient safety organizations to encourage safe practices and to develop interventions to prevent surgical fires. FDA publicized the initiative launch by means of a FDA Safety Communication on preventing surgical fires (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm275189.htm), a webpage on preventing surgical fires (http://www.fda.gov/preventingsurgicalfires), and a video available through Medscape (http://www.medscape.com/viewarticle/751171).

Concurrently, Pennsylvania Patient Safety Authority analysts are reexamining events of surgical fires reported to the Authority and will publish results in an upcoming issue of the *Pennsylvania Patient Safety Advisory*. The Authority has previously published a patient safety toolkit specifically discussing airway fires during surgery; for more information, see http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/airway_fires/Pages/home.aspx.

Scan this code with your mobile device's QR reader to access the Authority's airway fires toolkit.

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Quarterly Update: What Might Be the Impact of Using Evidence-Based Best Practices for Preventing Wrong-Site Surgery? Results of Objective Assessments of Facilities' Error Analyses

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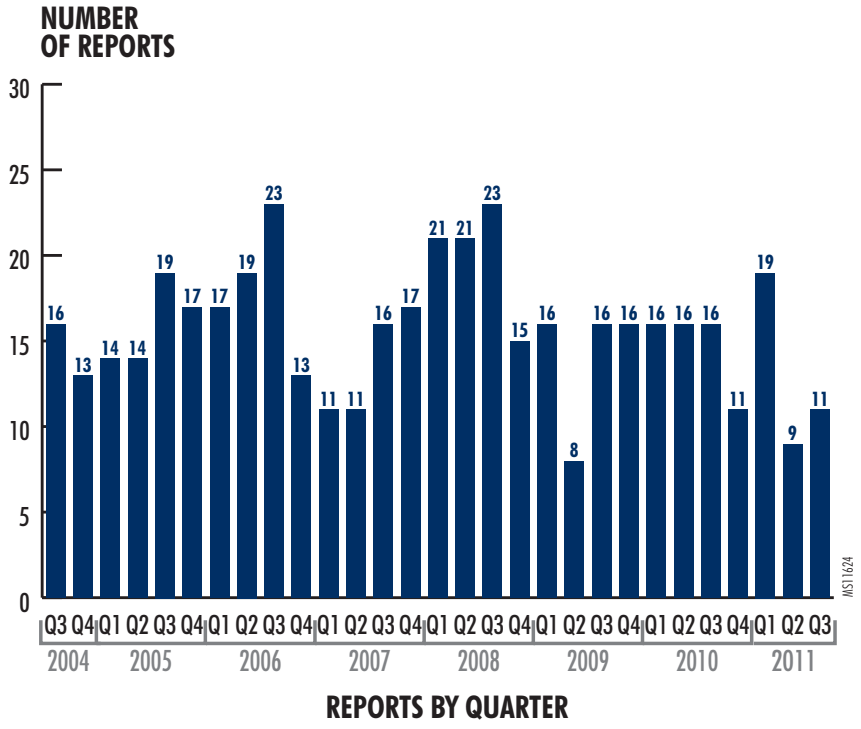
Pennsylvania healthcare facilities reported 11 wrong-site surgeries to the Pennsylvania Patient Safety Authority during the most recent reporting quarter, which is an increase from the previous quarter, but matches the third lowest quarterly number of event reports (see Figure). This update includes any belated additions and corrections from previous reporting quarters; specifically, the identification and deletion of a second, duplicate event report of a wrong-site surgery in the first quarter of 2006, resulting in minor adjustments to previous totals for the seven reporting years (June 2004 through September 2011).

Successful efforts to decrease wrong-site surgeries—reported previously by the Health Care Improvement Foundation Partnership for Patient Care wrong-site surgery collaboration (73%),[1] by the Veterans Health Administration medical team training program (25%),[2] and by a recent, unpublished, wrong-site surgery collaboration of facilities in a second region of Pennsylvania (0 events during operating room (OR) procedures in more than 1 year)— continue with an article in this issue of the *Pennsylvania Patient Safety Advisory* about the Minnesota Time Out.[5]

NEAR-MISS REPORTS

Some recent reports of wrong-site near misses illustrate the value of assessing near-miss events.

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



Scan this code with your mobile device's QR reader to access the Authority's wrong-site surgery prevention toolkit.

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Incorrect Specimen Labeling

Two near-miss reports of incorrect labeling of specimens illustrate the importance of following good practices to prevent mislabeled pathology specimens.

> *The specimen requisition sheet and the specimen container were incorrectly labeled with another patient's name and number. The physician was notified and correctly identified and labeled the specimen requisition sheet and the specimen container for this patient.*

> *A pathologist, while reading slides on the case, discovered that the wrong laterality was put on both the specimen container and slip (left/right)—[laterality was] right on both, and it should have been left.*

All paperwork, especially preprinted labels, from the previous patient should be cleared before bringing another patient into the OR. The site of the specimen should be verified by the surgeon before the specimen leaves the room.

Critical Near Misses

The Authority received a report of a patient scheduled for removal of a ureteral stent from the wrong-side. As it turned out for the patient, there was only one stent and the correct stent was removed.

The World Health Organization High 5s project has identified three near-miss situations as critical near misses that necessitate root-cause analyses:[4]

1. **Procedures that are done correctly despite incorrect information, such as described in the event report above.** However, the Authority would not include doing the correct procedure on the wrong patient as a critical near miss; the Authority would consider operating on the wrong patient as a wrong-site procedure, even if the patient received a medically appropriate procedure.
2. **Errors caught by the last step of the Universal Protocol, the time-out, such as described in the September 2011 *Advisory*.**[5] At least three earlier reports have been found in the reporting system since July 2004:

   > *The left knee was prepped for surgery. The OR schedule, patient consent, patient verification, and physician marking all listed the right knee. The error was discovered during the time-out. The right knee was prepped and draped, and the procedure was performed.*

   > *A patient was intubated, prepped and draped; the time-out was performed and team realized wrong leg. The patient was reprepped and redraped. [Staff] continued with the correct-site surgery.*

   > *The OR staff initially draped the wrong leg before a knee arthroscopy procedure. The error was caught during the time-out process. The correct leg was draped, and the procedure completed by the surgeon.*

3. **Near-miss situations resulting in cancellation of the procedure.** These events have been reported approximately once per year. They occurred when the patient's understanding was different than the documented information, when drops were put in the wrong eye, and when an incorrect consent could not be corrected because the patient had been sedated. The Authority would not include cancellation of a procedure based on identification that the patient was the wrong patient as a near miss that fell into this critical category, just any cancellation affecting the patient who was supposed to get the procedure, based on identification of the wrong patient, wrong procedure, or wrong site.

Treating critical near misses as seriously as wrong-site events should help maintain awareness of the constant risk of wrong-site events.

OBJECTIVE ASSESSMENTS OF THE IMPACT OF EVIDENCE-BASED BEST PRACTICES TO PREVENT WRONG-SITE SURGERY

The best practice principles for preventing wrong-site surgery have been identified,[6] updated, and supported by their evidence base.[5,7] Collaborative efforts with the Health Care Improvement Foundation Partnership for Patient Care to upgrade compliance with the best practice principles were effective in reducing wrong-site surgeries in 30 facilities in the Philadelphia area.[1] A similar, unpublished collaborative effort in facilities in a second region of Pennsylvania resulted in 0 wrong-site surgeries in facility ORs during OR procedures in more than 1 year. A subjective analysis of the narratives of all wrong-site surgery reports from June 28, 2004, through June 30, 2011, to determine the potential impact of each evidence-based best practice principle was published in the September 2011 *Advisory*.[5] The following is an objective assessment of the impact of each evidence-based best practice principle, based on the error analysis forms completed by facilities' patient safety officers (PSOs).

Since August 2007, the Authority has asked each PSO who submits a report of a wrong-site surgery to use a standardized error analysis form when doing the root-cause analysis.[8,9] These standardized error analysis forms provide a structure for a complete assessment of all evidence-based best practice principles that might be deficient, rather than just focus on the specific causes of the reported event. The forms include yes/no questions relating to the evidence-based best practice principles to prevent wrong-site procedures. Questions did not relate to three evidence-based best practice principles: (1) the correct operation and site is recorded on the history and physical examination (principle 2), (2) all information is verified by the

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Table. Deficiencies of Evidence-Based Best Practice Principles in Error Analyses of Wrong-Site Operative Procedures

ASSESSMENT*	YES	NO	UN-KNOWN	NA	% YES OR NO	% YES OF YES/NO	% NO OF YES/N0	EVIDENCE-BASED BEST PRACTICE PRINCIPLE†
The correct site was specified on the schedule.	80%	9%	2%	9%	89%	90%	10%	1. The correct site of the operation should be specified when the procedure is scheduled.
The name of procedure(s) was stated correctly on the consent. The correct site/side/level/digit was clearly stated on the consent.	80%	13%	6%	1%	93%	86%	14%	3. The correct operation and site should be specified on the informed consent.
The person obtaining the scheduling information verified the information provided from the surgeon's office.	61%	5%	15%	19%	67%	94%‡	6%	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.
All information from the surgeon's records was available in the operating suite for verification against primary sources of information.	78%	5%	6%	11%	83%	93%	7%	5. The surgeon should have supporting information uniquely found in the office records at the surgical facility on the day of surgery.
A member of the operating room (OR) staff performed the preoperative reconciliation.	83%	8%	6%	3%	91%	91%	9%	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 and surgeon before the patient enters the OR. 6A. RN should verify preoperatively.
Preoperative verification against the consent and patient records was done by the surgeon prior to the time-out.	67%	17%	6%	9%	84%	80%	20%	6B. Surgeon should verify preoperatively.
Verification of patient's information about full name, date of birth, procedure, and correct site or side, if any, was done with identification (ID) band, consent, schedule, and surgeon's documents in the patient's record.	91%	8%	2%	0%	98%	92%	8%	6C. All information, including patient's information, should be verified preoperatively.
All information was verified by the registered nurse (RN) preoperatively.	78%	16%	6%	0%	94%	83%	17%	6A, 6C. RN should verify all information.
All information was verified by the RN and the surgeon preoperatively.	63%	29%	9%	0%	91%	69%	31%	6A, 6B, 6C. The RN and the surgeon should verify all information.
The patient was asked to state his or her full name, date of birth, procedure, and correct site or side, if any.	78%	13%	6%	2%	91%	86%	14%	7. All verbal verification should be done using questions that require an active response of specific information, rather than a passive agreement.
The patient identified by stating full name and date of birth was verified by preoperative RN using patient name and date of birth on ID band.	95%	2%	3%	0%	97%	98%	2%	8. Patient identification should always require two unique patient identifiers.

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Table. Deficiencies of Evidence-Based Best Practice Principles in Error Analyses of Wrong-Site Operative Procedures (continued)

ASSESSMENT*	YES	NO	UN-KNOWN	NA	% YES OR NO	% YES OF YES/NO	% NO OF YES/N0	EVIDENCE-BASED BEST PRACTICE PRINCIPLE†
The surgeon reconciled any discrepancies using original documents.	1%	5%	4%	91%	5%	95%‡	5%	9. Any discrepancies in the information should be resolved by the surgeon, based on primary sources of information, before the patient enters the OR.
Marked properly with verification.	34%	41%	7%	18%	75%	56%‡	44%	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.
The operative site was marked with the physician's initials.	31%	40%	5%	24%	71%	43%	57%	11. The site should be marked by the provider's initials.
The time-out was done in the OR.	81%	16%	2%	0%	98%	83%	17%	13. Separate formal time-outs should be done for separate procedures, including anesthetic blocks, with the person performing that procedure.
The incision was made after the time-out.	61%	6%	2%	31%	67%	91%	9%	14. All noncritical activities should stop during the time-out.
The operative site marking was visible during the time-out.	53%	22%	2%	23%	74%	71%	29%	15. The site mark should be visible and referenced in the prepped and draped field during the time-out.
Verification in the time-out included verification of correct patient, with identification with ID wristband and chart, and verification of procedure and site.	50%	21%	24%	5%	71%	70%	30%	16. 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.
The time-out involved the surgeon, anesthesia provider, nursing staff, and surgical technician.	70%	19%	5%	6%	88%	79%	21%	17. All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.
A member of the operating team raised a specific concern about possible wrong-site surgery at any point before the incision, when the time-out verification or site mark were questionable.	8%	50%	2%	41%	57%	50%‡	50%	19. Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed.
The surgeon responded to a specific concern a member of the operating team voiced about possible wrong-site surgery.	10%	3%	2%	84%	13%	97%‡	3%	20. 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.
Written interpretation of intraoperative images relevant to the case were available in the OR within the time needed to make intraoperative decisions.	27%	14%	6%	53%	41%	85%‡	15%	21. Verification of spinal level, rib resection level, or ureter stented should require radiological confirmation, using a stable marker and readings by both a radiologist and the surgeon.

* Total number of responses is 129 for each assessment.
† Best practice principles 2, 12, and 18 were not assessed.
‡ "Yes" responses, when compared to "No" responses, include "NA" responses.

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circulating nurse upon taking the patient to the OR (principle 12), and (3) the surgeon specifically empowers team members to speak up if concerned (principle 18). Each deficiency in best practice principles that is identified may be causal, incidental, or contributory to the reported event. This impact analysis focuses on the deficiencies identified by the questions in the systematic review of evidence-based best practice principles.

As of the end of June 2011, the Authority has received 129 completed error analysis forms assessing deficiencies of evidence-based best practice principles associated with wrong-site OR procedures. These error analysis forms represented 51% of all 254 wrong-site procedures during that time. All questions were answered in all forms.

The results (see Table) are presented in the numerical order of the evidence-based best practice principles and grouped according to the four key groups of best practice principles identified by the subjective analysis of the narrative of all wrong-site surgery reports:[5,10]

A. Preoperative verification of the completeness and accuracy of all the information relevant to the operation (principles 1 through 5). At minimum, this information includes the following:
   - Schedule
   - Consent
   - History and physical examination, including office notes if relevant
   - Laboratory results
   - Imaging studies
   - Pathology reports, if relevant

Optimally, this information is all verified to be complete and accurate before the day of elective surgery. Ideally, it would be known to be complete and accurate before leaving the surgeon's office.

B. Verification and reconciliation of the relevant information and marking of the site by the person doing the procedure on the day of surgery before the patient enters the OR (principles 6 through 11).

C. A properly done time-out, meaning one that actively engages all members of the operating team, references the site mark in the prepped and draped field, and empowers all members of the team to speak up if concerned (principles 12 through 20).

D. When appropriate, intraoperative verification of the anatomic site, specifically for spinal surgery, rib resections, and ureteral stenting. Such verification requires proper localization of the site by imaging studies, ideally with independent confirmation by both the surgeon and an imaging specialist (principle 21).

A. Preoperative verification of the completeness and accuracy of all the information relevant to the operation (principles 1 through 5).

The completeness and accuracy of the information on the consent, regarding the exact procedure and the exact site of the procedure, were deficient in 14% of the analyses of 129 wrong-site events. The correct site was not specified on the schedule according to 10% of the analyses. Information from the surgeons' records that might have been useful for verification was not available in 7%. Early reconciliation, before the day of surgery, was not done for 6%, not including patients for whom early reconciliation was not possible. The completeness and accuracy of information on the history and physical examination was not assessed.

B. Verification and reconciliation of the relevant information and marking of the site by the person doing the procedure on the day of surgery before the patient enters the OR (principles 6 through 11).

The error analyses revealed that the surgeons did not do preoperative verification with comparison against relevant written information in 20% of wrong-site procedures, whereas the preoperative nurse did not perform verification in 9%. This difference in deficiencies of preoperative verification between surgeons and nurses was statistically significant by chi-square test ($X^2 = 6.29$, $p < 0.05$). The verification failed to include all relevant patient information in 8% of procedures and did not require the patient to verbalize the information in an active voice ("My name is . . . .") in 14%. The net effect was that the preoperative nurse failed to do verification, against all relevant information, according to 17% of analyses; and verification by two providers, the nurse and physician, using all relevant information, was deficient in 31% of analyses. Best practice principles with good compliance and minimal deficiencies included the surgeon reconciling discrepancies when they were identified, deficient in only 5% of analyses, and using two identifiers, the least common deficiency, at 2%.

Marking the site properly, including verifying the location against relevant patient information as well as the patient's understanding, was deficient in 44% of the analyses of wrong-site events in which marking the site was applicable. When marking the site was applicable, the surgeon's initials were used in only 43% of the analyses, the word "yes" in 41%, and other, unspecified notations, if any, in the remainder of the analyses.

C. A properly-done time-out, meaning one that actively engages all members of the operating team, references the site mark in the prepped and draped field, and empowers all members of the team to speak up if concerned (principles 12 through 20).

Failure to do a time-out in the OR was reported in 17% of the analyses of wrong-site events. The surgeon apparently

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did not wait for the time-out before making the incision in 9%.

The site marking was not visible in the prepped and draped field during the time-out according to 29% of the analyses. Verification did not include checking information about the patient (identity, procedure, and site) against the written information in 30% of the analyses. The time-out did not involve all members of the operating team in 21%.

As a result, information was not correct or the site mark was not visible during the time-out and team members failed to raise concerns according to 50% of the analyses. However, a concern was raised and the surgeon failed to respond in only 3% of analyses. Specific empowerment by the surgeon, encouraging team members to speak up if concerned, was not assessed.

D. When appropriate, intraoperative verification of the anatomic site, specifically for spinal surgery, rib resections, and ureteral stenting. Such verification requires proper localization of the site by imaging studies, ideally with independent confirmation by both the surgeon and an imaging specialist (principle 21).

Deficiencies of intraoperative verification of the anatomic site, when appropriate, were reported in 15% of analyses.

The objective assessment of the impact of following evidence-based best practice principles to prevent wrong-site surgery, using information from uniform error analyses of 129 wrong-site operative procedures, supports the previously reported subjective analysis of the report narratives.[5] All four groups of best practice principles would address deficiencies commonly found in the error analyses of wrong-site operative procedures:

1. Preoperative verification
2. Verification and marking of the site by the person doing the procedure on the day of surgery before the patient enters the OR
3. Properly done time-outs, engaging all members of the operating team, referencing the site mark in the prepped and draped field, and the surgeon empowering all members of the team to speak up if concerned
4. Intraoperative verification of the anatomic site, when indicated, by imaging studies

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Success in Preventing Wrong-Site Procedures in Minnesota with the Minnesota Time Out

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Editor's Note

The Pennsylvania Patient Safety Authority is pleased to report another success in improving wrong-site surgery from colleagues in Minnesota, who have also undertaken a project to prevent wrong-site surgery in their state.

In Minnesota, as in Pennsylvania, wrong-site surgeries and wrong-site invasive procedures are issues of great concern. In 2008, Minnesota used a collaborative approach to develop a human-factors-based time-out process known as the Minnesota Time Out. Since spring 2011, an effort has been under way to implement the Minnesota Time Out statewide, with a goal of having every hospital and ambulatory surgery center perform the specific steps of the time-out for every invasive procedure, every time.

During the first seven years in which Minnesota's mandatory statewide adverse event reporting law has been in effect (2003 to 2010), 155 (11%) of the 1,403 adverse events that were reported to the Minnesota Department of Health by hospitals and ambulatory surgery centers were wrong-site procedures. The number of reported events in this category increased from 13 in year one to 31 in year seven, with nearly one-third resulting in a need for additional treatment, in some cases a second corrective procedure. Roughly 45% of these wrong-site procedures occurred outside of the operating room (OR), most commonly in interventional radiology, anesthesia, radiation therapy, and preoperative areas.

Data submitted under the adverse event reporting law underwent a thorough review beginning in 2007 that uncovered a number of common system breakdowns that contributed to the wrong-site procedures. Despite the existence of nationwide standards such as the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™, compliance with best practices for preventing wrong-site procedures was inconsistent, with site marking and time-outs present in only about half of all reported events in 2007. Based on these findings, in 2008 the Minnesota Department of Health and the Minnesota Hospital Association (MHA) began working closely with the University of Minnesota's Center for Design in Health, a research center that works to integrate human factors system design into healthcare work processes, to develop a more rigorous time-out process grounded in human factors principles.

Researchers from the Center for Design in Health observed surgeries in eight facilities around Minnesota in 2008 to document weaknesses in preprocedure verification processes. Their findings were strikingly consistent across observed facilities. Regardless of facility size, geographic location, and procedure type, the team observed the following:

- Inconsistent site-marking practices, including cases without site marks, cases in which the site was marked in the OR rather than in preoperative areas, cases in which site marks were removed or obscured, and cases in which site marks were ambiguous or were made without reference to source documents
- Inconsistent time-out processes, including cases with no time-out, cases in which team members did not cease other activities or actively participate in the time-out, cases in which information for the time-out was provided from memory rather than with the use of source documents, and cases in which the time-out was done without the surgeon present

Based on these observations, the researchers worked with the department of health and MHA to develop a comprehensive preprocedure verification process, the Minnesota Safe Surgery process. The steps in the time-out portion of this process, and the rationale for each, are outlined in the following discussion.

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MINNESOTA TIME OUT

The Minnesota Time Out is a critical component of the Minnesota Safe Surgery process. Each step of the time-out has been designed based on human factors and cognitive science principles to create an effective time-out that engages the full procedure team.

IMPLEMENTATION AND DISSEMINATION

Since its development in 2008, the Minnesota Time Out has been incorporated into statewide wrong-surgery prevention work, with the goal of establishing this more prescriptive, more rigorous time-out as the statewide community standard (see Table). To accelerate this work, MHA convened a group that included the Minnesota Department of Health, the Minnesota Medical Association, the Minnesota Medical Group Management Association, the Minnesota Ambulatory Surgery Center Association, and the MMIC Group, a medical professional liability insurance company. This group of organizations established the Minnesota Safe Surgery Coalition to address challenges related to prevention of wrong-site procedures and to brainstorm strategies for leveraging each organization's resources and influence to push for statewide implementation of best practices to prevent wrong-site procedures.

During the spring of 2011, the Safe Surgery Coalition initiated a three-year campaign to eliminate wrong-site procedures, with the first year focusing on ensuring that the Minnesota Time Out was conducted for every patient, every invasive procedure, every time. Each facility that signed up to participate in the Minnesota Time Out campaign is required to have its chief executive officer sign off on this commitment, and participating organizations have access to training, videotaped simulations of the time-out for auditing practice, and other resources, including time-out videos, sample policies and scripts, and talking points. To assist in engaging physicians in the process, MHA developed a "Physician Peer-to-Peer" DVD that features prominent Minnesota surgeons talking about the importance, value, and simplicity of the Minnesota Time Out. More than 100 facilities across the state are currently involved in the campaign (see Figure).

While the journey to prevent wrong-site procedures in Minnesota is far from over, this concerted statewide effort to support implementation of the Minnesota Time Out is starting to bear fruit. Since Minnesota began requiring reporting of wrong-site procedures in 2003, the number of days between events has averaged roughly 13. During the first six months of the current reporting year, prior to

Table. The Minnesota Time Out

STEP	RATIONALE
1. Person performing procedure initiates, using a phrase such as "Let's do the time-out now."	The team is more likely to cease activity and come together for the time-out if it is initiated by the person performing the procedure; the person performing the procedure is the only one who can know when he or she is ready to begin.
2. Team ceases all activity.	Active listening and participation: team cannot cognitively engage in time-out if engaged in other activities.
3. Designated staff member, other than person performing procedure (e.g., in the operating room [OR], the circulator), verbally states patient name, procedure, and location while referring to source documents. In the OR, the anesthesia care provider then provides patient name and procedure from his or her documentation.	Source documents have been verified prior to the procedure and should be an accurate source of information. All team members must have an active role in the time-out in order to be cognitively engaged. Requiring an active response (rather than "I agree") from all team members and providing each with an active role counters rote recitation.
4. Designated staff member, other than person performing procedure (e.g., in the OR, the scrub staff member), locates and verbally confirms visualization of site mark, and states where it is located.	The site mark has already been verified against source documents; it must be visualized as part of the time-out.
5. Person performing procedure verbally states procedure, including location, from memory.	Providing information from memory increases focus on the procedure. The surgeon is the last to verify in order to control for hierarchy or power differential (i.e., if the surgeon states information first, the team is more likely to agree rather than provide independent verification).

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Figure. Minnesota Time Out

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the launch of the time-out campaign, the average number of days between events was 11, and the state was on track for another increase in the annual number of events. In the latter half of the reporting year, the average number of days between events has risen to roughly 30, and Minnesota is on track to achieve a roughly 20% reduction in these serious—and preventable—events.

Time will tell whether this reduction will be sustainable, but Minnesota's experience in working to establish a consistent and effective time-out process as the statewide community standard in hospitals and ambulatory surgery centers has provided a number of key lessons about how to develop and implement process changes within and across organizations, as well as lessons about the sometimes hidden barriers to change that often derail safety campaigns. The process has highlighted, once again, the importance of clear leadership expectations and standards, particularly for surgeons, in conducting the time-out. It has also shown that a prescriptive process can be successful, as long as those who are carrying it out are well-versed in the rationale for the steps, know what to look for when auditing the process, and have the authority to speak up when the process is not being followed. These key lessons can offer insight into not only how to design a comprehensive safe-surgery process, but also how to engage organizations and team members to successfully implement and sustain the key best practices that will have an impact on outcomes.

For more information about the Minnesota Time Out and the Minnesota Safe Surgery Coalition, visit http://www.mnhospitals.org/index/timeout.

HYDROMORPHONE LABELING REVISIONS APPROVED

In response to medication errors reported to the U.S. Food and Drug Administration (FDA), the Institute for Safe Medication Practices, the Pennsylvania Patient Safety Authority, and other reporting programs, FDA has approved labeling revisions to HYDROmorphone products to promote safe use and prevent associated medication errors.[1] In June 2011, FDA approved the revisions for Dilaudid® (1 mg/mL, 2 mg/mL, 4 mg/mL) and Dilaudid-HP (10 mg/mL). These revisions pertain to the prescribing information, container labels, and carton labels; for example, revisions addressed better organization of information in the labeling, such as placing dosing information and warnings first. In addition, the intravenous starting dose has been reduced to 0.2 mg to 1 mg (originally 1 mg to 2 mg). The complete prescribing information is available from the manufacturer at http://www.purduepharma.com/PI/prescription/DilaudidInjectionsPI.pdf.

The Authority has previously published on medication errors associated with HYDROmorphone. A patient safety toolkit, including the previous *Pennsylvania Patient Safety Advisory* articles, a process measures and outcomes tool, and excerpted prescribing information, is available from the Authority at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Pages/home.aspx.

Note

1. Institute for Safe Medication Practices (ISMP). FDA Advise-ERR: FDA approves HYDROmorphone labeling revisions to reduce medication errors. *ISMP Med Saf Alert* 2011 Oct 20; 16(21):1-2.

Scan this code with your mobile device's QR reader to access the Authority's HYDROmorphone toolkit.

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PENNSYLVANIA PATIENT SAFETY ADVISORY

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

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for more than 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.