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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Falls Risk Assessment: A Foundational Element of Falls Prevention Programs

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ABSTRACT

Falls risk assessment is a foundational element of falls prevention programs. Many falls risk assessment tools have been developed to screen for risk factors most predictive of falls. Studies have found that these tools accurately identify patients who will fall or those who are at high risk of falling with a sensitivity and specificity of greater than 70%. Pairing risk assessment with functional assessment tests and injury risk assessments shows promise of further delineating patients at highest risk of falls and falls-with-injury events. Initial screening for falls risk using these tools forms the basis for further risk assessment and formulation of a multifactorial falls prevention plan with interventions targeted to the risk factors identified. In 2011, the Pennsylvania Patient Safety Authority received reports of more than 32,000 falls. Of these patients who fell, 64% were reported to have had a falls risk assessment completed, 60% had been identified as at risk for falling, and 65% were reported to have had prevention strategies in place. While these statistics may reflect a lack of documentation, rather than a deficiency in practice, evaluation of compliance with best practices with respect to falls prevention is warranted, beginning with performance of a falls risk assessment for all patients. (Pa Patient Saf Advis 2012 Sep;9[3]:73-81).

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

INTRODUCTION

Falls are the leading cause of injury-related death in adults over age 65, with death rates rising sharply over the past decade. One out of three adults over age 65 falls each year, and adults age 75 or older are four times as likely to suffer an injurious fall as adults age 65 to 74.[1] Hospitalization increases this risk due to the interplay of intrinsic falls risk factors (e.g., symptoms of illness, treatment side effects) and extrinsic falls risk factors (e.g., unfamiliar environment, intravenous lines and other attachments).[2]

The majority of falls can be attributed to a physiologic cause, with 78% of falls labeled "anticipated" (i.e., physiological falls that can be predicted in patients exhibiting clinical signs that contribute to increased falls risk), and 8% labeled "unanticipated" (i.e., physiological falls that cannot be predicted before their first occurrence). The remaining 14% of falls are labeled "accidental" (i.e., the result of mishaps often attributed to environmental causes). The differentiation of fall types is important because methods for prediction and prevention differ according to the fall type. Anticipated physiological falls can be prevented through screening for falls risk factors, in-depth assessment, and implementation of targeted prevention strategies. Accidental falls can be prevented through environmental controls that seek to provide a safe environment. Unanticipated physiological falls are, by their nature, not preventable at first occurrence.[3]

There is increasing regulatory and reimbursement pressure on hospitals to prevent patient falls. In 2002, hospital falls resulting in patient death or serious disability were labeled as serious reportable events by the National Quality Forum (NQF).[4] In 2008, these serious reportable events were labeled as hospital-acquired conditions (HACs) subject to nonpayment by the Centers for Medicare and Medicaid Services (CMS).[5] And beginning in federal fiscal year 2015, hospitals in the worst-performing quartile in terms of national HAC rates will receive a 1% reduction in Medicare payments across the board for all discharges as part of the Patient Protection and Affordable Care Act.[6]

Considering the growing population of older adults and their increased risk of falls and falls injuries, the cost of falls is expected to grow in terms of both human suffering and financial cost to individuals and healthcare providers. CMS has recognized this as a focus area for improvement as part of the Partnership for Patients (PFP), an initiative that aims to decrease HACs by 40% by the end of 2013.[7] Recognizing that not all falls are preventable, the specific goal related to falls is "to cut the number of preventable fall injuries in half while maintaining or increasing patients' mobility."[8] The Pennsylvania Patient Safety Authority is currently partnering with the Hospital and Healthsystem Association of Pennsylvania and 81 hospitals across the state as part of the PFP Hospital Engagement Network (HEN) Falls Reduction and Prevention Collaboration.

FALLS IN PENNSYLVANIA

Falls continue to be one of the safety events most frequently reported to the Pennsylvania Patient Safety Authority.[9] In Pennsylvania, the rate of hospital falls with trauma is 0.581 per 1,000 discharges, and this is slightly higher than the national rate of 0.562 per 1,000 discharges.[10] Nationally, patient falls with injuries are estimated to cost $19 billion per year in direct medical costs.[11] At the level of the individual patient, the average increase in facility operational costs for a serious falls injury is $13,316, and the average increase in length of stay is 6.27 days.[12] Based on these numbers, the additional operational cost to Pennsylvania hospitals for falls with harm in 2010 is estimated to

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have been $15,406,612 and 7,254 days in additional length of stay.* This operational cost does not include additional costs (e.g., legal fees, potential lost revenue due to patient dissatisfaction) that may have been incurred as a result of these falls.

Between 2008 and 2010, Pennsylvania hospitals reported 135,221 falls, of which 85.7% (n = 115,884) occurred in inpatient care areas (e.g., medical-surgical units, critical care units, inpatient psychiatric units), 10.0% (n = 13,538) occurred in care areas that provide services to outpatients and inpatients (e.g., emergency department, radiology), and 4.3% (n = 5,799) occurred in ancillary departments, labs, or unspecified locations.[13] The largest number of inpatient falls (N = 115,884) occurred in general medical-surgical units (38.3%, n = 44,400). Eight other inpatient care areas (e.g., psychiatric units, critical care units, rehabilitation units) account for the remaining 61.7% (n = 71,484) of inpatient falls.[13]

FALLS RISK ASSESSMENT IN PENNSYLVANIA

In a review of falls-related sentinel events (i.e., falls resulting in death or permanent loss of function) reported from 2004 to 2011, the Joint Commission identified a deficiency in assessment (i.e., adequacy, timing, or scope of assessment) as the number one root cause.[14] Authority analysts queried the Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS) database for falls events reported during 2011 to evaluate whether or not patients who fell had a completed falls risk assessment, were identified at risk for a fall, and had prevention strategies or protocols in place.

In 2011, 32,802 patient falls were reported. Data from these falls event reports were analyzed following a three-step process. Primary analysis of these reports revealed 64% (n = 21,117) with completed falls risk assessments, 5.2% (n = 1,712) lacking falls risk assessments, and 30.4% (n = 9,973) with a risk assessment status that was unknown. The 30.4% finding suggests that, at minimum, there was no reported documentation that this activity was performed. The subsequent analyses took the lack of documentation into consideration.

The second analysis focused on the percentage of falls events reported for patients who were identified as at risk for a fall. In order to identify patients at risk for falls, risk assessments must have been completed. Therefore, falls event reports indicating completion of falls risk assessments (N = 21,117) were used for this analysis. Of these falls events, the analysis showed that 77.2% (n = 16,302) were reported for patients who were identified as at risk for a fall, 18.5% (n = 3,907) were reported for patients identified as not being at risk for a fall, and 4.3% (n = 908) were reported for patients with risk statuses labeled as unknown.

Once a patient is identified as at risk for a fall, the next step in a falls program is to perform an in-depth assessment of the risk factors identified through screening and to implement targeted falls prevention strategies. This final analysis evaluated whether the implementation of prevention strategies or protocols differed when risk assessments were completed and falls risks were identified. Three separate analyses were performed. The analyses showed that less than half (44.7%, 14,672 of 32,802) of the falls event reports indicated that all three activities had been implemented and documented (i.e., completed risk assessment, falls risks identified, and falls prevention strategy in place). Table 1 shows the different levels of falls prevention strategy implementation, stratified by completed falls risk assessment and falls risk identification.

RISK ASSESSMENT

Falls risk assessment is a foundational element of falls prevention programs. A number of organizations have developed evidence-based clinical guidelines for falls prevention, all of which begin with some form of falls risk assessment.[15-22] It is recommended that a falls risk assessment be done on admission, upon transfer from one unit to another, with any status change, following a fall, and at regular intervals.[15,18] In 2005, the Joint Commission required "an initial assessment of a patient's risk of falling, as well as conduct of periodic reassessments to enable actions to address potentially increased risks" as part of what was a new National Patient Safety Goal (NPSG) at that time: to "reduce the risk of patient harm resulting from falls."[23] This NPSG was upgraded to a standard in 2010, with the following two elements of performance: "the hospital assesses and manages the patient's risks for falls," and "the hospital implements interventions to reduce falls based on the patient's assessed risk."[24]

RISK ASSESSMENT TOOLS

Over 400 independent risk factors have been studied and found to be associated with increased incidence of falls.[25,26] Using a retrospective case-control study design, researchers have narrowed this long list of potential risk factors to shorter lists of key risk factors found to be most significantly associated with falling. These risk factors have then been translated into falls risk assessment tools.[25,27,28] Other risk assessment tools have been created by individual facilities as part of quality improvement efforts based on review of the literature and facility-specific information from incident reports and medical record reviews for falls. The validity of falls risk assessment tools is measured in terms of sensitivity and specificity.

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* Additional costs were calculated using the average additional cost per falls with harm ($13,316) multiplied by the Authority's total number of reported falls with harm in 2010 (1,157). The additional length-of-stay days were calculated using the average additional length-of-stay days (6.27) multiplied by the Authority's total number of reported falls with harm in 2010.

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Table 1. Prevention Strategy or Protocol Implementation According to Risk Assessment and Risk for Fall as Reported to the Pennsylvania Patient Safety Authority in 2011

PREVENTION STRATEGIES OR PROTOCOLS IN PLACE	ALL PATIENTS WHO FELL, % (NO.)	PATIENTS WHO FELL WHO HAD A COMPLETED RISK ASSESSMENT, % (NO.)	PATIENTS WHO FELL WHO HAD A COMPLETED RISK ASSESSMENT AND FALLS RISKS IDENTIFIED, % (NO.)
Yes	65.2 (21,390)	82.2 (17,590)	87.4 (14,672)
No	15.0 (4,928)	10.0 (2,148)	9.5 (1,590)
Unknown	19.8 (6,484)	7.8 (1,652)	3.1 (519)
Total	**100 (32,802)**	**100 (21,390)**	**100 (16,781)**

Sensitivity is the ability to correctly identify at-risk patients who do end up falling (i.e., patients assessed at high risk among all of the patients who fell). Specificity is the ability to correctly identify a patient not at risk of falling (i.e., patients identified at low risk among all those who did not fall).

In a review of the literature from 2001, Perell et al. identified 20 risk assessment methods, including 14 nursing falls risk assessment tools and 6 functional assessment tests in use across acute care, long-term care, and community settings. The median sensitivity for the nursing falls risk assessment tools (e.g., Morse Fall Scale) was calculated to be 81% (range of 43% to 100%), with a median specificity of 75% (range of 44% to 88%). The median specificity of the functional assessment tests (e.g., Timed Up and Go) was found to be 85% (range of 77% to 93%), with a median specificity of 78% (range of 38% to 87%). Based on these findings, Perell et al. advocate the use of existing tools rather than the development of new tools, recommending the following criteria for selecting the most appropriate tool for specific settings: high sensitivity, specificity, and interrater reliability; similarity of patient population to ones in which the instrument was developed or studied; written procedures explicitly outlining appropriate use of the tool; reasonable time required for administration; and established thresholds identifying when interventions are necessary.[2]

In a similar review by Scott et al., nursing falls risk assessment tools and functional assessment tests were evaluated for validity, with results presented according to the settings in which they were tested. Within the acute care setting, five nursing falls risk assessment tools and three functional assessment tests were evaluated. The eight tools were found to have sensitivity ranging from 66% to 93% and specificity ranging from 25% to 88%. The authors concluded that several tools exist that demonstrate moderate-to-good reliability and that selection of the tool must be guided by the clinical context and the identified purpose of the tool (e.g., quick identification of high-risk populations, reduction of risk through reliable identification of remediable risk factors).[29]

In a systematic review of 13 falls risk assessment tools, Oliver et al. identified six risk factors that repeatedly emerged as significant in tools with levels of sensitivity and specificity over 70%, though no single tool assessed all six factors: history of falls, gait instability, lower-extremity weakness, altered mental status (e.g., agitated confusion, impaired judgment), altered elimination (e.g., urinary incontinence, frequency, need for assisted toileting), and prescription of high-risk medications (i.e., medications associated with higher falls risks).[30]

Table 2 provides a side-by-side comparison of falls risk assessment tools currently in use by hospitals in the Pennsylvania PFP HEN Falls Reduction and Prevention Collaboration: the Morse Fall Scale, the Hendrich II Fall Risk Model, and the Johns Hopkins Fall Risk Assessment Tool. The Morse Fall Scale was developed in the 1990s and is in widespread use across the United States. It is one of only two falls risk assessment tools that have been validated prospectively with sensitivity and specificity testing in its development and in subsequent remote cohorts. The other is the STRATIFY tool, which was developed in and is in more common use across the United Kingdom.[30]

The Hendrich II Fall Risk Model is another tool in common use across the United States. It was developed in an acute care setting with a diverse patient population and has been tested for validity in other settings on a limited basis. Initial results suggest superior predictive validity, reproducibility, and feasibility for use in acute care settings as compared with the Morse Fall Scale and the STRATIFY tool.[31]

The Johns Hopkins Fall Risk Assessment Tool was developed and implemented in 2003 at the Johns Hopkins Hospital. It has been evaluated for content validity and acceptability for clinical users in the adult clinical care units where it was implemented; however, the authors of the tool acknowledge that further validity and reliability testing is necessary.[32]

LIMITATIONS OF FALLS RISK ASSESSMENT TOOLS

Most falls risk assessment tools that have been tested for validity have been evaluated within the same patient population for which the tools were designed, so the accuracy of the tools has not been validated across different care settings with different patient populations.[30,33,34] Simple

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Table 2. Risk Factors Assessed by Falls Risk Assessment Tools in Use by Hospitals Participating in the Pennsylvania Hospital Engagement Network Falls Reduction and Prevention Collaboration

RISK FACTORS	MORSE FALL SCALE	HENDRICH II FALL RISK MODEL	JOHNS HOPKINS FALL RISK ASSESSMENT TOOL
History of falls	√		√
Gait instability	√	√	√
Lower-extremity weakness			
Altered mental status	√	√	√
Altered elimination		√	√
High-risk medications		√	√
Secondary diagnosis	√		
Ambulatory aid	√		√
Intravenous line or heparin lock	√		
Dizziness or vertigo		√	√
Depression		√	
Male gender		√	
Advanced age			√
Automatic high- or low-risk triggers			√
Sensitivity	78%	74.9%	Not tested
Specificity	83%	73.9%	Not tested

Note: Sensitivity and specificity data for Morse Fall Scale is from: Morse JM, Morse RM, Tylko SJ. Development of a scale to identify the fall-prone patient. *Can J Aging* 1989;8:366-77. Sensitivity and specificity data for Hendrich II Fall Risk Model is from: Hendrich AL, Bender PS, Nyhuis A. Validation of the Hendrich II Fall Risk Model: a large concurrent case/control study of hospitalized patients. *Appl Nurs Res* 2003 Feb;16(1):9-21. Shaded rows indicate the six risk factors frequently found to be significant in risk assessment tools with high levels of sensitivity and specificity, as identified in: Oliver D, Daly F, Martin FC, et al. Risk factors and risk assessment tools for falls in hospital in-patients: a systematic review. *Age Ageing* 2004 Mar;33(2):122-30.

falls risk assessment tools have been found to have sensitivity and specificity greater than 70%,[30] but results can vary greatly when tested across varying patient populations.[34] The use of tools itself has been called into question based on research finding nursing clinical judgment is comparable to the use of risk assessment tools in identifying patients at risk to fall,[35-38] though the accuracy can vary based on nursing role and experience level.[35]

Regardless of the falls risk assessment method selected, it has been recommended that hospitals periodically test for internal validity using a two-by-two table to evaluate sensitivity and specificity.[39] Vassallo et al. have cautioned against relying on such testing for validity within the clinical setting. The challenge in evaluating the sensitivity and specificity of falls risk assessment methods is the fact that the identification of someone at a high risk of falling may be associated with implementation of falls prevention measures, even in the absence of a formal falls prevention program. Therefore, the rate of patients falling in the high-risk group may appear quite low (i.e., high sensitivity and low specificity) because interventions that successfully prevented falls were implemented.[38]

Though commonly referred to as risk "assessment" tools, these tools have alternatively been labeled risk "screening" tools.[17,22,37] This difference in terminology may be important in conveying the purpose of these tools. They are intended to be used as a consistent and reliable screening tool for identifying patients at risk of falling. They do not take the place of a thorough history and physical assessment. Screening should be followed by an in-depth multifactorial risk assessment and formulation of a plan of care detailing targeted falls prevention interventions.[15,17-22,40]

INDIVIDUAL FALLS RISK FACTORS

Falling is a complex phenomenon that results from a combination of risk factors. Meta-analyses of individual retrospective case-control studies have been completed in order to calculate the relative risk associated with each risk factor. Table 3 shows the risk factors associated with the highest risk of falling, along with their relative risk ratios.[41] Beyond the risk factors included in falls risk assessment or screening tools, these risk factors should be evaluated as part of an in-depth multifactorial risk assessment.

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Table 3. Falls Risk Factors and Associated Relative Risk

RISK FACTOR	MEAN RELATIVE RISK RATIO (RANGE)
Muscle weakness	4.4 (1.5-10.3)
History of falls	3.0 (1.7-7.0)
Gait deficit	2.9 (1.3-5.6)
Balance deficit	2.9 (1.6-5.4)
Use of assistive device	2.6 (1.2-4.6)
Visual deficit	2.5 (1.6-3.5)
Arthritis	2.4 (1.9-2.9)
Impaired activities of daily living	2.3 (1.5-3.1)
Depression	2.2 (1.7-2.5)
Cognitive impairment	1.8 (1.0-2.3)
Age 80 or older	1.7 (1.1-2.5)

Source: Rubenstein LZ, Josephson KR. The epidemiology of falls and syncope. *Clin Geriatr Med* 2002 May;18(2):141-58.

PROFILE OF THE HOSPITALIZED PATIENT AT RISK TO FALL

Systematic review of studies involving risk factors for hospital falls reveals the profile of the patient at greatest risk of falling to be someone with a history of previous falls, impaired mobility, cognitive impairment, and special toileting needs.[42] Advanced age,[41,42] medications that act on the central nervous system,[42] and depression[42-44] are also contributors.

History of Falls

History of falling within a 1- to 12-month period has been evaluated across multiple studies and found to predict future falls with statistical significance and high relative risk. Because of this, it has been suggested that all falls risk assessments begin with screening for a history of falls within the previous 12-month period.[45]

Impaired Mobility

Gait speed and stride length decrease markedly beginning at age 85 for women and age 90 for men. Slower gait speed has been found to significantly correlate with increased falls.[46] In patients without a history of falling, screening for balance and gait problems significantly predicts future falls more than other risk factors.[45]

Cognitive Impairment

A clear link between increased falls risk and delirium and dementia has been established, especially when agitation and wandering behaviors are exhibited.[38,41,42,45] However, there is also evidence that decreases in global cognition and cognitive processing speed also increase falls risk in older adults without delirium or dementia.[47,48]

Toileting

Studies evaluating the circumstances of patient falls in the hospital setting have estimated up to 50% to be associated with toileting or other elimination concerns (e.g., incontinence, urinary frequency, diarrhea).[2,28,42,49,50] Toileting-related falls have also been found to increase the risk of fall-related injuries by an odds ratio (OR) of 2.4.[49]

Advanced Age

Risk for falls and falls with injury increase with age, with adults age 80 or older being in the highest-risk group.[1,41]

Medications

Certain medications have been found to have a significant association with falls in the elderly, including sedatives and hypnotics, antidepressants, and benzodiazepines.[51,52] In addition, falls risk in older adults has been found to increase with the use of cardiac drugs (including diuretics, antihypertensives, and antiarrhythmics) and analgesic drugs (opioid and nonopioid), as well as with the use of four or more medications, regardless of drug class.[53]

The Beers criteria, published by the American Geriatrics Society and recently updated in 2012, is a useful guideline for identifying potentially inappropriate medication use in older adults that contribute to adverse patient outcomes. The Beers criteria specifically identifies the following drugs to be avoided in patients with a history of falls or fractures: anticonvulsants, antipsychotics, benzodiazepines, nonbenzodiazepine hypnotics, tricyclic antidepressants, and selective serotonin reuptake inhibitors.[54] In an analysis of falls reported to the Authority in 2006, the medications most often mentioned in the reports included anxiolytics (benzodiazepines) and hypnotics, antidepressants, neuroleptics, opioid analgesics/antagonists, and insulin/oral hypoglycemics.[55]

The impact of medication on falls risk may be more pronounced in older adults, but it affects younger adults as well. Increased falls risk has been found in younger adults ages 25 to 60 who are taking two or more medications, most notably antihypertensives and cholesterol-lowering drugs.[56] In either age group, the challenge has been to separate the effects of the medication from the symptoms of the disease process itself and to evaluate the risks and benefits of treatment versus nontreatment when attempting to adjust medication regimens in order to minimize risk of falling.[57]

Depression

Depression and its association with increased falls and falls injury rates has been studied. Use of antidepressants, especially selective serotonin reuptake inhibitors, has been found to have a strong

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association with falls and falls with injury. But apart from medication use, symptoms of depression, ranging from questionable to clinically significant, have been found to be independent predictors of falls[43,44] and have been included in at least one formal falls risk assessment tool.[28]

FUNCTIONAL ASSESSMENT TESTS

Several simple screening tools have been created to assess functional mobility. The Timed Up and Go test is one such tool that requires patients to rise from a chair, ambulate three meters, turn, return to the chair, and sit. Patients who require more than 14 seconds to complete this test are more likely to fall (sensitivity and specificity of 87%),[58] though debate exists as to the cutoff that is most sensitive and specific.[59]

A similar test called the Get Up and Go test was originally included as part of the Hendrich II Fall Risk Model but later modified to only include the observation of the patient rising from a seated position while resting their hands on their thighs. Patients who require use of their hands to push up in a single attempt are more likely to fall than those able to rise without using their hands (OR = 2.16). Those who push up and require multiple attempts have further increased risk of falling (OR = 4.67). And patients unable to rise have the highest risk of falling (OR = 10.08).[28]

Because history of falls and impaired mobility carry the highest relative risk of falls, screening for these two risk factors is often recommended as a simple and effective risk assessment method in outpatient areas, where each patient encounter is time-limited.[17,18,45]

INJURY RISK ASSESSMENT

Most falls do not result in injury.[1,9,13,41] But when they do, older adults are at a much higher risk of dying as a result of their injuries, with men over 70 and nursing home residents over age 85 having the highest mortality rates.[60-62] The following risk factors for injurious falls have been identified: cognitive impairment, presence of at least two chronic conditions, balance and gait impairment, low body mass index, female gender, poor vision and hearing, multiple falls, dizziness, and use of mechanical restraints.[41,63] Rubenstein and Josephson found that these risk factors for injurious falls match risk factors for falls in general, with the exception of female gender and low body mass index, which matches the profile of patients with osteoporosis who are prone to fall-related fractures.[41]

Use of an injury risk assessment algorithm labeled "ABCS" has been recommended as part of two falls prevention guidelines.[17,22] This algorithm was developed as part of a quality improvement project targeted to reducing falls with serious injury on medical-surgical units.[64] The letters represent risk factors for severe injury: **A**ge ≥ 85, **B**ones (e.g., osteoporosis, history of previous fracture, bone metastases, prolonged steroid use), **C**oagulation (e.g., bleeding disorders, anticoagulation), and **S**urgery (i.e., postsurgical patients, especially those who had recent limb amputation or major abdominal or thoracic surgery).[17,22]

Application of the ABCS injury risk algorithm is independent of falls risk assessment. Patients with risk factors for injury are at risk for suffering injury related to any number of causes other than falls (e.g., excessive bleeding from invasive procedures, fractures due to weight-bearing activities that place stress on weakened areas of bone). Combining the results of falls risk assessment with injury risk identification is recommended to help identify and focus heightened awareness on patients at highest risk for falls with serious injury.[62]

RISK REDUCTION STRATEGIES

Based on a review of the literature and evidence-based falls prevention guidelines, hospitals may consider the following strategies for falls risk assessment:

- Screen all patients for risk of falling.[15-22]
- Select a risk assessment tool that targets risk factors most predictive of falls.[25]
- Assess and periodically reassess the accuracy of the falls risk assessment tool within the clinical setting.[17,39]
- Evaluate the falls risk assessment tool across different clinical areas with different patient populations.[30,33,34]
- Use caution when interpreting validity of risk assessment tools within the clinical setting (i.e., a tool that identifies patients at risk who do not fall may be interpreted as having low specificity when in fact this may be the result of successful prevention strategies).[38]
- Consider screening patients for falls risk in outpatient areas using history of falls and a functional assessment test, such as the Timed Up and Go test.[17,18,45]
- Provide ongoing education to clinical staff on proper use of falls risk assessment tools.[15-22]
- Measure compliance with performance of risk assessments periodically, with the goal of 100% compliance.[17,18,20,22]
- Consider combining falls risk assessment with injury risk assessment to identify patients with the highest risk of falls with harm.[17,22,62,64]

Falls researchers have recommended that facilities choose from existing tools that have been tested for validity;[2,27] however, the Authority recognizes that some hospitals may be using facility-designed falls risk assessment tools or tools created through modification of existing tools. In this case, it is suggested that hospital falls prevention teams assess the validity of the tool internally, ensuring assessment for risk factors identified in the literature as being most predictive of falls. If validity cannot be confirmed, use of evidence-based falls risk assessment tools with established validity is suggested.

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CONCLUSION

Falls prevention begins with screening for falls risk using a falls risk assessment tool. A large number of falls risk assessment tools have been created for use in hospitals.[2] Clinical judgment alone can be equally valid in some settings.[35-38] However, risk assessment tools offer the advantage of process standardization, a key to high reliability.[65] There is sufficient evidence to support the continued use of the Morse Fall Scale and the Hendrich II Fall Risk Model, as reported to be in use by hospitals across Pennsylvania participating in the PFP HEN Falls Reduction and Prevention Collaboration. The Johns Hopkins Fall Risk Assessment Tool requires further testing to establish validity.[32] The process of falls risk assessment does not end with screening for risk through use of these tools. Screening is to be followed by an in-depth assessment of each risk factor identified.[15,17-22,40]

Risk assessment alone does not prevent falls. Effective falls prevention interventions are multifactorial, provided by a multidisciplinary team, targeted to common falls risk factors for all patients, and tailored to each patient's specific falls risk factors.[40] Falls risk assessment is the foundational element necessary to establishing a successful falls prevention program. Hospitals must first perform a thorough evaluation of their current falls risk assessment processes before shifting focus to prevention interventions.

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Events Associated with the Prescribing, Dispensing, and Administering of Medication Loading Doses

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ABSTRACT

A loading dose is an initial dose of medication administered to rapidly achieve therapeutic levels. The determination of a loading dose can be complicated, involving calculations dependent upon patient characteristics. This, combined with the need to also administer maintenance doses, creates complexity and opportunities for errors. From June 2004 through May 2012, Pennsylvania facilities reported to the Pennsylvania Patient Safety Authority 580 events associated with the prescribing, dispensing, and administering of medication loading doses, 15 of which were harmful events. The most common types of events reported included "loading dose omitted or delayed," "wrong loading dose given," and "loading dose given multiple times." The predominant medication associated with these reports was vancomycin (14.8%, n = 86). Phenytoin was the medication most frequently involved in harmful events (26.7%, n = 4). Strategies to prevent errors associated with loading doses include developing standardized clinical guidelines on how to prescribe, administer, and monitor loading and maintenance doses; standardizing electronic and paper order sets and protocols; and including a thorough review of current drug therapy during patient handoffs. (Pa Patient Saf Advis 2012 Sep;9[3]:82-8.)

INTRODUCTION

A loading dose is an initial large dose of medication administered to rapidly achieve therapeutic levels in the body.[1,2,3] The clinical and therapeutic need for administration of a loading dose can vary based on the patient's condition and the medication. For example, a therapeutic level of phenytoin may be needed quickly to stabilize a patient after a seizure.[4] Other medications commonly administered with loading and maintenance doses include the antidote acetylcysteine, the cardiovascular agent digoxin, and the anticonvulsant fosphenytoin. Loading doses are typically followed by maintenance doses, which are given in lower doses to maintain therapeutic levels on a medium- to long-term basis. The combination of loading doses and maintenance doses creates complexity in prescribing, dispensing, and administering medications. This combination can lead to medication errors stemming from all nodes in the medication-use process.

There is scarce literature that addresses the problems and errors associated with loading dose regimens. A study by Hayes et al. demonstrated the complexity of acetylcysteine dosing regimens (which includes loading and maintenance doses) for the treatment of acetaminophen overdoses.[5] This retrospective chart review of a regional poison control center's records found a 33% error rate, which included medication errors in all phases of the medication-use process. The types of errors found included incorrect dose, incorrect infusion rate, and more than one hour of interruption in therapy. A case report by Cottington et al. described a fatality from a gross overdose administered for a loading dose test of methionine.[6] Another study by Oudin et al. found prescribing problems with vancomycin loading doses.[7] Of the 13 prescription errors the authors found, seven involved vancomycin loading doses, including five cases in which the loading dose was not prescribed, one case of a prescription delay, and one case of higher-than-intended dosing.

In November 2010, the National Patient Safety Agency (NPSA) in the United Kingdom published an alert regarding fatalities associated with loading dose errors and strategies to prevent their occurrence.[2,3] From January 2005 through April 2010, the NPSA's National Reporting and Learning System received 1,165 reports related to loading doses, including 2 fatalities (both involving phenytoin), 4 cases of severe harm, and 102 cases of moderate harm. The cases that resulted in severe patient harm or death involved incorrect loading doses, omitted or delayed loading doses, or unintentional continuation of loading doses.[2]

Analyses of events involving loading doses of medications reported by Pennsylvania healthcare facilities to the Pennsylvania Patient Safety Authority have identified the most common types of events and medications associated with the prescribing, dispensing, and administering of medication loading doses in Pennsylvania.

METHODOLOGY

The term "loading" was used to query all event types in the Pennsylvania Patient Safety Reporting System (PA-PSRS) database reported from June 2004 through May 2012. The initial query yielded 905 reports. After eliminating reports that were not applicable (e.g., "patient bumped forehead while loading on wheelchair lift in van," "continue offloading pressure on the heel"), 580 reports were analyzed in detail to identify trends and contributing factors.

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AGGREGATE ANALYSIS

From events reported from June 2004 through May 2012, analysts identified 580 events involving breakdowns in the prescribing, dispensing, and administration of medication loading doses. A breakdown of these events by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention's harm index,[8] shows that nearly 79% (n = 458) of the events reached the patient (harm score = C to I). Overall, 97.4% (n = 565) of the events were reported as Incidents (harm score = A to D) and 2.6% (n = 15) as Serious Events (harm score = E to I), including two events resulting in death.

In total, there were over 70 medications associated with loading doses involved in events reported to the Authority. Table 1 lists the top 20 medications involved in events related to loading dose issues. The antibiotic vancomycin was the most frequently reported medication (14.8%, n = 86); six anti-infective agents were in the top 20. In contrast, the United Kingdom's NPSA incidents related to loading doses in its November 2010 Rapid Response Report identified warfarin as the most frequently reported medication involved.[3] While 10 medications (i.e., amiodarone, caffeine citrate, clopidogrel, digoxin, gentamicin, heparin, magnesium sulfate, morphine, phenytoin, vancomycin) appear in the top 20 medications involved in events associated with loading doses in both Pennsylvania and the United Kingdom, only phenytoin appears in the top five medications for both. Other drugs in the top five in the United Kingdom include amiodarone and digoxin.

Six high-alert medications, drugs that bear a heightened risk of causing significant patient harm when used in error,[9,10] appear in the top 20. Of the reported harmful events, the high-alert medications morphine, digoxin, and HYDROmorphone were involved in roughly half (n = 7) of these events (see Table 2).

Table 1. Top 20 Medications Involved in Events Associated with the Prescribing, Dispensing, and Administering of Medication Loading Doses from June 2004 through May 2012 (n = 452)

MEDICATION NAME	NO. OF EVENTS	% OF TOTAL EVENTS (N = 580)
Vancomycin	86	14.8
Clopidogrel	54	9.3
Phenytoin	50	8.6
HYDROmorphone*	26	4.5
Morphine*	23	4.0
Acetylcysteine	22	3.8
Digoxin*	22	3.8
Fosphenytoin	22	3.8
Azithromycin	19	3.3
Gentamicin	18	3.1
Tigecycline	16	2.8
Caspofungin	16	2.8
Caffeine citrate	14	2.4
Amiodarone*	11	1.9
PrednisoLONE	10	1.7
Heparin*	10	1.7
Magnesium sulfate*	9	1.6
PHENobarbital	8	1.4
Fluconazole	8	1.4
MethylPREDNISolone	8	1.4

* A high-alert medication

Table 2. Medications Involved in Harmful Events Associated with the Prescribing, Dispensing, and Administering of Medication Loading Doses from June 2004 through May 2012

MEDICATION NAME	HARM SCORE I†	HARM SCORE F‡	HARM SCORE E§	NO. OF EVENTS
Phenytoin	1	1	2	4
Morphine*			3	3
Digoxin*	1		1	2
HYDROmorphone*			2	2
Aminocaproic acid		1		1
PHENobarbital		1		1
ClonazePAM			1	1
LevETIRAcetam			1	1
Total Reports of Harm				**15**

* A high-alert medication

† An event occurred that contributed to or resulted in death.

‡ An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.

§ An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.

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Table 3. Top Event Types Associated with Prescribing, Dispensing, and Administering Medication Loading Doses from June 2004 through May 2012 (n = 357)

EVENT TYPE	EVENT SUBTYPE	NO. OF EVENTS	% OF TOTAL REPORTS (N = 580)
Loading dose error	Loading dose omitted or delayed	148	25.5
	Wrong loading dose given	88	15.2
	Loading dose given multiple times	41	7.1
Maintenance dose error	Maintenance dose missed	37	6.4
	Maintenance dose given at wrong time	23	4.0
	Wrong maintenance dose given	20	3.4

Note: Based on information contained within the reports and event descriptions, Authority analysts categorized reports into two event types and related event subtypes.

Authority analysts first categorized the types of events into two groups—those involving an error with the loading dose and those involving an error with the maintenance dose. Analysts then further categorized the reports into subtypes of these two general classifications. Table 3 lists the top event types. It should be noted that not enough information was provided to determine what occurred in roughly 20% (n = 117) of reports.

FOCUSED EVENT ANALYSIS

Loading Dose Omitted or Delayed

The goal of administering a loading dose of certain medications is to reach therapeutic drug concentrations or levels within the body as soon as possible. An omitted or missed loading dose may contribute to therapeutic failure and deterioration of the patient. Analysts identified "loading dose omitted or delayed" as the most frequently reported (25.5%, n = 148) type of event associated with the use of medications requiring loading doses. This is comparable to what the NPSA noted in its November 2010 Rapid Response Report.[3] In that report, the NPSA found that omission or delayed administration of a loading dose occurred in 24% of incidents that were related to loading dose issues. This represented the second most frequently reported event in the NPSA data set.

In Pennsylvania, five medications, namely vancomycin (24.3%, n = 36), clopidogrel (12.2%, n = 18), phenytoin (11.5%, n = 17), morphine (5.4%, n = 8), and gentamicin (5.4%, n = 8) were involved in nearly 60% (n = 87) of omitted or delayed loading dose events.

Transfer within and between facilities introduces vulnerability to the system,[11] making it easier for an error to occur and reach the patient. Breakdowns or interruptions when patients were transferred between units within a hospital or between hospitals was a leading contributor (16.2%, n = 24) to omitted loading doses. Often, this involved situations in which a loading dose was ordered in the emergency department (ED), but the patient was transferred prior to receiving the dose, as the following examples illustrate:

> *Orders written at 2200 in ED for IV [intravenous] Dilantin® loading dose. Patient presented to floor at approximately 0200. The Dilantin [loading dose] was not administered in ED. Patient admitted with diagnosis of new onset seizures.*

> *Patient prescribed vancomycin protocol in ED. Loading dose for protocol sent to ED at approximately 9:30 to be administered at 10:00. Pharmacist spoke to nurse on unit about another patient when she learned that [the] loading dose was not administered to her patient. Protocol was then adjusted appropriately.*

Wrong Loading Dose

Analysts identified wrong loading dose events as the second most frequently reported (15.2%, n = 88) events associated with the use of loading doses. This should not come as a surprise, as the determination of a loading dose can be complicated, involving calculations dependent upon patient characteristics such as weight or organ function and/or laboratory results. Comparatively, the NPSA found that the prescribing or administration of an incorrect loading dose was the most frequent (41%) event type related to loading dose issues.[3]

Once again, vancomycin was the drug most frequently involved (17%, n = 15) in these events. Other medications involved in wrong loading dose events included clopidogrel (10.2%, n = 9), HYDROmorphone (8%, n = 7), morphine (4.5%, n = 4), and acetylcysteine (4.5%, n = 4).

In 31.8% (n = 28) of wrong loading dose events, a maintenance dose was ordered or administered as the loading dose. As a result, a lower dose than clinically indicated was administered. While many of the event reports do not describe why this dose mix-up occurred, a number do indicate that the wrong dose was selected on the unit when pharmacy delivered the loading dose and maintenance dose(s)

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at the same time. For example, see the following:

> *Physician ordered tigecycline 100 mg IVPB [IV piggyback] stat followed by an order for tigecycline 50 mg IVPB every 12 hours. According to the pharmacy, the doses were dispensed, but the RN [registered nurse] administered tigecycline 50 mg IVPB as the initial stat loading dose instead of the 100 mg bag.*

Loading Dose Given Multiple Times

A third subtype of loading dose error is "loading dose given multiple times." Authority analysts identified this subtype as the third most frequently reported (7.1%, n = 41) loading dose event. The NPSA also noted that a loading dose was repeated in error in 7% of loading dose incidents in the United Kingdom.[3] These events can result in supratherapeutic drug concentrations or levels within the body leading to adverse events. In Pennsylvania, 7.3% (n = 3) of these events resulted in harm, accounting for 20% of all harmful events associated with the prescribing, dispensing, and administering of medication loading doses.

Clopidogrel was the drug most frequently involved (24.4%, n = 10) in these events. Other drugs involved in "loading dose given multiple times" events include digoxin (9.8%, n = 4), phenytoin (7.3%, n = 3), and fosphenytoin (7.3%, n = 3).

Similar to "loading dose omitted or delayed" events, vulnerabilities introduced during the patient transfer process was the leading contributor (19.5%, n = 8) to events involving multiple administrations of a loading dose. For example, see the following:

> *Patient was admitted through the ED with seizures. In the ED, the patient was loaded with fosphenytoin along with benzodiazepines. The patient was admitted to the ICU [intensive care unit] and, in the ICU, continued to have seizure activity. The physician in the ICU ordered a loading dose of fosphenytoin. After the medication was administered, it was discovered that the patient had already received a loading dose in the ED. The patient received a total of 2,400 mg of fosphenytoin instead of 1,200 mg. Per the physician, it was reported to him that the patient only received "benzos" in ED. However, alerts did fire in the computer system for "duplicate therapy," and the first dose was documented in the EMAR [electronic medication administration record].*

> *Patient was admitted through the ED. Report was taken by charge nurse. The nurse in the ED did notify charge nurse that the patient had been given 1 mg loading dose of Dilaudid® prior to coming to the floor. Patient arrived to the floor, and there was a delay in patient getting put in the system by admissions. . . . Loading dose was administered a second time, as it was not marked off on floor orders. After being started on PCA [patient-controlled analgesia], patient was found to have low O_2 [oxygen] saturations and had to be placed 6 L NC [nasal cannula].*

However, in 48.8% (n = 20) of "loading dose given multiple times" events, insufficient information was provided to determine what contributed to the event.

RISK REDUCTION STRATEGIES

Healthcare facilities can strive to identify systems-based causes of the errors associated with the prescribing, dispensing, and administering of medication loading doses and implement effective risk reduction strategies to prevent harm to patients. Although many of the reports submitted to the Authority did not explicitly reveal all of the causes and contributing factors, healthcare facilities may consider the strategies described in this section, which are based on a review of events reported to the Authority, observations from the Institute for Safe Medication Practices, and recommendations in the literature.

- Review organizational processes associated with medications requiring loading doses in order to identify risks.
- Restrict and limit the physical availability of medications requiring loading doses, as appropriate.[3]
- Develop standardized clinical guidelines on how to prescribe, administer, and monitor loading and maintenance doses.[3]
- Standardize electronic and paper order sets and protocols. Ensure that these order sets are well designed. Well-designed order sets have the potential to
  - coordinate care by communicating best practices across disciplines and lines of service,
  - reduce variation and accidental oversight through standardized formatting and presentation,
  - enhance workflow with instructions that are easily understood and intuitively organized, and
  - reduce the risk for medication errors through integrated safety alerts and reminders.[12,13]
- Establish guidelines for communication during patient transfers. Items to consider for inclusion are
  - a brief overview of the patient's status,
  - essential patient information,
  - physician orders that will be implemented pre-transport (e.g., loading dose, sedation, pain management),
  - physician orders that will need to be implemented post-transport, and
  - confirmation of patient arrival time.[11]

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— Provide clear documentation to ensure that all applicable patient information is available and communicated to the next level of care.[14]

— Include a thorough review of current drug therapy during handoffs in care. Such reports, particularly at a change of shift, can help with the timely discovery of instances when prescribed medications have been omitted by accident.[15]

— Explore having pharmacy dispense loading and maintenance doses separately, closer to the time when each one is to be administered, so they do not arrive on the patient care unit at the same time. This may help reduce the risk that both doses will be stored near each other on the patient care unit and confused for one another.

— Consider differentiating the packaging and labeling of loading doses and maintenance doses to reduce the risk that they may be confused for one another.

CONCLUSION

Loading doses are administered to rapidly achieve therapeutic levels in the body and are typically followed by maintenance doses to maintain therapeutic levels on a medium- to long-term basis. The combination of loading doses and maintenance doses creates complexity in the medication-use process and can lead to medication errors. In Pennsylvania, 580 medical error reports indicating the occurrence of an event associated with the prescribing, dispensing, and administering of medication loading doses were reported to the Authority from June 2004 through May 2012. The predominant types of events identified through analysis of event descriptions are "loading dose omitted or delayed," "wrong loading dose given," "loading dose given multiple times," "maintenance dose missed," "maintenance dose given at wrong time," and "wrong maintenance dose given." There are similarities in the types of events, frequency of the events, and medications involved in the events seen in Pennsylvania and the United Kingdom.[3] Strategies to reduce the risk of errors include developing clinical guidelines and standardizing electronic and paper order forms and protocols to guide clinical practice, reduce variation, and improve drug information communication.

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LEARING OBJECTIVES

- Recognize the most frequently reported event types involving the prescribing, dispensing, and administering of medication loading doses.
- Recall causes and contributing factors associated with the predominant types of events involving the prescribing, dispensing, and administering of medication loading doses.
- Identify the most frequently reported medications involved in events associated with the prescribing, dispensing, and administering of medication loading doses.
- Distinguish between effective and ineffective strategies to reduce the risk of events involving the prescribing, dispensing, and administering of medication loading doses.

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 questions.

1. Which of the following is the most frequently reported type of event associated with the prescribing, dispensing, and administering of medication loading doses?
   a. Loading dose administered at the wrong rate
   b. Loading dose given multiple times
   c. Loading dose omitted or delayed
   d. Maintenance dose missed
   e. Wrong loading dose given
2. Which of the following is a leading factor in omitted or delayed loading dose events in Pennsylvania facilities?
   a. Pharmacy delivery of the loading dose and maintenance dose(s) to the unit at the same time
   b. Breakdowns when patients were transferred between units within a hospital
   c. Failure to follow protocol guidance when prescribing, dispensing, or administering a loading dose
   d. Omission of an independent double check
   e. Limited physical availability of medications requiring loading doses
3. The top four medications involved in events associated with the prescribing, dispensing, and administering of medication loading doses include all of the following EXCEPT:
   a. Acetylcysteine
   b. Clopidogrel
   c. HYDROmorphone
   d. Phenytoin
   e. Vancomycin

The patient was admitted through the emergency department (ED) with seizures. In the ED, the patient received a loading dose of fosphenytoin. The patient was admitted to the intensive care unit (ICU) and, in the ICU, continued to have seizure activity. The physician in the ICU ordered a loading dose of fosphenytoin. After the medication was administered, it was discovered that the patient had already received a loading dose in the ED. The patient received a total of 2,400 mg of fosphenytoin instead of 1,200 mg. Per the physician, it was reported to him that the patient had only received benzodiazepines in the ED. However, alerts did fire in the computer system for "duplicate therapy," and the first dose was documented in the electronic medication administration record.

4. Select the most appropriate strategy to help prevent this event from reoccurring.
   a. Differentiate the packaging and labeling of loading doses and maintenance doses to reduce the risk that they may be confused for one another.
   b. Restrict and limit the physical availability of medications requiring loading doses, as appropriate.
   c. Standardize electronic and paper order sets and protocols.
   d. Establish a protocol to guide communication during patient transfers that includes the physician orders implemented pre-transport and those that still need to be executed.
   e. Develop standardized clinical guidelines on how to prescribe, administer, and monitor loading and maintenance doses.

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SELF-ASSESSMENT QUESTIONS (CONTINUED)

A physician ordered tigecycline 100 mg intravenous (IV) piggyback statim (stat) followed by an order for tigecycline 50 mg IV piggyback every 12 hours. According to the pharmacy, the loading and maintenance doses were dispensed and delivered to the unit. The nurse inadvertently administered the tigecycline 50 mg IV bag as the initial stat loading dose instead of the tigecycline 100 mg IV bag.

5. Which of the following factors may have contributed to this wrong loading dose event?
   a. Communication during handoff failed.
   b. The patient's loading dose was miscalculated.
   c. A loading dose of the medication was not required for this patient.
   d. Tigecycline was available as a floor stock item.
   e. Pharmacy delivered both the loading dose and maintenance dose to the unit at the same time.
6. Which of the following strategies would be *most* effective in reducing the risk of this wrong loading dose event?
   a. Store loading and maintenance doses apart from one another in pharmacy and patient care areas.
   b. Dispense loading and maintenance doses from pharmacy separately, closer to the time when each one is to be administered.
   c. Differentiate the package type and design of loading doses and maintenance doses.
   d. Restrict and limit the physical availability of medications requiring loading doses.
   e. Develop standardized clinical guidelines on how to prescribe, administer, and monitor loading and maintenance doses.

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Impact of Implementation of Evidence-Based Best Practices on Nursing Home Infections

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ABSTRACT

Reports of inconsistencies in the implementation of evidence-based infection control best practices and the number of deficiency citations for infection control problems in nursing homes indicate the need to identify barriers to the integration of infection control practices in this setting. The Pennsylvania Patient Safety Authority conducted on-site assessment visits to 10 Pennsylvania nursing homes with high healthcare-associated infection (HAI) rates and 10 with low HAI rates. The assessment's purpose was to study the impact of various levels of implementation of infection prevention best practices on HAI rates and to assess patterns of care that could be targeted for improvement. Authority analysts assessed the implementation of 50 evidence-based infection prevention best practices. Analysis of the aggregate assessment data from the visits demonstrated a relationship between high infection rates and low implementation of best practices. Compared with nursing homes with low infection rates, those with high rates were deficient in one or more of six levels of implementation for 45 of the 50 best practices. The assessments identified multidisciplinary implementation barriers in nursing homes with high HAI rates at the leadership, physician, clinical, and support staff levels and recognized patterns of care that nursing homes could target for improvement. (Pa Patient Saf Advis 2012 Sep;9[3]:89-98.)

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

INTRODUCTION

The problem of healthcare-associated infections (HAIs) in nursing homes has been increasingly recognized over the last two decades.[1] More robust literature and development of evidence-based recommendations devoted to nursing home infection control have resulted in the widespread initiation of infection control programs in this setting.[1] Yet limited studies are available to evaluate the effectiveness or level of adoption of specific basic infection control measures to minimize HAIs in nursing homes.

Long-term care facilities must have individualized infection control programs, as mandated by the Centers for Medicare and Medicaid Services' *State Operations Manual*[2] and Pennsylvania Act 52 of 2007.[3] In a seven-year study of infection control deficiency citations, Castle et al. found that an average of 15% of all nursing homes in the United States received a deficiency citation for infection control each year between 2000 and 2007.[4] In a 2005 study, the results of a 43-item survey of 37 Michigan nursing homes found significant variability in implementation of infection control methods and guidelines.[5] Strides have been made in infection control research in the nursing home setting; however, the number of deficiency citations for infection control problems and the inconsistencies in the implementation of infection control practices suggest the need for increased emphasis and research focusing on identifying barriers to implementing infection control best practices in nursing homes.

A major focus of the Pennsylvania Patient Safety Authority is to drive targeted research, education, and guidance efforts in infection control and prevention based on the Authority's analysis of the HAI data reported by Pennsylvania nursing homes through the Authority's reporting system as required by Pennsylvania Act 52. Authority analysts conducted an outreach project in order to study the impact of various levels of implementation of infection prevention practices on HAI rates in Pennsylvania nursing homes and to assess patterns of care that could be targeted for improvement. This Authority study specifically sought to determine in which infection prevention domains nursing homes performed well or poorly, in which implementation categories there were differences in the performance of facilities with low or high HAI rates, respectively, and what elements of best practice were most lacking in areas of poor performance.

METHODS

Participants and Data Sources

Study participants were selected from Pennsylvania nursing homes with overall HAI rates at either the high or low end of the performance spectrum. Nursing homes were sorted into performance quartiles based on HAI reports submitted to the Authority from March 2010 through May 2010. Selection criteria involved analysis of characteristics of the nursing homes falling into the highest HAI-rate quartiles and those falling into the lowest HAI-rate quartiles of all nursing homes reporting statewide, the distribution of HAIs across all reportable infection types, and the occurrence of HAIs in multiple care areas.

Twenty nursing homes were selected that consistently reported utilization data (resident-days and Foley catheter-days): 10 with rates in the highest HAI quartile (referred to as "H-HAI" nursing homes for the purposes of this article) and 10 with infection rates in the lowest quartile ("L-HAI" nursing homes). Facilities selected for the study ranged from 19- to 453-bed facilities (the median was 142 beds) and included a cross-section of corporate and single-owned facilities providing transitional care, nursing care, rehabilitation, and subacute care. A secondary data review was performed for the three months

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immediately prior to each assessment visit to determine continued appropriateness for inclusion in the respective high- or low-HAI-rate categories. The study was conducted employing the Authority's Long-Term Care Best-Practice Assessment Tool, which is based on best-practice strategies selected from current guidelines that have been shown in the research literature to deliver better quality and promote positive outcomes. Data from 8 of the 10 L-HAI facilities was available for analysis. Figure 1 shows that of the 10 nursing homes selected with high HAI rates, 9 had significantly higher rates than the state pooled mean rate (0.742 HAIs per 1,000 resident-days). Further, all eight nursing homes selected with low HAI rates had rates that were significantly lower than the state pooled mean rate.

Study Design

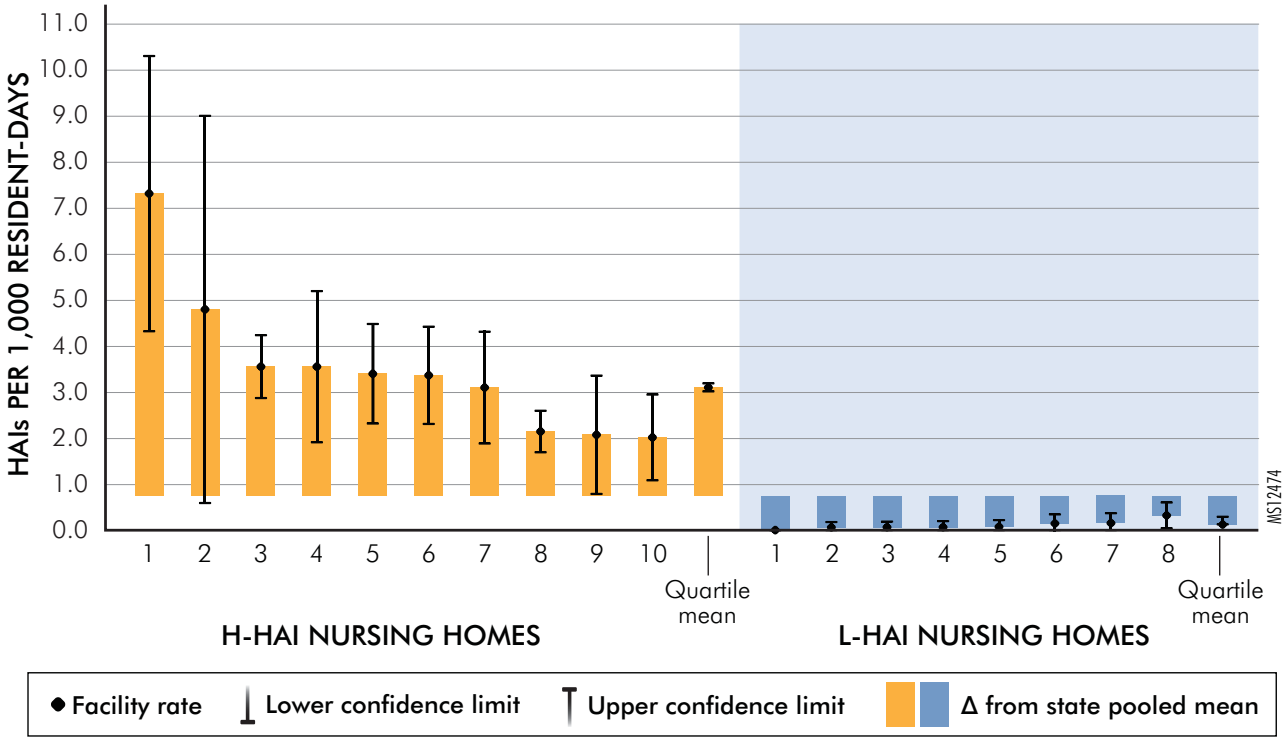
The Authority's Long-Term Care Best-Practice Assessment Tool was designed to assess the structure and function of nursing homes' infection control programs by measuring the level of implementation of current best practices in seven domains: hand hygiene, environmental, urinary tract infection (UTI), respiratory tract infection (RTI), gastrointestinal (GI) and multidrug-resistant organism (MDRO) infection, skin and soft-tissue infection (SSTI), and outbreaks.

Specific best practices listed in each of the seven domains were based on clearly defined interventions found in the literature and current guidelines for infection categories by which self-assessment could be easily completed and on HAIs that are reportable to the Authority. The tool incorporated a scoring system that identified the level of implementation for each of the 50 best practices. Six secondary implementation categories were used to measure how each of the best practices were integrated into a facility's infection control program structure and clinical practice functions. The tool can be accessed at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.

The tool's implementation categories associated with infection control program *structure* assessed the following:

— Integration of best practices into the facility infection control plan, which is consistent with goals that are updated annually

Figure 1. Healthcare-Associated Infection (HAI) Rates For Individual Nursing Homes, March 2010 to May 2010



Note: **H-HAI = nursing homes with high rates of HAIs; L-HAI = nursing homes with low rates of HAIs. The state pooled mean rate of 0.742 HAIs per 1,000 resident-days reflects data reported to the Pennsylvania Patient Safety Authority from March 2010 to May 2010.**

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— Policies and procedures that reflect the facility infection control plan
— Documentation of education provided on infection control goals and policies

The tool's implementation categories associated with infection control program *clinical practice* assessed the following:

— Standard documentation methods in use
— Monitoring, documentation, and evaluation of process and outcome measures
— Assigned accountability and follow-up by managers and leaders

Assessment Interviews

Administrative and infection prevention staff from each of the 20 facilities agreed to an on-site consultation to participate in the best-practice assessment. The on-site consultations were conducted from October 2010 through November 2011, beginning with the H-HAI facilities. The authors looked for (and failed to find) evidence that would have suggested differences in rates simply reflected in vigilance around surveillance and reporting. Assessment methods during the on-site visit included a determination of adequate surveillance and reporting practices, a review of the availability of administrative support and resources, and a detailed analysis of the facility's self-assessment. Assessment tools used included the best-practice survey, record reviews, observational rounds, and staff interviews. Each facility received a written follow-up report summarizing barriers to adherence to best practice for each facility, as well as positive findings and opportunities for improvement.

RESULTS

While both H-HAI and L-HAI nursing homes routinely implemented infection surveillance activities and documented outcome measures, standardized process measurement and evaluation of implementation of specific infection control practices were often not a priority. The results of the study were measured by comparing the differences in the percentage of H-HAI and L-HAI nursing homes showing full implementation of each of the 50 best practices in three levels of analysis: domain assessment, implementation category assessment, and best-practice performance.

Domain Assessment

Overall, the scores for both H-HAI and L-HAI nursing homes were lowest in full implementation of hand hygiene best practices. The highest overall scores for the L-HAI homes were in implementation of SSTI prevention practices; the highest scores for the H-HAI homes were in implementation of GI and MDRO infection prevention practices. Compared with H-HAI nursing homes, L-HAI nursing homes scored better in full implementation of best practices in five of the seven assessment domains (see Figure 2). H-HAI nursing homes scored lower than L-HAI nursing homes in full implementation of best practices for UTI (L-HAI: 83%, H-HAI: 70%), followed by SSTI (L-HAI: 95%, H-HAI: 84%), hand hygiene (L-HAI: 75%, H-HAI: 65%), environmental control (L-HAI: 84%, H-HAI: 76%), and RTI (L-HAI: 85%, H-HAI: 79%). H-HAI nursing homes scored better than L-HAI facilities in implementation of outbreak control practices (L-HAI: 77%, H-HAI: 84%), as well as in the GI and MDRO infection domain (L-HAI: 86%, H-HAI: 88%).

Implementation Category Assessment

Assessment of the six implementation categories found notable differences between H-HAI and L-HAI nursing homes in implementation of best practices (see Tables 1 and 2). Overall, L-HAI nursing homes scored higher in full implementation of best practices in five of the six implementation categories:

1. Integration of best practices into the facility infection control plan, which is consistent with goals that are updated annually (L-HAI: 78%, H-HAI: 57%)
2. Policies and procedures that reflect the facility infection control plan (L-HAI: 90%, H-HAI: 86%)
3. Education provided on infection control goals and policies (L-HAI: 89%, H-HAI: 88%).
4. Standard documentation methods in use (L-HAI: 81%, H-HAI: 70%)
5. Monitoring, documentation, and evaluation of process and outcome measures (L-HAI: 75%, H-HAI: 71%)

H-HAI and L-HAI nursing homes both scored 91% in overall implementation of assigned accountability and follow-up by managers and leaders.

The H-HAI nursing homes scored higher in individual categories for implementation of a plan, goals, education, documentation, monitoring and assigned accountability for outbreak control. H-HAI homes also scored higher in integration of hand hygiene best practices into the facility infection control plan, education for environmental control, monitoring for RTI, and assigned accountability and monitoring for GI and MDRO infection.

There was no difference between the H-HAI and the L-HAI nursing homes in the individual categories of integration of GI and MDRO infection prevention best practices into the facility infection control plan or in implementation of policies and procedures that reflect the facility infection control plan for SSTI and outbreak control. (For an interactive graphic of the scores, see http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/Pages/Home.aspx.)

Best-Practice Performance

This level of analysis identified which specific elements of best practices were most lacking and indicated practices that could be targeted for improvement. Study findings are described here by individual

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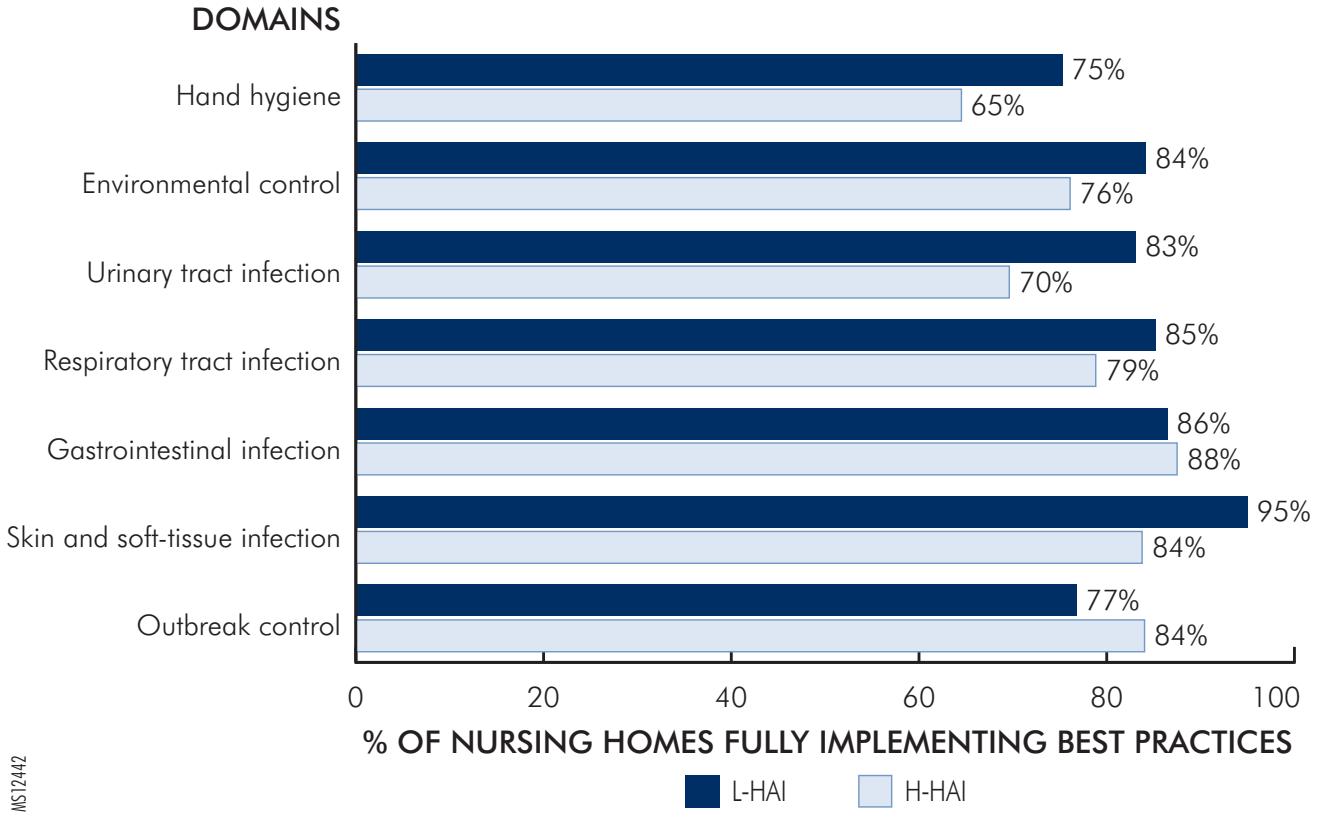
Figure 2. Difference in Percentages of Full Implementation of Nursing Home Best Practices



Note: **L-HAI = Nursing homes with low rates of healthcare-associated Infections; H-HAI = nursing homes with high rates of healthcare-associated infections**

domain. Figures associated with each domain demonstrate the percentage of H-HAI nursing homes that scored higher or lower than the L-HAI nursing homes in full implementation of each best practice across all six implementation categories.

UTIs. Compared with L-HAI nursing homes, H-HAI nursing homes scored lower across all six implementation categories in full implementation of written criteria for Foley catheter use and in implementation of standing orders to remove catheters if criteria are not met. H-HAI nursing homes also scored lower in integration of all nine UTI prevention practices into the facility infection control plan and goals. (See Figure 3.)

H-HAI nursing homes also lacked full implementation of the following categories:

— Education, monitoring, and assigned accountability for the institution of a toileting and hydration program

— Development of policies, procedures, and documentation for a daily review of Foley catheter necessity

— Documentation of use of a Foley securement device and proper positioning of Foley drainage bags

— Policies, education, documentation, and assigned accountability for daily and postincontinence perineal care

— Policies, education, monitoring, and assigned accountability for assuring that a closed, sterile system is in place

— Documentation and monitoring for aseptic Foley insertion and maintenance

Strategic approaches to sustain low UTI rates in the L-HAI nursing homes included oversight by the director of nursing of admission assessments of residents with Foley catheters, assigned accountability for catheter removal decisions, monitoring of catheter maintenance, and a written training program for nursing assistants. Additional strategies included use of a bladder scanner to measure bladder volume and use of silver-coated catheters.

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Table 1. Average % of Full Implementation of Combined Best Practices for Nursing Homes with Low Rates of Healthcare-Associated Infections, by Domain and Implementation Category

	STRUCTURE CATEGORIES			CLINICAL PRACTICE CATEGORIES		
DOMAIN	Plan	Policy	Education	Documentation	Monitoring	Accountability
Hand hygiene	73%	84%	84%	61%	66%	84%
Environmental control	88%	98%	85%	65%	70%	100%
Urinary tract infection	75%	86%	89%	82%	76%	90%
Respiratory tract infection	79%	91%	91%	84%	71%	95%
Gastrointestinal and multidrug-resistant organism infection	**78%**	91%	91%	91%	78%	91%
Skin and soft-tissue infection	84%	**95%**	98%	97%	97%	98%
Outbreak control	71%	**84%**	80%	80%	64%	80%

Note: Shaded cells reflect a higher level of implementation when compared with nursing homes with high rates of healthcare-associated infections (H-HAI). Bolded percentages indicate no difference when compared with H-HAI nursing homes.

Table 2. Average % of Full Implementation of Combined Best Practices for Nursing Homes with High Rates of Healthcare-Associated Infections, by Domain and Implementation Category

	STRUCTURE CATEGORIES			CLINICAL PRACTICE CATEGORIES		
DOMAIN	Plan	Policy	Education	Documentation	Monitoring	Accountability
Hand hygiene	76%	77%	83%	37%	31%	83%
Environmental control	74%	96%	98%	28%	62%	98%
Urinary tract infection	32%	79%	80%	72%	70%	84%
Respiratory tract infection	52%	85%	89%	74%	79%	94%
Gastrointestinal and multidrug-resistant organism infection	**78%**	90%	90%	88%	85%	95%
Skin and soft-tissue infection	30%	**95%**	96%	95%	90%	96%
Outbreak control	86%	**84%**	87%	86%	74%	87%

Note: Shaded cells reflect a higher level of implementation when compared with nursing homes with low rates of healthcare-associated infections (L-HAI). Bolded percentages indicate no difference when compared with L-HAI nursing homes.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was -4.86, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.001.

SSTIs. The most notable difference between the H-HAI and the L-HAI nursing homes in the SSTI prevention domain was found in the H-HAI nursing homes' lack of incorporation of all eight SSTI best practices into the facility infection control plan and goals, as well as a lack of nutrition and hydration protocols in all six implementation categories. H-HAI nursing homes also scored lower in implementation of policies, documentation, and monitoring of daily skin inspection procedures, as well as in education, documentation, monitoring, and accountability for reassessing pressure ulcer risk.

H-HAI nursing homes also lacked full implementation of policies for promoting wound healing and in education and monitoring for pressure-minimizing protocols. (See Figure 4.) (Figures 4 through 9 are available exclusively with this article online at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Sep;9(3)/Pages/home.aspx.)

Strategies to sustain low SSTI rates in the L-HAI nursing homes included highly structured skin rounds—including a specific day and time for rounds completed by a wound specialist and a nurse—a dedicated skin care nurse or consultant, monthly physician specialist rounds, and oversight by nursing administration. Other factors contributing to low SSTI

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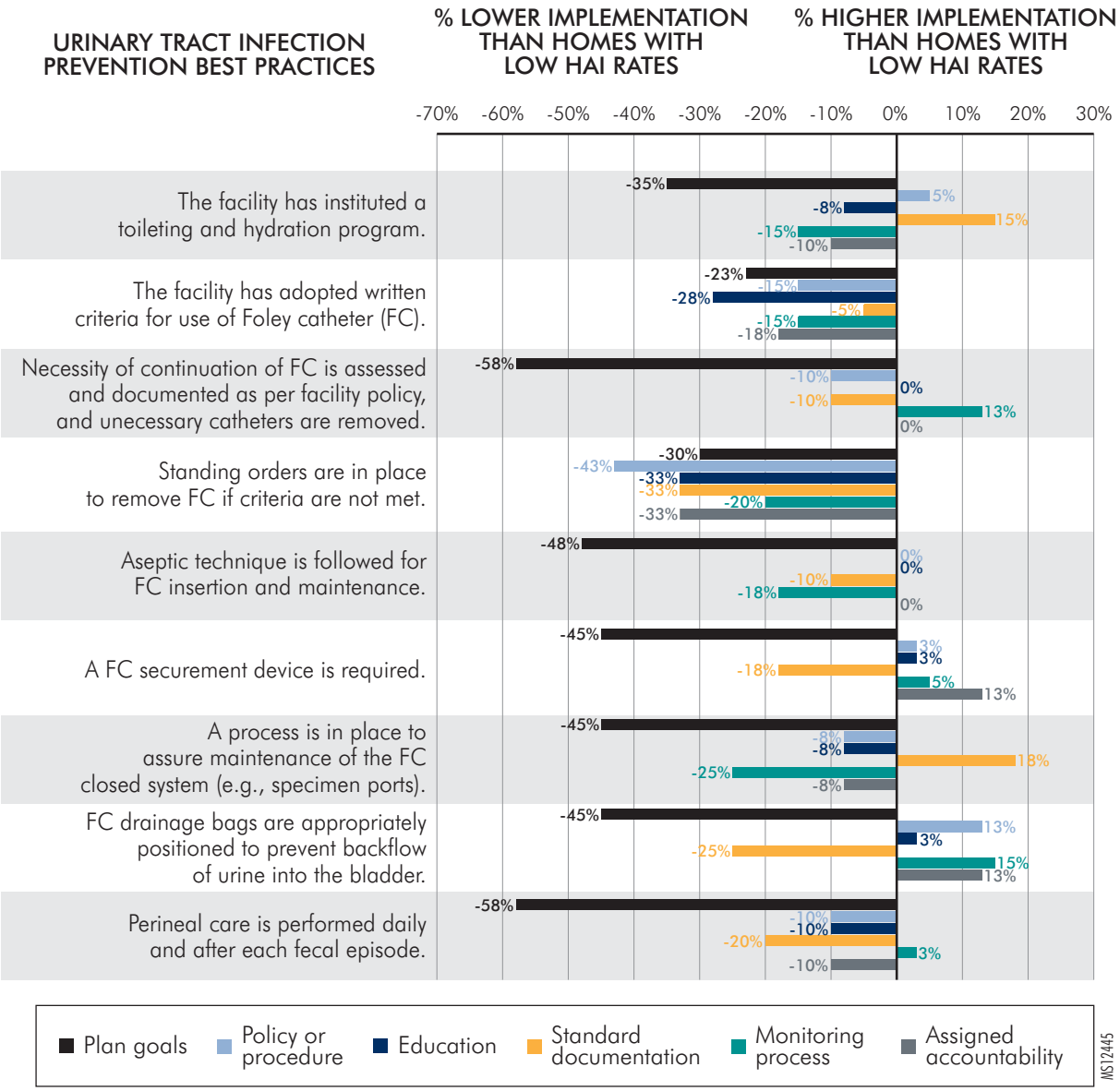
Figure 3. Comparison of Implementation of Urinary Tract Infection Prevention Best Practices for Nursing Homes with High Rates of Healthcare-Associated Infections (HAIs) and Nursing Homes with Low HAI rates



rates were implementation of a novel feedback communication loop with written receipts for delivery of messages, a rotating mattress replacement program, a low incidence of bedbound residents, and a high nurse-to-resident ratio.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was -5.23, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.001.

Hand hygiene. Across all six implementation categories, H-HAI nursing homes were most lacking in implementation of an individualized program to monitor hand hygiene compliance. H-HAI nursing homes also scored lower in documentation and process monitoring for all of the hand hygiene best practices, including the following:

— Clinician's demonstration of understanding hand hygiene rationale, indications, and methods

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— Availability of alcohol-based handrubs and gloves at the point of care
— Glove changes in between residents and in between clean and dirty activities on the same resident
— Handwashing with soap and water when hands are visibly soiled and before and after resident care
— Residents' and families members' knowledge about hand hygiene

H-HAI nursing homes also lacked full implementation of staff education on the glove changing process and developing facility infection control goals and policies to help residents and family members become knowledgeable about hand hygiene. H-HAI nursing homes also failed to assign accountability for clinical staff understanding about hand hygiene. (See Figure 5 online.)

Analysis of interviews with infection prevention representatives from the L-HAI nursing homes found that successful implementation of hand hygiene best practices was associated with the use of hand hygiene competency checklists, involvement of administrative staff with hands-on monitoring and interventions in hand hygiene practices across all disciplines on a daily basis, and the availability of hand sanitizers at each point of care and in critical access areas. Also helpful were hand hygiene reminder paycheck inserts, annual hand-hygiene-specific in-services, and the use of individual, personal-size hand sanitizers.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was -3.19, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.001.

Environmental control. The most notable difference between L-HAI and H-HAI nursing homes' performance was the H-HAI nursing homes' lack of standard documentation for best practices for glove use and for handling, cleaning, and disinfecting reusable equipment, surfaces, and linens, as well as lower scores on incorporation of all of these environmental control best practices (except for glove use) into the facility's infection control plan and goals. Additionally, H-HAI nursing homes showed opportunities for improvement in policy development for linen handling and environmental surface disinfection, as well as in monitoring of glove use, equipment disinfection, and linen disposal. H-HAI nursing homes also failed to assign accountability to assure proper cleaning of environmental surfaces. (See Figure 6 online.)

L-HAI nursing homes described several strategies for sustained environmental infection control, including use of a predetermined daily cleaning schedule and cleaning checklists, cleaning frequency increases based on clinical input, a structured clean/dirty workflow process in laundry areas, and staff access to sufficient resources.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was -2.34, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.01.

RTI (lower respiratory tract infection [LRTI] and influenza-like illness [ILI]). The most notable difference between the H-HAI nursing homes' and L-HAI nursing homes' performances in the LRTI and ILI domains was the H-HAI nursing homes' lack of institution of a standardized oral care and aspiration prevention program across all six implementation categories. H-HAI nursing homes also lacked implementation of the following practices:

— Integration of a respiratory etiquette program into the facility infection control plan, goals, and policies
— Development of policies and an education program for a standing order immunization process
— Provision of an education and infection control plan and policies for use of single-dose aerosolized medications
— Documentation and education with regard to separation of ill employees from residents
— Development of policies and a written plan to monitor, assign accountability for, and document cleaning and disinfection of respiratory equipment
— Establishment of a plan and policies to assure education, documentation, and assigned accountability for use of sterile catheters and techniques for suctioning.

However, H-HAI nursing homes did score higher than L-HAI facilities in all implementation categories with respect to employee influenza immunization programs and separation of residents with communicable diseases from other residents. (See Figure 7 online.)

Nursing homes with low RTI rates associated successful prevention with routine dental care, an intense mobilization program, communication alerts for clusters of infections, and triggers for new tracheostomy consults. Some nursing homes found success with the services of a respiratory therapist who also performed regular educational and competency activities for the nursing staff. Additional interventions that may have impacted rates of influenza and pneumococcal pneumonia and invasive disease included preprinted vaccination orders, increased staff vaccination, and vaccination consents obtained at the time of admission by the facility admissions director.

A two-tailed statistical test for comparing the proportions of two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group.

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The resultant z-score was -2.69, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.01.

Outbreak control. Multiple opportunities for improvement for H-HAI nursing homes were found in this level of analysis of individual best-practice assessment (see Figure 8 online), including in the following practices:

— Incorporating methods to investigate cases that rise above the facility's normal baseline into the facility infection control plan, policies, and procedures
— Assigning accountability and developing documentation methods for identifying increased numbers of outbreak cases
— Developing a policy and documentation, monitoring, and accountability methods for monitoring of infection control measures and isolation
— Instituting policies, education, documentation, and accountability for specific outbreak case definition and timely institution of infection control

H-HAI nursing homes did score higher than L-HAI homes in all six categories of full implementation for conducting case finding and in having procedures to identify transmission of disease.

The visited facilities described successful outbreak control strategies, including using a case-tracking form and the 24-hour report for identification of increasing infection trend action plans, placing residents in private rooms, and a using cohort/quarantine system to respond to a potential outbreak.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was 2.52, indicating that the difference between the H-HAI group and L-HAI group was significant at the p value < 0.01.

GI and MDRO infection. Compared with L-HAI nursing homes, those with high HAI rates scored lower in documentation of ensuring compliance with precautions, as well as in documentation, monitoring, and incorporation of communication of GI and MDRO prevention practices into the facility infection control plan. The overall lowest scores in this domain for both L-HAI and H-HAI nursing homes were in implementation of antimicrobial monitoring best practices. In individual categories, H-HAI homes scored lower in integration of antimicrobial monitoring into the facility plan, goals, policies, and educational programs. Overall, H-HAI homes scored slightly better than L-HAI homes in all implementation categories for posting transmission-based precaution signage. (See Figure 9 online.)

L-HAI nursing homes described several strategies to sustain low GI and MDRO infection rates, including a novel feedback loop among nursing assistants, nurses, and administration, which requires documentation of communication of infectious cases; preemptive isolation and intervention with suspect contagious cases; and a removal-from-isolation protocol. Approaches that may have contributed to low GI and MDRO rates were special *Clostridium difficile* cleaning protocols, an active antimicrobial stewardship program with oversight by the director of nursing, and the use of private rooms for each resident. Additional resources can be accessed in the Authority's online norovirus prevention toolkit at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/dec7(4)/Pages/141.aspx.

A two-tailed statistical test for comparing the proportions of the two groups' compliance rates was run on the percentage of responses of full implementation for the H-HAI group against the L-HAI group. The resultant z-score was 0.32, indicating that the difference between the H-HAI group and L-HAI group was not significant at the p value < 0.636.

BARRIERS

Assessment visits to H-HAI facilities identified multiple barriers to staff and administrative performance of best practices for prevention of HAIs. Specific barriers reported included unavailability of alcohol-based handrub stations at the point of care, monitoring of antimicrobial use performed only at the pharmacy level, a lack of knowledge of aspiration prevention strategies, use of the outdated practice of routine changing and irrigation of Foley catheters, and refusal of physicians or residents to remove Foley catheters that do not meet evidence-based insertion criteria.

Facility-wide barriers affecting all assessment domains included high acuity, low staffing, and limited consultant services. Infection prevention designees described lack of training, responsibility for multiple roles and multiple campuses, and lack of administrative support for infection control programs. Notable throughout the H-HAI survey results was an absence of structured and/or documented monitoring programs and communication strategies to involve and educate staff on infection issues and an absence of ownership of improvement projects, as well as a lack of infection control education for family members and residents. Limited space to separate clean and dirty items and unavailability of resources were also cited by H-HAI nursing homes as barriers to best-practice performance. While every facility had a process improvement or safety committee in place, H-HAI nursing homes described reactive versus proactive infection prevention programs, a lack of root-cause analysis for infection issues, and the frequent institution of infection control strategies without a planned approach.

LIMITATIONS

The study results are limited by several factors. Analysis of the nursing homes' HAI rates was based on compliance with HAI reporting to the Authority. The

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sample size of 20 nursing homes was limited and, in order to achieve diversity in size and patient population, participants were specifically selected (i.e., not selected randomly). The analysts conducted all 10 L-HAI nursing home assessment visits; however, data from two facilities was not available for analysis. Therefore, data analysis on the assessment results was based on 10 H-HAI nursing homes and 8 L-HAI nursing homes. Practices from the new norovirus guidelines published by the Centers for Disease Control and Prevention (CDC) after development of the Long-Term Care Best-Practice Assessment Tool were not available for the GI and outbreak control domain assessments.

DISCUSSION

Monitoring compliance with best practices aimed at preventing HAIs is fundamental to improvement. The Authority's Long-Term Care Best-Practice Assessment Tool and consultation program were designed to assist nursing homes to increase success with integrating infection control best-practice concepts into clinical practice by exploring nursing homes' areas of greatest challenge. The practices listed under each of the seven assessment categories mirror current evidence-based guidelines and could be considered a "bundle" for success in that category. The implementation categories identify the particular area in which resources may need to be directed.

The tool was designed to apply a multidisciplinary approach to information gathering for the assessment and facilitates several different methods of review to simplify the process for monitoring compliance with best practices. The tool is compact, customizable, and contains elements that can be measured by clinical observation at the bedside, by interviews, and by record review. Once populated with data, the tool displays a snapshot of the existence and extent of process defects and barriers to HAI prevention in nursing home residents and provides both a pre- and postintervention assessment. It can be used to demonstrate the evidence needed to justify or prioritize implementation of appropriate prevention strategies and resources and to gain a fresh perspective on the effectiveness of improvement strategies needed to enhance the infection control program. The tool has been updated to include best-practice elements from the new CDC norovirus guidelines.[6]

CONCLUSION

The results of this study suggest an association between high infection rates and limited implementation of best practices in Pennsylvania nursing homes. Examination of the differences between L-HAI and H-HAI nursing homes' applications of specific best practices within multiple levels of implementation revealed that nursing homes reporting high HAI rates also had limited adoption of best practices in one or more levels of implementation for 45 of the 50 best practices in the survey. Opportunities for improvement for H-HAI nursing homes were identified in all seven infection control domains and across all six categories of best-practice implementation. The interviews and observations conducted by the authors uncovered multidisciplinary implementation barriers in the H-HAI nursing homes at the leadership, physician, clinical, and support staff levels.

This study reveals the variability in implementation and maintenance of infection control practices in nursing homes and demonstrates the need to better identify and overcome barriers to implementing infection control best practices in this setting. This survey identified problems that are likely present in almost all nursing homes to some extent and demonstrated multiple methods to focus on problems that nursing homes could reasonably address to improve infection control. The L-HAI nursing homes' strategies for success in each of the domains are previously mentioned. In addition, this study suggests that moving best practices from evidence to the bedside by fully implementing those practices at a higher level in each of the six implementation categories may be associated with lower infection rates.

Nursing homes with consistently low infection rates described facility-wide strategies for success that require high visibility of managers on resident care units in order to enhance communication, resolve problems, investigate changes in conditions, ensure accountability, reward staff performance, and foster an "it's okay to speak up" culture. Frequent competency evaluations at all staff levels ingrain best practices in a structured framework for application at the bedside. Corporate and administrative support was evident for trained infection prevention designees who implemented nationally recognized, standardized surveillance methods to actively search for HAI cases. Multiple communication methods and feedback loops—such as a multidisciplinary daily triage at each nursing station, standardized structured reports, and frequent, interactive educational programs—keep staff informed. A highly structured process-monitoring system supports a strong infection control program and a proactive performance improvement process.

MOVING FORWARD

The Authority survey results identified suboptimal patterns of care, thus providing a targeted focus for follow-up education programs that can be widely applied in the long-term care setting for collaboration with nursing homes to overcome obstacles to full implementation of the current best practices for HAI prevention and for development of a consistent framework to integrate successful infection control strategies into clinical practice. To support the Authority's goal to minimize HAIs in Pennsylvania nursing homes, the next step of following

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up with nursing homes involved in this project is currently underway to compare pre- and postintervention HAI rates and methods of overcoming barriers. Multiple infection control educational strategies and toolkits can be found at http://www.patientsafetyauthority.org.

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The Breadth of Hospital-Acquired Pneumonia: Nonventilated versus Ventilated Patients in Pennsylvania

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ABSTRACT

Considering the evolution of measures designed to prevent nosocomial pneumonia, it makes clinical and financial sense to focus efforts on patients who require mechanical ventilation. Patients at risk for ventilator-associated pneumonia (VAP) are easily identified because they require an endotracheal tube or tracheostomy, require life support, and are commonly admitted to specific areas of the hospital. However, Pennsylvania data reveals that mortality rates for patients with nonventilator-hospital-acquired pneumonia (NV-HAP) are comparable to mortality rates for patients with VAP. Using Pennsylvania data, Pennsylvania Patient Safety Authority analysts have also determined that NV-HAP affects more people than VAP and is as lethal as and more costly than VAP. Furthermore, NV-HAP is a safety issue that is on the rise in patients in the conventional ward, and it is likely to be underreported. Data suggests that if VAP prevention is a focus at a facility, perhaps NV-HAP prevention should also share the spotlight. (Pa Patient Saf Advis 2012 Sep;9[3]:99-105.)

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

INTRODUCTION

Hospital-acquired pneumonia (HAP), according to the Centers for Disease Control and Prevention (CDC), "has accounted for approximately 15% of all hospital-associated infections."[1] HAP taxonomy separates event cases into those patients requiring mechanical ventilation and those who do not require ventilator support. A patient receiving mechanical ventilation who is confirmed to have nosocomial pneumonia while on the ventilator is classified as having ventilator-associated pneumonia (VAP). For the purpose of this article, a patient who develops nosocomial pneumonia and is not ventilated is classified as having nonventilator-HAP (NV-HAP). The most recent CDC guideline for preventing HAP identifies that "the primary risk factor for the development of hospital-associated bacterial pneumonia is mechanical ventilation."[1] The CDC guideline stated that some reports showed that "patients receiving continuous mechanical ventilation had 6-21 times the risk of developing hospital-associated pneumonia compared with patients who were not receiving mechanical ventilation."[1] Furthermore, CDC identified that "because of this tremendous risk, in the last two decades, most of the research on hospital-associated pneumonia has been focused on VAP."[1] Literature highlighting incidence and outcome data with regard to NV-HAP is sparse. Esperatti et al. hypothesized that this lack of data "may be caused in part by the dispersion of cases within hospital wards, hindering surveillance."[2]

BACKGROUND

Considering the evolution of measures designed to prevent nosocomial pneumonia, it makes clinical and financial sense to focus efforts on patients who require mechanical ventilation. Patients at risk for VAP are easily identified because they require an endotracheal tube or tracheostomy, require life support, and are commonly admitted to specific areas of the hospital. The intensive care unit (ICU) is one such care area where resources, such as specially trained staff, ventilators, and interventions, could be matched to patient needs.

The CDC provides a surveillance definition for VAP and modules in the National Healthcare Safety Network (NHSN) that enable VAP infection tracking. Standardized surveillance case definitions and a searchable national database provide information for calculating the projected costs of VAP. Therefore, VAP is an identifiable, trackable, fiscally measurable target with evidence-based preventive care bundles that can be applied with focused resources. The Institute for Healthcare Improvement states that "many hospitals have achieved significant reductions in VAP rates in their critical care units, some even reaching zero by taking a comprehensive and multidisciplinary approach to ventilator care."[3] Pennsylvania hospitals have shown impressive VAP rate reductions with the adoption of the adult VAP bundle and innovation by way of developing evidence-based practices in the form of neonatal and pediatric VAP prevention bundles.[4] Literature suggests that VAP bundles positively impact VAP infection rates; however, VAP is not the only piece in the nosocomial pneumonia puzzle.

METHODS

Pennsylvania state law requires that all healthcare-associated infections are reported through NHSN. Pennsylvania Patient Safety Authority analysts queried NHSN for complete nosocomial pneumonia data sets from calendar years 2009 through 2011, inclusive of the total inpatient population for Pennsylvania acute care facilities. Analysts also extracted data for nosocomial pneumonia that contributed to death during that same time period. Of those cases in which nosocomial pneumonia contributed to death, ventilator status was also extracted. Time series data was aggregated into yearly subtotals and a final total for analysis.

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Table 1. Pennsylvania Nosocomial Pneumonia and Related Deaths

YEAR	NO. OF NV-HAP CASES	NO. OF NV-HAP DEATHS	% OF NV-HAP CASES CONTRIBUTING TO DEATH	NO. OF VAP CASES	NO. OF VAP DEATHS	% OF VAP CASES CONTRIBUTING TO DEATH
2009	1,976	363	18.4 (95% CI: 16.5 to 20.3)	922	163	17.7 (95% CI: 15.0 to 20.5)
2010	1,848	366	19.8 (95% CI: 17.8 to 21.8)	737	144	19.5 (95% CI: 16.3 to 22.7)
2011	1,773	315	17.8 (95% CI: 15.8 to 19.7)	640	127	19.8 (95% CI: 16.4 to 23.3)
Total	**5,597**	**1,044**	**18.7 (95% CI: 17.5 to 19.8)**	**2,299**	**434**	**18.9 (95% CI: 17.1 to 20.7)**

Note: NV-HAP refers to nonventilator-hospital-acquired pneumonia and VAP refers to ventilator-associated pneumonia.

RESULTS

Table 1 shows the number of NV-HAP and VAP cases for 2009, 2010, and 2011 from NHSN, with the total for all three years. Also included in the table is the yearly and combined totals for deaths related to either VAP or NV-HAP. Table 1 also depicts the percentage of patients for which NV-HAP or VAP contributed to their deaths. Comparing the data year to year, considering the confidence intervals, there were no statistically significant differences between the two groups. The mortality rates for patients with NV-HAP and VAP were comparable.

NV-HAP has the potential to be more costly than VAP. Table 2 depicts a comparison of the estimated costs for VAP and NV-HAP cases[5] over three years in Pennsylvania.

DISCUSSION

As previously noted,[1] the majority of knowledge related to HAP has focused on VAP. VAP is an important subset of HAP; however, if the hypothesis noted by Esperatti et al. is valid, the true incidence of NV-HAP may be underestimated. In a multicenter study of NV-HAP in patients cared for outside of the ICU, Sopena and Sabrià realized that the number of patients with nosocomial pneumonia is increasing in the conventional hospital ward.[6] Werarak et al. noted in their study that the differences in outcomes related to NV-HAP and VAP are not significant; however, NV-HAP patients did experience hypoxic episodes more often than patients with VAP.[7] Their apparent observation is important given the potential damage repeated hypoxic episodes may have on a patient's well-being. Because NV-HAP is on the rise in patients cared for in the conventional ward and tends to be underreported, NV-HAP may become more costly if prevention efforts continue to focus largely on VAP.

Etiology of HAP

Major factors that increase the patient's risk for pneumonia include aspiration, stroke (because of impaired swallowing function or diminished gag reflex), older age, altered level of consciousness (for example, due to medications, substance abuse, or seizure), gastroesophageal reflux disease, and poor oral hygiene.[8] For infection to occur, several conditions need to occur in succession. These conditions are referred to as the *chain of infection*.[9] Those conditions needed to complete the chain of infection include the following:

1. Pathogen in sufficient numbers (dose)
2. Pathogen of sufficient virulence
3. Susceptible host
4. Mode of transmission or transfer of the pathogen from source (reservoir) to host
5. Portal of entry into the host

Major risk factors for pneumonia understandably allude to the oronasopharynx, oral cavity, and maintenance of functional, chemical, and mechanical safeguards against pathogen invasion. Part of the pathogenesis of HAP involves the oral cavity as a source and reservoir for bacteria that may then cause systemic disease. Li et al. noted that "the teeth are the only nonshedding surfaces in the body, and bacterial levels can reach more than 10^{11} microorganisms per mg of dental plaque."[10] The presence of subgingival biofilm serves as a continual and enormous bacterial load.[10]

Pathogenic organisms in the oropharynx may be endogenous or exogenous. Endogenous pathogens may be present secondary to the patient's dental state, underlying comorbidities, or overgrowth from recent antibiotic use. Exogenous pathogens may be present from the patient's native environment, the hospital environment, or medical devices (such as suction catheters and endotracheal tubes [ETTs]) and due to inadequate hand hygiene, cross-contamination, or translocation. Poor oral hygiene increases plaque load, which increases the level of enzymes in saliva.[10] Furthermore, an increased presence of oral proteolytic enzymes may change the lining of the mouth, increasing attachment and colonization by exogenous or endogenous pathogenic bacteria.[11]

For a host to be susceptible, immunity needs to be adversely affected. Interrupting the first line of human defense to bacterial invasion may result in significant insult that could easily lead to HAP. Mechanical defenses include an intact, moist, and healthy oral lining and mucosa. Healthy, intact oral epithelial

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Table 2. Estimated Costs of NV-HAP and VAP Cases

YEAR	NO. OF NV-HAP CASES	COST FOR NV-HAP CASES	NO. OF VAP CASES	COST FOR VAP CASES
2009	1,976	$55,343,808	922	$34,521,524
2010	1,848	$51,758,784	737	$27,594,754
2011	1,773	$49,658,184	640	$23,962,880
Total	**5,597**	**$156,760,776**	**2,299**	**$86,079,158**

Note: NV-HAP refers to nonventilator-hospital-acquired pneumonia and VAP refers to ventilator-associated pneumonia. The estimated average cost per NV-HAP case is $28,008. The estimated average cost per VAP case is $37,442. Average costs derived from the following study: Kalsekar I, Amsden J, Kothari S, et al. Economic and utilization burden of hospital-acquired pneumonia (HAP): a systematic review and meta-analysis. *Chest* 2010 Oct;138(4_MeetingAbstracts):739A.

cells not only provide a physical barrier against infection but are capable of mediating a chemical response to the invasion of pathogenic bacteria.[12] Functional cilia in the nares and healthy mucosa help limit intrusion of inhaled potential pathogens from entering the airway. The presence of an intact cough and gag reflex also protects the patient from aspiration of oral contents into the lungs. Given the list of major risk factors for HAP, one can easily realize how the innate immune system may be compromised in an at-risk patient. Therefore, patients at risk for HAP are susceptible hosts.

The mode of transmission has been partially explained during the discussion of oral colonization of potential pathogens and biofilm as a constant reservoir. The bacteria are transferred from the oral cavity into the lungs because of lapses in basic host defenses. In VAP cases, the internal and external lumens of the ETT or tracheostomy tube may become covered in biofilm contributing to bacterial transfer as well as aspiration of subglottic secretions containing bacteria derived from oral plaque biofilm. The portal of entry into the host is the oral cavity, the aerodigestive tract, and the ETT or tracheostomy tube, if present, thereby completing the chain to HAP.

Oral Hygiene

During a systematic literature review, Scannapieco et al. noted a 40% decrease in HAP with combined interventions that included mechanical or topical chemical disinfection (or both) or topical oral antibiotic use.[13] Paju and Scannapieco state that "institutionalized but non-ventilated patients . . . appear to benefit from improved oral care by showing lower levels of oral bacteria and fewer pneumonia episodes and febrile days."[14] A statistically significant difference ($p = 0.044$) in oral hygiene index (OHI) scores among individuals with respiratory disease and those with no disease has been noted by Scannapieco et al.[15] Furthermore, individuals with median OHI scores are 1.3 times as likely to have respiratory disease, and those with maximum OHI scores are 4.5 times as likely to have respiratory disease.[15]

The Dental Professional

Healthcare settings depend on teamwork to drive positive patient outcomes; a multidisciplinary approach for planning care is essential for delivering effective complex care. A multidisciplinary approach is also essential for preventing complications associated with exposure to the healthcare setting, such as HAP. Adachi et al. correlated weekly dental cleaning by a hygienist with less fever and fatal pneumonia.[16] In a similar study, Abe et al. noted a reduction in influenza infection related to weekly professional dental cleaning.[17]

Just as a cardiologist is consulted to care for a patient with an underlying heart condition even though a cardiac condition may not be the primary reason for admission, a cardiologist's expertise is utilized to plan treatment and preventive care. The same line of reasoning holds true for those who practice medical and surgical dentistry and for the registered dental hygienist. The dental professional may be a missing link in the chain of HAP prevention.

NV-HAP PREVENTION STRATEGIES

Plotting a Course

VAP was discussed as a logical place to start the battle against HAP; however, NV-HAP requires a different approach. The population of patients who may develop NV-HAP could prove to be quite large—are there focal points for implementing preventive measures? To assist the clinician in focusing efforts on care areas, Authority analysts looked to the data. Table 3 provides a view of NV-HAP by NHSN location type for Pennsylvania, by pooled mean and percentiles. This table is presented in a format similar to an NHSN report. The Authority analysts chose to use patient-days as the unit-specific denominator for the development of this analysis. The Authority's choice of denominator was limited by the constraints of available data. Analysis by patient-days may *underestimate* the true rate of NV-HAP since this metric potentially lowers rates in regard to extensions of length of stay related to NV-HAP. Authority analysts did not have access to unit-level specific admissions by location type for this analysis, hence the use of patient-days by location type. Rates in Table 3 are reflected as per 1,000 patient-days.

Targeted Intervention

After a patient population or unit is identified at the facility level, proven interventions and lessons derived from VAP prevention activities can be applied to the NV-HAP patient. Selected interventions from the literature that may be applicable to the NV-HAP population are reflected in the Figure.

(continued on page 105)

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Table 3. Distribution of NV-HAP Cases (based on aggregate data for Pennsylvania for 2009, 2010, and 2011)

UNIT TYPE*	NO. OF LOCA-TIONS	NO. OF NV-HAP CASES	PATIENT-DAYS	POOLED MEAN[†,‡]	PERCENTILE[‡,§]				
					10%	25%	(Median) 50%	75%	90%
Critical Care									
Neurologic	3	11	40,512	0.272			0.247		
Cardiothoracic	33	216	930,991	0.232	0.062	0.133	0.210	0.363	0.484
Surgery	16	154	670,509	0.230	0.040	0.121	0.210	0.330	0.459
Trauma	11	107	515,252	0.208	0.153	0.183	0.207	0.286	0.319
Medical/surgical	137	848	4,480,656	0.189	0.000	0.051	0.123	0.249	0.449
Neurosurgical	8	85	454,838	0.187			0.139		
Cardiac	29	131	927,286	0.141	0.000	0.038	0.109	0.195	0.330
Medical	31	190	1,364,397	0.139	0.016	0.056	0.099	0.246	0.347
Burn	4	7	82,443	0.085			0.082		
Respiratory	2	4	65,637	0.061			0.080		
Cardiothoracic pediatric	3	8	180,915	0.044			0.000		
Nursery	24	25	1,049,229	0.024	0.000	0.000	0.000	0.022	0.071
Medical/surgical pediatric	6	7	343,164	0.020			0.004		
Ward									
Genitourinary	3	12	124,972	0.096			0.110		
Neurologic	9	39	410,219	0.095			0.078		
Pulmonary	4	32	359,703	0.089			0.071		
Neurosurgical	8	27	354,410	0.076			0.075		
Surgical	48	312	4,209,299	0.074	0.000	0.037	0.069	0.113	0.168
Vascular surgery	2	5	70,231	0.071			0.060		
Medical/surgical	152	1673	23,904,085	0.070	0.000	0.018	0.052	0.096	0.158
Medical	58	507	8,064,412	0.063	0.000	0.019	0.035	0.070	0.116
Orthopedic	50	133	2,145,512	0.062	0.000	0.000	0.044	0.093	0.186
Gynecology	8	3	157,176	0.019			0.000		
Gerontology	2	2	118,333	0.017			0.023		
Behavioral	110	90	8,258,652	0.011	0.000	0.000	0.000	0.015	0.075
Medical pediatric	4	5	472,100	0.011			0.002		
Orthopedic pediatric	3	1	95,976	0.010			0.000		
Nursery	79	10	1,362,609	0.007	0.000	0.000	0.000	0.000	0.000

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Table 3. Distribution of NV-HAP Cases (based on aggregate data for Pennsylvania for 2009, 2010, and 2011) (continued)

UNIT TYPE*	NO. OF LOCA-TIONS	NO. OF NV-HAP CASES	PATIENT-DAYS	POOLED MEAN†,‡	PERCENTILE‡,§				
					10%	25%	(Median) 50%	75%	90%
Behavioral health pediatric	12	2	302,401	0.007	0.000	0.000	0.000	0.000	0.007
Postpartum	63	12	1,944,665	0.006	0.000	0.000	0.000	0.000	0.026
Rehabilitation pediatric	5	1	176,551	0.006			0.069		
Medical/surgical pediatric	44	5	959,543	0.005	0.000	0.000	0.000	0.000	0.000
Behavioral health adolescent	11	2	417,412	0.005	0.000	0.000	0.000	0.000	0.014
Labor & delivery/ postpartum	43	4	837,294	0.005	0.000	0.000	0.000	0.000	0.000
Labor & delivery	22	1	426,176	0.002	0.000	0.000	0.000	0.000	0.000
Rehabilitation	82	163	5,649,493	0.029	0.000	0.000	0.020	0.062	0.128
Specialty Care Area									
Bone marrow transplant	5	33	291,857	0.113			0.133		
Hematology/ oncology	16	172	1,905,141	0.090	0.000	0.025	0.063	0.110	0.192
Solid organ transplant	1	2	24,645	0.081			0.081		
Hematology/ oncology pediatric	4	13	297,827	0.044			0.024		
Solid organ transplant pediatric	1	1	83,559	0.012			0.012		
Step-Down Unit									
Adult	73	379	5,332,998	0.071	0.000	0.010	0.046	0.102	0.156
Nursery	23	12	484,825	0.025	0.000	0.000	0.000	0.044	0.114
Pediatric	4	2	190,271	0.011			0.010		
Long-Term Acute Care									
	28	117	2,688,812	0.044	0.000	0.000	0.020	0.073	0.122

Note: NV-HAP refers to nonventilator-hospital-acquired pneumonia. Locations that are not represented reported no events.

* Units are based on National Healthcare Safety Network classifications.

† Pooled mean = total infections ÷ total patient-days x 1000

‡ Per 1000 patient-days

§ For locations that have less than 10 units, reporting percentile distributions have not been calculated.

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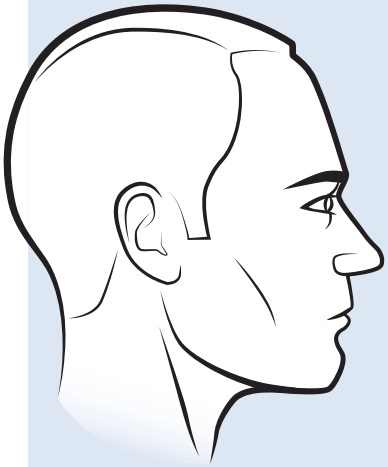
Figure. Selected Interventions to Prevent Nonventilator-Hospital-Acquired Pneumonia

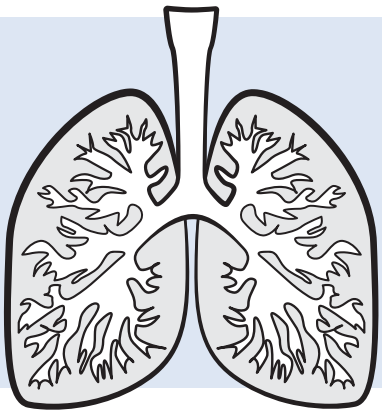


Selected interventions to prevent colonization:

- Provide information about optimal pulmonary state.
- Optimize functional reserve capacity.
- Strengthen patient's resistance to atelectasis.
- Maintain patient's resistance to infection:
  - Perform hand hygiene.
  - Institute a routine oral hygiene regimen.
  - Eliminate oral bacterial reservoirs.
  - Consult with a dental professional.
  - Protect oral epithelial cells and nasal passages by providing moisture and avoiding large-bore nasogastric tubes.
  - Avoid unnecessary antibiotics.
  - Avoid unnecessary stress ulcer prophylaxis (if necessary, consider a cytoprotective agent).
  - Consider chlorhexidine oral rinse or chlorhexidine bath for select patient populations.

Selected interventions to prevent aspiration:

- Teach techniques for optimizing cough and airway clearance.
- Avoid unnecessary medications that reduce level of consciousness.
- Maintain head of the bed at 30 degrees or greater unless contraindicated.
- Encourage ambulation.
- Provide subglottic suctioning.
- Consult with speech and/or swallowing professionals when appropriate.



Holistic prevention strategies:

- Administer vaccines and immunizations.
- Provide smoking cessation counseling.
- Institute environmental infection control measures.
- Encourage personal hygiene, including hand hygiene.
- Evaluate the patient's risk for aspiration.
- Provide dementia screening.
- Assess the patient's nutritional status.
- Encourage routine professional dental care.

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Notes

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(continued from page 101)

CONCLUSION

The chain of infection that perpetuates HAP can be broken with appropriate interventions. In the case of VAP, the majority of interventions are aimed at reducing the risk for aspiration, decolonizing the oral cavity, maintaining the aerodigestive tract, and protecting the mouth. Furthermore, if oral hygiene is compromised, the oral cavity and nasopharyngeal tract will serve as a constant reservoir of pathogens.

Currently, NV-HAP bundles are lacking in the peer-reviewed literature. Focusing care on reservoirs and the portal of entry may be the most realistic approach for preventing NV-HAP at this time. Improving oral hygiene and collaborating with a dental professional may prove essential in preventing NV-HAP (and VAP). NV-HAP in Pennsylvania may potentially have a greater impact than VAP. If VAP prevention is a focus at a facility, perhaps the prevention of NV-HAP—which has the potential to affect more patients, be more costly, and be as lethal as VAP—deserves to share the spotlight.

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Update on the Prevention of Retained Surgical Items

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ABSTRACT

Surgical items such as sponges, sharps, and instruments may be retained following surgery and lead to serious patient harm. In June 2009, the Pennsylvania Patient Safety Authority reported that the prevention of retained foreign objects, now commonly referred to as retained surgical items (RSIs), requires application of a multidisciplinary, consistent approach utilizing current best practices. Since publication of the June 2009 Pennsylvania Patient Safety Advisory, *the Association of periOperative Registered Nurses (AORN) has published additional guidance for the prevention of RSIs. Further guidance to assist in implementation of recommended best practices since the Authority's report include strategies related to therapeutic packing, minimally invasive procedures, and unidentified device fragments. Ongoing analysis of events reported to the Authority show that in 2011, Pennsylvania healthcare facilities reported 452 events involving RSIs. During this time, Pennsylvania healthcare facilities also reported 1,930 events involving incorrect counts of needles, sponges, or equipment. Authority reports suggest that RSI prevention remains a challenge and that continued diligence in RSI prevention efforts is essential. (Pa Patient Saf Advis Sep;9[3]:106-10.)*

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

INTRODUCTION

The Pennsylvania Patient Safety Authority reported on the risk of the retention of foreign objects related to the failure to account for all sponges, sharps, and instruments postoperatively in the June 2009 article "Beyond the Count: Preventing the Retention of Foreign Objects."[1] Retained foreign objects are now more commonly referred to as retained surgical items (RSIs) in order to differentiate them from "foreign objects," which may include swallowed pennies, pins, shrapnel, bullets, and other objects.[2] The surgical team routinely relies on sponge, sharp, and instrument counts to reduce the risk of RSIs. Because counting alone may be insufficient, the Authority presented multipronged risk reduction strategies, including improved perioperative processes, perioperative team communication, and the use of assistive technology.

Since publication of the article, further guidance has been published for the prevention of RSIs. First, in 2011, the National Quality Forum (NQF) changed its definition of when surgery ends from when the incision is closed to when the patient leaves the operating or procedure room. This change has implications for actions the perioperative team should take prior to the patient leaving the operating room (OR).[3] Second, the Association of periOperative Registered Nurses (AORN) has issued an implementation guide for recommended practices for the prevention of RSIs.[4] AORN's implementation guide updates AORN recommendations referenced in the June 2009 *Pennsylvania Patient Safety Advisory*.[5] The purpose of the AORN implementation guide is to assist the perioperative team in implementing AORN-recommended practices in hospital, ambulatory, and other perioperative practice settings.[4]

REPORTS TO THE AUTHORITY

Ongoing analysis of the Pennsylvania Patient Safety Reporting System database for reports related to RSIs showed that in 2011, Pennsylvania healthcare facilities reported 452 events involving RSIs. During this time, Pennsylvania healthcare facilities also reported 1,930 events involving incorrect counts of needles, sponges, or equipment. An incorrect count may be a significant patient safety risk because RSIs have been reported to be 100 times as likely to occur when there is a surgical count discrepancy.[6]

Of the 452 reports to the Authority involving RSIs, 101 (22.3%) of the RSIs were associated with an incorrect count. In 153 (33.8%) of the 452 total reports, the RSI caused patient harm, and in 132 (29.2%), the patient could have been harmed if the event was not prevented (i.e., "near miss"). Forty-nine reports (10.8%) were events in which objects were intentionally left in the patient. Thirty-six (73%) of these intentionally retained objects were sponges left in place as packing for the wound. According to AORN-recommended practices, these objects are considered therapeutic packing and not RSIs. The remaining intentionally retained objects, which included a needle, surgical instruments, a plastic cap, and other objects, were left in place because the risk of removal was deemed greater than the risk of leaving the object in place. Those items are considered unretrieved device fragments and are reportable as RSIs.

Not all of the 452 reports identified the type of retained item. A total of 301 reported events identified the RSIs as follows:

- Sponges, 30.2%
- Medical instruments, 16.3%
- Needles, 13.0%
- Other (e.g., guidewires), 40.5%

ADDITIONAL GUIDANCE FOR THE PREVENTION OF RSIs

As reports to the Authority indicate, RSI events continue to occur. The first update

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related to RSI prevention since publication of the June 2009 *Advisory* is a revision to the definition of when surgery ends. NQF previously defined when surgery ends as "after counts have concluded, the surgical incision has been closed, and/or operative device(s) such as probes have been removed, regardless of setting."[7] In 2011, NQF modified its definition for the end of surgery to "after all incisions or procedural access routes have been closed in their entirety, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room."[3] The revised definition is significant because it encourages OR staff to use all available measures to prevent RSIs after the incision is closed while the patient is still under anesthesia and in the OR. Further guidance issued since the publication of the June 2009 *Advisory* include additional strategies related to teamwork, the surgical count, therapeutic packing, sharps and needles, instruments, minimally invasive procedures, unretrieved device fragments, and radiographic screening. Recent reports to the Authority illustrate the continued importance of adopting effective strategies to mitigate this ongoing safety risk.

Multidisciplinary Approach

An Authority report illustrates an instance in which multidisciplinary team efforts prevented an RSI:

> *Throughout the procedure, many instruments were added to the counts and two surgeons were operating together. All counts were reconciled at the end of the case except for needle holders. The circulator's initial counts were 10, but only 9 were accounted for. The circulator made the surgeon aware of discrepancy in count, an x-ray was done at the end of case, and the patient was cleared of any retained instrument.*

A successful RSI prevention program requires a consistent, multidisciplinary approach that involves all members of the perioperative team during all surgical and invasive procedures. AORN-recommended practices emphasize that the responsibility for preventing RSIs is shared among the perioperative team, including the registered nurse (RN) circulator, scrub person, surgeon, anesthesia professionals, and others assisting in the procedure. Significantly, the entire surgical team may be held legally responsible for RSIs.[4] AORN makes recommendations specific to members of the perioperative team. Recommendations for surgeons and first assistants to prevent an RSI include the following:[4]

- Maintaining awareness of items used
- Using radiopaque soft goods
- Communicating to the perioperative team when placing an item in the wound
- Acknowledging the start of the count process
- Performing a methodological exploration of the wound at the start of the first closing count
- Notifying the perioperative team when items have been returned to the field after counts have been completed

The RN circulator is assigned the responsibility to notify the team if there is a discrepancy in the count and to receive acknowledgement from the team so that other actions can be taken to find the missing item, such as a search of the operative field, floor, and trash buckets. Anesthesiologists are urged to maintain situational awareness during surgical procedures by planning actions that do not interfere with the counting process. Anesthesia professionals should communicate with the perioperative team about items inserted or removed from the oropharynx. Radiologists and radiologic technologists and the perioperative team must communicate effectively when imaging is needed about what item is being searched for specifically, the best type of imaging to locate the missing item, and the most appropriate views; providing a sample of the item will also help with its identification in x-ray images.[4]

Surgical Count

Reports to the Authority show that incorrect surgical counts may lead to an RSI.

> *An incorrect sponge count was identified. The surgeon proceeded with closure, and an x-ray was completed. A retained sponge was noted. A laparotomy to remove the foreign body was completed immediately.*

> *The sponge count was incorrect. The surgeon stated he was not going back in to get it at this time due to a planned re-exploration in several days. The OR supervisor was present and aware of all the above. At the end of the surgery, the sponge count was incorrect. An x-ray was obtained and read by the radiologist. The x-ray confirmed a retained sponge in the incision. The retained sponge was removed by surgeon and counts were correct.*

> *Surgery was performed for a ruptured abdominal aortic aneurysm. The abdomen was left open. A postoperative abdominal x-ray was obtained, and an area of densities that could have been within the body [was identified]. An abdominal computed axial tomography showed the possibility of a retained object. An exploratory laparotomy was performed, and the retained laparotomy sponge was removed.*

AORN provides a number of specific recommended actions related to the surgical count. The following are best practices not previously reported by the Authority:[4]

- Use only radiopaque soft goods in the wound, including towels.
- Separate sponges completely.
- View sponges concurrently (e.g., two perioperative team members should view and count the sponges together).

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— Break bands on radiopaque soft goods before counting takes place.
— Avoid altering sponges.
— Dispense dressing sponges only after the final count has been completed.

Therapeutic Packing

AORN-recommended practices now specify strategies related to therapeutic packing, which is when soft goods are left in place intentionally for therapeutic reasons. A patient may leave the OR with packing in place, but items used in therapeutic packing are not considered RSIs. However, if not accounted for, therapeutic packing may increase the risk of an incorrect count at subsequent operations. Authority reports demonstrate the importance of accounting for therapeutic packing during the counting process.

> *The patient underwent an exploratory laparotomy. The sponge count was incorrect, as sponges remained in the abdomen with a vacuum dressing from a previous surgery. Sharps, instruments, and soft goods were not counted as the abdomen was closed. Nurses requested the surgeon to stop and allow surgical counts. The surgeon closed the abdomen with vacuum dressing, and a portable abdominal x-ray was performed in the surgical intensive care unit. Nine radiopaque markers from sponges were visualized in the pelvis. The surgical team was aware of the intended retained packing material. No harm to patient.*

> *A trauma patient had previous surgery in which eight sponges were intentionally retained, according to a previous OR record. Eight sponges were removed during the current procedure; at completion of surgery, an x-ray was taken to confirm no retained sponges.*

AORN recommends that healthcare organizations develop policies and procedures to standardize processes related to therapeutic packing and the plan for removal that include communication about therapeutic packing to the perioperative staff and documentation requirements.[4] Additional AORN guidelines include the following:

— Isolate and identify the therapeutic packing as being from the original procedure; do not include therapeutic packing that has been removed in the count for the removal procedure.
— Require the surgeon to conduct a methodical wound exploration and to consider ordering an intraoperative radiograph to confirm that all items have been removed.
— Document the count as reconciled if all soft goods have been removed and accounted for.
— Inform the patient and family members if any items have been intentionally left in the wound.

Sharps and Needles

Sharps such as needles and blades may be opened onto the sterile field and must be accounted for during the counting process.[5] Reports to the Authority demonstrate the importance of reconciling an incorrect sharp or needle count.

> *The needle count was incorrect at closing. No needle was located despite exam of drapes, sterile field, and floor and using magnet. Fluoroscopy [was performed] for a possible retained needle prior to transfer from the OR bed. No needle was seen by the surgeon in the room. The case is pending review by a radiologist.*

> *The staff verbalized that they had seen a needle fall onto the floor and out of vision. The needle was not found. Final counts were conducted to find one needle that was missing. An x-ray was taken. The radiologist reported a foreign body was seen on the image. The surgeon examined the image and verbalized the foreign body was not a needle but were clips used during the procedure, not a retained object.*

> *The patient had abdominal surgery and the needle count was off. An x-ray was taken but nothing was found. Later, a CT [computed tomography scan] showed the retained needle. The patient was taken back to the OR for removal.*

> *The patient had open-heart surgery completed with the count showing a knife blade was missing. A post-op x-ray was done and read as no retained radiopaque surgical instruments identified.*

AORN recommends the following best practices to help prevent the retention of a needle or blade:[4]

— The RN circulator and the scrub person should view packaged items when they are opened because packaging errors may occur that may lead to incorrect counts.
— Needles in the surgical field should be carefully tracked so the team can identify what type of needle is missing if there is a count discrepancy.
— If small needles are used frequently, policies should specify what size needles should be searched for on a radiograph, who should read the films, and who should inform the patient.
— Containment devices should be used for sharps to decrease the chance of needlestick injuries.
— The scrub person should verify that needles returned from the operative field are intact.
— The surgeon should notify the entire team and perform a wound exploration when a broken needle is identified.

Instruments

Reports to the Authority show that instruments (e.g., forceps) and pieces of instruments (e.g., drill bits) may be

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retained if not accounted for in the counting process.

> *On the initial count in the OR, forceps were not recorded [on the count sheet]. An x-ray was taken prior to closure to confirm no instruments were retained; none were found.*

> *A drill pin was misplaced. An x-ray was done. Radiology verified that the pin was in the femoral canal. The pin was removed using a laparoscopic grasper and fluoroscopy during the same procedure.*

> *The patient came to the OR for resection of a thoracic tumor. During the closing count and final count, there were two missing instruments from the thoracotomy tray. An x-ray was obtained that showed the instruments were not retained in the patient. The patient was awakened and transferred to the postanesthesia care unit.*

> *A patient was scheduled for a cystoscopy. During the procedure, a tip from the resectoscope (from a previous procedure) was found lodged in the urethra.*

AORN recommends the following best practices to help prevent the retention of instruments or pieces of instruments:[4]

- Perform a count when sets are being assembled before sterilization to provide an inventory; however, this count should not be considered the initial surgical count.
- Count multiple pieces of instruments separately, and document the information on the count sheet.
- Use preprinted count sheets for instruments to provide an inventory of what is in the instrument set.
- If possible, limit the number and type of instruments to streamline the counting process.

Minimally Invasive Procedures

The Authority reported on the risk of RSIs during minimally invasive procedures and presented a number of risk reduction strategies.[8] Previously published literature about prevention of RSIs was generally focused on prevention strategies in the OR setting. The following reports to the Authority demonstrate the continuing importance of RSI prevention strategies during any minimally invasive procedure, including those performed outside the OR, to prevent the risk of patient harm.

> *An interventional nurse using guidewire through the brachial vein encountered resistance and withdrew the needle. The nurse observed a frayed end of guidewire. The procedure was terminated, and an x-ray was obtained revealing a small retained portion of the guidewire. Vascular surgery was consulted, and a plan was developed to remove the fragment as an outpatient procedure within the next week.*

> *When removing a drain at the bedside, one piece retracted back inside. The patient was taken to interventional radiology, where the foreign body was removed.*

> *The patient was undergoing a robotically assisted laparoscopic hysterectomy. Early in the case, the surgeon requested placement of a vaginal cuff occluder to prevent the loss of insufflated air. At the conclusion of the case, the patient had a laryngospasm. The registered nurse later noted the vaginal cuff occluder was still in place. The physician removed the occluder that day. No harm occurred to the patient.*

AORN also recommends that counts should be performed during minimally invasive procedures such as laparoscopy and thoracoscopy.[4]

Unretrieved Device Fragments

A device fragment may be noticed and not retrieved because the risk of retrieval is considered by the surgeon to be greater than the risk of retention. Such unretrieved device fragments are considered RSIs. A fragment of a medical device that separates or breaks and is unintentionally left in a patient after a procedure is also considered an RSI.[9] Authority reports show the risk of the retention of a device fragment if not accounted for during a procedure.

> *The patient was undergoing a cataract removal. The phacoemulsion handpiece was introduced into the eye, and a piece of metal was spotted in the eye. The metal piece was successfully removed and sent to pathology. There was concern that this may have come from a handpiece device. The physician reports that this piece of metal came through the phacoemulsion, and the physician believes the metal was in the sleeve at assembly of the handpiece and, once infusion started, was flushed into the eye.*

> *The patient underwent a robot-assisted laparoscopic gynecological procedure without apparent complication. One week later, the patient called the physician, stating there was something in her vagina. An examination revealed that a piece of a device used to position the uterus remained following the procedure. The device piece was removed without complication.*

> *During surgery, the tip of the arthroscopic ablation wand fell off in the patient. An x-ray obtained at the end of the procedure verified no retained material in the knee.*

AORN recommends adding any device that may separate or fragment to the final time-out checklist so that all perioperative team members are aware of this risk.[4] The surgeon should announce to the perioperative team during the final time-out that the device could fragment or detach in order to raise awareness and to remind the team to check for this possibility prior to wound closure. If a device fragment is left in the wound intentionally

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(i.e., because the device cannot be retrieved or because the risk to the patient of removal of the device fragment is greater than the benefit of removal), the patient must be informed of the risks associated with the intentionally retained device fragment, which may include migration of the device fragment and the potential for infection, and of the types of procedures that should be avoided in the future (e.g., magnetic resonance imaging).[10]

Radiographic Screening

The Authority previously reported on the effectiveness of intraoperative and postoperative radiographic screening.[1] The Authority presented risk reduction strategies that included radiographic screening at the end of cases involving an incorrect count, an emergent procedure, an unexpected change in procedure, or a high patient body mass index.[1,11,12] AORN recommends implementing the following best practices:[4]

— If a facility does not have radiograph capabilities, develop detailed policies and procedures outlining steps for the perioperative team to follow, including transfer of the patient to a facility with radiograph capability.

— Use language on a radiograph request that can be understood by non-OR personnel.

— Create an educational board depicting commonly retained items for the radiology department staff to use for comparison.

CONCLUSION

Ongoing analysis of reports to the Authority demonstrates that Pennsylvania healthcare facilities would benefit by continuing efforts to prevent the retention of surgical items. Implementation of current best practices may be accomplished by emphasizing that a consistent multidisciplinary team effort be made to reduce the risk of RSIs, including strict adherence to a standardized counting process and reconciliation of the count before the patient is taken from the OR or procedure room. These preventive strategies are critical and apply equally to minimally invasive procedures.

NOTES

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Quarterly Update on Preventing Wrong-Site Surgery

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There were reports of 10 wrong-site surgeries during the second quarter of 2012, plus one report of belated awareness of wrong-site surgery in a prior quarter, discovered as a result of a lawsuit, resulting in a total of 491 since reporting began in July 2004. The reports this quarter matched the third-lowest number of reports in a quarter since statewide reporting began June 28, 2004 (see Figure). During this quarter, Pennsylvania operating rooms went—for the third time—for more than a month (32 days) without any reports of wrong-site surgery. During this past academic year (July 2011 through June 2012), there were 47 reports of wrong-site surgery, which is below the historical average of 63 and the lowest yearly total since data collection began in mid-2004. The two-year rolling average (51 per year) is also the lowest since reporting began. It is encouraging to see that implementation of the 21 principles to prevent wrong-site surgery is proving effective.

There were several instructive reports of near misses during the quarter.

The importance of proper scheduling:

> *This patient was scheduled for a total hip. There was miscommunication regarding the procedure to be performed, and the OR [operating room] instruments were incorrectly prepared. This was not realized until after the incision was made. The correct implant was able to be obtained in a timely manner.*

The possibility of marking errors:

> *The surgeon marked the patient's surgical site in preoperative [holding] immediately after checking the history and physical and the operative consent and confirming with the patient. Then, the surgeon marked the incorrect side. The patient then called the nurse over to the bedside and stated, "He marked the wrong side."*

> *The OR schedule stated a left-side hernia repair. All documentation and consent was for the right. The surgeon marked the left side in error. The RN [registered nurse] hand-off communication prevented error.*

It is notable that the patient did not tell the surgeon he was making an error but told the nurse afterward. A good handoff caught the other error.

The importance of including images in the verification process:

> *A patient was scheduled for a right carotid endarterectomy. The surgeon had marked the operative site, and all notes on chart, surgical schedule, and operative consent stated right carotid endarterectomy. The surgeon changed the side of surgery to left side after reviewing x-rays. . . . MD had new consent signed to reflect change.*

The possibility of errors with whiteboards:

> *[A patient] presented for a procedure on a foot. The greaseboard had the incorrect (left) side listed. Patient had surgery on the correct side.*

The importance of the time-out for catching errors:

> *A patient was scheduled through surgeon's office for right vitrectomy. During the time-out procedure, the patient stated he was to have surgery on the left eye.*

> *During the time-out process, the anesthesia provider/relief staff stated the wrong patient name for the intended procedure while looking at the anesthesia chart. The wrong name was discovered by the circulating nurse, and the time-out process and all activities stopped. It was determined the wrong patient was charted on from the beginning of the case by anesthesia provider. . . . The correct patient chart was opened by anesthesia, and we proceeded with the time-out, with all in agreement that we had the correct*

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

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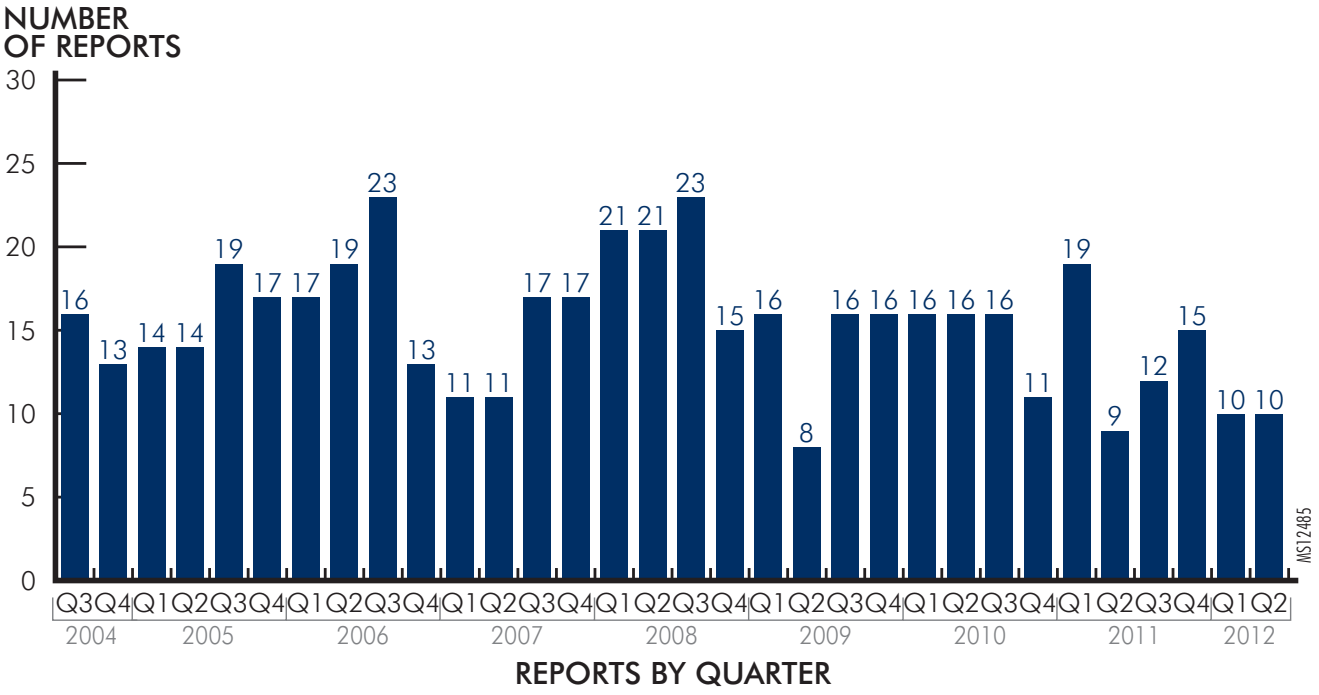
Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter



> *patient and procedure. . . . No harm to patient.*

The possibility of errors from specimen labeling:

> *[A breast] specimen label was incorrectly labeled with the wrong side. It was also entered into the computer incorrectly, with the left side [listed] when it was the right breast mastectomy. The error was corrected before taking the specimen [to pathology].*

Comments on the Pennsylvania Patient Safety Authority's Recommendations to Prevent Wrong-Site Surgery have been received from medical professional societies in Pennsylvania and from Pennsylvania facilities that do surgery. Those comments, with analyses and responses, will be published in a forthcoming supplementary *Pennsylvania Patient Safety Advisory*.

Corrections

The following corrections have been made to the respective articles. The editor regrets the errors.

Arnold TV, Barger DM. Falls rates improved in southeastern Pennsylvania: the impact of a regional initiative to standardize falls reporting. Pa Patient Saf Advis [online] 2012 Jun [cited 2012 Jul 3]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Jun;9(2)/Pages/37.aspx. *The article contained statements in error. The data analysis should have indicated that during the initiative, two hospitals within the same health system jointly reported falls events. The two hospitals were represented as one for the duration of the initiative, and as a result, the falls rates were revised to reflect patient-days from both facilities.*

Clarke JR. Quarterly update on preventing wrong-site surgery. Pa Patient Saf Advis [online] 2012 Jun [cited 2012 Jul 3]. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Jun;9(2)/Pages/69.aspx. *The article contained inaccurate information. The Pennsylvania Patient Safety Authority received corrected information from the Pennsylvania Health Care Cost Containment Council about the number of procedures done in Pennsylvania hospitals and ambulatory surgical facilities from July 1, 2007, through June 30, 2011. As a result of this new information, the rates for wrong-site surgery were updated.*

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