

PENNSYLVANIA PATIENT SAFETY ADVISORY



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Patient Safety Authority

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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 problems in which urgent communication of information could have a significant impact on patient outcomes.

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Delirium: Patient Safety Event Reporting and Strategies to Improve Diagnosis, Prevention, and Treatment

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ABSTRACT

The Pennsylvania Patient Safety Authority has seen an increase in the number of delirium-associated patient safety events reported through the Pennsylvania Patient Safety Reporting System over the past decade, with 446 events reported from acute care facilities between January 2005 and December 2014. Of these, 14.3% (n = 64) were identified as Serious Events resulting in patient harm. Predisposing factors for delirium identified in the reports included age 65 or older, male gender, preexisting cognitive impairment, depression, and severe illness. Categories of potential precipitating risk factors for delirium identified in the reports were intercurrent illness or other physiologic cause, specific medications, environmental factors, and surgery or procedures requiring sedation. Evidence-based guidelines and risk reduction strategies are available to assist healthcare providers to diagnose, prevent, and treat delirium. Implementation of these guidelines and strategies has the potential to improve clinical outcomes and decrease harm for patients at risk for developing delirium. (Pa Patient Saf Advis 2015 Sep;12[3]:85-95.)

INTRODUCTION

Delirium is a potentially preventable condition that has been associated with patient harm, up to and including death.^{1,2} Despite occurring frequently in hospitalized patients, delirium often goes undetected or misdiagnosed, particularly among older patients in whom delirium can be mistaken for dementia. While delirium may be superimposed on dementia, the two conditions are distinct.

Dementia is a chronic condition characterized by progressive decline in several areas of cognitive function, while delirium is a temporary confusional state characterized by sudden onset, a fluctuating course, and difficulty sustaining attention.^{3,5} These symptoms may also be accompanied by an altered level of consciousness.^{3,4} Three delirium subtypes have been recognized based on the level of psychomotor agitation displayed by patients: hyperactive, hypoactive, and mixed.^{3,4,6} All three types can be associated with hallucinations and delusions, though these perceptual disturbances are more prevalent with hyperactive delirium.⁷

Delirium incidence varies widely, ranging from 15%⁸ to 56%³ of hospitalized older adults, depending on variables such as age, comorbidities, care setting, and diagnostic criteria.⁸⁻¹² This rate can reach as high as 75%¹³ for critically ill patients of all ages and 85%¹⁴ for older adults receiving end-of-life care. Researchers have identified two categories of risk factors influencing the development of delirium: predisposing factors (i.e., chronic risk factors that make a person vulnerable to delirium) and precipitating factors (i.e., acute insults that can trigger the onset of delirium). Of special concern, in patients with multiple predisposing factors, fewer or less severe precipitating factors are necessary to trigger the onset of delirium.¹⁵

The two predisposing factors associated with the highest risk of developing delirium during hospitalization are age 65 or older and preexisting cognitive impairment, particularly in the postoperative, intensive care, and palliative care settings. Other predisposing risk factors include depression, severe or terminal illness, metabolic derangements, prior stroke, poor functional status, decreased oral intake, sensory impairments, history of alcohol abuse, and male gender.⁶

Precipitating factors for delirium can be organized into four categories: (1) specific medications (e.g., sedatives, narcotics, anticholinergic drugs), (2) intercurrent illness or other physiologic cause (e.g., stroke, infection, substance withdrawal), (3) surgery or procedures requiring sedation, and (4) environmental factors (e.g., sleep deprivation, use of restraints, presence of medical device attachments such as intravenous or urinary catheters, intensive care unit [ICU] setting).^{4,6}

Multiple serious outcomes have been associated with delirium, including increased morbidity, length of hospital stay, healthcare costs, institutionalization, and mortality.^{1,2} The risk for poor outcomes is increased when delirium goes undetected and untreated, which is estimated to occur in one-third to one-half of all cases, especially in cases of hypoactive delirium.^{10,16} Once thought to be a transient condition without long-term adverse effects, it is now recognized that even a single episode of in-hospital delirium can be associated with persistent cognitive impairment, functional decline, and increased risk of death up to a year following hospital discharge.^{1,2}

Pennsylvania Patient Safety Authority analysts reviewed delirium-associated patient safety events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS). Analysts reading event reports were able to identify the event types, levels of harm, predisposing risk factors, and potential precipitating factors most commonly reported. Analysts also conducted a literature search to gather evidence-based



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guidelines and risk reduction strategies available to assist healthcare providers to diagnose, prevent, and treat delirium.

METHODS

Analysts queried the PA-PSRS database for events containing the terms “delirium” or “delirious” (including misspellings) that were reported over a 10-year period, from January 2005 through December 2014. These reports were then analyzed individually to identify events involving patients experiencing delirium. Reports containing the search terms without evidence of delirium occurring during the current hospitalization, or relevance to the event being reported, were excluded (e.g., a patient was administered psychotropic medication in error and was monitored for signs of delirium but remained cognitively intact; delirium assessments were not documented over several days in the ICU; a family member mentioned that a patient developed delirium due to morphine during a prior hospitalization). The remaining reports were analyzed

according to submission date, event type, harm score, care area, and patient age. In addition, qualitative analysis was performed to identify predisposing risk factors and potential precipitating factors described in the event report narratives.

RESULTS

Analysts identified 476 events reported through PA-PSRS between January 2005 and December 2014 that contained the terms “delirium” or “delirious” (including misspellings). Of these, 446 events involving patients experiencing delirium were identified for further analysis.

Submission Date, Event Type, and Harm Score

Reports through PA-PSRS for events involving patients with delirium have increased over time, with an average of 16.3 events reported per quarter in 2014, compared with 2.5 per quarter in 2005 (see Figure 1). Of the 446 total delirium-associated events reported over this

10-year period, falls were the most commonly reported PA-PSRS event type (n = 158, 35.4%), followed by adverse drug events (n = 71, 15.9%). See Table 1 for a full list of delirium-associated PA-PSRS event types.

The majority of delirium-associated patient safety events were reported as Incidents without harm to patients (n = 382, 85.7%), with the remainder reported as Serious Events resulting in patient harm (n = 64, 14.3%).

Care Area and Patient Age

Delirium-associated events were reported in all facility care areas, with nearly half of all events (n = 222, 49.8%) reported from general care areas. Table 2 displays the number and percentage of delirium-associated patient safety events reported from each care area.

Nearly two-thirds of delirium-associated events were reported for patients age 60 or older (n = 294, 65.9%), though events were reported involving patients as young

Figure 1. Delirium-Associated Events Reported through the Pennsylvania Patient Safety Reporting System, by Quarter, 2005 through 2014



Note: The dotted line is the linear trend line of reports by quarter.

Table 1. Delirium-Associated Events Reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), by Event Type,* 2005 through 2014

PA-PSRS EVENT TYPE	NO. (%)
Fall	158 (35.4)
Adverse drug reaction (not a medication error)	71 (15.9)
Complication of procedure/treatment/test	65 (14.6)
Other/miscellaneous	65 (14.6)
Error related to procedure/treatment/test	32 (7.2)
Skin integrity	28 (6.3)
Medication error	24 (5.4)
Equipment/supplies/devices	2 (0.4)
Transfusion	1 (0.2)
Total	446 (100.0)

* Event types are defined by PA-PSRS taxonomy and are assigned to events by healthcare facilities at the time of report submission.

Table 2. Delirium-Associated Events Reported through the Pennsylvania Patient Safety Reporting System, by Care Area, 2005 through 2014

CARE AREA	NO. (%)
General care (includes medical, surgical, telemetry, oncology, pediatric, transitional, and hospice inpatient units)	222 (49.8)
Psychiatric and chemical dependency (includes adult, geriatric, adolescent, and child psychiatric units and chemical dependency inpatient units)	55 (12.3)
Intensive care (includes medical, surgical, cardiac, transplant, and trauma critical care units)	52 (11.7)
Rehabilitation and long-term care	22 (4.9)
Emergency and trauma	21 (4.7)
Intermediate care	20 (4.5)
Operating room and perioperative (includes ambulatory surgical units and preoperative, operative, and postoperative care areas)	20 (4.5)
Diagnostic testing and procedural	18 (4.0)
Nonclinical, administrative, and other	12 (2.7)
Outpatient clinics	4 (0.9)
Total	446 (100.0)

as under one year of age. Figure 2 shows the age distribution for these events in 10-year increments.

Predisposing Risk Factors

Male gender and age 65 or older were the most prevalent predisposing risk factors for delirium identified in reports of delirium-associated patient safety events, represented in 57.0% (n = 254) and 54.3% (n = 242) of total reports, respectively. Information gathered from event report narratives identified cognitive impairment as a potential predisposing factor in 14.3% (n = 64) of reports and depression in 10.8% (n = 48) of reports. Age 65 or older combined with cognitive impairment was identified in 10.5% (n = 47) of reports. Severe illness, as a predisposing factor, was assessed indirectly through the care area type, with 11.7% (n = 52) of events reported for patients receiving care in ICUs.

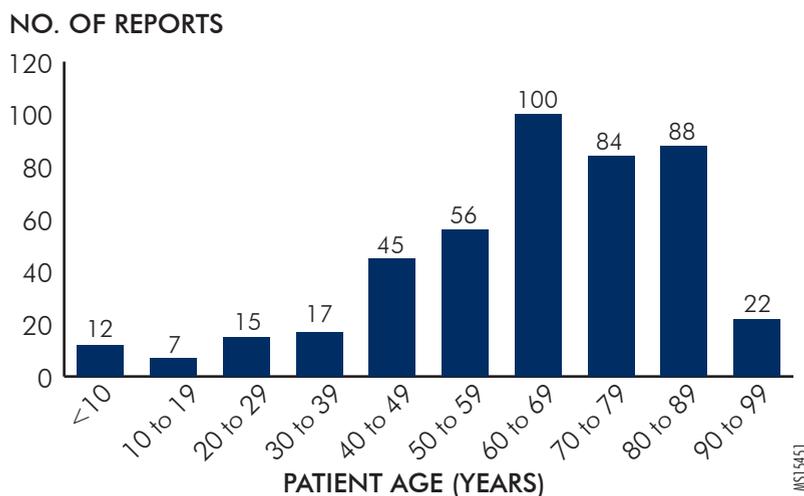
Potential Precipitating Factors

Intercurrent illness or other physiologic cause was the most prevalent category of potential precipitating factors for delirium identified in report narratives (n = 204, 45.7%), followed by specific medications (n = 131, 29.4%), environmental factors (n = 102, 22.9%), and surgery or procedures requiring sedation (n = 48, 10.8%).

Half of all reports contained information that identified a single potential precipitating factor (n = 225, 50.4%), nearly one-third identified multiple factors (n = 145, 32.5%), and the remainder did not mention any precipitating factors (n = 76, 17.0%).

Figure 3 shows the top specific factors mentioned in PA-PSRS event report narratives for each category of potential precipitating factors for delirium. For a full list of the potential precipitating factors identified in the PA-PSRS delirium-associated patient safety event reports, see Table 3, exclusively available with the online version of the article

Figure 2. Delirium-Associated Events Reported through the Pennsylvania Patient Safety Reporting System, by Patient Age Group, 2005 through 2014 (N = 446)



at [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/Sep;12\(3\)/Pages/home.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/Sep;12(3)/Pages/home.aspx).

PA-PSRS Event Reports

Analysts reviewing PA-PSRS reports have identified the occurrence of delirium, in and of itself, as the adverse event that is being reported. But in many cases, delirium is reported together with a secondary adverse event (e.g., patient fall, inappropriate removal of medical equipment). While the majority of events were reported as Incidents, some deidentified examples of Serious Events are as follows:

- Falls resulting in fracture, intracranial bleeding, and/or death
- Death following failure to recognize an arrhythmia due to patient removal of cardiac monitoring leads
- Deep-vein thrombosis associated with use of an intravenous catheter in a patient arm that was restrained or covered with a tubular bandage (presumably to camouflage the

catheter and/or prevent the patient from removing it)

The following are examples of delirium-associated patient safety events reported to PA-PSRS.* In each of these reports, predisposing and potential precipitating factors were identified from information contained in the event narratives.

Delirium during an intravascular procedure requiring emergency surgery. This report mentions two predisposing factors (i.e., 65 or older and male gender) and potential precipitating factors in two categories—intercurrent illness or other physiologic cause (i.e., coronary occlusion) and surgery or procedures requiring sedation (i.e., percutaneous coronary intervention).

This [>70-year-old male] patient was transferred from another facility for emergency percutaneous coronary intervention due to an acutely

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

occluded coronary artery. During the procedure in the cath lab, the patient experienced acute delirium from an indeterminate cause. The patient unexpectedly attempted to get off the bed while the catheter was in the aorta. Due to this unexpected movement, the groin sheath became dislodged and caused vascular injury to the common femoral artery, aorta, and right ventricle. The patient underwent emergency coronary artery bypass grafting, as well as repair of the femoral artery and aorta.

Undiagnosed sepsis in a behavioral health patient. This report mentions two predisposing factors (i.e., age 65 or older and male gender) and potential precipitating factors in three categories—intercurrent illness or other physiologic cause (i.e., sepsis), specific medications (i.e., benzodiazepine and antipsychotic medication), and environmental factors (i.e., sleep deprivation).

A [>65-year-old male] was admitted to the behavioral health unit with an elevated temperature, anxiety, restlessness, and fluctuating orientation. He was on 1:1 observation for safety, and his condition progressively worsened with near delirium symptoms and insomnia, and lorazepam and haloperidol [were not effective]. During morning care, the patient was noted to become increasingly short of breath, with cyanotic lips and diaphoresis. His temperature rose to more than 103 with an elevated blood pressure and heart rate. An emergency code was called, and the patient was transferred to the intensive care unit with a diagnosis of sepsis.

Postoperative delirium in an ICU patient.

This report mentions one predisposing factor (i.e., age 65 or older) and potential precipitating factors in three categories—surgery or procedures requiring sedation (i.e., the patient was recovering from an

unspecified surgery), specific medications (i.e., opioid and anticholinergic medication), and environmental factors (i.e., ICU setting).

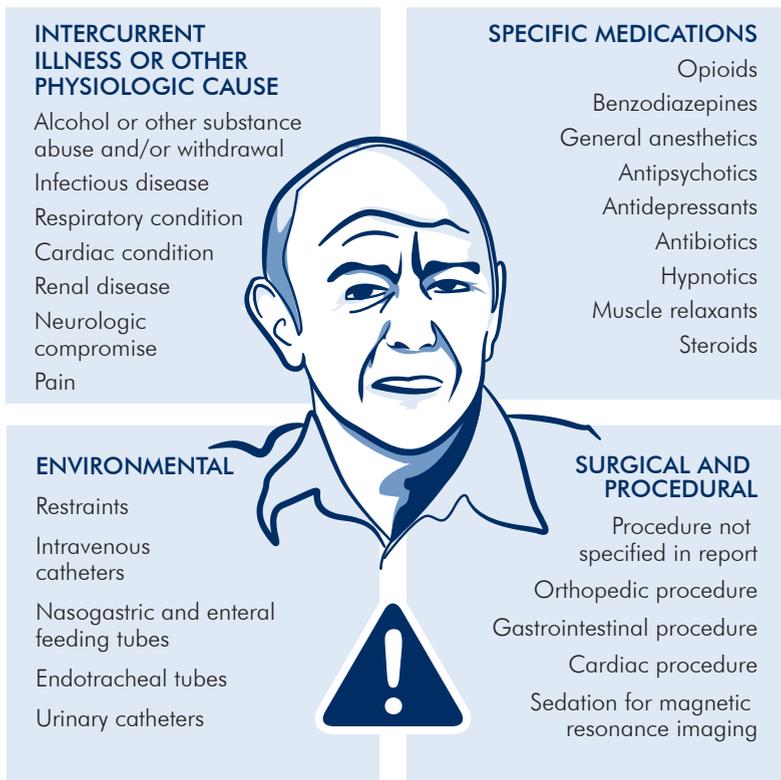
Delirium, disorientation, and confusion were identified postoperatively in a [>75-year-old female] with previous sensitivity to opioids that was undocumented in the electronic health record side effect profile prior to the current reaction. This reaction could have been precipitated and/or continued due to morphine, fentanyl, oxybutynin, and/or rocuronium administration. Other contributing factors were the patient's age and ICU stay. All suspect medications were discontinued, and low-dose intravenous haloperidol every eight hours was initiated. The patient's confusion slowly decreased, and she was back to baseline seven days later.

Postprocedural delirium. This report mentions one predisposing factor (i.e., age 65 or older) and one potential precipitating factor in the category of surgery or procedures requiring sedation (i.e., the patient underwent a computed tomography angiogram).

The emergency response team was called for tachycardia and altered mental status in an [>80-year-old male] patient following a computed tomography angiogram. On exam, the patient was awake, following commands, and oriented to place but disoriented to time and person. There was no focal motor weakness or sensory change. His heart rate was in the 120s with sinus rhythm, blood pressure was 165/83, and oxygen saturation was 95% on 2 liters of oxygen. The patient was transferred to the intensive care unit for evaluation of tachycardia and delirium.

Repeated removal of feeding tube by a delirious patient. The following two event reports involve the same patient.

Figure 3. Top Potential Precipitating Risk Factors for Delirium, by Category, as Identified in Delirium-Associated Events Reported through the Pennsylvania Patient Safety Reporting System, 2005 through 2014



Note: Potential precipitating factors were identified as a result of qualitative analysis of event report narratives and are listed in order of frequency, beginning with the most frequently reported in each category. Please see Table 3 (exclusively available with the online version of the article) to view a complete list of potential precipitating factors and the numbers of event reports that mention each specific factor.

No predisposing factors are mentioned, and the only potential precipitating factor mentioned is in the category of environmental factors (i.e., presence of a medical device attachment). These reports highlight the fluctuating nature of delirium.

The patient is a [>60-year-old female] found with her small bore nasogastric feeding tube pulled out and lying on the bed beside the patient. At last nursing assessment, two hours prior, the tube was in place and secured

to the nose and cheek. The patient had pulled this tube out earlier, but at assessment she was alert and oriented, and the delirium screen was negative.

Patient found again with the feeding tube out and the oxygen tubing and collar removed from the tracheostomy. The patient is still alert and oriented times 3 with a negative delirium screen. She was unable to explain why the tube was pulled out again.

Lack of consensus regarding delirium diagnosis. The following report does not mention any predisposing factors and only mentions one potential precipitating factor in the category of intercurrent illness or other physiologic cause (i.e., withdrawal). This report highlights the challenge faced in accurately screening for and identifying delirium, and it supports the need for an evidence-based, uniform approach to diagnosis.

All day, this [>50-year-old male] patient was trying to leave and had been talked out of it. Psychiatry saw the patient earlier and felt that the patient was suffering from delirium due to detox, but [psychiatry] was not willing to involuntarily commit him. The physicians and nurses thought that he was alert, oriented, and knew what he was doing. The patient demanded to leave, and the attending could not convince him to stay. He signed out against medical advice and was given his belongings. The sitter wheeled him to the front door because the patient said he called a cab. The administrator on duty that night got a call from the wife asking why he was home, because the psychiatric nurse had said we should not discharge him under any circumstances.

DISCUSSION

The Authority has seen a nearly seven-fold increase in the number of delirium-associated patient safety events reported over the past decade (see Figure 1). This increase should not be inferred to represent an increase in the incidence of such events. While this may be the case, the increase may also be the result of heightened awareness and improved recognition of delirium. This increase in the number of delirium-associated patient safety events reported to the Authority occurred at the same time that delirium received increased attention in clinical, healthcare services research, and patient safety circles. As evidence of this increased

attention, the amount of scientific literature published each year on the topic of delirium has been steadily increasing over the past decade, with just 834 documents published in 2005 compared with 1,427 in 2014, according to a query of Scopus.¹⁷

During this same time period, delirium has received increased attention as a potentially preventable hospital-acquired condition. In 2008, the Centers for Medicare and Medicaid Services included delirium in the list of hospital-acquired conditions subject to nonpayment as part of the proposed changes to the inpatient prospective payment system;¹⁸ however, this was removed from the final rule during the public comment phase. While recognized as a hospital-acquired condition, it was not included in the list of conditions subject to nonpayment for three chief reasons: (1) evidence exists that delirium prevention protocols can only prevent 30 to 40% of all delirium cases; (2) there can be difficulty defining, diagnosing, and differentiating delirium from other conditions; (3) and delirium may be caused by many factors unrelated to clinical care of the patient.¹⁹

PA-PSRS Reports: Limitations and Key Findings

Because of challenges in screening for and accurately diagnosing delirium, the Authority recognizes that the reports identified in the current analysis most likely underrepresent the actual number of events occurring that involve patients experiencing delirium, particularly in the early years of the reporting program. Also, identification of predisposing risk factors (other than gender and age) and potential precipitating risk factors is limited to those described in the event narratives provided by reporters. Additional factors associated with these events may have been unaccounted for in the reports. For instance, in a report of postoperative delirium, anesthesia may have also been a precipitating factor; however, if anesthesia was not explicitly mentioned in the event report,

only the surgical procedure itself could be identified as a precipitating risk factor. Despite these limitations, it is interesting to note that information contained in these reports is congruent with what has been found in the delirium research.

Delirium is associated with increased morbidity and mortality.^{1,2,4} In the current analysis, 14.3% of delirium-associated patient safety events reported through PA-PSRS from 2005 through 2014 were reported as Serious Events with harm to patients. In contrast, only 3.5% (n = 76,807 of 2,199,605) of all events reported by acute care facilities during the same 10-year time period represented Serious Events.²⁰

The development of delirium is associated with predisposing and precipitating risk factors, and the etiology of delirium is often multifactorial.^{4,6,15} Predisposing and potential precipitating risk factors identified in PA-PSRS reports of delirium-associated patient safety events are in agreement with those found in the literature. Age 65 or older and male gender are predisposing factors identified in over 50% of reports. Cognitive impairment, depression, and severe illness are also mentioned in the reports. Of note, age and gender are required data entry fields in PA-PSRS, while information about other predisposing factors can only be gleaned from information submitted in the free-text event description. Other predisposing factors may have been present in a higher number of events but not mentioned in the detailed event description.

Nearly a third of the reports of delirium-associated events mentioned multiple potential precipitating factors. Information about potential precipitating factors can only be gleaned from information submitted in the free-text event description. These precipitating factors are labeled as “potential” due to the fact that the reports do not definitively identify them as causing the delirium.

Reducing Delirium in the Hospital Setting

Systematic review of studies evaluating the effectiveness of delirium prevention interventions suggests that staff education and multicomponent strategies to prevent or treat delirium in hospitalized patients are generally effective.²¹

Reducing delirium in older adults. One multicomponent delirium prevention program that has been well-studied and proven to be effective is the Hospital Elder Life Program (HELP). The Yale Delirium Prevention Trial evaluated the effectiveness of HELP and found it significantly reduced the number and duration of delirium episodes in older adults. HELP interventions are delivered by a specially trained interdisciplinary team that consists of a geriatric nurse specialist and an elder life specialist and may include a geriatrician, recreation therapists, physical therapists, and volunteers.²² Interventions provided by this team target six predisposing or precipitating factors for delirium that are amenable to intervention in the hospital setting: cognitive impairment, sleep deprivation, immobility, visual impairment, hearing impairment, and dehydration. More information about the program can be found on the HELP website at <http://www.hospitalelderlifeprogram.org>.

Reducing delirium in the ICU. The American College of Critical Care Medicine published guidelines in 2013 for the management of pain, agitation, and delirium (PAD) in adult ICU patients. These guidelines were an update and revision to the 2002 *Clinical Practice Guidelines for the Sustained Use of Sedatives and Analgesics in the Critically Ill Adult*. The goal of the guidelines is to provide a road map for evidence-based best practices, including nonpharmacologic and pharmacologic interventions targeted to reducing all three conditions.²³

The delirium guideline suggests specific screening tools (i.e., the Confusion

Assessment Method for the ICU (CAM-ICU) or the Intensive Care Delirium Screening Checklist), nonpharmacologic interventions (e.g., early mobilization, sleep promotion), and pharmacologic interventions (e.g., administering dexmedetomidine rather than benzodiazepines for sedation in adult ICU patients with delirium unrelated to alcohol or benzodiazepine withdrawal). The guideline also suggests that the most effective method for implementing these practices is through incorporating the PAD guidelines into an institution-specific protocol, to be delivered by an interdisciplinary team.²³

Reducing postoperative delirium in older surgical patients. The *Clinical Practice Guideline for Postoperative Delirium in Older Adults* was published by the American Geriatrics Society in October 2014. This guideline is specific to patients age 65 or older and provides recommendations for nonpharmacologic and pharmacologic interventions to prevent and treat delirium in the perioperative setting. The interventions unique to this guideline include using regional anesthesia rather than general anesthesia (though the level of evidence was acknowledged to be low for this intervention); optimizing postoperative pain control, preferably with nonopioid pain medications; and avoiding medications postoperatively that are known to be precipitating factors for delirium, especially cholinesterase inhibitors and benzodiazepines. Similar to guidelines for the prevention and treatment of delirium in the general patient population, this guideline emphasizes the importance of developing a multicomponent, nonpharmacologic prevention plan delivered by an interdisciplinary team and providing ongoing delirium educational programs for healthcare professionals.²⁴

RISK REDUCTION STRATEGIES

The following strategies may be useful to healthcare facilities seeking to improve the diagnosis, prevention, and treatment of delirium.

Diagnosis

- Assess all patients for predisposing factors for delirium upon admission, in particular those age 65 or older and those with cognitive impairment or severe illness.²⁵
- Establish baseline cognitive status in patients with preexisting cognitive impairment or those at high risk for delirium by obtaining a detailed history from the patient's family member or caregiver.^{4,6}
- Use assessment tools such as the Mini-Mental State Exam or Clock Drawing Test to establish baseline cognitive function and assess for changes as indicated.^{4,6,26}
- Monitor at-risk patients for the following signs and symptoms of delirium:^{4,6}
 - Acute change in cognitive function
 - Inability to establish, sustain, or shift attention
 - Disorganized thinking, as manifested by rambling or incoherent speech, disorientation, or problems with memory
 - Altered level of consciousness, ranging from agitated and hypervigilant to lethargic and stuporous
 - Psychomotor agitation or retardation, hallucinations, delusions, emotional lability, and sleep-wake cycle disturbances
- Consider screening at-risk patients using a validated tool, such as the Confusion Assessment Method (CAM) tool or the CAM-ICU (designed to be used with critically ill, intubated, and/or nonverbal patients).^{4,6,21,23,26-28}

Prevention

- Implement a multicomponent delirium prevention plan tailored to each patient's identified predisposing risk



- factors and potential precipitating factors.^{22,25}
- Consult a geriatric specialist for older adults, especially those who are frail, have multiple comorbidities, or are on multiple medications.^{4,22,25,29}
- Involve the multidisciplinary team in the delirium prevention program.^{22,23,25}
- Maintain continuity in caregivers, and avoid moving the patient to different locations when possible.²⁵
- Promote orientation by providing a calendar and a clock and explaining to the patient where he or she is, why he or she is there, who each staff member is, and what the role of each staff member is.^{22,25}
- Encourage visitation from family, friends, and people familiar to the patient.²⁵
- Provide cognitively stimulating activities, such as reminiscence.^{22,25}
- Prevent dehydration and/or constipation, and promote good nutrition by encouraging adequate intake of food and fluids.^{22,25}
- Treat intercurrent illness and physiologic conditions known to be precipitating factors for delirium, such as hypoxia, infection, pain, and alcohol or other substance withdrawal.^{23,25}
- Conduct a medication review, and adjust the patient’s medication regimen to decrease or eliminate polypharmacy and deliriogenic medications.²⁵
- Provide hearing and vision aids to correct for sensory impairments.^{22,25}

- Provide an environment conducive to sleep, and promote good sleep habits.^{22,23,25}
- Promote mobilization through ambulation or active range of motion regularly throughout the day.^{22,23}

Treatment

All of the interventions listed as risk reduction strategies for the prevention of delirium are also applicable to the treatment of delirium. In addition, the following strategies may be considered:

- Enlist the help of a healthcare professional who is trained and competent in the diagnosis and treatment of delirium whenever possible.²⁵ For older adults, consultation with a team of geriatric specialists has been proven to be effective.²² For younger adults with extreme agitation or life-threatening behavioral disorders, a psychiatric consultation is recommended.⁴
- Identify and treat the underlying cause for the delirium (e.g., treat underlying infection, adjust medication regimen to avoid culprit drugs).²⁵
- Attempt de-escalation with verbal and nonverbal techniques in patients exhibiting psychomotor agitation and distress.²⁵
- Avoid restraint use. Consider the use of restraints only in patients who are violent and at risk of harming themselves or others, or in those who may be at risk for removing important devices necessary for care, especially in the ICU setting (e.g., endotracheal tubes, arterial lines).⁴

- Consider short-term use of haloperidol (less than one week) *only in distressed patients* who do not respond to nonpharmacologic intervention. Start with a low dose and titrate up slowly, especially in older adults.^{4,25} Obtain a baseline electrocardiogram and monitor for prolongation of the corrected QT interval during treatment. Provide continuous cardiac monitoring for patients receiving intravenous haloperidol.³⁰
- Avoid the use of antipsychotic drugs in patients with Parkinson disease or Lewy body dementia.^{4,25}
- Assess the medical, cognitive, and functional status of delirious patients regularly until a return to baseline is observed.^{4,23}
- Consider a comprehensive geriatrics assessment or neuropsychological testing in patients whose cognitive and functional statuses do not return to baseline within one to two months of an episode of delirium.⁴

CONCLUSION

Delirium is a common syndrome in hospitalized adults, particularly those age 65 or older, and has been recognized as a hospital-acquired condition that can result in serious harm to patients. Risk for developing delirium is influenced by predisposing and precipitating factors, many of which are modifiable. Hospitals are encouraged to implement an interdisciplinary, multicomponent delirium prevention plan targeted to these contributing factors to improve clinical outcomes and decrease harm.

NOTES

1. Cole MG, Ciampi A, Belzile E, et al. Persistent delirium in older hospital patients: a systematic review of frequency and prognosis. *Age Ageing* 2009 Jan;38(1):19-26.
2. Witlox J, Eurelings LS, de Jonghe JF, et al. Delirium in elderly patients and the risk of postdischarge mortality, institutionalization, and dementia: a meta-analysis. *JAMA* 2010 Jul 28;304(4):443-51.
3. Inouye SK. Delirium in older persons. *N Engl J Med* 2006 Mar 16;354(11):1157-65.
4. Marcantonio ER. In the clinic: delirium. *Ann Intern Med* 2011 Jun 7;154(11):ITC6-1-ITC6-16.
5. Lyons DL, Grimley SM, Sydnor L. Double trouble: when delirium complicates dementia. *Nursing* 2008 Sep;38(9):48-54.
6. Ting Hshieh T, Inouye SK. Delirium. Chapter 21. In: Williams BA, Chang A, Ahalt C, et al., eds. *Current diagnosis and treatment: geriatrics*. 2nd ed. New York: McGraw-Hill; 2014.
7. Boettger S, Breitbart W. Phenomenology of the subtypes of delirium: phenomenological differences between hyperactive and hypoactive delirium. *Palliat Support Care* 2011 Jun;9(2):129-35.
8. Marcantonio ER, Goldman L, Mangione CM, et al. A clinical prediction rule for delirium after elective noncardiac surgery. *JAMA* 1994 Jan 12;271(2):134-9.
9. Marcantonio ER, Flacker JM, Wright RJ, et al. Reducing delirium after hip fracture: a randomized trial. *J Am Geriatr Soc* 2001 May;49(5):516-22.
10. Rudolph JL, Jones RN, Levkoff SE, et al. Derivation and validation of a preoperative prediction rule for delirium after cardiac surgery. *Circulation* 2009 Jan 20;119(2):229-36.
11. Ely EW, Shintani A, Truman B, et al. Delirium as a predictor of mortality in mechanically ventilated patients in the intensive care unit. *JAMA* 2004 Apr 14;291(14):1753-62.
12. Rudolph JS, Marcantonio ER. Postoperative delirium: acute change with long-term implications. *Anesth Analg* 2011 May;112(5):1202-11.
13. Ely EW, Shintani A, Truman B, et al. Delirium as a predictor of mortality in mechanically ventilated patients in the intensive care unit. *JAMA* 2004 Apr 14;291(14):1753-62.
14. Casarett DJ, Inouye SK; American College of Physicians-American Society of Internal Medicine End-of-Life Care Consensus Panel. Diagnosis and management of delirium near the end of life. *Ann Intern Med* 2001 Jul 3;135(1):32-40.
15. Inouye SK. Predisposing and precipitating factors for delirium in hospitalized older patients. *Dement Geriatr Cogn Disord* 1999 Sep-Oct;10(5):393-400.
16. Inouye SK, Foreman MD, Mion LC, et al. Nurses' recognition of delirium and its symptoms: comparison of nurse and researcher ratings. *Arch Intern Med* 2001 Nov 12;161(20):2467-73.
17. Scopus [database search]. [cited 2015 May 28]. Atlanta: Elsevier BV. <http://www.scopus.com/term/analyzer.url?sid=D6A2BA457F42166EBDF10583175D70BE.ZmAYsXCHIBxxTXbnsoe5w%3a290&origin=resultslist&src=s&s=TITLE-ABS-KEY%28delirium%29+AND+PUBYEAR+%3e+1999+AND+PUBYEAR+%3c+2015&sort=plf-f&sdt=b&sot=b&sl=61&count=14065&analyzeResults=Analyze+results&txGid=D6A2BA457F42166EBDF10583175D70BE.ZmAYsXCHIBxxTXbnsoe5w%3a35>
18. Centers for Medicare and Medicaid Services. Medicare program; proposed changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; proposed changes to disclosure of physician ownership in hospitals and physician self-referral rules; proposed collection of information regarding financial relationships between hospitals and physicians. *Fed Regist* 2008 Apr 30;73(84):23528-938. Also available at <http://www.gpo.gov/fdsys/pkg/FR-2008-04-30/pdf/08-1135.pdf>
19. Centers for Medicare and Medicaid Services. Medicare program; proposed changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; payments for graduate medical education in certain emergency situations; changes to disclosure of physician ownership in hospitals and physician self-referral rules; updates to the long-term care prospective payment system; updates to certain IPPS-excluded hospitals; and collection of information regarding financial relationships between hospitals. *Fed Regist* 2008 Aug 19;73(161):48434-9083. Also available at <http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf>
20. Pennsylvania Patient Safety Authority. [Annual reports, 2005 through 2014] [online]. [cited 2015 May 29]. <http://patientsafetyauthority.org/PatientSafetyAuthority/Pages/AnnualReports.aspx>
21. Greer N, Rossom R, Anderson P, et al. *Delirium: screening, prevention, and diagnosis—a systematic review of the evidence*. Washington (DC): US Department of Veterans Affairs; 2011 Sep.
22. Inouye SK, Bogardus ST Jr, Charpentier PA, et al. A multicomponent intervention to prevent delirium in hospitalized older patients. *N Engl J Med* 1999 Mar 4;340(9):669-76.
23. Barr J, Fraser GL, Puntillo K, et al. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit. *Crit Care Med* 2013 Jan;41(1):263-306.
24. American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults. American Geriatrics Society clinical practice guideline for postoperative delirium in older adults [online]. 2014 Oct 10 [cited 2015 Jun 5]. <http://geriatriccareonline.org/ProductAbstract/american-geriatrics-society-clinical-practice-guideline-for-postoperative-delirium-in-older-adults/CL018>
25. National Institute for Clinical Excellence. Delirium: diagnosis, prevention and management [online]. 2010 Jul [cited 2015 May 29]. <http://www.nice.org.uk/guidance/cg103/resources/guidance-delirium-pdf>
26. Registered Nurses Association of Ontario. Screening for delirium, dementia and depression in older adults [online]. 2003 Nov [cited 2015 May 29]. http://rnao.ca/sites/rnao-ca/files/Screening_for_Delirium_Dementia_and_Depression_in_the_Older_Adult.pdf
27. Inouye SK, van Dyck CH, Alessi CA, et al. Clarifying confusion: the confusion assessment method. A new method for detection of delirium. *Ann Intern Med* 1990 Dec 15;113(12):941-8.
28. Wong CL, Holroyd-Leduc J, Simel DL, et al. Does this patient have delirium? Value of bedside instruments. *JAMA* 2010 Aug 18;304(7):779-86.
29. Siddiqi N, Stockdale R, Britton AM, et al. Interventions for preventing delirium in hospitalised patients. *Cochrane Database Syst Rev* 2007 Apr 18;(2):CD005563.
30. Wenzel-Seifert K, Wittmann M, Haen E. QTc prolongation by psychotropic drugs and the risk of Torsade de Pointes. *Dtsch Arztebl Int* 2011 Oct;108(41):687-93.



LEARNING OBJECTIVES

- Recognize factors that influence the development of delirium.
- Recall the predominant event types and potential precipitating factors for delirium identified in events reported to the Pennsylvania Patient Safety Authority.
- Differentiate predisposing and potential precipitating factors for delirium.
- Distinguish between predisposing and potential precipitating factors that are more or less likely to be associated with delirium.
- Identify strategies to improve the diagnosis, prevention, and treatment of delirium.

SELF-ASSESSMENT QUESTIONS

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

1. Which of the following predisposing factors are associated with the highest risk for developing delirium during hospitalization?
 - a. Age 65 or older and depression
 - b. Male gender and history of alcohol abuse
 - c. Cognitive impairment and age 65 or older
 - d. Prior stroke and depression
2. Which of the following statements about delirium is not true?
 - a. Delirium has been associated with increased risk of death up to a year following hospital discharge.
 - b. Hallucinations and delusions are perceptual disturbances that are most prevalent in cases of hypoactive delirium.
 - c. Use of haloperidol is suggested only in distressed patients who do not respond to nonpharmacologic intervention.
 - d. In patients with multiple predisposing factors, fewer or less severe precipitating factors are necessary to trigger the onset of delirium.
3. Which of the following event types in Pennsylvania is most frequently reported for delirium-associated events?
 - a. Adverse drug reaction (not a medication error)
 - b. Complication of procedure/treatment/test
 - c. Medication error
 - d. Fall
4. The most prevalent category of potential precipitating factors for delirium identified in report narratives was _____.
 - a. surgery or procedures requiring sedation
 - b. intercurrent illness or other physiologic cause
 - c. specific medications
 - d. environmental factors
5. Which of the following scenarios describe a patient at *highest* risk for delirium?
 - a. A 45-year-old woman with a recent history of hospitalization for major depressive disorder is admitted for a total abdominal hysterectomy and will receive general anesthesia during the procedure.
 - b. A 60-year-old man with active alcohol abuse is hospitalized with pancreatitis and being treated prophylactically with oxazepam to prevent withdrawal symptoms.
 - c. A 70-year-old woman with diabetes and peripheral vascular disease is admitted for intravenous antibiotic treatment for cellulitis due to a cat scratch on her leg.
 - d. An 80-year-old man with vascular dementia due to multiple strokes is hospitalized for failure to thrive, dehydration, and evaluation for a possible small bowel obstruction.
6. All of the following are risk reduction strategies that a hospital can take to improve the diagnosis and prevention of delirium *except*:
 - a. Establish baseline cognitive status in patients with preexisting cognitive impairment or those at high risk for delirium by obtaining a detailed history from the patient's family member or caregiver.
 - b. Screen at-risk patients using a validated delirium screening tool, such as the Confusion Assessment Method (CAM) tool or the CAM for the intensive care unit (CAM-ICU).

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(continued from page 94)

- c. Limit the number of outside visitors for patients with hyperactive delirium in the intensive care unit
- d. Consult a geriatric specialist for older adults, especially those who are frail, have multiple comorbidities, or are on multiple medications.

Questions 7 and 8 refer to the following scenario:

You are the nurse caring for a 70-year-old man admitted to the hospital for cardiac bypass surgery. After five days in the critical care unit, the patient is being transferred to your telemetry unit. When receiving report from the critical care nurse, you learn that the patient has a preexisting diagnosis of mild cognitive impairment due to a traumatic brain injury from a motor vehicle accident 10 years ago and that he was placed in bilateral wrist restraints while intubated but that he has been out of restraints since being extubated early this morning and “has been very quiet all day.”

7. In the above scenario, which of the following describes predisposing factors that suggest this patient is at high risk for delirium?
 - a. Age 65 or older, male gender, and cognitive impairment
 - b. Age 65 or older, cardiac surgery, and critical care environment
 - c. Age 65 or older, restraint use, and cognitive impairment
 - d. Age 65 or older, restraint use, and cardiac surgery
8. In the above scenario, which of the following describes precipitating factors that suggest this patient is at high risk for delirium?
 - a. Age 65 or older, cardiac surgery, and critical care environment
 - b. Age 65 or older, restraint use, and cardiac surgery
 - c. Critical care environment, restraint use, and cardiac surgery
 - d. Critical care environment, restraint use, and cognitive impairment

Questions 9 refers to the following scenario:

After receiving the patient in your unit, you orient the patient to his room and complete a physical assessment. The patient is awake and oriented to person, place, and time. Before leaving the room, you assist him to sit in a chair and demonstrate the use of the call bell and the television remote. An hour later, the patient’s daughter arrives and comes to the nurses’ station to speak with you, saying, “Something just isn’t right with my dad. He is acting strange, and I found him with his call bell and television remote tangled up in his intravenous tubing.”

9. In the above scenario, which of the following best describes the appropriate immediate actions to be taken?
 - a. Untangle the patient’s intravenous tubing, obtain information from the daughter about the patient’s baseline cognitive status, screen him for delirium using the CAM tool, obtain a repeat set of vital signs, and notify the physician of the daughter’s concerns and your assessment findings.
 - b. Untangle the patient’s intravenous tubing, obtain a repeat set of vital signs, screen him for delirium using the CAM tool, and reassure the daughter that this is normal for older patients just coming out of critical care and that his mental status should clear up within the next 24 hours.
 - c. Screen for delirium using the CAM tool, notify the physician of the daughter’s concerns, and request an order for bilateral wrist restraints to prevent the patient from pulling at his intravenous tubing.
 - d. Obtain a repeat set of vital signs, screen for delirium using the CAM tool, move the patient to an observation room, notify the physician, and request an order for haloperidol in case the patient gets more confused overnight.



Medication Errors Affecting Pediatric Patients: Unique Challenges for This Special Population

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ABSTRACT

From January 2013 through October 2014, 4,065 medication errors involving pediatric patients and taking place in a general acute care hospital not specializing in pediatrics were reported to the Pennsylvania Patient Safety Authority. Almost 18% (n = 715, 17.8%) of the reported events reached the patient and either required additional monitoring to preclude harm or caused actual harm. These reports were analyzed to determine if the events involved unique challenges when providing medications to the pediatric patient as well as to classify the events by node, related processes, possible causes, and contributing factors. When looking at the age ranges of patients involved in events, 28.1% (n = 201) of the reports involved neonates and 60.2% (n = 431) involved patients younger than five years of age. While there were events that included unique challenges to providing medications to the pediatric patients, most events mentioned challenges similar to those encountered in providing medications to adults. Important risk reduction strategies include dispensing medications for individual patients in a patient-specific, ready-to-administer form whenever possible and ensuring ready access to appropriate and current clinical information about patients. (*Pa Patient Saf Advis* 2015 Sep;12[3]:96-102.)

INTRODUCTION

The pediatric patient population can be considered in the developmental subcategories of preterm neonates (less than 36 weeks' gestation), full-term neonates (birth to 30 days of age), infants (1 through 11 months of age), toddlers (1 through 4 years of age), children (5 through 11 years of age), and adolescents (12 through 17 years of age). These young patients have not only some unique diseases and medical conditions but also an increased risk of adverse drug events, for several reasons:

- Pharmacokinetic parameters are different at various developmental stages.^{1,4}
- Multiple calculations are needed to individualize doses on the basis of age, weight (mg/kg), or body surface area (mg/m²).¹
- Most medications used in the care of children are formulated and packaged primarily for adults. Therefore, extemporaneous preparation is common because of the lack of available dosage forms and concentrations for pediatric and neonatal patients.¹
- Precise dose measurement and appropriate drug delivery systems are necessary; many medication delivery systems are not designed for pediatric patients.¹
- Children, especially young, small, or sick children, are usually less able to physiologically tolerate a medication error because renal, immune, and hepatic functions are still maturing.⁵
- Many children, especially very young children, cannot communicate effectively to providers regarding adverse effects of medications.⁵
- There is a lack of published information and US Food and Drug Administration (FDA)-approved product labeling addressing the dosing, pharmacokinetics, safety, efficacy, and clinical use of some medications in pediatric patients.¹

In addition, a 100-fold difference can exist between a medication dosage for an adolescent and that for a preterm neonate. A pediatric dose could be one-tenth of an adult's dose but still be 10 times the appropriate dose for a preterm neonate. All of these challenges could easily contribute to medication errors in this population.

Pediatric inpatients may experience three times as many medication errors as adult inpatients, and these errors are frequently harmful.⁶ For children, 1% of all medication errors carry significant potential for harm, with 0.24% of errors causing actual harm.⁶ Takata et al. were the first to develop and evaluate a trigger tool to detect adverse drug events in an inpatient pediatric population, which identified an 11.1% rate of adverse drug events in pediatric patients.⁷ Their study also showed that 22% of those adverse drug events were preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively.

Stockwell et al. also developed and pilot-tested a trigger tool that would identify the most common causes of harm in pediatric inpatient environments; in evaluating 600 patient charts, 240 harmful events ("harms") were identified, resulting in a rate of 40 harms per 100 patients admitted and 54.9 harms per 1,000 patient-days across the six academic children's hospitals.⁸ At least one harm was identified in 146 patients (24.3% of patients). Of the 240 total events, 108 (45.0%) were assessed to have been potentially or definitely preventable.

The United States Pharmacopeial Convention's MEDMARX database showed that almost 2.5% of pediatric medication errors in 2006 and 2007 led to patient harm.⁹

The most common types of harmful medication errors were improper dose or quantity (37.5%), omission error (19.9%), unauthorized or wrong drug (13.7%), and prescribing error (9.4%).

The Joint Commission published a Sentinel Event Alert in 2008 to address the prevention of pediatric medication errors and noted that most healthcare settings are primarily built around the needs of adults.⁵ Many settings lack trained staff oriented to pediatric care, pediatric care protocols and safeguards, and/or up-to-date and easily accessible pediatric reference materials, especially with regard to medications. Emergency departments (ED) may be particularly risk-prone environments for children. Based on these concerns, as well as the aforementioned unique challenges of this population, this article specifically focuses on medication errors involving patients younger than 18 years of age that took place in general acute care hospitals not focused on pediatrics (i.e., pediatric hospitals were excluded) in Pennsylvania.

METHODS

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events reported to the Pennsylvania Patient Safety Authority from January 1, 2013, through October 31, 2014, in which the patient age was less than 18 years and the event took place in a general acute care hospital that does not specialize in pediatrics. The query yielded 4,065 medication error reports, which analysts reviewed and categorized by error according to interpretation of the event. If an event fit into more than one category, the analysts determined, when possible, the primary reason for the event, using only information provided within the report. Analysts also identified events involving high-alert medications, based on the *ISMP List of High-Alert Medications in Acute Care Settings*.¹⁰

RESULTS

Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index,¹¹ shows that 74.1% (n = 2,983 of 4,065) of the events reached the patient (harm score = C through I); almost 18% (n = 715, 17.8%) of the events were reported as harm score D or greater, which indicates that many pediatric patients required extra monitoring or intervention to preclude harm; and only 0.4% (n = 15) of the events resulted in patient harm (harm score = E through I). The distribution of harm scores reported by pediatric hospitals compared with general acute care hospitals is skewed toward higher, or more serious, harm scores in the general acute care hospitals (see Figure 1).

While review of any event involving a pediatric patient, including a near miss or close call, may provide clues to the multifactorial reasons why an error occurred, further analysis focused on those events

that required at least extra monitoring or intervention to preclude harm as well as those events that resulted in harm to the patient (events with harm scores of D through I, n = 715).

Overall, 54 unique care areas were associated with events that required extra monitoring or intervention or that resulted in harm involving the pediatric population. The most common units implicated in these events were neonatal intensive care units (21.2%, n = 152 event reports), pediatric units (15.9%, n = 114), and EDs (8.5%, n = 61). Intensive care unit settings accounted for 30.2% (n = 216) of the cited locations and 31.8% (n = 228) of the locations were not pediatric-specific care areas (e.g., ED, medical-surgical unit).

When looking at the age ranges of patients involved in events, 28.0% (n = 200) of the reports with harm scores of D through I involved neonates, and 60.1% (n = 430) involved patients younger than five years of age (see Figure 2).

Figure 1. Distribution of Harm Scores of Events Involving Pediatric Patients, January 2013 through October 2014, as Reported to the Pennsylvania Patient Safety Authority

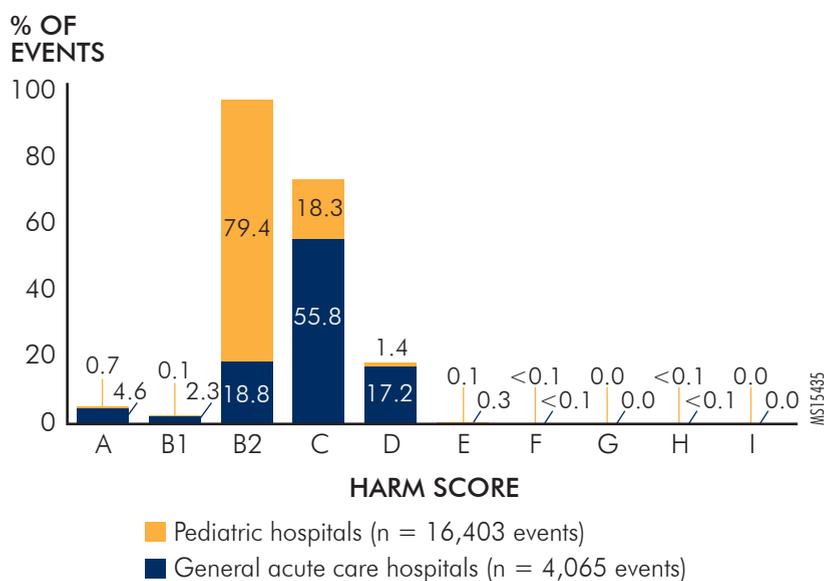
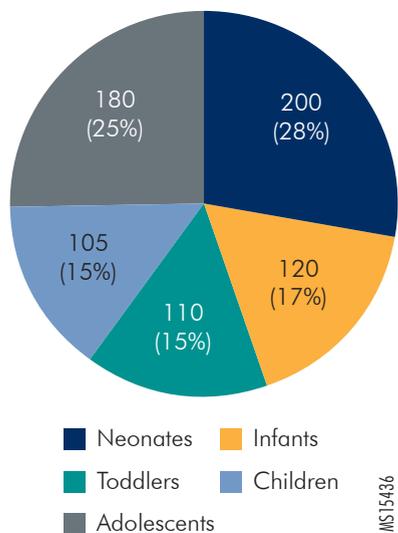


Figure 2. Medication Events with Harm Scores of D through I, by Pediatric Sub-population, January 2013 through October 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 715)



Note: Neonates (birth to 30 days of age), infants (1 through 11 months of age), toddlers (1 through 4 years of age), children (5 through 11 years of age), and adolescents (12 through 17 years of age)

The most common classes of medications cited were antibiotics (14.7%, n = 105), opioids, (8.1%, n = 58), intravenous (IV) fluids (5.9%, n = 42), and vaccines (4.7%, n = 34). Almost 25% (n = 176, 24.6%) of the reports involved at least one high-alert medication. Among reports involving high-alert medications, the three classes most commonly cited were opioids (e.g., morphine) (33.5%, n = 59), parenteral nutrition (22.7%, n = 40), and insulin (11.9%, n = 21); combined, these represented roughly 68% (n = 120) of the events involving a high-alert medication.

DISCUSSION

Wrong-Dose Scenarios

Based on the event types selected by reporting hospitals, more than half of all

reports with harm scores of D through I (51.7%, n = 370) involved patients receiving the wrong dose of a medication. Roughly 22% (n = 161) of the reports indicated that the patient received too much medication (i.e., wrong-dose/overdosage and extra-dose events), 16.3% (n = 117) stated that patients received an insufficient dose (i.e., drug omission and wrong-dose/underdosage events), and 12.8% (n = 92) involved wrong rates, wrong duration, or the wrong strength/concentration, which all could have resulted in either an over- or underdose of the drug. When analyzing the overdose events, analysts identified that 5.4% (n = 39 of 715) of the events resulted in patients receiving medication overdoses ranging from 2-fold to 100-fold in scale.

Following are examples of reports of multiple “fold” errors occurring during the administration process.*

During nursing report and the confirmation of drips, I noticed that the midazolam drip was running at an alarming rate of 1 mg/kg/hr for a total of 12.3 mg of midazolam per hour in a [less than 3 year old] patient. I asked the nurse if she indeed intended to run it at such a high rate and she confirmed. I then checked the order and it had been ordered as such. I immediately contacted the physician and informed him of the rate and he came to the room. The dose was decreased to 0.1 mg/kg/hr.

The prescriber was entering medication for conscious sedation for the procedure. He inadvertently entered into the computer 230 mg instead of 23 mg. The nurse prepared the medication and had it checked by another nurse. Neither nurse realized the dose was wrong. This medication is not used frequently in the ED. The medication was administered. After

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

the procedure, when it took longer for the patient to awaken from sedation, the error was discovered.

An infant was delivered and admitted to the ICN [intensive care nursery]. The infant was intubated and on a ventilator. The infant was administered a morphine sulfate infusion at the rate of 17 mL/hr instead of 0.17 mL/hr for approximately one and a half hours. The physician was notified, and the infant was monitored with every-five-minute vital signs and additional laboratory studies.

Non-Patient-Specific Dosage Forms

Healthcare professionals often cannot use a commercially available formulation to prepare and administer the appropriate medication dose for a pediatric patient.¹² For example, because small children cannot swallow tablets and capsules, suspension or solutions may need to be compounded or tablets may be crushed and capsules opened so they can be mixed with food (e.g., applesauce) or beverages (e.g., juice, formula). Such manipulation can not only cause solubility and bioavailability problems but can increase the potential for error. Analysis of reported events (n = 715) reveals that this specific situation was the most commonly (4.3%, n = 31) mentioned pediatric-specific problem.

Following are examples of reports of errors involving the provisions of non-patient-specific doses:

A [less than six months old] male was ordered morphine sulfate 0.24 mg oral solution (10 mg/5 mL) via a NGT [nasogastric tube] every six hours. The nurse gave 0.24 mL (0.48 mg) via NGT, a double dose. No adverse event to patient.

Nursing was about to give a dose of morphine and realized that the syringe pharmacy brought up was not

wasted to the appropriate dose. Nursing then realized that the previous dose that the patient received was an overdose. The syringe was never wasted prior to administration, as evidenced by looking back at the bag the medication came up in. It was assumed by nursing that pharmacy had already made the waste.

While there were some reports that mentioned the unique challenges associated with medication use with the pediatric population, most reports described scenarios similar to the normal challenges described in earlier *Pennsylvania Patient Safety Advisory* articles—for example, breakdowns associated with information about patients, mix-ups due to similar drug names or packaging, and errors associated with the use of IV pumps and IV lines.

Insufficient Patient-Specific Information

To guide appropriate drug therapy, practitioners can obtain pertinent demographic and clinical information, including the patient's name, age, weight, medical conditions, medication allergies, medication lists, and laboratory results, in order to select the appropriate medications, doses, and routes of administration as well as to monitor the effects of the medications.¹³ In a prospective cohort study of nonobstetric adult patients at two tertiary hospitals, which involved a systems analysis of events, inadequate availability of patient information was associated with 18% of events.¹⁴

Previous *Advisory* articles addressed issues associated with inaccurate patient information, including errors involving patient weights (e.g., mix-ups between pounds [lb] and kilograms [kg]),¹⁵ patients prescribed medications to which they were allergic,¹⁶ breakdowns obtaining accurate medication lists during reconciliation,¹⁷ and wrong-patient errors.¹⁸ From this analysis of events that required additional monitoring or caused harm, 9.4% (n = 67) of

reports mentioned a breakdown with information about the pediatric patient.

Following are examples of reports of errors associated with breakdowns with patient information:

Patient was ordered ibuprofen 10 mg/kg by mouth (PO). The patient weighs 23 lb (10.45 kg), and the dose of ibuprofen was calculated at 10 mg/lb, not 10 mg/kg. The patient was administered 230 mg of ibuprofen PO. Physician assistant and mother of patient notified immediately. Mother instructed not to give ibuprofen to child again for the next 24 hours.

A patient was given a prescription for amoxicillin 500 mg 1 tablet TID [three times a day] x 10 days. An allergy was listed in the computer for Augmentin® (amoxicillin/clavulanate potassium). The patient's parent called after discharge to advise [about the] rash and requested we add amoxicillin as an allergy.

Similar Medication Names and Similar Packaging

A similarity of characters in brand drug names, generic names, and brand-to-generic names can lead to confusion, with similar-sounding drug names adding to those problems. These similarities are compounded by practitioners attempting to keep up with the vast array of new products introduced to the marketplace, illegible handwriting, orally communicated prescriptions, similar labeling or packaging of medications, and proximity for look-alike names (e.g., ZyPREXA® [OLANzapine] and ZyrTEC® [cetirizine]) to one another in electronic order entry systems.¹⁹ In fact, research has identified that a frequent (29%) cause of pharmacy drug dispensing errors is failure to accurately identify drugs, usually due to confusion between look-alike or sound-alike drug names.¹⁴ Ambiguous and confusing packaging and labeling, either

due to similarity in the manufacturer's provided package or pharmacy-prepared package, significantly contribute to the risk of medication errors.²⁰

Analysis of events reported to the Authority involving the pediatric population with harm scores of D though I shows that 6.0% (n = 43) of reports specifically cite or allude to wrong-drug errors with similar naming or packaging contributing to the event. When looking specifically at errors involving vaccines (n = 35), over 33% (n = 12) of these events were categorized as wrong-drug errors.

Following are examples of reports of errors associated with similar medication names and packaging:

The patient was to be given 650 mg of Tylenol® (acetaminophen) but was erroneously given 10 mg of Haldol® (haloperidol). Provider was notified immediately and ordered a one-time dose of Cogentin® (benztropine) 1 mg, which was given right away. [The cause of the error cited in the actual report was similar package and labeling.]

The infant was ordered eyedrops—tropicamide and phenylephrine. I went into his medication basket and grabbed the two eyedrop containers. After “dropping the eyes,” I had discovered that I had grabbed and administered phenylephrine and atropine in error.

Patient ordered tetanus and diphtheria toxoids absorbed (Decavac®), but tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, absorbed (Boostrix®) was selected upon removal from the automated dispensing machine; the nurse documented that Boostrix was administered.

IV Pump and IV Line Mix-Ups

The most common issue mentioned in reports involving medication errors in the



pediatric population were those associated with the use of IV pumps and/or IV lines (11.9%, n = 85). Of the reports mentioning problems with the use of IV pumps (58.8%, n = 50 of 85), including programming wrong rates, inappropriately turning pumps off, or not turning pumps back on, 44.0% of those reports (n = 22 of 50) specifically described drug overdoses or infusions that were infused at significantly faster rates. The remaining 41.2% (n = 35 of 85) of reports mentioned errors with IV lines, with 40.0% (n = 14) of these reports specifically describing mix-ups between IV lines, including mistaking infusion lines for mother/infant pairs of patients. An analysis of non-age-specific medication errors associated with IV lines, published in the March 2014 issue of the *Advisory*, revealed similar issues involving IV lines, including rate-of-infusion mix-ups and line mix-ups (22.6%).²¹

Following are examples of reports of errors associated with use of IV pumps and IV lines:

Hyperalimentation was ordered to run at 3.8 mL/hr. The patient's pump read 83 mL [had] infused. One hour later, their pump alarmed because the "Volume to Be Infused" had been infused. The nurse read the pump and it read "Volume Infused 122 mL," meaning that 39 mL had infused. The rate was set at 38 mL/hr, not 3.8 mL/hr. Reported incident to the doctors, and repeat glucose was 474 mg/dL.

A 31-year-old female post-Cesarean section requested IV ketorolac for pain. Dose ordered was 30 mg IV. Ketorolac syringe was inadvertently connected to infant's IV while patient was holding the infant for feeding. Nurse administered unknown amount of ketorolac to the infant (estimated 0.1 mL to 0.2 mL before error was discovered). Patient monitoring was conducted on the advice of Poison Control. Patient was transferred to tertiary care.

RISK REDUCTION STRATEGIES

The medication events reported to the Authority involving patients younger than 18 years of age in general acute care organizations reveal the complex nature and large variety of factors that contribute to errors. Some of those factors were an extension of the unique challenges associated with providing medications to a younger age group. However, many of the factors were the same as seen in events associated with adults. Unfortunately, most of the reports did not describe the errors in great detail or include the causes and contributing factors linked to the errors; however, these reports, observations from the Institute for Safe Medication Practices, and recommendations in the literature do offer strategies that healthcare facilities may consider to decrease risk in the medication-use process for the pediatric population.

Pediatric-Specific Strategies

Prescribing node. Analysis of the events reported to the Authority revealed that at least 13.1% (n = 94) of the events originated in the prescribing process, with 20.2% (n = 19 of 94) of those resulting in an overdose to the patient. Thus, the use of a computerized prescriber order entry (CPOE) system with an effective clinical decision support system may help to catch prescribing errors that could result in an overdose. In addition, during the prescribing process, the following strategies may help to prevent these types of events:²²

- Confirm that the patient's actual weight, in kg, is correct, as this will be used for weight-based dosing.
- Include weight, dose basis (e.g., mg/kg/dose), and total dose on orders and prescriptions.
- Check that the weight-based dose does not exceed the recommended dose.
- For handwritten orders, avoid use of a terminal zero to the right of the decimal point (e.g., use 5 rather than 5.0) and use a zero to the left

of a dose less than 1 (e.g., use 0.1 rather than .1) to minimize 10-fold dosing errors.

- Stay current and knowledgeable concerning changes in medications and treatment of pediatric conditions.
- Consult a pharmacist if possible, particularly when there is a need to adjust a dose or dosing interval for neonates (e.g., renal impairment) or for calculations based on body surface area.

Patient-specific doses. The following strategies may assist organizations in reducing the risk associated with manipulating medications to provide an accurate dose of medication to pediatric patients:

- Dispense medications for individual patients in a patient-specific, ready-to-administer form whenever possible.²³ When this is not possible, provide clear preparation instructions prior to administration.
- Utilize standardized protocols, approved by the pharmacy and therapeutics (P&T) committee, for commonly prescribed pediatric medications (e.g., amoxicillin, acetaminophen) to more easily facilitate pharmacy dispensing of patient-specific, ready-to-administer doses.
- For those medications that will be stored in an automated dispensing cabinet (ADC), consider the following:¹³
 - Stock only pediatric concentrations of oral liquids and injectable medications in pediatric and neonatal ADCs.
 - Limit the variety and quantity of medications in ADCs.
 - Require an independent double check before administration of a high-alert medication obtained from an ADC.

Administration node. The following strategies can help reduce the risk of

error prior to and during medication administration:¹

- Compare the first dose of medication dispensed with the prescriber’s original order and the medication administration record (MAR). This can help confirm that the correct medication, dose, and dosage form has been provided. Check that the ordered drug and dose are appropriate for the patient.
- Address any concerns (e.g., the need for multiple dosage units to obtain a single dose, unusual dosage form or volume for the individual patient) prior to administration of the drug.
- Subsequent to administering the dose, verify the medication against the MAR. Transcribed MARs for future doses must be verified with the old MAR to confirm accurate transcription.
- Program smart pumps to include pediatric-specific drug libraries that contain medications used in the pediatric population, and have dose checking enabled to check both dose basis (e.g., mg/kg/dose) and total dose
- Require an independent double check for high-alert medications.
- Keep medications in their original packaging until they are ready for administration.²⁴

Patient Information

It is important that all healthcare workers involved in patient care have ready access to appropriate and current clinical information about patients to aid in the appropriate selection of medications, calculation of doses, and evaluation of orders.¹ To help accomplish this, consider the following:

Patient weights. To prevent mix-ups between the units of measures of lb and kg, standardize the measurement and communication of patient weight to metric units of measure (kg).¹⁵ Official product labeling for medications provides

weight-based dosing using only the metric system (e.g., mg/kg).²⁵

Patient drug allergies. Upon admission to a facility, list patient allergies, a description of the reaction to the allergen, and if possible, the date that the reaction took place on all admission order forms.¹⁶ Review all paper and online data collection forms to determine the location (e.g., front of medical record, on the top of order forms, designated MAR locations, computer screens, resident assessment forms) in which practitioners will document and retrieve complete allergy information, including descriptions of the reaction(s). Standardize the location of this information throughout the organization, including the ED, operating room, imaging services, and general medical-surgical care areas.¹⁶

Patient identification. While the Joint Commission has a National Patient Safety Goal to improve the accuracy of patient identification, the proper use of two patient identifiers may still not be performed at all times.^{26,27} Consider verification processes using at least two patient identifiers for all patient-associated tasks, including prescribing, reporting of test results, and communication of medication information among providers. A proper identification check not only consists of confirmation with the patient but also requires confirmation with the MAR or patient chart, patient armband, patient-specific medication labels, and/or other records.¹⁸

Look-Alike Medication Names and Packaging

Perform a failure mode and effects analysis (FMEA). Before adding a medication that could be used in the pediatric population to your organization’s formulary, consider gathering an appropriate interdisciplinary team (e.g., P&T committee) to perform an FMEA to determine potential hazards with that medication.¹⁹ Evaluation of the look-alike potential

of product names and containers in all possible areas of storage throughout the organization, not just the pharmacy, may be necessary.

The P&T committee may also verify that drugs are appropriate for use in the pediatric population (e.g., concentrations, dosage forms, inactive ingredients) as well as approve clinical pathways, protocols, preprinted orders/CPOE order sets, and dose calculation forms. The committee could appoint and oversee a multidisciplinary team for this purpose.¹

Product storage and listings. Separate products with look-alike names on storage shelves, computer screens, and any printed prescriber or stock order forms.²⁸

Product differentiation. Modifying look-alike drug names by using mixed-case letters and bolding to draw attention to the letters that differ in their names can help distinguish similar drug names. This strategy is commonly referred to as “tall man lettering” (e.g., hydrALAZINE and hydrOXYzine). This strategy may be considered to differentiate drug names on product labels, on storage bin labels, and in computer pick lists or drop-down menus.

IV Line Mix-Ups

Set up infusions completely and one at a time. When preparing to administer multiple infusions to a pediatric patient, ensure that the line for the first medication is inserted into the pump prior to preparation of the second medication. Physically tracing the line can help ensure that the correct channel and the correct IV line have been used to program the infusions.²¹

Label IV lines. Affixing the name of the drug being infused to each IV line (at the end closest to the patient) and above each channel on the pump may help prevent IV line mix-ups.²⁹ This practice may also help prevent errors if tubing has to be detached from patients during procedures, imaging, or transfer.



CONCLUSION

Analysis of medication error events reported to the Authority from non-pediatric-specific acute care organizations revealed some causes or contributing

factors that are unique to the pediatric population, such as 10- and 100-fold over- or underdoses. Yet most of the reports showed that the challenges in providing appropriate medications to pediatric patients are actually similar to

those encountered for adult patients. Organizations may consider providing medications in a patient-specific dose as often as possible while also applying other strategies, including many that work for adults, for pediatric patients.

NOTES

1. Levine SR, Cohen MR, Blanchard NR, et al. Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther* 2001;6:426-42.
2. Levine S. The forgotten patients: establishing pharmacist competency in pediatric therapeutics. *Hosp Pharm* 2002;37:800-3.
3. Gupta A, Waldhauser LK. Adverse drug reactions from birth to early childhood. *Pediatr Clin North Am* 1997 Feb;44(1):79-92.
4. Kearns GL, Abdel-Rahman SM, Amler SW, et al. Developmental pharmacology—drug disposition, action, and therapy in infants and children. *N Engl J Med* 2003 Sep 18;349(12):1157-67.
5. Joint Commission. Preventing pediatric medication errors [online]. Sentinel Event Alert 2008 Apr 11 [cited 2015 Mar 31]. http://www.jointcommission.org/sentinel_event_alert_issue_39_preventing_pediatric_medication_errors
6. Cimino MA, Kirschbaum MS, Brodsky L, et al.; Child Health Accountability Initiative. Assessing medication prescribing errors in pediatric intensive care units. *Pediatr Crit Care Med* 2004 Mar;5(2):124-32.
7. Takata, GS, Mason W, Taketomo C, et al. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Pediatrics* 2008 Apr;121(4):e927-35.
8. Stockwell DC, Bisarya H, Classen DC, et al. A trigger tool to detect harm in pediatric inpatient settings. *Pediatrics* 2015 Jun;135(6):1036-42.
9. Hicks RW, Becker SC, Cousins DD. MEDMARX® data report: a chartbook of medication error findings from the perioperative settings from 1998-2005. Rockville (MD): United States Pharmacopeia Center for the Advancement of Patient Safety; 2006.
10. Institute for Safe Medication Practices. ISMP list of high-alert medications in acute care settings [online]. 2014 [cited 2015 Apr 3]. <http://www.ismp.org/Tools/institutionalhighAlert.asp>
11. National Coordinating Council for Medication Error Reporting and Prevention. NCC MERP index for categorizing medication errors [online]. 2001 Feb [cited 2014 Jun 29]. <http://www.nccmerp.org/medErrorCatIndex.html>
12. Nahata MC. Paediatric drug therapy II—drug administration errors. *J Clin Pharm Ther* 1988 Dec;13(6):399-402.
13. Cohen MR. Causes of medication errors. Chapter 4. In: Cohen MR, ed. *Medication errors*. 2nd ed. Washington (DC): American Pharmacists Association; 2007:56.
14. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995 Jul 5;274(1):35-43.
15. Medication errors: significance of accurate patient weights. Pa Patient Saf Advis [online] 2009 Mar [cited 2015 Apr 6]. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Mar6\(1\)/Pages/10.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Mar6(1)/Pages/10.aspx)
16. Medication errors associated with documented allergies. Pa Patient Saf Advis [online] 2008 Sep [cited 2015 Apr 6]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5\(3\)/Pages/75.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/75.aspx)
17. Gao T, Gaunt MJ. Breakdowns in the medication reconciliation process. Pa Patient Saf Advis [online] 2013 Dec [cited 2015 Apr 6]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Dec;10\(4\)/Pages/125.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Dec;10(4)/Pages/125.aspx)
18. Yang A, Grissinger M. Wrong-patient medication errors: an analysis of event reports in Pennsylvania and strategies for prevention. Pa Patient Saf Advis [online] 2013 Jun [cited 2015 Apr 6]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Jun;10\(2\)/Pages/41.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Jun;10(2)/Pages/41.aspx)
19. Medication errors linked to drug name confusion. PA PSRS Patient Saf Advis [online] 2004 Dec [cited 2015 Apr 6]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2004/dec1\(4\)/Pages/07.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2004/dec1(4)/Pages/07.aspx)
20. Drug labeling and packaging—looking beyond what meets the eye. PA PSRS Patient Saf Advis [online] 2007 Sep [cited 2015 Apr 6]. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4\(3\)/Pages/69b.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4(3)/Pages/69b.aspx)
21. Wollitz A, Grissinger M. Aligning the lines: an analysis of IV line errors. Pa Patient Saf Advis [online] 2014 Mar [cited 2015 Apr 5]. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Mar;11\(1\)/Pages/01.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2014/Mar;11(1)/Pages/01.aspx)
22. American Academy of Pediatrics. Prevention of medication errors in the pediatric inpatient setting [policy statement]. *Pediatrics* 2003 Aug;112(2):431-6.
23. Johnson KB, Butta JK, Donohue PK, et al. Discharging patients with prescriptions instead of medications: sequelae in a teaching hospital. *Pediatrics* 1996 Apr;97(4):481-5.
24. Thigpen J. Minimizing medication errors. *Neonatal Netw* 1995 Mar;14(2):85-6.
25. Institute for Safe Medication Practices. 2014-15 targeted medication safety best practices for hospitals [online]. 2013 Dec [cited 2015 Apr 6]. <http://www.ismp.org/tools/bestpractices/TMSBP-for-Hospitals.pdf>
26. Phipps E, Turkel M, Mackenzie ER, et al. He thought the “lady in the door” was the “lady in the window”: a qualitative study of patient identification practices. *Jt Comm J Qual Patient Saf* 2012 Mar;38(3):127-34.
27. Henneman PL, Fisher DL, Henneman EA, et al. Providers do not verify patient identity during computer order entry. *Acad Emerg Med* 2008 Jul;15(7):641-8.
28. Inadvertent mix-up of morphine and hydromorphone: a potent error. PA PSRS Patient Saf Advis [online] 2007 Sep [cited 2015 Apr 6]. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4\(3\)/Pages/86.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4(3)/Pages/86.aspx)
29. Smetzer JL, Cohen MR. Preventing medication errors related to drug delivery devices. Chapter 12. In: Cohen MR, ed. *Medication errors*. 2nd ed. Washington (DC): American Pharmacists Association; 2007:278.



Pregnancy-Related Unplanned Returns to the Operating Room

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ABSTRACT

From January 2010 through December 2014, hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities reported 8,569 events involving pregnant women to the Pennsylvania Patient Safety Authority. Of these reports, 1,031 involved an unplanned return to the operating room. These events most frequently occurred either at the beginning of pregnancy (generally related to termination of a pregnancy) or in the immediate postpartum period. The most frequently reported causes of pregnancy-related unplanned returns to the operating room included the following: incomplete abortion or abortion with a report of hemorrhage or perforation requiring a surgical procedure (44.7%); postpartum hemorrhage (28.4%); postpartum retention of placenta or products of conception (15.0%); postpartum laceration requiring surgical repair (7.6%); and other events (4.3%). Literature supports that those healthcare organizations that have implemented evidence-based systematic protocols and simulation-based education report better patient outcomes. (Pa Patient Saf Advis 2015 Sep;12[3]:103-9.)

INTRODUCTION

The American Congress of Obstetricians and Gynecologists (ACOG) considers unplanned return to the operating room (OR) during the same admission an indicator that can be used to assess quality and track improvement in the practice of obstetrics and gynecology. The indicator is intended to identify events in which patients return to the OR after inpatient or outpatient surgery because of complications or untoward outcomes related to the original procedure.¹

Early in the pregnancy, unplanned returns to the OR may be related to abortions. Abortions can be accomplished medically, by administration of medications, or surgically. Known complications include incomplete abortion, hemorrhage, damage to the uterus and surrounding organs, infection, and rarely, death; several of these complications may require surgical intervention. Ongoing patient assessment, both pre- and postprocedure, is key in readily identifying potential risks and complications.^{2,5}

Immediately following delivery of an infant, postpartum hemorrhage is a major cause of maternal morbidity and mortality in the United States and the world. Postpartum hemorrhage is defined as vaginal bleeding in excess of 500 mL within 24 hours of delivery, with severe hemorrhage defined as greater than 1,000 mL of blood loss.⁶⁻⁸ A woman who has recently delivered an infant can be at risk for postpartum hemorrhage because of uterine atony, lacerations, retention of placental tissue, and uterine inversion or rupture.⁸⁻¹¹

Literature supports that prompt identification and appropriate treatment of patients at risk for postpartum hemorrhage can decrease the incidence of adverse outcomes. Standardization of treatment guidelines, staff education, training, and especially simulation and prompt intervention are imperative in preventing injury and death.^{6,7,10,12-14}

Pennsylvania healthcare facilities have reported events to the Pennsylvania Patient Safety Authority that are associated with pregnancy-related, unplanned return to the OR. Many maternal morbidity and mortality events are preventable through skilled care during labor and delivery, and quality improvement can be achieved by reviewing near misses as well as actual adverse outcomes.^{6,7,12} Best practices in the literature support patient safety practices that can prepare staff to respond in a swift and efficient manner to complications that may occur during pregnancy.

METHODS

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events reported by hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities from January 1, 2010, through December 31, 2014. The search criteria to identify events involving pregnant women included reports involving female patients between 10 and 60 years of age and containing the following terms in the narrative field: “pregnan,” “d&c,” “dilat,” “abort,” “fetus,” “fetal,” “partum,” “gestat,” “deliver,” “miscarry,” “cramp,” “stillborn,” “nonviable,” and “non-viable.”

All reports that identified aborted procedures not related to a pregnant woman, such as colonoscopy aborted due to inadequate preparation, were eliminated from the review. Reports involving an unplanned return to the OR were identified either from the event type coding or from information in the narrative details.

RESULTS

The initial query found 8,569 reports of events involving pregnant women, and the most frequently reported event type was complication of a procedure, treatment, or test (see the Table). Of these 8,569 reports, 1,031 involving an unplanned return to the OR were identified either from the event type coding (n = 261) or from information in the narrative details (n = 770).

The types of events identified among pregnancy-related unplanned returns to the OR were as follows:

- Incomplete abortions or abortions that resulted in increased bleeding or organ perforation that required an additional surgical procedure (44.7%)
- Postpartum hemorrhage (28.4%)
- Retained placenta (15.0%)
- Genital tract lacerations requiring surgical repair (7.6%)
- Other (4.3%)

The following are samples of events reported to the Authority. The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

The following two reports are examples of medical and surgical abortion complications:

A patient was seen for a medical abortion. The patient returned one month later for an ultrasound and examination. The physician detected a live intrauterine pregnancy at twelve weeks and four days. The physician determined that the medical abortion had failed. The physician performed a surgical abortion that same day.

Patient presented for an elective termination of pregnancy. The surgical termination was started with local anesthetic and ultrasound guidance after adequate dilation. The physician noted some bleeding with removal of the cervical dilator. The physician completed the procedure,

and the patient continued to bleed briskly. The physician provided fundal massage and the patient was administered misoprostol and methergine. The patient was transported to another facility. The patient was brought to the OR and had significant blood in the uterus, thinned out uterine segments, and an inability to stop the bleeding. The patient had an abdominal hysterectomy, received a total of 6 units of blood, and was admitted to the hospital.

The following three reports are examples of postpartum hemorrhage complications:

The patient sustained postpartum hemorrhage following delivery due to uterine atony and required blood transfusion, examination under anesthesia with placement of a Bakri balloon, and uterine curettage. Patient was found to have cervical lacerations, with a required repair done at time of procedure.

The patient delivered a full-term infant vaginally. A retained placenta was noted. Part of the placenta was delivered with gentle traction and uterine massage after signs of placental separation. The placenta was palpated partially through the cervical os. The uterus was explored multiple times, and blood clots were removed along with placental fragments. The patient was taken to operating room,

where large amounts of clotted material were removed and the uterus was further explored. Retained placental tissue approximately twelve centimeters in diameter was gently removed. The uterine bleeding continued, and methergine was administered. The estimated total blood loss was 1,250 mL.

The patient delivered an infant vaginally without complication. Physician called to postpartum unit for postpartum hemorrhage. A large blood clot was evacuated, and patient was monitored for signs of increased bleeding. Patient had two more episodes of bleeding and ultrasound that showed possible retained products of conception. The patient was taken to the OR and placed under general anesthesia. Further inspection by physician revealed a 2 cm laceration on the left vaginal wall. The laceration was repaired, and the patient was transfused with two units of packed red cells. Patient's condition stabilized, and the fundus remained firm and mid-line throughout the episode.

Table. Frequency of Pregnancy-Related Reports by Event Type, 2010 through 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 8,569)

EVENT TYPE	NO. OF REPORTS	%
Complication of a procedure/treatment/test	5,150	60.1
Other/miscellaneous	1,496	17.5
Error related to a procedure/treatment/test	1,389	16.2
Medication error	417	4.9
Equipment/supplies/devices	82	1.0
Adverse drug reaction	35	0.4

DISCUSSION

Induced Abortions

The most common type of reported event occurring during early pregnancy was induced abortion that was incomplete or in which other complications required a further surgical procedure. In the

Pennsylvania, induced abortions can be performed at up to 23 weeks' gestation. After 24 weeks' gestation, the attending physician and another physician who has examined the patient must validate that the abortion is necessary to preserve the life of the mother or prevent serious risk of substantial and irreversible impairment of bodily function.¹⁵ The most recent Pennsylvania Department of Health vital statistics report states that 33,166 abortions were performed in 2012. Of these, 65.7% were accomplished by suction curettage, 25.9% were accomplished medically, and 8.4% were accomplished by dilation and evacuation.¹⁶

Abortions can be performed by medical or surgical methods. Medical abortions, also referred to as medication abortions, comprise 16.5% of all abortions done in the United States and are usually performed within the first 63 days after the first day of the last menstrual period. The US Food and Drug Administration–approved regimen and other regimens generally use oral mifepristone and vaginal, buccal, or sublingual misoprostol to induce the abortion.^{4,17} Mifepristone ends the pregnancy by blocking the hormone necessary for maintaining a pregnancy, while misoprostol causes the uterus to contract, expelling the pregnancy.¹⁷ In most cases, the abortion is complete within two weeks from the time of final medication administration.^{17,18}

Medical abortion is 92% to 99% effective at ending early pregnancies.^{4,5} Failures may require additional medication or a surgical procedure to completely terminate the pregnancy.¹⁹ An examination is usually performed one to two weeks after the medication administration to determine if a medical abortion is complete, using ultrasound and other diagnostic measures to determine if the gestational sac has been expelled.⁴ If the gestational sac is present on follow-up, the pregnant woman may be offered expectant care, with continued monitoring to see if

further tissue is expelled on its own; an additional dose of misoprostol to induce further uterine contractions and expulsion of the gestational sac; or a surgical procedure, such as a uterine aspiration.^{2,4,19}

If a woman elects to have a surgical abortion, the type of surgical procedure performed will depend on the woman's stage of pregnancy. In the first trimester, the most frequent type of surgical abortion is suction aspiration or suction curettage, in which the uterine contents are removed via a suction device. After 12 to 14 weeks' gestation, dilation and evacuation is commonly utilized to terminate the pregnancy.²

Postoperative complications of surgical abortion include hemorrhage, infection, uterine/bowel/bladder perforation, cervical laceration, and retained products. In addition, complications may arise related to the use of sedation or anesthesia.^{2,15,20} In a retrospective study of second-trimester abortions performed between 2004 and 2007, Frick et al. found that major complications occurred in 1.3% of the cases, with the greatest risk of complications in patients with a history of one or more previous cesarean deliveries. Advanced gestational age and insufficient cervical preparation requiring further dilatation was also associated with an increased risk of major complications. Cervical lacerations were the most common complication, with this risk increasing with greater gestational age.²¹

Niinimäki et al. compared the incidence of immediate adverse events and complications in 42,619 women—of whom 22,368 underwent medical abortions and 20,251 underwent surgical abortions at up to 63 days' gestational age—between 2000 and 2006. Outcomes monitored included hemorrhage, postabortion infection, incomplete abortion, injuries or other reasons for surgical operations, thromboembolic disease, psychiatric morbidity, and death. The study found that

women who had medical abortions had an increased incidence of adverse events, the most frequent being hemorrhage and incomplete abortions, but that complications requiring surgical intervention were more frequent in women who had a surgical abortion.³

Best-Practice Strategies for Induced Abortions

A thorough patient history and physical examination includes assessment of gestational age. Both gestational age and a woman's personal preferences will be factors in deciding on a medical or surgical procedure.^{2,3,22}

In the case of medical abortions, the patient may self-administer medication at home to complete the abortion, so the provider generally considers whether the patient will be able to comply with this step.^{2,4} Patient counseling addresses expected amounts of bleeding and cramping as the pregnancy is expelled, as well as signs and symptoms of excessive bleeding, and instructions regarding pain management.⁴ Follow-up is often scheduled for one to two weeks later, in person or via telephone, to determine if the abortion is complete.^{2,4} Serial beta human chorionic gonadotropin levels can be drawn on the day of mifepristone administration and one week later; a significant drop in levels suggests termination of the pregnancy.⁴

Grossman et al. performed a retrospective study comparing outcomes for women who underwent medical abortions via telemedicine versus an in-person appointment with a physician. Women who selected to use telemedicine completed a medical history and received an ultrasound exam by clinic staff. This information was sent electronically to the physician, who reviewed the information and consulted with the patient via a secured teleconferencing system. If the patient proceeded with the medical abortion, the physician released the medication at the clinic. The physician observed the patient taking the

medication and gave instructions for at-home medication administration and routine follow-up as per protocol. Telemedicine was found to be effective and acceptable for women who selected this approach.²³

If a woman elects a surgical abortion, gestational age is still a consideration. Informed consent will be obtained for the procedure and sedation or anesthesia, if they will be administered. Surgical abortion includes the risk of injury to the cervix, uterus, and surrounding organs and the risk of postsurgical hemorrhage, so staff need to be able to recognize and respond to adverse events. Providers need to have the following:²

- Emergency equipment
- Training
- Protocols to transfer the patient to a higher level of care as needed

Protocols to treat postprocedure hemorrhage may include the following:²

- Reaspirating the uterus
- Uterine massage
- Administering uterotonic medications
- Hemostatic techniques, such as inserting a Bakri balloon as tamponade

The surgical abortion offers the advantage of being complete after the procedure is finished; the patient does not require a follow-up visit unless a complication arises.

Postpartum Hemorrhage

In the analysis, reports related to postpartum hemorrhage comprised 28.4% of pregnancy-related events of unplanned returns to the OR. Reports related to retained placental tissue and genital tract lacerations, both of which may contribute to postpartum hemorrhage, comprised an additional 22.6% of the reports.

Postpartum hemorrhage is a low-frequency but high-risk event during labor and delivery, responsible for 25%

of maternal mortality worldwide.^{8,10} A 2011 report from the Center for Disease Control and Prevention's Pregnancy Mortality Surveillance System indicates that hemorrhage is the fourth leading cause of pregnancy-related mortality in the United States, following cardiovascular diseases, noncardiovascular diseases, and infection or sepsis.²⁴ Rocha Filho et al. studied the occurrence of obstetric complications in Brazil, from June 2009 to June 2010, and found that out of 9,555 women who sustained an obstetric complication, only 8% sustained an antepartum or intrapartum hemorrhage, but these hemorrhages were responsible for 18.2% of maternal near misses and 10% of maternal death cases.²⁵

Rapid recognition and treatment of postpartum hemorrhage, including initiating prompt resuscitation, are necessary, as untreated postpartum hemorrhage can result in a fatal outcome to a healthy woman within a few hours.^{8,26} In particular, staff's inability to correctly assess blood loss has led to underestimation and failure to identify postpartum hemorrhage.^{7,10,11,12,27} Some patients may have risk factors for postpartum hemorrhage identified before or during labor (e.g., placenta accreta, increta, or percreta); however, a majority of women who sustain postpartum hemorrhage exhibit no risk factors.^{6,7,13,26,28} The leading cause of postpartum hemorrhage during and after the third stage of labor is uterine atony, defined as the uterus' inability to contract after delivery of the fetus.^{6,9,29}

Other causes of postpartum hemorrhage include trauma to the genitourinary tract, such as lacerations of the cervix, vagina, or perineal area; retained placental tissue; clotting disorders; or an inverted or ruptured uterus.^{6,29}

Prevention and Treatment of Postpartum Hemorrhage

In the last few decades, the shift to more aggressive active management of the third stage of labor (AMTSL) has given

providers more methods with which to potentially avert adverse maternal outcomes and save women's uteri.^{6,7,9,10} Preventive methods include administration of subcutaneous oxytocin combined with controlled cord traction and fundal massage after delivery of the placenta; keeping the woman's bladder empty; replacing fluids intravenously; careful examination of the genital tract for signs of lacerations; and examination of the placenta to determine if any tissue may have been retained.^{6,8,10,29,30}

Treatment for uterine atony can include uterotonic medications, uterine massage, bimanual compression of the uterus, use of a balloon tamponade, or other hemostatic measures. Repair of birth canal lacerations and manual removal of retained placenta may be attempted in the delivery room but may also require moving the patient to the OR to facilitate prompt treatment, pain control, and patient comfort, including utilizing general anesthesia.^{6,30}

Surgical interventions to control hemorrhage may include dilation and curettage (D&C) to remove retained placental tissues; B-Lynch suturing to exert continuous vertical compression on the uterine vascular and muscular systems; and internal iliac artery ligation or stepwise devascularization. If the facility has interventional radiology services, uterine artery embolization can be performed, which may spare the uterus and preserve fertility.^{30,31} In some circumstances, hysterectomy may be the optimal option to save the woman's life.^{6,9,30}

Best-Practice Strategies for Postpartum Hemorrhage

Literature supports implementation of evidence-based systematic protocols for recognition and response to postpartum hemorrhage to improve patient outcomes.^{10,12,13,14,32,33} The Council on Patient Safety in Women's Health Care has published an obstetric hemorrhage patient safety bundle that may assist healthcare

facilities develop their own standards. The process is outlined in “Four Rs: Readiness, Recognition and Prevention, Response, and Reporting/Systems Learning.”³³

The California Maternal Quality Care Collaborative (CMQCC) has also published a toolkit that presents evidence-based protocols to help providers recognize and respond to postpartum hemorrhage, from the stages of early assessment and AMTSL through managing more severe hemorrhage scenarios.¹⁰ The management algorithm is based on the patient’s vital signs, blood loss, and other physiologic criteria, and it addresses options such as administration of intravenous fluids, medications, and transfusions, as well as various surgical interventions. To access the CMQCC Obstetric Hemorrhage Toolkit, see <https://www.cmqcc.org/resources-tool-kits/toolkits/ob-hemorrhage-toolkit>.

As postpartum hemorrhage is an infrequent event in most birthing facilities; staff may not have actual experience managing this complication. Simulation training has been found to be an effective educational tool, ranging from tabletop exercises to employing simulation educators who role-play while using low-technology torsos or other props or high-technology electronic manikins that can “deliver” an infant manikin and demonstrate hemorrhage and other abnormalities. Simulation-based education allows staff to practice clinical skills and teamwork, including communication, and provides an opportunity to assess environmental resources.^{10,33}

Several healthcare organizations have published results of patient safety initiatives addressing postpartum hemorrhage. In a published account from Pennsylvania, Lehigh Valley Hospital initiated multiple actions, such as establishing a team and providing simulation and crew resource training to improve team communication, to reduce birth-related traumas in

FOUR Rs: READINESS, RECOGNITION AND PREVENTION, RESPONSE, AND REPORTING/SYSTEMS LEARNING

Readiness

Every unit

- Hemorrhage cart with supplies, checklists, and instruction cards for intrauterine balloons and compression stitches
- Immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team—who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

Recognition and Prevention

Every patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Measurement of cumulative blood loss (formal, as quantitative as possible)
- Active management of the 3rd stage of labor (department-wide protocol)

Response

Every hemorrhage

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
- Support program for patients, families, and staff for all significant hemorrhages

Reporting/Systems Learning

Every unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for system issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

Reprinted from the following: Council on Patient Safety in Women’s Health Care. Patient safety bundle: obstetric hemorrhage [online]. 2015 May [cited 2015 Jul 20]. <http://www.safehealthcareforeverywoman.org/downloads/Hemorrhage-Bundle/Final-Hemorrhage-Bundle-v2-5-14-15.pdf>

2006. Quality measurements included maternal death, maternal admission to the intensive care unit, return to the OR, transfusions given, and third- and fourth-degree lacerations. The hospital reported a 2% decrease in birth-related trauma over a two-year period.³⁴

In Honolulu, Hawaii, Pacific Health implemented simulation training addressing

massive hemorrhage. This training resulted in reduced staff response time for several key portions of their postpartum hemorrhage protocol, including recognition of the problem and getting medications, all supplies, and blood products for transfusion into the patient’s room.³⁵



Wagner et al. studied the implementation of evidence-based protocols, team training with an emphasis on communication, and simulation training at a tertiary care facility from 2007 to 2009. They measured 11 adverse outcome indicators and showed that implementing comprehensive patient safety initiatives resulted in reduced adverse outcomes, including peripartum hysterectomy, unplanned transfer to the intensive care unit, birth trauma, return to the OR, and uterine rupture.³⁶

CONCLUSION

Unplanned returns to the OR can occur because of complications or untoward

outcomes related to the procedures undergone by pregnant women. In the events reported in Pennsylvania from 2010 through 2014, 1,031 reports of unplanned returns to the OR for women of childbearing age involved a pregnancy-related event. These event reports were clustered around two distinct times in the pregnancy. At the beginning of pregnancy, unplanned returns to the OR were often related to abortions that were incomplete or were associated with increased bleeding or injury to the uterus. In the immediate postpartum period, unplanned returns to the OR were often related to postpartum hemorrhage, retained placental tissue, or genital tract lacerations.

With regard to abortions, best-practice guidelines suggest careful assessment to determine the appropriate procedure based on the stage of the pregnancy and the patient's personal preference; follow-up care will be guided by the type of procedure performed. With regard to postpartum hemorrhage, research shows multiple preventive measures that may result in fewer or less severe adverse patient outcomes. Literature shows that healthcare organizations that have implemented standardized protocols for recognizing and responding to postpartum hemorrhage and simulation-based education have improved patient outcomes.

NOTES

1. Connolly TP. Unplanned return to the operating room in a community hospital-based obstetrics and gynecology residency. *J Am Osteopath Assoc* 2003 Mar;103(3):123-5.
2. National Abortion Federation. 2015 clinical policy guidelines [online]. [cited 2015 Apr 13]. http://prochoice.org/wp-content/uploads/2015_NAF_CPGs.pdf
3. Niinimäki M, Pouta A, Bloigu A, et al. Immediate complications after medical compared with surgical termination of pregnancy. *Obstet Gynecol* 2009 Oct;114(4):795-804.
4. American College of Obstetricians and Gynecologists, Society of Family Planning. Medical management of first-trimester abortion [practice bulletin online]. 2014 Mar [cited 2015 Feb 23]. <http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Medical-Management-of-First-Trimester-Abortion>
5. Cleland K, Creinin MD, Nucatola D, et al. Significant adverse events and outcomes after medical abortion. *Obstet Gynecol* 2013 Jan;121(1):166-71.
6. Postpartum hemorrhage [online]. [cited 2015 Apr 23]. <http://pphprevention.org/pph/php>
7. Westmead Hospital. Obstetric anaesthesia [online]. 2010 [cited 2015 Apr 13]. http://www.westmeadanaesthesia.org/documents/westmead_obstetric_manual.pdf
8. World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage [online]. 2012 [cited 2015 May 14]. http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/9789241548502/en
9. Steer PJ. The surgical approach to postpartum haemorrhage. *Obstetrician Gynaecologist* 2009 Oct;11(4):231-8.
10. Lyndon A, Lagrew D, Shields L, et al., eds. *Improving health care response to obstetric hemorrhage*. Sacramento (CA): California Maternal Quality Care Collaborative/California Department of Public Health; 2015 Feb.
11. Callaghan, WM, Kuklina EV, Berg CJ. Trends in postpartum hemorrhage: United States, 1994-2006. *Am J Obstet Gynecol* 2010 Apr;202(4):353.e1-6.
12. Bingham D, D'Alton M. Safety action series: overview of the National Partnership for Maternal Safety [online]. 2014 May 20 [cited 2015 April 13]. http://www.safehealthcareforeverywoman.org/downloads/Safety-Action-Series-Presentation_5.20.14_Overview-of-the-National-Partnership-for-Maternal-Safety.pdf
13. American Hospital Association, US Department of Health and Human Services Partnership for Patients, Health Research and Educational Trust. Obstetrical harm change package: recognition and prevention of obstetrical related events and harm 2014 update [online]. [cited 2015 Apr 13]. http://www.hret-hen.org/index.php?option=com_phocadownload&view=category&download=1393:obstetrical-adverse-events-change-package-2014&id=70:obstetrical-adverse-events
14. Kozhimannil KB, Sommerness S, Rauk P, et al. A perinatal care quality and safety initiative: are there financial rewards for improved quality? *Jt Comm J Qual Patient Saf* 2013 Aug;39(8):339-48.
15. 18 Pa. Cons. Stat. § 3201-3220. Abortion Control Act. Also available at <http://www.legis.state.pa.us/cfdocs/legis/LI/consCheck.cfm?txtType=HTM&ttl=18&div=0&chpt=32>
16. Pennsylvania Department of Health. Pennsylvania vital statistics 2012: induced abortions [online]. [cited 2015 May 10]. <http://www.portal.state.pa.us/portal/server.pt?open=514&objID=596032&mode=2>
17. Planned Parenthood Federation of America. The difference between the morning after pill and the abortion pill [online]. 2013 Dec [cited 2015 Feb 23]. http://www.plannedparenthood.org/files/6413/9611/5654/Difference_Between_the_Morning-After_Pill_and_the_Abortion_Pill.pdf
18. Verschoor MAC, Lemmers M, Bossuyt PM, et al. Surgical versus expectant management in women with an incomplete evacuation of the uterus after treatment with misoprotol for miscarriage: the MisoREST trial. *BMC Pregnancy Childbirth* 2013 May 2;13:102.

19. Ashok PW, Templeton A, Wagaarachchi PT, et al. Factors affecting the outcome of early medical abortion: a review of 4132 consecutive cases. *BJOG* 2002 Nov;109(11):1281-9.
20. Wieslander CK, Marshall DD. Perioperative, intraoperative, and postoperative complications in gynecologic surgery. Chapter 45. In: DeCherney AH, Nathan L, Laufer N, et al., eds. *CURRENT diagnosis & treatment: obstetrics & gynecology* [online]. 11th ed. 2013 [cited 2015 Apr 13]. <http://accessmedicine.mhmedical.com/content.aspx?sectionid=41008637&bookid=498&Resultclick=2>
21. Frick AC, Drey EA, Diedrich JT, et al. Effect of prior cesarean delivery on risk of second-trimester surgical abortion complications. *Obstet Gynecol* 2010 Apr;115(4):760-4.
22. Edlow AG, Hou MY, Maurer R, et al. Uterine evacuation for second-trimester fetal death and maternal morbidity. *Obstet Gynecol* 2011 Feb;117(2 Pt 1): 307-16.
23. Grossman D, Grindlay K, Buchacker T, et al. Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstet Gynecol* 2011 Aug;118(2 Pt 1):296-303.
24. Centers for Disease Control and Prevention. Pregnancy mortality surveillance system [online]. [cited 2015 Jun 26]. <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html>
25. Rocha Filho EA, Costa ML, Cecatti JG, et al. Contribution of antepartum and intrapartum hemorrhage to the burden of maternal near miss and death in a national surveillance study. *Acta Obstet Gynecol Scand* 2015 Jan;94(1):50-8.
26. Faulkner B. Applying lean management principles to the creation of postpartum hemorrhage care bundles. *Nurs Womens Health* 2013 Oct;17(5):400-11.
27. Pritchard J. Obstetrical hemorrhage. Chapter 41. In: Cunningham FG, Leveno KJ, Bloom SL, et al., eds. *Williams Obstetrics* [online]. 24th ed. 2014 [cited 2015 Apr 13]. <http://accessmedicine.mhmedical.com/content.aspx?sectionid=59789185&bookid=1057&Resultclick=2>
28. Hoffman MS, Karlinski RA, Mangar D, et al. Morbidity associated with nonemergency hysterectomy for placenta accreta. *Am J Obstet Gynecol* 2010 Jun;202(6):628.e1-5.
29. Tucker R, Platt M. Obstetric and gynecological emergencies and rape. Chapter 38. In: Stone CK, Humphries RL, eds. *CURRENT diagnosis & treatment emergency medicine* [online]. 7th ed. 2011 [cited 2015 Apr 13]. <http://accessmedicine.mhmedical.com/content.aspx?bookid=385§ionid=40357254>
30. American College of Obstetricians and Gynecologists. ACOG practice bulletin: clinical management guidelines for obstetrician-gynecologists number 75, October 2006: postpartum hemorrhage. *Obstet Gynecol* 2006 Oct;108(4):1039-47.
31. Angstmann T, Gard G, Harrington T, et al. Surgical management of placenta accreta: a cohort series and suggested approach. *Am J Obstet Gynecol* 2010 Jan;202(1):38.e1-9.
32. Institute for Healthcare Improvement. IHI perinatal improvement community: perinatal improvement change package (revised 2014) [online]. 2014 [cited 2015 Apr 13]. <http://www.ihio.org/Engage/collaboratives/PerinatalImprovementCommunity/Documents/Driver%20Change%20Document%202013%202014%20Sept%202013%20logo.pdf>
33. Council on Patient Safety in Women's Health Care. Patient safety bundle: obstetric hemorrhage [online]. 2015 May [cited 2015 May 18]. <http://www.safehealthcareforeverywoman.org/downloads/Hemorrhage-Bundle/Final-Hemorrhage-Bundle-v2-5-14-15.pdf>
34. Institute for Healthcare Improvement. Reducing birth-related trauma and liability exposure [online]. [cited 2015 Apr 13]. <http://ihi.org/resources/Pages/ImprovementStories/ReducingBirthRelatedTrauma.aspx>
35. Hawai'i Pacific Health. Clinical care surveillance [online]. [cited 2015 Apr 13]. http://s3.amazonaws.com/rdcms-himss/files/production/public/FileDownloads/2012%20Enterprise%20Award_Hawai'i%20Pacific%20Health%20CLINICAL%20CARE%20SURVEILLANCE.pdf
36. Wagner B, Meirowitz N, Shah J, et al. Comprehensive perinatal safety initiative to reduce adverse obstetric events. *J Healthc Qual* 2012 Jan-Feb;34(1):6-15.



The Current State of “Wrong Patient” Insulin Pen Injections

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ABSTRACT

Thousands of patients in the United States have received injections from potentially contaminated insulin pens, typically involving inappropriate or unrecognized sharing of a patient’s previously used insulin pen device. Analyst query of the Pennsylvania Patient Safety Reporting System identified 82 reports of potential or actual wrong-patient errors with the use of insulin pen devices in Pennsylvania from 2005 through 2014. Over half (n = 43) of the reports describe actual administration events, 35.4% (n = 29) were close calls, and the remaining 12.2% (n = 10) did not indicate whether or not administration took place. Nearly two-thirds (n = 54) of the 82 events, including 67.4% (n = 29) of the actual administration events, occurred during 2013 or 2014. Despite widespread media coverage, recommendations from national organizations, and application of strategies considered best practices, wrong-patient insulin pen injections continue to occur. Hospitals are encouraged to analyze their own wrong-patient events with the use of insulin pens and examine their current insulin practices as they decide whether to use insulin pens, vials, or a combination of the two. (Pa Patient Saf Advis 2015 Sep;12[3]:110-5.)

INTRODUCTION

Thousands of patients in the United States have received injections from potentially contaminated insulin pens, typically involving inappropriate or unrecognized sharing of a patient’s previously used insulin pen device. Analyst query of the Pennsylvania Patient Safety Reporting System (PA-PSRS) revealed similar event reports in Pennsylvania.

A variety of insulin pen devices are currently available in the United States. Insulin pen devices were originally developed to facilitate accurate and easy patient self-administration of insulin.¹⁻⁵ The pen devices are designed to be used multiple times by a single patient, using a new needle with each injection; these devices are not to be used for more than one patient. Practitioners and patients may not recognize that biological contamination of the insulin solution contained in the pen is possible during regular use of the device.

Several studies found that regurgitation of biological material into the insulin cartridge can occur during administration, creating a risk of pathogen transmission if the pen device is used for more than one patient. Use of a new needle does not reduce this risk. Sonoki et al. detected hemoglobin in 4.1% of insulin cartridges tested.⁶ In a study of 120 patients, Le Floch et al. detected non-inert material, including squamous and other epithelial cells, in 58% of the insulin cartridges tested.⁷ In 2013, Herdman et al. conducted an analysis of newer models of insulin pens, introduced after those earlier studies, and found contamination in 5.6% of cartridges in used pens.⁸

Since 2009, several cases of inappropriate sharing and wrong-patient use of insulin pen devices have been reported in the national media and literature (see Figure 1). These cases have involved thousands of patients and required large-scale efforts to notify patients and test patients for HIV and hepatitis. In each of these events, sharing or reuse of pens may have taken place over a period of years before the practice was identified.

METHODS

Pennsylvania Patient Safety Authority analysts searched for and reviewed insulin-related events that were reported through PA-PSRS from 2005 through 2014 to identify cases and contributing factors of wrong-patient errors and inappropriate sharing of insulin pens. Specifically, the “medication prescribed” and “medication administered” fields in medication error event reports were queried by the brand and nonproprietary names of the insulin products approved and on the market. This resulted in a data set with 23,159 reports. The initial query was not limited to the names of insulin pen devices, as facilities are not required to submit specific, official brand names or device information in medication product information fields.

The event descriptions contained in the resultant data set were then searched for the term “pen” as well as the names of the various approved insulin pen products to identify events involving the use of pen devices. The “medication prescribed” and “medication administered” fields were also examined to identify events involving pen devices when possible.

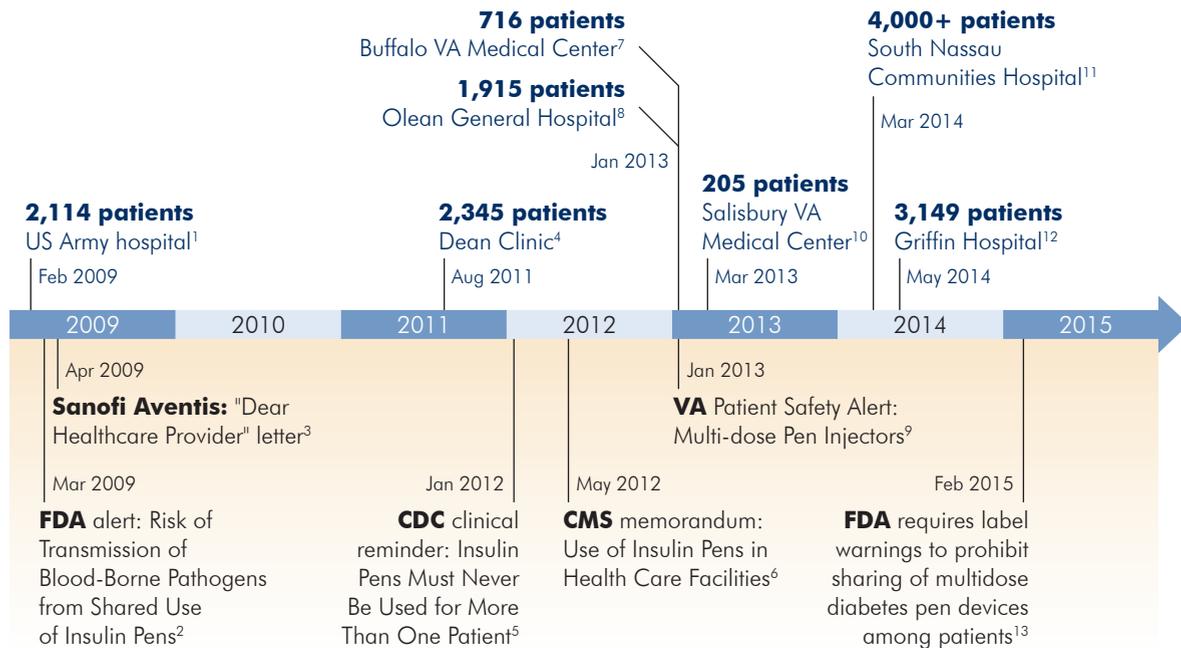
RESULTS

Analysts identified 82 reports of potential or actual wrong-patient errors with the use of insulin pen devices. Over half (n = 43) of the reports described actual administration events (e.g., a patient received a dose of insulin from another patient’s pen), 35.4% (n = 29) were close calls in which actual administration did not occur, and the remaining 12.2% (n = 10) did not indicate whether or not administration took place.



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

Figure 1. Timeline of Nationally Reported Cases of Insulin Pen Sharing and Recommendations from National Organizations



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Refer to the "Notes: Figure 1" section at the end of this article for the corresponding references.

Nearly two-thirds (n = 54) of the 82 events, including roughly 67.4% (n = 29) of the 43 actual administration events, occurred during 2013 or 2014. Figure 2 illustrates the increasing trend in reported events.

Twenty-five different facilities in Pennsylvania reported events. The facilities ranged in size and facility type from critical access hospitals to large teaching facilities. Analysts also identified that events have occurred in all six regions of the commonwealth, as adopted by the Authority (see Figure 3).

Analysts were able to determine contributing factors when sufficient detail was provided in the event description. Improper or untimely disposal of a previous patient's insulin pen upon patient discharge or

transfer was cited in 12.2% (n = 10 of 82) of all reports and 16.3% (n = 7 of 43) of reports involving actual administration of insulin. Analysts were not able to determine if an actual administration took place in the other three reports.

Following is an example of an untimely disposal of a previous patient's insulin pen contributing to a wrong patient error. Note that the details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

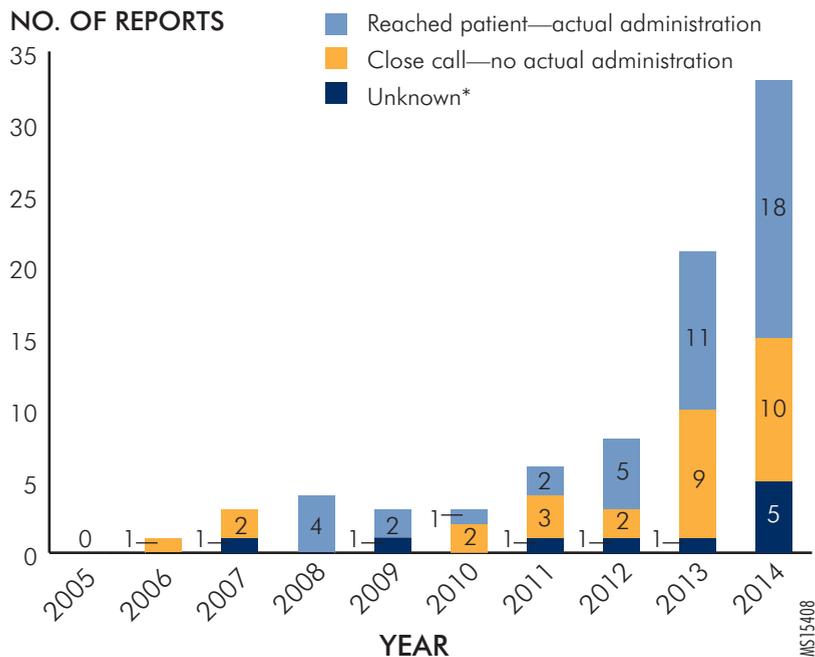
Previous patient was discharged from this room. This patient was admitted to the same room. Previous patient's insulin pen was left in the medication server box. New patient was given correct dose of correct medication from the previous patient's insulin

pen. Event found upon pharmacy technician rounding on the medication server boxes after event occurred.

Mix-ups between roommates were cited in 6.1% (n = 5 of 82) of all the reports. Nearly 10% (n = 4 of 43) of the actual administration errors were associated with mix-ups between roommates, as shown in the following example.

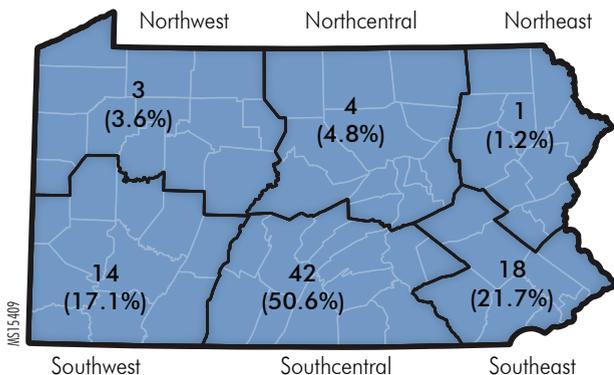
The patient received insulin from roommate's insulin pen. Physician notified. Lab work ordered. Both the patient and her family notified of incident. Consent obtained for blood work. Insulin pens handed to nurse placed in drawer. [Nurse] removed pens and scanned to administer without looking at labels.

Figure 2. Number of Wrong-Patient Events Involving Insulin Pen Devices Reported by Year to the Pennsylvania Patient Safety Authority, 2005 through 2014 (N = 82)



* The reports did not provide enough detail to determine if an actual wrong-patient administration occurred.

Figure 3. Pennsylvania Patient Safety Authority Wrong-Patient Insulin Pen Events by Region of the Commonwealth, 2005 through 2014 (N = 82)



Note: As with all reporting systems, the type and number of reports collected are dependent on the degree to which facility reporting is accurate and complete. The reporting cultures and patterns in each facility, and their interpretations of what occurrences are reportable, do lead to reporting variation.

Roughly 6% (n = 5 of 82) of all the reports also indicated that storage-related issues (e.g., insulin pens returned to wrong storage bin, insulin pens not stored in patient-specific bins) contributed to the events. All five events resulted in an actual wrong-patient insulin administration, including the following example.

I gave the patient her Novolog® [insulin aspart (rDNA origin) injection]. After giving it, I realized that it was the Novolog pen from the patient in [room A]. The patient in [room A] had the patient in [room B's] Novolog in her drawer and vice versa. Unknown if the patient in [room A] received insulin from wrong pen prior to discovery.

Other contributing factors included distractions (4.9%, n = 4 of 82), time pressures (4.9%, n = 4 of 82), wrong patient label on pen (1.2%, n = 1 of 82), and medication not available (1.2%, n = 1 of 82).

DISCUSSION

An increase in the number of reported potential or actual wrong-patient errors with the use of insulin pen devices occurred in 2013 and 2014 (see Figure 2). It is not known why this surge occurred. One possible explanation may be that staff awareness of the risks may have been elevated with the national media coverage and internal hospital staff education programs. Another possible explanation is that the use of insulin pens in hospitals may have risen, thereby increasing opportunities for close calls and events. However, it is likely that the actual incidence of potential and actual wrong-patient errors with insulin pen devices is higher, as many events may go unnoticed or unreported.

The national reports and Pennsylvania data illustrate that unsafe practices with the use of insulin pens place patients at risk of bloodborne pathogen transmission. It should be noted that while the level of biological contamination is

believed to occur in sufficient quantities to transmit bloodborne pathogens, to date, there is no clear evidence of pathogen transmission from pen sharing.⁹ However, it cannot be stated strongly enough that insulin pen sharing, whether intentional or not, could lead to this adverse outcome.^{6,9}

In response to the nationally reported cases of insulin pen sharing, a number of national organizations and agencies, including the Centers for Medicare and Medicaid Services,¹⁰ Centers for Disease Control and Prevention,¹¹ US Food and Drug Administration,¹² Safe Injection Practices Coalition,¹³ American Society of Health-System Pharmacists Foundation,¹⁴ and Institute for Safe Medication Practices,¹⁵⁻¹⁷ have published extensively on insulin pen safety and provided recommendations to prevent inadvertent exposure to bloodborne pathogens (see Figure 1). Recommendations have largely focused on education, labeling, policy creation, and monitoring, including the following:^{11,12,13,18}

- Never use insulin pens for more than one person, even when the needle is changed. They are designed for use by a single patient only.
- Clearly label insulin pens with the person’s name or other identifying information to ensure that the correct pen is used exclusively on one individual. Take care to not cover essential product information (e.g., product name) or the dosing window.
- Hospitals and other facilities that use insulin pens and similar devices should have policies addressing safe use.
- Hospitals should have a program to ensure that staff are appropriately educated in advance of introducing these products and to actively monitor to ensure strict adherence to safe practices.
- If multipatient use is identified, promptly notify exposed individuals and offer appropriate follow-up,

including bloodborne pathogen testing.

Unfortunately, hospitals may find it difficult to maintain effective ongoing education and monitoring because of staff turnover and other pressures.¹⁷ Breakdowns in these processes will enable hazardous conditions to persist because it only takes a few practitioners who are not aware of the risks of disease transmission to inadvertently expose patients to pathogens.

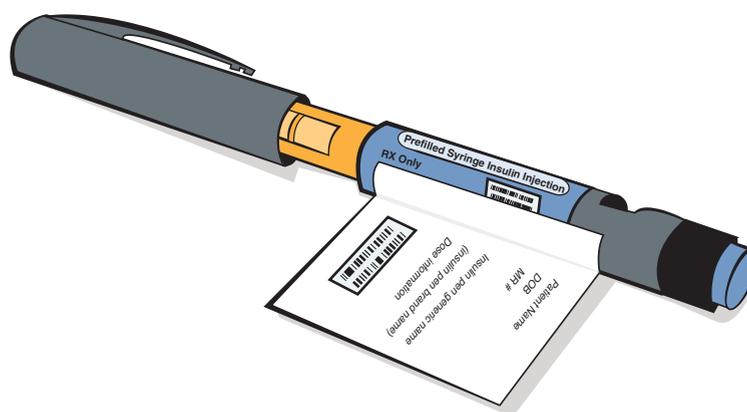
Current pen designs also provide challenges to applying patient-specific labels. In order to avoid affixing the label to the removable pen cap or covering critical drug information (e.g., drug name), pharmacy staff members must affix a flag label to the limited free space that exists on the pen body (see Figure 4).¹⁷

Faced with the risk of disease transmission, one multihospital system chose to move beyond the recommendations described above.¹⁹ They conducted detailed failure mode and effects analysis and employed safety best practices, in

addition to ongoing education, to reduce the risk of wrong-patient insulin pen errors. Their strategies included the following:

- Standardize to use pen devices for only one type of insulin product, a rapid-acting insulin, and dispense other insulin products in vials or pharmacy-prepared syringes.
- Apply tamper-evident tape to help identify previously used pens.
- Cover the manufacturer’s bar code on the pen with an order-specific, bar-coded label to associate the specific pen with a specific patient.
- Implement highly visible alerts and hard stops in the bar-code system if the wrong patient’s identification band is scanned.
- Monitor bar-code administration records on a daily, weekly, and monthly basis to evaluate scanning compliance, identify close calls, and identify potential wrong-pen injections in which the nurse received a “wrong

Figure 4. Diagram of Insulin Pen with Flag Label Attached



Limited free space on the pen device for application of a patient label requires a pharmacy staff member to affix a “flag” label. Care must be taken to attach the label to the body of the pen without covering the drug name, expiration date, lot number, and dosing window. If the label is affixed to the pen cap, the pen is no longer labeled once the cap is removed.

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pen” alert but manually documented administration in the electronic medication administration record without scanning the correct pen.

Despite these additional layers of safety, these hospitals identified seven instances in which a pen was reused on another patient during the first three months following implementation. In more than 400 events, the nurse picked the wrong patient’s insulin pen but the error was caught by the bedside bar-code scanning system prior to administering the dose. However, the facilities also identified that bar-code scanning did not occur in roughly 800 instances when insulin was administered with a pen device.¹⁹

Analysis of the contributing factors showed that most of the events were not due to knowledge deficits of the danger of sharing pens but were primarily associated with system issues, human error, and at-risk behaviors. Similar to what was found in the events reported to the Authority, untimely removal of pens from

units upon patient discharge or transfer; accidentally retrieving the wrong patient’s pen from a proximal medication bin; dispensing the pen to the wrong patient bin; putting the pen back into the wrong patient bin after use; and other system and behavioral issues contributed to the wrong-patient events. Presented with continued vulnerabilities despite the implementation of the higher-leverage strategies mentioned above, the hospital system decided to discontinue the use of insulin pens and dispense the rapid-acting insulin in 3 mL vials.¹⁹

LIMITATIONS

In-depth analysis by the Authority of wrong-patient events with the use of insulin pens occurring in Pennsylvania hospitals is limited by the information reported through PA-PSRS, including the event descriptions. Inconsistent use of product names and spellings confounds the identification of insulin-pen-related reports. As a result, additional wrong-patient events may have been

reported but were not identified by the query and analysis.

CONCLUSION

Despite widespread media coverage, recommendations from various national organizations, and application of strategies considered best practices, wrong-patient insulin pen injections continue to occur, and patients continue to be vulnerable to the risk of wrong-patient errors and potential transmission of bloodborne pathogens with insulin pens. This has prompted some organizations to question if the risk of disease transmission is best mitigated by not using insulin pens in the inpatient settings.^{19,21} However, the alternative use of insulin vials in inpatient settings is associated with its own set of hazards and error risks.²² Hospitals are encouraged to collect and analyze their own wrong-patient events with the use of insulin pens and closely examine their current insulin practices as they decide whether to use pens, vials, or a combination of the two.

NOTES

- Graff MR, McClanahan MA. Assessment by patients with diabetes mellitus of two insulin pen delivery systems versus a vial and syringe. *Clin Ther* 1998 May-Jun;20(3):486-96.
- Korytkowski M, Bell D, Jacobsen C, et al. A multicenter, randomized, open-label, comparative, two-period crossover trial of preference, efficacy, and safety profiles of a prefilled, disposable pen and conventional vial/syringe for insulin injection in patients with type 1 or 2 diabetes mellitus. *Clin Ther* 2003 Nov;25(11):2836-48.
- Kroon L. Overview of insulin delivery pens. *J Am Pharm Assoc* (2003) 2009 Sep-Oct;49(5):e118-31.
- Molife C, Lee LJ, Shi L, et al. Assessment of patient-reported outcomes of insulin pen devices versus conventional vial and syringe. *Diabetes Technol Ther* 2009 Aug;11(8):529-38.
- Carter J, Beilin J, Morton A, et al. Usability, participant acceptance, and safety of a prefilled insulin injection device in a 3-month observational survey in everyday clinical practice in Australia. *J Diabetes Sci Technol* 2009 Nov 1;3(6):1425-38. Also available at <http://dst.sagepub.com/content/3/6/1425.full.pdf+html>
- Sonoki K, Yoshinari M, Iwase M, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. *Diabetes Care* 2001 Mar;24(3):603-4.
- Le Floch JP, Herbreteau C, Lange F, et al. Biologic material in needles and cartridges after insulin injection with a pen in diabetic patients. *Diabetes Care* 1998 Sep;21(9):1502-4.
- Herdman ML, Larck C, Schliesser SH, et al. Biological contamination of insulin pens in a hospital setting. *Am J Health Syst Pharm* 2013 Jul 15;70(14):1244-8.
- Hakre S, Upshaw-Combs DR, Sanders-Buell EE, et al. An investigation of bloodborne pathogen transmission due to multipatient sharing of insulin pens. *Mil Med* 2012 Aug;177(8):930-8.
- Centers for Medicare and Medicaid Services. Use of insulin pens in health care facilities [online]. 2012 May 18 [cited 2015 Apr 27]. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-30.pdf>
- Centers for Disease Control and Prevention. CDC clinical reminder: insulin pens must never be used for more than one person [online]. 2012 Jan 5 [cited 2015 Apr 27]. <http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html>
- US Food and Drug Administration. Information for healthcare professionals: risk of transmission of blood-borne pathogens from shared use of insulin pens [online]. 2009 Mar 19 [cited 2015 Apr 27]. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm133352.htm>

13. One and Only Campaign. Insulin pen safety—one insulin pen, one person [online]. 2012 [cited 2015 Apr 27]. <http://www.oneandonlycampaign.org/content/insulin-pen-safety>
14. Cobaugh DJ, Maynard G, Cooper L, et al. Enhancing insulin-use safety in hospitals: practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm* 2013 Aug 15;70(16):1404-13.
15. Institute for Safe Medication Practices. Reuse of insulin pen for multiple patients risks transmission of bloodborne disease. *ISMP Med Saf Alert Acute Care* 2009 Feb 12;14(3):1-2. Also available at <http://www.ismp.org/newsletters/acutecare/articles/20090212-2.asp>
16. Institute for Safe Medication Practices. Cross contamination with insulin pens. *ISMP Med Saf Alert Acute Care* 2008 Mar 27;13(6):1-2.
17. Institute for Safe Medication Practices. Hazard alert: do not use an insulin pen for multiple patients. *ISMP Med Saf Alert Acute Care* 2012 Jan 1;17(1):1,4.
18. Schaefer MK, Kossover RA, Perz JF. Sharing insulin pens: are you putting patients at risk? *Diabetes Care* 2013 Nov;36(11):e188-9. Also available at <http://care.diabetesjournals.org/content/36/11/e188.full>
19. Institute for Safe Medication Practices. A crack in our best armor: “wrong patient” insulin pen injections alarmingly frequent even with barcode scanning. *ISMP Med Saf Alert Acute Care* 2014 Oct 23;19(21):1-5. Also available at <http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=92>
20. Institute for Safe Medication Practices. Ongoing concern about insulin pen reuse shows hospitals need to consider transitioning away from them. *ISMP Med Saf Alert Acute Care* 2013 Feb 7;18(3):1-2. Also available at <http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=41>
21. US Department of Veterans Affairs. Patient safety alert: multi-dose pen injectors [online]. 2013 Jan 17 [cited 2015 Apr 27]. <http://www.patientsafety.va.gov/docs/alerts/AL13-04MultiDosePens.pdf>
22. Institute for Safe Medication Practices. A clinical reminder about the safe use of insulin vials. *ISMP Med Saf Alert Acute Care* 2013 Feb 21;18(4):1-4. Also available at <http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=42>

NOTES: FIGURE 1

1. Institute for Safe Medication Practices. Reuse of insulin pen for multiple patients risks transmission of bloodborne disease. *ISMP Med Saf Alert Acute Care* 2009 Feb 12;14(3):1-2. Also available at <http://www.ismp.org/newsletters/acutecare/articles/20090212-2.asp>
2. US Food and Drug Administration (FDA). Information for healthcare professionals: risk of transmission of blood-borne pathogens from shared use of insulin pens [online]. 2009 Mar 19 [cited 2015 Apr 27]. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm133352.htm>
3. Sanofi Aventis. Safe use of insulin pens and other diabetes products [letter online]. 2009 Apr [cited 2015 Apr 27]. <http://www.ismp.org/newsletters/acutecare/articles/hcp-Letter.pdf>
4. Seely R. Dean Clinic says patients may have been exposed to hepatitis, HIV [online]. *Wis State J* 2011 Aug 13 [cited 2015 Apr 27]. http://host.madison.com/news/local/health_med_fit/dean-clinic-says-patients-may-have-been-exposed-to-hepatitis/article_5806e8b6-d261-11e0-8dcb-001cc4c002e0.html
5. Centers for Disease Control and Prevention (CDC). CDC clinical reminder: insulin pens must never be used for more than one person [online]. 2012 Jan 5 [cited 2015 Apr 27]. <http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html>
6. Centers for Medicare and Medicaid Services (CMS). Use of insulin pens in health care facilities [online]. 2012 May 18 [cited 2015 Apr 27]. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-30.pdf>
7. Burruss L. Insulin injection errors may have exposed veterans to viruses [online]. *CNN* 2013 Jan 17 [cited 2015 Apr 15]. <http://www.cnn.com/2013/01/14/health/new-york-va-virus-exposure>
8. Associated Press. Olean General Hospital warns 1,915 patients of possible HIV exposure from insulin pens [online]. *Huffington Post* 2013 Jan 24 [cited 2015 Apr 27]. http://www.huffingtonpost.com/2013/01/24/olean-general-hospital-hiv-exposure-patientsinsulin-pens_n_2543648.html
9. US Department of Veterans Affairs (VA). Patient safety alert: multi-dose pen injectors [online]. 2013 Jan 17 [cited 2015 Apr 27]. <http://www.patientsafety.va.gov/docs/alerts/AL13-04MultiDosePens.pdf>
10. Whisenant D. Salisbury VA: same insulin pens used on more than one patient [online]. *WBTW* 2013 Mar 7 [cited 2015 Apr 27]. <http://www.wbtv.com/story/21546682/salisbury-va-insulin>
11. L.I. hospital: reused insulin pen part may mean hepatitis, HIV risk for patients [online]. *CBS New York* 2014 Mar 11 [cited 2015 Apr 27]. <http://newyork.cbslocal.com/2014/03/11/li-hospital-reused-insulin-pen-part-may-mean-hepatitis-hiv-risk-for-patients>
12. Quayle MA. Griffin hospital: insulin pen misuse could have infected patients with disease [online]. *New Haven Register* 2014 May 17 [cited 2015 Apr 15]. <http://www.nhregister.com/general-news/20140516/griffin-hospital-insulin-pen-misuse-could-have-infected-patients-with-diseases>
13. US Food and Drug Administration. FDA drug safety communication: FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients [online]. 2015 Feb 25 [cited 2015 Apr 27]. <http://www.fda.gov/Drugs/DrugSafety/ucm435271.htm>

Antimicrobial Therapy for Pneumonia in Pennsylvania Long-Term Care: A Spotlight on Culture

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ABSTRACT

In the United States, pneumonia is responsible for an estimated 60,000 deaths annually of people age ≥ 65 years and is the fifth leading cause of death within this population. Because of the prevalence of pneumonia, antibiotics are widely prescribed and administered in the long-term care (LTC) community. Empiric antibiotic therapy is sometimes used to target the pathogens that commonly cause pneumonia in a specific population, but without confirmatory cultures, antibiotic selection may not be optimal. To gauge the extent of culture-guided antimicrobial therapy for pneumonia in Pennsylvania LTC facilities, Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System database. The percentage of LTC residents who received antibiotics for pneumonia in the absence of culture data ranged from 85.2% to 91.0% across Pennsylvania regions. There is a pressing need to attempt to collect culture data, rather than relying on empiric treatment algorithms, in order to tailor treatment to a specific pathogen as often as clinically possible. (Pa Patient Saf Advis 2015 Sep;12[3]:116-8.)

INTRODUCTION

In the United States, pneumonia is responsible for an estimated 60,000 deaths annually of people age ≥ 65 years and is the fifth leading cause of death within this population.¹ Loeb states that “residents of long-term care facilities—a distinct subpopulation of elderly people—are at particularly high risk for developing pneumonia.”¹ Because of the prevalence of pneumonia and other conditions such as urinary tract infection, antibiotic use is common in the long-term care (LTC) community. Furthermore, the Centers for Disease Control and Prevention (CDC) states that “antibiotic-related complications, such as diarrhea from *C. difficile*, can be more severe, difficult to treat, and lead to more hospitalizations and deaths among people over 65 years.”² CDC asserts that antibiotics are among the most commonly prescribed medications in LTC facilities and that nationally, “up to 70% of long-term care facilities’ residents receive an antibiotic every year.”²

Several guidelines for the treatment of pneumonia with antibiotics exist,^{3,6} and depending on the resident’s medical history or the constellation of residents in a particular care area, a clinician may need to choose between treatment algorithms. For example, a resident who has had no hospital admissions, is active, and is visited frequently by friends and family may be at risk for community-acquired pneumonia, whereas a resident with frequent admissions to the hospital and a history of multidrug-resistant organism infection may be an ideal candidate for a healthcare- or hospital-associated pneumonia antibiotic treatment algorithm. Treatment decisions can be more complicated for those residents who frequently require outpatient services external to the LTC facility and have a high volume of friends and family visits, as they may be exposed to both community and healthcare-associated bacteria and viruses.

Given the variety of pathogens causing pneumonia, culture data obtained to guide pneumonia treatment would appear to be an ideal approach to optimize care. However, obtaining diagnostic cultures in LTC remains challenging for several reasons, including the following:

- Debilitated residents may be unable to produce specimens in a quantity suitable for culture.
- Staff may not be trained in, or comfortable with, proper culturing techniques.
- Alternative culture techniques, such as nasopharyngeal lavage or bronchial aspirate lavage, are often unavailable or inappropriate.
- Residents may be colonized with potentially pathogenic bacteria in addition to infection-causing bacteria.

Because obtaining culture data for diagnosis of pneumonia in LTC facilities is challenging, diagnosis may be criteria- and symptom-based. Empiric antibiotic therapy is often used to treat pathogens that commonly cause pneumonia in a specific population.^{4,7,8}

To evaluate the extent to which culture-guided antimicrobial therapy for pneumonia in Pennsylvania LTC facilities occurs, Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database.

METHODS

Analysts queried PA-PSRS for pneumonia events reported from April 1, 2014, through March 31, 2015. This time period was chosen because it is the first full year of data available since PA-PSRS was updated to version 2 in April 2014. The updated version includes data fields specific to whether a culture was performed, combined with

antibiotic administration data fields in relation to a pneumonia event. For this query, “culture” was defined as microbiologic culture collected as part of the pneumonia reporting pathway. The data was then sorted by geographic region and converted to percentages in order to normalize for population distribution. Facilities reporting no pneumonia events were removed from the analysis.

RESULTS

The percentage of reported events in which residents received antibiotics for pneumonia in the absence of culture ranged from 85.2% to 91.0% across Pennsylvania regions (see Figure 1). The results indicate treatment for the majority of residents who meet pneumonia criteria is empiric rather than culture-directed.

Figure 2 depicts the number of pneumonia events reported, per facility, in which antibiotics were administered in the absence of microbiologic culture data compared with pneumonia events in which antibiotics were administered and a culture had been performed. As shown in the figure, the vast majority of pneumonia events were treated with antibiotics in the absence of microbiologic culture data, and nearly all of the facilities submitting reports were more likely to treat pneumonia with antibiotics without a culture than with a culture.

DISCUSSION

The Importance of Culture

Antimicrobial treatment for pneumonia in Pennsylvania LTC facilities seems to be guided by diagnostic criteria sets, empiric therapy algorithms, and clinician experience rather than by culture data. Culture data and laboratory-guided antimicrobial therapy are necessary for optimal antibiotic use. Tracking and reporting antibiotic prescribing patterns helps optimize therapy for individuals and may decrease the emergence of antibiotic-resistant organisms.

Figure 1. Percentage of Reported Long-Term Care Pneumonia Events, Fitting Pennsylvania Patient Safety Reporting System Criteria, for Which the Patient Had Been Treated with Antibiotics Absent Bacteriologic Culture Data, by Region, April 2014 through March 2015

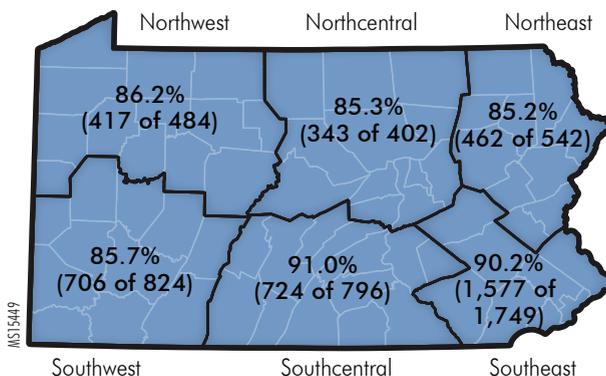
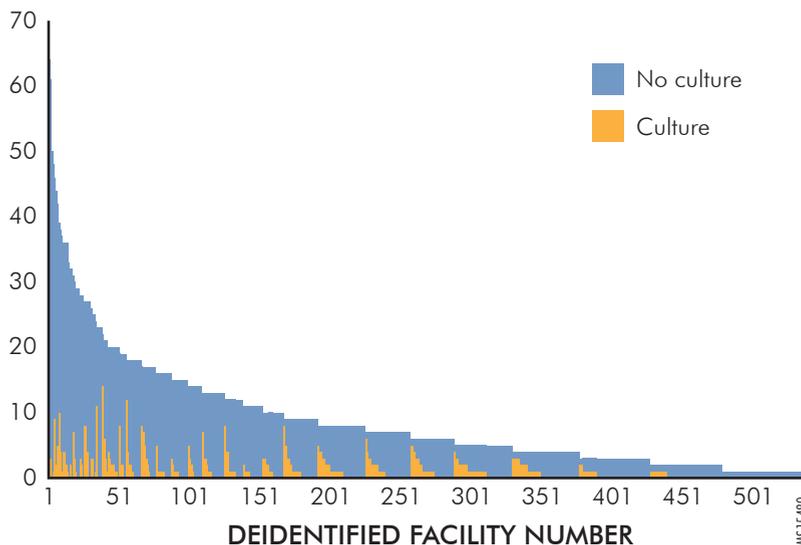


Figure 2. Treatment of Pneumonia Events with Antibiotics, per Facility, as Reported through Pennsylvania Patient Safety Reporting System, April 2014 through March 2015

NO. OF PNEUMONIA EVENTS TREATED WITH ANTIBIOTICS





Leadership support, accountability, drug expertise, and education are imperative in terms of optimizing antimicrobial use. Furthermore, “[microbiologic] cultures may have a major impact on the care of an individual patient and are important for epidemiologic reasons, including the antibiotic susceptibility patterns used to develop treatment guidelines.”⁵ In 2000, the Society for Healthcare Epidemiology of America noted that “the use of empiric antibiotics does not eliminate the need to establish the causative etiologic agent whenever possible.”⁴

Infectious-Disease Consultation

In addition to challenges to effective culture collection, other challenges related to infectious-disease management in LTC facilities include lack of access to an accurate and complete medical record, lack of time and reimbursement, and poor clinical and nursing support.⁹

It has been noted that these challenges combined with a lack of microbiologic culture data contributes to inappropriate antibiotic prescribing.^{4,10} In an effort to curb inappropriate antimicrobial use, Jump et al. noted the value of infectious-disease consultation services for the LTC setting. Postintervention, the researchers found a significant reduction in total antimicrobial use, including fluoroquinolones, and a decline in the rate of change of positive *Clostridium difficile* tests.¹¹ Fluoroquinolone use is common in the treatment of pneumonia and is a risk factor for developing *C. difficile* infection.

CONCLUSION

Healthcare in general has been slow to respond to the emerging threat of antibiotic resistance that has been developing for at least 25 years.¹² Given the importance of establishing the causative

infectious agent whenever possible, there is a pressing need to attempt to collect culture data in order to tailor treatment to a specific pathogen as often as clinically possible and to not rely on extended empiric therapy. The establishment of antibiotic stewardship programs and infectious-disease consultation has been shown to decrease the risks from antibiotic use (especially *C. difficile*) in individual facilities and the LTC community as a whole.

A crucial step for the future of antibiotic stewardship is the collection of resident-level culture data, thereby creating pathogen-specific data in order to guide antibiotic stewardship activities and enhance the effectiveness of infectious-disease specialist consultation. Further guidance on implementation of specific strategies for addressing practice gaps and opportunities for improvement in antibiotic stewardship will be presented in future *Pennsylvania Patient Safety Advisory* articles.

NOTES

- Loeb M. Pneumonia in older persons. *Clin Infect Dis* 2003 Nov 15;37(10):1335-9.
- Centers for Disease Control and Prevention. Antibiotic use in nursing homes. Get Smart About Antibiotics Week: November 18-24, 2013 [online]. 2013 [cited 2015 Jun 1]. <http://www.cdc.gov/getsmart/healthcare/learn-from-others/factsheets/nursing-homes.html>
- Kollef MH, Morrow LE, Baughmann RP, et al. Health care-associated pneumonia (HCAP): a critical appraisal to improve identification, management, and outcomes—proceedings of the HCAP Summit. *Clin Infect Dis* 2008 Apr 15;46 Suppl 4:S296-334.
- Nicolle LE, Bently DW, Garibaldi R, et al. Antimicrobial use in long-term-care facilities. *Infect Control Hosp Epidemiol* 2000 Aug;21(8):537-45.
- Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. *Clin Infect Dis* 2007 Mar 1;44 Suppl 2:S27-72.
- American Thoracic Society, Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. *Am J Respir Crit Care Med* 2005 Feb 15;171(4):388-416.
- Furman CD, Rayner AV, Tobin EP. Pneumonia in older residents of long-term care facilities. *Am Fam Physician* 2004 Oct 15;70(8):1495-1500.
- Stone ND, Ashraf MS, Calder J, et al. Surveillance definitions of infections in long-term care facilities: revisiting the McGeer criteria. *Infect Control Hosp Epidemiol* 2012 Oct;33(10):965-77.
- Caprio TV, Karuzu J, Katz PR. Profile of physicians in the nursing home: time perception and barriers to optimal medical practice. *J AM Med Dir Assoc* 2009 Feb;10(2):93-7.
- Van Schooneveld T, Miller H, Sayles H, et al. Survey of antimicrobial stewardship practices in Nebraska long-term care facilities. *Infect Control Hosp Epidemiol* 2011 Jul;32(7):732-4.
- Jump RL, Olds DM, Seifi N, et al. Effective antimicrobial stewardship in a long-term care facility through an infectious disease consultation service: keeping a LID on antibiotic use. *Infect Control Hosp Epidemiol* 2012 Dec;33(12):1185-92.
- Cohen ML. Epidemiology of drug resistance: implications for a post-antimicrobial era. *Science* 1992 Aug 21;257(5073):1050-5.

Quarterly Update on Wrong-Site Surgery: Eleven Years of Data Collection and Analysis

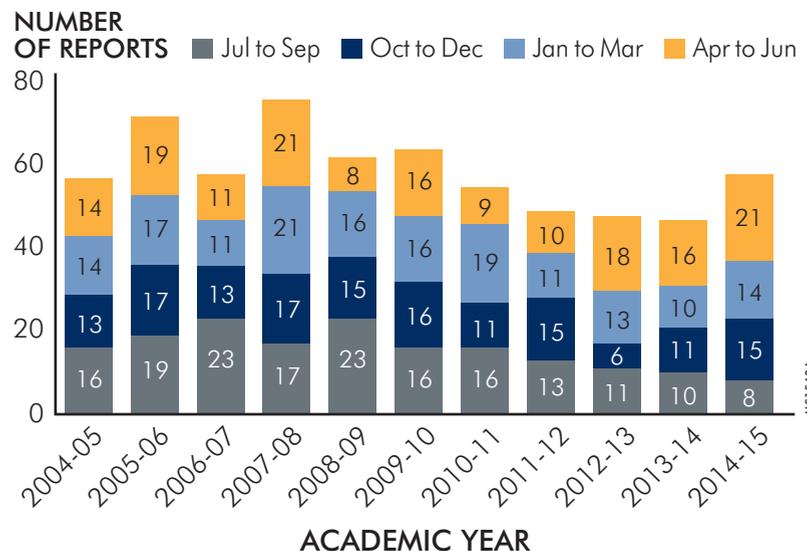
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Since July 2004, 646 wrong-site surgery events have been reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) and analyzed by the Pennsylvania Patient Safety Authority. Data collected through the fourth quarter of the 2014-2015 academic year marks 11 complete years of review and analysis. As noted in the Figure, steady progress was made in the number of events reported since the 2007-2008 academic year—the year the Authority’s Preventing Wrong-Site Surgery project began. However, throughout the 2014-2015 academic year, consistent regression was noted in the number of quarterly events reported as compared with the two previous years, with the exception of the first quarter. A total number of 58 events were reported in the most recent academic year, reflecting the highest number of events since 2009-2010.

Twenty-one events were reported in the last quarter of the 2014-2015 academic year, the highest quarterly number of reported events since the first quarter of the 2008-2009 academic year (i.e., 27 quarters of data collection). Of the events reported from Pennsylvania operating rooms (ORs) this quarter, 23.8% (n = 5) accounted for wrong-site anesthesia blocks—one of which was administered by an anesthesiologist and the other four by surgeons. The other types of wrong-site surgery events were as follows: wrong-site procedures (23.8%, n = 5), three of which were wrong-site hand procedures involving a trigger finger release; misidentified spinal levels (23.8%, n = 5); wrong-side procedures (14.3%, n = 3); wrong-side ureteral stent placements (9.5%, n = 2); and a wrong-side pain management procedure (4.8%, n = 1).

The three most common types of wrong-site OR procedures reported through PA-PSRS since July 2004 continue to persist and account for more than 50% of events: anesthetic blocks by anesthesiologists and surgeons (27.4%, n= 177 of 646), wrong-level spinal procedures (12.7%, n = 82 of 646), and pain management procedures (11.1%, n = 72 of 646).

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



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

The reason for the observed regression is not clearly understood. Familiar mishaps and system failures continue to occur in all three phases of the Universal Protocol.¹ To maximize its effectiveness and ensure the success of any wrong-site surgery program, it is essential that surgical teams (1) ensure that all preoperative documents are verified against the primary sources and (2) maintain situational awareness not only during the time-out but also throughout the procedure.²

An essential step in the preoperative verification and reconciliation process is confirming that all the patient documents (i.e., OR schedule, consent, and history and physical) align with the patient's understanding of the procedure. The following scenario illustrates the potential outcome when this practice is overlooked:*

Patient arrived for a right transforaminal epidural steroid injection. Patient was asked where he was having pain. The patient used his left arm and pointed to the location on the patient's back. The physician then marked the patient's back. The

patient was brought to the procedure room and assisted to the prone position on the procedural table. The time-out was completed. The patient's procedure started, and the appropriate spinal level was identified by fluoroscopy. The patient was injected at the appropriate spinal level at the site marking on the left side. Immediately following the injection, the patient stated that he felt symptoms from injection on the left but his pain was on his right side. The consent was then checked and noted that the patient's pathology was noted to be on the right side.

Between 2007 and 2014, the Authority led three collaboration projects to help drive change in about 80 healthcare facilities. Through these collaborations and independent requests, the Authority has performed on-site consultations and observations of Pennsylvania ORs. Failure to visualize and reference the site mark in the prepped and draped field is a consistently observed deficiency that is relayed during team debriefing sessions. The following report is an example of such an observation:

Patient was having a left shoulder arthroscopy and a trigger finger release of the left ring finger. The

correct surgical sites were marked with the patient's approval, and a surgical time-out was performed prior to case. The shoulder procedure was done first. Once completed, the OR circulator reviewed the procedure and site to be done next for the trigger finger release. The surgeon started to make an incision on the left thumb in error. The circulator stopped the surgeon as soon as the incision was made. The incision was closed and the correct trigger finger release was performed.

Please visit the Authority's website for the full suite of wrong-site surgery prevention tools at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx>. The newest addition to the collection is the Gap Analysis and Action Plan to Prevent Wrong-Site Surgery tool. This tool provides surgical teams with the opportunity to identify potential practice gaps as compared with the 21 evidenced-based best practices issued by the Authority.³

To request additional information about the Authority's Preventing Wrong-Site Surgery program, including an on-site consultation, Pennsylvania hospitals and ambulatory surgical centers may contact their patient safety liaison.

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

NOTES

1. Joint Commission. The Universal Protocol for preventing wrong site, wrong procedure, and wrong person surgery [poster online]. [cited 2015 Jul 21]. http://www.jointcommission.org/assets/1/18/UP_Poster1.PDF
2. Clarke JR. Wrong surgery: why does not the Universal Protocol solve the problem? *Am J Surg* 2015 Jul;210(1):14.
3. Pennsylvania Patient Safety Authority. Principles for reliable performance of correct-site surgery [online]. 2012 Dec [cited 2015 Jul 21]. <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/principles.aspx>

Identify Sufficient Supplemental Oxygen for Patient Intrahospital Transport

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*After returning from radiology, an elderly patient with multiple medical problems was found in the ED [emergency department] treatment room with a pulse oximetry of 73%, bradycardic, and unresponsive. It was identified that the portable oxygen tank on the patient's bed was empty. The patient was intubated and admitted to the coronary care unit.**

Challenges in ensuring sufficient oxygen during patient transport, initially identified in a September 2005 *Pennsylvania Patient Safety Advisory* article,¹ persist in Pennsylvania hospitals. Patients who have a critical need for continuous supplemental oxygen add an additional layer of risk during intrahospital transport.^{2,3} Such patients are usually supplied by a central oxygen source. Once removed from a central oxygen source, they are supplied by a portable source (i.e., oxygen tank) for use throughout transport, including during wait and reconnection times, to various sites within the hospital for tests, procedures, and therapies. Using situational awareness and calculators to determine the anticipated duration of oxygen therapy needed may help avoid events with unintended interruptions in the administration of oxygen.

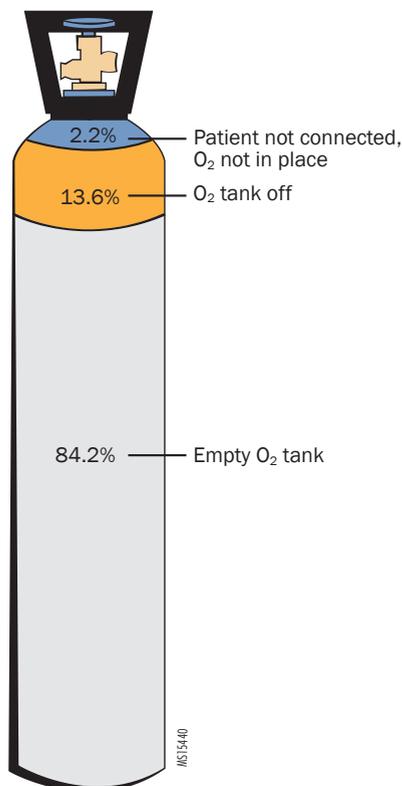
Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events during the most recent 10-year reporting period, January 1, 2005, through December 31, 2014, that contained the keywords “oxygen tank,” “O₂,” “air,” or “empty O₂ tank” and events reported as respiratory care medical gas errors. The query identified 393 oxygen tank–related events (including some previously discussed in the 2005 article), of which analysis determined 360 were associated with unintended interruptions in the administration or management of oxygen therapy. Empty oxygen tanks accounted for 84.2% (n = 303 of 360) of the event reports. See the Figure.

The majority of event reports related to empty oxygen tanks, 96.4% (n = 292 of 303), occurred in settings such as medical-surgical units, rehabilitation units, diagnostic imaging locations, and emergency departments. Only 3.6% (n = 11 of 303) of the empty oxygen tank–related event reports occurred in an intensive care unit.

Healthcare personnel responsible for transporting patients requiring supplemental oxygen help confirm whether the oxygen tank selected for use contains enough oxygen for the duration of time needed to complete the test or procedure, transport the patient to and from the test or procedure site, and reconnect the patient to the central oxygen source, including wait times throughout these processes. Calculating whether the amount of oxygen in the tank is adequate can avert transporting a patient with an empty or insufficiently filled oxygen tank. Calculations can be performed using formulas,⁴ look-up tables,^{1,5} or calculator applications available both online and as mobile apps.^{4,6,7}

An Internet search identified several online oxygen tank calculator applications.^{4,6,7} It is important to note that while calculator applications are useful, there may be little to no regulatory oversight or assessment of their accuracy.^{8,9,10} One calculator requires knowing the size of oxygen tank (e.g., E tank), the remaining tank pressure (i.e., pounds per square inch), and the flow rate of oxygen to the patient (liters per minute) to calculate the remaining duration of oxygen delivery.⁴ Another calculator allows the user to either determine the amount of time remaining in the tank based on a particular gauge pressure or determine the necessary gauge pressure required for the estimated duration of time the tank will be in use.⁷ Both calculators provide the formulas so the user can verify the results.^{4,7}

Figure. Pennsylvania Patient Safety Reporting System Oxygen (O₂) Tank Event Reports, January 1, 2005, through December 31, 2014 (N = 360)



* The details of this PA-PSRS event narrative have been modified to preserve confidentiality.

Before connecting a patient to a portable oxygen tank, determining whether the tank contains a sufficient amount

of oxygen for the duration of patient transport, including the time for the procedure or test in addition to wait

and reconnection times, can help avoid unintended interruptions in providing supplemental oxygen.

NOTES

1. Continuity of oxygen therapy during intrahospital transport. PA PSRS Patient Saf Advis [online] 2005 Sep [cited 2015 Jun 29]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/sep2\(3\)/Pages/09.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/sep2(3)/Pages/09.aspx)
2. Safe intrahospital transport of the non-ICU patient using standardized handoff communication. Pa Patient Saf Advis [online] 2009 Mar [cited 2015 Jun 30]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Mar6\(1\)/Pages/16.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Mar6(1)/Pages/16.aspx)
3. Michael R. Hospital nursing policies changes regarding portable oxygen containers [online]. [cited 2015 Jun 30]. <http://www.innercircle.org/living-justice/1253953/Hospitalnursingpolicieschangesregardingportableoxygencontainers>
4. Oxygen cylinder and O2 tank duration calculation [online]. [cited 2015 Jun 29]. <http://www.medfixation.com/oxygen-cylinder-tank-calculation>
5. US Department of Veterans Affairs National Center for Patient Safety. Escorts improving patient safety [online]. NCPS Tips 2002 Mar-Apr [cited 2015 Aug 4]. <http://www.patientsafety.va.gov/docs/TIPS/TIPSMar02.pdf>
6. O2 remaining in e-cylinder calculator [online]. [cited 2015 Jul 10]. <http://www.manuelsweb.com/O2remaining.htm>
7. Cornell University Weill Medical College. Oxygen tank duration [online]. 2013 Feb 22 [cited 2015 Jul 10]. <http://www-users.med.cornell.edu/~spon/picu/calc/o2tankd.htm>
8. US Food and Drug Administration. Mobile medical applications: guidance for industry and Food and Drug Administration staff [online]. 2015 Feb 9 [cited 2015 Jul 14]. <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>
9. Bierbrier R, Lo V, Wu RC. Evaluation of the accuracy of smartphone medical calculation apps [online]. J Med Internet Res 2014 Feb 3 [cited 2015 Jul 14]. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3936266>
10. Mosa AS, Yoo I, Sheets L. A systematic review of healthcare applications for smartphones [online]. BMC Med Inform Decis Mak 2012 Jul 10 [cited 2015 Jul 14]. <http://www.biomedcentral.com/content/pdf/1472-6947-12-67.pdf>



The 160-Pound Computer That Can Be Mass-Produced by Unskilled Labor

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After three years of training, John Glenn rocketed into space aboard the Mercury capsule Friendship 7. He became the third American in space and the first to orbit Earth. The historical flight was no easy feat. At the end of his first orbit, a yaw attitude jet clogged, forcing Glenn to abandon the automatic control system and use the manual electrical fly-by-wire system.¹

Astronaut Glenn's landmark flight took place in 1962, supported by then state-of-the-art technology. Plans for the flight took into account the possibility that system components could fail or malfunction, with catastrophic results, so backup strategies addressed the need for a manual control system.² In fact, although the historical flight overall was a resounding success, some components of the spacecraft did not function properly,¹ requiring Glenn's knowledge and skills.

In accounts of the postflight debriefing, Scott Crossfield, a test pilot and aeronautical engineer,³ asked, "Where else would you get a non-linear computer weighing only 160 pounds, having a billion binary decision elements, that can be mass-produced by unskilled labor?"⁴ His recognition of the important capabilities of humans is relevant to our understanding of processes that support safer healthcare.

In working toward safer healthcare, we seek causes for outcomes that are perceived as unsafe or are thought to be less satisfactory than might have been expected. Various investigative processes may be used, such as root-cause analysis.⁵ It can be tempting, and may be a fundamental psychological tendency (e.g., hindsight bias) as well as an industry norm, to try to identify the action (or inaction) of a person as a cause for an unsatisfactory outcome, despite teachings to the contrary.⁶ Although many of the healthcare conditions we treat are biologic and not man-made, all of the healthcare delivery systems that we work within have been created by humans. If they fail, or do not succeed sufficiently, and we search for what we think may be a cause, we are bound to find a human:

The search for a human in the path of a failure is bound to succeed. If not found directly at the sharp end—as a "human error" or unsafe act—it can usually be found a few steps back. The assumption that humans have failed therefore always vindicates itself.⁷

Sometimes we are reminded that "to err is human,"⁸ or even "to err is human—and let's not forget it."⁹ Indeed, humans do make errors, and according to the Institute of Medicine (IOM), one of the greatest contributors to accidents in healthcare is human error.⁸ However, IOM, Lucian Leape, and others explain that human errors are often induced by system failures.^{8,10}

It is also humans who solve problems and rescue patients, humans who figure out compensatory strategies when expected resources are not available or do not function as expected or when novel circumstances arise. People working in healthcare are among the most educated and dedicated workforce in any industry.⁸ Rollin J. (Terry) Fairbanks asserts that "to better is human"¹¹ and Richard Holden states that "to blame is human, but the fix is to engineer."⁶ Safety is not inherent in systems. The systems themselves are contradictions among multiple goals that people must pursue simultaneously. People create safety.⁶

Computers and other technologies have improved the safety and capabilities of healthcare, just as they have improved the safety and capabilities of aeronautics. The contributions of technology are integral and essential in healthcare delivery. However, when our protocols are insufficient for the tasks at hand and our technologies

malfunction, it is the human element that we rely on to adapt, just as the human capabilities of John Glenn ensured the success of the Friendship mission. When

caring for patients within our complex healthcare delivery systems, there are many aspects of care that can and should be standardized and computerized, but

the unique skills, knowledge, and even compassion of this special type of 160-pound computer remain essential.

NOTES

1. National Aeronautics and Space Administration. Glenn orbits the Earth [online]. 2012 Feb 16 [cited 2015 Jul 10]. https://www.nasa.gov/centers/glenn/about/bios/mercury_mission.html
2. Preparing a man to orbit. In: Swenson LS Jr, Grimwood JM, Alexander CC. This new ocean: a history of Project Mercury [online]. NASA Special Publication-4201. 1989 [cited 2015 Jul 10]. <http://history.nasa.gov/SP4201/ch13-2.htm>
3. National Aeronautics and Space Administration. NASA Dryden biographies, former pilots: A. Scott Crossfield [online]. 2014 May 7 [cited 2015 Aug 12]. <http://www.nasa.gov/centers/armstrong/news/Biographies/Pilots/bd-dfrc-p021.html>
4. An American in orbit. In: Swenson LS Jr, Grimwood JM, Alexander CC. This new ocean: a history of Project Mercury [online]. NASA Special Publication-4201. 1989 [cited 2015 Jul 10]. <http://history.nasa.gov/SP4201/ch13-4.htm>
5. Deutsch ES. "What goes wrong" (Safety-I) and "what goes right" (Safety-II). Pa Patient Saf Advis [online] 2015 Jun [cited 2015 Jul 10]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/Jun;12\(2\)/Pages/83.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2015/Jun;12(2)/Pages/83.aspx)
6. Holden RJ. People or systems? To blame is human. The fix is to engineer. *Prof Saf* 2009 Dec;54(12):34-41.
7. Hollnagel E, Woods DD. *Joint cognitive systems: foundations of cognitive systems engineering*. Boca Raton (FL): Taylor and Francis; 2005.
8. Kohn LT, Corrigan JM, Donaldson MS, eds. Institute of Medicine. *To err is human: building a safer health system*. Washington (DC): National Academy Press; 2000.
9. Croskerry P. To err is human-and let's not forget it. *CMAJ* 2010 Mar 23;182(5):524.
10. Leape L. Cultivating and sustaining respectful behavior. Keynote presentation at: 17th Annual NPSF Patient Safety Congress; 2015 Apr 30; San Antonio (TX).
11. MedStar Health National Center for Human Factors in Healthcare [website]. [cited 2014 Nov 2]. Washington (DC): National Center for Human Factors in Healthcare. <http://medicallhumanfactors.net>

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THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

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