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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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Frequent Monitoring and Behavioral Assessment: Keys to the Care of the Intoxicated Patient

INTRODUCTION

Intoxicated patients and those under the influence of alcohol, regardless of care setting, pose unique challenges to healthcare providers, who must manage patient aggression, gain cooperation with treatments, and monitor the patient for changes in condition, including gradual or acute deterioration.

The World Health Organization (WHO) estimates that 38.3% of the world’s population drinks alcohol. Individuals older than 15 years drink 6.2 liters on average per year, and globally, harmful use of alcohol causes about 3.3 million (5.9%) deaths every year. Two-thirds of American adults consume alcohol, up to 10% abuse it, and acute intoxication is associated with traffic accidents, domestic violence, homicide, and suicide. A 2014 survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) noted that “24.7% of people ages 18 or older reported that they engaged in binge drinking† in the past month; 6.7% reported they engaged in heavy drinking in the past month.” In the United States, it is estimated that more than 600,000 emergency department (ED) visits are directly related to alcohol intoxication.

The Centers for Disease Control and Prevention reports that excessive alcohol use is responsible for an annual average of 88,000 deaths and 2.5 million years of potential life lost. More than half of these deaths and three-quarters of the years of potential life lost were due to binge drinking.

Nationally, Pennsylvania ranks in the top tertile† at 18.5% for age-adjusted prevalence of binge drinking among adults age 18 years or older and in the middle tertile at 7 drinks per occasion for the average largest number of drinks consumed by binge drinkers on any occasion in the past month.

Pennsylvania Patient Safety Authority analysts analyzed Serious Events associated with alcohol use, abuse, and intoxication in all care areas and found that failures or inadequacies of assessing and monitoring were associated with patient harm. Analysts sought to describe the evidence-based best practices for the assessment and management of intoxicated patients.

METHODS

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for event reports related to alcohol intoxication, including reports that described patients under the influence or abuse of alcohol in all acute level facilities, including hospitals, birthing centers, abortion clinics, and ambulatory surgical facilities in Pennsylvania submitted between January 1, 2005, and December 31, 2015. The following search terms were used to identify applicable events: alcohol, intoxicated, inebriate, ETOH, drunk, under the influence, unconscious, police, blood alcohol content, BAC, Narcan, sleep off, banana bag, and detox. The initial query resulted in 9,536 reports.

The query was re-run to exclude patients age 0 to 17 years (n = 349) because of the unique needs and different treatment approaches for this population, events occurring more than 24 hours after admission (n = 2,888), and events unrelated to alcohol intoxication.

ABSTRACT

Worldwide, harmful use of alcohol causes more than 3 million deaths per year. Two-thirds of American adults consume alcohol and up to 10% abuse it. In the United States every year, more than 600,000 emergency department visits are related to alcohol intoxication. Pennsylvania ranks in the top third for binge drinking in the United States. Between January 1, 2005, and December 31, 2015, more than 9,500 alcohol-related events were reported to the Pennsylvania Patient Safety Authority through its Pennsylvania Patient Safety Reporting System. Review of narratives revealed 1,327 event reports involving acute alcohol intoxication in adults; 69 were identified as Serious Events, including deaths. Most events occurred in the emergency department. A majority of Serious Events involved patient falls. Other findings, such as seizures, combative ness, suicide-related, and leaving against medical advice occurred.

Frequent monitoring and behavioral assessment are key elements to the care and prevention of harm of the intoxicated patient. (PA Patient Saf Advis 2017 Jun;14[2]:45-54.)

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* Binge drinking is defined as four or more drinks for a woman or five or more drinks for a man on an occasion during the past 30 days.

† Tertile: Any of the two points that divide an ordered distribution into three parts, each containing a third of the population.
intoxication (n = 3,975; e.g., events classified as skin integrity or transfusion, events involving staff or visitors, and events reporting only a past medical history of alcohol use). The revised query resulted in 2,324 reports. Analysts individually reviewed the event report narratives and excluded an additional 95 events unrelated to alcohol intoxication. Of the three main “direct mechanisms of harm caused by alcohol consumption in an individual” presented in the WHO report, the analysts focused on “intoxication, leading to impairment of physical coordination, consciousness, cognition, perception, affect or behavior,” because this mechanism of harm was the most prevalent in the PA-PSRS database.

Patients presenting for detoxification (n = 544) and those in withdrawal (n = 358; i.e., beyond the intoxication phase) were excluded unless the event narrative mentioned both intoxication and detoxification or withdrawal. The final sample size analyzed was 1,327 alcohol intoxication-related events.

Analysts conducted a review of the literature and an Internet search to obtain epidemiological data and information on alcohol use and abuse and to identify assessment and care management strategies to reduce the likelihood of patient harm. Interviews with addiction specialists were conducted to clarify and refine the approach to data analysis.

RESULTS

Harm

The Authority uses the harm level definitions as defined by the MCARE Act. Most events, 94.8% (n = 1,258) were classified as Incidents (i.e., events, occurrences, or situations that could have injured the patient but did not) and 5.2% (n = 69) of the reports represented Serious Events (i.e., events causing temporary or permanent harm or death).

Care Area

As seen in Figure 1, most intoxicated patients presented to the ED. Of the 926 ED patients, 7.3% (n = 68) were admitted to the hospital and more than a third (34.8%, n = 322) eloped, left before treatment was completed, or left against medical advice. In certain ancillary departments (i.e., surgical services, imaging, and outpatient clinics), instances were noted in which testing, treatments, or surgeries were cancelled because of patients arriving under the influence of alcohol or intoxicated.

The following is an example of a cancellation:

Upon arrival to the pre-op area for a scheduled surgical procedure, nursing staff noticed that the patient had an odor of alcohol. Upon further evaluation by anesthesia, the patient admitted to ingesting alcohol prior to the procedure. Surgeon notified and the surgery was cancelled.

Ancillary departments comprised 7.4% (n = 98) of the care areas noted. Of the 98 ancillary department events, 82.6% reports originated from the laboratory. Failure to document or properly report critical alcohol serum lab results led to delays in care. The following is an example of an improperly reported critical value event:

A critical value for serum alcohol was not called and/or documented in the computer system within the expected time frame.

Serious Events

Of the 5.2% (n = 69 of 1,327) events that were reported as Serious Events, the majority 72.5% (n = 50) as shown in Figure 2, were reported as harm score E (i.e., an event occurred resulting in temporary harm and required treatment or intervention).

Of the 69 Serious Events reported, 55.1% (n = 38) described delay or failure to observe, assess, or recognize change in condition as factors contributing to the harmful event. Reports of patient deaths accounted for 7.2% (n = 5 of 69) of the Serious Events and three of the five deaths were attributable to the aforementioned factors. The following are examples of Serious Events mentioning those factors:

Patient admitted to [unit] as a 302 ‡. Nurse returned to room after checking lab results to find patient [had eloped]. Authorities notified.

The patient was being evaluated for possible drug and alcohol overdose. When nurse came back into room, he noticed an empty pill bottle at the bedside. The patient [allegedly] ingested more than 30 benzodiazepine tablets.

The patient, who was under the influence of alcohol, was being evaluated for right sided pain. The patient was in CT [unattended] and upon return to the ED the patient’s condition deteriorated, requiring intubation.

Patient admitted to a monitored unit with alcohol intoxication and other medical co-morbidities. The patient went into a lethal cardiac arrhythmia and was

---

* Serious Events are events, occurrences, or situations involving the clinical care of a patient in a medical facility that either: (a) resulted in death, or (b) compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.

† The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality. None of these event narratives came from the co-author’s facility.

‡ A 302 commitment in Pennsylvania is an involuntary commitment into a mental health institute for emergency psychiatric evaluation.
found unresponsive a couple of hours later. The patient later died.

Associated findings. As seen in Figure 3, findings associated with intoxication mentioned in some events are consistent with characteristics and behaviors of intoxicated patients. Seizure activity, including delirium tremens, was the most frequently mentioned finding. All of the patients experiencing seizure sustained a fall, with harm ranging from abrasion to fracture; eight occurred in non-psychiatric EDs and two on intermediate/specialty units. Suicide, including suicide attempts and suicidal ideation, was the second most frequently mentioned finding. Of the two completed suicides, one followed an inpatient admission and subsequent ED visit; the other occurred in the facility. Both patients had comorbid behavioral health diagnoses. The other patients sustained harm ranging from self-inflicted wounds to cardiac and respiratory arrest; Most suicide-related events occurred in non-psychiatric EDs. The following is an example of a suicide-related event:

The patient was brought to the ED with alcohol intoxication after a suicide attempt. Patient had been acting cooperatively until staff found patient with [equipment] cables [wrapped] around neck. Staff intervened and patient was placed on one-to-one observation.

Combativeness was the third most frequently mentioned finding. Half of the combative patients attempted to physically harm staff and half sustained a dislocation or actual or probable fracture, two of which occurred as a result of physical restraint and the others sustained harm including lacerations; seven injuries occurred in the ED and one on an inpatient rehabilitation unit.

Patients who took sedative-hypnotics, opioids, or other drugs; ingested hand sanitizer or mouthwash; plus those who eloped account for 14.5% (n = 10) of the other findings mentioned. The majority of these 10 were ED patients.

Event type. As seen in Figure 4, the majority, 61% (n = 42 of 69), of Serious Events were falls; 64.3% (n = 27) of the 42 falls were unobserved. Of the 35.7% (n = 15) that were observed, staff attempted, unsuccessfully, to prevent the fall. Patients experiencing seizure activity accounted for...
23.8% (n = 10) of the 42 falls. Of the 27 unobserved falls, 7 patients experienced seizure activity, and of the 15 observed falls, 3 patients experienced seizure activity.

The following are examples of reported falls with harm events:

- Patient was intoxicated, climbed over the side rails, fell to the floor, and landed on the left hip. X-ray confirmed a fracture and patient went to surgery.
- While standing for additional x-rays, the patient fell forward, landing on [her] face. The fall resulted in a laceration and a probable [cervical] fracture.
- Patient was intoxicated upon arrival to ED and sustained a scalp laceration. CT showed an epidural hematoma. While waiting to be transferred to [an inpatient unit], the patient fell out of bed. A repeat CT showed an [increasing hematoma]. The patient was then admitted to a [critical care unit].

Reports of other/miscellaneous events accounted for 27.5% (n = 19 of 69) of the Serious Events. The following are examples of reported other/miscellaneous events that show a range of care challenges with this patient population:

- Patient was [intoxicated and violent] upon arrival to ED. The patient was placed in restraints and later found to have deep lacerations to torso. Broken glass was used by the patient to [self-inflict these injuries]. The patient was taken to the OR for exploratory surgery and there was no permanent injury sustained.
- An [intoxicated] patient became [extremely violent]. Staff was unable to [verbally] de-escalate the situation and the patient began kicking and...
punching staff and police officer used a Taser [to gain control of the patient].

A patient with a history of a psychiatric disorder was brought to the ED intoxicated. Patient was kept overnight for observation. During morning assessment patient denied that [her binge drinking] was a suicide attempt. Patient contracted for safety and was [agreeable to inpatient treatment]. [Several hours later,] the patient began yelling and started to vomit. [She] lost consciousness, [stopped breathing], and required intubation. A repeat ETOH [ethyl alcohol] level was elevated. Staff noticed an empty bag of hand sanitizer in the trash. The patient was admitted to a [telemetry] bed.

**DISCUSSION**

**Acute Symptom Assessment**

“A person is said to suffer from alcohol intoxication when the quantity of alcohol the person consumes produces behavioral or physical abnormalities.

In other words, the person’s mental and physical abilities are impaired.”

In addition to observable impaired physical and mental abilities, alcohol levels can be measured in the breath or blood. Studies have found, however, that the level of blood alcohol concentration (BAC) correlates poorly with physical and mental impairments depending on the alcohol tolerance of the individual.\(^{11,12,13}\) An overreliance on these concentrations may hinder healthcare providers’ ability to protect these patients from harm. Assessment of signs and symptoms in a person who has been drinking have proved effective in accurately determining alcohol intoxication, and the BAC can verify a patient’s report of intoxication.\(^{15}\)

Teplin and Lutz’s Alcohol Symptom Checklist (ASC) is an observational measure of intoxication and is used in situations in which objective measures of alcohol are unavailable.\(^{17}\) The ASC is a reliable, easy, and efficient tool that can be used in lieu of a BAC when, for example, an intoxicated patient refuses diagnostic testing.\(^{17}\)

In a 2013 study by Volz et al., the authors measured the effectiveness of a behaviorally-based alcohol intoxication scale for assessing a patient’s readiness for transfer from the ED to the behavioral health unit “rather than relying solely on a BAC level.”\(^{14}\) Patients who met specific criteria in this behavioral scale were found to be medically stable after transfer.\(^{14}\)

Failure to observe, assess, or recognize changes in patient condition were associated with harmful events and deaths as identified and reported through PA-PSRS. Alcohol intoxication causes changes to several organ systems, including cardiovascular, neurological, endocrine, and pulmonary; and the degree of impact depends on the amount of alcohol consumed and the patient’s tolerance level.\(^{2,18,19}\) Care of the patient is aimed at managing the intoxication symptomology, comorbidities, and acute injuries. Treatment interventions include physiologic monitoring, frequent observation and rounding, supportive care, and prevention of harm or injury.\(^{18}\) Frequent rounding and direct observation, including waking sleeping patients to assess responsiveness, is associated with decreases in secondary harm.\(^{18,20}\)

**Reoccurrence Prevention – Screening and Brief Intervention**

Implementing screening for alcohol-dependent drinkers and providing brief
intervention for those who screen positive or at-risk for alcohol dependency is shown to reduce the quantity of alcohol consumed and re-visits to the ED.\textsuperscript{16,21-24} Varying levels of screening, brief intervention, and follow up may be incorporated into interventions with the intoxicated patient. Initial screening serves as the basis for determining appropriate intervention.

Screening and brief intervention is supported by the American College of Emergency Physicians (ACEP), the Emergency Nurses Association, and the American College of Surgeons’ Committee on Trauma, which “recommends that all trauma centers incorporate alcohol screening and brief intervention as part of routine trauma care” and those with “sufficient resources” discuss or offer follow-up options.\textsuperscript{16,23,26}

Several screening tools are advocated, including a single alcohol screening question (SASQ), the Alcohol Use Disorders Identification Test (AUDIT), the Cutting down, Annoyance by criticism, Guilty feelings, and Eye openers (CAGE) questionnaire, the CRAFFT Substance Abuse Screening Test, and the Paddington Alcohol Test.\textsuperscript{21,27-32} These evidence-based screening tools are tailored for time-pressed environments such as the ED and take into account the possibility of patient underreporting of alcohol intake.

Brief interventions are short counseling sessions. The goal of brief intervention is to help patients make decisions to lower their risk for alcohol-related incidents. Giving information and feedback about screening results helps point out the danger and educate patients on acceptable limits of alcohol intake. The Table identifies alcohol use screening tools and brief intervention resources found in the literature, the predictive trait of the tool, and which population they have been used to evaluate.

Understanding the patient’s perception of drinking helps enhance motivation to promote change in drinking habits.\textsuperscript{16,33} Giving advice and negotiating helps the patient take steps and commit to change.\textsuperscript{30} Following up reinforces the intervention and can include various forms of contact such as phone calls, appointments with primary care physicians, and referral to Alcoholics Anonymous.\textsuperscript{21,33} ED DIRECT is a mnemonic that helps providers remember components of this brief intervention.\textsuperscript{25} Supported by ACEP, ED DIRECT is administered in the ED to “at-risk” or “harmful” drinkers with a goal of speaking with a counselor while in the ED or referral to primary care or specialized treatment program.\textsuperscript{25}

Healthcare providers’ attitudes, biases, and perceptions of alcohol-intoxicated patients are associated with inadequate assessment and the lack of frequent monitoring and use of behavioral assessment scales.\textsuperscript{34-36} Ongoing staff education on the rationale and use of objective assessment scales and screening tools; in conjunction with education regarding their own attitudes and perceptions, are keys to successful implementation of these useful strategies.\textsuperscript{16,30}

**Facility Recommendations to Improve Patient Safety**

A number of recommendations were submitted in event reports specific to reported challenges.

These recommendation examples are typical of those proposed by facility staff for patients who fell:

- Use fall precautions including a bed alarm and place patient on continuous observation.
- Notify family. Perform neurologic assessments frequently, closer monitoring of patients who are at increased fall risk, and place the patient in a room closer to the nurse’s station.

Provide reminders to patient and family, maintain communication.

Intoxicated patients should be assessed as high fall risk and those with gait disturbances shall have staff in attendance.

Patients who leave against medical advice (AMA) pose unique considerations for staff. As shown in these examples, facility staff feel obligated or are required to discharge these patients under supervision:

- The patient was [insistent on leaving AMA]. [The patient was taken] into police custody to ensure [she] would not be a danger to [herself] or others.
- The local police provided the [intoxicated] patient transportation home.
- The patient [was discharged] AMA accompanied by a friend.

Facility staff also note the need for frequent communication, closer observation, and follow-up phone calls as indicated in these examples:

- When there is a delay, communicating with the patient and family frequently may help decrease frustration.
- Frequently monitor patients who have mentioned the desire to leave.
- A follow up phone call was made to ensure the patient arrived at the treatment facility.

The ingestion of hand sanitizer is on the rise nationally,\textsuperscript{37} although not prevalent in the reported events submitted through PA-PSRS, where 1.6% of all events (n = 21 of 1,327) and 4.3% of Serious Events (n = 3 of 69) involved the ingestion of hand sanitizer or other ethanol-containing products. Intoxicated patients and those with alcohol use disorders are more likely to consume this product while in the hospital because of its availability. Although most instances

(continued on page 52)
Table: Alcohol Use Screening and Brief Intervention Resources

<table>
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<tr>
<th>RESOURCE</th>
<th>DESCRIPTION</th>
<th>POPULATION ADDRESSED</th>
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</thead>
<tbody>
<tr>
<td>Single Alcohol Screening Question (SASQ)⁷</td>
<td>A single screening question for identifying hazardous drinking and alcohol use disorders.</td>
<td>The study focused on adult patients presenting to emergency departments within 48 hours of an injury.</td>
</tr>
<tr>
<td>Alcohol Use Disorders Identification Test (AUDIT)²,³</td>
<td>A screening instrument for proactive identification of hazardous and harmful alcohol consumption. The instrument is a 10-item questionnaire that covers the domains of alcohol consumption, drinking behavior, and alcohol-related problems.</td>
<td>The 1993 study focused on subjects recruited from representative primary health care facilities in six countries (age not specified). The 2005 study focused on patients 18 years or older presenting to one of three hospital emergency departments within 48 hours of an injury.</td>
</tr>
<tr>
<td>Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers questionnaire (CAGE)³,⁴</td>
<td>A screening instrument for identifying a high likelihood of the presence of alcoholism.</td>
<td>The 1984 study focused on male patients in an alcoholism rehabilitation facility. The 2005 study focused on patients 18 years or older presenting to one of three hospital emergency departments within 48 hours of an injury.</td>
</tr>
<tr>
<td>Car, Relax, Alone, Forget, Friends, Trouble questionnaire (CRAFFT)⁵</td>
<td>A screening instrument for identifying substance-related problems and disorders.</td>
<td>The study focused on adolescents, age 14 to 18 years, coming for routine medical care to an adolescent and young adult medical practice.</td>
</tr>
<tr>
<td>Paddington Alcohol Test (PAT) and brief intervention⁶,⁷</td>
<td>A screening instrument for identifying alcohol-related problems. A referral to an alcohol health worker made while the patient is still in the emergency department.</td>
<td>The May 2004 study focused on adult patients presenting to the emergency department. The October 2004 study focused on adult patients 18 years or older presenting to an emergency department and having a positive PAT screen.</td>
</tr>
<tr>
<td>Screening and brief intervention (BI) in the emergency department⁸</td>
<td>A review of four studies that offered brief interventions to patients, while still in the emergency department, whose injuries were alcohol-related. The effect of the BI was generally positive (i.e., patients decreased their alcohol consumption and alcohol-related negative consequences after the BI when assessed 3 to 12 months after their initial emergency department visit).</td>
<td>The studies focused on adolescent and adult patients 13 years or older admitted to an emergency department or trauma center.</td>
</tr>
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</table>

Notes
of intentional hand sanitizer ingestion result in little or no harm to the patient, a literature review of published cases and a query of the National Poison Data System identified cases of moderate to severe harm. The study suggests increasing awareness among healthcare providers of this growing problem and taking steps such as removing hand sanitizers from at-risk patients’ rooms and frequent patient monitoring.

Although it was beyond the scope of this article to address the management of alcohol withdrawal, the possibility cannot be ignored that an alcohol-dependent patient may remain in the ED or hospital long enough to be at high risk for developing withdrawal even if presenting for an unrelated complaint. Researchers recommend that healthcare providers be familiar with the care and management of alcohol withdrawal, including symptom recognition, medication regimens, and supportive care such as frequent monitoring, limiting sensory stimulation, and providing reassurance.

LIMITATIONS

Relevant information is derived from the event type taxonomy and from free-text narratives; categorization and narrative detail were provided by PA-PSRS reporters.

Reporters may have used the terms “intoxication,” “detoxification,” and “withdrawal” interchangeably and in combination when providing the narrative detail. Analysts sorted the events based on the use of these terms as described in the methods section and every effort was made to classify events into these categories accurately.

CONCLUSION

Caring for and safeguarding intoxicated patients poses unique challenges, including managing patient aggression, monitoring patients for deterioration, and gaining cooperation with treatments. About 5% of the intoxication-related events reported to the Authority were Serious Events (i.e., events in which patients sustained harm). Pennsylvania acute level facilities reported that among intoxicated patients, the occurrence of falls, seizures, suicide attempts, combative ness, and patients leaving against medical advice were common. Failure to adequately monitor and assess intoxicated patients contributed to the majority of harm experienced by these patients and in rare instances resulted in death. Behavioral assessments and frequent or continuous monitoring, supplemented by objective measurements such as blood alcohol concentration in combination with symptom management, are key to avoiding harm and caring for these patients.

NOTES


INTRODUCTION

The overall dispensing accuracy rate in community pharmacies is estimated to be 98.3% (77 errors among 4,481 prescriptions).\(^1\) Despite this level of accuracy, about 4 errors occur per day in a pharmacy filling 250 prescriptions daily. Extrapolating these numbers means that an estimated 64 million errors occur during the dispensing of 4 billion prescriptions annually in America’s pharmacies.\(^2\)

Outpatient pharmacies operate in a variety of settings, including entities affiliated with or located within hospitals, health systems, and clinics as well as freestanding pharmacies. The pharmacists who staff these pharmacies provide a variety of services to the community, including dispensing prescriptions, administering immunizations, providing medication-therapy management, providing patient education, and making recommendations for over-the-counter medications.

When dispensing medications, pharmacists perform tasks that can be repetitive, yet require high levels of professional training and optimal performance under considerable time constraints.\(^3\) Dispensing a prescription can involve more than 40 separate steps.\(^4\) Combine this with the numerous distractions from telephones, e-mails, customers, and the supervision of technicians, and a system emerges that is perfectly positioned to facilitate errors at any step in pharmacy dispensing process.

The outpatient pharmacy setting provides a unique problem, that errors might go unnoticed for months and may result in negative outcomes. Patients usually receive a 30-day supply of medication and possibly up to a 90-day supply with a prescription. If an error occurs, the patient may end up using the wrong therapy or wrong dose for a significant period of time.

Pennsylvania Patient Safety Authority analysts examined medication errors coded to have occurred in an outpatient pharmacy setting to determine the types of events, the steps in the pharmacy dispensing process in which the event occurred (when that information was available), and contributing factors.

METHODS

Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for errors from January 2005 through December 2016, looking for events that were categorized as occurring in a hospital’s outpatient pharmacy setting. To identify potential event reports, analysts queried the care-area field for: Pharm*, Phar*, or Rx* and the care-area name field for: out*, comm*, reta*, or amb*. This query yielded 1,044 event reports. The medications involved in the reports were standardized to either their brand or generic name. A medication was considered to have reached the patient if the medication left the control of the pharmacy or pharmacy staff and was dispensed or delivered to the patient. Reporters assigned harm scores, which are adapted from the National Coordinating Council for Medication Error Reporting and Prevention harm index,\(^5\) and categorized events based on the type of error.

ANALYSIS

Event reports were categorized by their event type. The top five event types (Figure 1) comprised 69.9% of the reports. The top three event types were wrong drug, medication list incorrect, and wrong dose/over dosage. The ages of the patients involved in the events were as follows: 9.8% (n = 102) involved pediatric patients (younger than 18 years of age), 73.6% (n = 769) involved adult patients (age 18 to 64), and 16.6% (n = 173) involved elderly patients (age 65 or older). More than half (56.2%; n = 587)
of the events reached the patient (Harm Score C–I; Figure 2). Analysts also identified that 5.9% (n = 62) of the events submitted to the Authority involved delivery of a prescription to the patient’s home or other location.

**Wrong Drug**

Wrong drug errors comprised 19.6% (n = 205) of all the errors, and 89.3% (n = 183) of these errors reached the patient. It should be noted that nearly half (48.3%, n = 99) of the reports did not provide the names of both medications involved (e.g., the report only listed one drug when two drugs were involved) in the medication name fields. There were 105 different drugs mentioned in reports and 147 unique combination of drugs involved in wrong drug errors. The most common drug mentioned in reports of wrong drug errors was the opioid analgesic traMADol (10.7%, n = 22), of which the majority (68.2%, n = 15) were drug mix-ups with traZODone, an antidepressant. The next most common drug involved in wrong drug errors was metoprolol (5.4%, n = 11), with 72.7% (n = 8) of the mix-ups occurring between immediate release metoprolol tartrate and long-acting metoprolol succinate.

The other wrong drug mix-ups worth noting were within drug classes rather than individual medications. Mix-ups between different oral contraceptive products comprised 7.8% (n = 16) of the errors. Mix-ups between different insulin products comprised 7.3% (n = 15). The remaining 68.8% (n = 141) of the errors involved at least 121 different medications. Following are examples of wrong drug errors reported through PA-PSRS:

*Patient received traZODone instead of traMADol. After taking the dose, she fell on floor. She felt woozy and sleepy. Received multiple traZODone*

*The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.*
tablets. Called pharmacy to report error. Noticed tablets were different. Patient received tra2Done instead of traMADol in his dispensed medication prescription. He actually took his wife’s medication that was also filled incorrectly.

Patient was prescribed triamcinolone and label was typed for triamcinolone. Nystatin was dispensed. Nystatin did not help the patient’s poison ivy and additional prednisONE was dispensed.

Patient received Singulair® [montelukast] 10 mg and Zyrtec® [cetirizine] 10 mg. Each bottle was labeled with opposite drug and directions. Patient had remaining Zyrtec from previous fill in her old bottle. Therefore, for a few days, she had been taking two Zyrtec tablets and no Singulair. She reported feeling a little drowsier than usual.

Two tablets of pravastatin 20 mg were found in a bottle of Paxil® [PARoxetine] 20 mg filled by the outpatient pharmacy. Pravastatin was in the robot and was exchanged out for Paxil. The pharmacist believes two tablets of the pravastatin must have remained behind when exchanging out for Paxil. The patient brought the incorrect tablets back to the pharmacy and the error will be addressed with next training to be sure robot is empty of all drugs when exchanging out.

Medication List Incorrect
The second most common event type selected by facilities was medication list incorrect (17.0%, n = 178). Within this category, analysts identified 15 different types of errors. The top error types were incorrect instructions (23.0%, n = 41), medication not discontinued (13.5%, n = 24), and wrong strength (13.5%, n = 24). See Figure 3. At least 80 different medications were involved in errors. Only SEROquel® (QUetiapine; 12.4%, n = 22), an antipsychotic agent, was involved in more than 10% of the medication list incorrect events. Nearly 28% (n = 49) of the events involved antipsychotics, while 12.4% (n = 22) involved antidepressants. Following are some reported errors in which the medication list was incorrect:

<table>
<thead>
<tr>
<th>ERROR TYPE</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect instructions</td>
<td>41 (23.0%)</td>
</tr>
<tr>
<td>Medication not discontinued</td>
<td>24 (13.5%)</td>
</tr>
<tr>
<td>Wrong strength</td>
<td>24 (13.5%)</td>
</tr>
<tr>
<td>Missed order</td>
<td>20 (11.2%)</td>
</tr>
<tr>
<td>Duplicate order</td>
<td>18 (10.1%)</td>
</tr>
</tbody>
</table>

Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 2005 through December 2016.

Wrong Dose/Over Dosage
The third most common event type was wrong dose/over dosage (14.7%, n = 153). In 36.6% (n = 56) of the events there was a two-fold overdose, while 3.9% (n = 6) involved a 10-fold overdose. Nearly 35% (n = 53) of the event reports did not have enough information to determine the amount of drug the patient received. In 11.8% (n = 18) of the events, the actual product dose strength was correct, but the instructions would have had the patient take a higher dosage. Of these overdoses, 85.0% (n = 130) reached the patient. In 14.4% (n = 22) of these events, the patient took at least one dose of the medication. Discovery of some of these errors did not occur until the time of the patient’s first refill (11.8%, n = 18) or even months after the initial dispensing of the prescription (7.8%, n = 12). There were 98 different drugs mentioned in wrong dose/over dosage reports, including vitamin D (5.2%, n = 8), metFORMIN (4.6%, n = 7), hydroCHLOROthiazide (3.3%, n = 5), and lansoprazole (2.6%, n = 4).

The following are examples of reported wrong dose/over dosage events:

- Directions on the label were to inject 0.4 mL (5,000 units) [epoetin alfa] via IV every 7 days. Actually, the correct volume to inject for 5,000 units is 0.25 mL. Labs drawn to assess harm. No harm to patient.
A 60-year-old female was prescribed PROzac® [FLUoxetine] 20 mg by mouth, 2 capsules daily. Pt received 40 mg PROzac capsules (80 mg), which she took 2 of daily for one month. The doctor was notified by outpatient pharmacist.

A prescription for vitamin D 5,000 units daily was filled erroneously with 50,000 units daily, which the patient took for one month.

A prescription written for methotrexate 10 mg was entered as 10 tablets (25 mg dose). This prescription was refilled two more times. A subsequent prescription was called in and filled correctly, but [the patient’s] mom kept giving as before. Error discovered after discussion with the patient’s mother and review of medications with her. Physician made aware of error. Confirmed that there was no patient harm.

Notified provider that he did not write out units and that the prescription for insulin regular was misunderstood as 150 units. Also, the pharmacist did not call to clarify the prescription with the provider and notified the social worker that the prescription could only be partially filled due to limited stock.

The pharmacist who was checking reports noticed an error [involving Lisinopril-hydroCHLORothiazide] that perpetuated for 10 months. The physician’s office was contacted and since the patient was doing well, the decision was made to keep the dose as it had been dispensed and taken by the patient.

Wrong Dose/Under Dosage
Under dosing was identified in 10.2% (n = 106) of the events. In 40.6% (n = 43) of the errors, the selected strength was half the prescribed strength. Incorrect drug strength was cited in 42.5% (n = 45) of the errors, 10.4% (n = 11) had incorrect instructions leading to an under dose, and 4.7% (n = 5) had an incorrect quantity. More than 20% (n = 22) of the reports did not have enough information to determine the type or cause of the error. Although 78.3% (n = 83) of the errors reached the patient, only 20.8% (n = 22) of the incorrect prescriptions were actually taken by the patient, with 11.3% (n = 12) of the patients taking the dose for at least one month. There were 71 different medications involved in the errors, including lisinopril (5.7%, n = 6), levothyroxine (3.8%, n = 4), simvastatin (3.8%, n = 4), and furosemide (2.8%, n = 3).

Following are reported examples in which drugs were under dosed:

TraZODone 50 mg was processed and dispensed instead of 100 mg. The patient had trouble sleeping and noticed the pills were different but didn’t say anything. The error was caught on next refill.

The pharmacy received a prescription for tacrolimus 0.5 mg/mL electronically and dose for the patient is 4 mg every 12 hours. Pharmacy filled prescription as tacrolimus 0.5 mg/mL, [take] 2 mL (1 mg) by mistake.

The patient was prescribed Lantus® [insulin glargine] 70 units subcutaneous at bedtime as prescribed. The label and instructions were incorrectly listed as 30 units at bedtime. The patient has not required additional care or medication. No current lab work in computer system.

The patient’s mother called nursing for refill of medication [topiramate]. It was then discovered that the patient had been dispensed the wrong dosage and patient had been receiving wrong dose [for 3 days].

Wrong Patient
Wrong patient errors comprised only 8.4% (n = 88) of all events. Of these errors, 90.9% (n = 80) reached the patient, although only two of the reports indicated that the patient had ingested the medication. Nearly 24% (n = 21) of the events occurred during the order entry phase, while 73.9% (n = 65) of the events occurred when dispensing the medications to the patient. More than a third (35.4%, n = 23) of the 65 errors that occurred when dispensing the medication involved home delivery services. In fact, more than a third (37.1%, n = 23 of 62) of the events involving home delivery were wrong patient errors. Following are examples of wrong patient errors:

During the process of setting up home deliveries via courier, one patient received another’s medication via the mail, and vice versa. [The mix-up involved Xanax® (ALPRAzolam) and Truvada® (emtricitabine and tenofovir disoproxil fumarate)]. The patient realized that the patient name [printed] on the bottle was not hers and recognized the medication was not prescribed to her. She contacted the pharmacy and returned the medications to pharmacy via mail. The patient did not take any of the medication.

Two prescriptions were presented to staff—one for the husband and one for the wife. The husband was supposed to get citalopram and his wife was supposed to get metoprolol. The wife received both prescriptions in her name. She said she took one of the citalopram since her name was on it. Verified with the wife that she only took one dose. Incorrectly labeled bottle was brought back by the patient and replacement was given to her. The patient’s only complaint was that she was lightheaded and dizzy and that her blood pressure was a little elevated that day.

The patient received medication prescribed for another patient. The patient did not read label and took the medication for three months.
DISCUSSION

There are many differences between inpatient and outpatient pharmacies. An inpatient pharmacist may fill orders for medications, monitor patient medication therapies, provide drug information, and prepare infusions. Outpatient pharmacists provide many similar services (e.g., filling prescriptions, educating patients, administering immunizations, providing medication therapy management, calling doctor’s offices to get refills or clarify prescriptions) but are also tasked with calling insurance companies for reimbursement, completing transactions with customers at the point of sale, completing business reviews, and running a business.

The quantity of medication dispensed of any given prescription is different between outpatient and inpatient pharmacies. While inpatient pharmacies typically provide one day’s worth of medications for a given patient in the hospital, in the outpatient setting, 30- and occasionally 90-day prescriptions are dispensed. Also, errors (e.g., wrong drug, wrong strength) that occur in the hospital setting have more opportunities to be caught by other practitioners before reaching the patient than in the outpatient setting. Outpatient dispensing errors frequently reach patients, who may fail to notice their prescription is not what it should be. In 12.7% (n = 33 of 259) of the wrong doses, both over and under dose, reports noted that patients took at least one dose of a medication that was not the correct strength or amount. Of these reports, 81.8% (n = 27 of 33) of the patients took at least one full month of the incorrect strength, and the error was found upon refill. In fact, 48.5% (n = 16 of 33) of patients were reported to have taken the incorrect strength for multiple months. For the wrong drug errors, 17.6% (n = 36 of 205) of patients who received the wrong drug took at least one dose of the medication, with 36.1% (n = 13 of 36) of the patients taking at least one month’s worth.

Wrong drug and wrong dose errors occurred during both the order entry and production stages of the dispensing process. Order entry is the stage in which the prescription details are entered or selected in the pharmacy computer system. Findings from other error reporting programs are similar to those identified in the events submitted to the Authority. For example, in one event, methotrexate, a high-alert medication (i.e., a medication that bears a heightened risk of harm if used in error), was incorrectly selected in the computer system instead of metolazone, a diuretic. The patient took the medication daily for one week until she developed mouth ulcers. In a second example, a wrong dose error was reported after a patient brought in a new prescription for oxyCODONE 5 mg. To expedite the dispensing process, the pharmacist copied the patient’s previous oxyCODONE 30 mg prescription. However, he failed to edit the product dose strength, leading to the patient receiving the wrong dose. The same pharmacist conducted the final verification immediately after completing order entry and filling the prescription, limiting the effectiveness of the check. Ideally, one person (e.g., pharmacy intern, pharmacy technician, second pharmacist) performs data entry for the prescription, allowing the verification pharmacist to perform a truly independent double check.

Analysts identified events in which the wrong drug or wrong strength of a medication was selected from the pharmacy shelf during the production stage of the dispensing process. The production stage of the pharmacy workflow includes activities such as retrieving the drug stock bottle from the pharmacy shelves, counting out the number of tablets to be dispensed, and applying the computer-generated prescription label to the prescription container. Similar medication errors have been repeatedly detailed in the literature. For example, an error occurred when the antidepressant Brintellix (vortioxetine, brand name now Trintellix®) was retrieved from the pharmacy shelf instead of Brilinta® (ticagrelor), an antiplatelet agent. The two drugs were stored side by side, and the wrong product was selected. The patient fell and was admitted to a hospital with a periorbital hematoma after taking Brintellix for nine days. In another event, the incorrect strength of ARIpiprazole, an antipsychotic, was nearly dispensed to the patient. The bottles of ARIpiprazole 2 mg and ARIpiprazole 5 mg, both from the same manufacturer, looked alike with similar size, shape, color, and labeling. Additionally, the strength of each product was displayed in a small font size on the far right edge of the main panel of the label and could be missed if the bottle was turned slightly.

Analysts identified that 8.4% (Figure 1) of the events submitted to the Authority were wrong patient errors; however, this error might be more common than indicated. A study conducted by the Institute for Safe Medication Practices (ISMP) found that a correctly filled prescription was given to the wrong patient at the point of sale once for every 1,000 prescriptions. With close to 4 billion prescriptions dispensed each year, an average of seven wrong patient errors happens each month at every pharmacy across the United States. This number does not take into account a person getting the wrong medication because the wrong patient’s name was chosen when entering the prescription into the computer system. In addition to the potential harm from receiving another patient’s medications (e.g., administration of a contraindicated medication, omission of the correct medication, misuse of the incorrectly dispensed medication), a wrong patient error can result in a breach of protected health information.
Another way a correctly filled medication can be given to a wrong patient is when pharmacy staff selects the wrong patient’s bag from the will call area and bypasses recommended ways of verifying a patient’s identity, such as using two patient identifiers. Failing to use two patient identifiers also reduces the likelihood that a pharmacy technician or pharmacist will catch wrong patient errors that occurred when entering the prescription into the computer system. Considering that only half of patients confirm their name on a prescription label, and only about three-quarters confirm the medication’s name prior to use, this can result in a patient taking another patient’s medication.

Another issue that predominantly affects the outpatient setting is the practice of delivering prescriptions to the patient’s home or location by courier or mail. Although delivery services can offer convenience and help ensure homebound patients receive their medications, there are potential failure modes that could impact patient safety. The first issue is the inability to accomplish verification using two patient identifiers if the patient is not home or if the prescription is delivered by a commercial courier or through the mail. This may lead to a patient getting another person’s medication, an error identified in 35.4% of the wrong patient dispensing errors that involved delivery services. A second risk with home delivery is the decreased likelihood that the pharmacist provides education to the patient. Although a medication-information insert may be delivered to the patient with the prescription, the pharmacist is not immediately available to provide direct patient counseling. The pharmacist must take steps to contact and convey important medication information to the patient by telephone. If the medication has complex instructions for use or has dangerous side effects, this barrier to patient education can prove dangerous to the patient. This was the case in one event in which a patient received a three-cycle supply of lomustine, a chemotherapeutic agent, from a mail-order pharmacy. However, the patient was to take one cycle’s worth of medication and then be reevaluated. To dispense the correct dose of lomustine 150 mg, the pharmacy sent three separate prescription bottles, one with 100 mg capsules, one with 40 mg capsules, and one with 10 mg capsules with the instructions to take a dose from each bottle for a “total of 150 mg daily once per month as directed.” The patient, who did not receive counseling from the pharmacy, took the entire three-cycle (9 capsules) supply and died 6 weeks later. A major contributing factor to the event was that the pharmacy sent enough capsules for three cycles of therapy instead of just one.

An article published December 2016 in the Chicago Tribune highlighted the potential shortcomings of current drug-drug interaction screening processes. For the article, reporters presented prescriptions with known contraindications to concomitant use (e.g., a chronic cholesterol medication and an acute care antibiotic) and recorded the number of times interaction was missed. Among the community pharmacies presented with these prescriptions, the interaction was missed between 30% and 72% of the time. What makes this worrisome is that in each encounter, the prescriptions were filled at the same pharmacy. The rate of missed interactions and therapeutic duplications are likely to only be higher if the patient is filling prescriptions at different, unrelated pharmacies with non-interfaced computer systems (e.g., two different retail pharmacy companies, a mail order pharmacy and a local independent pharmacy). Access to the patient’s inpatient and outpatient medical record, which some hospital and health system outpatient pharmacies have, can help the pharmacists obtain a fuller picture of the patient’s health history and identify potential drug-related problem interactions and duplications.

Although automation can increase the efficiency of the dispensing process, it can also be involved in errors. There were several events submitted to the Authority in which look- or sound-alike drugs contributed to wrong drug errors with the use of automation. For example, in one report, the traMADol cell or bin in the pharmacy robot was refilled incorrectly with traZODone. When wrong drug errors involving automation occur, the error can occur multiple times over the course of days, impacting multiple patients, until the error is discovered. This type of error, which can also include filling the cell with the incorrect drug strength, has also been reported in the literature. For example, a pharmacy technician inadvertently loaded one cell in a robot with two different medications. It was thought that she only scanned the first bottle of medication she added to the cell and skipped scanning the second bottle, which was a different medication. The patient discovered that the prescription vial contained two different medications and reported the error before the mistake caused any harm.

LIMITATIONS

In-depth analysis by the Authority of events involving hospital and health-system outpatient pharmacies is limited by the information reported through PA-PSRS, including the event descriptions. As with all reporting systems, the type and number of reports collected depend on the degree to which facility reporting is accurate and complete. Although the narrative fields of the reports help analysts discern what happened during the event, they often do not contain details describing how the event deviated from the standard operation, the specific stage of the pharmacy workflow process in which the error occurred, or which factors contributed to the event. It is important to note that these reports are from outpatient pharmacies affiliated with hospitals or health systems and the results of this study may not apply to other types of pharmacies.
RISK REDUCTION STRATEGIES

One of the most important differences between the inpatient and outpatient pharmacy is the opportunity to intercept errors. Unlike inpatient settings, once an error occurs in an outpatient pharmacy, fewer healthcare practitioners handle the medication and can possibly intercept the error before it reaches the patient. The final dispensed prescription is in the control of the patient rather than a nurse or healthcare practitioner, as in an inpatient setting. Patients who do not notice an error in their prescription may continue to take the incorrect medication until either the pharmacy notices the error upon refill, or the patient experiences a treatment failure or other harm. This means that outpatient pharmacies and other stakeholders need to critically evaluate the systems in place, identify opportunities for improvement, and implement high-leverage risk reduction strategies. The reality that the patient is the final line of defense against error also means that outpatient pharmacies must engage patients to help identify and catch mistakes. Consider the strategies described below, which are based on a review of current literature, events reported to the Authority, and observations from the ISMP.

Triage and Order Entry

- Establish a policy that requires collection and use of the patient’s date of birth when the prescription is presented to pharmacy staff and when selecting a patient in the pharmacy computer system.
- For prescriptions that are phoned to the pharmacy, use preprinted prescription phone pads that prompt the receiver to ask for the patient’s date of birth, allergies, and purpose of the drug.
- Flag patients with similar names in the computer system so that an alert will appear when these patients are selected during order entry. If applicable, use a patient’s middle initial to differentiate patients with the same first and last name in the system. Use modifiers such as Jr. and Sr. when applicable.
- When searching for a drug in the pharmacy computer system during order entry, type the drug name using the first four or five letters and its strength. Instruct pharmacy staff to not first retrieve the medication stock bottle from storage and then scan the product’s barcode as a means to enter (or select) the drug in the pharmacy computer system. If the wrong product is selected from storage at order entry, there will be no opportunity to catch a potential drug selection error later in the dispensing process by scanning the barcode.

Production

- Take the drug monograph or pharmacy label to the shelf to get the drug and verify the National Drug Code (NDC) on the label matches the NDC on the bottle. Return drug stock bottles to shelves immediately after filling the prescription to avoid crowding the work counter.
- Implement barcode scanning to identify when the wrong product is selected from the shelf. Review compliance with barcode scanning to ensure staff complies with this safety step.
- Require scanning of each stock bottle or package (e.g., inhaler, insulin cartridge) when more than one stock bottle or package is needed to fill a prescription or a cell in a dispensing robot.

Verification

- Use the original prescription or an image of the original prescription when conducting verification and medication utilization review. Encourage the pharmacist to check the data entry against the prescription rather than the vial to guard against confirmation bias.
- For refills, check the scanned image of the original prescription, and verify the prescription is being dispensed correctly.
- Enlist clinical staff to report inappropriate or irrelevant alerts. An expert committee within the organization can review questionable or frequently overridden alerts, recommending system customizations and providing feedback to database providers.
- Educate pharmacists on using the clinical decisions support (CDS) tools available in the pharmacy computer system. CDS tools are intended to support rather than replace the clinical judgment of the pharmacist.

Point of Sale

- Ask the patient to provide at least two patient identifiers, including their full name and date of birth, when picking up prescriptions. This is important for all patients, even those well known to pharmacy staff. Compare the patient-provided identifiers to the information in the computer system or on the prescription receipt.
- Employ technological solutions to help ensure verification of the patient’s identity. One possibility is to build a blind prompt into the point-of-sale computer system that requires the pharmacy staff member to ask for the patient’s date of birth and then key punch it into the register. If the date of birth does not match the patient’s profile or is not entered, the transaction cannot be completed.
- Open the prescription bag and have the patient review the pharmacy labels and contents of each prescription container to
verify that the medication is correct. The use of a will call system that employs clear plastic hanging bags to hold prescription containers and receipts awaiting pick up can facilitate this process.

- Provide patient education. Include a discussion of the medication’s purpose to help ensure the correct medication is being dispensed to the correct patient. When analyzing the events reported to the Authority, it appeared that many could have been caught if patient counseling had taken place.

- Employ scripted patient education and checklists, especially for high-alert medications, to aid in educating patients and to promote consistent discussions.

- If the medication is being used off label, ensure that the patient understands why their doctor chose this medication for them.

- Avoid asking a “yes” or “no” question when verifying the patient’s identity (e.g., by reading aloud the patient’s date of birth) or when providing patient education. Ask the person to supply the information so that you can confirm it. When asked “yes” or “no” questions, patients may answer “yes” and confirm the information presented was correct, only to take home someone else’s medication.

- If a friend or family member is picking up the patient’s prescription or it is delivered to the patient’s location, send instructions for the patient to open the package at home, check the contents before taking any of the medication, and call the pharmacist with any concerns or questions. For high-alert drugs or drugs with potentially harmful side effects, particularly if it is the first time the patient is receiving the medication, consider proactively calling the patient to review important information to reduce the risk of misuse.

### Storage

- Ensure stickers, labels, or markings do not obscure the manufacturer’s barcode.

- Review inventories periodically to check that manufacturer’s barcodes are not covered up.

- Face labels forward when bottles are stored on the shelf.

- For look-alike products, explore ordering one of the medications from a different manufacturer. Also, avoid labels that separate the strength from the product name. A good reference to check for container label appearance is DailyMed, a service provided by the U.S. National Library of Medicine (http://dailymed.nlm.nih.gov/dailymed/index.cfm).

- Ensure look- and sound-alike names and packaging are sufficiently separated, regardless of normal alphabetical placement. Inform staff of the reasons for relocating these problematic drugs. Provide signage to direct staff to the storage site for relocated medications.

- Use shelf dividers to keep stock separated and neatly organized on shelves.

- Add shelf talkers (a product or sign designed to call attention to products on a shelf) at specific storage locations or use other strategies (e.g., Tall Man lettering [see https://www.ismp.org/tools/tallmanletters.pdf]) to help staff identify look-alike medications or medication pairs that have been involved in dispensing errors.

### Quality Processes

- Have pharmacy managers or medication safety officers periodically perform quality-control checks by observing the process at the different phases of the dispensing process, including the point of sale, to ensure adherence to standardized work practices.

- Proactively conduct comprehensive safety assessments of the systems in place in the pharmacy. One tool that can help pharmacies evaluate their current systems is the free 2017 Institute for Safe Medication Practices Medication Safety Self Assessment® for Community/Ambulatory Pharmacy.

- Develop and operate a continuous quality improvement (CQI) program to enhance patient safety, identifying and evaluating quality-related events and constantly enhancing the efficiency and effectiveness of the structures and processes that determine the outcomes of medication dispensing and use.

- Work with hospital or health-system information technology staff and health information technology vendors to establish access to the inpatient medical health record. Access to the patient’s full medical health record better enables the pharmacist to perform a full medication reconciliation and screening for interactions and duplications.
CONCLUSION

With an estimated 64 million medication errors occurring each year in the outpatient setting and an average of 87 outpatient medication errors reported to the Authority annually, the chance of a serious error harming a patient is a real possibility. In Pennsylvania 56.2% (n = 587) of reported outpatient medication errors reached the patient. Outpatient pharmacies provide the last opportunity for a healthcare professional to intervene to ensure patients receive and take the correct medication in the correct manner. By reviewing patients’ medications upon each fill and providing patient counseling, outpatient pharmacists can make certain that patients are receiving the correct therapy. Educating and empowering patients to engage in patient counseling can prepare them to serve as the final barrier in preventing errors from negatively impacting themselves and help ensure that they are getting the therapy they need.

NOTES

Bullying in Healthcare: A Disruptive Force Linked to Compromised Patient Safety

INTRODUCTION
Patient safety officers (PSOs) from Pennsylvania facilities contacted the Pennsylvania Patient Safety Authority for information about workplace bullying to help healthcare workers address such behaviors. Bullying, a type of disrespect, is a threat to patient safety because it inhibits teamwork, obstructs communication, and impedes implementation of new practices. A bullied healthcare worker may not speak up with pertinent clinical information or point out a safety problem to the team.

Workplace bullying has increasingly become part of the national dialogue since the Joint Commission recommended adoption of a zero-tolerance policy toward bullying behaviors in 2008. The Workplace Bullying Institute defines bullying as repeated mistreatment of an intended target in one or more combinations of the following forms: verbal abuse; threatening, humiliating, or intimidating behaviors (including nonverbal); or work interference (e.g., sabotage). The Joint Commission does not consider the following behaviors to be bullying: illegal harassment, discrimination, setting high workplace standards, having a different opinion, or giving constructive feedback.

State legislators in 29 states, including Pennsylvania, and 2 territories have introduced bills to address workplace bullying. In addition, the American Nurses Association, the American College of Obstetricians and Gynecologists, and the Lucian Leape Institute at the National Patient Safety Foundation are among the institutions that have published position papers on this subject. The Institute for Safe Medication Practices (ISMP) conducted national surveys of healthcare workers about disrespectful behavior; results indicate that continued negative behaviors encountered by healthcare workers are influencing communication and suggest that healthcare facilities need to take further actions to address this issue.

A 2010 Pennsylvania Patient Safety Advisory article on disruptive behavior reported delays in communication between clinicians could potentially compromise patient safety. The Joint Commission does not consider the following behaviors to be bullying: illegal harassment, discrimination, setting high workplace standards, having a different opinion, or giving constructive feedback.

METHODS
Analysts queried the PA-PSRS database for reports of events that occurred over a two-year period from July 1, 2014, through June 30, 2016, using the following keywords and derivations: bellig*, bully, coerc*, cried, cry, disrupt*, holler, in charge, intimidat*, profan*, refuse, repeated, rude, scream, threat, throw, upset, yell. The wildcard character (*) ensured that the search also yielded events containing other word forms (e.g., disrupt* returns both disruptive and disruption). Events identified by relevant monitor codes to classify events were also included in the dataset.

Analysts manually reviewed the resulting set of 5,807 event report narratives to identify reports describing behaviors synonymous with bullying using the Workplace Bullying Institute definition. Event reports were then grouped into related categories by harm score, event type categories, event reporting taxonomy, and care area. Excluded were event reports addressing bullying by or toward patients.

* The term bullying may overlap with terms such as incivility; horizontal, lateral, or workplace violence; and unprofessional, disruptive, or disrespectful behavior.
Analysts conducted a review of the literature to identify prevalence and strategies to reduce bullying in healthcare facilities. Interviews were conducted with executive leaders, clinical practitioners, and nurse educators to identify best practices and resources to reduce bullying and patient harm.

RESULTS
Analysts identified 44 events describing bullying between healthcare providers including physicians, nurses, and technicians. Although analysts recognize that bullying represents repetitive behaviors over time, the examples in PA-PSRS demonstrate individual situations in isolation that, if repeated, could confirm bullying.

The identified events were reported in five event type categories with 56.8% (n = 25 of 44) reported in “other/miscellaneous,” followed by 27.3% (n = 12) reported in “error related to procedure/treatment/test” (Table 1).

Most of the events described overt bullying with no direct patient harm. Analysts found 77.3% (n = 34) of the PA-PSRS events involved a physician engaging in verbally abusive behavior. The remaining events (n = 10) involved a nurse or technician. Twenty-seven percent (n = 12) of the events were witnessed by a patient.

Examination of event descriptions revealed five categories of bullying behaviors based on the Workplace Bullying Institute definition. Analysts assigned some events to more than one category, resulting in 92 entries. The top two event categories in order of frequency were verbal abuse and intimidating behaviors (Table 2).

Analysis of care areas where bullying events were identified revealed three top areas where the events occurred: perioperative care areas 29.5% (n = 13 of 44); medical/surgical units 25.0% (n = 11); and the emergency department 15.9% (n = 7; Figure).

Bullying Events
Analysts interviewed a healthcare provider who spoke to the Authority on the condition of anonymity and described a bullying situation over the course of 15 years involving a nursing supervisor. She described the supervisor as harsh and abrupt with others, who used condescending tones, eye rolling, and deep sighing when new workers did not understand instructions.

At least two nurses left their positions in a month’s time after working with the supervisor, while other workers were afraid and avoided working with the individual, she said. Some repeat patients would request another nurse and indicated on questionnaires that the nurse was “mean,” she said. When the supervisor’s behavior was brought to leadership’s attention, the nurse said, it was not addressed. “We were told that this is just the way she is,” she said.

Examples of bullying events reported to the Authority in PA-PSRS are presented by category, as follows:

Verbal abuse
Night nurse yelled at other nurses with a negative and aggressive attitude after she was questioned about her documentation of assessments done during her shift. She stated, “How dare I question her” after asking for the information.

The radiology technician yelled at the nursing staff for not entering the procedure correctly [into the electronic health record]. This took place in front of the patient.

Table 1. Bullying Events by Event Type* (N = 44)

<table>
<thead>
<tr>
<th>EVENT TYPE</th>
<th>NO. (%) OF EVENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error related to procedure/treatment/test</td>
<td>12 (27.3)</td>
</tr>
<tr>
<td>Complication of procedure/treatment/test</td>
<td>5 (11.4)</td>
</tr>
<tr>
<td>Medication error</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Transfusion</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Other/miscellaneous</td>
<td>25 (56.8)</td>
</tr>
</tbody>
</table>

Note: As reported to the Pennsylvania Patient Safety Authority, July 1, 2014, through June 30, 2016.

* Event types are defined by Pennsylvania Patient Safety Reporting System taxonomy and are assigned to events by healthcare facilities at the time of report submission.

Table 2. Bullying Events by Description of Event* (N = 44)

<table>
<thead>
<tr>
<th>CATEGORIES</th>
<th>NUMBER OF EVENTS</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal abuse (e.g., rude behavior)</td>
<td>34</td>
<td>77.3</td>
</tr>
<tr>
<td>Intimidating behaviors (e.g., badgering)</td>
<td>32</td>
<td>72.7</td>
</tr>
<tr>
<td>Work interference (e.g., sabotage)</td>
<td>13</td>
<td>29.5</td>
</tr>
<tr>
<td>Humiliating behaviors (e.g., mimicking)</td>
<td>7</td>
<td>15.9</td>
</tr>
<tr>
<td>Threatening behaviors (e.g., frightening)</td>
<td>6</td>
<td>13.6</td>
</tr>
</tbody>
</table>

Note: As reported to the Pennsylvania Patient Safety Authority, July 1, 2014, through June 30, 2016.

* These events total more than 100% because some reports described more than one event category.
**REVIEWS & ANALYSES**

**Intimidating behaviors**

Patient admitted with bleeding and needed an order and consent for a blood transfusion. Physician refused to speak to the patient to obtain the consent and told the nurse that it would be the nurse’s fault if the patient dies. He repeated his order and hung up the phone. Patient had been transferred from the cardiac care unit with stable vital signs. The patient’s pulse became irregular and blood pressure dropped. Patient was otherwise without symptoms. (The nurse) called the physician and informed him of change in vital signs, and asked him if he wanted a cardiology consult. (The physician) told nurse seven times (the nurse) was incompetent, never to call him again and tell him what to do. No new orders were given.

**Work interference**

Physician was notified of a patient injury by the charge nurse. Due to a miscommunication about which patient was involved with the event, the physician thought the patient was a new admission. Physician fired off multiple questions and would not allow the nurse to answer her inquiries. The nurse tried again to give appropriate information about the injury [using the facility-approved format] and the physician again interrupted the nurse.

Nurse asked physician to perform medication reconciliation together [to prepare a patient for discharge] and physician refused. The nurse attempted to go through the list; however, the physician continued to interrupt the nurse and stated everything was fine.

**Threatening behaviors**

Surgeon insisted on modifying equipment in a manner that was against hospital policy. After lengthy arguments between the healthcare workers, the surgeon refused to perform the procedure unless the modifications were made. The nurse stated she was being forced to practice contrary to hospital policy.

**Humiliating behaviors**

Nurse asked physician to re-sign a consent form since there was no witness for the original consent. Instead of signing the form where it was indicated, the physician signed it on the witness line and stated to the nurse, “There, you have a witness.”

**DISCUSSION**

**Impact of Bullying on Patient Safety**

Of the 44 bullying events reported to PA-PSRS from July 1, 2014, through June 30, 2016, most occurred in the perioperative area, involved physicians as the perpetrators, and included verbal abuse and intimidating behaviors. The small number of events reported over the two-year period may reflect a lack of recognition of bullying behaviors, particularly if they are covert; a reluctance to report for fear of retribution; and absence of a PA-PSRS category for bullying as it relates to patient safety.

Leape and colleagues propose that disrespectful behavior causes the dysfunctional culture found in healthcare and inhibits progress in patient safety. He attributes this to the high stress environment found in healthcare, the hierarchical structure of the workforce, and the autonomous behavior of professionals who resist following safe practices. Disruptive behaviors can affect one’s ability to think clearly, making unsafe acts and errors more likely. Caregivers may even divert...
their attention from the patient to that of self-protection, as evidenced by avoidance of the instigator. Bullying may inhibit cross-monitoring by team members who are reluctant to speak up.

Understanding prevalence and consequences. The Workplace Bullying Institute estimates that 27% of adult Americans have experienced workplace bullying and another 21% have witnessed it. A Joint Commission survey found 50% of nurses were victims of disruptive behaviors and 90% witnessed these behaviors. Other researchers state the true number of bullying events is unknown, because it is often unrecognized and underreported.

In ISMP’s 2013 survey, 4,884 healthcare workers (i.e., physicians, nurses, pharmacists, quality/risk managers) responded that disrespectful behaviors most often encountered were as follows:

- Negative comments about colleagues (73%)
- Reluctance or refusal to answer questions or return calls (77%)
- Condescending language or demeaning comments or insults (68%)
- Impatience with questions or hanging up the phone (69%)
- Reluctance to follow safety practices or work collaboratively (66%)

Compared with survey results from 10 years earlier, ISMP found disrespectful behaviors continue to be prevalent, with little improvement.

Bullied workers may experience humiliation and powerlessness in response to behaviors that range from the overt such as verbal outbursts and physical threats, to the subtle or covert such as eye rolling or purposefully holding back patient information. Bullying behaviors may contribute to low worker morale, absenteeism, and high rates of turnover of highly qualified staff. There is also a financial cost associated with bullying such as training new staff, which is estimated at $100,000 per new hire.

Evaluating the culture. In an interview with the Authority, Grena Porto, RN, ARM, CPHRM, vice president, risk management, ESIS ProClaim, and a member of the Joint Commission’s Patient Safety Advisory Group, stated that as recently as 10 years ago, few people thought of bullying as a patient safety issue. Porto, who was instrumental in developing the Joint Commission’s Sentinel Event Alert on this topic, also stated that today, no one questions that bullying and other disruptive behaviors have a profound impact on patient safety.

Hospitals can take the first step to determine how bullying impacts patient safety in their facility, by administering the AHRQ (Agency for Healthcare Research and Quality) survey on the patient safety culture, which can be accessed at http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html. Porto also recommends conducting focus groups of healthcare workers from various shifts and departments to gain a clearer understanding of the culture.

Bullying on the Frontline. Bullying can occur in all areas of healthcare. It takes strong medical-staff leadership to tackle disruptive physician behavior, Porto said. “Depending on the situation, it may just mean sitting down with the physician over coffee,” she said. More serious episodes of bullying or repeated patterns of bullying behavior may require a stronger approach, including discipline and termination as appropriate. It is important to intervene early, tailor actions to the situation, and ensure that medical leaders are actively involved in the process, she said.

Studies show yelling, insulting other healthcare workers usually of lesser status (i.e., medical students), and refusing to follow established policies are the most common types of behaviors reported for physicians. Behaviors of physicians found by analysis of the PA-PSRS events included shouting and insulting language directed towards others in supporting positions (e.g., nurses, technicians).

Nurses can be compassionate to patients, but may also be “horrific” to each other, according to Renee Thompson, DNP, RN, CMSRN, CEO and president of RTConnections, LLC, based in Pittsburgh. Thompson, an author and expert about nurse bullying, said, “Every single day of my life, a nurse reaches out to me about being a target of bullying.”

Nurses work in extremely stressful situations in which they are dealing with life and death in unpredictable circumstances, Thompson said. “We haven’t taught nurses good coping mechanisms,” she said. “So they lash out at each other and then that becomes their pattern.”

Working with a bully can be a huge distractor that impacts patient safety, Thompson said. “How can you really focus on your patient if you are worried about keeping out of harm’s way of the bully,” she said. “If you are uncomfortable about being open and honest with someone, how can you share information about your patients? It stops the flow of information.”

Thompson advocates for training managers about bullying behaviors. Frontline managers determine the culture in the nursing unit, but no one is teaching the frontline managers how to set expectations with the staff, how to hold people accountable, and how to create a culture of professionalism, she said.

The Role of Leadership

Leadership support is crucial in introducing, setting policy, and maintaining a successful anti-bullying program. Kendra Aucker, president and CEO, Evangelical Community Hospital, Lewisburg, PA, discovered that 30% of the employees who completed a survey in 2015 measuring the “culture of respect” answered that abusive behavior...
was tolerated at the hospital, 25% were frequently bullied, and 40% found it unpleasant to work with other departments.19 “I read this and couldn’t believe it,” she said. “I thought this was unacceptable and we have to start now to address this.”

Aucker introduced policies on anti-bullying and respectful workplaces (http://patientsafety.pa.gov/pst/Pages/PSAPatientSafetyTopicList.aspx) for every level of the organization to help establish a safety system and culture.19 In addition, she met with about 1,100 employees over several months in informal meetings entitled “Coffee with Kendra” to get firsthand insight into the culture. “I was told about outbursts, shouting, passive-aggressive behaviors, and other ways we treated one another,” she said. “We would never achieve a higher level of patient care unless we changed our attitudes and our behaviors. There is an expectation in the way you treat the people you work with, and that translates to how you treat the people you care for.”

She worked in committees to alleviate some of the system problems causing frustrations that lead to bullying behaviors, focused on the departments with the lowest survey scores, instituted training programs for staff and managers, wrote about the improvements in e-mail blasts, and talked about the issues in a “state of the union” address.19

With someone willing to listen and determined to make changes, Aucker said, staff began speaking out about situations that could jeopardize patient safety. “The patient is the center of all that we do, and that includes our behavior,” she said.19 If employees could not change their behaviors, then this was not the organization for them anymore, she said. A year after the survey, Aucker said improvement was measured with an employee engagement survey, which found a 38% decrease in the percentage of employees who felt disengaged.

“I am very proud of the work force,” she said. “Behavior isn’t always black and white, but you have to feel free to speak up and stand up for yourself if you feel you are a victim of bullying or bad behavior. You have to take responsibility for yourself and other people. While there is still lots of work to be done, patients are talking to us about how kind and helpful staff are to them.”

It is imperative that hospitals develop a leadership team, including middle managers and unit managers who can lead by example and model the desired behaviors, Porto said. “It is critical to understand that even managers and senior leaders are capable of bullying behavior, and organizations who fail to identify and address such behaviors in leaders cannot succeed in establishing a culture of safety,” Porto said.13

Limitations
Limitations of this study include scant detail in some PA-PSRS reports, the potential to misinterpret information in the narrative descriptions in the reports, and the possibility that reporters used terms not included in the search strategy. Although analysts recognize that bullying represents repetitive behaviors, PA-PSRS events demonstrate individual situations in isolation that, if repeated, could confirm bullying. Events may not be recognized as reportable by frontline staff if bullying is viewed as “normalized” behavior, because of the lack of a structured data field for reporting bullying or employee events or because of fear of retribution. Bullying events, especially those in which there is physical harm between providers, may be reported as an Infrastructure Failure, which is not reported to the Authority.

RISK REDUCTION STRATEGIES
The following strategies suggested in the literature, and by anti-bullying groups and professionals, may be useful to healthcare workers, managers, and senior leaders seeking to reduce bullying and other disruptive behaviors.

**All Healthcare Workers**

- Report and document bullying behaviors through established protocols.20
- Review personal behaviors (e.g., do you sometimes ridicule or joke about a new or inexperienced co-worker?) and take steps to modify these behaviors (e.g., seek out an Employee Assistance Program).18
- Learn scripting techniques to help stop a bullying situation such as D.E.S.C. (i.e., describe, express, suggest, consequences).21
- Think about strategies to handle a bullying situation (e.g., staff members feeling tensions rising, can call out, “Tempo!” as a reminder for everyone to calm down, or when a bullying situation occurs, have workers notify others so they can stand beside and support the bullied worker).22
- Know your healthcare facility’s policy and procedure on bullying, so you can refer to it and seek help, as needed.20

**Managers**

- Observe staff at work and during key interactions such as change-of-shift reports to identify patterns of unacceptable behavior or communication.13
- Appoint preceptors who will uphold a zero-tolerance policy for bullying behaviors and can serve as a resource for those on the receiving end of bullying behavior.13,23
- Ask senior leaders for educational classes on bullying for staff and managers.20
- Engage organizational staff members with expertise in this area (e.g., human resources experts) to be available to staff, as needed.21
— Know your facility’s policy and procedure addressing bullying, and enforce it in your department.20
— Place posters and fact sheets about bullying in your break and locker rooms.13,18
— Ensure each bullying incident is resolved in a manner that protects the person being targeted and enhances the overall unit or departmental culture.24

**Senior Leaders**

— “Declare a new day” by not letting past events disrupt new efforts, and move forward regardless of past events.25
— Survey the staff to establish a baseline about bullying behaviors in your facility and conduct ongoing monitoring13,19
— Develop or review existing policies and procedures on bullying, and make sure they follow current state and federal standards and professional behavior standards.3,20

Recommended elements include zero tolerance, non-retaliation towards those who report/cooperate in investigations, responding to witness (e.g., patients), and defining disciplinary actions.3
— Ask for input from staff to ensure staff co-owns the process and expectations.23
— Establish a multi-disciplinary committee of senior leaders, managers, and healthcare workers to review bullying events.3,10
— Encourage employees to report incidents of bullying, and provide feedback on these behaviors to all employees.19
— Offer educational programs on strategies for conflict resolution and encourage employees to participate.3
— Lead by example and model non-bullying behaviors.15

**CONCLUSION**

Analysts identified 44 bullying events reported through PA-PSRS over a two-year period; most occurred in the peri-operative area and were overt actions such as verbal abuse and intimidating behaviors. Limitations of reporting bullying behaviors are discussed and include lack of recognition of bullying behaviors, particularly if they are covert, and a reluctance to report for fear of retribution. Bullying behaviors may threaten the safe care of patients by inhibiting teamwork, obstructing communication, and delaying implementation of new practices. Studies show that bullying decreases morale and increases absenteeism and turnover of highly qualified staff. Studies suggest that hospitals take a focused look at these behaviors and institute effective policies with leadership support, educate staff and managers to recognize and handle bullying situations, and involve medical staff leadership.

**NOTES**

3. Behaviors that undermine a culture of safety. The Joint Commission; 2008 Jul 9. 3 p. (Sentinel Event Alert; vol. 40). Also available: https://www.jointcommission.org/assets/1/18/SEA_40.PDF.
INTRODUCTION

Imagine a basic tool used for performing a task, such as a chisel. The chisel is a raw powerful tool that one strikes with a hammer, commonly used for removing large chunks of material. A chisel has a handle for stabilization, a striking surface, and a flat, angled cutting edge. Not complex or compound, the chisel nowadays is usually fabricated from a single piece of hard metal, is easy to wipe off and sharpen, and maintains its cutting edge for long periods of use, requiring little maintenance. Now, imagine a tool designed for cutting delicate objects, such as a small pair of scissors. The chisel has one cutting edge that moves in one direction, whereas scissors have two cutting edges that move in opposite directions, requiring the addition of a hinge pin. The scissors require sharpening of two indexing edges, lubrication of the hinge pin, and a specific interface with the operator through the two handles. As the precision of work increases, tools seem to become more complex and require more care for proper operation. Care and maintenance of complex tools, in turn, directly affects the quality of work when the tool is used.

The same principles can be applied to tools used for operations and procedures conducted on living beings. Tools evolve into instruments and devices as the complexity, delicateness, and success of a procedure increase, and their use directly influences a patient’s real or perceived wellbeing. The straight Hibbs chisel, used in orthopedic surgery to remove large pieces of bone, is made of smooth, high-quality stainless steel; with no material gaps, channels, or overlaps, and it is easy to clean, disinfect, and maintain. Compare the Hibbs chisel to the Pratt-Smith hemostatic forceps (Pratt hemostat), with the Pratt’s T-shaped, tube-like tip with precise, fine, serrated jaws, ratcheting handle, and smooth hinge action (see Figure 1). Based on its design and intended function (clamping delicate tissue) the Pratt hemostat has more nooks and crannies that are difficult to adequately reprocess and facilitate the accumulation of biofilm. Thus, the design of medical devices, equipment, and instruments may provide ideal spaces for bioburden accumulation, and subsequent development of biofilm, especially if compound hinges, gaps, channels, or lumens are present.

Bioburden

Bioburden is “the degree of microbial contamination or microbial load; the number of microorganisms contaminating an object.” Colloquial clinical use of the term bioburden includes both microscopic debris and debris that is visible to the naked eye and refers to tissue, body fluids, bacteria, or any other biologic material present on, or in, an instrument or device after use on, or in, a patient. Varying degrees of bioburden will be present on an object after use on a patient; the accumulation of bioburden on used equipment is unavoidable. Once bioburden is present on a surface, biofilm formation is not far behind.

Biofilm

Surface bioburden to any degree facilitates the formation of biofilm. Biofilm is “a slime-enclosed community of bacterial colonies that is very difficult to eradicate even with the most powerful antibiotics or sterilizing systems. Biofilms can occur on any body surface, on teeth (as dental plaque), medical equipment, medical tubing, contact lenses and elsewhere.” It is important to note that biofilms can be visible to the naked eye in an aquatic or industrial environment, for example when pipes are fouled, but biofilms can also be microscopic and can develop on the surfaces of medical devices and equipment very rapidly (within minutes).
Healthcare-Associated Infection and Endotoxin

The published literature has examples of healthcare-associated infections (HAIs) linked to instruments and equipment that have been processed appropriately but, because of their design, have proved to be difficult to clean and disinfect or sterilize despite following the manufacturer’s cleaning instructions. Furthermore, there is evidence of infection transmission when cleaning and sterilization procedures have not been adhered to, or where quality control has been poor. Several researchers have also noted the risk of endotoxin presence on surgical instruments, which may contribute to orthopedic prostheses loosening. The risk of complications and frequency of these types of events is difficult to determine; peer-reviewed literature addressing the topic is lacking. Many adverse outcomes related to the use of poor quality instruments are likely to go unrecognized, especially if the result of an event is latent in a patient’s course.

METHODS

To help inform healthcare facilities about the prevalence of inadequate reprocessing of surgical instruments, Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database to identify acute-care event reports associated with bioburden on surgical instruments reported from January 1, 2005, through December 31, 2015. The end of 2015 was the last complete data set at the time of the query for all data sets. Analysts then compared the resultant trend identified within PA-PSRS data with Pennsylvania Health Care Cost Containment Council (PHC4)* acute care procedural denominator data within the same time frame to account for potential artifact within PA-PSRS data, in the event that increased volume reporting affected prevalence trends. The PHC4 acute care procedural denominator data report was produced using operating room revenue codes within a claim record to capture and count the number of operating room revenue codes per claim record thereby arriving at the denominator of inpatient claim records. PA-PSRS event reports include a free-text narrative section for reporters to augment the event report. Analysts also compared reports and narratives to discern any recurrent themes.

Authority analysts interviewed six individual operating room clinicians from four hospitals in different regions in Pennsylvania. The interviewees were informed that the Authority had received reports of surgical instruments with bioburden and or debris present after reprocessing that were for use in operating rooms. Interviewees were asked to describe rationales and possible explanations that they believed contributed to these events. Interviewees agreed to speak with the Authority on a guarantee of complete anonymity for themselves and their institutions. Interviews were conducted via phone and were structured in an open format without specific questions posed by the analyst.

RESULTS

Quantitative Results

Figure 2 shows a general increase in the number of bioburden related events reported through PA-PSRS during the years 2005–2015. Figure 3 shows the rate of reported events per 1,000 inpatient claim records per year. Figure 3 mimics the trend identified in Figure 2 and demonstrates a general increase in bioburden prevalence per year, accounting for the number of patients. Figure 4 displays the rate of bioburden reports per 1,000 inpatient claim records by event type per year. Figure 4 further validates the initial trend of an increased bioburden prevalence over time isolated within PA-PSRS data.

* The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care, and increasing access to health care for all citizens. While PHC4 has provided data for this study, PHC4 specifically disclaims responsibility for any analyses, interpretations, or conclusions.
Qualitative Examples

The following narratives from events reported through PA-PSRS are examples of the adverse impact ineffective cleaning and sterilization procedures can have in a clinical setting:

* Loaner instruments ran through washer decontaminator then wrapped and run through sterilizer. While setting up, staff noticed dried blood on the set.

* While pushing bone graft into the instrument, a large piece of dried tissue from a previous case came out onto the field, contaminating the patient’s bone graft and set-up.

* Debris from a prior procedure dislodged from the endoscope and floated into the ventricle, unable to retrieve. Ventricle flushed and patient placed on antibiotics.

* Laminectomy with local bone graft. Staff noted that a sterilized instrument pan containing spinal instruments was found to be contaminated with old bone and tissue from a previous case. The case was delayed.

* Fragments of bone cement were observed in the patient’s knee, and the surgeon had not used cement. The scrub nurse noticed the instrument impactor in the set had cement from a previous case on it. Wound class was changed from 1 to 2.

Interview Results

The following problematic, common themes emerged during interviews with six individuals involved in surgical instrument reprocessing and use:

- Reprocessing staffing patterns not aligned with increases in surgical case loads

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

Unrealistic expectations related to reprocessing production pressure (demands for quicker turnaround of instruments)

Subpar levels of surgical instrument stock

Re-processors’ unfamiliarity with manufacturer’s instructions for use and care of instruments

Operating room staff not consistently wiping, precleaning, or soaking instruments prior to sending for reprocessing

Used surgical instrument trays sitting for prolonged periods of time before being sent for reprocessing

The operating room and reprocessing departments treated as separate teams—a lack of cohesion between departments

Lack of standardized training and education

Poor workflow design in the reprocessing department

Inconsistent auditing of process measures and quality indicators

When considering the quantitative and qualitative data, the explanations provided by the interviewees seem to deserve investigation for quality improvement because the prevalence of events shows an upward trend over time. All interviewees stated that their individual hospitals were aware of and actively addressing the issue of surgical-instrument reprocessing quality.

LIMITATIONS

Limitations of PHC4 data on the procedural denominator data report as per PHC4:


The analysts note the limitations of the PHC4 data collection method by using claim records and revenue codes. Thus, the bioburden rates per surgical procedure shown in Figure 4 might be lower than typical instrument bioburden prevalence per procedure in a clinical setting.

The Authority acknowledges that the interview data is of a limited nature and likely does not represent all conditions across Pennsylvania.

DISCUSSION

High-quality reprocessing of surgical instruments and equipment is a mission critical task. Although the interview evidence is limited, it must be considered that all interviewees noted some amount of separation and discordance between the operating room and reprocessing departments. The operating room and its patients depend on the reprocessing department; operating room services cannot exist without an adequate flow of quality surgical instruments and equipment. Efforts can be considered to unify departments and processes around the care and maintenance of mission critical items, such as surgical instruments, devices, and equipment.
As demonstrated by the examples of the Hibbs chisel and Pratt hemostat, surgical equipment comes in all shapes and sizes, with varying levels of complexity. Based on the design and complexity level, some instruments may be inherently easier to clean and subsequently disinfect or sterilize appropriately. Reprocessing and operating room staff need to have access to each instrument’s instructions for use that include particular methods for cleaning, care, disinfection, sterilization, and maintenance. As noted in the results, there have been many reports of debris lodged on and inside instruments, especially those with gaps, lumens, and channels. Once debris dries inside or on an instrument surface, the instrument becomes increasingly difficult to clean; thus when cleaning starts at the point of use (in the operating room), removing debris at the point of reprocessing becomes more effective.9 Equipment design plays a vital role in determining how easily an effective, high-quality reprocessing method can be accomplished. There are examples in the literature of infection transmission occurring after a device was processed according to the manufacturer’s instructions, essentially due to device design that made adequate reprocessing difficult.4 When purchasing equipment and instruments, the design and the entire use, reprocessing, and reuse cycle should be considered. An optimal approach would bring all users of an instrument to the table during the evaluation for purchase, to gather input on the features and design of the device. If reprocessing staff point out that the design of a device is problematic from a cleaning perspective, it may warrant evaluating equipment of a different design that can perform the same task. If there are no other alternatives, instructions about how to process the device need to be explored. For example, ultrasonic washers may be needed, or a facility may need to purchase more washers, adding time and cost to the process for a given piece of instrumentation. The Authority has a sample tool available, providing equipment-purchasing guidance in terms of integrating equipment into the work place. The tool is available with an accompanying Pennsylvania Patient Safety Advisory article at http://patientsafety.pa.gov/psa/Pages/PSAPatientSafetyTopicList.aspx.

The data presented in this article scrapes the surface on a multitude of factors that affect the critical task of reprocessing surgical instruments and equipment. Quantitative, qualitative, and expert interview data have been compiled to provide insight into the complexity of a process that affects patient outcomes, patient satisfaction, staff satisfaction, workflow, finance, and other variables. The data and concepts presented herein are intended to give facilities a starting point for self-assessment of the reprocessing continuum, inclusive of all users and departments that interact with surgical instruments and equipment, to find quality-improvement opportunities.

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NOTES

FROM THE DATABASE

Radiology Contrast Concerns: Reports of Extravasation and Allergic Reactions

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A Pennsylvania healthcare facility identified a neurological adverse event in a few patients within 8 hours of receiving an intravenous (IV) contrast agent for a radiologic study. This facility, which used low osmolar, nonionic, monomer, and nonionic iso-osmolar dimer contrast in the studies, contacted the Pennsylvania Patient Safety Authority to inquire whether similar events were reported elsewhere in Pennsylvania. Analysts addressed the request through a focused analysis of radiology contrast events in hospitals of a similar size to the requesting hospital (i.e., hospitals with 300 beds or more).

Contrast media is used as an advanced imaging technique to improve diagnosis, and it is generally safe and effective.\(^1\) It is estimated that contrast media is used in millions of radiological studies annually.\(^2\) Imaging studies that may require iodinated contrast media include x-ray studies, computed tomography (CT) scans, arteriograms, and interventional radiologic procedures.\(^3\) Iodinated contrast media is the most commonly used IV contrast agent.\(^4\) An estimated 2% to 17% of patients receiving contrast media experience an adverse effect, regardless of the contrast type.\(^4,5\) Adverse reactions mostly occur with IV administration; however, they also occur with intra-arterial and nonvascular injections.\(^3\) Knowledge of adverse reactions, prevention, preparation, and adequate response when a reaction occurs are essential to providing safe care to patients undergoing imaging studies with contrast agents.\(^2\)

METHODS

In response to the request, Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) to identify radiology contrast–related events in hospitals with 300 beds or more over a 2-year period, from January 2014 through December 2015. The following search terms and word roots were used to identify applicable events: procedu, omni, visip, power inject, contrast, mri, and mra. The query identified more than 4,600 event reports. Analysts reviewed individual free text fields, such as the event narratives, using key terms including the following: MRI, contrast, power injection, study, procedure, infiltration, extravasation, allergic reactions, adverse events, Omnipaque\(^®\), and Visipaque\(^™\). Of the 4,609 events, 544 were excluded because they had no relevance to contrast administration (e.g., contrast was not given, or was mentioned incidentally). The remaining 4,065 event reports addressed IV, oral, and enteral routes of contrast administration.

Analysts conducted an extensive review of the literature and an Internet search to obtain epidemiological data on the use of radiologic contrast media, adverse reactions, and treatments. A medical librarian assisted with a search for published articles indexed through July 31, 2016, in AccessMedicine, EBSCO Biomedical Reference, Embase, Google, Google Scholar, PubMed, Cochrane, Scopus, and UpToDate databases and search engines. Searches included terms such as radiocast agents, media, contaminate, neurological, microemboli, and stroke.

RESULTS

Harm and patient age. The majority of the event reports were Incidents (i.e., near miss event or events that reached the patient but did not result in harm or require additional interventions): 99.2% (n = 4,034 of 4,065). The remaining 0.8% (n = 31) events were Serious Events, in which an event reached the patient and resulted in harm—including severe extravasations, nephrotoxicity, and cardiac events—and required additional intervention.
Patients in the age group 50 to 59 years had the largest number of reported events (19.8%, n = 805) and patients 60 years or older accounted for 46.5% (n = 1,889) of reported events; these findings parallel findings in the study by Ha, Kim, and Sohn. Patients in the age group newborn to 18 years had the fewest number of events reported (2.1%, n = 87).

**Radiology contrast route.** Administration of IV radiology contrast was noted in 89.9% (n = 3,653 of 4,065) event reports. Oral or enteral routes were noted in 2.8% (n = 112) of the event reports, and the remaining events lacked a description of the route of contrast administration (7.4%; n = 300).

**Adverse effect conditions.** Not all patients experienced an adverse event and not all conditions caused or explained the adverse event. Almost two-thirds of the event reports (63.4%; n = 2,577 of 4,065) were related to IV contrast infiltrations or extravasations. Another 22.1% (n = 897) were related to allergic reactions. Analysts identified eight types of adverse effects associated with contrast media–related event reports (see Figure). Although less frequently reported, complications of oral contrast included vomiting (n = 8), with the potential for aspiration.

The most frequently reported body system affected was the integumentary system, due to the infiltrations and extravasations as noted above, followed by the renal system at 1.3% (n = 51 of 4,065). There were no reports of neurological adverse effect conditions in this period.

**DISCUSSION**

**Adverse reactions.** Acute reactions to contrast media, including allergic and allergic-like reactions, can be divided into three categories: mild, moderate, and severe. Mild symptoms typically include erythema, nausea, vomiting, pruritus, headache, and mild urticaria. Patients who experience mild reactions require little intervention beyond routine patient care and monitoring and will typically recover in a few hours. Patients with moderate reactions may have any or all of the mild symptoms and additionally might exhibit bronchospasm, moderate urticaria, chest pain, dyspnea, hypotension or hypertension, tachycardia or bradycardia, and other vasovagal responses. Patients with moderate reactions may require therapeutic intervention and monitoring, but most do not require admission. Severe reactions occurred in fewer than 1% of patients who received contrast and happen quickly after administration of contrast, usually within 20 to 30 minutes. Immediate intervention is required because severe reactions can be life-threatening. Severe reactions may include laryngeal edema, severe bronchospasm, seizure, convulsion, unresponsiveness, and death. Delayed reactions, those appearing more than 30 minutes or within 7 days of receiving contrast, occur in 8% to 30% of patients, and the percentage depends on the molecular structure of the iodi nated contrast given (e.g., ionic versus non-ionic monomers). Delayed reactions include rash, urticaria, flu-like symptoms, and polyarthropathy.

Treating patients who have known contrast allergies or patients at risk for an allergic reaction, such as those with prior sensitivity to contrast, includes preventive interventions such as administering corticosteroids.

An extensive literature search specifically addressing neurological adverse reactions was performed to address the initial inquiry into this topic. This search identified no studies directly linking radiologic contrast media alone to neurological adverse reactions. Neurologic complications, such as stroke and myocardial
infarction, can be associated with air embolism, and "clinically significant air emboli are potentially fatal"; they are most commonly associated with the use of power injectors.2,4

The literature search returned two older studies linking particulate matter with the risk of emboli formation and the possibility of cardiac and neurologic adverse events.3,8 Winding studied angiographic contrast media in ampules and vials. Particles were found in all brands tested and the author recommended "contrast media be passed through a filter during administration."7

Hirakawa and coauthors studied radiographic contrast media administered intravenously through an automatic injector and noted that "particulate contamination of the radiographic contrast media occurs as a result of the interaction with silicone and sulfur on the surface of the disposable syringe components. High speed injection increases the risk of contrast media contamination from the particulate matter after transfer from the vial to a disposable syringe."9 A sampling of two package inserts for radiographic contrast media includes a standard recommendation to "visually inspect the product for discoloration and particulate matter prior to administration."9,10

Extravasation. These events occur when vascular access is compromised and the contrast media enters the surrounding tissue. Contrast media is toxic to surrounding tissues, especially skin, with a local inflammatory response that can peak in 24 to 48 hours.2 Pain (e.g., burning or stinging) or swelling or tightness are the main patient complaints when extravasation occurs; however, some patients experience little or no discomfort.2 Physical examination may uncover a site that is edematous, erythematous, and tender in mild cases and painful or blistering in moderate cases.2,4 Treatment for a contrast-media extravasation is aimed at the clinical manifestations present and may include elevation of the affected extremity above the heart to promote reabsorption, application of either warm or cold compresses, and monitoring of the limb for several hours.2,4 Compartment syndrome is a severe injury that is more likely to occur after extravasation of larger volumes of contrast media.2 Physical assessment may uncover progressive swelling, increasing or severe pain, change in sensation, and decreased circulation.2,4 Medical follow up is recommended and surgical consultation may be warranted.2,4 The American College of Radiologists recommends "close clinical follow up for several hours for all patients experiencing an extravasation."10

Risk factors. The following risk factors can predispose a patient to an adverse event: previous severe reaction to a contrast agent, history of multiple allergies, asthma, dehydration, diabetes, renal disease, sickle cell anemia, polycythemia, myeloma, cardiac disease, thyroid disease (e.g., hyperthyroidism, carcinoma), anxiety, age older than 60 years, concomitant use of certain intra-arterial injections such as papaverine, and certain medications such as beta blockers and metformin.2,5,6

As noted in the PA-PSRS data, patients age 60 years or older accounted for 46.5% of the event reports. Incidentally, the administration of metformin was reported in 26 of the event reports. Staff education on all risk factors including screening for patient age may help reduce the risk of an adverse event or reaction. Likewise, education on the importance of timing the administration of metformin relative to the administration of radiologic contrast media may help reduce likelihood of a delay in obtaining the contrast study and the risk of nephrology complications.

For a list of evidence-based resources on the safe use of radiologic contrast media, see "Safe Use of Radiologic Contrast Media."

CONCLUSION

Although the administration of radiologic contrast media is generally safe, it is not without risks. As seen in the PA-PSRS data and literature, most adverse events are mild and do not result in permanent patient harm. Knowledge, prevention,
recognition, and prompt management of adverse reactions to radiologic contrast media can all contribute to providing safe care to patients undergoing contrast-related studies. Additionally, knowing the types and severity of radiology contrast events that occur in a facility can guide staff in proactive prevention and screening strategies and in implementing the appropriate responsive actions to mitigate patient harm.

NOTES


Bridging the Gap between Work-as-Imagined and Work-as-Done

To improve the safety and quality of healthcare, we try to understand and improve how healthcare providers accomplish patient care “work.” This work includes synthesizing information from a patient’s history and physical examination or from a handoff; performing tests or procedures; administering medications; and providing information so that patients can make the best choices for themselves. Sometimes this work flows very well and everyone is pleased with the results. Sometimes this work does not unfold in the way that was anticipated. Perhaps the patient’s condition is more complicated than usual, or perhaps a needed resource—a medication, a piece of equipment, available operating room time, or a consultant—is not readily available. Perhaps there is time pressure, or we encounter distractions and interruptions. Healthcare providers often complete tasks that are necessary for patient care despite obstacles in their path, and without necessarily reporting, let alone fixing, those obstacles.

Efforts to improve healthcare work will not succeed without recognizing that there is a difference between a theoretical construct of “work-as-imagined” and the reality of “work-as-done” (see Figure). Work-as-imagined is the illusory ideal state. Hollnagel describes work-as-imagined as what designers, managers, regulators, and authorities believe happens or should happen, which becomes the basis for design, training, and control. In contrast, work-as-done is what truly occurs and what people actually do during patient care.¹

Although a complete and perfect understanding of work-as-done is a worthy goal, healthcare delivery is a complex adaptive system that is in constant evolution with fluid, dynamic changes.²⁻⁶ Complete understanding is an unattainable ideal. Work-as-imagined provides information based on conceptual processes; it can offer a valuable hypothetical construct of the work in question, and may be used to develop theoretical concepts and generalizable guidance. Work-as-imagined may not reflect actual conditions that impact patient care at the “sharp end,” the point in patient care that directly impacts patients. However, exploring the gap between work-as-imagined and work-as-done does afford opportunities to look at work through a variety of lenses, each of which provides complementary information. Each lens has attributes and limitations; a preliminary exploration of several potential lenses, such as “work-as-documented” and “work-as-observed,” follows.

With the blossoming of computer science, discrete event simulation can be used to analyze patient flow, predict demands for services, and mathematically model the impact of interventions on patient care processes. Standardized parameters for process components can be manipulated to calculate the effect of increasing patient volume or restructuring patient flow processes (e.g., change the triage process, add an ultrasound machine). Discrete event simulation can facilitate analysis of nonlinear interactions between variables and their intermediary agents; this could be considered “work-as-abstacted.”⁷

“Work-as-observed” occurs when care providers know they are being watched, whether informally by trainees or colleagues during patient care, or formally, such as during evaluations (e.g., certification examinations) or as participants in research. The well-known Hawthorne effect posits that participants modify their actions when they know they are being observed.⁸ As a consequence, the work that occurs during, for example, executive walkrounds, may not fully represent the work that occurs in normal situations.

Documentation, fundamentally linked to patient care activities, serves many masters. Documentation is used to communicate meaningful patient care information, support
billing, and provide medicolegal information. The accuracy and completeness of "work-as-documented" may be impacted by the skills and memory of the person documenting, the ease or challenge of the documentation process, and the temporal distance between the patient care event and the opportunity to document. When a scribe is added to the documentation process, opportunities for incomplete understanding and miscommunication may arise. Understanding work-as-done by using administrative databases, chart audits, and trigger tools relies on work-as-documented.

Claims are written demands for compensation for medical injury, which may be submitted by patients and their families because they have been advised...
to sue; because they perceive physician dishonesty; because they seek information, resources for future medical costs, or revenge; or for other reasons. Work-as-claimed is a lagging indicator, often reflecting occurrences that are several years old. The relationship between medical malpractice events and medical malpractice claims is complicated and nonlinear. Some claims are without merit, whereas the majority of patients who sustain a medical injury as a result of medical malpractice events and medical errors, and compensation payments in medical malpractice litigation. N Engl J Med. 2006 May 11;354(19):2024-33. Also available: http://dx.doi.org/10.1056/NEJMoa054479. PMID: 16687715.


SAVES, SYSTEM IMPROVEMENTS, AND SAFETY-II

“Saves, System Improvements, and Safety-II” is an occasional feature in the Pennsylvania Patient Safety Advisory, highlighting successes of healthcare workers in keeping patients safe. The Safety-II approach assumes that everyday performance variability provides adaptations needed to respond to varying conditions and that humans are a resource for system flexibility and resilience.

An Unexpected Problem: Was the Response Correct?

The following event report was submitted through the Pennsylvania Patient Safety Reporting System (PA-PSRS):*

A patient arrived for a routine after-hours radiologic study and expressed that she was not feeling well. As the study began, she indicated that she was having trouble breathing. The technician noted a decreasing oxygen saturation, and the patient described increased difficulty breathing. The technician placed the patient on oxygen according to the organization’s [emergency response] policies and called 911. The technician monitored the patient until the ambulance crew arrived and took responsibility, and the patient was transported to an acute care facility.

The facility praised the technician for acting promptly and correctly.

Healthcare providers sometimes encounter situations in which they respond to a patient’s unexpected deterioration but are unsure whether their actions were too aggressive. This technician may have wondered whether his or her actions on the patient’s behalf were medically correct and, further, whether those actions might prompt a reprimand for disrupting a scheduled study. This report provides an important example of reinforcing correct actions. Learning from failures and errors is important, but successes also provide learning opportunities. Learning from success is particularly important when learners are unsure whether the success is a result of their abilities and efforts or occurred as a lucky outcome; such learning is important when the cost of errors is high.1 The Pennsylvania Patient Safety Authority applauds this facility for supporting the technician and for sharing their actions through PA-PSRS.

Note


* The details of the PA-PSRS event narrative in this article have been modified to preserve confidentiality.
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ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute’s expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures, and drug technology.

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