Pennsylvania Patient Safety Advisory

March 2019, Vol. 16, No. 1
See the Action Agenda (/ADVISORIES/Pages/201903_ActionAgenda.aspx) for this issue.

Reviews & Analyses

Patient Self-Harm in the Nonpsychiatric Setting (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_SelfHarm.aspx)
Acts of patient self-harm may challenge even the best-laid safety plans in unanticipated and potentially devastating ways. Pennsylvania healthcare facilities have reported more than 600 events describing intentional bodily harm outside of psychiatric settings, ranging from possession of means to self-harm to completion of a self-harm act.

Drug Shortages: Shortchanging Quality and Safe Patient Care (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_DrugShortages.aspx)
The struggle by healthcare providers to manage drug shortages has led to negative downstream effects on patients, including instances of unsafe or compromised practice and potentially harmful medication errors.

Exploring Vulnerability to Patient Safety Events along the Age Continuum (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_EventsbyAge.aspx)
Attention to the event types and patterns of vulnerability that predominate in specific age cohorts may help facilities prioritize interventions.

From the Database

Incidence of Concurrent Surgery in Pennsylvania (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_ConcurrentSurgery.aspx)
In response to an inquiry, Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System database for events involving concurrent and overlapping surgery and procedures in hospitals and ambulatory surgical facilities.

Other Features

Celebrate the 2019 I AM Patient Safety Winners (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_IAPS.aspx)
The Pennsylvania Patient Safety Authority’s annual I Am Patient Safety contest promotes individuals and groups within Pennsylvania’s healthcare facilities who have demonstrated an exceptional commitment to patient safety. The nominations described scenarios of team work, high reliability, communication, innovation, event reporting, transitions of care, and more.

Are Humans the Problem in Patient Safety? (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_Commentary.aspx)
Encouraging humans to be adaptable improves their skill at navigating complexity, solving problems, and ultimately, improving patient safety.

Safety Stories: Missing the Mark (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_SafetyStories_Mark.aspx)
This recurring feature, in this example, highlights a hazard that exists if the individual drawing up medication does not recognize that a syringe is incorrectly marked.
Patient Self-Harm in the Nonpsychiatric Setting

Abstract

624 patient self-harm events in nonpsychiatric settings submitted through PA-PSRS in academic years 2016 through 2018*

Top care area: Emergency Department
233 reports

Top age cohort: 25 to 34 years
171 reports

Examples of hazards:

Risk Reduction Strategies
- Training for patient observers
- Proactive ligature-risk assessment
- Regular environmental inspections

* Reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), July 1, 2015, through June 30, 2018.

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_SelfHarm.aspx
Amidst the quest to protect patients from healthcare-associated harm, acts of patient self-harm may challenge even the best-laid safety plans in unanticipated and potentially devastating ways. A query of the Pennsylvania Patient Safety Reporting System database for reports submitted from July 1, 2015, through June 30, 2018, using the event type "Patient Self-Harm" identified 624 reports describing a spectrum of events involving intentional bodily harm outside of psychiatric settings—from possession of means to self-harm to completion of a self-harm act. Emergency departments and medical-surgical units were the most common event locations, and ingestion accounted for more than 40% of the reports describing self-harm acts. A list of risk reduction strategies and resources, including the Pennsylvania Patient Safety Authority's ligature-risk assessment initiative, is provided.

Introduction

Patients in hospitals sometimes harm themselves intentionally. These acts, defined broadly as self-harm, may have varying goals and outcomes—the most devastating being suicide, a "never event" in the eyes of the healthcare community at large. This safety risk has been compounded by the rise in mental illness and substance abuse and the need to care for many of these vulnerable individuals in nonpsychiatric settings. To explore this topic further, an analysis of self-harm events in the nonpsychiatric setting was conducted using the Pennsylvania Patient Safety Reporting System (PA-PSRS) database.

Methods

Pennsylvania Patient Safety Authority analysts queried the PA-PSRS database for event reports submitted from July 1, 2015, through June 30, 2018, using the taxonomy's event type "Patient Self-Harm." This time period represents the first three complete academic years (i.e., July through June) since patient self-harm was added as a discrete PA-PSRS event type in April 2015. Reports from psychiatric facilities, psychiatric units, chemical dependency units, and outpatient psychiatric clinics were excluded due to differences in staff training, expertise, and the care environment.

Analysts manually reviewed 890 report narratives and applied the following exclusion criteria:

- Insufficient detail to suggest that the act was intentional (e.g., delirious patient pulled out catheter), n = 117
- Incidental harm to self (e.g., patient walked into a table), n = 103
- Not a direct act of damage to one's body (e.g., elopement, discharge against medical advice), n = 40
- Insufficient detail in report to analyze event, n = 4
- Violent threat or act toward others, n = 1
- Description of an event occurring in a psychiatric care area, n = 1

The remaining reports were analyzed by harm score, facility type, patient age, and patient gender. Reports submitted by hospitals were further analyzed to determine the care area and whether the event occurred off the unit or outside of the facility (i.e., after discharge, during elopements, or between outpatient encounters).

Analysts categorized each report using four self-harm categories, as described in Table 1.
Table 1. Self-Harm Categories

<table>
<thead>
<tr>
<th>SELF-HARM CATEGORY</th>
<th>DESCRIPTION</th>
<th>EXAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Means</td>
<td>Possession of an item that could be used for a self-harm act, but was identified before use</td>
<td>Razor discovered and confiscated</td>
</tr>
<tr>
<td>Threat</td>
<td>Verbal statement or gesture expressing a desire to engage in a self-harm act</td>
<td>&quot;I'm going to kill myself&quot;</td>
</tr>
<tr>
<td>Attempt</td>
<td>An effort to initiate a self-harm act that was stopped by staff or patients themselves</td>
<td>Patient attempted to ingest battery and was stopped before it was swallowed</td>
</tr>
<tr>
<td>Act</td>
<td>Initiation of a self-harm behavior that may be partially or completely executed, and may or may not require medical attention</td>
<td>Patient cut wrist with razor; patient found with phone cord wrapped around neck</td>
</tr>
</tbody>
</table>

Reports in the self-harm "act" category were further characterized by mechanisms of injury, as described in Table 2. A single report could involve multiple mechanisms of injury.

Table 2. Self-Harm Act Mechanism of Injury

<table>
<thead>
<tr>
<th>MECHANISM OF INJURY</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Includes oral, nasal, injection (not via peripheral or central catheter). Includes intentional ingestion of illicit substances, regardless of ability to determine intended outcome based on the report.</td>
</tr>
<tr>
<td>Laceration, puncture, scratch</td>
<td>Includes cutting and stabbing.</td>
</tr>
<tr>
<td>Blunt injury</td>
<td>Impact or collision with a surface, object, or part of one's body.</td>
</tr>
</tbody>
</table>
| Strangulation—divided into three subtypes: | Applied the definition provided by Sauvageau and Boghossian:* "Asphyxia by closure of the blood vessels and/or air passages of the neck as a result of external pressure on the neck."
| Ligature strangulation | "Pressure on the neck is applied by a constricting band tightened by a force other than the body weight." |
| Manual strangulation | "External pressure on the structures of the neck by hands, forearms, or other limbs." |
| Hanging             | "Pressure on the neck is applied by a constricting band tightened by the gravitational weight of the body or part of the body." Includes partial or complete suspension. |
| Intravenous (IV) or medical device tampering | Includes injection into peripheral and central lines and manipulation of devices such as IV pumps. Includes intentional ingestion of illicit substances, regardless of ability to determine intended outcome based on the report. |
| Insertion of foreign object | Includes non-oral orifices, such as rectum or urethra. |
Other Mechanism of injury that falls outside of the categories above, such as anorexia, bulimia, drowning, wound interference, biting.

Unable to determine Insufficient detail in report to further categorize self-harm act mechanism of injury.


Analysts conducted a review of the literature to collate relevant background and risk reduction strategies related to self-harm in nonpsychiatric settings.

**Results**

The query identified 890 reports, of which 266 were excluded, leaving 624 reports for further analysis.

**Harm Score**

More than 80% of reports were submitted as Incidents (80.9%; n = 505 of 624; Figure 1). The most frequent harm score was D, an event that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm (49.2%; n = 307). Of the 119 Serious Events, events that contributed to or resulted in temporary harm and required treatment or intervention were most common (i.e., harm score E). Ten (1.6%) of the reported events resulted in death.

**Figure 1. Reports of Self-Harm by Harm Score (N = 624)**

<table>
<thead>
<tr>
<th>Harm Score</th>
<th>Number of Reports</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (Incident)</td>
<td>24 (3.8%)</td>
<td>24 (3.8%)</td>
</tr>
<tr>
<td>B1</td>
<td>7 (1.1%)</td>
<td>7 (1.1%)</td>
</tr>
<tr>
<td>B2</td>
<td>24 (3.8%)</td>
<td>24 (3.8%)</td>
</tr>
<tr>
<td>C</td>
<td>143 (22.9%)</td>
<td>143 (22.9%)</td>
</tr>
<tr>
<td>D</td>
<td>307 (49.2%)</td>
<td>307 (49.2%)</td>
</tr>
<tr>
<td>E</td>
<td>90 (14.4%)</td>
<td>90 (14.4%)</td>
</tr>
<tr>
<td>F</td>
<td>17 (2.7%)</td>
<td>17 (2.7%)</td>
</tr>
<tr>
<td>G</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>H</td>
<td>2 (0.3%)</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>I</td>
<td>10 (1.6%)</td>
<td>10 (1.6%)</td>
</tr>
</tbody>
</table>

**Note:** Reported through the Pennsylvania Patient Safety Reporting System, July 1, 2015, through June 30, 2018.

**Facility Type and Care Area**
Hospitals submitted more than 99% of the reports (99.5%; n = 621 of 624). Within hospitals, the highest number of reports occurred in the emergency department (37.5%; n = 233 of 621), followed closely by medical-surgical units (34.0%; n = 211; Figure 2). Twenty reports described events occurring outside of the hospital, such as after discharge, during elopements, or between outpatient encounters. These reports were submitted under several different care areas including emergency department and other, and accounted for 4 of the 10 reports that resulted in death (i.e., harm score I).

Figure 2. Reports of Self-Harm in Hospitals by Care Area (N = 621)

**NUMBER OF REPORTS**

<table>
<thead>
<tr>
<th>CARE AREA</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency department</td>
<td>233 (37.5%)</td>
</tr>
<tr>
<td>Medical-surgical</td>
<td>211 (34.0%)</td>
</tr>
<tr>
<td>Critical care &amp;</td>
<td>53 (8.5%)</td>
</tr>
<tr>
<td>Intermediate care</td>
<td></td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>37 (6.0%)</td>
</tr>
<tr>
<td>Unit/services</td>
<td></td>
</tr>
<tr>
<td>Extended care</td>
<td>20 (3.2%)</td>
</tr>
<tr>
<td>Outpatient clinics</td>
<td>14 (2.3%)</td>
</tr>
<tr>
<td>Other*</td>
<td>53 (8.5%)</td>
</tr>
</tbody>
</table>

**Note:** Reported through the Pennsylvania Patient Safety Reporting System, July 1, 2015, through June 30, 2018.

* Other care area includes surgical services, ancillary departments, imaging, diagnostic laboratories, physical plant, obstetrics, and events reported as care area "Other."

**Gender and Age Cohort**

Figure 3 shows the distribution of reports by age cohort and gender. The age cohort 25 to 34 years had the highest number of reports for both males and females (27.4%; n = 171 of 624). The overall number of reports was nearly evenly split between males and females (49.4% and 50.6%, respectively).
Self-Harm Category

The distribution of reports by the 4 self-harm categories assigned by analysts, described in Table 1, is as follows: 3.4% means (n = 21 of 624), 5.4% threat (n = 34), 2.7% attempt (n = 17) and 88.5% act (n = 552).

Figure 4 displays the mechanism of injury for the 552 reports involving self-harm acts.
More than 40% of the self-harm acts involved ingestion (41.8%, \( n = 231 \) of 552); examples of specific substances include illicit drugs, hand sanitizer, and batteries (e.g., from hearing aids, telemetry monitors). Ingestion of illicit drugs accounted for 4 of the 10 reports that resulted in death; injection of unknown substances into IV devices, categorized as "IV or medical device tampering," accounted for an additional 2 reports resulting in death.

Laceration, punctures, and scratches occurred in 22.1% of the self-harm acts (\( n = 122 \)); examples of specific instruments used include plasticware, razor blades, and caps (e.g., toothpaste, marker, lotion).

Blunt injury, such as head banging, hitting self, and punching walls, occurred in 19.7% of the self-harm acts (\( n = 109 \)).

Strangulation occurred in 11.6% of self-harm acts (\( n = 64 \)). Examples of materials used for the most common strangulation type, ligature, include linens (e.g., sheets, blankets, pillow cases), cords (e.g., telemetry, call light, phone), and patient garments (e.g., belt, pants, paper scrubs). Four out of seven strangulations by hanging involved patient garments, and the most common ligature point was a door, including frames and hardware.

Themes from Event Narratives

Patient Monitoring
Event reports described supervision of patients at high risk of self-harm by both hospital personnel, such as sitters, and external personnel, such as correctional officers. Reports demonstrate mixed effects of supervision, including prevention, early interception, and delayed detection.

An example of an event report demonstrating how supervision prevented a self-harm act is as follows:

1:1 sitter observed the patient trying to wrap the monitor cord around her neck. Patient was stopped.

Maintaining a line of sight on patients, even while in the bathroom, is an important safety intervention. The following is an example of an event report describing deviation from this practice:

When 1:1 sitter checked on the patient in the bathroom, the patient was found to be cutting himself with a toothpaste cap.

Event reports also describe detection of self-harm acts by remote monitoring; examples are as follows:

Security officer saw patient on camera with gown tied around neck.

Telemetry alarming for high heart rate. Found patient with phone cord tied around his neck.

**Visitors**

Event reports describe several roles played by visitors including as reporters, inhibitors, and enablers of self-harm means, attempts, and acts.

An example of an event report in which a visitor prevented an act of self-harm is as follows:

The patient attempted to cut herself with a soda can tab but husband stopped her.

An example of an event report in which a visitor enabled self-harm means is as follows:

Patient ingested unknown item. Oxycodone pills were found in bag brought in by the patient's friends.

**Threats Inside and Outside of the Patient Room**

Event reports describe a variety of facility locations, both inside and outside of the patient room, where self-harm attempts and acts occurred.

An example of an event occurring in a classic patient room location—the bathroom—is as follows:

Patient cut right arm with a plastic knife from her food tray while in the bathroom.

An example demonstrating the need to evaluate self-harm risks outside of patient rooms—such as hallways and workstations—is as follows:

Patient swallowed a push pin she obtained while walking in the hallway with staff.

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

**Limitations**

Despite mandatory reporting laws, PA-PSRS data are subject to the limitations of self-reporting, including the complexities of selecting the appropriate harm score and care area. Analyst ability to categorize reports as self-harm means, threats, attempts, and acts was limited to the information provided in the event narratives. Although this analysis made every attempt to exclude unintentional harm to self, the inability to differentiate reports by suicidal and nonsuicidal intent is an acknowledged limitation. Illicit drug use, regardless of outcome (e.g., high, overdose), was...
included in this self-harm data set because of the intentional nature of engaging in this self-destructive behavior. This analysis does not include reports of suicide attempts that did not result in an injury requiring additional healthcare services, which are submitted through PA-PSRS as Infrastructure Failures.7

Risk Reduction Strategies

The following risk reduction strategies come from event report recommendations and from the literature.

• Assess nonpsychiatric staff members' comfort, knowledge, and competence caring for patients at risk of self-harm. Based on each role's scope of practice, education may focus on dialoguing with patients about self-harm behaviors, identifying environmental hazards, using de-escalation techniques, or implementing appropriate risk reduction strategies.8,9

• A typical emergency department bay or medical-surgical room, unless designed specifically to accommodate a patient at risk of self-harm, may be an unsafe environment. Use a checklist to inspect rooms of at-risk patients to identify and remediate environmental hazards, such as unsecured supplies and long tubing or cords. Conduct inspections prior to admission and on regular intervals throughout the patient's stay (e.g., every shift).10

• Establish screening and assessment guidelines that support early identification of patients at risk for self-harm.8,11 Consider implementing universal screening, followed by assessment if screening is positive, at all points of entry, including the emergency department.12

• Conduct a proactive ligature risk assessment. The Authority has numerous resources on this topic and is available to conduct proactive ligature risk assessment training for Pennsylvania facilities. For more information and a list of resources see Patient Safety Topics: Behavioral Health (http://patientsafety.pa.gov/ADVISORIES/Pages/201903_SelfHarm.aspx).

• Incorporate attention to ligature points and hazardous materials in the design of patient rooms—when possible, eliminate unnecessary risks. For a short video tour demonstrating examples of specific design elements, see Up Front: Facility and Fixture Design Help Protect Suicidal Patients (https://www.betsylehmancentermerga.gov/news/safety-news-better-designed-rooms-protect-suicidal-patients).

• Provide training for observers of high-risk patients. Encourage therapeutic interactions that go beyond just observing, such as having conversation or doing an activity with the patient. See the International Association for Healthcare Security and Safety's (IAHSS) resource, Guidance for Training for Observers of High-Risk Patients (https://iahssf.org/assets/IAHSS-Foundation-Patient-Observer-Training-1.pdf), which addresses training needs of both direct and remote patient observers.

• Ensure facility protocols address particularly sensitive safety issues such as the role of external patient monitors (e.g., police officer, correctional officer), restrictions and terms of visitation, and searching and securement of patient belongings.11

• Review the Joint Commission's National Patient Safety Goal 15.01.01 (https://www.jointcommission.org/assets/1/18/R3_18_Suicide_prevention_HAP_BHC_12_7_18_Rev_FINAL.pdf) for suicide prevention, effective July 1, 2019, for psychiatric hospitals, psychiatric units, and patients with a primary psychiatric condition in general hospitals, to identify evidence-based best practices that could be applied in nonpsychiatric settings that may care for patients with psychiatric comorbidities.
Conclusion

The prevention, detection, and response to patient self-harm are serious safety concerns in nonpsychiatric settings. This analysis demonstrates vulnerabilities—in the environment of care, workflow, procedures, and staff training—that may be overlooked or unanticipated. The intent of this analysis was to share the lessons learned by healthcare facilities in Pennsylvania to raise awareness and encourage a proactive approach to risk assessment.

Notes


Drug Shortages: Shortchanging Quality and Safe Patient Care

Abstract

Drug shortages are a public health crisis that has persisted for many years in the U.S. health system. The daily struggle of shortage management by healthcare providers has led to negative downstream effects on patients, including instances of unsafe or compromised practice and potentially harmful medication errors. A total of 448 medication error event reports associated with drug shortages were submitted to the Pennsylvania Patient Safety Authority from July 2004 through June 2018. Nearly three-quarters (71.0%; n = 318) of events reached the patient. Drug shortage reports involved 173 individual drugs, representing 57 different drug classes, with the most commonly reported drugs being analgesics, followed by antibiotics, electrolytes, and antidotes (e.g., reversal and rescue agents). The total number of reports was distributed evenly among the prescribing, dispensing, and administering nodes of the medication use system. High levels of frustration and tension among providers facing shortages that lack clearly defined or communicated management strategies are apparent from the reports. Organizations may use the data in this article and the revised Drug Shortage Assessment Checklist to inform proactive efforts, standardize protocols in drug shortage situations, prevent similar errors from occurring, and strengthen our national culture of safety.

Introduction

Drug shortages, declared an "urgent public health crisis" by the American Medical Association (AMA) in 2018, have challenged the provision of optimal patient care and appropriate drug therapy for more than two decades.\(^1\) Between 2011 and 2013, U.S. hospitals were forced to expend an estimated annual average of $229.7 million on unusually costly generic products and alternative therapies.\(^2\) Surveys of healthcare providers conducted by the Institute for Safe
Medication Practices (ISMP) from 2001 to 2017 indicate that shortages are long-standing and lingering issues in the national and global landscape of healthcare. Shortages are caused by a multitude of factors, and circumstances can rapidly deteriorate under the acute stress of isolated natural disasters and changes in the economy.

In 2017, the U.S. Food and Drug Administration (FDA) recognized 39 new drug shortages, with additional challenges ascribed to destroyed drug manufacturing facilities in Puerto Rico during a devastating hurricane season. But the status of U.S. drug shortages has been only exacerbated, and not caused, by these recent natural disasters. The need for comprehensive solutions to this ongoing crisis was emphasized by AMA Board Member William E. Kobler, MD, who stated, "The fact that drug shortages worsened when major hurricanes struck drug production facilities on Puerto Rico highlights the need to evaluate and plan for hazards that pose a threat to critical infrastructure for manufacturing pharmaceutical and medical products."

The availability of a drug product can be affected by any combination of factors throughout the supply chain, which involves many stakeholders. Members of the supply chain include raw material producers, manufacturers, regulators, wholesalers, vendors, purchasers (e.g., healthcare organizations), and, finally, healthcare providers. Some factors contributing to shortages include the complex nuances of the drug product market, manufacturing and quality issues, manufacturer business decisions, production delays, restricted distribution, and inventory practices.

Shortages impact the prescribing, dispensing, and administering nodes of the medication use system within healthcare facilities and destabilize systems built for medication safety. The daily struggle by healthcare providers to manage shortages has led to negative downstream effects on patients, including instances of unsafe or compromised practice and potentially harmful medication errors. ISMP surveys have revealed many frustrations and unsafe conditions faced by physicians, nurses, and pharmacists. Respondents also reported many examples of medication errors due to shortage situations, including peripheral nerve blocking agents (e.g., bupivacaine with EPINEPHrine 1:200,000) compounded at the wrong concentration.

Data from the Pennsylvania Patient Safety Reporting System (PA-PSRS) are used to inform changes in clinical practice with the intent of reducing the risk and severity of future patient safety events. Pennsylvania Patient Safety Authority analysts reviewed medication errors associated with drug shortages submitted through PA-PSRS from July 2004 through June 2018 and in this report identify the reasons these events took place, discuss the use of best practices, and provide system-based risk reduction strategies and recommendations.

**Methods**

Safety analysts queried the PA-PSRS database for medication errors and adverse drug reaction reports containing terms such as "shortage," "back order," and "out of stock" that occurred from the beginning of data collection in July 2004 through June 2018. The query yielded 915 reports. After reading the reports, analysts excluded 467 reports that did not concern potential or actual medication errors associated with shortages (e.g., wasting of narcotics, failure to "read back" orders). A total of 448 reports were include in the final analysis.

Reporting facilities provided the medication names, patient care area, event type (e.g., dose omission), event description, and PA-PSRS harm score, (adapted from the National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] harm index). If the medication name field was left blank, an analyst adjusted the field when the medication name was provided within the free text of the event description field. In addition, reported details and summary case narratives were reviewed for common themes and contributing factors associated with the events reported and categorized by analysts into one of three nodes of the medication-use process—prescribing, dispensing, and administering.
Results

When stratified by PA-PSRS harm score, the majority (71.0%; n = 318 of 448) of drug shortage events reached the patient (harm score category, C to I; Figure 1).

The reported event did not reach the patient (harm score category, A, B1, or B2) in 29.0% (n = 130 of 448) of the submitted cases. These events are commonly referred to as good catches, because the hazard or event was intercepted by a healthcare provider before reaching the patient.

The following are examples of good catch reports related to drug shortages submitted through PA-PSRS:

- **Shortage in corticosteroids per pharmacy, staff received [methylPREDNISolone] 125 mg vials for the patient's 80 mg ordered dose instead of 40 mg vials. Patient received correct dose, no harm.**

- **Etomidate 20 mg was ordered, [automated dispensing cabinet (ADC)] listed 40 mg/10 mL as stock, but bin stocked with 20 mg ampules. Etomidate has been on national shortage / backorder. Supply has been sporadic, the incorrect size was placed in [ADC] so that floor would not be without medication. [ADC] has since been changed to match the size currently available.**

- **Patient was ordered D50 [dextrose 50%]. When accessing [ADC], D50 was listed as out of stock. Another staff member reported that she used the last one two days ago. Dose was obtained from ICU [intensive care unit] (instead of accessing the crash cart). [Leadership] indicated there was a nationwide shortage of D50; ER was unaware.**

Nearly all reports (96.9%; n = 434 of 448) were submitted as medication errors, with a much smaller percentage (3.1%; n = 14 of 448) categorized as adverse drug reactions. The top event types selected by PA-PSRS reporters are listed in the Table, with the most frequently selected event types including "Medication error—other," "Medication error—dose omission," and "Medication error—prescription/refill delayed."

<table>
<thead>
<tr>
<th>EVENT TYPE</th>
<th>NO. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication error—other</td>
<td>120 (26.8)</td>
</tr>
</tbody>
</table>

Note: Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018.
The number of reports submitted per year can be seen in Figure 2. The least number of reports in a calendar year (1.8%; n = 8 of 448) was submitted in 2006. The year with the greatest number of submitted reports was 2012 (16.5%; n = 74), with the most frequently cited medication shortage in 2012 involving the opioid analgesic naldixipine (25.7%; n = 19 of 74). In 2017, the most commonly reported medication shortage involved morphine (13.4%; n = 9 of 67).

Figure 2. Medication-Related Events Due to Drug Shortages, by Quarter (N = 448)

A total of 173 unique drugs were reported to the Authority, which analysts subcategorized into 57 drug classes (Figure 3). The most commonly cited drug classes included analgesics, antibiotics, electrolyte supplements (e.g., potassium chloride, calcium chloride), and antidotes (e.g., reversal agents, rescue agents, rapid sequence intubation [RSI] medications).
Medications that pose an increased risk of patient harm when involved in medication errors, also known as high-alert medications, were involved in nearly one-half (46.2%; n = 207 of 448) of reports. The most common high-alert drug classes included opioid analgesics, injectable benzodiazepines, and parenteral electrolyte supplements (e.g., potassium chloride, sodium bicarbonate).

Analysts categorized each report into one of three nodes of the medication use system—prescribing, dispensing, or administering—then further categorized each report into node-specific event subtypes (Figure 4).

**Figure 3. Top 10 Drug Classes Involved in Medication-Related Events Due to Drug Shortages (N = 448)**

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>NUMBER OF REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics*</td>
<td>81 (18.1%)</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>55 (12.3%)</td>
</tr>
<tr>
<td>Electrolyte supplements*</td>
<td>39 (8.7%)</td>
</tr>
<tr>
<td>Antidotes*</td>
<td>27 (6.0%)</td>
</tr>
<tr>
<td>Benzodiazepines*</td>
<td>19 (4.2%)</td>
</tr>
<tr>
<td>Hormones</td>
<td>15 (3.3%)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>14 (3.1%)</td>
</tr>
<tr>
<td>Anticoagulants*</td>
<td>11 (2.5%)</td>
</tr>
<tr>
<td>Total parenteral nutrition*</td>
<td>11 (2.5%)</td>
</tr>
<tr>
<td>Intravenous/irrigation fluids</td>
<td>10 (2.2%)</td>
</tr>
<tr>
<td>Vasopressors*</td>
<td>10 (2.2%)</td>
</tr>
</tbody>
</table>

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018. Percentages in the table are based on N = 448. The number of events (n = 292 of 448) represented in the table correspond to the top 10 medication classes involved in drug shortage–related medication errors.

* Drug classes that may include high-alert medications.
Prescribing

There were 126 reports describing events that occurred during the prescribing node. The most common (44.4%; n = 56 of 126) event subtype related to the prescribing node was wrong drug or product selection. Delays in care may occur when a prescriber orders a drug that is unavailable because of a shortage and follow-up is required by the pharmacist or nurse to contact the prescriber and determine a suitable alternative. In addition, there are times when a prescriber attempts to order an appropriate alternative drug, but that alternative has not been entered into the electronic health record’s (EHR) drug library, leading to a delay in therapy. Following are examples of actual or potential therapy delays reported through PA-PSRS:

**MD [medical doctor] ordered Bactrim™ [sulfamethoxazole and trimethoprim] 160 mg IV. Paged attending. IV form on national backorder. Attending verified resident meant to order PO [by mouth]. Resident changed order to PO form.**

Patient had previously exhibited an acute oculogyric crisis after receiving Haldol™ [haloperidol]. This was an acute crisis that could have been life threatening. The Physician provided a verbal order to the charge RN [registered nurse] forCogentin® [benztropine mesylate] 2 mg IM STAT. RN contacted the pharmacy and was informed that the medication was on back order and was not available and recommended IM [intramuscular] Benadryl™ [diphenhydramine]. Physician attempted to order the medication through CPOE [computerized physician order entry] and Benadryl 50 mg IM PRN [as needed] was not an available option—so the physician wrote the order as a written order on the chart. IM Benadryl was not available in the [ADC]; however, one dose was located in [an ADC on another unit]. There was a delay in providing emergent care that was needed for the patient.

Other event subtypes in the prescribing node included errors occurring during therapeutic substitution (23.0%; n = 29 of 126), limitations on prescribed quantity or duration (15.1%; n = 19), wrong dose or concentration (13.5%; n = 17), and errors due to inaccurate order sets that were not updated with the alternative drug (4.0%; n = 5).

Following are examples of errors that occurred during therapeutic substitution:
Chemo [chemotherapy] orders for patient written by MD, for [methotrexate], including pre and post hydration orders. Physician did not recognize that orders contained Sodium bicarbonate. This medication is on critical shortage and is being omitted from [methotrexate] bag; hydration is being replaced with sodium acetate. Physician did not closely look at orders before signing them.

Order for Niferex™ [iron polysaccharide] 220 mg TID [three times daily] written (660 mg Elemental Iron). Physician was thinking of Ferrous Sulfate Elixir 220 mg po TID (132 mg of Elemental Iron), liquid Niferex on backorder so pharmacist substituted Ferrous Sulfate Elixir.

Prescribers may also be unaware that the pharmacy department has set limitations on ordering drugs on shortage, such as limiting duration or quantity dispensed or requiring some form of approval by the prescriber before the medication can leave the pharmacy. Following are examples of events where the pharmacy placed restrictions on ordering drugs on shortage:

Order for bicarb [sodium bicarbonate] drip was rejected by overnight pharmacy staff citing reasons of "does not meet approval criteria." Drug had been on shortage (requiring approval), but has resolved recently since supply on-hand.

IV Fluid of D5/0.45% [dextrose 5% in 0.45% normal saline] w/ KCl [potassium chloride] 20 mEq/L entered by RN as per protocol. Potassium level was 4.6. When I called RN to clarify if this IVF with K [intravenous fluid with potassium] was correct she said she was just re-ordering previous day's IVF because it had been discontinued. (IVF was d/c'd [discontinued] d/t [due to] 24 hr Duration as per IV shortage policy.)

Dispensing

There were 173 reports submitted describing events that occurred during the dispensing node. The most common event subtype related to dispensing was administration delay due to pharmacy's prior removal of a floor stock item from the ADC, medication cart, or drug box (35.8%; n = 62 of 173). Nearly one-half (43.5%; n = 27 of 62) of reports in this event subtype involved delayed procurement of antidotes or rescue agents, including those used in code situations. Following are example reports in which treatment with a rescue agent was delayed due to changes in dispensing:

Patient's blood glucose registered 18 [mg/dL] on glucometer. RN repeated test additional times to confirm blood glucose. Tried to get Dextrose 50% from [ADC], but none available. No Dextrose available in crash cart. Pharmacy sent 2 syringes. But medication currently restricted due to [manufacture] backorder.

DOPamine infusion [was empty]. Went to [ADC] to get med. Out of Stock. Called Pharmacy for DOPamine stat. Since med not immediately available in [ADC], DOPamine pulled from crash cart. Med arrived from Pharmacy [10 minutes later]. Pt experienced drop in [blood pressure] before rebounding when med resumed.

Other event subtypes in the dispensing node included significant delay in dispensing therapy due to pharmacy compounding workflow changes (30.1%; n = 52 of 173), wrong product dispensed or product mislabeled (21.4%; n = 37), incorrect or change in products stocked in ADC pocket (6.9%; n = 12), and intentional or unintentional stocking of expired product (5.8%; n = 10).

Additional examples of events that occurred within the dispensing node include the following:

The patient was ordered Valium® [diazePAM], and there was a delay in pharmacy filling the medication [the ADC] with valium for [almost an hour]. The nurse spoke to pharmacy about the delay. It was discovered that the delay is due to a national shortage of diazePAM that requires additional compounding in the pharmacy.

Patient with frequent episodes of bradycardia. Order received to keep external defibrillator and atropine at bedside. Pharmacy notified of need for Atropine. Dose provided noted to have expired. When Pharmacist notified, informed nurse that all they had was expired [because] medication is on back order.
Due to an ongoing nationwide drug shortage, the pharmacy has not been able to obtain the single dose vials or ampules of nalbuphine 10 mg/mL that we usually use and would prefer to use. Intermittently, larger 10 mL vials of nalbuphine became available. The pharmacy has been drawing from the 10 mL vial into smaller vials (1 mL doses) with limited dating. When the 10 mL vial first became available it was a concentration of 20 mg/mL, so it was necessary to dilute with normal saline to the 10 mg/mL we wanted. [At month's end] the clerk was able to get another box of 10 mL vials. The clerk did not remember that it was 20 mg/mL before and didn't specifically mention to anyone that the new one was 10 mg/mL. The pharmacists and techs continued to use the old formula with dilution, so it is likely that [over the next couple of weeks] vials labeled 10 mg/1 mL were only 5 mg/1 mL.

Administering

There were 149 error reports submitted describing events that occurred during the administration node. Actions during this node are typically performed by nurses and involve procuring the medication or administering it to the patient. The most common (36.2%; n = 54 of 149) event subtype was wrong dose administered due to unfamiliarity with concentration changes in pharmacy-specific compounded products or products from different manufacturers. The following are examples of wrong dose errors reported during administration:

- **Norepinephrine 4 mg/250 mL premix in MAR [medication administration record].** Norepinephrine 8 mg/250 mL infusing. Found with bag change. During report double-concentrated because of shortage.

- **Nurse did not look at the concentration of the med and patient received a total of 6 mg of HYDROMorphine instead of 3 mg as ordered.** Contributing factors: HYDROMorphine shortage results in different concentrations being placed in [ADC]. Warning in [ADC] was not read carefully by nurse [because] dose ordered was 0.5 mg and our usual concentration has been 1 mg vials.

- **MD ordered Lasix™ [furosemide] 40 mg IV for an ED [emergency department] patient.** RN prepared medication from dispensing system from 40 mg selection. RN thought they were 20 mg vials due to prior shortage of 40 mg vials. RN [administered] 2 vials that were 40 mg. Patient without any issues or side effects.

Other event subtypes included skipped or missed doses while waiting for future drug shipments to arrive (31.5%; n = 47 of 149), improvised and unsafe compounding practices (14.1%; n = 21), administration of the wrong drug (10.7%; n = 16), and administration of incomplete therapy (7.4%; n = 11).

Additional examples of errors during the administration node include the following:

- **Pharmacist called unit to report that patient had an RN [on a previous day] who documented liquid multivitamin given.** Pharmacist stated that this medication was falsely documented given because the medication has not been available in the hospital for weeks due to being on backorder.

- **Pt. had D5 NSS [dextrose 5% in normal saline solution] maintenance fluids running instead of D5 LR [dextrose 5% in lactated Ringer solution] infusing.** Noted at change of shift during report. Nightshift RN stated physician wanted D5NSS ordered, however due to hospital shortage of this fluid did not order. However, D5NSS was hung and infusing when order in computer has D5LR. Maintenance fluid bag of D5NSS was not scanned. Dayshift RN upon assuming care of pt. scanned and hung D5LR per order.

- **IVIG [intravenous immune globulin] therapy with recommendation for IVIG 50 grams IV.** Pharmacy was able to provide only 35 grams due to national shortage. Physician was notified.

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

Discussion
Nearly three-quarters of reports concerning drug shortages involved events that reached the patient. Three nodes of the medication use system (i.e., prescribing, dispensing, administering) are equally affected by drug shortages, with the number of submitted error reports similar among all three.

From July 2004 through June 2018, the number of reports submitted through PA-PSRS involving drug shortages has increased, with 2012 including the greatest number. FDA, in a 2012 report, referred to that period as the "height of the shortage crisis," because shortages tracked by the agency quadrupled from 61 in 2005 to more than 250 by 2011. Actions taken by FDA and other stakeholders in the years since 2012 have led to a reduction in the number of new tracked shortages each year, with 26 announced in 2016. Unfortunately, the number of new shortages increased again in 2017 after a devastating hurricane season and because, at the same time, a major manufacturer closed certain operations for remediation and upgrade. The overall trend indicates that the crisis has continued despite fluctuations from year to year, including a recent increase in number of active shortages.

The list of medications involved in drug shortage reports submitted to the Authority is lengthy and diverse. Analgesics were most commonly involved in drug shortage–related errors, along with antibiotics, electrolyte replacements, and antidotes (e.g., reversal agents, rescue agents, RSI medications). Several reports showed nurses struggling to procure dextrose 50% to treat patients with severe hypoglycemia. It is unclear from the reporting details whether any of these patients were currently on insulin therapy. One report described a patient with a severe dystonic reaction to an antipsychotic medication, for which access to appropriate anticholinergic therapy was delayed. Hospital providers routinely treat patients who have acute, urgent conditions such as these for which therapy cannot be delayed, often scrambling for limited or risky options.

Other product shortages affected patient care in more subtle ways. The high number of reports of vitamin shortages mainly affected appropriate and safe therapy with parenteral nutrition (PN) admixtures. Pharmacists were often forced to omit vitamin and electrolyte replacements from PN compounds for both adult and pediatric patients. In 2013, ISMP survey data also found that shortages of PN components caused a wide range of patient harm, including deficiencies in serum electrolytes, increased risk of precipitate when substituting calcium chloride for calcium gluconate, and increased burden of cost from imported PN components.

There is increased risk of errors when a prescriber must change his or her practice to include use of less-familiar alternative medications, especially those that may be less efficacious, have less desirable adverse effect profiles, or require unusual or more involved (e.g., more frequent administration) dosing regimens. Selection of alternative therapies is time consuming and often results in delayed therapy.

In addition, therapeutic substitutions may be written into institutional policies and involve auto-conversion of a shortage drug to a predefined alternative. In some situations, the substitution may be done automatically by the EHR software. However, in other situations, the substitution requires order discontinuation and re-entry by another provider, typically the pharmacist. Human error can easily be introduced at this step. Another potential risk is that providers may be unaware of, or disagree with, automatic therapeutic substitutions currently approved at their facility.

Risk of medication errors increases when a pharmacy must alter standard dispensing practices and change the standard, protocol-based ways a medication is prepared, labeled, distributed, and stored. Shortages of both small- and large-volume parenteral base solutions have forced pharmacies to prepare drugs in nonstandard concentrations, leading to downstream issues with administration of many medications. To conserve use of small-volume parenteral products, many pharmacies have dispensed IV antibiotics in IV push form, so the high number of reports detailing errors with antibiotics was expected. Other errors were due to fluid shortages involving delivery of chemotherapy agents, a class of high alert medications, and investigational drugs.
In shortage situations, pharmacies may alter medication storage practices by stocking alternative products in ADCs or by completely removing items from ADCs that nurses are accustomed to easily locating. Changes in ADC stocking, especially in short-term situations without prior notice, can stress nurses. Frequent alterations in the concentration or formulation of products may cause additional confusion as providers and nurses try to keep track of the modifications.

For example, a nurse may become accustomed to the use of furosemide 20 mg vials in place of furosemide 40 mg vials after a prolonged shortage of the latter. When the furosemide 40 mg vials become available again and are stocked in the ADC, the nurse may not notice the change in concentration, as observed in the error example included above.

In response to shortages, hospitals have relied more heavily on 503A and 503B compounders to supply prefilled syringes. Unfortunately, these compounders may deviate from USP <7> labeling standards, with little FDA labeling oversight. As a result, nurses, as well as pharmacists and prescribers, contend with confusing dose expressions and look-alike labeling on prefilled syringes, which have resulted in wrong drug errors and 10-fold opioid overdoses.

A common theme across ISMP surveys on drug shortages has been increased interdisciplinary tension and frustration among pharmacy staff and other providers. As one respondent commented in 2001: "There [are] always hard feelings between pharmacy and physicians when they must change their practices because we can't get a drug. Nurses feel caught in the middle and are upset about using alternative drugs with which they are unfamiliar." Analysts identified similar sentiments in the PA-PSRS data. Reporting expressed misdirected frustration with colleagues, such as "demanding tone" used by providers requesting shortage medications from pharmacy. Pharmacy personnel, in turn, may have added stress from extrinsic factors that interfere with their responsiveness to the routine medication supply and demand in the hospital.

Limitations

Analysis by the Authority of events involving drug shortages is limited by the information submitted through PA-PSRS by reporting facilities. Error reporting programs in general are limited by the quantity and quality of reports, which are highly dependent on the complexity of the reporting system as well as the ability of each reporting facility to identify events and submit complete and accurate information. 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 or which factors contributed to the event.

Risk Reduction Strategies

Providers are acclimated to the clinical troubleshooting required to work around drug shortages, in part because these deficiencies have persisted for many years. It may be best for clinicians to stop accepting drug shortages as standard practice because they are, in fact, public health crises. Hospitals can do little to prevent drug shortages, which is why institutions should employ emergency-management methods and disaster-response tools to manage their occurrence. This includes robust medication error reporting during shortages to identify risks associated with drug shortages. A collaborative and structured approach is essential; ISMP survey data indicate that less tension among healthcare providers during shortages was more likely when establishments had a formal process in place for handling them.

Consider the strategies described below, which are based on a review of current literature, events submitted to the Authority, and observations from ISMP:
• Develop an ongoing strategy to prepare for drug shortages, standardize how shortages are approached, communicate to stakeholders updates on shortages (as well as changes in practice as a result of shortages), and monitor interventions that are implemented (i.e., choosing an alternative drug).

• Establish the infrastructure necessary to manage drug shortages. Depending upon the size and nature of the institution, this may include forming an interdisciplinary drug shortage team and resource allocation committee.

• Form a proactive process for approving alternative therapies in anticipation of potential drug shortages. This may include use of failure mode and effects analysis (FMEA) to identify changes necessary to implement the alternative and associated risks.

• Exercise caution when purchasing and employing imported items or products supplied by 503A and 503B compounders. Labelling practices may deviate from USP standards and introduce additional risk of misinterpretation by providers.

• Employ multiple communication methods to keep affected healthcare providers informed of the status of drug shortages in a timely manner. For example, communication through the EHR may be used to alert clinicians of a shortage situation at the point of prescribing and to suggest a therapeutic alternative.

• Outline steps necessary to address ethical considerations that may arise because of drug shortages.

• Remain transparent by disclosing relevant information regarding drug shortages to patients as well as current mitigation strategies being used to improve patient safety in these circumstances.

• Use data and information from event reporting systems, federal agencies, professional organizations, focus group meetings, discussions during hospital rounds, and other means to learn about hazardous conditions, good catches, and other events associated with drug shortages so that actions can be taken to proactively mitigate future risks.

A sample drug shortage checklist that is intended to identify options and risk reduction strategies that may be helpful when a facility anticipates or is faced with a drug shortage can be found here:

Conclusion

This analysis of reports submitted to the Authority found that errors and hazards related to drug shortages are nearly equally distributed among the prescribing, dispensing, and administering nodes of medication use. Over the span of the first 14 years of reporting medication errors to the Authority, reports concerning drug shortages submitted were sparse, indicating potential underreporting in this topic of concern. In an extensive list of medications reported, the most common medication shortages across the years have involved opioids, antibiotics, electrolytes, and antidotes (reversal and rescue agents). Nearly three-quarters of these events reached the patient.

Risk reduction strategies may include both an evaluation of how shortages affect each node and employment of emergency-management methods and disaster-response tools. Organizations can use this information, along with the revised Drug Shortage Assessment Checklist, to assess safety gaps in their current processes to minimize risk to patients and design systems to prevent similar errors from occurring in this ongoing public health crisis.
Notes


Exploring Vulnerability to Patient Safety Events along the Age Continuum

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Abstract

Exploring Vulnerability to Patient Safety Events along the Age Continuum

85 years of age or older
- Highest proportion of Serious Event types Fall and Skin Integrity
- Highest rate of admission per population (rate = 0.49)

65 through 74 years of age
- Highest number of annual admissions (n = 272,254)
- Highest number of total events (n = 45,737) and Serious Events (n = 1,276) reported
- Highest rate of Serious Events/1,000 admissions (rate = 4.68)

5 through 14 years of age
- Highest rate of total events reported/1,000 admissions (rate = 511.1)
- Highest proportion of event type Medication Error

0 through 4 years of age
- Highest proportion of Serious Event type Complication of Procedure/Treatment/Test
- Highest proportion of total event type Error related to Procedure/Treatment/Test

Notes: Data reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), January 1, 2017, through December 31, 2017.
To identify age-related patterns of events that could have or did result in unanticipated patient harm, the Pennsylvania Patient Safety Authority developed a data snapshot from more than 260,000 event reports submitted by Pennsylvania hospitals through the Pennsylvania Patient Safety Reporting System during 2017. For almost all age cohorts, the most common event type was Error related to Procedure/Treatment/Test while among Serious Event reports (i.e., event resulting in harm), the most common event type was Complication of Procedure/Treatment/Test. Differences in event report patterns for children, adolescents, and young adults compared with events involving adults and elderly patients were noted. For adults 75 years or older, the number of event reports decreased, while the rate of involvement in a patient safety event report relative to estimated population increased as patient age increased. For adults 25 years or older, the number of reports involving two event types—Fall and Skin Integrity—increased with advancing age. Although the increased rate of total event reports at the extremes of age relative to estimated population was unsurprising, the decreased rate of Serious Events in the very elderly, and the increased rate of total and Serious Events in the age cohort of 5 to 14 years relative to number of admissions were unanticipated. Attention to the event types and patterns of vulnerability that predominate in specific age cohorts may help facilities prioritize interventions.

Introduction

The rate of admissions by estimated population increases at the extremes of age, but the relationship of age to patient safety events bears exploration. For example, only a few reports may involve patients 85 years or older, but a greater proportion of these elderly patients may be involved in patient safety events.

To develop a data snapshot of the rates and types of hazards encountered by patients throughout the age continuum, analysts reviewed and categorized events submitted by Pennsylvania hospitals through the Pennsylvania Patient Safety Reporting System (PA-PSRS), and calculated event rates using statewide estimated population and admission data as denominators.

Methods

Analysts queried the PA-PSRS database for all events and event types from Pennsylvania hospitals that resulted or could have resulted in unanticipated harm submitted from January 1, 2017, through December 31, 2017. The Medical Care Availability and Reduction of Error (MCARE) Act of 2002 mandates that hospitals and certain other facilities report incidents and serious events, ranging from unsafe conditions to death, through PA-PSRS, which may be the most comprehensive state-based collection of patient safety events in the United States. The query identified 263,320 events of which 63 (0.02%) events were excluded for lack of an identified age. The remaining 263,257 events were categorized by event type and age cohort, using increments of 10 years (e.g., 5 to 14 years, 15 to 24 years) with the exception of age cohorts of 0 to 4 years and 85 years or older. The age cohorts were selected to correspond to the age ranges provided in state population and Pennsylvania Health Care Cost Containment Council (PHC4)* admission data. State population data for 2017 were estimated by extrapolation from 2010 through 2016 data using estimates provided through the U.S. Census Bureau. Admissions (equivalent to discharges from Pennsylvania hospitals) data for 2017 were obtained from PHC4.

Event types in PA-PSRS are as follows:

- Medication error
The rates of admissions to estimated population were calculated by dividing the number of admissions by the estimated population for each age cohort. These rates were compared with 2010 data reported by the Centers for Disease Control and Prevention (CDC).\(^5\)

Event report rates were calculated by dividing the number of event reports by Pennsylvania estimated population (i.e., number of events per 100,000 persons) and by the number of admissions (i.e., number of events per 1,000 admissions), respectively, for each age cohort. Rates were computed for both the total number of reports (Incidents and Serious Events combined) and the number of reports of Serious Events as defined in the MCARE Act.\(^1\)

Events by type were also analyzed in proportion to the total number of reports for both total events and Serious Events (i.e., the percentage of the total number of reports for each event type category per age cohort).

Relative risk (RR) was calculated by dividing each cohort's Serious Event rate by an index cohort's Serious Event rate, defined as the largest cohort by estimated population or number of admissions. The reference group for the RR calculation by estimated population was the 55- to 64-year cohort while the reference group for the RR calculation by number of admissions was the 65- to 74-year cohort.

* 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 regardless of ability to pay. PHC4 has provided data to this entity in an effort to further PHC4's mission of educating the public and containing health care costs in Pennsylvania.

PHC4, its agents, and staff, have made no representation, guarantee, or warranty, express or implied, that the data—financial, patient, payor, and physician-specific information—provided to this entity, are error-free, or that the use of the data will avoid differences of opinion or interpretation.

This analysis was not prepared by PHC4. This analysis was done by the Pennsylvania Patient Safety Authority. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.
Results

Admission to Estimated Population Rate

Figure 1 compares the number of admissions (actual) and population (estimated) in Pennsylvania for 2017 and shows the rate of admissions to estimated population by age cohort. Although the 55- to 64-year cohort was estimated to be the most populous (n = 1,819,252; 14.2% of the total estimated state population), the 65- to 74-year cohort had the largest number of admissions (n = 272,254) in 2017.

The rate of admissions by estimated population was 0.22 admissions per estimated population (22 admissions for every 100 persons) for the 0- to 4-year cohort; the rate dropped 10-fold (rate = 0.02) for the 5- to 14-year cohort. However, the rate of admissions per person after the 5- to 14-year cohort climbed steadily through subsequent cohorts, with the cohort age 85 years or older having the highest rate, at 0.49 per person (49 admissions for every 100 persons). These rates correspond to 2010 data reported by CDC. 

Event Rates by Age Cohort

Figure 2 shows the number and rate of total events and Serious Events by estimated population and number of admissions per age cohort. Analysis of the 263,257 event reports submitted during 2017 identified that the 65- to 74-year cohort had the largest number of total events (n = 45,737) as well as the largest number of Serious Events (n = 1,276).
Analysis of events by estimated population shows patients 0 to 4 years of age had a higher rate of overall events than other cohorts, up to the 65- to 74-year cohort; the lowest rate was for the 5- to 14-year cohort (892.25 events per 100,000 persons), then rose with each subsequent cohort, peaking at the rate of 7,093.66 events per 100,000 persons for the 85 years or older group.

The Serious Event rate by estimated population was lowest in the 5- to 14-year cohort (5.94 Serious Events per 100,000 persons) and generally increased with advancing age, with the highest rate in the 75- to 84-year cohort (158.87 Serious Events per 100,000 persons).

The highest total event rate per admission was found in the 5- to 14-year cohort (511.12 events per 1,000 admissions) with much lower rates in other cohorts. However, Serious Event rates per admission were highest in the 45- to 54-year cohort through the 75- to 84-year cohort, with more than 4 Serious Events per 1,000 admissions for all four cohorts.
Event Types by Age Cohort

Figure 3 shows the number and proportion of events to the total number of reports, for both total events and Serious Events, by event type and age cohort.

Among all cohorts, with the exception of the 5- to 14-year group, the event type Error related to Procedure/Treatment/Test was the most common event type. The proportion of event reports related to Medication Errors was largest in children, adolescents, and young adults, yet the number of medication error events varied along the age cohort continuum.

In comparison, the event type Complication related to Procedure/Treatment/Test predominated in Serious Event reports for all age cohorts except for the cohort 85 years or older. The number and proportion of Serious Event reports involving Fall and Skin Integrity increased with advancing age.
Relative Risk

Figure 4 shows relative risk (RR) of Serious Event by the top five event types and age cohort, relative to the cohort with the highest estimated state population (i.e., 55 to 64) and relative to the cohort with the highest number of admissions in Pennsylvania (i.e., 65 to 74).

Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 1, 2017, through December 31, 2017.

* Comprises event types Adverse Drug Reaction (not a medication error), Equipment/Supplies/Devices, Patient Self-Harm, and Transfusion

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_EventsbyAge.aspx
Relative risk (RR) of a Serious Event in all event types by estimated population was lower in all age groups younger than the index group, with the exception of medication errors for the 0- to 4-year cohort, which had a 61% increased risk (RR = 1.61). Age cohorts 65 to 74 years or older had higher RRs than the index cohort for all event types. The RR of Serious Fall Events increased by more than 100% for cohorts older than the 55- to 64-year cohort, with the cohort 85 years or older having an RR six times the estimated population index cohort.

Overall RR for a Serious Event had limited variability when adjusted for admissions.

Figure 4. Relative Risk of Serious Event by Top Five Event Types and Age Cohort
Relative to Number of Admissions and Index Age Cohort (65 to 74)

RELATIVE RISK

AGE COHORT (YEARS, INCLUSIVE)

0-4 5-14 15-24 25-34 35-44 45-54 55-64 65-74 75-84 85+ 0.0 0.5 1.0 1.5 2.0 2.5 3.0

Relative to Population and Index Age Cohort (55 to 64 years)

RELATIVE RISK

AGE COHORT (YEARS, INCLUSIVE)

0-4 5-14 15-24 25-34 35-45 45-54 55-64 65-74 75-84 85+ 0.0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0

EVENT TYPES
- Fall
- Skin Integrity
- Medication Error
- Error related to Procedure/Treatment/Test
- Complication of Procedure/Treatment/Test


Note: Data reported through the Pennsylvania Patient Safety Reporting System, January 1, 2017, through December 31, 2017. Pennsylvania population data for 2017 was estimated by extrapolation from 2010 through 2016 data and estimates provided through the U.S. Census Bureau. Admissions (equivalent to discharges from Pennsylvania hospitals) data for 2017 were obtained from Pennsylvania Health Care Cost Containment Council (PHC4).

Admissions RR = SE per 100 admissions for age cohort / SE per 100 admissions for age cohort with most admissions (65 through 74 years).

Population RR = SE per 100,000 population for age cohort / SE per 100,000 population for age cohort with largest population (55 through 54 years).

RR, Relative risk; SE, Serious Event.
**Discussion**

Two patterns emerged from this data snapshot. In adults, the rate of total events and Serious Events relative to estimated population generally increased with increasing age; however, the rate of Serious Events relative to the number of admissions peaked in the 45- to 84-year cohorts and then declined sharply for the cohort of very elderly patients (older than 85 years). It may be assumed that very elderly patients are more frail, but the relationship between frailty and unanticipated harm is unknown.6-8

Conversely, at the other end of the age spectrum, both the total number of event reports and the rate of reports by estimated population were increased for patients younger than 5 years of age. The relatively large proportion of medication events in pediatric patients may be related to the need for patient-specific, weight-based calculations.9 The patterns of Serious Event type proportions for the 5- to 24-year cohorts were inconsistent with other age cohorts.

The increase in the rate of total events and Serious Event reports per admission in the 5- to 14-year cohort was unanticipated and offers an opportunity for further analysis. Identifying the types and patterns of event reports by age may help providers prioritize which interventions may be of the most value for individual patients.

**Limitations**

Despite the mandatory reporting requirement in Pennsylvania,1 the type, quantity, and quality of reports depends on the reporter as well as the design and implementation of the reporting system. The reporting cultures and patterns in each hospital and their interpretations of what occurrences are reportable can lead to reporting variations.

This analysis did not include hospitals’ reports of healthcare-associated infections in Pennsylvania, which are submitted through CDC's National Healthcare Safety Network10 and may disproportionately impact patients at different ages.

Although some Pennsylvanians may seek hospital care outside of Pennsylvania, and some individuals who are not residents of Pennsylvania may seek care inside Pennsylvania, use of a statewide database allowed analysis of event reports aggregated from 237 hospitals,11 which helps provide information relative to the entire population of the Commonwealth.

**Conclusion**

This data snapshot, based on more than 260,000 event reports submitted through PA-PSRS during 2017, identified age-related patterns of events that could have or did result in unanticipated patient harm. Although the increased rate of total event reports at the extremes of age relative to estimated population was unsurprising, the decreased rate of Serious Events in the very elderly, and the increased rate of total and Serious Events in the 5- to 14-year cohort relative to number of admissions were unanticipated. Attention to the event types and patterns of vulnerability that predominate in specific age cohorts may help facilities prioritize interventions.

**Notes**


Introduction

In late 2018, the Pennsylvania Patient Safety Authority received an inquiry about whether healthcare facilities in Pennsylvania had reported events of concurrent surgery. In response, the Authority queried its database for both concurrent and overlapping surgery that occurred in 2017.

Definition and Literature

In 2016, the American College of Surgeons published a bulletin (http://bulletin.facs.org/2016/06/looking-forward-june-2016/) that defined overlapping and concurrent surgeries as follows:¹

"Overlapping – critical elements of the first operation are complete and the primary surgeon is no longer needed. The surgeon may supervise the start of another operation while a qualified healthcare professional performs the final rudimentary components of the first operation. Less commonly, the primary surgeon will have completed the critical elements of the first operation and begun performing key portions of the second procedure in another room.

Concurrent – critical or key components of the procedure for which the primary attending is responsible are occurring all or in part at the same time."

ACS does not support concurrent surgery, stating: "A primary attending surgeon's involvement in concurrent or simultaneous surgeries on two different patients in two different rooms is not appropriate."¹ Leven, Moon, and Payne note that some specialty societies like the American Academy of Orthopedic Surgeons likewise deem concurrent surgery as inappropriate, and opine that the practice of overlapping surgery presents professional, legal, and ethical concerns.²

Analysts were unable to identify large-scale studies of concurrent surgery. A study by Dy et al. addressed the safety of overlapping orthopedic surgeries at five academic institutions during 2015.³ Overlapping surgeries occurred in 40% of the cases and the frequencies of perioperative complications were larger in the non-overlapping surgery group than in the overlapping surgery group. They concluded that "overlapping inpatient orthopedic surgery does not introduce additional perioperative risk for the complications" they studied.³ The authors recommend that individual surgeons and facility leaders determine the suitability of this practice at their own institutions.³
Events in Pennsylvania

Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events involving concurrent and overlapping surgery and procedures in hospitals and ambulatory surgical facilities that occurred during calendar year 2017 (most recent complete calendar year at time of the request). Analysts queried the free-text event narratives and recommendations for the following key words and phrases, including variations: "concurrent," "overlap," "simultaneous," "double book," "2 rooms," and "two rooms."

The queries yielded 860 events, which were each manually reviewed. Using the ACS definitions, analysts identified 15 events (1.7% of 860) in which the narrative or recommendations indicated that the surgeon was operating in more than one room at the same time (i.e., overlapping); for example, the attending surgeon started the second case while the resident was closing the first case. Eleven of these events indicated that the overlap contributed to the reason for which the event was reported; for example, the overlap contributed to a delay in starting the next case. None of the 15 events resulted in patient harm.

There was no clear evidence of a surgeon performing critical elements of an operation on more than one patient at a time (i.e., concurrent). In one event there was insufficient information to determine whether the two surgeries were concurrent.

Despite mandatory reporting laws, PA-PSRS data are subject to the limitations of self-reporting. It is possible that processes that occur but are not thought to contribute to unsafe conditions or harm may not be reported through PA-PSRS.

Although overlapping surgery is a common practice and permissible by regulators, specialty organizations and federal bodies state that overlapping surgery should have appropriate oversight and monitoring and be clearly communicated to the patient during the informed consent process.\(^1\,2\,4\,6\)

Conclusion

A search of data reported through PA-PSRS revealed 15 examples of overlapping surgery and no definitive events involving concurrent surgeries occurring in 2017.

Notes


Celebrate the 2019 I AM Patient Safety Winners

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Introduction

Each year, the Pennsylvania Patient Safety Authority recognizes individuals across the Commonwealth for their commitment and dedication to patient safety through our I AM Patient Safety contest. The Authority received 153 nominations in 10 categories. The nominations described scenarios of teamwork, high reliability, communication, innovation, event reporting, transitions of care, and more. With a section of the Strategic Plan being a focus on the patient, it was exciting to learn that we received our first nomination from a patient's family member.

The participating judges described the nominations as amazing, inspirational, enlightening, inquisitive, empowering, and "eye-opening to the wonders" that occur daily in Pennsylvania healthcare facilities. Judges commented that the stories are "not to be put on a shelf but deserve recognition" and are "impressive examples of how healthcare providers go above and beyond what is expected!" Determining one winner from each category proved difficult, given the numerous wonderful stories submitted.

As you read through the following descriptions, consider how you could apply the solutions they convey at your organization or in your daily practice and think about stories you can nominate for the next I AM Patient Safety contest!

Winners*

Executive Director's Choice Award


UPMC Hamot

The Transport Team at UPMC Hamot places patients first every day! Thirty-three team members work together 24/7 to support clinical staff by moving patients as efficiently and safely as possible—averaging 400 patient moves a day. They also respond to emergency situations and perform chest compressions during patient resuscitations.

3/21/2019

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_IAPS.aspx
Implementation of a patient flow application has taken the Transport Team to new heights: Prior to implementation, transporters were decentralized, with each person assigned to a specific department unless needed elsewhere; however, transporters are now dispatched by proximity and priority—resulting in increased efficiency, improved transport times, and cross-training throughout the hospital. They now coordinate multiple destinations into one trip, which has greatly enhanced patient safety and satisfaction. The transport team is trained to better understand the needs of patients with disabilities and is seen as an advocate and resource in this patient population. The team also provides training on the mechanical lift for all new nurses and patient care technicians during employee orientation.

The Transport Team has been responsible for five good catches in the last six months, and in 2018, three transporters received the prestigious Josie King Award for their quick responses to a patient in distress. Day in and day out, the transporters strive to offer the best possible patient experience during transport by maintaining good, open communication during hand-off and treating each patient as if they were a member of their own family.

### Ambulatory Care/Surgery

**SUSP Team:** Rodney Abney, Maureen Aitken, Jean Albany, Debbie Allmond, Dr. Andrew Beaver, Teresa Bolden, Dottie Borton, Dr. Jack Cohen, Dr. Richard Fine, Denise Grobelny, Julie Hensler-Cullen, Lamont Irvin, Tisa Julius, Rob Levin, Dr. Eric Sachinwalla, Karen Schwartz, Mark Talamona, Tom Trout, and Annette Yerkes

**Einstein Medical Center Elkins Park**

Surgical site infections (SSI) in the United States are a leading cause of morbidity and mortality among all hospital-acquired infections, and they also are among the most preventable healthcare-associated infections. As such, decreasing SSI has become a priority for orthopedic surgeons around the nation, including those at Einstein Medical Center Elkins Park.

After noting a rise in SSI throughout the Einstein network (2.8% compared to the statewide average of 0.82–0.89%) in 2014, Elkins Park hospital staff established a Surgical Unit Safety Practice (SUSP) committee to address the issue. The multidisciplinary team was tasked with reviewing all processes and procedures around total joint replacement surgery, from patient consultation through rehabilitation. Of particular concern was the timing of administering antibiotics before and after surgery.

The SUSP team used gap analysis and tracers to identify ways to reduce SSI in total hip and knee arthroplasty. In January 2015, they introduced a standardized care bundle to monitor antibiotic compliance and documentation, which includes a checklist that follows the patient from the orthopedic surgeon’s office through discharge. The staff was required to sign their initials on this bundle tag beside the tasks for which their department was responsible as they were completed.

The whole staff embraced the new tool, collaborating with the SUSP team to implement it and help refine and improve the process. The impact on patient safety and outcomes was immediate and dramatic. SSI associated with hip and knee arthroplasty fell to 1.2% in 2015, less than 1% in 2016, and 0% in the first quarter of 2017. Following this success, the team has been expanding the tool to other surgical procedures.

### Best Use of Authority Resources

Sandra Bach, safety coach champion; Aileen Bojko, safety coach champion and clinical nurse manager; Jadwiga Bobowska, risk manager and patient safety officer; Susan Reichenbach, vice president and chief quality officer; and Tracy Duffy, director of staff development

**Phoenixville Hospital**

Good catch reporting is an important component of a facility's patient safety program, as it promotes a culture of safety and enhances employee engagement.
Phoenixville Hospital's Safety Coach Committee routinely reviews and reports the findings from Pennsylvania Patient Safety Authority Advisory articles. Following the September 2017 Advisory article "Promote a Culture of Safety with Good Catch Reports (ADVISORIES/Pages/201709_goodcatch.aspx)," the committee recommended analysis of hospital data to determine its ratio of good catches to serious events.

They used the Pennsylvania Patient Safety Reporting System (PA-PSRS) harm scores and reporting tool described in the article and calculated good catch-to-serious event ratios, which were below the 2016 statewide ratios. Subsequently, they decided to develop a Good Catch Program and shared their findings with senior administrative leadership, who fully supported the initiative.

The Good Catch Program, which employed the best practices referenced in the Advisory article, debuted in March 2018 during Patient Safety Week. The committee sent emails to staff educating them on the definitions, rationale, benefits, and procedures for good catch reporting. They also engaged staff with online surveys to vote on a logo for the program and take a good catch quiz at the end of Patient Safety Week. Phoenixville's safety coaches promoted awareness and reporting of good catches via the facility's online event reporting system, and they formed subcommittees to administer quarterly Good Catch awards.

In the first quarter following the launch of the Good Catch program, the facility's good catch-to-serious event ratio doubled. Furthermore, analysis of good catches by event type provides important information for process improvement initiatives.

Focus on the Patient

Don Warnick and Peggy (Karish) Leschak
St. Clair Hospital

According to the Centers for Disease Control and Prevention, one person dies by suicide every four hours in Pennsylvania. The Joint Commission lists suicide as the 10th-leading cause of death in America—a higher mortality than traffic accidents and homicides—and estimates 49–65 inpatient hospital suicides occur annually.

Following a near miss at St. Clair Hospital, a multidisciplinary team consisting of emergency department (ED), behavioral health, information technology (IT), and patient safety leads determined that the central point of failure was related to the unavailability of essential patient history regarding previous self-harm and suicidal attempts. Two months later, Hospital Information System Department members Don Warnick and Peggy (Karish) Leschak had developed an IT solution that searches a patient's electronic medical record (EMR) at registration for a history of self-harm and, if found, alerts the admissions team and clinical caregivers in real time. They also added a triage process to the EMR that uses the Columbia-Suicide Severity Rating Scale (C-SSRS) to identify patients who may require close observation based on how their answers to the questions compare to their history.

Data obtained in the first two months after implementation revealed that 100 patients seen in the ED had a discrepancy between the answers on the C-SSRS and their history of self-harm; these patients were given additional assessments and interventions to ensure their safety. Because the new process has been working so seamlessly in the ED, Don and Peggy also will implement these enhancements throughout the inpatient departments as well.

Improving Diagnosis

Dr. Robert Gayner, VPMA, St. Luke's University Hospital - Bethlehem, and chief of Nephrology, St. Luke's University Health Network
St. Luke's University Hospital - Bethlehem

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_IAPS.aspx
Dr. Robert Gayner, chief of nephrology at St. Luke's University Hospital Network, working with a multidisciplinary team, discovered that many patients were being misdiagnosed with acute kidney injury (AKI) or had undiagnosed AKI. As patients' electronic health records often retain diagnoses, these inaccuracies had the potential to cause unnecessary treatments and put patients at higher risk for AKI comorbidities.

Dr. Gayner worked diligently to educate caregivers about the Kidney Disease Improving Global Outcomes (KDIGO) criteria for diagnosing AKI throughout the hospital. Among the many components of this educational outreach, he and the team developed a standardized AKI bundle to help all network inpatient and outpatient providers recognize AKI and identify patients at high risk for AKI when they arrive for a surgical procedure.

Dr. Gayner also issued a set of practice standards to mitigate the risk of AKI, which includes a preoperative nephrology consult for patients depending on their baseline kidney function. He worked closely with the clinical informatics team to automatically identify patients who were at risk for AKI or who had an AKI event in the hospital and trigger clinical decision-making support mechanisms to assure timely and effective care across all disciplines.

These initiatives have been implemented networkwide and have resulted in a 37% reduction in the overall rate of AKI; decreased patient mortality; and improved appropriate diagnosis, treatment, and ongoing management of this patient population.

**Individual Impact**

**Stephanie LaJohn**

*Shriners Hospitals for Children® – Erie Ambulatory Surgery Center (ASC)*

Nurse anesthetist Stephanie LaJohn has a way with children, treating every patient as if they were her own child and quickly winning their trust. She puts even the most anxious children at ease before surgery, reassuring them that she will be with them throughout it and calmly explaining what is going to happen in terms they can understand. She even turns anesthesia into a fun game; for example, she lets kids choose from 20 different flavors for the "anesthesia" and lines their breathing mask with lip gloss so they smell the flavor they picked instead of the anesthetic gases. She gets them excited about going to the operating room to help "blow up her balloon," and as they watch the balloon grow on the anesthesia machine, she often holds them in her lap and sings them softly to sleep. Then when they wake up, she always has a special, parent-approved sweet treat waiting for them. Every day, Stephanie demonstrates how much she loves her patients in her dedication to ensuring their safety, comfort, and peace of mind.

**Innovation**

**Rose Hall, RT. (R) (CT), Lisa Griffin, RT. (R) (CT), and Dr. Ryan Lee**

*Einstein Medical Center Philadelphia*

Extravasation of intravenous contrast during a computed tomography (CT) scan is a common event that can harm patients, with rare instances of severe complications. Besides the possible complications of contrast extravasation and causing inconvenience to the patient, these events also require additional patient assessment and observation that may impact the workflow of the healthcare team.

During monthly quality improvement meetings, Rose Hall, Lisa Griffin, and Dr. Ryan Lee identified a trend of increased contrast extravasation and decided to design a process to reduce these events. They observed that the rates of contrast extravasation were lower when using a dual-head power injector—used for CT coronary angiograms—rather than the routine precontrast test bolus administered via hand injection. So they implemented a new protocol in May 2016 which requires a power injected 30cc saline bolus through the patient's IV, prior to administering the iodinated contrast. The power injected test bolus is actively observed by the CT technologist at the...
scanner gantry to look for signs of extravasation; if the saline extravasates, a new IV site of access is attempted. If contrast still extravasates despite a successful saline test bolus, the event is reported by the performing CT technologist, and postcontrast extravasation protocols are followed.

Comparing the rate of contrast extravasation before and after the power injected saline bolus intervention protocol was implemented reveals a 53% reduction in the extravasation rate as compared to the baseline period. The process has provided a safe and effective method to reduce IV contrast extravasation, increase patient safety, improve healthcare staff efficiency, and contribute to better outcomes when performing contrast-enhanced CT scans.

Long-Term Care

Environmental Services Department
South Mountain Restoration Center

Environmental services is a key line of defense against the spread of bacteria in a healthcare facility, and the 21 staff members of the Environmental Services (ES) Department at South Mountain Restoration Center take their role very seriously. They ensure a clean, sanitary, and comfortable environment for their residents and consistently go beyond their routine responsibilities. For example, they helped implement a new evidence-based practice to prevent healthcare-associated infections, and they took the initiative to ramp up disinfection and cleaning of high-touch surfaces during flu season—which contributed to a 0.04% incident rate of influenza in 2018. After an inspection and consultation from the Infection Control Assessment and Response Program, ES implemented a pilot project to install more alcohol-based hand rub stations to assist in infection control. They installed or repositioned 70 dispensers in one unit and tracked data and reported back to the Quality Assurance Committee. Moreover, some ES staff are certified for direct care and volunteered a combined total of more than 470 hours to assist with residents—just one of the many ways they frequently interact with residents and strive to make them feel at home.

Safety Story (Near Miss or Close Call)

Stacy Green
St. Christopher's Hospital for Children

While caring for a patient at St. Christopher's, registered nurse Stacy Green heard strange popping from beneath the child's bed. When she investigated the noise, she discovered a stripped and frayed power cord—which was sparking dangerously. She immediately assured the patient was safe and unharmed, and notified biomedical services and her supervisor. The bed was quickly taken out of service, and she submitted a safety event report, which was shared along with photos of the damaged electrical cord the next day at leadership's daily safety huddle. As everyone grasped the urgency and risk to patient safety, the biomedical and quality department embarked on an audit of every patient bed. Armed with a script to discuss the inspections with concerned patients and families, the inspection team found three more beds with damaged cords and removed them from service. The incident and timely response from Stacy, hospital leadership, quality staff, and biomedical staff prompted a new protocol: The Environmental Service department now inspects patient bed electrical cords when they clean rooms following a patient's discharge. The hospital also reported the incident to the U.S. Food and Drug Administration's Medical Product Safety Network. Subsequently, the bed manufacturer investigated the incident, replaced the frayed cords at the facility, and issued a national alert to their customers with guidance on correct cord storage, inspection, and replacement. Thanks to Stacy's commitment to a culture of safety and timely safety event reporting, hospital leadership was able to take action to prevent patient harm in her organization and possibly others.
Transparency and Safety in Healthcare

Patricia Bambrick, Colleen Arnold, Bev Genetin, Andrew Urbach, Diane Hupp, and the Patient Safety & Quality Department

UPMC Children’s Hospital of Pittsburgh

Ten years ago, a medical error in mixing intravenous potassium resulted in a patient's death at UPMC Children's Hospital of Pittsburgh—but now the mother of that patient has nominated the hospital for their efforts to promote safety and minimize or prevent medical errors since her daughter's death. Specifically, she wants to recognize the Patient Safety & Quality Department and Patricia Bambrick, Colleen Arnold, Bev Genetin, Andrew Urbach, and Diane Hupp, and the countless changes they have made throughout the healthcare system to help save lives.

Following that event a decade ago, the hospital not only apologized to the family for the medical error, but also shared their plans to correct the problem so it would never happen again to another family. The hospital implemented numerous safeguards in the pharmacy, established a patient safety and quality committee, and adopted a "just culture" that embraces mistakes as a part of the learning process. Having the courage to admit errors helps the healing process and learning the causes of mistakes provides opportunities to educate staff and design safer systems of care. To foster this culture, the employee website has a section about near misses and catches, and staff members are rewarded for reporting medical errors. Other changes include a patient safety week, hospital rounds, and routine evaluations of systems, as well as an annual Patient Safety Conference. At the first conference, held in memory of the girl who died due to a medical error, her mother was able to share her story publicly—and heal.

Video

Kathryn Farrell, professional practice consultant; George Shafer, nurse manager; and the Therapeutic, Intervention, Presence, and Sanctuary (T.I.P.S.) Team

Penn Medicine Pennsylvania Hospital

Patient safety and patient experience go hand in hand, and structures and processes must be in place to create a cohesive, consistent approach to care—especially at a teaching hospital that is part of a large academic health system, like Penn. So a team determined that the following behaviors were necessary to put patients’ needs first:

Therapeutic—convey respect for a person’s well-being through words and body language

Intervention—assist or refer to staff who can help

Presence—be mindful of where you are and who you are with

Sanctuary—create an atmosphere that makes patients, families, and staff feel safe

To present these Essential Behaviors for all interactions, known as T.I.P.S., to staff in a fun and impactful way, the team created a professional video highlighting employees and patients (https://vimeo.com/arsenalmediaworks/review/214737147/a5b3fa261f) describing their care experiences with T.I.P.S behaviors. It includes employees from many departments, from clinical staff to executive leadership—emphasizing that T.I.P.S was a strategic priority. The 10-minute video was shown in 30-minute sessions and is available to all employees on the hospital's intranet. It is reviewed annually and as needed at the unit/department level. It is also available to patients. The T.I.P.S. initiative also included commitment pledges, posters, badge buddies, and story sharing about positive behaviors.

The Essential Behaviors have had a positive impact on the patient experience; the hospital's overall rating rank has increased by 44 points, and by 20 points in its "likelihood to recommend" score. There also has been a noticeable shift in employee behavior toward prioritizing patients’ needs.
* Any included numbers and/or results were provided for publication by the recognized healthcare facilities. The Pennsylvania Patient Safety Authority has not independently verified, and bears no responsibility or liability for, these numbers and/or results.
Are Humans the Problem in Patient Safety?

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Introduction

Despite the education and dedication of healthcare professionals, undesired patient outcomes can occur. Patient safety events in Pennsylvania involving temporary or permanent harm or death were presented in the previous issue of the Pennsylvania Patient Safety Advisory, in an article titled "Are You Ready to Respond? Reports of High Harm Complications after Surgery and Invasive Procedures." High harm events are devastating for patients, families, and care providers and may be even more distressing if human errors contributed to the event. Because some events of patient harm involve human error, some people may question whether humans are the problem, the weak link in our efforts to provide safe healthcare.

Complexity

In their efforts to prevent the recurrence of events involving patient harm, healthcare facilities have implemented learning processes such as root cause analyses (RCAs). Contemporary RCAs seek to deconstruct patient safety events to identify one or more known or previously unrecognized threats to patient safety that aligned to allow errors or harm to occur.

Advances in understanding the multifactorial etiology of harm, such as James Reason’s "Swiss cheese model," search for failures proximal to the final act of commission or omission in the belief that a combination of factors contributes to an event in which a patient is harmed. These factors may arise suddenly, or may be "latent safety threats" that were introduced in time periods long before the harm event and then coalesced with unintended consequences.

Although the Swiss cheese model expands our analysis beyond the final act by a provider at the "sharp end," this perspective is still often limited to seeking discrete points of failure without recognizing the impact of interactions between components or the dynamic contributions of the healthcare environment. Knowing how each part of the healthcare delivery system works—at a sequential or interdependent level—is important, but it will not necessarily provide us with an understanding of how the system works as a whole.
As an (albeit limited) example, specific parts of a car need to work in order to drive—the engine, the brakes, the steering assembly, and so on. Nevertheless, having a mechanically functional car does not ensure that drivers will arrive safely at their intended destination. Many factors can impact a driver's success, including their own driving skill, road conditions, weather, and the skill of other drivers. Although drivers may intend to drive smoothly from their starting point to their endpoint, they inevitably make unanticipated adjustments along the way.

Although some healthcare delivery activities can appropriately be reduced to linear, sequential processes, other activities are interdependent, and some are complex adaptive processes that interact with and impact each other. Healthcare professionals must negotiate systems and balance choices much more complex than driving from point A to point B. In some circumstances, regulations and rigid protocols that restrict the options for provider actions are necessary and appropriate. In other circumstances, adaptability, resourcefulness, and even creativity are important. Healthcare delivery is a complex adaptive system with interactions and consequences that may not be completely predictable or even knowable.

Adaptation

To paraphrase a principle often attributed to James Reason, patient harm is infinitely creative. Evidence-based-practice principles provide important guidance but may not completely address the specific or unexpected circumstances of an individual patient. Healthcare professionals may need to solve problems for which there is no completely suitable, evidence-based process, such as when the preferred medication is unavailable because of a drug shortage, or when a new pattern of antibiotic resistance emerges, or when a patient exhibits a unique combination of medical conditions or injuries.

The National Academy of Medicine asserts that "people working in health care are among the most educated and dedicated work force in any industry." Humans sense-make, they find patterns in chaos and assign meaning to ambiguous data, which can occur only through human reflection. Humans solve problems, learn, invent, anticipate, create, and make decisions. They are the thinking part of the man-machine team.

Skilled, thoughtful, perceptive, and yes, imperfect, healthcare professionals must sort through the onslaught of new information, emerging technologies, competition for resources, ever-increasing societal expectations, and the personal preferences of individual patients to craft the safest healthcare delivery. Humans, regrettably, can create problems, but they also innovate and create ingenious solutions.

Encouraging humans to be adaptable improves their skill at navigating complexity, solving problems, and ultimately, improving patient safety. The ability of humans to solve problems and their capacity for compassion are invaluable resources. Humans can be part of healthcare delivery problems, but they are also essential and irreplaceable contributors to solutions.

Notes

1. Institute of Medicine Committee on Quality of Health Care in America. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): National Academy Press; 1999 Nov. 223 p. Also available: https://www.nap.edu/read/9728/chapter/1


The Mystery of the Missing Mark

The following event report was submitted through PA-PSRS:*  

_I started to draw up 1 mL of acetaminophen into a 3 mL syringe. I drew up the medication to the line where “1” was, looked at it, and thought it looked odd. Upon closer inspection, it was actually the 1.5 mL line, but the ”.5” wasn't there, and the 1 mL and 0.5 mL lines were also not on the syringe and appeared to have worn off. I checked our supplies and found another 15-20 syringes that also had several numbers worn off; I removed them from our supplies._

The author of this narrative points out the hazard that exists if the individual drawing up medication doesn't recognize that a syringe is incorrectly marked. The reporter is to be applauded for noticing and managing this unsafe condition.

A Resilience Engineering Perspective

The reporter's actions could be described using resilience engineering concepts, as described by Hollnagel.1 Resilient systems include the capacities to—

Monitor: know what to look for. The reporter in this event recognized that the volume of medication didn't look quite right and investigated further to identify that the volume mark was abnormal. This capacity to recognize a subtle defect was based on the reporter's previous experience; expertise can be hard to measure but was a component of this successful save.

Respond: know what to do. Upon recognizing the patient-care hazard, the reporter stopped administering the medication. Further, the reporter considered that the hazard could affect more than the single syringe in hand, and checked the facility's supplies.

Anticipate: know what to expect. The reporter considered that the misleading markings on the syringe might not be obvious to others and proactively minimized future hazard by removing the other affected syringes.

One additional characteristic of resilient systems is the capacity to _learn, to know what has happened_. The Authority hopes that presenting safety vignettes such as this one, which demonstrate actions that support resilience, will help providers across Pennsylvania (and beyond) provide safe healthcare.

* The details of the Pennsylvania Patient Safety Reporting System event narrative in this article have been contextually deidentified to preserve confidentiality.
Note


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