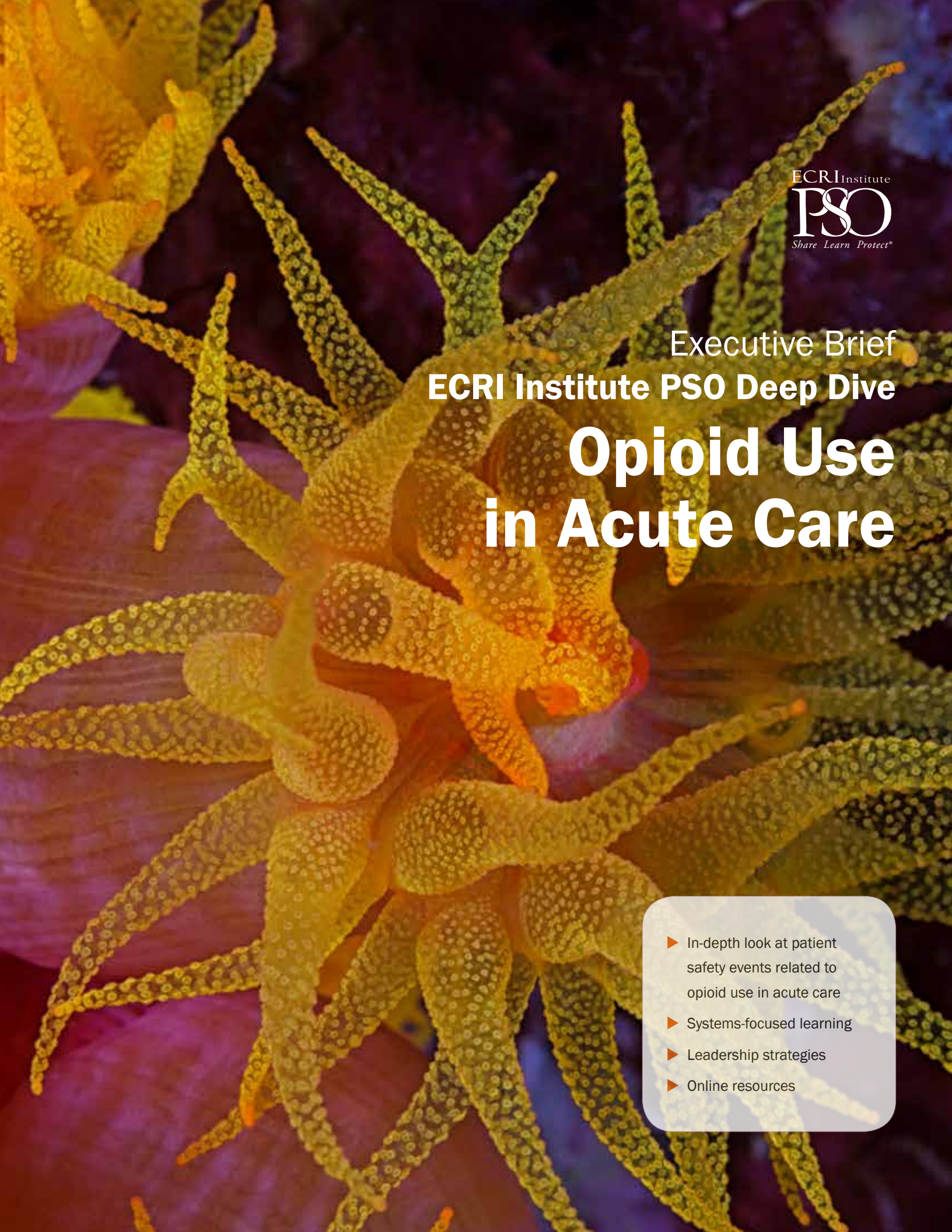

ECRI Institute PSO
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Executive Brief

ECRI Institute PSO Deep Dive

Opioid Use in Acute Care

- In-depth look at patient safety events related to opioid use in acute care
- Systems-focused learning
- Leadership strategies
- Online resources

MISSION STATEMENT

ECRI Institute PSO is a federally listed patient safety organization that is a component of ECRI Institute.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As a pioneer in this science for nearly 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research.

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Executive Brief

ECRI Institute PSO Deep Dive

Opioid Use in Acute Care

About ECRI Institute PSO

ECRI Institute PSO is one of the first patient safety organizations (PSOs) to be federally certified under the provisions of the Patient Safety and Quality Improvement Act (PSQIA).

PSQIA gives healthcare organizations a unique opportunity to voluntarily share their safety surveillance data in a protected environment so PSOs can aggregate and analyze the data. The law also charges PSOs with the responsibility to share the findings and lessons learned. The release of ECRI Institute PSO *Deep Dive™: Opioid Use in Acute Care* is in keeping with that responsibility.

Acknowledgments

ECRI Institute PSO thanks its collaborating member organizations and partner patient safety organizations (PSOs) for sharing their opioid-related events for this Deep Dive report. Over the course of six Deep Dive projects, participating healthcare organizations have explored multiple safety topics through the aggregated analysis of shared events. ECRI Institute PSO encourages its members to review ECRI Institute PSO *Deep Dive™: Opioid Use in Acute Care* and convene a multidisciplinary team to discuss the applicability of the findings to their organizations.

In addition to the many individuals at ECRI Institute who contributed to this report, ECRI Institute PSO acknowledges the following individuals for their insights:

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Executive Brief

Background*

Pain is common among patients in acute care settings, and it is not always effectively controlled through means other than opioids. Many hospital patients do have legitimate indications for opioids.

However, opioid therapy carries risks of harm, ranging from nausea or vomiting, itching, constipation, confusion, delirium, and allergic reactions to respiratory distress, respiratory depression with permanent injury, and possibly death. In addition to posing serious threats to patient safety, adverse events related to opioids can add substantial costs, in terms of both healthcare charges and liability. The public health crisis of opioid-related substance use disorder has heightened concerns about diversion of controlled substances in hospitals, particularly opioids. Opioid use—and misuse—is increasingly being addressed through laws, regulations, and standards. The use of opioids in acute care is also part of a larger discussion about the effective and safe management of pain. All of these factors contribute to making opioid therapy a prime concern for healthcare organizations. ECRI Institute PSO explored these issues, through the aggregated analysis of events shared by PSO members, in its sixth Deep Dive: ECRI Institute PSO *Deep Dive™: Opioid Use in Acute Care.*

* A free download of this Executive Brief and more information about the full report, ECRI Institute PSO *Deep Dive™: Opioids in Acute Care*, is available at http://www.ecri.org/opioids.

Opioids are the **second most frequent** class of medications to cause adverse drug reactions in hospitals

Source: Davies et al.

1. Loop diuretics
2. Opioid analgesics
3. Systemic corticosteroids

Patient Harm

Opioid-related adverse events can cause significant morbidity, even mortality. Unfortunately, opioid-related harm is not rare. Opioids are the second most frequent class of medications to cause adverse drug reactions in hospitalized patients, trailing only loop diuretics (Davies et al.).

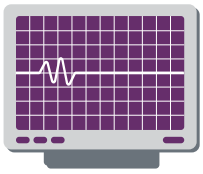
Oversedation and respiratory depression, which can lead to death if not quickly recognized and reversed, are prime concerns. In reviews of medication utilization, administration of naloxone, an agent used to reverse the effects of opioids, is often considered a general indicator that the patient suffered opioid-induced respiratory depression, although not every instance of naloxone administration represents a case of preventable opioid-induced respiratory depression. One estimate suggests that naloxone is given to about 0.2% to 0.7% of patients receiving opioids postoperatively (Weinger and Lee). Although these percentages might seem low compared with rates of surgical complications, for example, even low percentages can extrapolate to large numbers of patients. A rate of 0.5%, for example, equates to 1 patient out of 200—a substantial number given how many hospital patients receive opioids.

Naloxone, a reversal agent, is given to **2 to 7 of every 1,000** postoperative patients on opioids

Source: Weinger and Lee.

Oversedation and respiratory depression are not the only concerns. Opioids may also be associated with delirium, euphoria, dysphoria, hallucinations, dizziness, falls, nausea, vomiting, aspiration pneumonia, constipation, hypotension, itching, and allergic reaction, among other adverse effects (Joint Commission "Safe Use"; Hooten et al.). Long-term opioid use is associated with heightened sensitivity to pain and opioid tolerance (DuPen et al.).

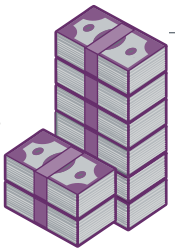
Cases of postoperative opioid-induced respiratory depression in an anesthesia closed claims analysis:



77% resulted in death or severe brain damage

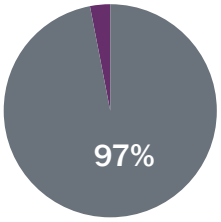
Source: Lee et al.

The median payment was $216,750, but about 1 in 4 payments was greater than $600,000



Source: Lee et al.

97% were preventable



Source: Lee et al.

Liability

Opioid-related liability claims can be costly. In a review of 357 anesthesia closed malpractice claims related to acute pain, researchers identified 92 cases in which postoperative opioid-induced respiratory depression definitely, probably, or possibly occurred. Nearly all cases of respiratory depression (97%) were preventable, according to physician reviewers, and 77% resulted in death or severe brain damage. Payment was made in 45% of cases. The median payment was $216,750, but about one in four payments was greater than $600,000. (Lee et al.)

Laws, Regulations, and Standards

Many laws, regulations, and standards pertain to opioids, and some have implications for use in acute care. Depending on the circumstances, problems involving opioids may invite scrutiny by any or all of the agencies discussed below.

The U.S. Food and Drug Administration (FDA) approves and regulates medications, including opioids and naloxone. As with other medications, FDA's involvement extends to approving product labeling and boxed warnings. (U.S. FDA) The U.S. Drug Enforcement Administration is responsible for enforcing the federal Controlled Substances Act and the regulations that implement it, ensuring that all transactions involving controlled substances occur within a "closed system" of distribution (U.S. DEA).

Several Centers for Medicare and Medicaid Services (CMS) regulations and interpretive guidelines—particularly those addressing nursing services, the medical record, and pharmacy services—discuss medication safety in detail. For patients receiving opioids, the interpretive guidelines stress the importance of timely assessment and appropriate monitoring. (CMS "State Operations Manual")

The opioid misuse epidemic has also made opioids in general an increasing focus for CMS. Although the agency's "Opioid Misuse Strategy 2016" focuses on outpatient prescribing, one of the strategy's four broad priorities is to "increase the use of evidence-based practices for acute and chronic pain management." The two objectives under this priority area are to expand the use of best practices and to promote the use of nonpharmacologic, non-opioid pharmacologic, and multimodal therapies as first-line strategies for managing pain. (CMS "Opioid Misuse Strategy 2016")

State laws and regulations address controlled substances and the practice and licensure of healthcare workers. Hospitals must report certain professional review actions to the National Practitioner Data Bank (NPDB) and the state licensing board, and malpractice payers, including self-insured organizations, must report certain medical malpractice payments to the NPDB. In recent years, many state initiatives, such as prescription drug monitoring programs (which often

Opioid-Related Efforts at the Federal Level: Implications for Acute Care

In July 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis issued its draft interim report to the president, which included several recommendations. Although the report is aimed largely at outpatient prescribing, following are recommendations from the report that may have implications for acute care settings:

- Require education for prescribers regarding opioid prescribing and the risk of substance use disorder, such as through medical and dental school curricula, required courses for all U.S. Drug Enforcement Administration registrants, and continuing education.
- Expand access to medication-assisted treatment (MAT) for substance use disorder.
  - The complexity of the medications used in MAT underscores the importance of prescriber competence in managing acute pain in patients undergoing MAT and coordination of acute pain management with providers of substance use disorder treatment.
- Require that naloxone be prescribed whenever a high-risk opioid is prescribed.
- Supply federal funding and technical support for sharing of information among state and federal (e.g., Veterans Health Administration) prescription drug monitoring programs.
- Harmonize patient privacy laws specifically addressing substance use disorder with the Health Insurance Portability and Accountability Act (HIPAA).
  - Under 42 CFR Part 2, providers of substance use disorder treatment who receive federal assistance must get the patient's written consent in order to share information with the patient's other healthcare providers. In July 2017, the Overdose Prevention and Patient Safety Act was introduced in the U.S. House of Representatives to align 42 CFR Part 2 with HIPAA.

Healthcare organizations should remain alert for the final report, which was due to be issued in fall 2017, and for any federal or state activity related to opioids.

Sources: President's Commission on Combating Drug Addiction and the Opioid Crisis. Draft interim report. 2017 Jul 31 [cited 2017 Aug 2]. https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf; Office of Tim Murphy, U.S. Congressman for the 18th District of Pennsylvania. Murphy introduces legislation to prevent overdose deaths, protect patients [press release]. 2017 Jul 28 [cited 2017 Aug 2]. https://murphy.house.gov/latest-news/murphy-introduces-legislation-to-prevent-overdose-deaths-protect-patients/

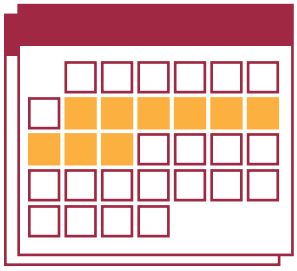
A case of postoperative respiratory failure adds:

Description	Debit	Credit
Additional healthcare charges for postoperative respiratory failure	$54,000	

$54,000 in additional healthcare charges

Source: Zhan and Miller

9 days to length of stay



Source: Zhan and Miller

require prescribers to check the state prescription database before prescribing opioids), have focused on outpatient prescribing; however, organizations must be familiar with any requirements that pertain to inpatient settings as well. Criminal codes may apply in the event of drug diversion or other unlawful possession or use.

Accrediting agencies also address pain management. Joint Commission recently made changes to its standards and elements of performance related to pain management. The agency revised its existing pain management standard; created an additional standard requiring hospitals to make "pain assessment and pain management, including safe opioid prescribing," an organizational priority; and added elements of performance addressing pain management to other existing standards. One element of performance for the new standard specifically states that hospitals should offer nonpharmacologic pain management modalities. (Joint Commission "Prepublication Requirements")

Healthcare organizations should watch for more laws, regulations, and standards related to opioids. At the federal level, the White House and legislators are contemplating actions to take in response to the opioid epidemic. Several of the steps being considered would have implications for acute care settings. For more information, see "Opioid-Related Efforts at the Federal Level: Implications for Acute Care."

Costs

Opioid-related adverse events can dramatically increase healthcare charges. Using a sample of more than seven million hospital discharges, researchers matched each case involving specific types of medical injury during hospitalization with control subjects who received care at the same hospital and had the same sex, age (within 10 years), race (white or nonwhite), and diagnosis-related group. Case and control subjects were also matched based on mortality risk due to comorbidity. The researchers calculated the charges attributable to the medical injury by comparing the total charges for the case with the mean for the matched controls. The study found that nearly $54,000 in excess charges could be attributed to postoperative respiratory failure (resulting from any cause, not just opioids). This injury was also associated with an excess hospital length of stay of nine days. (Zhan and Miller)

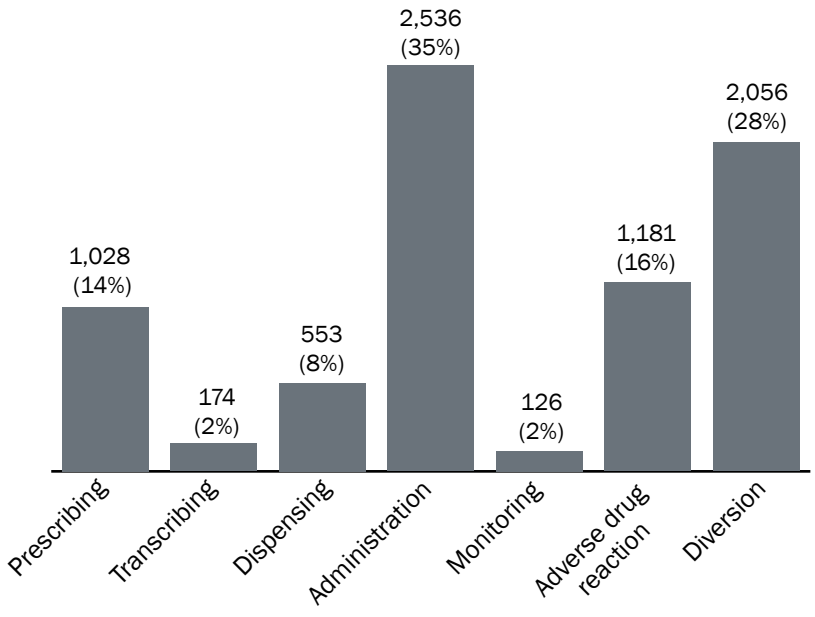
Results

ECRI Institute PSO searched its database for opioid-related events that occurred between January 1, 2014, and November 30, 2016. Of the 11,388 events analyzed by ECRI Institute PSO, 7,218 (63%) were deemed relevant and further classified according to the taxonomy that ECRI Institute PSO developed for analysts to use when classifying events. Hereafter, all data in this report refer to reports deemed relevant.

Taxonomy Categories

The taxonomy is based on stages of the medication use process, with additional categories for adverse drug reactions and drug diversion. For all of these categories except adverse drug reactions, the taxonomy includes several failure modes that analysts could select when reviewing events. Analysts could select more than one taxonomy category and more than one failure mode for each event.

Figure 1. Event Breakdown by Taxonomy Category



N = 7,218 events with at least one failure mode in the category.

Numbers add up to more than 7,218 and percentages add up to more than 100 because more than one category could be selected for each event.

MS17355

Harm Scores

A. Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)

B1. An event occurred but it did not reach the individual (near miss or close call) because of chance alone

B2. An event occurred but it did not reach the individual (near miss or close call) because of active recovery efforts by caregivers

C. An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission such as a missed medication dose does reach the individual)

D. An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm

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

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

G. An event occurred that contributed to or resulted in permanent harm

H. An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life)

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

ICU: intensive care unit

Within the taxonomy developed by ECRI Institute PSO, the administration and diversion categories accounted for the highest numbers of events. See **Figure 1. Event Breakdown by Taxonomy Category**.

ECRI Institute PSO analysts could identify multiple failure modes in a single event. For example, the following case involved failure modes in prescribing, transcribing, and dispensing:

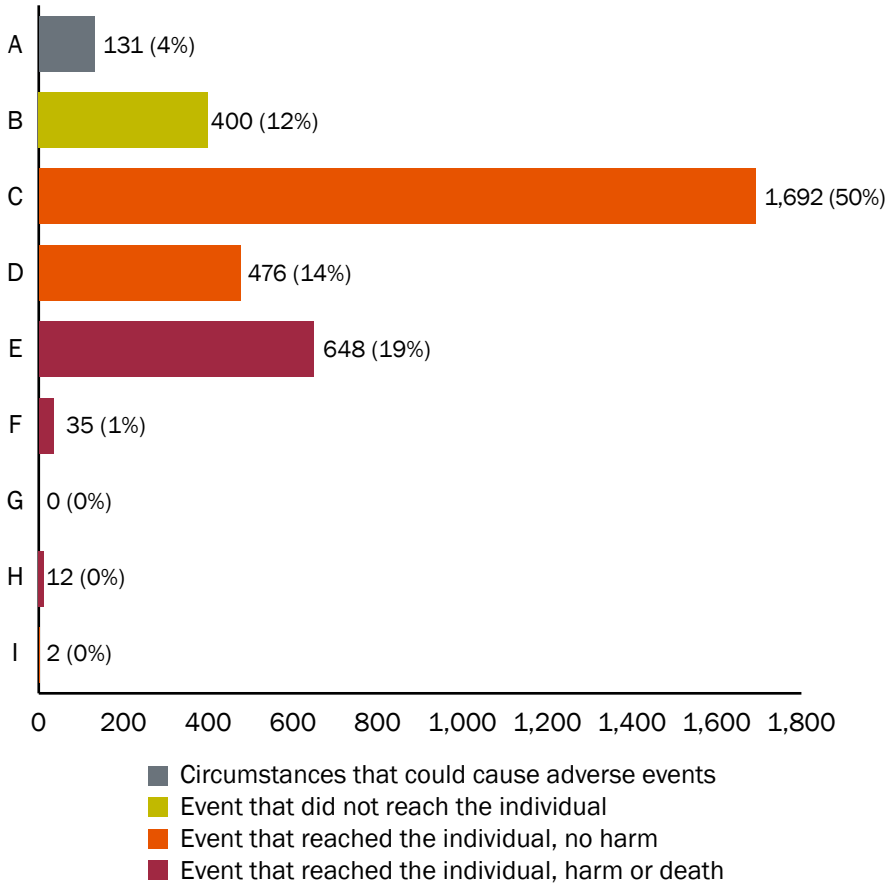
An emergency department (ED) technician entered 60 mg immediate-release morphine, twice a day, as a medication that the patient took before admission. A nurse practitioner ordered the medication for the patient, and a pharmacist verified the order. Both the nurse practitioner and the pharmacist overrode clinical decision support warnings indicating that the order exceeded the maximum dose. A staff member noticed the error: immediate-release morphine is not given in a dosage of 60 mg twice a day. The patient confirmed that she took 60 mg of extended-release morphine twice a day.

Harm

A total of 3,396 event reports (47%) indicated the level of harm that occurred. Harm scores, which are based on the National Coordinating Council for Medication Error Reporting and Prevention's "Index for Categorizing Medication Errors," were indicated by the individual reporting the event rather than ECRI Institute PSO analysts. The harm scores may represent correlation, contribution, or causation; ECRI Institute PSO analysts did not attempt to determine causation or contribution based on the often limited information available in reports.

Even so, it is notable that harm (categories E–I) was reported in 20% of events in which a harm score was indicated; in another 64% of cases, the event reached the individual but no harm occurred (categories C and D). See **Figure 2. Event Breakdown by Harm Score (for Events with a Harm Score Indicated)**. Because opioid-related harm is sometimes delayed or not detected (e.g., an overdose death following the purchase of medications that were diverted from a hospital),

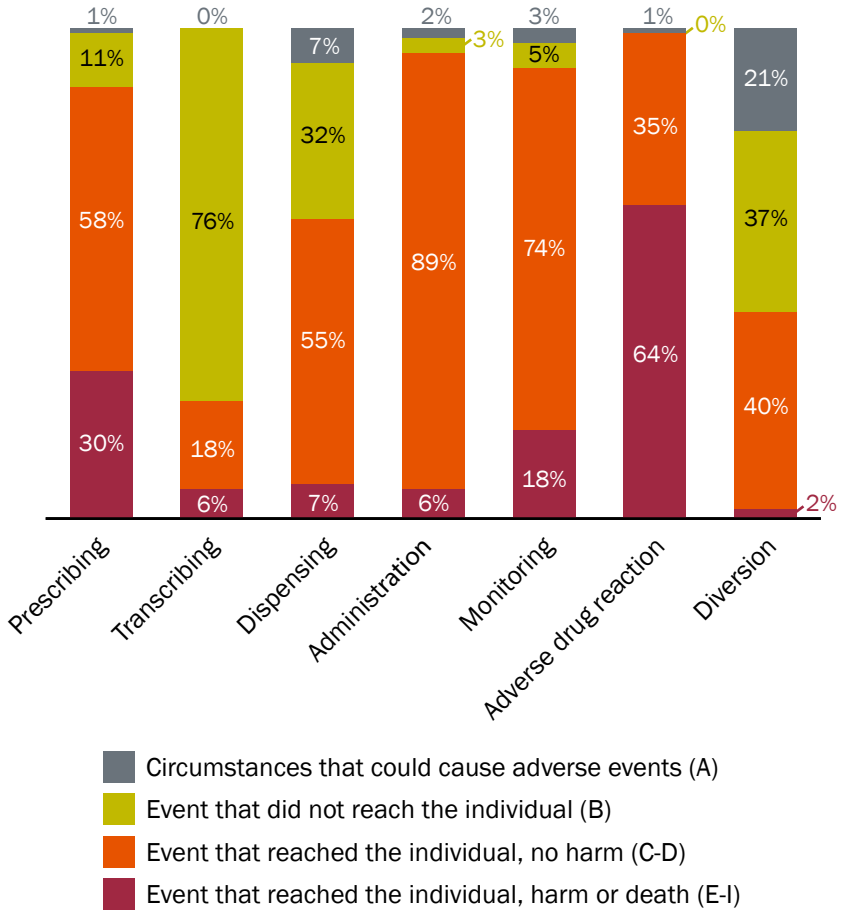
Figure 2. Event Breakdown by Harm Score (for Events with a Harm Score Indicated)



N = 3,396 events with a harm score indicated.
See "Harm Scores" for definitions and groupings of harm scores.

MS17356

Figure 3. Distribution of Harm in Each Taxonomy Category



N = 3,396 events with a harm score indicated.
Percentages do not always add up to 100 because of rounding.
See "Harm Scores" for definitions and groupings of harm scores.

MS17357

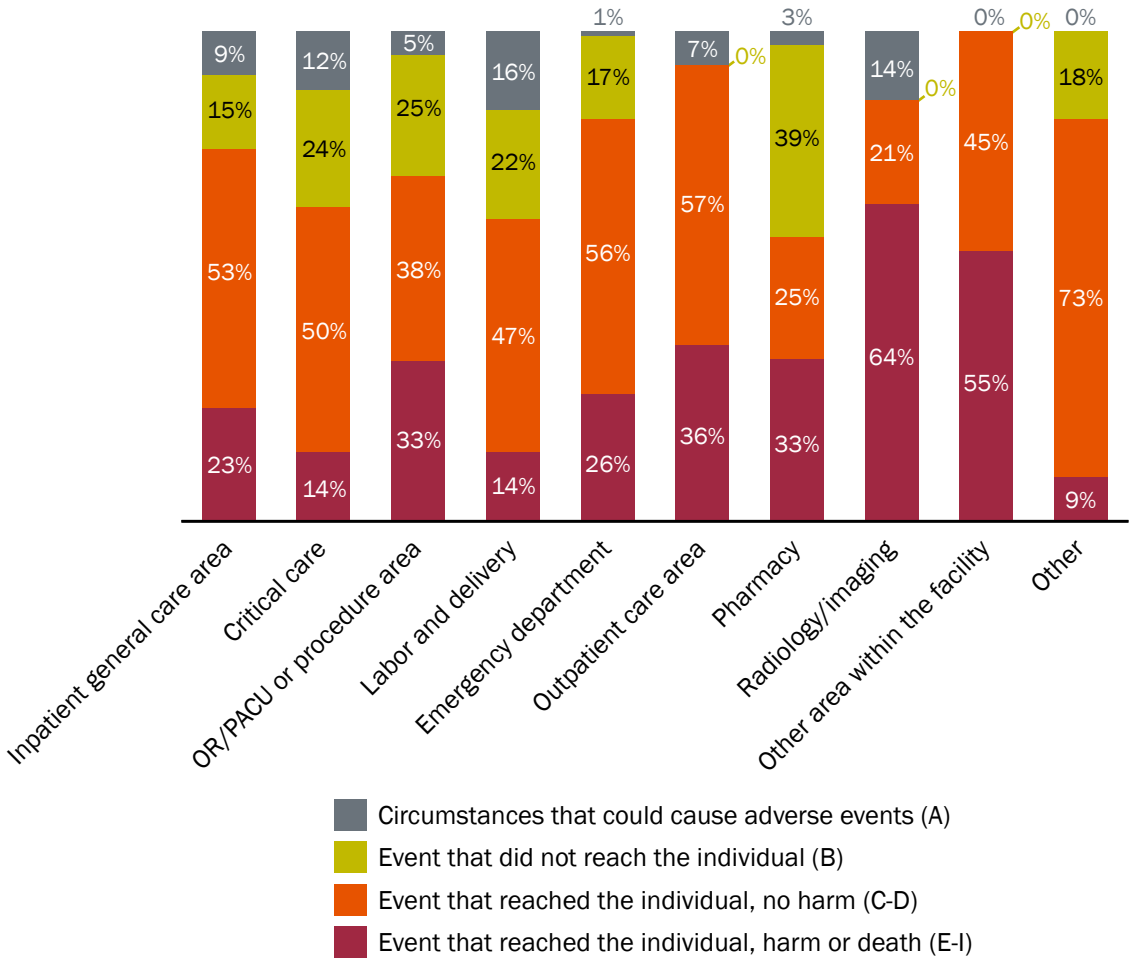
these data may not reflect a complete picture of the harm associated with opioids in hospitals.

Patient death occurred in two cases in which a harm score was reported but also in other cases in which no harm score was reported. Although it was usually not possible to tell whether the failure mode caused or contributed to the death, staff members reporting the event sometimes suggested that it had, as in the following event:

Deviation from dosage for hydromorphone. The event reached the patient; the patient died after the medication was administered. Referred for peer review.

Harm was not evenly distributed among the major taxonomy categories. In fact, the percentage of events that were associated with harm varied greatly among the categories. Aside from events involving adverse drug reactions, the two categories with the highest percentages of harm were prescribing and monitoring. Therefore, although prescribing and monitoring were not among the taxonomy categories with the highest numbers of events, they still pose significant concerns regarding the potential for significant harm. See **Figure 3. Distribution of Harm in Each Taxonomy Category**.

Figure 4. Distribution of Harm in Each Location



N = 1,716 events for which both the location and harm score were indicated.
Percentages do not always add up to 100 because of rounding.
See "Harm Scores" for definitions and groupings of harm scores.
OR: operating room; PACU: postanesthesia care unit.

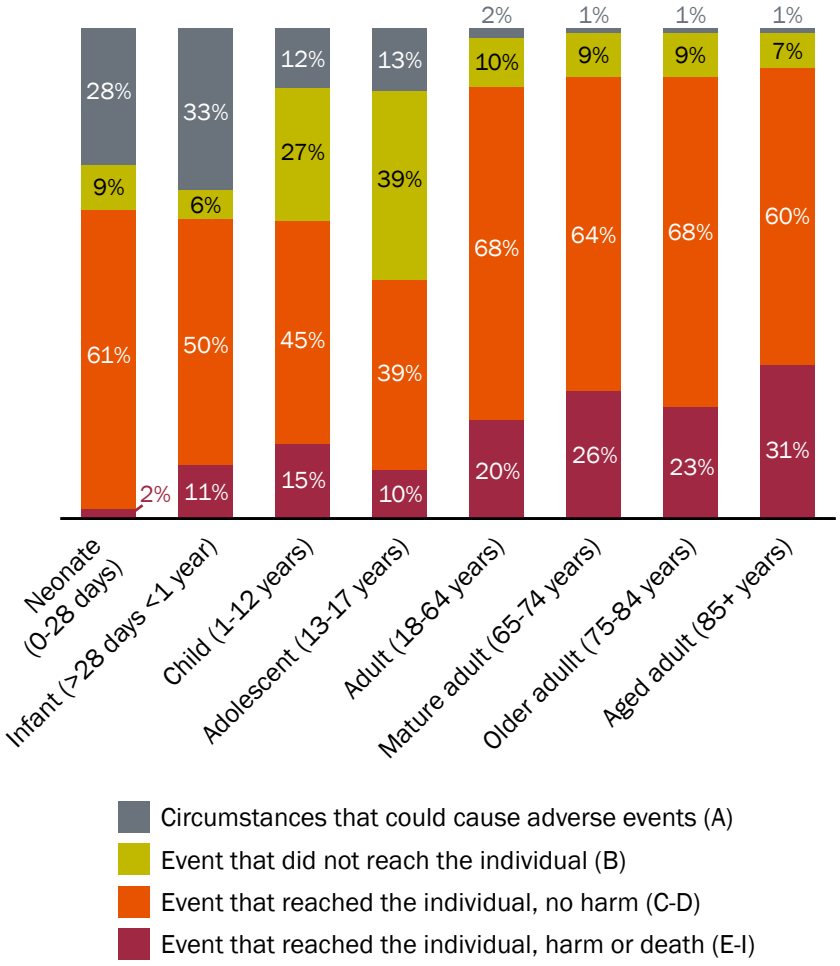
MS17358

Location

A location, based on the Agency for Healthcare Research and Quality's (AHRQ) Common Formats location categories, was known and indicated in 2,993 events (41%). Locations were indicated by the individual reporting the event rather than ECRI Institute PSO analysts, and only one location could be selected for each event. By far the most frequently implicated location was inpatient general care areas, such as medical-surgical units (43% of events with a location indicated). Other frequent locations included the pharmacy (13%), critical care areas (12%), the ED (10%), and operating rooms (ORs) or procedure areas such as the cardiac catheterization laboratory and endoscopy area, including recovery areas such as the post-anesthesia care unit (PACU) (9%).

Harm varied by location as well (see **Figure 4. Distribution of Harm in Each Location**). It is notable that some of the settings with the highest proportions of harm are those where patients' time on the unit is only temporary, such as for imaging, procedures, or outpatient care. This may suggest the need

Figure 5. Distribution of Harm in Each Age Group



N = 2,660 events for which both the age group and harm score were indicated.
Percentages do not always add up to 100 because of rounding.
See "Harm Scores" for definitions and groupings of harm scores.

MS17360

for more attention to care planning, transitions of care, and patient monitoring in these settings.

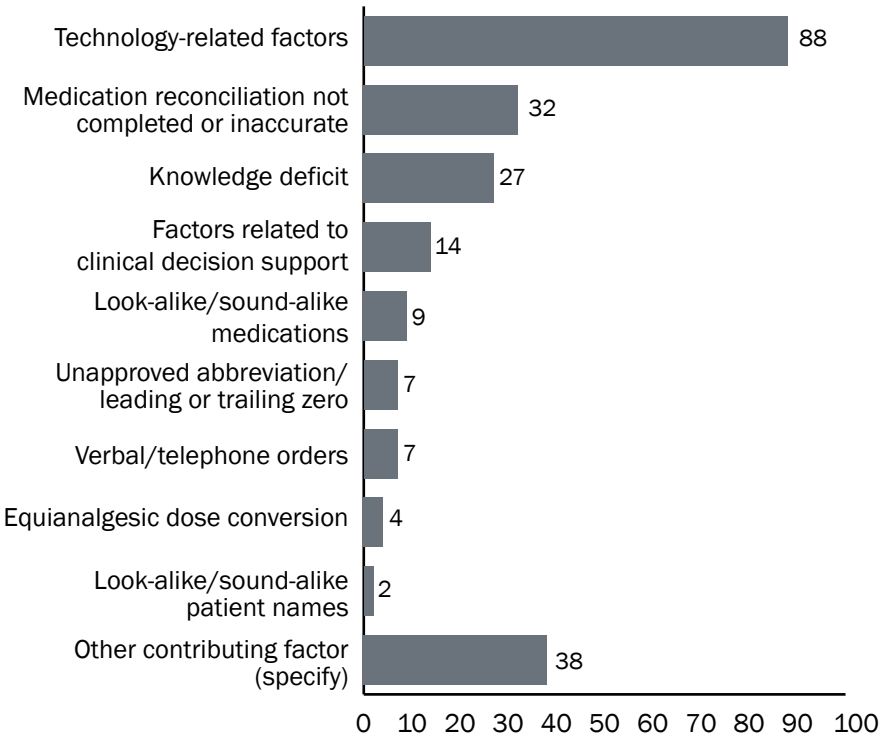
Healthcare organizations may wish to examine their own data regarding opioid-related events, including the prevalence and severity of harm, to determine whether certain locations are disproportionately represented. The patient population and service utilization of specific organizations or units should be taken into account.

Patient Age

A patient age category was indicated in 3,643 events (50%). Roughly half of these events (53%) involved adult patients, or those ages 18 to 64 years. Adults age 65 or older accounted for the next largest percentage (38%). Relatively few events (9%) involved minors.

Broadly speaking, the percentage of events involving harm increased as patient age increased; nearly one-third of events involving adults age 85 or older involved harm. See **Figure 5. Distribution of Harm in Each Age Group.** Age categories may

Figure 6. Contributing Factors Identified by Analysts



N = 215 events for which analysts identified contributing factors.
Numbers add up to more than 215 because more than one category could be selected for each event.

correlate somewhat with care areas where, for example, fewer opioids are prescribed, staff–patient ratios are higher or lower, or patient monitoring is more intensive. However, all patients receiving opioids should be considered to be at risk.

Just as healthcare organizations may analyze data regarding the locations of opioid-related adverse events, healthcare organizations may wish to examine their own data, including the prevalence and severity of harm, to determine whether certain age groups are disproportionately represented. The patient population and service utilization of specific organizations or units should be taken into account.

Contributing Factors

For 215 events (3%), ECRI Institute PSO analysts were able to identify at least one contributing factor. See **Figure 6. Contributing Factors Identified by Analysts**.

The most common contributing factor was factors related to technology; analysts who selected this contributing factor were prompted to choose a subcategory. Table 1. Contributing Factors Related to Technology outlines the number of events in which each subcategory was identified.

Table 1. Contributing Factors Related to Technology

Subcategory	Number of Events
Automated dispensing cabinet	33
Infusion pump	31
Patient-controlled analgesia	24

N = 88 events with technology-related contributing factors.

The events involving technology-related factors revealed a mix of human-factors issues and technical problems. Among events involving technology-related factors, errors in the programming of infusion pumps were frequent. In other instances, infusion pumps were found to be running at a rate other than what was ordered or the remaining volume was incorrect, but it was unclear from the event report whether this resulted from misprogramming, technical problems with the pump, or some other cause. Another frequent problem was discovering opioids that were intended to be delivered as patient-controlled analgesia (PCA) running instead as a continuous infusion, posing risks for substantial overdose. In other events, the wrong bag (e.g., the wrong concentration) was hung. Other issues included unavailability of desired medications or desired dosing in infusion pumps, sometimes leading to workarounds.

Many other technology-related events involved problems with interfaces between health information technology systems, particularly in the transmission of pain medication orders to the automated dispensing cabinet (ADC). These difficulties often led to delays in the delivery of pain medications. In some of these cases, the medication could not be accessed by override, requiring pharmacy involvement and further delaying care. The data set contained several events in which staff removed medications from the ADC for the wrong patient—and often administered the medication to the wrong patient before the error was discovered. ADC technical difficulties involving waste tracking were also frequent; some reports indicated that the ADC did not prompt the user to record the amount of waste when necessary.

Table 2. Contributing Factors Related to Clinical Decision Support

Subcategory	Number of Events
Clinical decision support not used/bypassed	6
Clinical decision support not available	5
Clinical decision support incorrect/inappropriate	3

N = 14 events with contributing factors related to clinical decision support.

Analysts who selected factors related to clinical decision support as a contributing factor were prompted to choose a subcategory. **Table 2. Contributing Factors Related to Clinical Decision Support** outlines the number of events in which each subcategory was identified.

In 38 events, analysts identified contributing factors not otherwise specifically listed in the taxonomy. Problems related to bar-code medication administration or scanning (7 events); health information technology (5 events); orders, forms, or consent (5 events); and labeling (2 events) together accounted for half the events in this category.

Action Plan: Organizational Strategies

Pain Management Team

Action Recommendation: Form an interdisciplinary team to improve pain management and the safety of opioid use in the hospital.

To improve pain management and the safety of opioid use in the hospital, it is of paramount importance to form an interdisciplinary team to guide the efforts. This team would lead related quality improvement initiatives, assess current practices, identify gaps and needs, design and implement interventions, and monitor performance. For some hospitals, the designation of a team may be more than simply a good idea; one element of performance for Joint Commission's new standard calling on hospitals to make pain management an organizational priority indicates that "a leader or leadership team" should be responsible for pain management and related performance improvement activities (Joint Commission "Prepublication Standards").

The Society of Hospital Medicine's (SHM) toolkit for reducing opioid-related adverse events suggests identifying a team leader to guide the project and liaise with executive sponsors, a project manager to coordinate the group's activities, and a champion—who may or may not also be the team leader—to promote the initiative. Executive sponsors, such as the chief medical officer or chief nursing officer, ensure that the team obtains necessary approvals and resources. Frontline clinical team members may include representatives from nursing, the pharmacy, hospitalist staff, surgery, anesthesia, respiratory therapy, and the ED. Other potential members include hospital leaders, a pain management specialist, a primary care physician, advanced practice providers, and an electronic health record (EHR) specialist. The toolkit also offers guidance regarding the formation of a charter for the project, setting of goals and objectives, rules for team operations and meetings, and the use of quality improvement tools. (SHM)

Support for the Initiative

Action Recommendation: Seek leadership support and frontline staff buy-in for the initiative.

To be effective, an initiative to improve the safety of opioids requires the support of leaders and frontline staff, as well as any committees that need to approve or monitor the progress of the initiative. For hospitals accredited by Joint Commission, leadership support is important for another reason: the agency recently added a standard requiring accredited hospitals to make "pain assessment and pain management, including safe opioid prescribing," an organizational priority (Joint Commission "Prepublication Standards"). SHM's toolkit suggests ways to identify key stakeholders, assess the support needed from each, and develop strategies to obtain that support. Involving all the identified stakeholders, particularly frontline staff, in designing improvement strategies can help garner buy-in. (SHM)

Framing the initiative in a strategic, mission-focused manner may help earn leadership support. The leadership package "Opioid-Related Events in Acute Care" illustrates patient safety, quality, and risk management concerns regarding opioid-related adverse events and lists questions for leaders to consider. These questions, which may be presented to the executive team or researched for presentation to leaders, frame opioid safety as a mission-centric strategic objective.

Gap Analysis

Action Recommendation: Conduct a gap analysis of policies, practices, tools, and resources pertaining to opioid safety.

When embarking on an opioid safety initiative, the team needs to understand current policies, practices, tools, and resources and what steps the organization must take to achieve its opioid safety objectives. Most hospitals have at least some room for improvement in regard to implementation of opioid safety practices.

The Pennsylvania Hospital Engagement Network sent a 45-item survey to hospitals participating in its adverse drug event project asking about their implementation of specific opioid safety practices. A total of 17 hospitals completed the assessment. For five items, the percentage of hospitals that had implemented the opioid safety practice described in the item exceeded 88%. These items related to use of a standardized pain scale; pharmacy purchasing or preparation of parenteral opioids; use of standardized order forms or order sets for PCA; pharmacist double checking of all opioids before dispensing; and segregation of morphine and hydromorphone in pharmacy storage.

However, the opioid safety practices described in at least seven other items had not been implemented at all in about half or more of the hospitals. These items related to inclusion of the milligrams per kilogram or micrograms per kilogram dose and the total calculated dose in orders for parenteral opioids in pediatric patients; easy pharmacist access to the patient's opioid tolerance status; restrictions on long-acting opioids; distinction between opioid-naïve and -tolerant status in pain management protocols; use of standardized order forms or order sets for oral and parenteral opioids (excluding PCA); use of "smart" infusion pumps with soft and hard stops during PCA; and access to equianalgesic dosing charts. Many other items described practices that were at best partially implemented in most hospitals. (Grissinger and Lamis)

To conduct a gap analysis, the team may need to collect and analyze data, review current policies and other documents, identify existing resources and tools, and talk with stakeholders. Factors to evaluate may include the following (SHM):

- External factors (e.g., laws and regulations, accreditation standards, guidelines)
- Relevant organizational policies
- Clinical support (e.g., pain management specialists, clinical decision support)
- Specific clinical tools (e.g., order sets)
- Provider and staff understanding of safe opioid use
- Provider, pharmacist, and nurse behaviors and concerns
- Availability and use of monitoring technology (e.g., capnography)
- Baseline metrics on the frequency of opioid-related respiratory depression and processes to promote safe use

Most of the chapters in the ECRI Institute PSO Deep Dive include a self-check tool that hospitals can use to evaluate their implementation of opioid safety practices. The team may use these self-check tools as part of the baseline assessment, as well as ongoing assessments. In addition, baseline and periodic assessments of provider and staff knowledge of safe opioid use can inform targeted education.

The findings of this Deep Dive illustrate the importance of including a wide range of locations in the gap analysis, not just inpatient general care areas. Locations such as critical care areas, the ED, ORs, and PACUs were frequently involved in events, and locations such as those where patients' time on the unit is only temporary (e.g., radiology, outpatient care areas) were associated with some of the highest proportions of harm.

The team may share the findings of the baseline assessment with some or all of the stakeholders. Much of the information collected at baseline may form the basis for monitoring of continued quality improvement efforts as the initiative progresses.

Human, Clinical, and Technological Resources

Action Recommendation: Identify existing and potential human, clinical, and technological resources to support safe opioid use.

Action Recommendation: Assess formulary options and the use of clinical decision support to standardize care appropriately while allowing for clinical judgment regarding the needs of the individual patient.

The pain management team should identify resources that currently support safe opioid use in the hospital, existing resources that could be enhanced or better leveraged to support opioid safety, and resources that could be introduced.

Examples of human resources and functions include the following:

- The pain management team and individual team members (including paid time for opioid safety activities)
- Pharmacist review of opioid prescribing
- Pain management and integrative medicine specialists
- Physical and occupational therapy
- A controlled substance diversion prevention program and team
- Behavioral health specialists
- Substance use disorder services
- Discharge planning resources for patients being discharged on opioids

Examples of clinical and technological resources include the following:

- A variety of nonpharmacologic strategies to manage pain (e.g., hot and cold packs, massage)
- Nonopioid pharmacologic pain management strategies and opioid-sparing techniques
- Formulary options based on evidence-based practices
- Tools for assessing patients before prescribing
- Prescription drug monitoring databases
- Prescriber, nurse, and pharmacist access to pain management protocols and guidelines
- Opioid dose conversion tools (e.g., tables, calculators)
- Clinical decision support tools
- Automated dispensing cabinets and related software
- Infusion pumps with dose error reduction systems
- Tools to support nurse monitoring of patients on opioids (e.g., sedation scale)
- Continuous monitoring technologies (e.g., minute volume monitoring, capnography)
- Technologies and software to prevent and detect drug diversion and analyze data
- Discharge planning resources for patients being discharged on opioids

Several organizations and guidelines promote multimodal analgesia, including nonpharmacologic and nonopioid pharmacologic options. Organizations should evaluate the need for budgetary and operational changes to support these goals. For example, current employees who are interested may be trained to provide some nonpharmacologic offerings, such as guided relaxation or distraction techniques. Additional staff may be hired to offer options such as acupuncture, massage, yoga, or tai chi. Nonopioid medications may call for budgetary analysis, as some may be more expensive than opioids, especially when administered on a scheduled, around-the-clock basis.

Acute care organizations should also evaluate their formulary and the use of clinical decision support to standardize care appropriately while allowing for clinical judgment regarding the needs of the individual patient. These issues are discussed in more detail in the full report.

Because the Deep Dive revealed a mix of human-factors issues and technical problems among technology-related contributing factors, organizations should strive to ensure not just that technologies are in place but also that they are used and function as intended. Steps may include evaluation of devices before purchase, including testing by frontline staff, and work system and process analysis (see the discussion “Proactive and Reactive Analysis”). Interfaces between health information technology systems, particularly in the transmission of pain medication orders to the ADC, may also require attention, and backup plans for efficient care processes may be needed in the event of system downtime or failure.

Proactive and Reactive Analysis

Action Recommendation: Analyze work systems, processes, and adverse events to optimize opioid safety.

Healthcare organizations seeking to improve opioid safety should analyze work systems and processes in order to identify and analyze hazards and design safety into the system. Organizations should consider applying both reactive and proactive strategies to improve performance and reduce harm.

The work system likely has a substantial impact on opioid safety. The Systems Engineering Initiative for Patient Safety model conceptualizes the work system as encompassing the person (e.g., provider, patient, biomedical engineer, unit clerk), the physical environment, organizational conditions, tasks, and technology and tools, all of which interact with one another (Carayon et al.). The pain management team may wish to evaluate the work systems in which prescribers, nurses, and pharmacists operate. For example, the American Society for Pain Management Nursing's (ASPMN) guidelines on opioid-induced respiratory depression address issues such as the practice environment, staffing, handoff communication, documentation, EHR systems and forms, quality improvement and reporting structures, and rapid response teams (Jarzyna et al.). Staffing issues to evaluate include patient–nurse ratios, nurse overtime, float nurses, pulling of nurses to other units, and nurse competencies regarding pain and opioids.

The team should identify high-risk processes within the opioid use continuum and conduct proactive risk analyses of those processes. Many methods of proactive analysis exist, but all focus on identifying and addressing concerns before an event happens. One method, failure mode and effects analysis, is a proactive, systematic method of identifying ways in which something, especially processes, can go wrong and actions to address them. Many organizations focus the efforts of their proactive analyses on high-risk processes. Lean and Six Sigma methodologies may also facilitate a proactive approach.

Reactive analysis may yield important insights into opportunities for improvement. For example, root-cause analyses (RCAs) may be conducted for opioid-related adverse events. Some organizations conduct mini-RCAs for all cases of naloxone administration in an effort to identify contributing factors and potential opportunities for improvement. Such an approach may also allow reviewers to distinguish cases of potentially preventable opioid-induced respiratory depression from those that might not have been prevented.

It is also important to consider work systems and processes when designing, implementing, and evaluating opioid safety strategies. It may help to keep processes simple, whenever safe and feasible to do so, and make it easy to do the safe thing but difficult to do the unsafe thing. By contrast, onerous processes, even if meant to enhance safety, could have the opposite effect. For example, clinicians and staff may use workarounds to circumvent new strategies that complicate workflows but provide little perceived benefit. Involving frontline staff in designing and testing opioid safety strategies may help prevent such problems. As changes are introduced, the work systems and processes should be reevaluated to determine whether the changes are effective, fit well within the workflow, and have not introduced unforeseen problems.

Policies and Procedures

Action Recommendation: Update relevant policies and procedures, striking a balance between allowing for clinical judgment and standardizing necessary elements.

Issues related to opioid safety may be addressed in a wide range of policies and procedures, such as those addressing general opioid safety, distribution of controlled substances, infusion therapy, epidural and intrathecal opioids, patient monitoring, and drug diversion. The pain management team may wish to review applicable policies and procedures, revise and harmonize them as needed, and write additional policies and procedures if required. The team should periodically review and update policies and procedures.

Care planning for patients on opioid therapy should be individualized (Jarzyna et al.). Therefore, policies and procedures should strike a balance between allowing for clinical judgment regarding the needs of individual patients and standardizing necessary elements to ensure safety. Policies and procedures that are extremely rigid may interfere with individualized care—and possibly engender workarounds—whereas those that allow vast leeway might not help to curb unsafe practices. This principle also applies to tools used to support compliance with policies and procedures, such as order sets and clinical decision support.

One particular issue to address in policies and procedures is the organization's approach to the use of range orders versus "dosing to numbers." There is a "nonlinear relationship" between pain scale ratings and opioid dose; orders that direct opioid dosing based solely on pain scale ratings—called dosing to numbers—have been linked to higher rates of adverse events (SHM). A position statement from ASPMN asserts that prescribing of opioids based exclusively on pain intensity should be prohibited, stating that "pain intensity is just one component of a proper pain assessment."

ASPMN recommends having pain management experts offer guidance in developing safe, effective practices for pain management. The position statement also specifically recommends that organizations list, in pain assessment policies and the EHR, both subjective measures (e.g., pain intensity) and objective measures for prescribers and nurses to consider before prescribing or administering opioids. Objective factors to consider may include patient age, comorbidities, response to previous treatments, use of other sedating medications, sedation level, and respiratory status (Pasero et al.)

The position statement recommends establishing a "foundation" of scheduled, around-the-clock nonopioid pain medications, as well as nonpharmacologic interventions, for postoperative and acute trauma pain, adding opioids on top of that foundation only as needed. It also advocates for the appropriate writing and interpretation of range orders, which ASPMN addresses in a separate position paper. (Pasero et al.) The full report includes a discussion about PRN therapy and range orders.

Education and Training

Action Recommendation: Educate clinicians and staff regarding opioids, their safe use, and relevant policies, procedures, and tools.

In this Deep Dive, knowledge deficit was the third most common contributing factor to opioid-related adverse events, and other sources have identified gaps in clinician and staff knowledge regarding safe use of opioids.

For example, as part of its adverse drug event collaboration, the Pennsylvania Hospital Engagement Network created an 11-item opioid knowledge quiz and distributed it to hospitals participating in the collaboration in 2012 and again in winter 2013–2014. Pharmacists, physicians, residents, physician assistants, nurse practitioners, and nurses from 10 hospitals completed the quiz during both periods; a total of 1,758 individuals from the 10 hospitals completed the survey in 2012, and 829 completed it in 2013–2014.

The average number of questions answered correctly was 6.5 in 2012 and 7.0 in 2013–2014, representing a statistically significant but small degree of improvement. In addition, four questions were each answered incorrectly by at least 40% of respondents, with two of those being answered incorrectly by 63%. These four questions asked respondents to identify patients who might be considered opioid tolerant, the most important predictor of respiratory depression in patients on intravenous (IV) opioids, agents that can potentiate the effects of hydromorphone for patients on ventilators, and the best option to control the pain of a patient who continues to report moderate to severe pain five minutes after receiving IV hydromorphone. (Gaunt et al.)

Education and training of clinicians and staff does not by itself guarantee improvement in opioid safety in the hospital. But it is necessary for such improvement. Healthcare organizations should educate prescribers, nurses, pharmacists, and others regarding opioids, their safe use, and relevant policies, procedures, and tools.

Repeated education and training on opioids may be more effective than single, infrequent sessions. Organizations should consider providing educational experiences in a variety of formats, media, and venues. Examples include grand rounds, morbidity and mortality conferences, simulation, discussion at medical staff meetings, interactive media, components of the credentialing and recredentialing process, one-to-one coaching, and accessible tools and guidelines. (Jarzyna et al.; SHM)

This Deep Dive includes a slide deck that may be incorporated into a comprehensive educational strategy. The training program may be used to educate prescribers, pharmacists, nurses, and others involved in the care of patients receiving opioids. Organizations may use the training program, modifying it as necessary to suit their audience and organizational practices, or develop their own.

Some of the health systems that ECRI Institute PSO spoke with for this Deep Dive said that they embrace transparency, highlighting adverse events involving opioids and discussing them openly with staff in an effort to underscore why the issue is important. In addition, Joint Commission's *Sentinel Event Alert* on safe use of opioids in hospitals suggests that organizations analyze adverse events, near misses, and staff observations to inform staff education. (Joint Commission "Safe Use") The training program included in this Deep Dive discusses a few events unearthed by this Deep Dive, but hospitals may wish to consider their own experience as well when designing educational sessions.

If after training and education providers and staff do not follow safe, evidence-based practices, reevaluation of the work system and processes may be indicated. See the discussion "Proactive and Reactive Analysis" for more information.

Quality Improvement and Feedback

Action Recommendation: Use quality improvement tools and approaches.

Action Recommendation: Give feedback on performance to individual clinicians and units, as appropriate.

During an opioid safety initiative and thereafter, it is vital to monitor performance in regard to pain management and opioid safety. A new element of performance for Joint Commission's existing standard addressing the medical staff's role in performance improvement indicates that the medical staff should take an active role in pain management by establishing quality metrics and analyzing performance data. Similarly, new elements of performance for existing standards addressing the collection and analysis of performance improvement data state that such data should include those pertaining to pain assessment, pain management (including interventions and their effectiveness), and the use of opioids (e.g., prescribing data, naloxone usage). (Joint Commission "Prepublication Standards")

The pain management team may help the medical staff develop metrics and will likely engage in the routine analysis of performance improvement data. The team should meet regularly to review performance regarding selected measures and plan ongoing quality improvement strategies. Different phases of an opioid safety initiative may call for more or less frequent meetings.

The team should track and analyze process and outcome measures related to opioid use and safety. A variety of means may be used to collect data, such as automated or triggered electronic reports, manual or electronic chart review, observation, analysis of departmental logs or reports (e.g., incident reports, administrative data, risk management data, rapid response team logs), and surveys of providers or patients. For each quantitative measure, organizations should choose metrics, such as percentages, rates, numbers, or medians, that are meaningful and meet their needs. Some events may call for more in-depth review instead of or in addition to quantitative tracking. See "Potential Measures for Opioid Safety" for a list of process and outcome measures that organizations may consider tracking, depending on their circumstances and needs. Periodic group discussions, walkrounds, surveys, and informal discussions with stakeholders not directly involved in the pain management team, including patients, may provide qualitative information that may not otherwise be captured.

Feedback on individual, unit-based, and organizational performance should be provided to various stakeholders, as determined by the pain management team. Prescribers may be given individualized feedback, such as reports regarding their patterns of opioid prescribing and naloxone administration. These reports may include comparison of the individual's performance with all other peers, top performers, or both. Unit leaders or unit-based opioid safety champions may receive feedback on their unit's performance. The organization may also wish to establish and evaluate nurse competencies in patient assessment, opioid administration (e.g., implementation of range orders, if the organization uses them), and patient monitoring.

Although naloxone administration is a key measure, and one widely used in the organizations participating in this Deep Dive, not every instance of naloxone administration necessarily represents a case of preventable opioid-induced respiratory depression. Naloxone does have other uses, and patients sometimes develop opioid-induced respiratory depression even when the opioid is prescribed and administered in an appropriate manner for the individual patient. An extremely low rate of naloxone administration could even represent underprescribing of appropriate opioid medications (SHM). The pain management team should keep these issues in mind when analyzing and acting on naloxone administration data.

Potential Measures for Opioid Safety

Potential Outcome Measures

- Review of patient deaths
- Related peer review cases
- Rapid response team calls related to opioids
- Naloxone usage (possibly excluding PACU, ED, or both)
- Unplanned transfers to intensive care unit owing to opioid-related events
- Unplanned mechanical ventilation owing to opioid-related events
- Opioid-related adverse effects other than oversedation (e.g., delirium, vomiting)
- Patient complaints about untreated pain
- Scores on Hospital Consumer Assessment of Healthcare Providers and Systems survey
- Calls to patient advocates
- Adherence to applicable accreditation standards
- Incidents involving diversion
- Liability or healthcare costs involved in opioid-related adverse events

Potential Process Measures

- Education of patients and family members
- Completion of a risk assessment before prescribing
- Prescribing and administration in accordance with policies
- Reviews of medication utilization (e.g., naloxone, high doses of opioids, long-acting opioids, supplemental oxygen)
- Response to clinical decision support alerts
- Documented patient monitoring in accordance with policies
- Staff understanding of procedures for responding to adverse events

Sources: Society of Hospital Medicine. Frederickson TW, Gordon DB, De Pinto M, et al., eds. Reducing adverse drug events related to opioids (RADEO): implementation guide. 2015 [cited 2017 Jun 6]. http://www.hospitalmedicine.org/Web/Quality_Innovation/Implementation_Toolkits/RADEO/Web/Quality___Innovation/Implementation_Toolkit/Radeo/radeo_home.aspx; Quinlan-Colwell, Ann, PhD, AHNBC, RN-BC (Clinical nurse specialist, pain management, New Hanover Regional Medical Center). E-mail to: ECRI Institute. 2017 Jul 14.

References

Carayon P, Schoofs Hundt A, Karsh BT, et al. Work system design for patient safety: the SEIPS model. Qual Saf Health Care 2006 Dec;15 Suppl 1:i50-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2464868/ PubMed: https://www.ncbi.nlm.nih.gov/pubmed/17142610

Centers for Medicare and Medicaid Services (CMS):

Opioid misuse strategy 2016. 2017 Jan 5 [cited 2017 Jun 13]. https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf

State operations manual. Appendix A: Survey protocol, regulations and interpretive guidelines for hospitals. 2015 Nov 20 [cited 2017 Apr 13]. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

Davies EC, Green CF, Taylor S, et al. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS One 2009;4(2):e4439. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2635959/ PubMed: https://www.ncbi.nlm.nih.gov/pubmed/19209224

DuPen A, Shen D, Ersek M. Mechanisms of opioid-induced tolerance and hyperalgesia. Pain Manag Nurs 2007 Sep;8(3):113-21. http://www.sciencedirect.com/science/article/pii/S1524904207000768?via%3Dihub PubMed: https://www.ncbi.nlm.nih.gov/pubmed/17723928

Gaunt MJ, Alghamdi D, Grissinger M. Results of the 2013-2014 opioid knowledge assessment: progress seen, but room for improvement. Pa Patient Saf Advis 2014 Sep [cited 2017 Jun 9]. http://patientsafety.pa.gov/ADVISORIES/Pages/201409_124.aspx

Grissinger M, Lamis RL. Results of the PA-HEN organization assessment of safe practices for a class of high-alert medications. Pa Patient Saf Advis 2013 Jun [cited 2017 Jun 9]. http://patientsafety.pa.gov/ADVISORIES/Pages/201306_59.aspx

Hooten M, Thorson D, Bianco J, et al. Pain: assessment, non-opioid treatment approaches and opioid management. Institute for Clinical Systems Improvement guidelines. 2016 Sep [cited 2017 Feb 16]. https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_neurological_guidelines/pain/

Jarzyna D, Jungquist CR, Pasero C, et al. American Society for Pain Management Nursing guidelines on monitoring for opioid-induced sedation and respiratory depression. Pain Manag Nurs 2011 Sep;12(3):118-45.e10. http://www.aspmn.org/documents/GuidelinesonMonitoringforOpioid-InducedSedationandRespiratoryDepression.pdf PubMed: https://www.ncbi.nlm.nih.gov/pubmed/21893302

Joint Commission:

Prepublication requirements: standards revisions related to pain assessment and management. 2017 Jun 19 [cited 2017 Jul 7]. https://www.jointcommission.org/assets/1/18/HAP_Pain_Jan2018_Prepub.pdf

Safe use of opioids in hospitals. Sentinel Event Alert 2012 Aug 8;(49):1-5. https://www.jointcommission.org/sea_issue_49/

Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology 2015 Mar;122(3):659-65. http://anesthesiology.pubs.asahq.org/article.aspx?articleid=2087871 PubMed: https://www.ncbi.nlm.nih.gov/pubmed/25536092

National Coordinating Council for Medication Error Reporting and Prevention. Index for categorizing medication errors. 2001 Feb 20 [cited 2017 Mar 7]. http://www.nccmerp.org/types-medication-errors

Pasero C, Quinlan-Colwell A, Rae D, et al. Prescribing and administering opioid doses based solely on pain intensity: a position statement by the American Society for Pain Management Nursing. Pain Manag Nurs 2016 Oct;17(5):291-2. http://www.aspmn.org/Documents/Position%20Statements/Dose_Numbers_PP_Final.pdf PubMed: https://www.ncbi.nlm.nih.gov/pubmed/27663218

Society of Hospital Medicine (SHM). Frederickson TW, Gordon DB, De Pinto M, et al., eds. Reducing adverse drug events related to opioids (RADEO): implementation guide. 2015 [cited 2017 Jun 6]. http://www.hospitalmedicine.org/Web/Quality_Innovation/Implementation_Toolkits/RADEO/Web/Quality___Innovation/Implementation_Toolkit/Radeo/radeo_home.aspx

U.S. Drug Enforcement Administration (U.S. DEA). Practitioner's manual. Section I: Introduction. 2006 [cited 2017 Apr 13]. https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section1.htm

U.S. Food and Drug Administration (U.S. FDA). Fact sheet: FDA opioids action plan. 2016 Sep 13 [cited 2017 Apr 12]. https://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM484743.pdf

Weinger MB, Lee LA. No patient shall be harmed by opioid-induced respiratory depression: proceedings of Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period conference. APSF Newsl 2011 Fall;26(2):21,26-8. http://www.apsf.org/newsletters/html/2011/fall/01_opioid.htm

Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA 2003 Oct 8;290(14):1868-74. http://jamanetwork.com/journals/jama/fullarticle/197442 PubMed: https://www.ncbi.nlm.nih.gov/pubmed/14532315

Opioid-Related Events in Acute Care

For the ECRI Institute PSO *Deep Dive™: Opioid Use in Acute Care*, analysts examined more than 7,200 opioid-related events reported to ECRI Institute PSO and its partner PSOs.

WHAT DO WE ALREADY KNOW?

HARM

Opioids are the **second most frequent** class of medications to cause adverse drug reactions in hospitals

Source: Davies et al.

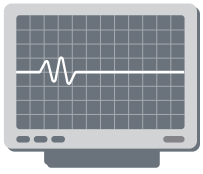
1. Loop diuretics
2. **Opioid analgesics**
3. Systemic corticosteroids

Naloxone, a reversal agent, is given to **2 to 7 of every 1,000** postoperative patients on opioids

Source: Weinger and Lee

LIABILITY

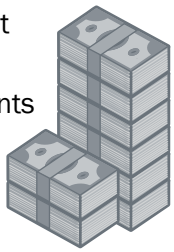
Cases of postoperative opioid-induced respiratory depression in an anesthesia closed claims analysis:



77% resulted in death or severe brain damage

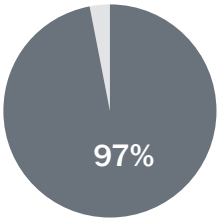
Source: Lee et al.

The median payment was $216,750, but about 1 in 4 payments was greater than $600,000



Source: Lee et al.

97% were preventable



Source: Lee et al.

COSTS

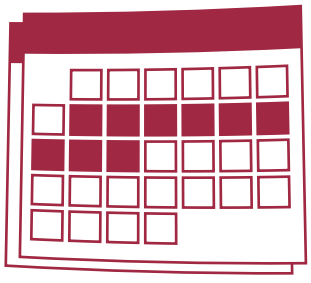
A case of postoperative respiratory failure adds:

Description	Debit	Credit
Additional healthcare charges for postoperative respiratory failure	$54,000	

Source: Zhan and Miller

9 days to length of stay

$54,000 in additional healthcare charges



Source: Zhan and Miller

REFERENCES

Davies EC, Green CF, Taylor S, et al. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. PLoS One 2009;4(2):e4439.

Lee LA, Caplan RA, Stephens LS, Posner KL, Terman GW, Voepel-Lewis T, Domino KB. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology 2015 Mar;122(3):659-65.

Weinger MB, Lee LA. No patient shall be harmed by opioid-induced respiratory depression: proceedings of Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period conference. APSF Newsl 2011 Fall;26(2):21, 26-8.

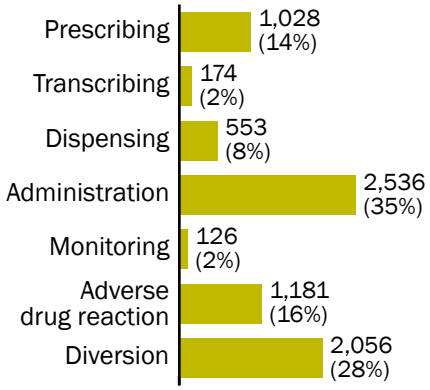
Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA 2003 Oct 8;290(14):1868-74.

WHAT DID ECRI INSTITUTE PSO LEARN?

ECRI Institute PSO analyzed 7,218 reports involving opioids over a nearly three-year period, using a taxonomy to analyze opioid-related failure modes.

FREQUENCY OF FAILURE MODES

Event Breakdown by Taxonomy Category



MOST COMMON FAILURE MODES

Administration: Wrong medication, wrong rate or frequency, wrong dose, incorrect or omitted documentation, administration of opioids without an order, inadequate patient assessment at administration

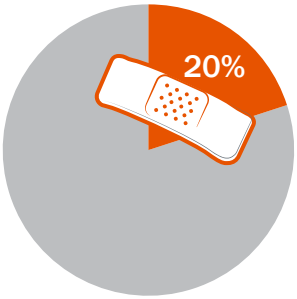
Diversion: Unsecured controlled substances, discrepancies between an opioid count and reconciliation, removal of opioids without documentation of administration, failure to witness or document wastage

Dispensing: Stocking or storage errors

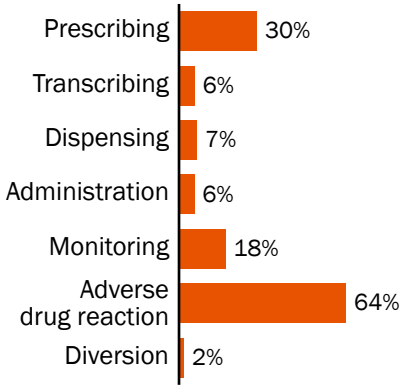
Prescribing: Polypharmacy, wrong dose, duplicate orders

HARM

Harm occurred in 20% of events with a harm score indicated.



Events with Harm in Each Taxonomy Category



FAILURE MODES MOST OFTEN ASSOCIATED WITH HARM

Monitoring: Failure to monitor analgesic effectiveness, failure to monitor sedation level

Prescribing: Inadequate risk assessment before prescribing, polypharmacy, failure to determine opioid tolerance, wrong dose, wrong rate or frequency, wrong route

Administration: Patient-controlled analgesia by proxy, unavailability of a reversal agent, failure to remove a used fentanyl patch

OPIOIDS: DO WE NEED TO IMPROVE?

QUESTIONS TO CONSIDER

- How might improving the safety of opioid use support our mission, vision, and goals?
- Do our culture, staffing, and work environment support safe opioid use?
- Who is responsible for opioid safety in our organization?
- In what ways do we monitor the safety of opioid use?
- How well do we perform, in terms of both outcomes and processes for opioid safety? What are our goals?
- Do we engage in analysis, discussion, and learning from opioid-related adverse events?
- Have we undertaken quality improvement initiatives related to opioids?
- What concerns do frontline staff have regarding opioid safety?
- How do we help set realistic patient expectations regarding pain in the hospital?
- What alternatives to opioids do we offer to manage patients' pain in the hospital?
- In recent years, are we seeing more patients with risk factors for opioid-induced respiratory depression, such as sleep apnea? Do our approaches adequately account for these risk factors?
- What commonalities are there among patients who experience opioid-related adverse drug events?
- How do we support ongoing education and training related to opioids?
- What measures, including policies, processes, and technologies, are in place to support safe opioid use?
- How effective are our methods of monitoring patients receiving opioids?
- Have we made prevention and detection of controlled substance diversion an organizational priority?
- Does our approach to inpatient opioid use comply fully with applicable laws, regulations, and standards?
- How might a high-profile opioid-related incident, such as a drug diversion, affect our reputation?
- Do providers and staff follow best practices related to opioids? If not, why not?
- Do clinicians feel pressured to prescribe and administer opioids to achieve patient satisfaction?
- What do our frontline staff do on a daily basis to facilitate safe use of opioids, and how can we support and build on those activities?

For information on accessing the full report, including more results, action plans, tools, and case studies, go to https://www.ecri.org/opioids.

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