Leadership

PAIN CONTROL POSES RISKS

For more than a decade, Joint Commission accreditation standards have underscored patients’ rights to have their pain assessed and managed (Joint Commission “Facts”). Healthcare providers have responded, approaching pain as the fifth vital sign and requiring assessment and measurement of pain, just as for other vital signs such as blood pressure, heart rate, and body temperature.

But pain management is not without risks. Opioids can keep patients pain-free, but if used inappropriately, they can lead to patient injury. Opioids, also called narcotic analgesics, are known as high-alert medications, which can cause significant harm to a patient or death if they are used incorrectly (Joint Commission “High-Alert”). Refer to “Common Opioids” for a list of those commonly used in hospitals.

Opioids’ sedative effects can spiral into respiratory depression and respiratory arrest, the most serious of opioid-induced adverse effects, if the patient receives too much of the drug. When respiratory depression becomes life threatening, the patient may require naloxone to reverse the effects of the opioid, resuscitation to restore breathing, and endotracheal intubation to deliver oxygen.

OPIOIDS AND MEDICATION ERRORS

Opioids are among the top drug categories associated with adverse drug events in hospitalized patients, prompting the Joint Commission to issue a Sentinel Event Alert in August 2012 to promote safer use of the drugs in hospitals (Joint Commission “Safe”). Sentinel events involving opioids represent about 2% of all sentinel events in the Joint Commission’s database for 2004 through 2011.

Other reports have also found that opioid medication errors are common in hospitals. For example, an analysis of almost 3,700 adverse drug reactions among hospitalized patients found that opioids were the second most frequently implicated drug group, following diuretics. (Davies et al.) Treating opioid-related adverse events can tack on additional days to the patient’s hospital stay and increase costs to care for each affected patient, according to an analysis conducted by researchers at Duke University School of Medicine (Oderda et al.).

Because of their harmful effects if used in error, opioids may also be more frequently associated with claims involving medication errors. In an analysis by The Doctors Company, a physician medical malpractice insurer, of 2,646 medical professional liability claims closed in 2011, 5.8% were associated with medications. Of those, opioids were the most frequently implicated medication class, representing 17.5% of all medication-related claims (Troxel).

“DARK SIDE” OF PAIN MANAGEMENT

Opioid-related events could be on the rise because clinicians are treating pain more aggressively in response to the Joint Commission’s pain management standards (Jarzyna et al.). Indeed, citing a twofold increase in opioid-related oversedation events following the implementation of a pain management program at a cancer center, one author calls opioid medication

Perfecting Pain Control to Eliminate Opioid Administration Errors

- Screen patients for risk of oversedation and respiratory depression.
- Standardize order sets for opioids and reversal agents.
- Establish protocols and checklists for opioid infusions.
- Require independent double checks of opioid doses and preparations.
- Establish patient monitoring protocols using pulse oximetry and capnography.
- Ensure access to reversal agents for opioid overdoses and to resuscitation equipment.
- Use infusions pumps with dose error reduction features, and set dose limits for opioids.
- Avoid creating patients’ unrealistic expectations for pain control.
errors the “dark side” of the Joint Commission’s pain management standards (McClead).

Tying hospital patient satisfaction scores, which factor the organization’s approach to pain control, to reimbursement could also lead to more aggressive approaches to pain management. Starting in 2012, the Centers for Medicare and Medicaid Services (CMS) began using results from the Hospital Consumer Assessment of Healthcare Providers and Systems, or HCAHPS, survey, a standardized survey instrument to measure patients’ perspectives of hospital care, to calculate incentive payments for hospitals providing high-quality care. The 27-question survey devotes three questions to pain management, giving healthcare facilities a powerful incentive to aggressively manage patients’ pain. Additionally, patients’ responses about pain management and other questions from the survey are made publicly available on CMS’s Hospital Compare website, which provides consumers with hospital-specific quality data based on information reported to the Medicare program.

While healthcare providers may feel pressure to do everything they can to control a patient’s pain, their prescription practices for opioids are also under greater scrutiny. Fatal prescription opioid overdoses now account for at least 15,000 deaths annually in the United States, surpassing the annual number of motor vehicle deaths as well as combined deaths from cocaine and heroin (Alexander et al.). The U.S. Food and Drug Administration says that extended-release and long-acting opioids, known as OxyContin, Duragesic, and other brand names, are misprescribed and misused. Consequently, the agency is stepping up efforts to educate doctors about proper pain management and drug selection and to improve patient awareness about how to use the drugs safely.

Balanced Approach to Pain Management
In this environment, where pain management is both a patient right and a patient safety risk, healthcare executives must take a leadership role in ensuring that their organizations have a balanced approach to pain management that addresses the patient’s pain control needs and also the patient’s right to receive safe, high-quality care.

If they haven’t done so already, healthcare executives should confirm that their organizations have addressed the concerns raised by the Joint Commission in its Sentinel Event Alert on the safe use of opioids in their facilities. To do so, their organizations should consider the following strategies:

► Examine medication events involving opioids in their organizations to identify any problem areas in the medication-use process related to pain medicines.

► Shift the focus from individual caregivers’ mistakes in handling opioids to system solutions that support the safe use of opioid analgesics.

► Recognize that the safe use of opioids requires a variety of interventions with the input of multiple disciplines within the organization, including medical staff, nursing, pharmacy, clinical engineering, and others.

This issue of PSO Navigator reviews events involving opioid administration reported to ECRI Institute PSO over a one-year period and, based on the findings, provides strategies to ensure the safe administration of these high-alert medications for acute pain.* For a summary of key strategies, refer to “Perfecting Pain Control to Eliminate Opioid Administration Errors.” While the focus of this article is on improving opioid administration, errors can also occur in other phases of the opioid-use process, such as prescribing and dispensing, and healthcare organizations should evaluate all phases of the medication-use process to reduce opioid-related events.

Common Opioids
- Fentanyl
- Hydrocodone
- Hydromorphone
- Meperidine
- Methadone
- Morphine
- Oxycodone

* In addition to the review provided by ECRI Institute PSO’s advisory council, ECRI Institute PSO acknowledges the input provided by Sydney M. Dy, M.D., M.Sc., associate professor, health policy and management, Duffey Pain and Palliative Care Program, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Medicine (Baltimore, Maryland), and Julie Waldfogel, Pharm.D., CPE, clinical pharmacy specialist, pain and palliative care, Johns Hopkins Hospital.
What We Are Seeing

OPIOID ADMINISTRATION ERRORS

ECRI Institute PSO reviewed events involving opioids reported to the organization during 2012 and found that events were commonly associated with the administration stage of the medication-use process, although those errors can start earlier in the process. For example, if a wrong-dose order is not caught when the pharmacist dispenses the drug, the nurse could unknowingly administer the wrong dose of the medication.

Because events are voluntarily reported to ECRI Institute PSO, the findings are a snapshot of medication events associated with opioids. Nevertheless, ECRI Institute PSO’s Deep Dive™ analysis of medication mishaps also found that most events occurred during medication administration. In that analysis, opioids were among the top medication categories associated with administration errors (see “Table 1. Opioids among Top Five Medication Classes Associated with Administration Errors”).

Not only were administration errors the most frequent of medication events in the PSO’s Deep Dive report, they were also the most serious. Preventing harmful errors at the administration stage is particularly challenging because there is no one between the nurse and the patient who might detect the potential error and intercept it.

In other studies of medication errors, opioid administration errors have figured prominently. In an analysis of 644 harmful opioid errors reported on inpatient units of 222 facilities, 60% were administration errors. (Dy et al.) The study excluded events associated with devices, such as patient-controlled analgesia (PCA), although it did include intravenous (IV) infusions of opioids. Common errors included the following:

- Starting IV infusions at too-high doses
- Confusing immediate-release and sustained-release oxycodone
- Forgetting to change or remove fentanyl patches

An analysis of 4,223 opioid incidents reported to the U.K.’s National Patient Safety Agency also found that the majority, 67%, were administration errors. Nearly 80% of the incidents occurred in hospitals; 6% of all incidents resulted in moderate harm to patients, and the remaining caused either low or no harm. (NPSA)

OPIOID ADMINISTRATION ERRORS

BY EVENT TYPE

ECRI Institute PSO reviewed the administration events involving opioids and found problems related to the wrong dose, wrong route of administration, and wrong drug administered. Events also occurred when caregivers were administering multiple pain modalities.

Wrong Dose

Several events involved the administration of the wrong opioid dose. For example, obtaining the wrong dose of a medication from an automated dispensing cabinet or neglecting to administer the correct dose, as in the following event:

_The patient was prescribed 7.5 mg of immediate-release morphine. The dose available in the dispensing cabinet was 15 mg. The nurse intended to split the tablet to modify the dose before giving it to the patient but did not do so before giving the whole tablet to the patient._

Several wrong-dose administration events occurred because an infusion pump was programmed...
incorrectly. Misplacement of a decimal point in programming the pump to deliver, say, 5 mg of an infusion of pain medication instead of 0.5 mg results in a tenfold medication dosing error, as in the following event:

A tenfold morphine overdose was administered by an incorrectly programmed infusion pump. The patient was given naloxone to reverse the effects of the overdose.

Wrong-dose errors also occurred with misprogramming of PCA pumps, as in the following event:

The PCA pump was programmed to deliver a demand dose of morphine every 10 minutes instead of every 30. The continuous rate was set correctly. The patient initiated several demand doses but did not experience any effects of oversedation when the error was caught.

Despite policies to prevent wrong-dose errors by requiring an independent double check of high-alert medications, such as opioid infusions, dosing errors occurred when the policies were ignored:

A PCA pump was set to deliver 2,000 mcg/mL of hydromorphone instead of 400 mcg/mL. A second nurse did not double check the infusion setting.

While some misprogramming events of a PCA pump had the potential to cause opioid overdoses, there were other programming errors that led to inadequate treatment of the patient’s pain, which can cause significant patient distress. The study of 644 harmful opioid errors found that while half of the errors (52%) were overdose mistakes, about one-fourth of the errors (23%) caused underdosing and uncontrolled pain (Dy et al.), as in the following event reported to ECRI Institute PSO:

During the shift change, the PCA pump settings were checked and found to be set to deliver a lower dosage of pain medicine than what was ordered. The continuous rate was set at 0.04 mg/hr instead of 0.4 mg/hr. The demand dose was set at 0.02 mg instead of the ordered demand dose of 0.2 mg.

Numerous wrong-dose errors involved very young or elderly patients. These and other patient groups—e.g., patients with sleep apnea, patients who are morbidly obese, patients taking other sedating drugs—are at higher risk of opioid-induced respiratory depression (Joint Commission “Safe”). Wrong-dose errors resulting in higher-than-prescribed opioid doses can increase that risk.

Wrong-Dose Errors with Patches
Several events involved fentanyl patches, which administer a potent opioid through the skin for around-the-clock treatment of severe pain for several days. Underdosing errors occurred when the patch was incorrectly applied—for example, the plastic peel-away section was applied to the skin instead of the patch. Overdosing errors occurred when caregivers neglected to remove a patch before applying another. Active ingredients remain in the patch even after the normal three days of wear. In the following event, the patient mistakenly had two patches, and both were delivering pain medication, resulting in a fentanyl overdose:

During the patient’s stay, the patient was given a fentanyl patch for chronic pain. The patient was discharged with a new patch. The patient was found unconscious at home the next day and readmitted. The first patch was not removed when the second patch was applied.

Wrong Route
Potentially fatal drug administration errors occurred when opioids were delivered by the wrong route for patients receiving multiple pain medications intended for delivery via different routes, as in the following event involving IV and epidural infusions for an infant:

An order for nurse-controlled analgesia (NCA) and an epidural infusion was given for an infant on a pediatric medical-surgical unit to treat pain following surgery. The nurse delivered a bolus IV infusion of pain medication that was intended for slower absorption as an epidural bolus. The infant experienced respiratory depression and needed to be resuscitated.

Wrong Drug
Some opioid medications, such as oxycodone, are available in immediate- and controlled-release formulations. The formulations are distinguished by an “IR” or a “CR” after the drug name. In one event, the patient was mistakenly given three
doses of the controlled-release formulation instead of the immediate-release tablets, which may have resulted in less pain relief for the patient.

Other events occurred with drug mix-ups. For example, in one event, the caregiver, trying to save time, pulled two drugs from a dispensing cabinet to give to two patients. The patient who was supposed to receive morphine by IV infusion was given an anti-inflammatory infusion intended for the other patient. In this case, there was no harm to the patient.

More serious mix-ups have occurred when hydromorphone (Dilaudid) is confused with morphine. Hydromorphone is an alternative to morphine for treating pain, and the two similarly named drugs are sometimes confused as equivalent; however, hydromorphone is at least four times as potent as morphine and, if mistakenly administered instead of morphine, can result in a lethal overdose of the drug (“Inadvertent”). With other event reporting programs, mix-ups of these two medications outnumber all other common medication pairs that contribute to wrong-dose errors (“Common”). Similar mix-ups have been reported to ECRI Institute PSO, as in the following event, which involved substituting morphine for the more potent hydromorphone:

I thought the doctor ordered morphine when Dilaudid was ordered. The patient received morphine.

Lessons Learned

Patient safety issues with opioids, such as the administration errors reported to ECRI Institute PSO, can arise due to a number of factors (Colquhoun et al.):

- Large selection of opioids, available in multiple concentrations
- Variety of dosage forms (e.g., tablets, injections, infusions, patches)
- Variety of formats for the drug’s release (e.g., immediate-release, controlled-release, extended-release)
- Look-alike and sound-alike names (e.g., hydromorphone and morphine)
- Administration by a variety of routes (e.g., oral, intramuscular, IV, epidural, transdermal)
- Administration often requiring other technology (e.g., IV infusion, PCA pumps)
- Patient monitoring requirements

Numerous strategies to reduce errors involving high-alert medications, such as opioids, address many of these issues by standardizing drugs and doses, limiting availability of floor stock, restricting access to opioids outside the pharmacy, differentiating look-alike and sound-alike products, and verifying the drug and dose with an independent double check before the
high-alert medication is administered. Refer to “Table 2. System Safeguards for Opioid Administration” for a summary of these approaches. The safeguards are presented in terms of their ability to stop errors from occurring. ECRI Institute PSO recommends that facilities consider a combination of strategies. Some, such as staff and patient education, while important, will not prevent all mishaps. They must be used with other higher-impact strategies, such as using infusion pumps with dose error reduction capabilities that can prevent wrong-dose errors, or with moderate-impact strategies, such as standardizing opioid therapy order sets, to reduce the likelihood that errors will occur.

More detailed information is available from ECRI Institute on the safe use of high-alert medications, safe medication administration, and other related topics (see “ECRI Institute Guidance”).

Three strategies to reduce errors with opioids—patient monitoring to detect respiratory depression, procedures for independent double checks, and opioid event analysis using the organization’s databases—deserve an in-depth look.

**Monitoring**

While opioid administration errors are the most common problem with opioids in the medication-use process, monitoring errors—insufficient, improper, or untimely monitoring—are the top issues leading to malpractice claims and lawsuits for patients receiving opioids. As illustrated in “Figure. Medication-Related Errors in Narcotic Analgesic Claims,” monitoring errors represented almost 35% of 30 claims involving opioids, according to the closed claims analysis of medication errors by The Doctors Company.

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**Table 2. System Safeguards for Opioid Administration**

<table>
<thead>
<tr>
<th>Low Impact</th>
<th>Moderate Impact</th>
<th>High Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop education programs to heighten clinical practitioners’ (nurses, pharmacists, and physicians) and patients’ awareness of opioid risks.</td>
<td>Eliminate multiple drug strengths where possible.</td>
<td>Dispense medications in unit-dose formulations.</td>
</tr>
<tr>
<td>Enlist pain specialists and pharmacists in developing a patient’s pain management plan.</td>
<td>Limit the variety of opioids available in the organization’s formulary.</td>
<td>Use premixed infusion products.</td>
</tr>
<tr>
<td>Ensure that patient information (e.g., known allergies to opioids) is readily accessible to staff.</td>
<td>Use the smallest drug concentration and dose for floor stock.</td>
<td>Remove concentrated oral opioids from floor stock and dispensing cabinets.</td>
</tr>
<tr>
<td>Develop goals with the patient for pain control, and avoid creating unrealistic expectations.</td>
<td>Standardize order sets for opioids and reversal agents.</td>
<td>Incorporate clinical decision support in electronic ordering systems to reduce drug ordering errors that escape detection.</td>
</tr>
<tr>
<td>Screen patients for risk of oversedation and respiratory depression.</td>
<td>Require pharmacy review of high-dose opioid orders that are not in the standard order sets.</td>
<td>Use technologies, such as bar-code administration systems, designed to enhance medication administration safety.</td>
</tr>
<tr>
<td>Require a full-body assessment of a patient’s skin when a fentanyl patch is applied to ensure no other patches remain, and document in the medication administration record where the new patch is placed on the patient.</td>
<td>Differentiate look-alike and sound-alike opioid therapies, such as morphine and hydromorphone; use tall man lettering to reduce confusion from look-alike names (e.g., HYDROMorphine and morphine).</td>
<td>Use infusion pumps with dose error reduction features, and set dose limits for opioids.</td>
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*For information on obtaining ECRI Institute reports, contact ECRI Institute PSO at psohelpdesk@ecri.org.*
Unrecognized opioid-induced sedation and respiratory depression is a serious patient safety concern. Several of the events reported to ECRI Institute PSO—e.g., wrong dose, wrong route of administration—either led to respiratory depression or had the potential to do so but were detected before patients were harmed.

Patients receiving opioids, particularly through infusions in which the risk of overdosing is high, must be carefully monitored to detect oversedation. Although staff should regularly check on the patient to assess pain level, responsiveness, respiratory rate, and other vital signs, this practice may be inadequate since an overly sedated patient can be aroused and asked to respond to questions but will fall back into deep sedation when the nurse leaves (Ritter).

ECRI Institute PSO and other organizations, such as the Institute for Safe Medication Practices and the American Society of Anesthesiologists, suggest that continuous monitoring with pulse oximetry and capnography may be appropriate in some cases, especially for patients identified as at risk of respiratory depression (ISMP; ASA). Risk factors include obesity, history of sleep apnea, older age, the need for increased opioid dosing, the first 24 hours after opioid therapy is started, and concomitant administration of other sedating agents, such as antihistamines (Jarzyna et al.).

While pulse oximetry monitoring, a technique to noninvasively monitor oxygen saturation, is in place in some organizations for patients receiving opioid infusions, capnography is less frequently used, even though it can provide earlier warning of respiratory depression than pulse oximetry (Nelson et al.). Capnography, or end-tidal carbon dioxide monitoring, is primarily used as a reliable monitor of respiratory rate. Since oxygen saturation is an indicator that only changes after respiration has become difficult, pulse oximetry may not indicate a problem with the patient’s breathing early enough for effective intervention.

Organizations should provide staff with guidance on when to use continuous monitoring with pulse oximetry and capnography for patients receiving opioids. One health system, recognizing that greater use of capnography to monitor patients was a “cultural shift,” emphasized frontline clinician involvement in developing policies and procedures for monitoring of patients receiving PCA therapy (Maddox and Williams).

Facilities should also educate staff to assess patients for risk of respiratory depression, be aware of the risk of oversedation, recognize signs of opioid toxicity, and know what to do when such

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**Figure. Medication-Related Errors in Narcotic Analgesic Claims**

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Percentage of Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring errors</td>
<td>34.5</td>
</tr>
<tr>
<td>Drug administration</td>
<td>17.2</td>
</tr>
<tr>
<td>Failure to follow guideline</td>
<td>13.8</td>
</tr>
<tr>
<td>Wrong medication</td>
<td>13.8</td>
</tr>
<tr>
<td>Ordering errors</td>
<td>10.3</td>
</tr>
<tr>
<td>Wrong dosage</td>
<td>10.3</td>
</tr>
</tbody>
</table>

events occur. For guidance, organizations may want to refer to the American Society for Pain Management Nursing’s Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression (Jarzyna et al.).

**Independent Double Checks**

Despite hospital policies requiring an independent double check before administration of a high-alert medication, such as an opioid, the events reported to ECRI Institute PSO indicate that staff sometimes ignored the policy or that mistakes occurred, even when an independent double check was performed.

An independent double check is effective only when two clinicians separately check the information—the drug, dose concentration, patient’s identification, and line connection and infusion pump setting if the drug is delivered by an infusion.

Organizations should periodically reinforce with staff the importance of independent double checks before opioids are administered and what is meant by the policy. A nurse can unintentionally bias another nurse by asking the individual to check that the pump is correctly programmed to deliver hydromorphone when the order actually says the infusion should contain morphine. The individual conducting the independent double check should compare the drug information and pump settings to the actual order. To simply confirm what one nurse asks another to check is not an independent verification of the planned drug administration.

**Event Analysis**

ECRI Institute PSO has found that events are sometimes misclassified. What looks like a medication error—a wrong dose of morphine was administered—may actually be a health information technology issue because the computerized provider order entry system failed to alert when the morphine dose exceeded preset safe dose limits. The result is that certain event reports, filled with important information, may go unused for detecting patterns and trends. When analyzing events involving opioids, organizations must mine their event reporting systems to identify all the events related to opioids. For example, searching for reports involving naloxone, an antidote for opioid overdoses, may uncover opioid dosing errors that would otherwise go unnoticed. Look for additional incidents, such as patient falls, intubation, and activation of a rapid response team—all of which could be related to opioid errors.

By identifying as many events as possible involving opioids, the organization can develop a full picture of its strengths and weaknesses to ensuring the safe use of opioids and then take steps to eliminate unsafe practices.

**REFERENCES**


Joint Commission:


Data Snapshot

Frequency/Severity Matrix for Near-Miss Events in Labor and Delivery Helps Prioritize Improvement Efforts

Including near-miss events in an event reporting program allows an organization to analyze the cause of system breakdowns and other factors contributing to their occurrence and to put prevention strategies in place before any patients are harmed. One healthcare system used a process to look at the frequency and possible severity of near-miss reports in labor and delivery to prioritize the events and prevention strategies.

Near-miss events were reported in 0.69% of the 203,708 deliveries performed in 2010 at the system’s 104 hospitals. The three most common types of near misses were medication error (33% of near misses), patient identification error (19%), and failure to obtain or delay in obtaining laboratory results (11%). Existing barriers (e.g., functions in the electronic medical record, protocols for multiple checks of patient identification bands) were highly effective in preventing many high-frequency, low-hazard errors from reaching the patient. However, barriers to prevent high-frequency, high-hazard errors—such as physician failure to respond (10% of near misses) and failure to follow protocol (9%)—from reaching the patient were few and less effective. The system used these findings to focus patient safety efforts on areas of greatest need and targeted its immediate resources on high-hazard, high-frequency events to reduce their frequency and to establish effective barriers to prevent errors from causing harm. The healthcare system reported that a matrix analysis, as depicted in the figure of near-miss events in labor and delivery, is more effective at targeting resources for patient safety.