Inpatient opioid safety events: beyond a justifiable adverse drug reaction

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Introduction and background

Opioids are high-alert, frequently used medications and their use is high risk and problem prone. The Vizient® Patient Safety Organization (PSO) team reviewed 56 opioid-related safety events in which naloxone was used to reverse adverse effects that were voluntarily reported to the PSO from January 2017 through May 2018. More than 70% of the events reviewed were classified as adverse events, not medication errors, and not preventable. Review of the events revealed improvement opportunities at each phase of the medication process.

Aim

To identify opportunities to improve quality, safety and health care outcomes related to opioid use.

Methods

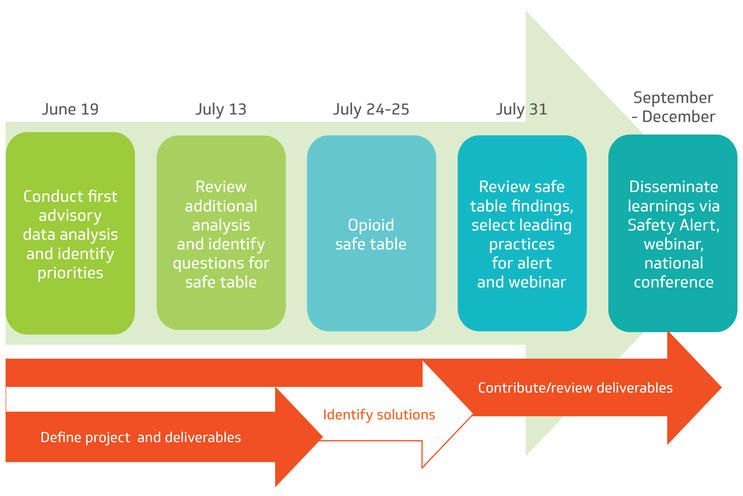
The Vizient PSO conducted a review of 56 opioid-related safety events that included documented naloxone use reported between January 2017 and May 2018. The study was limited to cases in which opioids were used for pain management.

The Vizient PSO invited an interdisciplinary team of experts including physicians, pharmacists, nurses, and directors of medication safety to advise on this topic. Members of this advisory team are specialists in pain management and are involved in opioid stewardship programs at their organizations.

Figure 1 shows the timeline for the opioid safety project. The advisory team reviewed the data analysis and results of a literature review and identified additional questions to be addressed during safe table deliberations and analysis. The safe table allows members to hold privileged and confidential deliberations and analysis about opioid use in the hospital setting and identify evidence-based leading practices that they could implement to improve quality, patient safety, and health care outcomes.

A Safety Alert was published to call attention to the opportunities identified, disseminate lessons learned, and provide evidence-based recommendations for preventing opioid-related adverse events. An opioid safety webinar to share leading practices will be held in November 2018 and will offer nursing, pharmacy and physician continuing education credits.

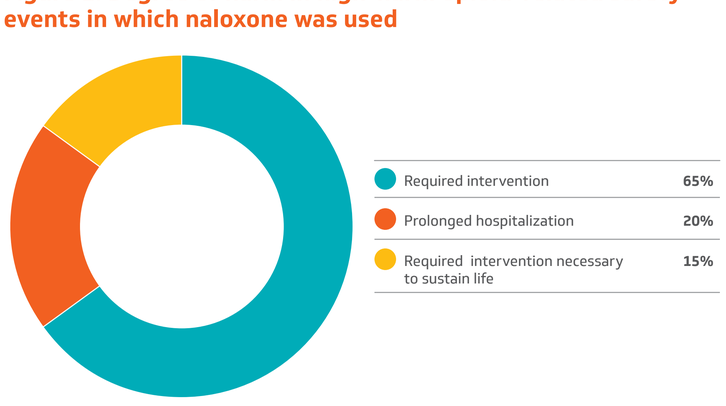
Figure 1. Opioid safety project timeline



Findings

A total of 56 cases were identified in which pain management with one or more opioids was associated with use of naloxone to reverse adverse effects. In more than a third of these cases, additional intervention was required to sustain life or hospitalizations were extended as a result of the event (Figure 2).

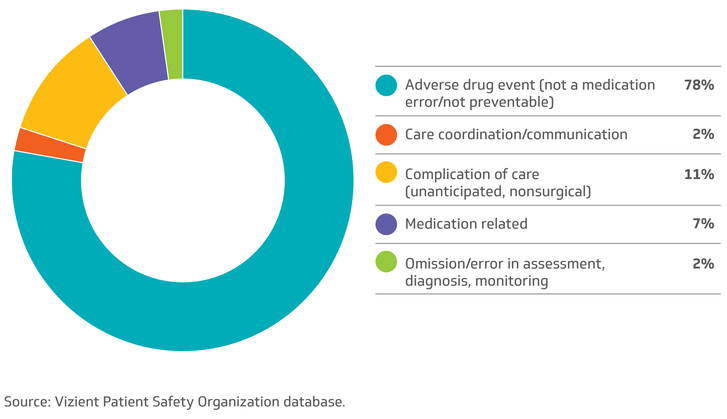
Figure 2. Degree of harm in high-harm opioid-related safety events in which naloxone was used



Source: Vizient Patient Safety Organization database.

Seventy-eight percent of the events were classified by the reporting organization as adverse events that were not preventable (Figure 3). Opportunities for improvement, including standardizing hospital procedures, were identified at each phase of the medication process.

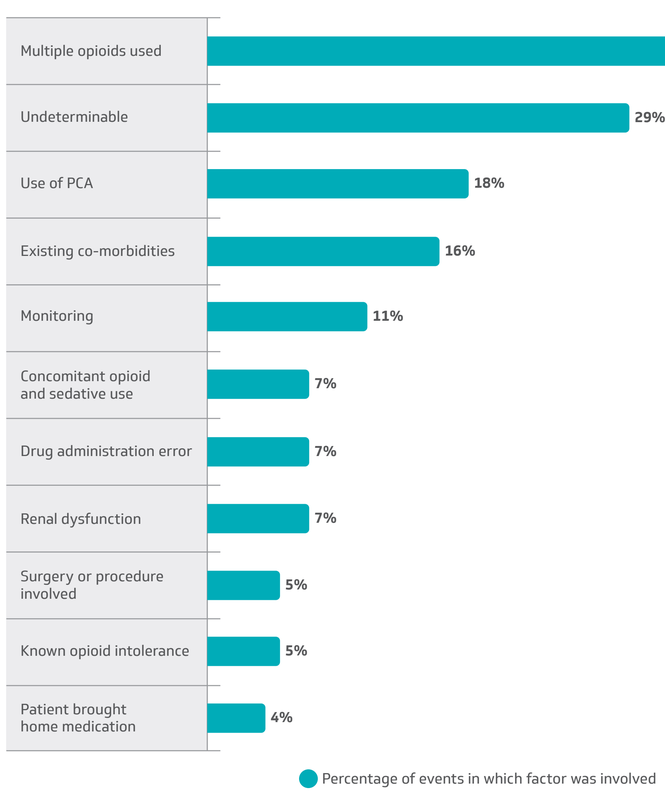
Figure 3. Reported event type classifications for high-harm opioid-related safety events in which naloxone was used



Source: Vizient Patient Safety Organization database.

Factors that contributed to the safety events and were reported in the Vizient PSO database were identified and compared against existing literature and by the expert advisory team (Figure 4).

Figure 4. Factors contributing to high-harm opioid-related safety events

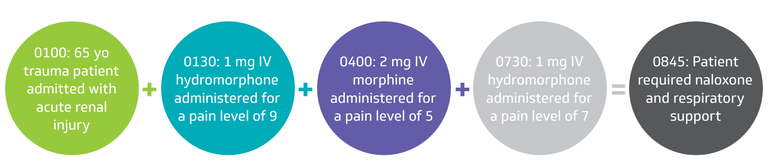


Source: Vizient Patient Safety Organization database.
Abbreviation: PCA = patient-controlled analgesia.

In a plurality of cases, multiple opioids and/or sedatives were given despite a Food and Drug Administration black-box warning about the dangers of additive respiratory depression associated with concomitant administration[1], outside of procedural sedation. It is critical to identify patients receiving both types of drugs and individualize their dosages.

When multiple opioids are prescribed for patients based on severity of pain and one is administered initially for severe pain, it is often unclear to nurses when to administer the next opioid for a lower pain level. For example, one patient over 65 with multiple comorbidities and post-traumatic injury was prescribed acetaminophen by mouth every 4 hours as needed for pain score 1-3, intravenous (IV) morphine every 6 hours as needed for pain score 4-6, and IV hydromorphone every 6 hours as needed for pain score 7-10. The patient deteriorated and required naloxone rescue. Review of the record revealed that the patient had received multiple doses within a 6-hour period for pain at various levels (Figure 5). It is also possible that the prescriber may not have fully understood the patient's risk factors and comorbidities. Factors such as advanced age, renal or hepatic impairment, obstructive sleep apnea (OSA), and opioid sensitivity should be taken into account when prescribing opioids.[2-3]

Figure 5. Timeline of an opioid-related safety event requiring naloxone and respiratory support



Source: Vizient Patient Safety Organization database.
Abbreviations: IV = intravenous, mg = milligram, yo = years old.

In some cases, patients were reported to have brought medications from home and self-administered them without providers' knowledge, resulting in adverse reactions.

There were also reports of patients with known drug dependence on methadone who required naloxone. It is not clear whether the providers relied on patient-reported history or checked with the methadone provider about dosages. This potential improvement opportunity was discussed in the safe table with regard to use of fentanyl patches in patients taking this medication for extended periods and the need to confirm patient history using a reliable pharmacy database or source.

Pulse oximetry is often used to monitor patients, but when supplemental oxygen is administered the patient's true respiratory status may be masked.[3] Therefore, oxygen saturation levels alone should not be relied on; monitoring of sedation level, quality and rate of respirations as assessed by a registered nurse is necessary. In high-risk patients who require supplemental oxygen, it is recommended that the quality of ventilation and respirations are monitored, such as continuous capnography monitoring.[3] In one case reported to the PSO, the patient's alarms had been turned off. Since it is well documented that alarm fatigue is a significant issue, monitoring devices must be supplemented with monitoring by an appropriately trained professional.

Forty-five percent of patients who required naloxone were age 65 and older; 90% of the PCA events and 45% of the multiple-opioid events reviewed were in patients 65 and older who are classified as high risk (Figure 6).

Figure 6. Percentage of patients 65 or older prescribed multiple opioids or PCA

Recommendations

Evaluate medication use to guide safer pain control.[2]

- Establish a leadership team that includes a representative from each phase of the medication process, including a patient, to evaluate and improve opioid use.
- Conduct a drug usage evaluation study and failure modes and effects analysis to evaluate each phase of the opioid medication process.
- Conduct a root-cause analysis for all unplanned uses of naloxone in cases where opioids are being given for pain management.
- Define structure, process, and outcome metrics for each phase in the opioid medication process to measure preventable adverse drug events (ADEs) and emergent reversals (e.g, number of naloxone use for ADE as determined by pharmacist, percent of opioid doses administered prior to pharmacist review, number of patients who met indications for continuous capnography and were not monitored).
- Review all opioid events submitted to the Vizient PSO for preventability; edit the event type prior to submitting; and share findings with front-line staff to help turn these events into learning opportunities.

Ensure that providers have access to the necessary clinical information when prescribing and that pharmacy verification is completed before administration of opioids.[4]

- Obtain an accurate medication history to avoid drug interactions and determine opioid tolerance; use a state-level prescription drug monitoring program to verify prior opioid use, dose, frequency, refills and renewals.[4,5]
- Identify risk factors for opioid related adverse effects (age >/ = 65 years; obesity, renal or hepatic impairment, respiratory dysfunction including chronic obstructive pulmonary disease and sleep apnea; opioid naïve, intolerance of or sensitivity to opioids; taking other central nervous system depressants); reduce the starting dose of opioids by at least 50% for high-risk patients.[1,2,5,8,9]
- Use screening tools for sleep apnea — such as STOP-Bang[10]— before prescribing opioids and take precautions to prevent hypoxia and respiratory depression.

Improve organizational opioid prescribing practices.

- Guide safe prescribing through order sets for pain management, including options for opioid-sensitive or opioid-naïve patients, and high-risk patients in a clinical decision support system.[6]
  - To prevent "opioid-stacking," for each patient, limit one active opioid order prescribed at a time with specific dose, criteria and frequency. If the patient requires an order to manage breakthrough pain, prescribe a short-acting opioid.
  - Use a multimodal pain management plan and begin pain management with nonopioid therapy whenever possible. When necessary, prescribe the lowest effective opioid dose, with consideration to the patient's comorbidities, risk factors, age and pain level.[2,5]
  - Reserve I.V. administration of opioids for when a patient is clinically unable to take oral opioids, immediate pain control or rapid titration is necessary.[7]
- Use validated or institutionally developed opioid dosage conversion charts when prescribing[11]; consider consulting a pain management specialist or pharmacist when there is uncertainty about a prescribed opioid dose.
  - Consider incomplete cross-tolerance when converting from one opioid to another and reduce the calculated dose by 25 to 50% when making conversions.[5]
- Evaluate PCA guidelines and prescribing practices.[8]
  - Carefully evaluate use of basal rates in patients with PCA pumps.
  - Assess the use of smart infusion pumps to prevent dose entry or programing errors.
  - Avoid use of other opioids and central nervous system depressants while the patient is using a PCA.
  - Conduct continuous capnography monitoring for patients on PCA pumps and require assessment by a clinician for respiratory depression and decreased mental status. Investigate use of PCA pumps that incorporate capnography monitoring technology.
  - Educate patients and family about PCA use before initiating a PCA; emphasize that family and friends may not administer on-demand doses.

Proactively monitor and assess patients who are prescribed opioids.

- When naloxone is given, watch patients for recurrent respiratory depression and decreased mental status after reversal in case repeat naloxone dosing is necessary; if appropriate, consider transferring the patient to an area with an adequate nurse-to-patient ratio to enable safe monitoring after naloxone administration.[12]
- Utilize continuous capnography monitoring in high-risk patients, patients with a PCA and patients receiving supplemental oxygen. Intermittent monitoring may not capture a patient's true ventilation status and delay recognition of over-sedation. Pulse oximeters display oxygen saturation levels and may conceal the patient's true respiratory status when supplemental oxygen is administered.[2,3]
- Require sedation scale documentation in the electronic medical record with tools such as the Pasero Opioid-induced Sedation Scale or Richmond Agitation-Sedation Scale prior to when an opioid dose is given, whenever a pain score is captured and when the effects of the opioid are at their peak (15 to 30 minutes after parenteral administration and one to two hours after oral administration), in addition to assessment of patient's vital signs, rate and quality of respirations at least every four hours, and more often for high-risk patients, extended release preparations, and patients on PCAs.[2,3,13]

Follow an organization's policies and procedures to ensure that the patient does not have access to medications from home during hospitalization to prevent drug interactions.

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