Lessons Learned from Opioid Events

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Today’s Objectives

- To Share the **What, Why and How**
  - What events we saw
  - Why events happened
  - How we can make care safer
About ECRI Institute

► Independent, not-for-profit applied research institute
► Improving safety, quality and cost effectiveness
► 50 year history, 450 multidisciplinary staff, 25 acre campus
► Evidence-Based Practice Center
► Federally Listed PSO
<table>
<thead>
<tr>
<th>Since 1971</th>
<th>Since 2003</th>
<th>Since 2008</th>
<th>Since 2013</th>
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<tbody>
<tr>
<td>Medical Product</td>
<td>Contractor for state</td>
<td>Patient Safety</td>
<td>Partnership for</td>
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<td>Reporting Voluntary</td>
<td>reporting</td>
<td>Organization</td>
<td>Health IT Patient</td>
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<td>Incidents, RCAs,</td>
<td>Mandatory Incidents</td>
<td>Voluntary</td>
<td>Safety</td>
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<td>Near Misses</td>
<td>Near Misses</td>
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<td>Voluntary multi-</td>
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<td>stakeholder</td>
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6 million reports
Motivation

72,000 in 2017

64,000

Overdose deaths (2016)

CDC


JAMA

• Daily reminders of addiction as public health issue
• Still seeing preventable events reported to PSOs
• Events in submitted RCAs
• Featured in Top 10s
Overdose deaths

Injuries, Costs, and Liability

**HARM**

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

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: Davies et al.

Source: Weinger and Lee

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**LIABILITY**

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

- 77% resulted in death or severe brain damage
- The median payment was $216,750, but about 1 in 4 payments was greater than $600,000
- 97% were preventable

Source: Lee et al.

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**COSTS**

A case of postoperative respiratory failure adds:

- 9 days to length of stay
- $54,000 in additional healthcare charges

Source: Zhao and Miller
Deep Dive Methodology

- Searched PSO database using opioid drug-related keywords
- Event dates Jan 1, 2014 and Sep 30, 2016 (2 yrs, 9 mos)
- Focused on high-yield event types:
  - Medications
  - Falls
  - Device/Supply/HIT
  - Surgery/Anesthesia
  - Other
- 11,386 events reviewed for relevance
- 7,218 deemed relevant and further classified
Methodology
Data Analysis

Inclusion criteria

- Event dates between 1/1/2014 – 9/30/2016
- Event Types - Medication, Falls, Device or Medical/Surgical Supply/HIT, Surgery or Anesthesia and Other
  - Events related to End of Life Care were excluded

- 11,388 events reviewed by analysts for relevance
- 7,218 deemed relevant and further classified
Taxonomy/Categories I

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.
Events with harm level noted

- Prescribing: 481
- Transcribing: 114
- Dispensing: 184
- Administration: 1586
- Monitoring: 73
- ADR: 782
- Diversion: 406

Harm
No Harm
Events with harm level noted

- Prescribing: 143
- Transcribing: 6
- Dispensing: 13
- Administration: 103
- Monitoring: 13
- ADR: 500
- Diversion: 9

After ADRs, Prescribing events are associated with most harm.
The next levels of the taxonomy were developed to identify specific processes and failure modes associated with each category.

<table>
<thead>
<tr>
<th>1. Prescribing</th>
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</thead>
<tbody>
<tr>
<td>1.1 Opioid risk assessment inadequate</td>
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<tr>
<td>1.1.1 Assessment not performed</td>
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<tr>
<td>1.1.2 Assessment incorrect</td>
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<tr>
<td>1.2.3 Assessment not documented</td>
</tr>
<tr>
<td>1.2 Failure to determine opioid tolerance</td>
</tr>
<tr>
<td>1.2.1 Tolerance not assessed</td>
</tr>
<tr>
<td>1.2.2 Tolerance assessed incorrectly</td>
</tr>
<tr>
<td>1.2.3 Tolerance not documented</td>
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Most Common Failure Modes in the Data Set

**Administration**
- Wrong medication administered
- Wrong rate or frequency
- Wrong dose
- Incorrect or omitted documentation
- Administration of opioids without an order
- Inadequate patient assessment at administration

**Dispensing**
- Stocking or storage errors

**Diversion**
- Unsecured controlled substances
- Discrepancies in opioid counts
- Removal of opioids without documentation of administration
- Failure to witness or document wastage

**Prescribing**
- Polypharmacy*
- Wrong dose*
- Duplicate order

*Failure modes associated with high frequency and high harm
Most Common Failure Modes Associated with Harm

**Administration**
- Patient-controlled analgesia (PCA) by proxy
- Unavailability of a reversal agent
- Failure to remove a used fentanyl patch

**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

*Failure modes associated with high frequency and high harm
Prescribing
Prescribing Events

- A patient was found unresponsive. Naloxone and oxygen were administered, and the patient responded. The patient had been prescribed many sedating medications, including large doses of opioids, although she had no history of taking opioids at home.

- Two sets of post-C-section orders were entered for the same patient. One set was ordered by anesthesia, and one set was ordered by obstetrics/gynecology. Each set contained orders for hydromorphone and at least one other opioid. The pharmacist noticed and discontinued all the duplicate orders.
Prescribing-Related Failure Modes

n = 1,028 events with at least one prescribing-related failure mode
Action Recommendations: Prescribing

► Patient Assessment: Assess patients for pain, risk of pain, and risk factors for opioid-related adverse events.

► Care Planning: Develop individualized pain management plans that consider the patient’s needs from the beginning of treatment though discharge and beyond.

► Therapy Selection and Dosing
  ■ Favor a multimodal approach to pain management, incorporating nonpharmacologic, nonopioid pharmacologic, or opioid-sparing modalities when appropriate.
  ■ Educate prescribers and develop clinical tools to support safe selection and dosing of opioid therapy.
**Action Recommendations: Prescribing**

- **Order Sets:** Standardize pain management options.
- **PRN Therapy and Range Orders:** Ensure that range orders are written in a clear and unambiguous manner.
- **Patient-Controlled Analgesia:** Enact systems and practices to improve the safety of PCA prescribing.
- **Clinical Decision Support:** Leverage clinical decision support functions to improve opioid prescribing.

**Order Review and Consultation:**

- Institute mechanisms to support effective pharmacist review of medication orders.
- Consider making specialists (e.g., pain management specialists) readily available for consultation and referral.
Challenge of CDS for opioids

- Wide range of appropriate doses
- Normal to have multiple active opioid orders concurrently for different pain levels, limiting relevance of alerts against duplicate therapy
- Respiratory depression is function of drugs administered, not necessarily of what has been ordered
- Multiple opioids administered concurrently with varying clearance times
CDS Strategies

- Alerts for drug-drug interactions (e.g., with benzodiazepines)
- Uncommon to force discontinuation of orders
- Automated prompt to reconsider necessity after 72 hrs
- Defaulting opioid orders to 3 or 7 days on ED discharge
- Max 30 days of therapy at discharge
- Cognitive aids for switching among opioids or renal dose adjustment
Administration
Administration Events

- The patient was administered 40 mg oxycodone in error. BCMA was not used as required. The nurse assumed that the tablets were 10 mg each but later discovered that they were 20 mg.

- When a patient was transferred from telemetry to the ICU, it was noted that the patient's level of consciousness had decreased; the order for a fentanyl patch was discontinued as a result. Four days later, two patches were found on the patient: one had no date, and the other was dated the day before the order was discontinued.
Administration-Related Failure Modes

n = 3,025 events with at least one administration-related failure mode
Action Recommendations: Administration

► Assess work systems and processes in order to identify and analyze hazards in opioid administration and design safety into the system.
► Engage patients and family members in developing their pain management plan.
► Conduct a pre-administration assessment before giving patients opioids.
► Consider implementing bar-code scanning technologies and ADCs in any clinical location where medication is administered.
► Review policies and procedures on medication administration
Action Recommendations: Administration

- Ensure that practitioners who administer opioids interpret range orders appropriately.
- Promote the safe administration of parenteral opioids by implementing evidence based processes.
- Monitor documentation practices to ensure that there is complete and accurate documentation of opioid administration.
- Ensure that practitioners who administer opioids possess the necessary skills for safe administration.
Monitoring
Monitoring Events

► In the early-morning hours, the patient asked for the nurse to come to the room. When the nurse entered the room, the patient, who was feeding her newborn, started to cry. She told the nurse that she didn't think she should have acetaminophen/oxycodone at night. She said, “I was holding him and the next thing I knew, he was crying on his belly on the floor beside the bed.” The baby’s vital signs were recorded and he was taken for assessment.

► An ED patient was given IV hydromorphone and discharged 23 minutes later—before the 30 minutes required by protocol. While walking out, the patient fell in the waiting room.
Monitoring-Related Failure Modes

n = 152 events with at least one monitoring-related failure mode
Action Recommendations: Monitoring

- Choose appropriate modalities, durations, intensities, and frequencies of monitoring for each individual patient.
- Continually evaluate patients in the PACU, and ensure that patients are not discharged from the PACU before standardized criteria are met.
- Ensure that patients receiving opioids in general inpatient care areas are appropriately monitored.
- Implement continuous monitoring, using transcutaneous minute ventilation monitoring or capnography, for patients at heightened risk for respiratory depression.
Action Recommendations: Monitoring

- Ensure that patients receiving opioids are adequately monitored during transport off of the clinical unit.
- Ensure appropriate monitoring of patients receiving opioids during moderate and deep sedation.
- Implement procedures, protocols, and systems for effective response to opioid-related adverse effects.
Areas to focus for risk mitigation

- Proactive assessment across medication use process
- Use data already available in your EHR
- Communicate back to clinicians
- Leverage technology for monitoring and intervention
INsight® Proactive Assessment

Why?

- Identify opportunities to mitigate risks
- Multidisciplinary perspective on risks related to current practices
- Measures staff perceptions of compliance
- Provides benchmarking reports that can be used to develop an action plan

Key Areas

- Prescribing
- Dispensing
- Administration
- Monitoring
- Quality
INsight® Proactive Assessment
Opportunities for improvement across all domains

- Hard stops for excessive opioid doses
- Equianalgesic dosing charts in pharmacy system
- Orders for reversal included whenever opioids prescribed
- Order sets distinguish naïve vs tolerant patients
- Pharmacy system checks for max daily opioid dose

N = 26 provider organizations
Encouraging signs

- Pennsylvania HEN helped hospitals reduce naloxone use 42% and RRT activation 58%
- Michigan HEN focus on perioperative use of opioids increased preop MOSS assessments by 40% and reduced preoperative naloxone to 0%
- Opioid prescribing dropped nationally 22% between 2014-17
- Increasing use of PDMPs
Thank you!