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ECRI Institute PSO Deep Dive: Opioid Use in Acute Care

Stephanie Uses, PharmD, MJ, JD
Patient Safety Analyst, ECRI Institute

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Objectives

- Understand the event analysis process utilizing the taxonomy developed to classify events related to opioid use
- Identify failure modes in medication practices involving opioids
- Recognize errors related to the use of opioids when they occur
- Identify strategies to improve practices around the use of opioid medications

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ECRI Institute

- 50 year history
- Independent non-profit with strict conflict of interest policies
- Multidisciplinary staff of 450
- Evidence-based Practice Center
- Patient Safety Organization
- Testing, investigation labs
- Deep expertise in systems improvement

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PSO Background

- Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) Signed into law July 29, 2005
- Final rule released November 21, 2008 and took effect January 19, 2009
- CMS issued final regulations for Sec. 1311 of the Affordable Care Act in March of 2016
  - PSOs and hospitals working together to collect, report and analyze patient safety events, and implementation of a comprehensive person-centered hospital discharge program;
    - or
  - documentation to reflect implementation of other patient safety initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events
- May 2016 Patient Safety and Quality Improvement Act of 2005- HHS Guidance

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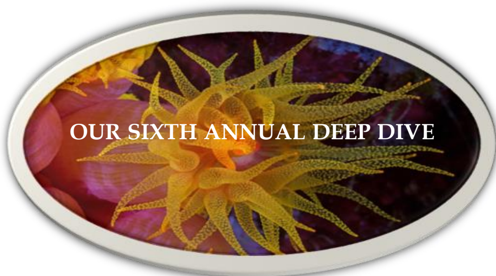

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Our Previous Deep Dive Reports

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6th Annual Deep Dive: It's More Than a Book!

- Infographics
- Case examples
- Action recommendations
- Interview-based case studies
- Supplementary articles

Ages of patients involved in events with prescribing-related failures

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Why Opioid Use in Acute Care?

- ECRI Institute identified more than 11,000 events reported that were related to opioid use between January 1, 2014, and November 30, 2016
- Adverse events related to opioid use are included in our Top 10 Patient Safety Concerns for 2018 as well as our Top 10 Health Technology Hazards for 2017

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Harm
What do we already know?

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

Source: 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.

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

Source: 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.

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Liability and Costs
What do we already know?

- Cases of postoperative opioid-induced respiratory depression in an anesthesia closed claims analysis
  - 77% resulted in death or severe brain damage
  - Median payment $216,750
    - But about 1 in 4 payments was greater than $600,000
  - 97% were preventable
- A case of postoperative respiratory failure adds:
  - $54,000 in additional healthcare charges
  - 9 days to length of stay

Sources: 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;233(3):659-65; 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.

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Concerns after Hospital Discharge

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CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search MMWR Only

Morbidity and Mortality Weekly Report (*MMWR*)

CDC > MMWR

Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015

Weekly / July 7, 2017 / 66(26);697–704

Gery P. Guy Jr., PhD[1]; Kun Zhang, PhD[1]; Michele K. Bohm, MPH[1]; Jan Losby, PhD[1]; Brian Lewis[2]; Randall Young, MA[2]; Louise B. Murphy, PhD[3]; Deborah Dowell, MD[1] (View author affiliations)

View suggested citation and related materials

Abstract

Background: Prescription opioid–related overdose deaths increased sharply during 1999–2010 in the United States in parallel with increased opioid prescribing. CDC assessed changes in national-level and county-level opioid prescribing during 2006–2015.

Methods: CDC analyzed retail prescription data from QuintilesIMS to assess opioid prescribing in the United States from 2006 to 2015, including rates, amounts, dosages, and durations prescribed. CDC examined county-level prescribing patterns in 2010 and 2015.

Results: The amount of opioids prescribed in the United States peaked at 782 morphine milligram equivalents (MME) per capita in 2010 and then decreased to 640 MME per capita in 2015. Despite significant decreases, the amount of opioids prescribed in 2015 remained approximately three times as high as in 1999 and varied substantially across the country. County-level factors associated with higher amounts of prescribed opioids include a larger percentage of non-Hispanic whites; a higher prevalence of diabetes and arthritis; micropolitan status (i.e., town/city; nonmetro); and higher unemployment and Medicaid enrollment.

3x higher

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Prescription Drug Monitoring Programs

- A Prescription Drug Monitoring Program (PDMP) is an electronic monitoring program that tracks controlled substance prescriptions in a state.
  - Allows providers to verify if patients are taking benzodiazepines and opioids together
    - What States Need to Know About PDMPs: https://www.cdc.gov/drugoverdose/pdmp/states.html
- The Oklahoma prescription Monitoring Program (PMP) was enacted into law by the Oklahoma Anti-Drug Diversion Act
  - Required all dispensers to submit prescription dispensing information within 5 minutes of dispensing a scheduled narcotic
    - Data Submission Dispenser Guide, Oklahoma Prescription Monitoring Program (OK PMP): https://www.ok.gov/obndd/documents/OK%20PMP%20Dispenser%20Guide_v1%200.pdf

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Naloxone Administration: First Responders

- First responders can administer naloxone **without a prescription** to patients exhibiting signs of opioid overdose
    - Okla. Stat. tit. §63-1-2506.1 Administration of opiate antagonists

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Naloxone Prescribing: Family Members

- Upon request, a provider may **prescribe** naloxone to a person who may have a family member exhibiting signs of an opioid overdose.
- The provider **must** provide education including:
  - Symptoms of an opioid overdose
  - Instruction in basic resuscitation techniques
  - Instruction on proper administration of naloxone
  - Importance of calling 911 for help
    - Okla. Stat. tit. §63-1-2506.2 Prescription of opiate antagonists to family members

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Safe Disposal

- October 27, 2018: 18th National Prescription Drug Take Back Day
- Controlled Substance Public Disposal Locations
  - Check your local pharmacies, hospitals, and police stations to see if they have secure collection receptacles
  - https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

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Drug Disposal Options

I need to get rid of this medication.

U.S. FOOD & DRUG

Do you have medicine you want to get rid of?

Do you have a drug take-back option readily available?

Check the DEA website, as well as your local drugstore and police station for possible options.

NO

Is it on the FDA flush list?

NO

Follow the FDA instructions for disposing of medicine in the household trash.

YES

Immediately flush your medicine in the toilet. Scratch out all personal info on the bottle and recycle/ throw it away.

YES

Take your medicine to a drug take-back location.

Do this promptly for FDA flush list drugs!

Deep Dive Methodology

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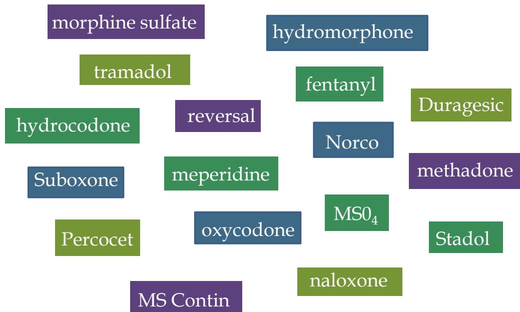
Selected Search Terms



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Data Analysis

- Initial return: 63,551 events
- Initial data inclusion
  - Event occurrence dates between January 1, 2014, and September 30, 2016, for 18,652 events
  - All event types
- Final data inclusion
  - Event types: medication, falls, device or medical-surgical supply/health information technology (HIT), surgery or anesthesia, and other
    - *Events related to end-of-life care were excluded*
- 11,388 events were reviewed by analysts for relevance
- 7,218 were deemed relevant and further classified

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Taxonomy

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Taxonomy/Category I

The first level of the taxonomy captured broad categories of medication processes in the hospital:

- Prescribing
- Transcription
- Dispensing
- Administration
- Monitoring
- Adverse drug reactions
- Diversion

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Taxonomy/Category II

The next levels of the taxonomy were developed to identify specific processes and failure modes associated with each category.

1. Prescribing	
1.1 Opioid risk assessment inadequate	
	1.1.1 Assessment not performed
	1.1.2 Assessment incorrect
	1.2.3 Assessment not documented
1.2 Failure to determine opioid tolerance	
	1.2.1 Tolerance not assessed
	1.2.2 Tolerance assessed incorrectly
	1.2.3 Tolerance not documented

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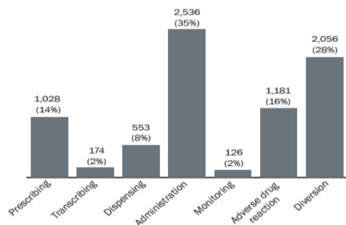
Event Breakdown by Taxonomy Category

Figure 1.1. 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.

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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.

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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.

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Prescribing

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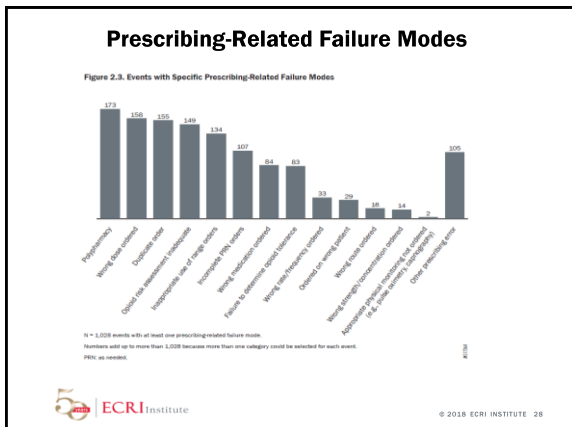

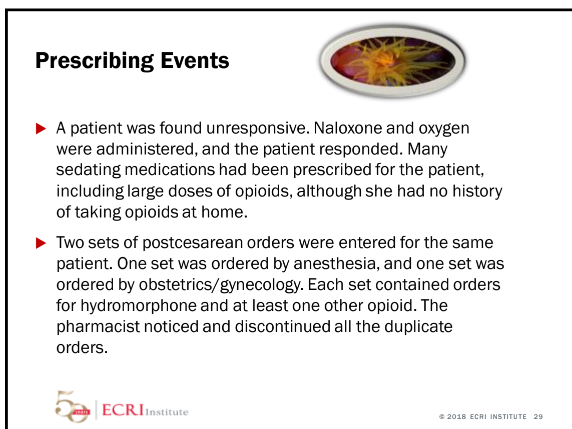

Action Recommendations: Prescribing

- **Patient assessment:** Comprehensively assess all hospital 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.

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Action Recommendations: Prescribing *(cont.)*

- **Order sets:** Standardize pain management options.
- **PRN (as-needed) 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.

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Dispensing

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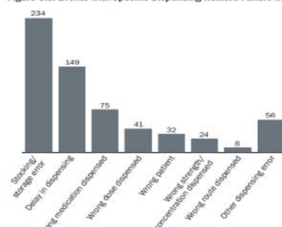
Dispensing-Related Failure Modes



N = 553 events with at least one dispensing-related failure mode.

Numbers add up to more than 553 because more than one category could be selected for each event.

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Dispensing Events

- Percocet 10 mg loaded into Percocet 5 mg bin in Pyxis.
- During a rapid response, the automated dispensing cabinet (ADC) on the unit did not have enough naloxone. The nurse had to go to another unit to retrieve the medication.

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Action Recommendations: Dispensing

- Purchasing, compounding, and labeling
  - Ensure purchasing and labeling support easy identification of medications and minimize the potential for mix-ups.
  - Purchase parenteral opioids in ready-to-administer form whenever possible, and whenever opioids must be prepared, limit their preparation to the pharmacy.
- Storage and stocking
  - Implement standardized, redundant procedures for storage and stocking of opioids and other medications.
- ADC functions, placement, and integration
  - Implement ADC features to minimize risk of medication errors.
  - Ensure an appropriate number and placement of ADCs in care areas, and integrate ADCs with other systems as needed.

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Action Recommendations: Dispensing *(cont.)*

- ADC setup
  - Establish criteria for choosing which medications to stock in ADCs, what quantities to stock for each medication, and where, within the ADC, to stock each medication.
- Overrides
  - Permit ADC overrides only for preapproved medications, and consider implementing retrospective review of overrides.
- Surveillance and quality assurance
  - Conduct periodic monitoring of the entire ADC system, addressing concerns as needed.

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Administration

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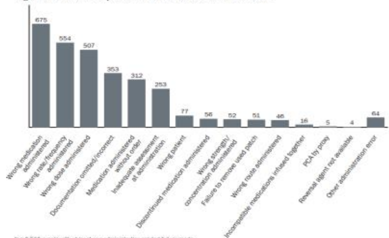
Administration-Related Failure Modes



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Administration Events

- Oxycodone 40 mg was administered to the patient in error. Bar-code medication administration (BCMA) was not used as required. The nurse assumed that the tablets were 10 mg each but later discovered that they were 20 mg each.
- When a patient was transferred from the telemetry unit to the intensive care unit, 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.

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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 preadministration assessment before giving patients opioids.
- Consider implementing BCMA scanning technologies and ADCs in any clinical location where medication is administered.
- Review policies and procedures on medication administration.

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Action Recommendations: Administration *(cont.)*

- 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 documentation of opioid administration is complete and accurate.
- Ensure that practitioners who administer opioids possess the necessary skills for safe administration.

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Monitoring

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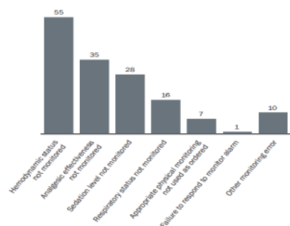
Monitoring-Related Failure Modes



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Monitoring Events

- Patient in PACU received 2 doses of 0.5mg hydromorphone 7 minutes apart. The patient was immediately sent to the floor and was not monitored after doses given consecutively. In PACU oxygen saturation was charted at 95% on room air but on arrival to the floor oxygen saturation was 78% on room air.
- An emergency department patient was given intravenous (IV) hydromorphone and discharged 23 minutes later—before the 30 minutes required by protocol. Then the patient fell while walking out of the waiting room.

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Action Recommendations: Monitoring

- Choose appropriate modalities, durations, intensities, and frequencies of monitoring for each individual patient.
- Continually evaluate patients in the postanesthesia care unit (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 capnometry, for patients at heightened risk for respiratory depression.

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Action Recommendations: Monitoring *(cont.)*

- 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.

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Diversion

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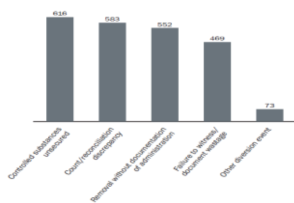
Diversion-Related Failure Modes

Figure 6.3. Events with Specific Diversion-Related Failure Modes



N = 2,056 events with at least one diversion-related failure mode.

Numbers add up to more than 2,056 because more than one category could be selected for each event.

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Diversion Events

- Oxycodone 40 mg was found at a patient's bedside (two tablets of 15 mg each and two tablets of 5 mg each). All four tablets were still in the original packaging from Pyxis. The order for the patient was 20 mg oxycodone PRN, and that dose should have been dispensed from Pyxis as one 15-mg tablet and one 5-mg tablet.
- An audit of controlled-substance pulls from ADCs in 24 hours identified a nurse whose number of pulls deviated substantially from the mean. For one patient, the nurse pulled two hydromorphone syringes, eight minutes apart, but documented administration of only one of the syringes. For another, the nurse pulled acetaminophen/hydrocodone from the ADC but never documented administration.

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Action Recommendations: Drug Diversion

- Organizational strategies
  - Implement a program to prevent and address diversion of controlled substances.
- Human resources and occupational health
  - Implement policies and procedures regarding substance use and diversion, recovery and support systems, and return to work.
- Storage, access, and chain of custody
  - Ensure tracking of, responsibility for, and controlled access to opioids and other controlled substances from their point of entry into the facility through their final disposition.

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Action Recommendations: Drug Diversion *(cont.)*

- Medication use continuum
  - Take steps to minimize the risk of drug diversion throughout the medication use continuum.
- Surveillance and reporting
  - Implement robust systems for surveillance and reporting of potential drug diversion.
- Investigation and response
  - Create a team and processes to guide investigations of and response to suspected drug diversion.
- Patients and visitors
  - Take steps to prevent, identify, and respond to drug diversion by patients or visitors.

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Conclusion: One Step at a Time

ECRI Institute encourages all healthcare organizations to consider the recommendations from this "Deep Dive" in order to support safe opioid use in hospitalized patients.

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Additional Resources

- Centers for Disease Control and Prevention (CDC)
  - CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html
- National Conference of State Legislatures
  - Prescribing Policies: States Confront Opioid Overdose Epidemic: http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx
- VA/DoD Clinical Practice Guidelines
  - Opioid therapy for Chronic Pain: https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf
- U.S. Drug Enforcement Administration
  - Practitioner's Manual: https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html

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Additional Resources *(cont.)*

- U.S. Food and Drug Administration (FDA)
  - Opioid Medications: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm
  - Risk Evaluation and Mitigation Strategy (REMS) for Opioid Analgesics: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm
  - Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm

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Questions?

Thank You

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