Dealing with Diversion: A Critical Component of the Opioid Crisis
Disclosure information

No conflicts to disclose.

Katrina Harper, PharmD, MBA, BCPS, DPLA
Senior clinical manager, center of pharmacy practice excellence
katrina.harper@vizientinc.com
Objectives

At the end of this activity, the Pharmacist participant will be able to:
• Introduce the impact of opioid therapy misuse and abuse in the U.S.
• Describe the scope of the issue of diversion by healthcare personnel
• Describe mitigation strategies to prevent diversion of controlled substances

At the end of this activity, the Pharmacy Technician participant will be able to:
• Articulate the risk that diversion poses to their own organization
• Describe important components of a diversion prevention, detection and response program
• Describe multiple strategies that can be implemented to minimize diversion risk while increasing diversion awareness among practitioners.
Opioid epidemic
THE OPIOID EPIDEMIC BY THE NUMBERS

130+
People died every day from opioid-related drug overdoses
(estimated)

11.4 m
People misused prescription opioids

47,600
People died from over dosing on opioids

2.1 million
People had an opioid use disorder

81,000
People used heroin for the first time

2 million
People misused prescription opioids for the first time

15,482
Deaths attributed to overdosing on heroin

28,466
Deaths attributed to overdosing on synthetic opioids other than methadone

SOURCES
2. NCHS Data Brief No. 293, December 2017
3 Waves of the Rise in Opioid Overdose Deaths

**Wave 1:** Rise in Prescription Opioid Overdose Deaths

**Wave 2:** Rise in Heroin Overdose Deaths

**Wave 3:** Rise in Synthetic Opioid Overdose Deaths

**Other Synthetic Opioids**
e.g., Tramadol and Fentanyl, prescribed or illicitly manufactured

**Commonly Prescribed Opioids**
Natural & Semi-Synthetic Opioids and Methadone

**Heroin**

**Deaths per 100,000 population**

**SOURCE:** National Vital Statistics System Mortality File.
Opioid stewardship
Statistics: prescription drug misuse

### Monitoring the Future Study: Trends in Prevalence of Various Drugs for 8th Graders, 10th Graders, and 12th Graders; 2017 (in percent)*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Time Period</th>
<th>8th Graders</th>
<th>10th Graders</th>
<th>12th Graders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Prescription Drug</td>
<td>Past Year</td>
<td>-</td>
<td>-</td>
<td>10.90</td>
</tr>
<tr>
<td>Adderall</td>
<td>Past Year</td>
<td>1.30</td>
<td>4.00</td>
<td>5.50</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>Past Year</td>
<td>3.50</td>
<td>5.60</td>
<td>5.90</td>
</tr>
<tr>
<td>Narcotics other than Heroin</td>
<td>Past Year</td>
<td>-</td>
<td>-</td>
<td>4.20</td>
</tr>
<tr>
<td>OxyContin</td>
<td>Past Year</td>
<td>0.80</td>
<td>2.20</td>
<td>2.70</td>
</tr>
<tr>
<td>Ritalin</td>
<td>Past Year</td>
<td>[0.40]</td>
<td>0.80</td>
<td>1.30</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>Past Year</td>
<td>2.00</td>
<td>4.10</td>
<td>4.70</td>
</tr>
<tr>
<td>Vicodin</td>
<td>Past Year</td>
<td>0.70</td>
<td>1.50</td>
<td>[2.00]</td>
</tr>
</tbody>
</table>

### National Survey on Drug Use and Health: Trends in Prevalence of Psychotherapeutics (Nonmedical Use) for Ages 12 or Older, Ages 12 to 17, Ages 18 to 25, and Ages 26 or Older; 2016 (in percent)*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Time Period</th>
<th>Ages 12 or Older</th>
<th>Ages 12 to 17</th>
<th>Ages 18 to 25</th>
<th>Ages 26 or Older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotherapeutics (Nonmedical Use)</td>
<td>Lifetime</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Past Year</td>
<td>6.90</td>
<td>5.30</td>
<td>14.50</td>
<td>5.90</td>
</tr>
<tr>
<td></td>
<td>Past Month</td>
<td>2.30</td>
<td>1.60</td>
<td>4.60</td>
<td>2.00</td>
</tr>
</tbody>
</table>

Around **46 PEOPLE** die every day from overdoses involving prescription opioids.
Sources of Prescription Opioids Among Past-Year Non-Medical Users

- Given by a friend or relative for free
- Prescribed by ≥1 physicians
- Stolen from a friend or relative
- Bought from a friend or relative
- Bought from a drug dealer or other stranger
- Other

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*Obtained from the US National Survey on Drug Use and Health, 2008 through 2011.*

*Estimate is statistically significantly different from that for highest-frequency users (200-365 days) (P ≤ .06).*

*Includes written fake prescriptions and those opioids stolen from a physician’s office, clinic, hospital, or pharmacy; purchases on the Internet; and obtained some other way.

Statistics: drug addiction in health care professionals

• Approximately 10% – 14% of healthcare workers are addicted to drugs.
  – More than 100,000 US doctors, nurses, pharmacists, technicians, and other health professionals
  – Rates of prescription drug abuse and addiction are 5 times higher among physicians than in the general population, with especially high rates of benzodiazepine and opioid abuse.

• Estimated that 12-16% of health care professionals will misuse substances at some point in their career
Statistics: drug diversion

Definition

• The transfer of a prescription drug from a lawful to an unlawful channel of distribution or their use for unintended purposes

Prevalence of non-medical prescription opioids users who obtained drugs via diversion:

• 0.8%

Reliable statistics are not available

• Many drug diversion cases go undiscovered or unreported
• A manager of controlled substance surveillance at one hospital recently reported identifying at least 1 healthcare provider each month stealing medication from the facility.

Cost

• The estimated cost of controlled prescription drug diversion and abuse to both public and private medical insurers is approximately $72.5 billion a year.
Landscape
Case Study

- 5 IR patients developed HCV infection
  - None were symptomatic
- 2 were organ transplant patients identified through routine screening conducted as part of facility protocols
- 1 was identified through evaluation of an unexplained increase in liver enzymes
- Through molecular analysis, the HCV isolates from the patients were found to be genetically related
- Record review revealed that all had received fentanyl in IR
- 21 IR employees were recorded as being at work when these patients received fentanyl and submitted blood for testing
- Hep C + radiology technician had a HCV strain that was genetically related to the patient isolates
  - Change needle on pre-drawn fentanyl syringes
  - Inject then replace needle and fill syringe with NS
Drug diversion risk

Risk to patients
• Care delivered by an impaired provider
• Medications withheld or substituted
• Transmission of bloodborne pathogens
  – Hepatitis C

By CRIMESIDER STAFF  CBS NEWS  September 12, 2012, 11:58 AM

Steven Beumel, former radiology technician, sentenced to 30 years in prison for infecting patients with Hepatitis C

A former radiology technician at the Mayo Clinic who caused a hepatitis C outbreak by swapping patients’ syringes and led to one person’s death has pleaded guilty to 10 crimes.
Drug diversion risk

Risk to staff

• Loss of license
• Accidents while working impaired/DUI
• Progression to illicit drugs and high-risk behaviors
• Health-related consequences of drug misuse
• Incarceration
• Death

Nurse Patricia Norman (Courtesy of Jerl Van)

Nurse Iyisha Keller (Courtesy of the Keller family)

Diversion in the headlines

- University of Michigan Health System
  - $4.3 million settlement
- Effingham Health System
  - $4.1 million settlement
- Rideout Health
  - $2.4 million settlement
- Massachusetts General Hospital
  - $2.3 million settlement
- CVS Pharmacy, Inc.
  - $1.5 million settlement
- Intermountain Health System
  - $1 million settlement
The Joint Commission (TJC)

TJC standards can help organizations counter drug diversion:

Medication Management

• Standard MM.01.01.03: The hospital safely manages high-alert and hazardous medications.
• Standard MM.03.01.01: The hospital safely stores medications.
• Standard MM.05.01.11: The hospital safely dispenses medications.
• Standard MM.05.01.13: The hospital safely obtains medications when the pharmacy is closed.
PC.01.02.07: The hospital assesses and manages the patient’s pain and minimizes the risks associated with treatment.

Element of Performance:
EP 8. The hospital educates the patient and family on discharge plans related to pain management including the following:

- Pain management plan of care
- Side effects of pain management treatment
- Activities of daily living, including the home environment, that might exacerbate pain or reduce effectiveness of the pain management plan of care, as well as strategies to address these issues
- Safe use, storage, and disposal of opioids when prescribed
Drug Diversion Risk Mitigation
Culture

Culture of accountability and reporting
• Be willing to have difficult conversations
• Progressive discipline for non-compliance in medication handling

Leadership priority
• Top down

All staff
Education
Policies and Procedures
Diversion Response
Diversion risk rounds
• Unannounced and at least quarterly
Key Culture Principles

- Leadership
- Continuous Training
- Multidisciplinary collaboration
- Standard policies and procedures
- State of continuous readiness and improvement
- Auditing Accountability and Responsibility
Developing a system-wide approach

Diversion is a multi-victim crime that poses a significant risk to patient safety

- Patient safety initiative

Comprehensive diversion prevent program

- Organization Oversight
- Culture
- Control
- Diversion Investigation
- Known Diversion
Organization oversight

Diversion prevention and oversight committee

Composition guidelines

- Pharmacy
- Nursing
- Anesthesia
- Security
- Risk management or general counsel
- Accreditation or magnet
- Chief medical officer (CMO)
- Compliance
- Diversion specialist
  - Daily operations
  - Collaborative relationship with external agencies
- Human resources
- Employee health
- Infection prevention
- Internal audit
- Quality and safety
- Finance
- Research department (if applicable)
- Ad hoc members (such as environmental services or laboratory when needed)
Using Naloxone to Reverse Opioid Overdose in the Workplace: Information for Employers and Workers

Introduction

Opioid misuse and overdose deaths from opioids are serious health issues in the United States. Overdose deaths involving prescription and illicit opioids doubled from 2010 to 2016, with more than 42,000 deaths in 2016 [CDC 2016a]. Provisional data show that there were more than 49,000 opioid overdose deaths in 2017 [CDC 2018a]. In October 2017, the President declared the opioid overdose epidemic to be a public health emergency.

Naloxone is a very effective drug for reversing opioid overdoses. Police officers, emergency medical services providers, and non-emergency professionals carry the drug for that purpose. The Surgeon of the United States is also urging others who encounter people at risk for opioid overdose naloxone available and to learn how to use it [USSG 2018].

The National Institute for Occupational Safety

https://www.cdc.gov/niosh/topics/opioids/framework.html
Control

Most common cause of diversion is access
ASHP Guidelines on Preventing Diversion of Controlled Substances

Purpose
Controlled substances (CS) diversion in health systems can lead to serious patient safety issues, harm to the diverter, and significant liability risk to the organization. Diversion driven by addiction puts patients at risk of harm, including inadequate relief of pain, inaccurate documentation of their care in the medical record, exposure to infectious diseases from contaminated needles and drugs, and impaired healthcare worker (HCW) performance.\textsuperscript{1,2} In addition to patient harm, there are regulatory and legal risks to the organization, including fraudulent activities that develop CSDPPs that include support systems for the workforce (e.g., employee assistance programs, professional monitoring programs), methods to monitor effectiveness of diversion prevention efforts, and patient safety considerations. Education on the signs and symptoms of impaired HCWs—supported by rigorous monitoring and surveillance, human resources management, awareness of state and national diversion reporting requirements, and substance abuse treatment programs—is paramount for healthcare organizations. In addition, healthcare organizations are not

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx?la=en&hash=DB693E5EB914C4FC6D4B0B6065B6D17C634D0ED6
Suspected diversion

• Prompt attention to suspicious data
• Defined process is in place for the internal and external reporting of medication diversion incidents
• The multidisciplinary team is in place to provide consultation, direction and oversight for suspected diversion incidents
• Review evidence
• A standardized process exists for interviewing suspected diverters
• Guidelines are in place for the handling of suspected impaired employees and drug testing
Confirmed diversion

- Code D or code N
  - Group of responders should be kept small
    - Diversion specialist and compliance officers
    - Pharmacy
    - Manager of suspected diverter
    - Human resources
    - Hospital and local law enforcement
    - Others as relevant
- DEA form 106
  - Report theft or significant loss of any controlled substance within one business day of discovery of such loss or theft
- Professional boards
- Law Enforcement
Conduct a comprehensive diversion risk assessment/ Internal review
### Failure modes and effects analysis (FMEA)

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Credible Threats in Hospitals)</td>
<td>diversion during manual transport from pharmacy to pt care area, or between pt care units</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failure Causes</td>
<td>open carts (no locks), have significant time under control of one person, cart moves through a very public area.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Vulnerability)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who/what does it?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Actor - internal, external)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did they do it?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Method)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Failure Effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Outcome)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Severity</strong></td>
<td>3.4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
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<tr>
<td><strong>Likelihood of Occurrence</strong></td>
<td>2.2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td><strong>Detection &amp; Response</strong></td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Control Maturity</strong></td>
<td>3.8</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>Operational Risk Score</strong></td>
<td>7.2</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td><strong>Risk Mitigation Score</strong></td>
<td>15.2</td>
<td>12</td>
<td>16</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td><strong>Risk Profile Number (RPN)</strong></td>
<td>109.44</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx
https://pdfs.semanticscholar.org/presentation/2653/651b2a24c2991bcdb9698a3e6accfbeb240f.pdf
Diversion risk assessment survey

Appendix B—Controlled Substances
Diversion Prevention Program
Self-Assessment Guide

Organization Oversight and Accountability

- The organization establishes a controlled substances (CS) diversion prevention program (CSDPP).
- The organization establishes an interdisciplinary CSDPP committee to provide leadership and direction for developing policies and procedures for overseeing the CSDPP. A pharmacy representative has a leadership role on the CSDPP committee, and there is a designated diversion officer who coordinates activities of the CSDPP.
- The diversion officer should have a license and a college degree in pharmacy or nursing, with at least 5 years of healthcare experience; ideally, the diversion officer would be a licensed pharmacist with 10 years or more of experience as a staff or managerial pharmacist and an advanced management degree (e.g., M.H.A. or M.B.A.). The diversion officer should have a thorough understanding of medication management systems and technologies (e.g., automated dispensing devices, medication cars, repackaging systems); CS surveillance and management systems and techniques; federal and state regulatory compliance requirements; and auditing techniques. The diversion officer should be familiar with operations of the pharmacy department (e.g., ordering, receiving, storage, distribution, administration, returns, wasting) as well as other pertinent areas (perioperative, anesthesia, procedure, clinic, research, and retail pharmacy areas). The diversion officer should be able to lead the complex investigatory processes of an interdisciplinary team, which will require strong analytical and communication skills, attention to detail, organization, ability to work independently and collaboratively, and a com-

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx
Diversion risk rounds

**Diversion risk rounds checklist**

The group doing rounds should be small. Rounds consist primarily of observation. Staff should be asked the questions below periodically in each unit, but these questions are not required on each set of rounds.

Determine where controlled substances are stored, transported and used in each area and assess for security and handling practices:

- How do controlled substances arrive in this location?
- Is the transport method into the unit and after removal from the drug cabinet secure?
- Where are controlled substances stored?
- Is storage secure?
- What is the process for removal of controlled substances?
- Are institutional policies and procedures for medication handling being followed?
- What is the process for returning unused controlled substances?
- What is the process for wasting controlled substances (i.e., should be done at the time of removal or as soon thereafter as possible, should be witnessed)?
- **Visualize** sharps containers and medication disposal containers for integrity, and the presence of unspent syringes or vials and pills. Per regulatory authorities, all sharps containers must be secured so that unauthorized individuals cannot easily remove them.
- How are PCAs and controlled medication drips handled?
- If required, are weekly drug cabinet inventories being done and documented?

**Potential questions for staff:**

- How are patient medications from home inventoried/stored?
- How are discrepancies resolved?
- Are staff aware of what diversion is and how to report it?
- Are staff aware of signs of diversion and impairment?
- What are the biggest controlled-substance security risks staff feel are present in their area (if I wanted to divert drugs, how would I go about doing it)?

**In procedural areas:**

- Are controlled substances removed from the cabinet early and placed in a location where they will be available during a case?
- If medication is removed early, is it identified by patient, initialed by the staff member and kept secure at all times during the procedure?
- Are there handoffs of controlled substances and are handoffs documented?
- How does wastage occur?
- Is waste tested by refractometry, and if so, is this being done according to policy?
- Is there ongoing auditing done of drug transactions in this area, and if so, by whom and how often?

Questions