



Unintended Consequences of Opioid Therapy

Side Effects, Addiction, Constipation and Diversion

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Disclosure information

No conflicts to disclose.

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Learning Objectives

- Discuss adverse events associated with opioid therapy
- Summarize principles of an effective opioid stewardship program
- List how to identify drug diversion
- Discuss the need for and purpose of implementing an Institutional Diversion Program

Opioid adverse events



Opioid complications and side effects

- **Common side effects:**

- Sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance, and respiratory depression.
 - Opioid-induced constipation (OIC) accounts from over 40% to 60% in non-cancer patients receiving opioids.
- Physical dependence and addiction

- **Less common side effects:**

- Delayed gastric emptying, hyperalgesia, immunologic and hormonal dysfunction, muscle rigidity, and myoclonus.

Opioid-induced constipation (OIC)

Treatment/Management:

- **Increasing dietary fiber, fluid intake, and physical exercise**
- **Prophylactic treatment for constipation**
 - All types of laxatives can be used as initial therapy except for the bulk-forming laxatives
 - The most common regimen is a stimulant (senna/bisacodyl) with or without a stool softener (docusate), or daily administration of an osmotic laxative (polyethylene glycol).
- **For refractory cases, newer agents may be used**
 - Methylnaltrexone (Relistor) - peripherally acting opiate antagonist
 - Lubiprostone (Amitiza) - type-2 chloride channel activator that increases secretion of fluid in the GI tract

Physical dependence and addiction

**184
people**



die each day in the US from
opioid-related overdoses¹

**\$78.5
Billion**



Total economic burden
estimated \$78.5 billion²

**1 in 8
ED visits**



are attributable to Mental
Health/Substance use
related causes³

**>50%
who misuse**



pain prescriptions obtain the
drug from a friend⁴

**1 in 96
odds**



of dying from an opioid-
related overdose exceeds
that for motor vehicle
crashes (1 in 103).⁵

**80%
of heroin**



users started by misusing
prescription opioid
analgesics.⁶

1: CDC, National Center for Health Statistics, Nov 2018

2: Florence et al., Med Care. 2016; 54(10): 901-906

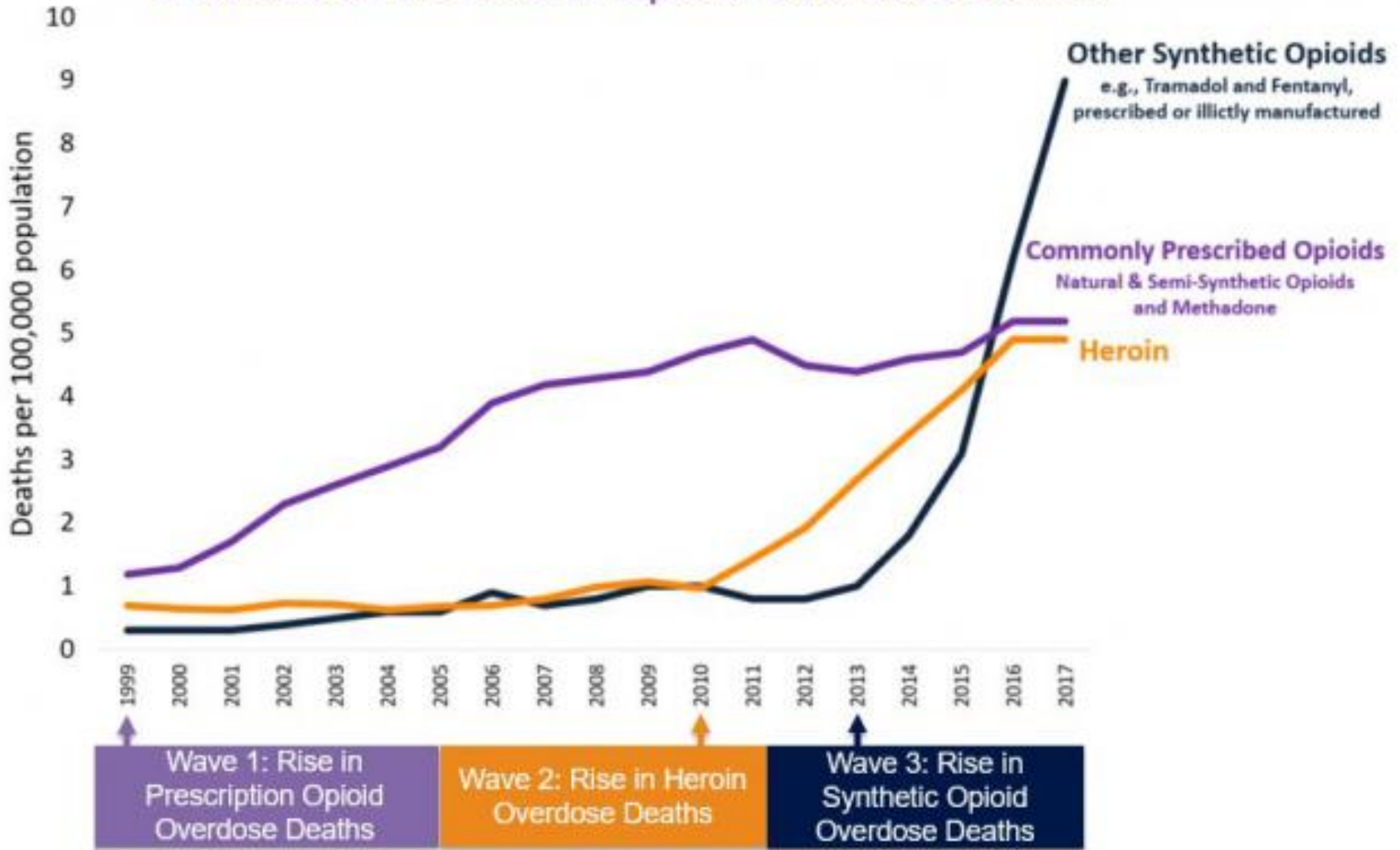
3: Healthcare cost and utilization project, AHRQ, Statistical Brief #216, December 2016

4: Substance Abuse and Mental Health Services Administration, (2018). Retrieved from <https://www.samhsa.gov/data/>

5: National Safety Council: <https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/data-details/>

6: Journal of Substance Abuse Treatment 89 (2018) 28-51

3 Waves of the Rise in Opioid Overdose Deaths

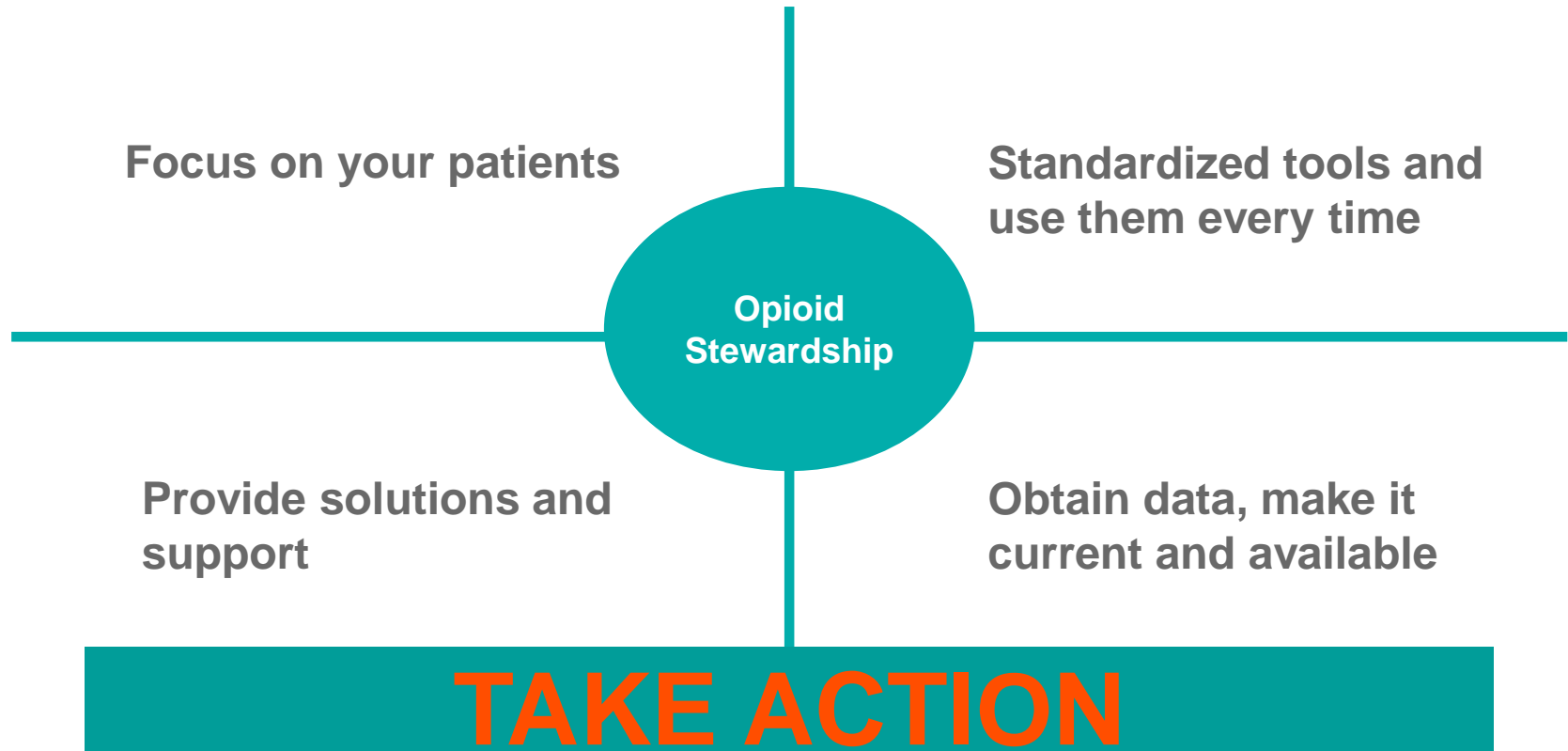


SOURCE: National Vital Statistics System Mortality File.

Opioid stewardship



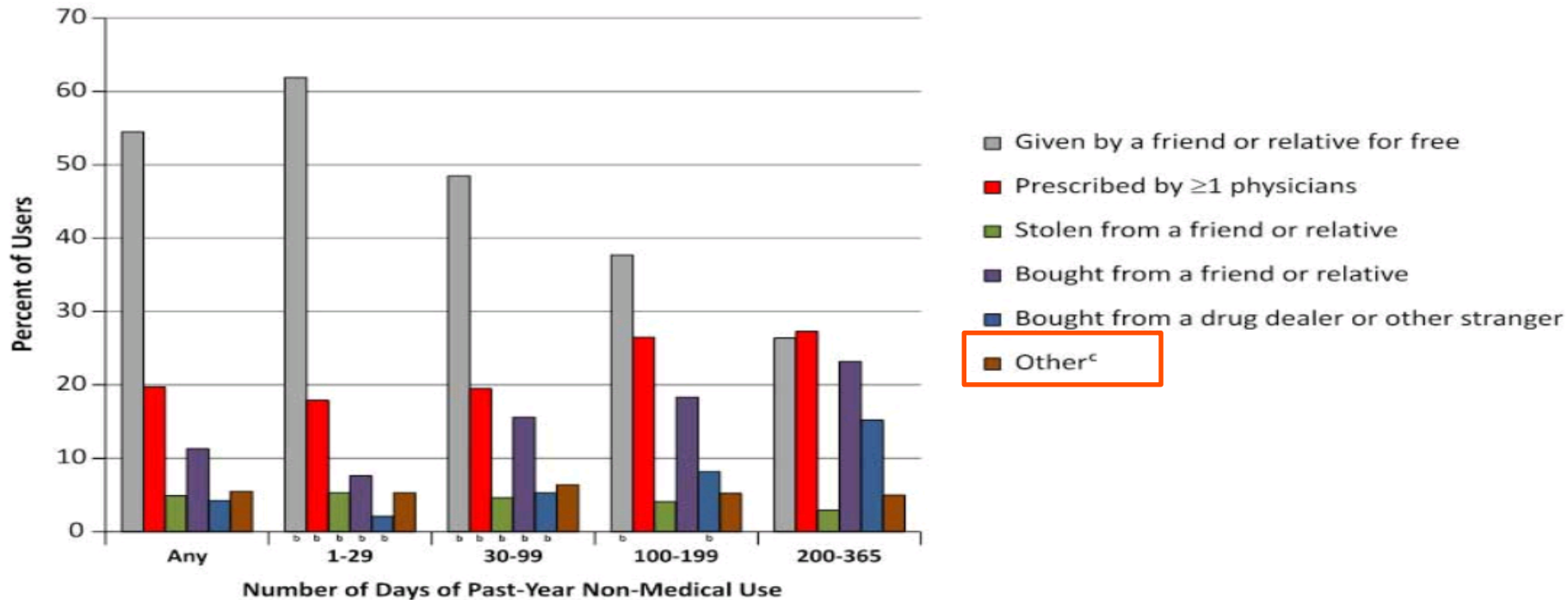
Opioid stewardship best practices



Drug diversion



Sources of Prescription Opioids Among Past-Year Non-Medical Users^a



^a Obtained from the US National Survey on Drug Use and Health, 2008 through 2011.⁵

^b Estimate is statistically significantly different from that for highest frequency users (200-365 days) ($P < .05$).

^c 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.

SOURCE: Jones C, Paulozzi L, Mack K. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008–2011. JAMA Int Med 2014; 174(5):802-803.

Statistics: drug addiction in health care professionals

- Rates similar to general population
 - 6 – 8% of Physicians, higher among Anesthesiologists
 - 9% of Pharmacists
 - 4.7 – 8.8 % of Nurses
- 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.

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 an 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

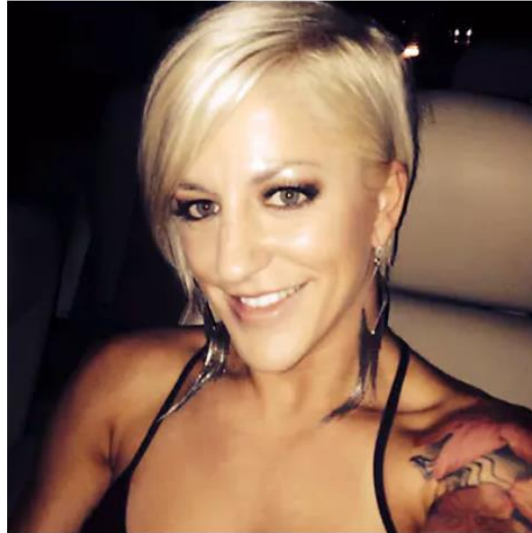


A former radiology technician at the Mayo Clinic who caused a hepatitis C outbreak by swapping patients' syringes and led to one person's death has pleaded guilty to 10 crimes.

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 Jeri 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



**Office of the Sp
for the City of N**
Bridget G. Brennan,

Department of Justice
U.S. Attorney's Office
District of Rhode Island

SHARE

FOR IMMEDIATE RELEASE

Tuesday, July 10, 2018

VA Medical Center Nurse Indicted, Arraigned for Allegedly Tampering With and Stealing Prescription Opioids

**For Immediate Release
July 8, 2014**

PROVIDENCE – A nurse employed at the Providence VA Medical Center was arraigned and pled not guilty today in U.S. District Court in Providence to a federal grand jury indictment charging him with stealing liquid opioids for his own personal use and replacing them with saline.

Contacts:

Kati Cornell
Special Narcotics Prosecutor's Office
(212) 815-0525

Jared Scott, 34, of West Warwick, was indicted on June 28, 2018, on one count each of tampering with

Former Pharmacy Director at Beth Israel Medical Center charged in theft of narcotic painkillers from hospital: Pills worth over \$5.6 million on black market

BRIDGET G. BRENNAN, New York City's Special Narcotics Prosecutor, announced today the indictment and arrest of ANTHONY D'ALESSANDRO, former Director of Pharmacy Services for Beth Israel Medical Center in Manhattan, for stealing and illegally possessing nearly 200,000 oxycodone pills, which he allegedly obtained from his place of employment since approximately 2009. These pills carried a street value of approximately \$5.6 million.

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

CULTURE
EATS STRATEGY
FOR BREAKFAST
AND TECHNOLOGY
FOR LUNCH
AND THEN...



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 professional responders carry the drug for that purpose. The Surgeon General of the United States is also urging others who encounter people at risk for opioid overdose to have naloxone available and to learn how to use it [USSG 2018].

The National Institute for Occupational Safety and Health (NIOSH) is working to help employers and workers understand the risks of opioid use in the workplace and how to prevent them.



Photo by ©Thinkstock

IDENTIFY
Workplace
Conditions



DETERMINE
Risk Factors



PROTECT
Workers and
Responders



DEVELOP
Methods for
Detection and
Decontamination



Control



Most common cause of diversion is access



Guidelines

ASHP Guidelines on Preventing Diversion of Controlled Substances

Am J Health-Syst Pharm. 2017; 74:e10-33

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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.^{1,2} In addition to patient harm, there are regulatory and legal risks to the organization, including fraudulent

tions develop CSDPPs that include support systems for the work force (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)

	SME 1	SME 2	SME 3	SME 4	SME 5	
Failure Mode (Credible Threats in Hospitals)	diversion during manual transport from pharmacy to pt care area, or between pt care units					
Failure Causes (Vulnerability)	open carts (no locks), have significant time under control of one person, cart moves through a very public area.					
Who/what does it? (Actor - internal, external)	staff,					
How did they do it? (Method)	remove or tamper with product from cart					
Failure Effects (Outcome)	poor pain control, risk of infection					
Severity	3.4	4	4	4	2	3
Likelihood of Occurrence	2.2	2	2	2	3	2
Detection & Response	4	3	4	4	4	5
Control Maturity	3.8	4	4	4	3	4
Operational Risk Score	7.2	8	8	8	6	6
Risk Mitigation Score	15.2	12	16	16	12	20
Risk Profile Number (RPN)	109.44					

<http://www.ihl.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^{a,b}

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 carts, 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?

<http://www.diversionspecialists.com/wp-content/uploads/Diversion-Risk-Rounds-A-Reality-Check-on-Your-Drug-Handling-Policies.pdf>

Questions



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