Drug Diversion Risks vs Exploiting Opportunities

New York State Council of Health-system Pharmacists

Janet M Kozakiewicz MS, PharmD, FASHP

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Conflict of Interest

Janet M Kozakiewicz MS, PharmD, FASHP has no reported conflict of interest

Objectives

- Review national and regional trends related to synthetic and non-synthetic opiate use
- Review several national cases related to diversion and its social impact
- Describe routine activity risk and the incidence of opiate use disorders (OUD) in healthcare professionals
- Formulate proactive diversion tactics to help prevent drug diversion

Definitions

- **Drug Abuse:** The willful consumption of illegal substances or legal, prescription drugs for the purpose of altering their mood, or getting "high
- **Drug Dependence**: When the body becomes physically dependent on a chemical and when it is taken away withdrawal occurs.
- **Drug Addiction:** When a person continues to use a substance despite harm and consequences. Unable to stop on their own.
- **Drug Diversion:** the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

Confronting the Opioid Epidemic

National Trends

National Drug Overdose Deaths 1999-2019

Figure 1. Age-adjusted drug overdose death rates, by sex: United States, 1999–2019

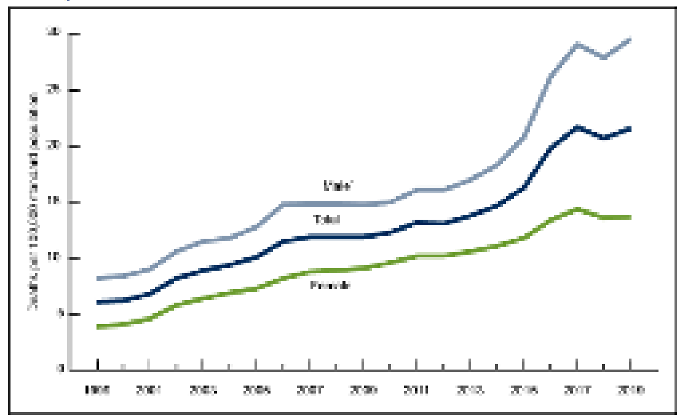
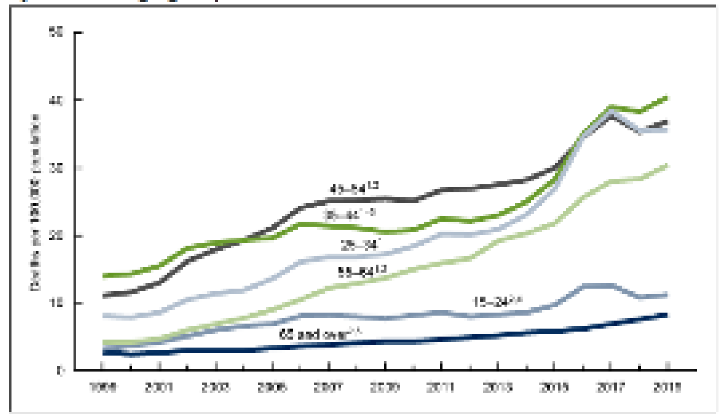


Figure 2. Drug overdose death rates among those aged 15 and over, by selected age group: United States, 1999–2019



SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.

State of the Overdose Crisis

Figure 3. Age-adjusted rates of drug overdose deaths involving opioids, by type of opioid: United States, 1999–2019

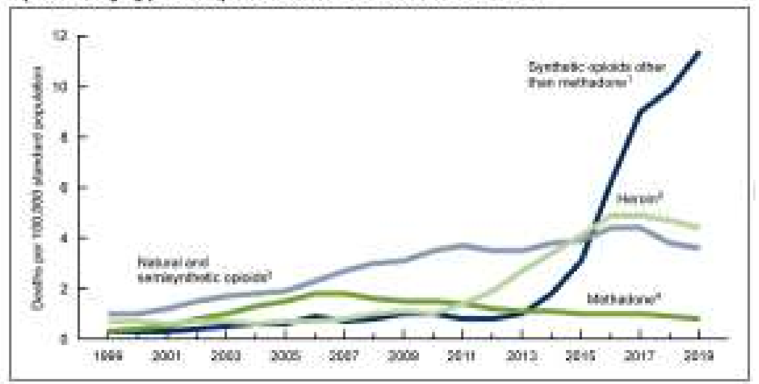
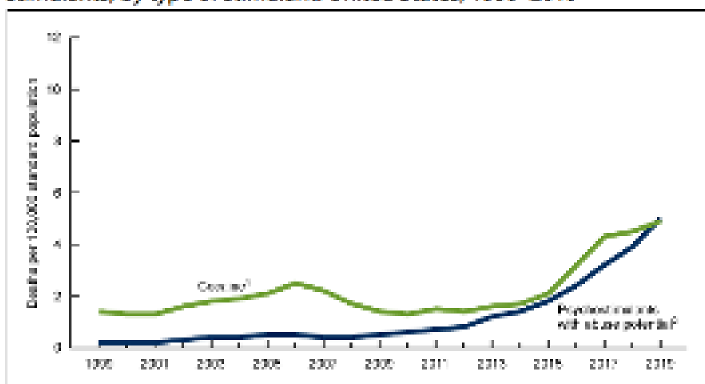


Figure 4. Age-adjusted rates of drug overdose deaths involving stimulants, by type of stimulant: United States, 1999–2019



SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.

State of New York’s Opiate Crisis

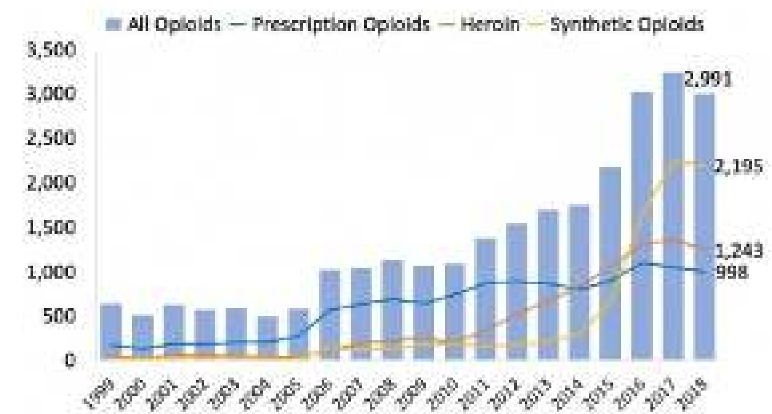


Figure 1. Number of drug and opioid-involved overdose deaths in New York, by opioid category. Drug categories presented are not mutually exclusive, and deaths may have involved more than one substance. Source: CDC WONDER, 2020.

Source: NIDA. 2020, April 3. New York: Opioid-Involved Deaths and Related Harms. Retrieved from https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/new-york-opioid-involved-deaths-related-harms on 2021, February 3

Question

Which is true about the most recent data related age adjusted overdose rates by sex in the United States?

a. Females are three times as likely to succumb to an overdose than males.
b. Males are twice as likely to succumb to an opiate overdose than females.
c. Until recently cocaine exceeded other psychostimulants with abuse potential as the number one cause of overdose with stimulants
d. b and c

Answer

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The Many Faces of Addiction

https://uw-media.usatoday.com/embed/video/7749035

The Cost of Failing to Monitor

Massachusetts General Hospital (MGH) September 28, 2015

Settlement: $ 2.3 Million

Violation: Federal Controlled Substance Act. 21C U.S.C 801-904

Investigation: in 2013 MGH disclosed that two nurses had stolen nearly 16,000 pills (mostly oxycodone) of controlled substances from the hospital. Drugs were taken from the automated dispensing system used to store and dispense medication to patients.

Findings:

- A DEA audit revealed over 20,000 pill count discrepancies that were unacted on.
- Hundreds of missing or incomplete required DEA inventories
- A nurse with a 12-year substance abuse problem had injected hydromorphone at work
- A physician prescribed controlled substances for patients without seeing them or maintaining a medical record
- Several other cases of diversion that went undetected by MGH
- Medial staff failing to properly secure controlled substances and on occasion bringing them to lunch.

Intermountain Health (IHC) December 11, 2017

Settlement: $ 1 Million

Violation: Federal Controlled Substance Act. 21C U.S.C 801-904

Investigation: prompted by a report of a medical assistant report of controlled substance diversion. −

Findings:

− A former medical assistant, clinic physician, and the IHC pharmacy used a physician's DEA registration to issue controlled substance prescriptions to herself and two family members.

− 244 prescriptions for oxycodone and another 151 prescriptions for other controlled substances were issued without legitimate medical purpose and were filled by the IHC's pharmacy and picked up by the medical assistant.

− IHC lacked controls to ensure that controlled substances are used for patient care and not diverted for non-medical purposes.

Effington Health System (EHS) May 16,2018

Settlement: $ 4.1 Million

Violation: Federal Controlled Substance Act. 21C U.S.C 801-904

Investigation: After receiving reports of diversion at EHS an investigation revealed that tens of thousands of oxycodone 30mg tablets were unaccounted for and believed to have been diverted over a 4-year period

Findings:

- EHS failed to notify the DEA of the suspected diversion with the time required by law

University of Michigan Health System (UMHS) August 30, 2018

Settlement: $ 4.3 Million

Violation: Federal Controlled Substance Act. 21C U.S.C 801-904

Investigation: prompted by 2 incidents whereby 2 employees (anesthesiology resident and a nurse) overdosed on opiates while at work, on the same day. The nurse died.

Findings:

- Failure to secure DEA registrations for 15 off-site ambulatory facilities.
  - Sent controlled substances, in excess of legal quantities, to clinics from the hospital supply
- Recordkeeping violations consisting of
  - failure to maintain complete and accurate controlled substance records
  - failure to notify the DEA in a timely manner of thefts or significant losses of controlled substances
- Deficient record keeping negatively impacted their ability to prevent controlled substance diversion

University of Texas Southwest Medical Center (UTSWMC) September 8, 2019

Settlement: pending

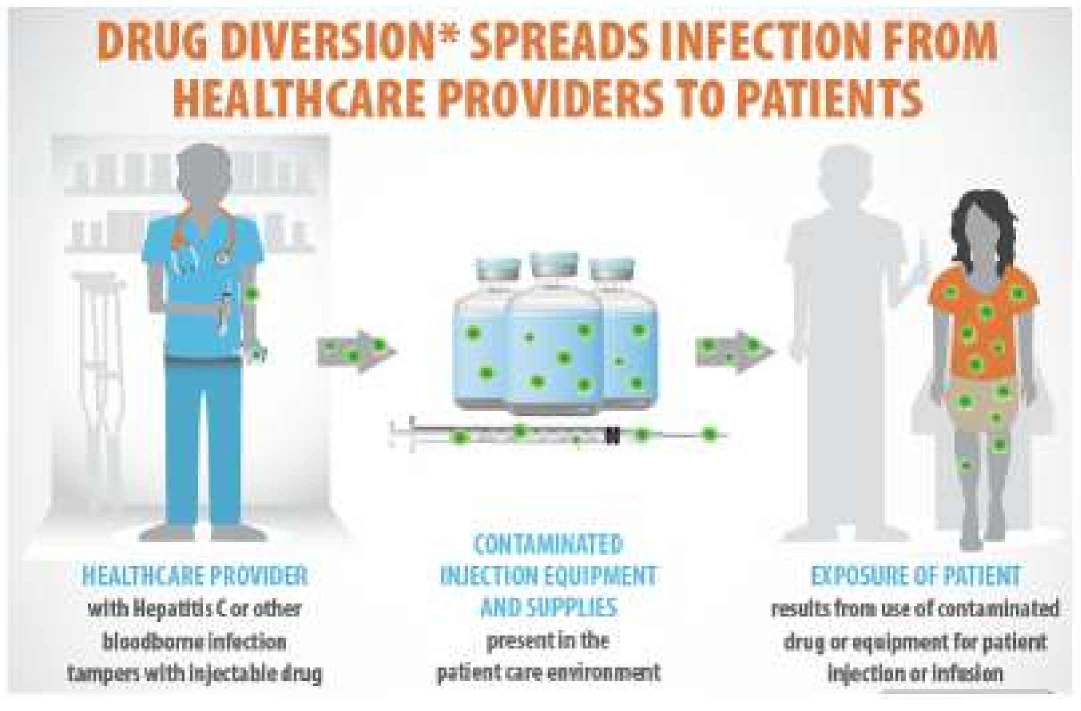
Violation: POTENTIAL Federal Controlled Substance Act. 21C U.S.C 801-904

Investigation: prompted by a Dallas Morning News report of two nurses who died inside hospital rooms at UTSWM from fentanyl overdose over a 2-year period.

Findings:

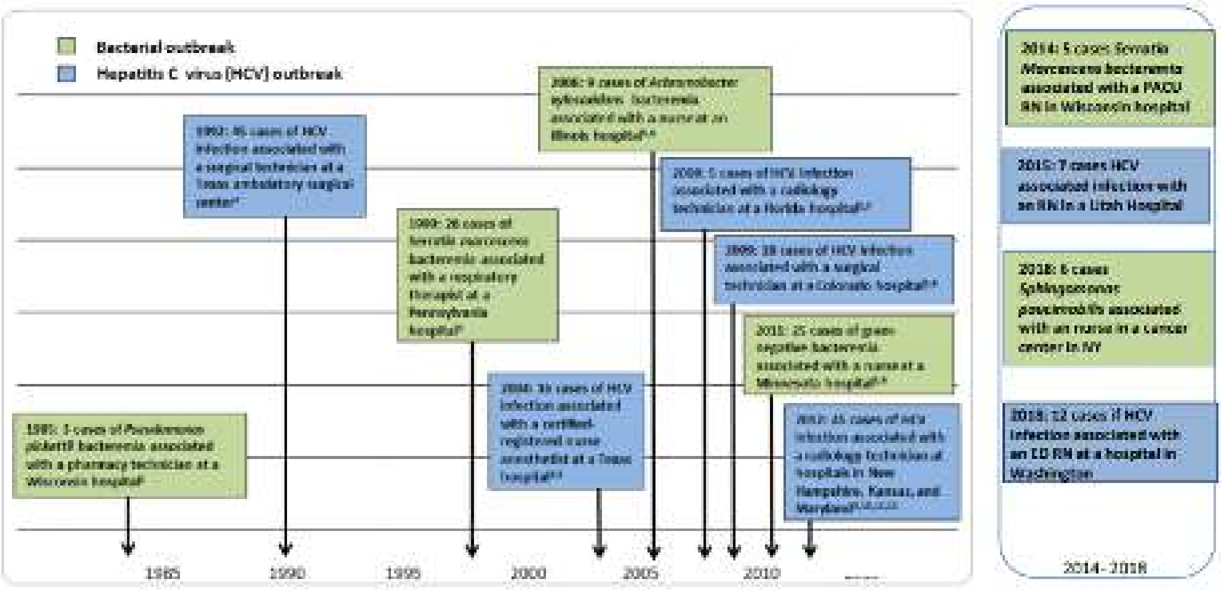
- Medications ordered and administered to patients were not accurately documented
- Medication waste not accurately or not documented
- Thirty-one reports of missing drugs not reported to the DEA over a three-year period (2016-2018)

Infectious Disease Consequences



Infectious Disease Consequences

U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013



https://www.cdc.gov/injectionsafety/drugdiversion/drug-diversion.html

The Anatomy of an Investigation

Drug Regulatory Requirements vs Best Practices

- Expectations are not explicit in the regulations
- The expectation is to adhere to best practice guidelines for patient safety and drug security
- This makes it hard to make the case for FTEs and technology dollars for proactive monitoring
- US Code 842 – Prohibited acts
  - 21 U.S.C 842 [c] [1] 8 - Every instance of incomplete documentation of administration and waste subject to up to a penalty of up to $10,000 / violation

Drug Regulatory Requirements vs Best Practices

Regulatory:

Refer to controlled substance and diversion related requirements that all facilities must comply with:

- CMS – Conditions of Participation (CoP)
  - 42 CFR 482,25 [a] – Pharmacy's role in ensuring safe use of medications throughout the hospital
  - 42 CFR 482.113 [c] 2 – Environment of care for patients is free from threat, abuse or harm
  - 42 CFR 482.12 [a] 5 and 482.22[b] – Ensure that the medical staff is accountable to the governing body for quality
  - 42 CFR 482.12 [e] - Hospital staff is required to comply with state and federal laws
  - 42 CFR 482.12 [e] 1 – Contracted workers are required to comply with state and federal laws (Anesthesia groups)
  - 42 CFR 482.23 [b] 6 – Nonemployee workers are required to comply with state and federal laws (Agency nurses)
  - 42 CFR 482.42 – Hospitals have ongoing surveillance to identify "infectious risks"
  - 42 CFR 482.13 [c] 1, 42 CFR 164 – HIPPA rules related to patient information
  - 42 CFR 482.25 [a] 3 – Policies and procedures to prevent diversion of controlled substances
  - 42 CFR482.25 [b] 2 [i] – All drugs and biologicals are secured and locked when appropriate
  - 42 CFR 482.25 [b] 2 – Individuals with access must be identified by job class in hospital policies and procedures
  - 42 CFR 482,23 [c] 1 and 42 CFR 482.25 [b] – Drugs cannot be administered without a valid order
  - 42 CFR 482.25 [b] 1 – Quantities of controlled substances are limited to prevent diversion and patient assessment of need
  - 42 CFR 482.25 [a]3 and 21 CFR 1304.04 – accurate records be kept (procurement – destruction)
  - 42 CFR 482.13 [a] 2 – Requires that hospitals promptly investigate and resolve patient complaints

Drug Regulatory Requirements vs Best Practices

Regulatory:
Refer to controlled substance and diversion related requirements that all pharmacies and pharmacist must comply with:

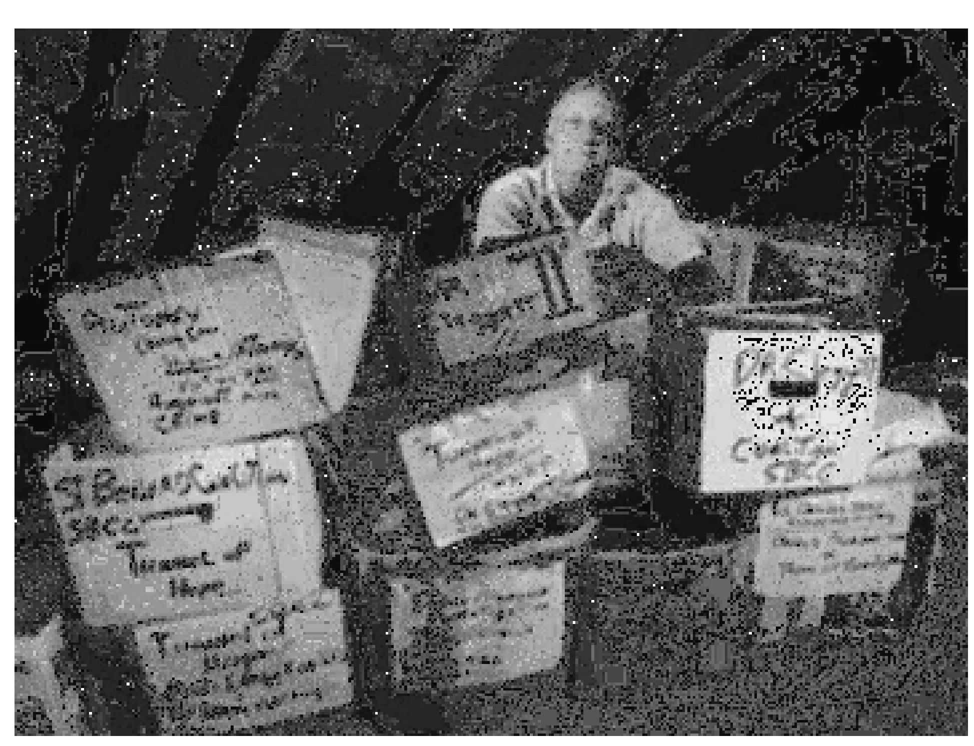
- Federal Drug Enforcement Agency (DEA)
  - Title 21 CFR Part 1300-end
- Federal Environmental Protection Agency (EPA)
  - Resource Conservation and Recovery Act (RCRA)
    - Compliant process for disposal and one that does not facilitate diversion

Drug Regulatory Requirements vs Best Practices

Best Practices and Guidelines:

- American Society of Health-system Pharmacists (ASHP)
  - Guidelines on the Preventing Diversion of Controlled Substances
- Institute for Safe Medication Practices (ISMP)
  - Guidance: The wasting of unneeded medications occurs at the time the medication is removed from the secured storage
  - Guidance: The use of automated dispensing cabinets provides for password security, unit specific privileges, biometric access, reconciliation of human resource records for employment and discharge.
  - www.ismp.org

Dan Schneider “The Pharmacist”



ASHP Guidelines on Preventing Diversion of Controlled Substances

Defines the core elements and controls of a controlled substance diversion prevention program

American Journal of Health System Pharmacy, Volume 74, Issue 5, 1 March 2017, Pages 325–348

Question

In addition to federal laws the Federal Drug Enforcement looks to best evidence practices when investigating a drug diversion case. These best practices include the following:

a. CMS – Conditions of Participation (CoP)
b. ASHP Guidelines on Preventing Diversion of Controlled Substances
c. ISMP Guidance on drug waste and automated dispensing cabinet use
d. b and c

Answer

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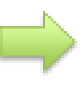
Common Risk Points for Diversion

Procurement – Purchasing Personnel

Risk		Mitigation
Purchasing drugs larger than needed quantities		• Utilize automated technology to order based on MAX/MIN • Limit on hand inventory to 4 days
Stolen DEA 222 Forms		Move to electronic CSOS ordering
Product container tampering		• Purchasing personnel are not the ones who receive the medication • Overt surveillance cameras
Unauthorized access to the inventory		Annual reconciliation of acce the Pharmacy and the vault

Preparation and Dispensing – Pharmacy Technicians & Pharmacists

Preparation and Dispensing

Risk	Mitigation
Oral controlled substances (CS) are replaced by a product of similar appearance when packaging	Utilize barcode enabled auto-packager or purchase as a unit dose product
Remove volume while prepping sterile products infusions 	• Utilize validation process for stock dilutions PRIOR to decanting • Utilize a gravimetrics solution & take pictures at each step • Overt camera over prep area
Removal of overfill from multiple dose vials	Utilize validation process to randomly test waste
Prepared syringes of CS are diluted or replaced with saline	Utilize validation process to randomly test waste

Preparation and Dispensing – Pharmacy Technicians & Pharmacists

Preparation and Dispensing

Risk	Mitigation
Intravenous CS preparations are left unattended on counters or pass through	• Overt cameras inside and outside the sterile products room. • Overt camera viewing pass-through • All CS are returned to a vault or secured/locked area immediately after final validation
Intravenous CS syringe tamper evident caps are not completely secured	Check that all tamper evident devices are secure PRIOR to returning to stock

Preparation and Dispensing – Pharmacy Technicians & Pharmacists

Preparation and Dispensing

Risk	Mitigation
Removal of drug from vials and returned to the vault	Check all caps as well as thin metal seal to make sure that it has not been tampered with/replaced when sending to an ADM or sterile products

Prescribing – Providers/Nurses

Risk		Mitigation
Prescriptions Pads stolen/forged		Electronic prescribing (EPCS)
Provider self prescribes		NY state law prohibits this practice
Verbal orders for CS are requested by an RN but order not placed in EPIC by the provider		Limit use of verbal orders to emergencies or when providers are in the OR/procedure
Hand written prescriptions are adulterated		Limit use of paper hand written prescriptions to downtime only
Patients doctor shopping		CT Prescription Drug Monitoring Program (CTPMP)

Prescribing – Providers/Nurses

Risk		Mitigation
Hospital DEA misuse		• Run a report weekly to look at providers who use the hospital DEA to ePrescribe CS T+1 day after a visit • Limit paper prescriptions for downtime use only • Run reports to evaluate printed prescriptions from the health record
Patient "doctor shopping"		• Insure that all providers access the PMP prior to prescribing any OP CS prescriptions
All medications administered on site not verified by a pharmacist		• Make it easy to use the PMP and Narx score when prescribing CS

Administration – Nurses/Anesthesiologists

Prescribing

Risk		Mitigation
CS are removed from automated dispensing cabinets (ADC) on discharged or transferred patients		Utilize data learning Software
Medications are removed and charted as given however not given		Hourly nurse rounding and monitoring of patient pain scores
CS are removed from ADC and look alike drug is substituted		• Hourly nurse rounding and monitoring of patient pain scores • Limit quantities available in the pockets
CS are removed from ADC when staff is off the clock		Integrate time card into data learning software

Administration – Nurses/Anesthesiologists

Prescribing

Risk	Mitigation
Unsecured Medications	LC and IVPB infusions are in locked boxes to prevent tampering my staff and visitors
Diversion in the OR	Eliminate the pre-drawing of syringes by purchasing them or preparing them yourself
Unauthorized access to ADMS and Anesthesia Systems	Create reasonable timeouts
Critical overrides	Limit critical overrides drugs and to emergencies ONLY or when there is a technology downtime

Waste and Removal – All disciplines

Waste and Disposal

Risk		Mitigation
Wasting of partial doses		Require cosigned/witnessed waste by the same discipline
Waste receptacles are stolen or accessed for drugs		Utilize non-retrievable waste system which deactivates CS waste in the container
Wasting drugs on site in the pharmacy (Expired, broken, etc)		Utilize a reverse distributor for all CS waste

Leveling the Playing Field

Definition of Risk

Traditional View

- "Negative" often characterized as a "threat"

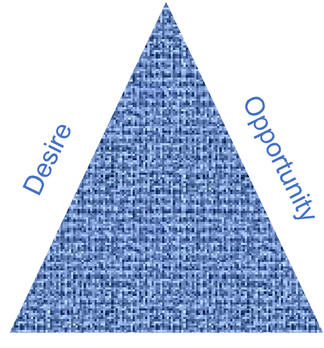
Contemporary View

- "Positive" often characterized as an "opportunity"

Principles of Opportunity and Crime

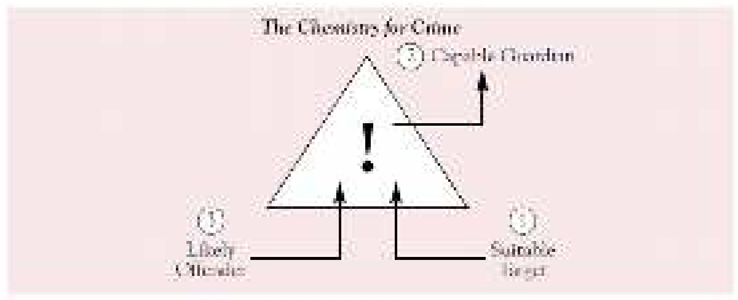
Ten Principles of Opportunities and Crime

- Opportunities play a specific role in causing all crime
- Crime opportunities are highly specific
- Crime opportunities are concentrated in time and space
- Crime opportunities depend on everyday movements
- One crime produces opportunities for another
- Some products offer more tempting crime opportunities
- Social and technological changes produce new crime opportunities
- Opportunities for crime can be reduced
- Reducing opportunities does not usually replace crime
- Focused opportunity reduction can produce wider declines in crime



Source: Felson, M. 1998. Crime and Everyday Life, 2nd Ed, Pine Forge Press

Routine Activity Risk



1. Suitable Target: Controlled substance
2. Capable Guardian: anybody whose presence or proximity would discourage a crime from happening
3. Likely Offender: Healthcare practitioner, healthcare paraprofessional, Healthcare ancillary service employee, visitor

Source: Felson, M. 1998. Crime and Everyday Life, 2nd Ed, Pine Forge Press

Routine Risk Activity

Four main elements that influence a target's risk: VIVA

- Value: Offenders are interested in targets of benefit or gain
- Inertia: Offenders will take items that are small and concealable
- Visibility: Refers to the exposure of theft targets to offenders
- Access: Refers to features of everyday life making it easy for offenders to get to targets.

"For the usual predatory crime to occur, a likely offender must find a suitable target in the absence of a capable guardian."

Source: Felson, M. 1998. Crime and Everyday life, 2nd Ed, Pine Forge Press

Question

Routine Risk Activity Theory identifies three components for a crime that include:

a. A suitable target, a capable guardian, and a likely offender

b. A suitable target, a locked compartment, and a likely offender

c. A suitable target, a capable guardian, and someone with access

d. A suitable guardian, a locked compartment, and someone with access

Answer

Routine Risk Activity Theory identifies three components for a crime that include:

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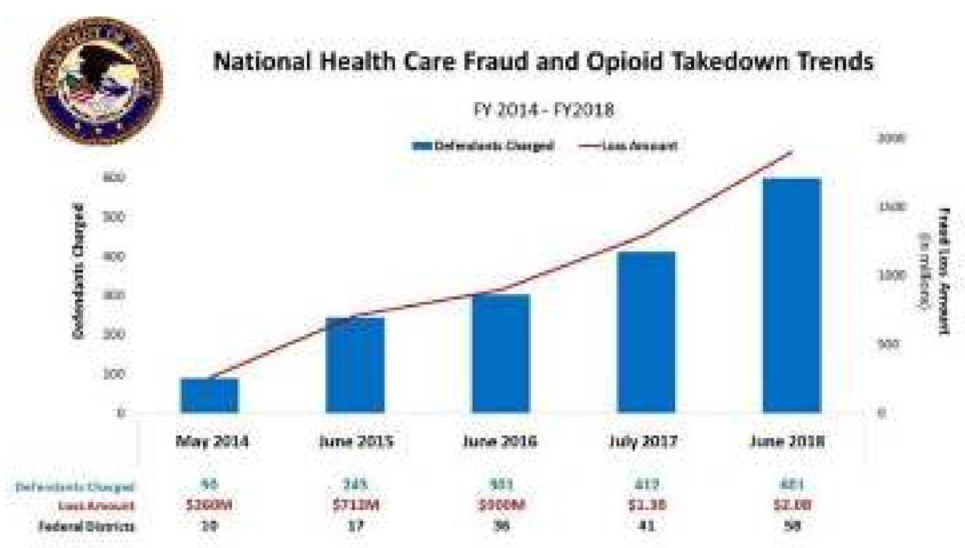
Case Based Proactive Drug Diversion Software

Why Proactive Drug Diversion Programs are Necessary

In February and March 2018, the DEA spearheaded drug diversion investigations with help from the HHS. These led to 28 arrests, 54 enforcement actions, 150 dispensing authority revocations, and 283 administrative actions.



Healthcare Worker Opiate Use Disorder Statistics

- Physicians and other Healthcare workers are addicted to drugs in the same proportion as the general population.
  - 10-14%
- Among medical professionals those at highest risk
  - Emergency room workers,
  - Anesthesiologists,
  - Psychiatrists
- Others with access to drugs
  - Nurses
  - Pharmacists
  - Pharmacy technicians

Pressures Inherent to the Medical Profession

- Educational demands
- Extended workdays
- Unexpected patient outcomes
- Stress brought on by long hours and large caseloads
- Availability and access
- Failure to report indiscretions
  - Livelihood
  - Financial

Drug Diversions Multiple Victims

- **Employee**
  - Health – morbidity/death
  - Progression to illicit substances
  - Risky behavior and incarceration
  - Loss of livelihood (licensure)
  - Loss of employment
- **Patient**
  - Risk of infection
  - Poor pain management
  - Providing care while impaired
- **Health-system**
  - Patient Harm (CDC estimates 30,000 exposed to Hep C over past 10 years)
  - Civil and regulatory penalties
  - Reputation and brand risk

Questions