Public Health Epidemic

2000-2014:
Unintentional drug overdose deaths in the US increased 137%, which was a 200% increase in overdose deaths involving opioids.

- 500,000 deaths due to prescription overdose

2015:
- Over 47,000 drug-related overdose deaths
- 28,647 deaths involved opioids, including heroin
- 19,000 deaths involved prescription opioid
- 1 death every 11.16 minutes
- 129 deaths every 24 hours

CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016
U.S. Drug Enforcement Administration

Diversion: A Public Health Threat

CDC: Nearly 30,000 exposed to Hep C over past decade by infected hospital employees using narcotics intended for patients
Hospitals/Clinics/Long Term Care Facilities

- CDC Estimate – 100,000 healthcare workers suffer from addiction
- Staff have easy access to medications
- Can move from facility to facility; sometimes with no record of arrest, discipline, or investigation
- Patients may not know if someone stole all or some of their medication but may feel results (i.e., waking up during surgery)

How Controlled Substances are Diverted

- Practitioners/ Pharmacists
  - Illegal distribution
  - Self abuse
  - Trading drugs for sex
- Employee pilferage
  - Hospitals
  - Practitioners’ offices
  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities
- Pharmacy / Other Theft
  - Armed robbery
  - Burglary (Night Break-ins)
  - In Transit Loss
- Patients
  - Individual and organized drug ring
  - Doctor-shopping
  - Feigning illness
  - Forged / fraudulent / altered prescriptions

It’s all about recordkeeping

- Civil penalties are per recordkeeping violation...DOJ raised from $10,000 to $14,502 effective August 1, 2016
- Even if the recordkeeping violation did not result in diversion of controlled substances
- A hospital’s good-faith intent is not enough to prevent potential penalties if recordkeeping violations exist
- The rules apply to each DEA registrant
Legal requirements for hospitals

- Register with DEA
- Have “effective controls and procedures” to guard against theft & diversion of controlled substances- **entire facility, not just pharmacy**
- Keep complete and accurate records
- Must “maintain, on a current basis, a complete and accurate record of each substance ... received, sold, delivered, ... or otherwise disposed of”

Complete and accurate records

- Receipt, transfer, or distribution requires:
  - DEA Form 222 for Schedule II drugs
  - Invoice for Schedule III-V drugs
- Biennial inventory
- Report any theft or significant loss to local DEA within 1 business day of discovery
- Registrant shall also submit a DEA Form 106, Report of Theft of Loss of Controlled Substances
What is a significant loss?

• 21 CFR § 1301.74(c)

“. . .When determining whether a loss is significant, a registrant should consider, among others, the following factors:

• (1) The actual quantity of controlled substances lost in relation to the type of business;
• (2) The specific controlled substances lost;
• (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
• (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
• (5) Whether the specific controlled substances are likely candidates for diversion;
• (6) Local trends and other indicators of the diversion potential of the missing controlled substance.”

Reporting Responsibilities

• Not reporting loss – not an option
• Don’t know who did it? – still need to report it
• Can always file amended DEA if initial numbers change
• Can notify local DEA office if “missing” drugs are accounted for
Reporting Responsibilities

• 21 CFR §1301.91 Employee responsibility to report drug diversion
  • It is the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer...The employer shall inform all employees concerning this policy

Recommendations

• Conduct mandatory training to include:
  – Duty to report loss or suspected misuse or abuse
  – The signs of substance abuse
• Take complaints seriously, do follow up
• Have a progressive discipline policy in place for staff who lose controlled substances or who cannot explain drug count discrepancies, and adhere to it

Recommendations

• Automatic drug dispensing machines
  – Keep accurate inventories
  – Restrict staff access
  – Short lockout times
  – Delete patient names upon discharge
• Have controlled substance surveillance software, and review the reports
• Address poor controls (e.g., blank prescription pads lying around, expired drugs in unlocked areas, not changing passwords; not controlling access to keys)
Recommendations

- **Surprise audits** (automated machines and/or cabinets)
  - Have witness when auditing, change witness
  - Audit different systems if your systems don’t talk to each other
- **Random urine screens**
- **Whenever possible**, include public safety officers when interviewing employees suspected of diversion

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**Hydrocodone**

- Hydrocodone / Acetaminophen (toxicity)
- **Similarities:**
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- **Brand Names:** Vicodin®, Lortab®, Lorcet®

- Currently, combination products are Schedule III
- **October 6, 2014** moved to SCHEDULE II

  - “Cocktail” or “Trinity”
    - Hydrocodone
    - Soma® / carisoprodol
    - Alprazolam / Xanax®

- Street prices: $2 to $10+ per tablet depending on strength & region

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**Oxycodone**

OxyContin controlled release formulation of Schedule II oxycodone

The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone.

Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high

10, 15, 20, 30, 40, 60, 80mg available

**Effects:**

- Similar to morphine in effects and potential for abuse/dependence

Oxycodone, Soma® / Xanax®

Street price: Approx. $80 per 80mg tablet

**NOTE:** New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.
Something to think about

• Given the street value of controlled substances, some people who divert them aren’t users of what they steal – they sell them or trade them for other drugs

Resources available on www.deadiversion.usdoj.gov

• Pharmacist’s Manual
• Practitioner’s Manual
• Security Manual
• Required reporting forms and rules
• U.S. Code/Code of Federal Regulations
• Lists of controlled substances and chemicals