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Understanding Diversion in the Pharmacy

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Scope of the Problem

- Diversion can’t be prevented entirely
- Substantial safety, quality, regulatory and legal risk
- Mitigate risk with formal program, transparency and culture change
Preventing Patient Harm

• Receiving care from impaired provider
• Untreated pain
• Exposure to bloodborne pathogens or exposure to unsafe substances
Preventing Institutional Harm

- Liability-civil, regulatory
- 340B and GPO compliance
- Negative publicity (brand at risk)
Preventing Community Harm

Ga Anesthesia Assistant Arrested For DUI
Propofol In Wrong Way Crash

Beverly Wilkins
Ongoing Threat

7,200 McKay-Dee and Davis Hospital patients could have been exposed to hepatitis C

5,000 Scripps Health, Swedish Hospital and Northwest Hospital & Medical Center patients offered hepatitis C testing

More than 200 patients seen at Shore Medical Center notified of potential exposure to hepatitis C
Goals

• Prevent, detect and respond

• Culture of ongoing awareness and accountability
Who?
Who Gets Involved in Diversion?

- Bad people?
- Less caring?
- Desire for drugs motivated career choice?
- Just nurses?
What Does a Diverter Look Like?
Where?
Anywhere controlled substances are found by anyone intent on diverting!
High Risk Areas

- Critical care and emergent care
- Surgical care (inpatient, outpatient, specialty)
- L&D
- Procedural areas
- Pharmacy
Why?
Occupational Factors

- Suppression of feelings and emotions
- Compassion fatigue and burnout
- Physical demands of job, injuries and chronic pain
- Ease of access to prescriptions and medication
- Knowledge and sense of control
What?
Drugs of Choice

Injectables:
- Hydromorphone
- Morphine
- Fentanyl
- Propofol

Pills and liquids:
Hydrocodone
Oxycodone
Drugs of Choice

• Benzodiazepines (lorazepam, alprazolam, clonazepam)
• Drugs to ease withdrawal and enhance impact of opioid (ondansetron, promethazine, diphenhydramine)
• Non-scheduled (cyclobenzaprine, gabapentin, ketorolac)
• Anesthesia gases
How?
Drug Transactions

- Patterns for patients
- Patterns over time for user
- Patterns for handling non-preferred drugs
Methods/Signs of Diversion

- Removal of medication when not needed
- Removal for discharged patient
- Removal of duplicate dose
- Removal of/diversion from fentanyl patches
Methods/Signs of Diversion

- Removal of medication without order
- Failure to waste
- Frequent wasting of entire doses
- Substitution in administration and wasting
Methods/Signs of Diversion

Giving less than ordered more frequently

• Order is for 2 mg morphine IV q 2 hr prn
• 2 mg syringe is available
• Nurse administers 1 mg dose at 8 am and another 1 mg dose at 9 am
• Patient has received 2 mg in 2 hr.
• Nurse has 2 mg of waste where he would have had none if he had administered the medication in one dose as envisioned
Methods/Signs of Diversion

- Removal of larger doses than necessary
- Withdrawal from PCA and drip lines
- Removal under sign-on of colleague
- Removal of unspent syringes from sharps boxes
- Pilfering patient medications brought from home
Methods/Signs of Diversion

- Removal of oral and injectable opioid at the same time
- Frequent breaking of containers for injectables
- Null/canceled transactions, particularly for a specific bin
- Cycle counts
- Floor charges
Program Essentials
Program Operations and Oversight

Diversion Specialist
• Daily operations-surveillance
• Database
• Educator

Other Key Functions
• Education
• Institutional resource
• Diversion risk rounds
• Community, LE and regulatory liaison
Program Operations and Oversight

Diversion Response Team

- Multidisciplinary
- Input from manager of suspected staff member
- Short notice and after normal business hours

Diversion Committee – multidisciplinary

- High level
- Ensures support and direction for program
- Data tracking over time
Diversion Committee Membership

Chair: Diversion Specialist

- Anesthesia
- Nursing (general, procedural)
- Pharmacy (med safety, narc)
- Security
- Risk Management
- Accreditation
- Chief Medical Officer
- Compliance

- Infection prevention
- Human Resources
- Employee Health
- Finance
- Laboratory
- Research
- COO or other C-Suite rep

- Ad hoc
Important Elements

- Policies to prevent, detect and properly respond to diversion
- Shared responsibilities between key departments
- Method of auditing
- Prompt attention to suspicious data
- Collaborative relationship with external agencies
- Education for all staff
- Diversion risk rounds
Screening For Risk

21 CFR 1301.90 Employee screening procedures

• Obtaining certain information is vital to assess the likelihood of an employee committing a drug security breach

• Need to know is a matter of business necessity, essential to overall controlled substances security

• Conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry
Screening for Risk

21 CFR 1301.93 Sources of information for employee checks

DEA recommends that inquiries concerning employees' criminal records be made as follows:

• Local inquiries. Inquiries made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions.

• DEA inquiries. Inquiries furnished to DEA Field Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.
Security from Procurement to Administration and Disposal

42 CFR §482.25(a) Standard: Pharmacy Management and Administration

- The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

- The hospital’s pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.
Controls and Safeguards

42 CFR §482.25(b) Standard: Delivery of Services

• In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

• Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to:

  Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed.
Controls and Safeguards

42 CFR §482.25(b)(1) - Medications must be dispensed by the hospital in a manner that is safe and meets the needs of the patient:

• Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
Security

42 CFR §482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area, and locked when appropriate.

• Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons

• If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained

• All controlled substances must be locked
• Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored?

• Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.
21 CFR §1301.91 Employee responsibility to report drug diversion

• Reports of drug diversion by fellow employees is necessary and also serves the public interest at large

• An employee with knowledge of drug diversion from his employer by a fellow employee is obligated to report to a responsible security official of the employer

• Confidentiality for those reporting

• Employer shall inform all employees concerning this policy
External Reporting

21 CFR §1301.76 Other security controls for practitioners

• Registrants required to notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft.

• Also complete and submit to the Field Office, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss.
Theft and Loss

- Diversion is theft, not loss
- Updates every 30 days
- For loss, no single objective standard, but instead view in context of a registrant's business activity and environment
- When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances
Theft and Loss

Determining significance of loss:

- Actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances lost;
- Whether the loss can be associated with access by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- 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,
- Whether the specific controlled substances are likely candidates for diversion;
- Local trends and other indicators of the diversion potential of the missing controlled substance.
Internal and External Collaboration

Internal

• Comprehensive program requires multi-departmental involvement
• Division of labor according to area of expertise
• Ensure communication between all involved and all relevant departments (some reporting must occur within very narrow timeframes)

External

• Know reporting channels, expectations and resources in advance
Diversion Risk Rounds

Unannounced and at least quarterly
Looking in the Pharmacy

• Lead by example
• Regular self-assessments
• Know where controlled substances exist, how they are accounted for, what auditing is in place and who has responsibility
Common Pharmacy Pitfalls

• No separation in ordering, receiving and stocking
• Lax physical security
• Lack of knowledge of inventory
• Not knowing limits of refractometer
• No plan for addressing potential tampering
• Not applying controls to retail environment
• No closed loop
Common Pharmacy Pitfalls

- Inability to quantify and track reverse distribution stock
- Inappropriate handling of controlled substance waste
- Not securing high risk non-controlled drugs
- Complacency regarding anesthesia
- Poor record keeping
Common Pharmacy Pitfalls

• Too much traffic and no record of who comes and goes
• No proactive diversion auditing
• Not enforcing discrepancy resolution
• Lax ADC privileging and revocation of status
• Not keeping PCA keys in single access bin in ADC
• Cumbersome and ineffective controlled substance tracking paperwork
In Conclusion

- Diversion is a ever present risk
- In order to protect patients, staff and the institution from harm, diversion must be addressed proactively
- A formal program is essential in ensuring that the risks associated with diversion are minimized
Thank you!

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Drug Diversion in the Pharmacy

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Pharmacist: 4LM6UE

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