Controlled Substance Diversion: Tales from the Front

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Objectives

- Understand the magnitude and implication of prescription drug diversion
- Identify potential points of concern for drug diversion
- Build effective analytic tools to assess controlled substance utilization
- Create controls to improve security of controlled substances
Prescription Drug Diversion

• America addicted more to pharmaceuticals than street drugs
• Estimated over 7 million non-medical users of prescription drugs
• Estimated that 12-16% of healthcare professionals will be addicted at some point in their career
Prescription Drug Diversion

- Approximately 30% of addictions start with abuse of prescription medication
- Triggers such as stress, back injury, migraine, accidents, etc
- Cost of non-medical prescription drug use to medical insurers is over $73 billion annually
Social Cost

- Reduced productivity
- Loss of employment
- Family impact
- Extreme cases can impact the health and safety of others
Colorado Case

- Surgical tech diverted fentanyl
- Self injected fentanyl using syringes that she later filled with saline and replaced
- Individual was infected with hepatitis C
- 10 hepatitis C cases linked back to the hospital
- 6,000 patients required notification of the potential exposure
Pharmacy Personnel Not Immune

- Sept. 16, 2009 Wilmington, DE “Pharmacy Employee Charged with Drug Theft”
- Sept. 4, 2009 Flora, IL “CVS Pharmacy Employee Charged with Alleged Drug Theft”
- Aug. 21, 2009 Denver, CO “Pharmacy Manager Accused of Drug Theft”
- Feb. 23, 2009 Muskogee, OK “Tribal Pharmacist Pleads Guilty to Drug Theft”
- Jan. 15, 2009 Bangor, MA “Pharmacist Gets Prison Time for Morphine Theft”
- Sept. 21, 2010 Bremerton, WA “License of Poulsbo pharmacist suspended for allegedly diverting opiates for own use”
Rx Drug Diversion

- Personal use
- Supply for a boyfriend, girlfriend, spouse, friend, etc
- Party supply
- Sale
  - Directly to “customers”
  - Through another “distributor”
Where Do you Start?

• Assess the culture in the organization
• Do you have a culture of responsibility around controlled substances?
• Remember – culture eats strategy and planning every time!
Culture

• Multidisciplinary approach
• Commitment to standard processes for monitoring and control
• Defined accountability and responsibility for monitoring and control
• Organizational priority
  – Must include senior leadership
Common Denominator

• In examining virtually every case of controlled substance diversion the one common denominator is ACCESS

• Must engineer systems that create controlled access

• Can not “short cut” control for convenience

• Can’t assume that individuals in positions of authority are exempt from controls

• Can’t circumvent controls due to familiarity
Retail Pharmacy Case

• RPH, 3 Techs, Part-Time RPh
• Worked together 8 years
• Busy operation; understaffed; limited resources
• RPh provided techs with access code to pharmacy; pre-signed invoices for payment; no separation of duties
• Tech ordered “extra” supplies of CIII’s and diverted for sale
Ordering Process

• Create system of checks and balances so that no one individual has total process control
• Limit number of individuals with DEA Power of Authority to order
• Order placed by specific individual
• Different individual receives order and places into stock
Order/Receipt

• Separation of duties is good but not infallible
• Individuals could agree to “work together” to beat the system
• Conduct periodic audits of controlled substance purchases matched against inventory receipts in the CS vault
• Ensure control of DEA 222 forms
• Consider use of CSOS electronic order system to streamline process and enhance security
• Evaluate integrity of delivery/receipt process
• Consider use of tamper resistant or tamper evident packaging when available
Receiving Case

- Medication deliveries set up to the receiving dock
- Immediately locked in cage for pharmacy pick-up
- Sleeves of 5 syringes randomly missing from packages of 10 on Clls
- All exterior packaging intact
- FBI engaged in investigation
Retail Case

• Tech diverting small quantities of cash and drugs
• Operation had separation of duties
• Diverter regularly bought co-workers “surprise” gifts
• Everyone “looked the other way” on where the extra money was coming from for these gifts
Storage

- Over 90% of hospitals utilize automated dispensing cabinets (ADC)
- Ideally an automated controlled substance vault should also be used
- The CS Vault will interface with the ADCs to create an audit trail for reconciliation of transactions to or from the vault
- Consider limited access to the CS Vault – who really needs to get into this?
- Ensure over-ride systems are checked for security
ADC Case

- Large quantities of missing Norco
- Specific floor but not specific ADC
- Reviewed last RN to access logs and discovered RNs accessing ADC that were not “on shift” or present
- Suspected stolen passwords
- Placed hidden camera in med rooms
- Found RN with multiple stolen passwords
- RN had figured out IT was doing system upgrades between 3:30am – 4am and there was enough network interruption to kick the ADCs into override
- Would log in with stolen password right at 3:30am and then just wait for override to initiate and steal the Norco
System Review

• Establish an audit process for controlled substance transactions
• In a manual system a review should occur to verify that CS dispense transactions actually made it to the intended destination
• Automated CS Vaults will generate transaction and discrepancy reports
• Ideally, the auditor should not be the same person involved in the transactions
Diversion Detection Software

- Consider the use of specific diversion detection software
- Transaction quantity analysis
  - System wide
  - Unit specific
- Transaction category analysis
- Ability to drill down to transactions per shift
- Waste transaction analysis; number of wastes and number of times same two people witnessed
- Override transaction analysis
- Discrepancy resolution analysis
- Ability to automatically flag alerts for hospital specific thresholds
- Ideally data should be real time
Patient Care Areas

• Best defense against diversion is a vigilant staff
  – pay attention and report suspicious behavior

• Support culture of responsibility by ensuring that this is included in nursing and pharmacy orientation and periodically reinforced
  – Grand rounds
  – Email reminders
  – CE sessions
  – Reminder signs in med rooms or CS vaults
Diversion “Red Flags”

- Changes in work habits, behavior, physical appearance
- Major change or chaos in personal life
- Change in CS usage patterns
- Patient complaints about pain control
- Large amounts of CS removed or larger doses requiring waste used when smaller dose available
- Unexplained absences on a regular basis during work
- Excessive “accidents” leaking bags, broken vials, spills etc
- Tablet/Capsule returns missing pieces or contents
- Inappropriate CS destruction
- Personnel “in the wrong place” without good reasons
- Personnel at work on days off or before/after shift
- Requests to care for specific patients using CS
- “Helps” other nurses administer their medications
Patient Care Area Documentation

- Passwords – how are these issued and controlled?
- Creation of “temporary” user accounts
- Bio ID option
- Inventory counts – for matrix type storage are inventory counts performed each time a med is accessed?
- Periodic audits to link dispensed meds to chart documentation to patient confirmation
- Discrepancy resolution should be a priority and a joint effort between nursing and pharmacy
Patient Care Area Storage

• How are controlled substances that are available for patient use monitored controlled:
  – PCA’s
  – IV Drips
  – OR’s
  – Procedural areas
ICU Case

- RNs in critical care unit reported multiple morphine drips “running ahead of schedule”
- Double checked pharmacy compounding process and pump settings
- Verified accuracy
- Placed hidden camera in next patient room
- Discovered MD removing solution from the patient’s bag while it was hanging in the room
Operating Rooms

- Evaluate the distribution system
- What does access look like during and after a case?
- How does documentation look?
  - Are there orders for the medication
  - Were the meds charted
  - Manual systems much easier to “game”
  - Inconsistency
OR Diversion

- Anesthesia sign out of CS with returns and documentation at end of day
- Techs reconcile usage and returns
- Random validation of returns using UV light technology
- Patients reporting decreased pain control post-op
- Tech noticed some unused vials had “loose” caps (but still intact)
- Tested these vials and found evidence of tampering
- Were able to work back and identify suspect anesthesiologist
- Had built a special needle that they fitted under the cap without unseating it and were withdrawing drug and then backfilling with saline
Returns/Waste

- Are controlled substances being wasted properly with appropriate witness/documentation?
- Are CS inappropriately thrown in sharps or trash?
- How are unused CS handled? Returns bin; returned to drawer; returned to pharmacy
Waste Diversion

• ES worker observed RNs improperly disposing of used CII syringes in the regular sharps containers
• Created a spreadsheet of all units where this practice was happening
• Would make sure they picked-up these containers for disposal
• Removed all of the “left over” drug from these syringes
Returns Waste

• Expired or waste returned to pharmacy
  – Use of med pending destruction report
  – On site destruction (DEA form 41) with minimum of two RPh witness
  – Use of Reverse Distributor (DEA 222)

• Are returns actually checked for potential tampering?
  – Use of systems to identify drug/concentration
  – Random audit of returns
Employees

• Clear policy on diversion/impairment
• Drug testing policy?
  – Screen on hire
  – For cause
  – Random
Diversion Investigation

- What happens when a diversion/suspected diversion is reported?
  - Immediate patient risk
  - Clear cut diversion
  - Suspected diversion
Suspected Diversion

• Who leads the investigation?

• Tools
  – Cameras
  – Reports
  – Drug Testing
  – Polygraph
Polygraph

- Employers generally cannot require a polygraph and can’t discharge, discipline or discriminate against employees for refusing the test.
- Options provided under the 1988 Employee Polygraph Protection Act.
Polygraph

- Exemption for drug security, drug theft, or drug diversion investigations.
- Key Polygraph Requirements include:
  - Incident part of ongoing specific investigation
  - Written statement to employee demonstrating facts and reasonable suspicion (access alone not enough)
  - 48 hour advance test notice
  - Written notice of test date, time, location
  - Interview of employee post-test with written action statement kept on file for 3 years
Utilization of Polygraph

- Suspected CII diversion; inventory did match records
- Tracked over time and found four possible suspects
- Drug testing was negative
- Utilized polygraph under exemption for drug theft and investigation
- Found two individuals diverting at the same time with neither aware of the others activities
Diversion/Investigation

- Multidisciplinary approach
  - Nursing, Pharmacy, HR, Security, Senior Leadership
- Established communication channel and identified personnel
Reporting

- Reports to professional licensing boards
- Consideration of theft/criminal prosecution
- Involvement of local law enforcement
- DEA Notification (Form 106)
Established Internal Process

• Status of employee
  – Administrative leave
  – Termination

• Use of EAP or State Rehab programs
  – Protection of the employee
  – Protection of the organization

• CEO notification
Summary

• Pervasive social problem
• Healthcare professionals not immune
• Creates serious patient safety concern
• Exposes organization to legal and regulatory sanctions
• Requires constant vigilance
• Multidisciplinary organizational commitment to a culture of responsibility
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