Health Facility Drug Diversion: Essential Compliance & Auditing Measures

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Discussion Topics

- Diversion defined
  - Scope of the problem
  - Profile and predisposing factors
  - Impact on the patient and institution
- Reporting requirements
- Components of a diversion prevention, detection and response program
- Auditing & Prevention
- Diversion Case Study

Drug Diversion

What is it?

How big is the problem?

Diversion Defined

Diversion:

✓**The use of prescription drugs for recreational purposes.**

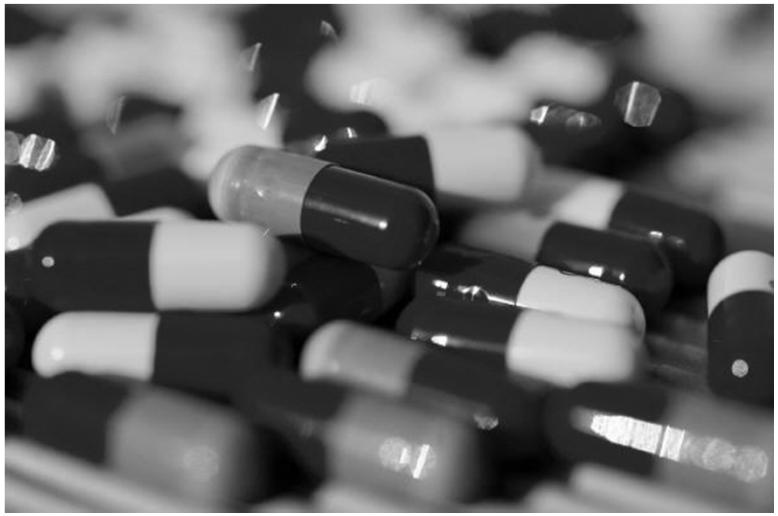
✓**Diverting a prescription drug for other than its intended purpose.**

Addiction:

✓**Continued use despite harm**

Healthcare Facility Drug Diversion

Theft of medication, including “waste,” from patients or health care facilities
for personal use



“Scheduled Drugs”

- **Developed by The Controlled Substances Act of 1970**
- **Currently there are 5 Schedules**
- **Schedule I:** no accepted medical use, high potential for abuse.
  - *Example: heroin, ecstasy*
- **Schedule II:** accepted medical use with severe restrictions with high potential for abuse.
  - *Example: cocaine, morphine*
- **Schedule III:** accepted medical use with moderate to low potential for abuse.
  - *Example: codeine, vicodin*
- **Schedule IV:** accepted medical use with potential for abuse, but less than Schedule III.
  - Example: valium, ambien
- **Schedule V:** accepted medical use with low potential for abuse.
  - *Example: Robitussin AC*
- State and local laws may be more restrictive

The Facts

- Reliable statistics on the prevalence of ***drug diversion*** by nurses are not available
- By its nature, diversion is a clandestine activity, and methods in place in many institutions leave cases undiscovered or unreported
- Drug diversion by health care providers is universal among institutions in the United States
- If your institution is not finding and reporting drug diversion, review your program with the goal of identifying its weak points

Who and Why?

Occupational factors

- Suppression of feelings and emotions
- Vicarious trauma
- Physical demands of job
- Legitimate use and chronic pain
- **Ease of access to prescriptions and medication**
- Knowledge and sense of control

The major factors impacting the incidence of drug misuse by healthcare professionals are access and availability of controlled substances.

Bell DM, McDonough JP, Ellison JS, Fitzhugh ED. Controlled drug misuse by Certified Registered Nurse Anesthetists. AANA J 1999;67(2):133-140.

Who and Why?

Profile

- High achiever
- Significant stress in personal life
- Night shift
- Critical care or other unit where nursing staff have increased autonomy
- Agency
- Legitimate prescription for drug being diverted
- Smoker

Our Experience

Approximately 1 nurse per month

- Award winners
- New Grads
- Team Leaders
- Pediatric and neonatal nurses
- Pregnant nurses
- Clusters of nurses

Impact on Patients

- Impairment and addiction put patients at risk
- Strong likelihood of denying patients appropriate pain relief
- Potential to expose patients to bloodborne pathogens
- Falsification of records (fraud)
- Theft

Tampering

Boulder Community Hospital

- Over 300 potential victims
- Sentenced to 54 months in federal prison followed by 3 years supervised release

Ashton Paul Daigle

Rose Medical Center

- Over 20 patients infected
- Plea bargain rejected, sentenced to 30 years

Kristin Parker

Tampering

David Kwiatkowski

Exeter Hospital –

- 8 states
- 3,798 tested from Exeter alone
- 44 cases of hepatitis C

St Cloud Hospital -

- Siphoned fentanyl from IV bags
- Replaced fentanyl with saline
- 24 patients infected with bacteria

Recognition of Patient Harm

Diversion doesn't always result in patient harm, but beware of these situations:

- Diversion of scheduled (non prn) doses
- Documentation of pain at the time medication is diverted
- Evidence of substitution and tampering, including transmission of infection
- Impairment resulting in patient harm or reckless endangerment

Impact on Institution

- Liability-civil, regulatory
- Negative publicity
- License and participation in Medicare/Medicaid in jeopardy

Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment.

State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

DEA

21 CFR 1301.90 Employee screening procedures. (Non-practitioners)

- DEA position that obtaining certain information by non-practitioners 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

DEA

21 CFR 1301.92 Illicit activities by employees

- Employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution
- Employer will immediately determine status of continued employment by assessing the seriousness of the violation, the position of responsibility held by the employee, past record of employment, etc.

Conditions of Participation

§482.13(c)(2) - The patient has the right to receive care in a safe setting

Hospital must:

- Protect vulnerable patients
- Identify and evaluate problems and patterns of incidents

Conditions of Participation

§482.25(a)(3) - Current and accurate records must be kept of the receipt and disposition of all scheduled drugs

- Records of all scheduled drugs must be maintained and any discrepancies in count reconciled promptly
- Must be capable of quickly identifying loss or diversion of controlled substances and determining the extent of the diversion
- Must have policies and procedures in place which minimize scheduled drug diversion

Conditions of Participation

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

- Storage procedures must prevent unmonitored access by unauthorized individuals
- Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area
- If tampering or diversion occurs, or if medication security otherwise becomes a problem, the hospital must 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

The Joint Commission

The hospital must safely:

- Manage high alert medications
- Store medications
- Control medications brought from home
- Dispense and administer medications
- Manage returned medications

and

- The hospital must evaluate the effectiveness of medication management system

Reporting

Reporting Controlled Substance Loss

- Three agencies place responsibility for security of all drugs in the healthcare setting on the Pharmacy
  - Drug Enforcement Agency (www.deadiversion.usdoj.gov)
  - The Joint Commission (www.jointcommission.org)
  - American Society of Health-System Pharmacists (www.ashp.org)
- Each state has a Pharmacy State Board that has a number of regulatory requirements

DEA UNITED STATES Drug Enforcement Administration TOUGH WORK.

American Society of Health-System Pharmacists® TOGETHER WE MAKE A GREAT TEAM

The Joint Commission

Reporting Is Essential

- **Must report to DEA immediately**
- **State Licensure Board and/or Professional Assistance**
- **Law Enforcement** - crimes, issues of abuse/neglect/reckless endangerment, fraud
- **Pharmacy Board**
- **FDA/OCI (tampering cases)**
- **OIG**

DEA

21 CFR 1301.91 Employee responsibility to report drug diversion

- Reports of drug diversion are necessary part of employee security program but also serve the public interest at large
- 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

Conditions of Participation

§482.25(b)(7) - Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate

- Controlled drug losses must be reported to DEA
- Some states mandate reporting of a crime or drug related crime

Getting Help

- Most states have an alternative program to assist in the rehabilitation of impaired healthcare professionals
- Law enforcement may use generic wording if an arrest is made and a “treatment in lieu of conviction” program may be offered
- Failing to report is not the compassionate approach

Why Don’t We Hear More?

- Fear of negative publicity
- Fear of State and Federal agency involvement

- Uncertainty about reporting requirements and avenues
- Justification that terminating the employee is enough

Consequences

- Diverter is dismissed/employment terminated or allowed to quit

- Potential of rehabilitation near zero

- Violates laws and regulations

- Disregards the well being of the diverter

- No reported history will bypass preventive screening at next employer

Internal Controls

Components of a diversion prevention, detection and response program

First Do No Harm

- Internal Controls
  - Preventive*
  - Detective
  - Automated
  - Manual
- Internal Control Failure Can Lead to Diversion
- Most common
  - Purchasing/Inventory
  - Wasting/Overrides
  - Point of Care

Not at *My* Hospital!

- Denial is common
- Diversion can happen anywhere
- Where you least expect it
- From those who you may least suspect
- Internal Controls protect
  - The facility
  - The employee
  - The patient

Inventory Management Audit Procedures

- Policies and procedures
  - Review & develop tests of controls
  - Human Resources and/or Law Department referenced related to loss or theft
  - Policies regarding random drug testing of employees with controlled substance access
  - Criminal background checks for potential of employees with controlled substance access

Inventory Management Audit Procedures

- Automated dispensing systems (cont)
- Physical controls
  - Location of workstations & accessibility by non users
  - Computer screens locked when not in use
- Automated Medication Unit Security
  - Passwords
  - Unsuccessful Log Ons
  - Limited User Access
  - Default Sign Off
  - Reports with User ID Listed

Inventory Management Audit Procedures

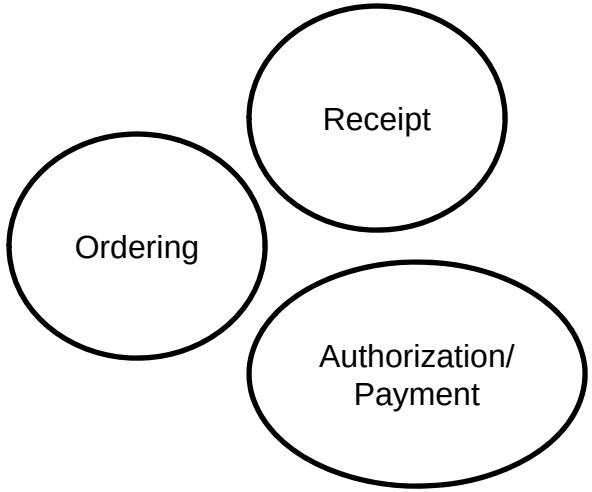
- **Specific controlled substance security**
  - Schedule II must be locked at all times
  - Schedule III – V may be dispensed throughout non-controlled stock
  - Analysis of dispensing, override and waste reports
- **General physical security**
  - Cameras
  - Alarm System
  - Panic Buttons
  - Physical Floor Plan
  - Employee Identification
  - Terminated Employee Process

Inventory Management Audit Procedures

- Inventory counts
  - Conduct a count of a sample of controlled substances with a pharmacy representative present
    - Note expiration dates and how products are stored (by date)
- Review sample of “Significant” loss of controlled substances
  - DEA Form-106 (breakage & spillage does not apply)
- Observe disposal and waste procedures for controlled substances
- Identify outdated stock procedures and inventory of items returned/destroyed

Inventory Management Audit Procedures

- Segregation of duties for following processes
  - Primary storage for controlled substances
  - Ordering controlled substances
  - Purchase requisitions
  - Purchase orders
  - Receiving report
  - Invoice processing
  - Control procedures
  - Physical inventory
  - Dispensing



- No one person should be given control of a related function

10 minute

~Break~

Recognizing Diversion Activity

Essential Components of Diversion Prevention and Detection Program

- Policies to prevent, detect and properly report diversion
- Collaborative relationship between nursing and pharmacy
- Method of surveillance/auditing including concurrent review of medical records
- Prompt attention to surveillance data received
- Collaborative relationship with law enforcement and regulatory agencies
- Education, education and education

Recognition of Diversion

- Hospitals may have automated drug cabinets that produce data about controlled substance transactions, but many diversion schemes can’t be detected this way.

- **Personal observation is vital!**
- **It may be the only clue.**

Education

Most essential component of any diversion program!

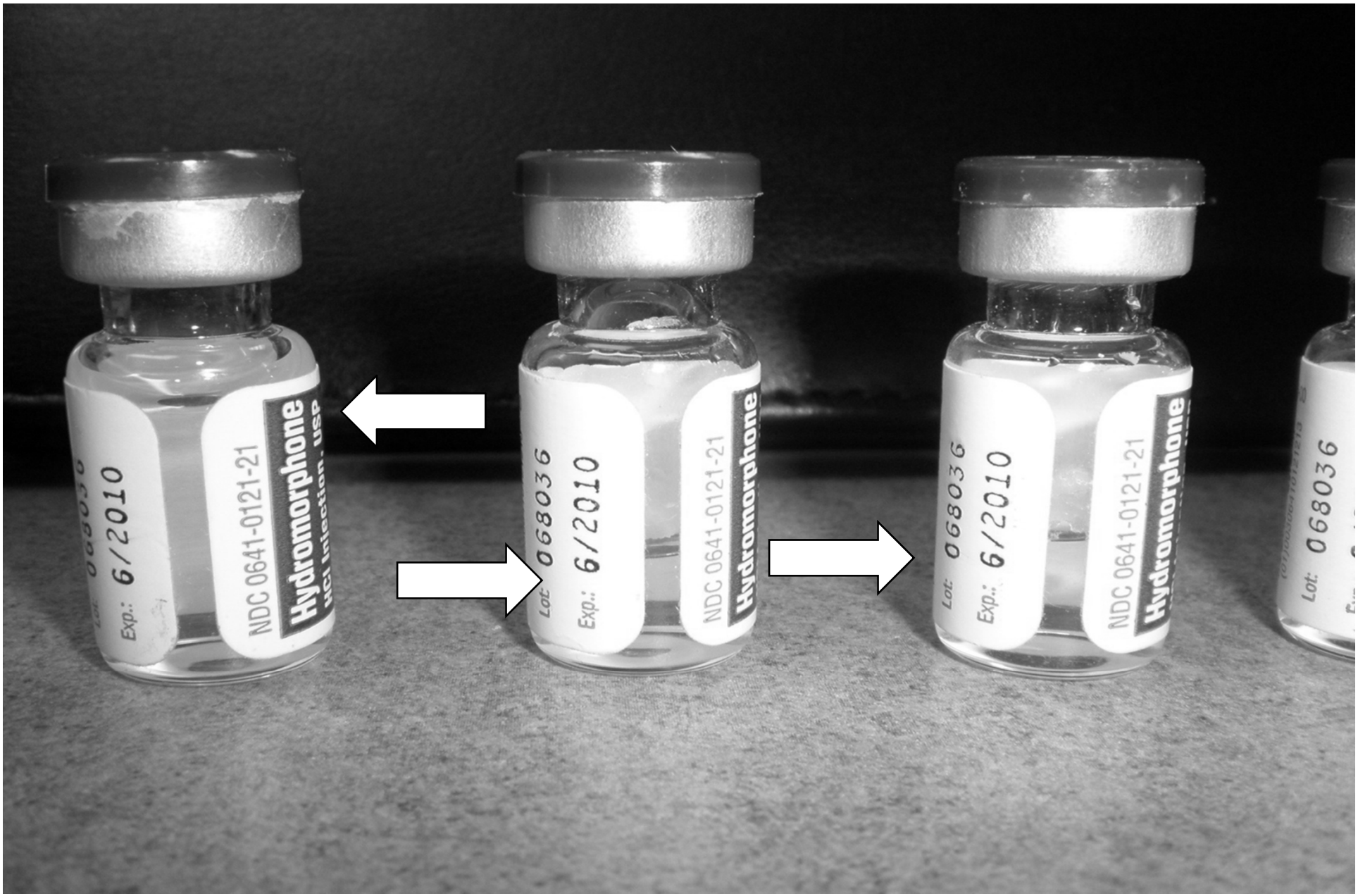
- All-inclusive
- At hire and at least annually
- Emphasize **recognition** and **reporting**

Goal – Develop a culture in which employees recognize the risks and feel individual responsibility for reporting

Education

- Tailor to audience
- Clinical Staff and Managers:
  - Methods of Diversion (Managers)
  - Behavioral Clues
  - Physical Signs of Opioid Abuse
  - How to Use Automated Data
- Make it real-use actual cases and examples

Compromised Vials



Recognition of Diversion/Impairment

- Tardiness, unscheduled absences and an excessive number of sick days used;
- Frequent disappearances from the work site and taking frequent or long trips to the bathroom or to the stockroom where drugs are kept;
- Volunteers for overtime and is at work when not scheduled to be there;
- Arrives at work early and stay late;
- Pattern of removal of controlled substances near or at end of shift;

Recognition of Diversion/Impairment

- Work performance alternates between periods of high and low productivity, may suffer from mistakes, poor judgment and bad decisions;
- Interpersonal relations with colleagues, staff and patients suffer. Rarely admits errors or accepts blame for errors or oversights (denial);
- Insistence on personal administration of injected narcotics to patients;
- Heavy or no "wastage" of drugs; and
- Pattern of holding waste until oncoming shift.

Signs of Opioid Abuse

Physical

- Constricted pupils
- Itching/Scratching
- Sweating
- Chills
- Runny nose
- Vomiting/Diarrhea
- Anorexia
- Tracks

Behavioral

- Malaise/Fatigue
- Euphoria
- Anxiety
- Insomnia
- Depression
- Apathy
- Paranoia

Program Structure

- Diversion Committee - multidisciplinary
- Diversion Response Team (including “go to person”)
- Diversion Risk Rounds (unannounced and at least quarterly)

Monitor for Risks!

Event Details

*** Describe the event in your own words:**

Oxycontin 20 mg was found lying on the counter in the front 3W med room. No discrepancy in either omnicell on the floor. Charge nurse indicated it was not there at 8:30am when she went through. Pharmacist found it at ~11am lying on the counter.

Event Details

*** Describe the event in your own words:**

MORPHINE 2MG CARPUJECT RETRIEVED FROM OMNICELL ALONG WITH LABETALOL FOR ADMINISTRATION TO PATIENT AND WENT TO NSG STATION 2. MEDS WERE ON CHART. I WAS CALLED TO OMNICELL TO WITNESS A WASTE. WHEN I RETURNED, THE MORPHINE WHICH WAS UNOPENED, WAS GONE. AN EXTENSIVE SEARCH WAS DONE BUT UNSUCCESSFUL. J [redacted], PHARMACIST, WAS INFORMED OF THIS EVENT.

Auditing

Policies and Procedures

- Pre-employment screening
- Drug handling
- Surveillance
- Reasonable suspicion drug testing
- Suspected diversion
- Confirmed diversion, including internal and external reporting

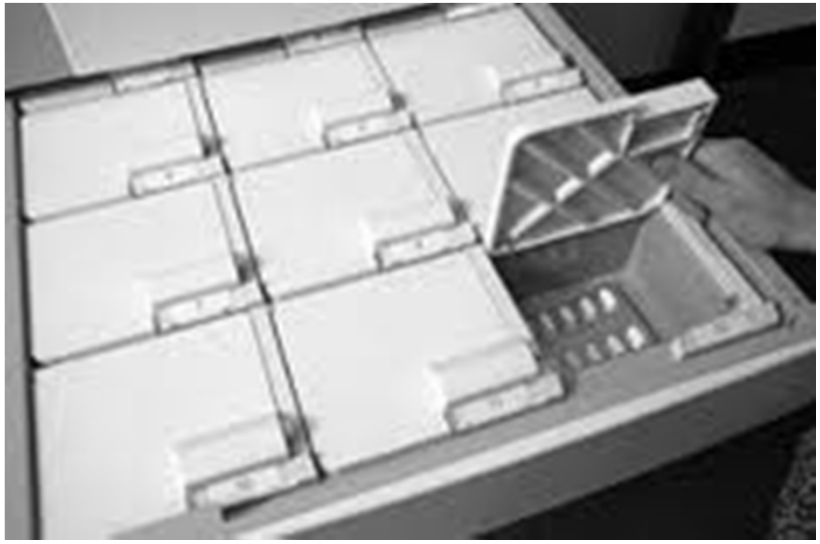
Understanding the Technology

- RN signs on with unique username and password
- RN selects the patient, drug desired and quantity
- Single bin is unlocked and nurse required to key in the quantity present before removal

- 2 users required for “waste” or return

Drug Cabinet

Single Access Bin

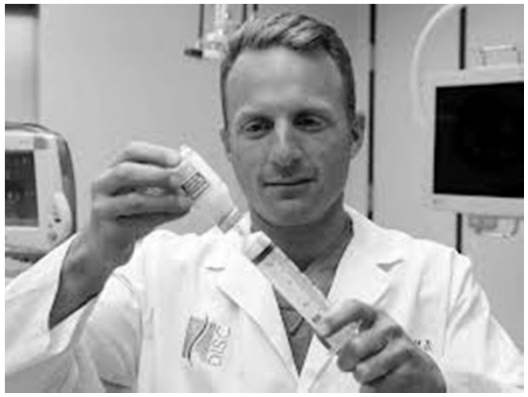


Wasting Injectable CS

Drugs of Choice

Injectables:

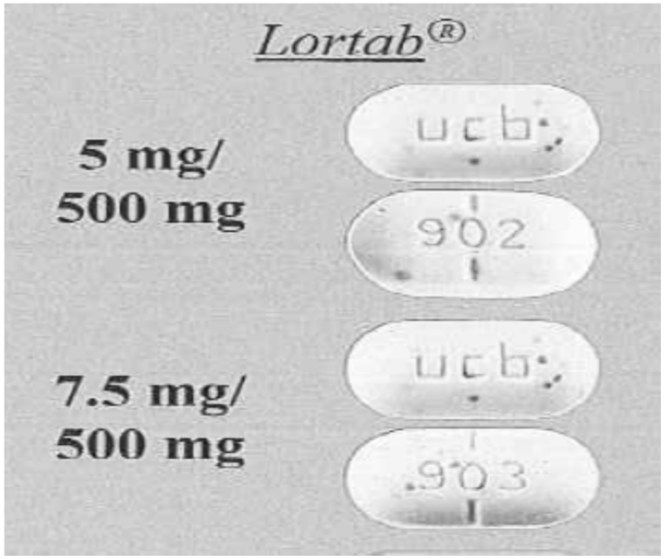
- Hydromorphone
- Fentanyl
- Propofol



Pills and liquids:

Hydrocodone

Oxycodone



Surveillance Technology

- Many hospitals have surveillance technology
- Not as common in long term care facilities
- Provides flags and reveals issues to focus on
- Many selective reports can be run when doing an investigation

Daily Surveillance Data

- All transactions for each user
- Discrepancies in the count
- Staff that are statistically significant when compared to their peers in withdrawals of a scheduled drug
- Instances in which a drug was removed without a recognized order (medication override)
- Drugs removed in large quantities
- Drugs removed in close time proximity
- Drugs removed for discharged patients

Methods of Diversion

Removal of medication when not needed

- Often initial method of diversion
- Very difficult to detect
- Falsification of records

Removal for discharged patient

Removal of duplicate dose

- May not be caring for patient
- May be preceptor

Removal of/diversion from fentanyl patches

- Removal of gel with syringe and needle
- Keeping new patch for self and putting used patch on patient

Removal When Not Needed

Pain Assess

* Final Report *

*** Final Report ***

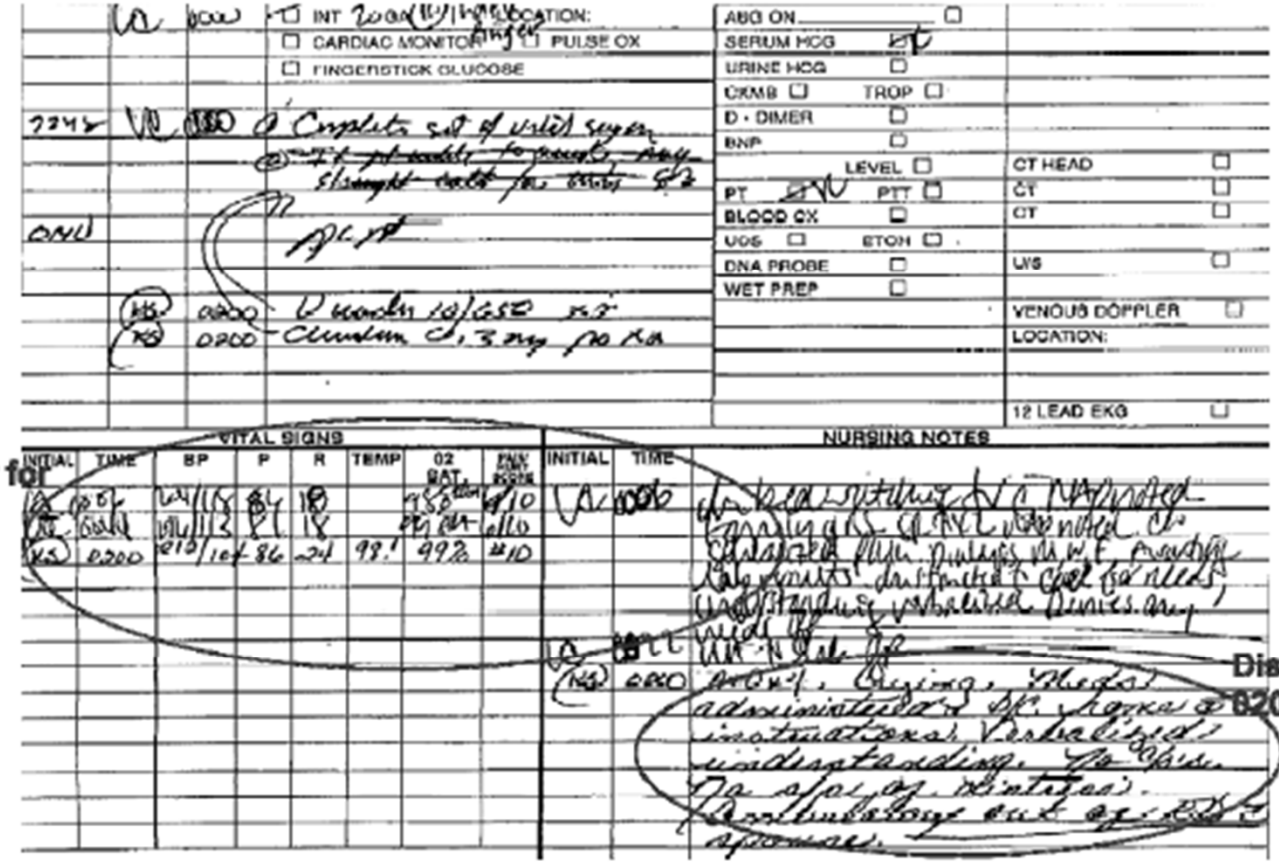
Pain Assessment Entered On: 04/13/10 20:38
Performed On: 04/13/10 18:00 by C

Pain Scale 0 - 10 Required
Pain Scale Patient Communication Status : Patient can communicate
Primary Pain Intensity : 0 None

(- 04/13/10 20:37

04/13/10 5:23 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I M	N
04/13/10 5:51 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I M	N
04/13/10 6:02 PM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I M	N

Withdrawal for Discharged Patient



No order for Dilaudid

03/21/10 4:11 AM	0706780	0706780	1ea	Hydromorphone 2mg SYRIN	IND WEST	N
03/21/10 9:18 PM	0706780	0706780	1ea	Hydromorphone 2mg SYRIN		N
03/22/10 2:01 AM	0706773	0706773	2ea	Hydrocodone/Acetam 5mg/325mg TAB		N
03/22/10 2:18 AM	0706780	0706780	1ea	Hydromorphone 2mg SYRIN		N

Duplicate Dose

Transactions by User

User Name
OmniSupplier:

Date/Time	Item ID	Charge ID	Quantity	Item Description	Type	Patient Name /Restock Order #	Login Pos ID
10/1 11:49 AM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I		N
10/1 12:31 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I		N
10/1 1:23 PM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I		N
10/1 1:53 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I		N
10/1 2:28 PM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I		N
10/1 4:56 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I		N
10/1 5:03 PM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I		N
10/1 6:09 PM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N
10/1 6:11 PM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I		N
10/2 8:14 AM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N
10/2 9:21 AM	0730457	0730457	1ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N
10/2 11:05 AM	0707174	0707174	1ea	Lorazepam 1mg TAB	I		N
10/2 11:06 AM	0756437	0756437	3ea	Oxycodone Immed. Rel. 5mg TAB	I		N
10/2 11:28 AM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I		N
10/2 11:28 AM	0707034	0707034	1ea	Diazepam 5mg TAB	I		N
10/2 12:35 PM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N
10/2 1:13 PM	0765073	0765073	1ea	Hydrocodone/Acetam 5mg/325mg TAB	I		N
10/2 1:18 PM	0765073	0765073	1 EA Returned	Hydrocodone/Acetam 5mg/325mg TAB	W-RT		N
10/2 1:18 PM	0765073	0765073	-1ea	Hydrocodone/Acetam 5mg/325mg TAB	R-BR		N
10/2 1:34 PM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I		N
10/2 2:01 PM	0710897	0710897	1ea	Morphine SR 15mg TAB	I		N
10/2 4:35 PM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N
10/2 5:06 PM	0707034	0707034	1ea	Diazepam 5mg TAB	I		N
10/2 5:36 PM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I		N
10/2 6:56 PM	0730473	0730473	1ea	Mepergan Fortis 1EACH CAPS	I		N
10/22 8:15 AM	0730473	0730473	1ea	Mepergan Fortis 1EACH CAPS	I		N
10/22 8:53 AM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I		N
10/22 9:00 AM	0707190	0707190	1ea	Lorazepam 0.5mg TAB	I		N
10/22 12:12 PM	0730473	0730473	1ea	Mepergan Fortis 1EACH CAPS	I		N
10/22 12:12 PM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I		N

Duplicate Dose

10/1	10:56 AM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	JE	N
10/1	10:56 AM	0707034	0707034	1ea	Diazepam 5mg TAB	I	JE	N
10/1	1:36 PM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I	HU	N
10/1	2:44 PM	0707208	0707208	1ea	Lorazepam 2mg INJ	I MO	HU	N
10/1	5:05 PM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	JE	N
10/1	5:59 PM	0705921	0705921	1ea	Morphine Oral 10mg/5ml LIQ	I	HU	N
10/1	7:48 AM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I	BA	N
10/1	9:24 AM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	PF	N
10/1	10:07 AM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	BA	N
10/1	11:47 AM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I	BA	N
10/1	2:01 PM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	PF	N
10/1	3:11 PM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I	BA	N
10/1	4:41 PM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I	WI	N
10/1	4:52 PM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	BA	N
10/1	5:25 PM	0705780	0705780	1 mg	Hydromorphone 2mg SYRIN	W-WS	BA	N
	Witness Name:							
10/1	5:25 PM	0705780	0705780	1 mg	Hydromorphone 2mg SYRIN	W-WS	BA	N
	Witness Name:							
10/1	5:26 PM	0705780	0705780	1 mg	Hydromorphone 2mg SYRIN	W-WS	BA	N
	Witness Name:							
10/1	6:51 PM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I	BA	N
10/1	8:54 AM	0765073	0765073	2ea	Hydrocodone/Acetam 5mg/325mg TAB	I	BA	N
10/1	9:13 AM	0765073	0765073	1ea	Hydrocodone/Acetam 5mg/325mg TAB	I	BA	N
10/1	9:43 AM	0705780	0705780	1ea	Hydromorphone 2mg SYRIN	I	BA	N
10/1	9:59 AM	0765115	0765115	1ea	Oxycodone/Acetamin 10/3 1tab TAB	I	LI	N
10/1	10:03 AM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I	LI	N
10/1	10:04 AM	0765115	0765115	1 EA Returned	Oxycodone/Acetamin 10/3 1tab TAB	W-RT	LI	N
	Witness Name:							
10/1	10:04 AM	0765115	0765115	-1ea	Oxycodone/Acetamin 10/3 1tab TAB	R-BR	LI	N
	Witness Name:							
10/1	11:09 AM	0730457	0730457	2ea	Oxycodone/Acetamin 5/3 1tab TAB	I	W	N

Removal of Duplicate Dose

Patient: MRN: Omnl: UT8E_1 -- 8 EAST (E801 - E809,E822 - E830)

Date/Time	Item ID	Charge ID	Type	Quantity	B / N	Item Description	User Name
06/01/12 21:03	0765115	0765115	I-UN	1 EA	B	Oxycodone/Acetamin 10/325mg 1tab TAB	Hi , Ra
06/02/12 05:11	0765115	0765115	I-UN	1 EA	B	Oxycodone/Acetamin 10/325mg 1tab TAB	Hi , Ra

Patient: MRN: Omnl: UT8E_2 -- 8 EAST- Cab 2 (E810 - E821)

Date/Time	Item ID	Charge ID	Type	Quantity	B / N	Item Description	User Name
06/01/12 21:40	0765115	0765115	I-UN	1 EA	B	Oxycodone/Acetamin 10/325mg 1tab TAB	Hi , Ra
06/02/12 05:07	0765115	0765115	I-UN	1 EA	B	Oxycodone/Acetamin 10/325mg 1tab TAB	Hi , Ra

END OF REPORT

Methods of Diversion

Removal of medication without order

- Medication override
- Falsification of “verbal order”

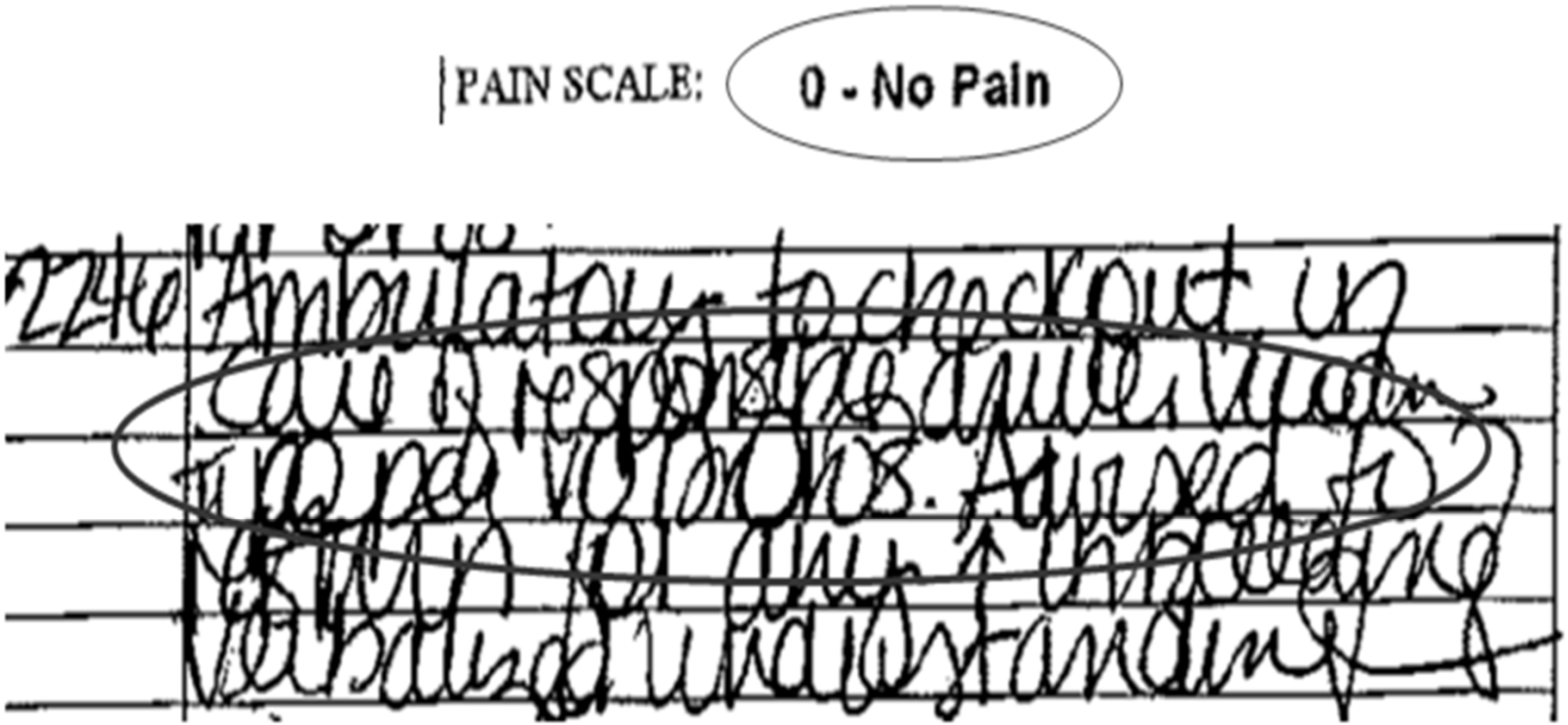
Removal and use from inconspicuous vessel

Medication Overrides

User Name:
OmniSupplier: UTI 24)

Date/Time	Item ID	Charge ID	Quantity	Item Description	Type	Patient Name /Restock Order #	Login Pos ID
01/23/08 7:09 PM	0705970	0705970	-1ea	Morphine 2mg SYRINGE	R-BR		N
Witness Name:							
01/23/08 6:57 PM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N
01/24/08 12:50 AM	0756874	0756874	6ea	Oxycodone 5mg/5ml LIQ	I MO		N
01/24/08 1:17 AM	0756437	0756437	0ea	Oxycodone Immed. Rel. 5mg TAB	N-WI		N
01/24/08 3:41 AM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N
01/24/08 3:43 AM	0756874	0756874	6ea	Oxycodone 5mg/5ml LIQ	I MO		N
01/24/08 4:17 AM	0705970	0705970	1ea	Morphine 2mg SYRINGE	I		N
01/24/08 6:18 AM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N
01/24/08 6:26 AM	0756874	0756874	6ea	Oxycodone 5mg/5ml LIQ	I MO		N
01/24/08 6:46 AM	0765115	0765115	2 TABS	Oxycodone/Acetamin 10/3 1tab TAB	W-WS		N
Witness Name: B							
01/24/08 8:19 PM	0756874	0756874	6ea	Oxycodone 5mg/5ml LIQ	I MO		N
01/24/08 9:28 PM	0730374	0730374	1ea	Morphine PCA 1mg/1ml VIAL	I		N
01/24/08 11:30 PM	0768192	0768192	2ea	Oxycodone 15mg/15ml LIQ	I		N
01/24/08 11:33 PM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N
01/25/08 1:41 AM	0768192	0768192	2ea	Oxycodone 15mg/15ml LIQ	I		N
01/25/08 3:37 AM	0730374	0730374	1ea	Morphine PCA 1mg/1ml VIAL	I		N
01/25/08 4:04 AM	0768192	0768192	2ea	Oxycodone 15mg/15ml LIQ	I		N
01/25/08 5:59 AM	0768192	0768192	2ea	Oxycodone 15mg/15ml LIQ	I		N
01/25/08 6:48 AM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N
01/30/08 7:51 PM	0765115	0765115	2ea	Oxycodone/Acetamin 10/3 1tab TAB	I MO		N

False Verbal Order



Ambulatory to checkout in care of responsible driver. Vicodin ii po per vo Dr. Oros

Methods of Diversion

Failure to waste

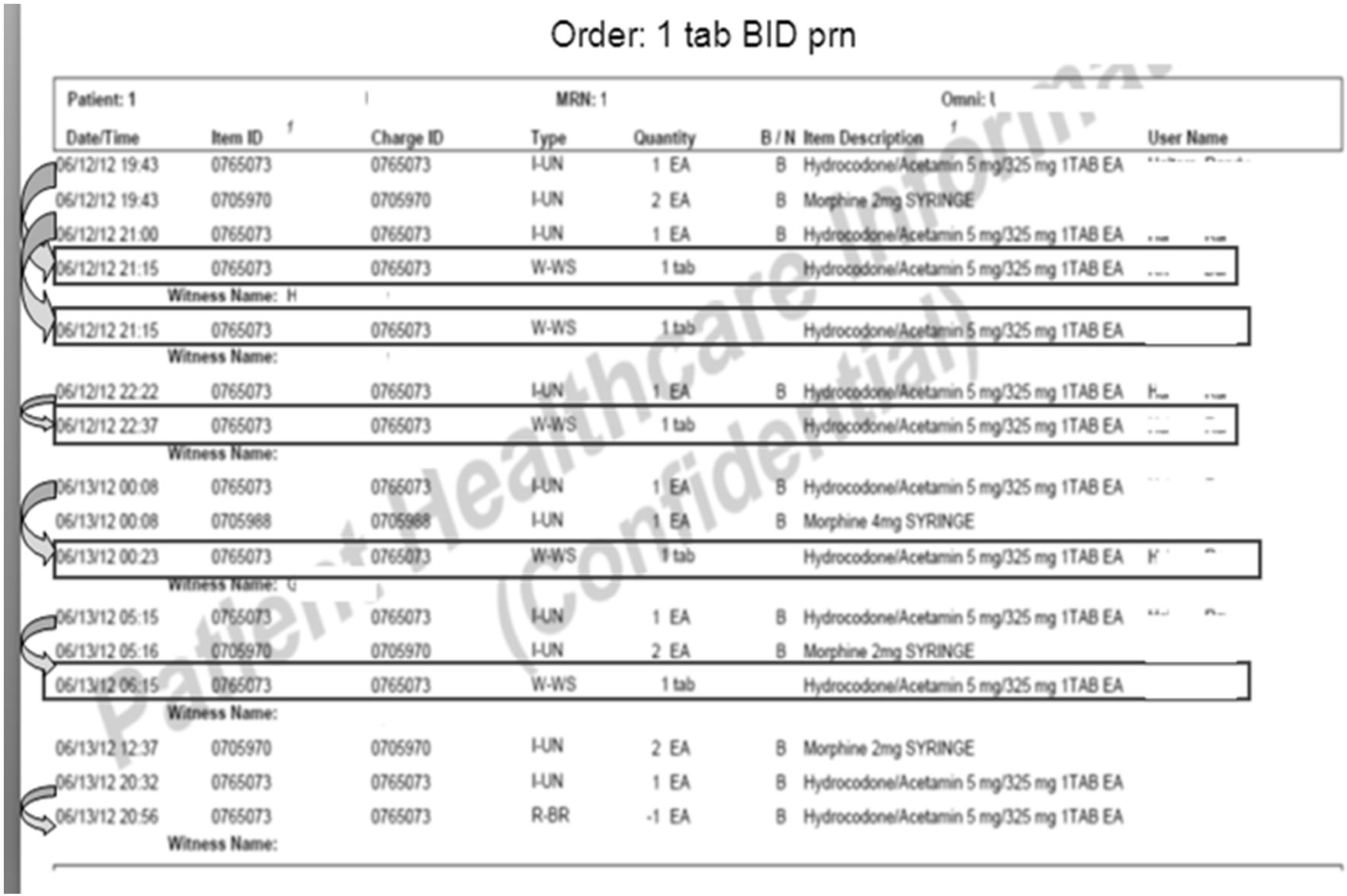
- Unwasted medication kept for self (proper waste procedure is to waste upon removing whenever possible)

Frequent wasting of entire doses (should be returned)

Substitution in administration and wasting

- Substitution of look-alike pills
- Saline substituted for injectable medication
- Potential for tampering charges

Frequent Wasting



Order: 1 tab BID prn

Patient: 1 MRN: 1 Omni: 1

Date/Time	Item ID	Charge ID	Type	Quantity	B / N	Item Description	User Name
06/12/12 19:43	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/12/12 19:43	0705970	0705970	I-UN	2 EA	B	Morphine 2mg SYRINGE	
06/12/12 21:00	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/12/12 21:15	0765073	0765073	W-WS	1 tab		Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name: H							
06/12/12 21:15	0765073	0765073	W-WS	1 tab		Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name:							
06/12/12 22:22	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/12/12 22:37	0765073	0765073	W-WS	1 tab		Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name:							
06/13/12 00:08	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/13/12 00:08	0705988	0705988	I-UN	1 EA	B	Morphine 4mg SYRINGE	
06/13/12 00:23	0765073	0765073	W-WS	1 tab		Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name: G							
06/13/12 05:15	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/13/12 05:16	0705970	0705970	I-UN	2 EA	B	Morphine 2mg SYRINGE	
06/13/12 06:15	0765073	0765073	W-WS	1 tab		Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name:							
06/13/12 12:37	0705970	0705970	I-UN	2 EA	B	Morphine 2mg SYRINGE	
06/13/12 20:32	0765073	0765073	I-UN	1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
06/13/12 20:56	0765073	0765073	R-BR	-1 EA	B	Hydrocodone/Acetamin 5 mg/325 mg 1TAB EA	
Witness Name:							

Auditing

- **Technology allows for optimal tracking of:**
  - **Purchasing**
  - **Inventory controls**
  - **Dispensing**
  - **Wastage**
  - **Patient Administration**
  - **Pain Control and Clinical Analysis**
  - **Medication Errors**

- **Technology alone is not the silver bullet**
  - **Policy/Procedures with Education/Training**
  - **Accountability**
  - **Monitoring/Tracking**
  - **Detection and Prevention of Inventory Loss**

Monitoring Suspicious Activity

- A single suspicious transaction may be easily explained
- Watch for a pattern of activity
- Consider using a “watch list”
- An intensified review may be warranted before you are sure (i.e., review of all transactions)

Auditing

- **Who are you protecting?**
  - **The organization's reputation**
  - **The patient**
  - **Family and Friends**
  - **The care givers**
- **With all this technology, what is the risk?**
  - **More sophisticated, more creative tactics**
  - **More harm**
- **Tools often under-utilized**
  - **Lack of awareness**
  - **Off the shelf instillation**
  - **Lack of reporting**
  - **Poor understanding of clinical processes**

Auditing

- **What can we do?**
  - **Learn more about the system used**
  - **Understand the capabilities of reporting**
  - **Use data to report regularly**
  - **Share the information to monitor**
  - **Require reporting and follow through**

- **Involve IT Support**

Auditing

- Investigate the system
- What are the recommended settings for the system used?
  - Understand the programming
    - What functions are “on”?
    - What is available that is “off”?
    - Why is it “off”? (This better be good!)
  - Understand the end user’s view
    - Who authorizes access?
    - What are the settings on access?
    - What are the different access levels?
    - How do these differ in different care areas?
    - Who can override?
    - Who can waste? What authorization is needed?

Auditing

	Area for Assessment	Current Practice/ Observations	Best Practice Recommendations
A	Users		
1	How is initial training completed for all users?		Written materials that are all placed on the intranet.
2	What is the process for assigning User IDs and passwords to new users?		ID should be the same.
3	What user templates are defined? How are user templates being used?		
4	What is the process if a user forgets their password?		
5	How is ongoing competency evaluated?		Develop competency test to complete after end user tr...
6	Is there a process for routine review of user inactivity?		...ctive user review.
7	What is the policy for managing routine terminations?		Collaborative review of process. HR, IT, Pharmacy
8	What is the policy for m... terminations?		
9	Is the Temporary User feature used? Who		

Auditing

- **Desk Review**
  - **Current Policies and Procedures**
    - **Are they current?**
    - **“Work-Arounds”?**
  - **Previous DEA Form 106’s**
    - ***Report of Theft or Loss of Controlled Substances***
  - **Completed DEA form 41’s**
    - ***Registrants Inventory of Drugs Surrendered***
    - Used in the disposal or destruction of a controlled substance
  - **Past purchase orders DEA form 222’s**
    - ***DEA Controlled Substance Order Form***
    - Must be used when Schedule I and II are bought, sold or transferred between qualified parties
  - **Data Reports**
    - Management Report Monitoring
    - Utilization Reports

Common Areas of Weakness

- Lack of internal controls over controlled substances stored in emergency kits for trauma or urgent needs
- Pain response documentation not regularly reviewed for patterns
- Inadequate segregation of duties
- End user passwords not changed per hospital policy
- End users not terminated from system
  - Job changes/responsibilities
  - Termination
- Discharged patient list remaining available for hours after DC
- Drug testing
  - Not done at pre-employment screening
  - Not performed randomly for staff with access
- Staff with no or little training/competency on system (poor practices)
- Built in System controls “turned off”- too cumbersome

Auditing Data

- Cancelled Transactions Report
- Discrepancies
- Overrides
- Medication Wastage
- Include in reports:
  - End User name
  - Workstation/Patient Care Area
  - Medication
  - Date and Time of transaction

Auditing Data

Reviewing the Report Data:

- Unusual or high patterns of:
  - Wastage
  - Overrides
- Patterns of “wasting partners”
- Time of transaction patterns
- Volumes of administration at unexpected levels based on patient care area
- Uneven administration to one patient or groups of patients in one area
- Floating nurses with higher than area administration averages, waste, discrepancies and/or override functions

Auditing Process

- **Survey Controlled Substance areas**
  - **Pharmacy**
  - **Medication Rooms**
- **Job shadowing**
  - **Pharmacy**
    - **Pharmacists**
    - **Techs**

("Account Number")

  - **Clinicians in Patient Care Areas**
    - **Nurses**
    - **Physicians**
    - **Mid-Level Staff (NP, PA who have access)**
  - **Operative Procedures**
    - **Pre-op**
    - **OR**
    - **Post op**

Auditing

- **Interview**
  - **What processes are used?**
  - **Have they been trained?**
  - **How often?**
  - **Proper segregation of duties?**
  - **Are there back up to staff who perform critical functions?**
- **Challenge their knowledge**
  - **Staff know where weaknesses are**
  - **Don’t fail to ask the obvious questions**

DIVERSION INVESTIGATIONS

When Diversion Suspected

- Diversion team put on alert
- Verification of data and analysis of situation
- Nurse immediately removed from patient contact or intercepted; drug cabinet access discontinued
- Initial interview of nurse including review of medical record and drug cabinet records
- Urine drug screen
- Suspension pending conclusion of investigation

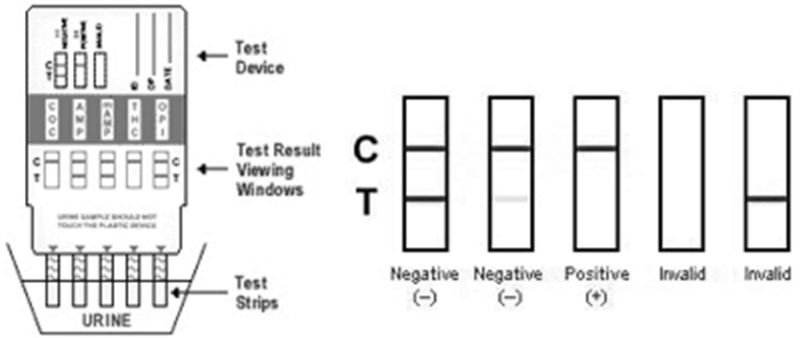
Drug Screen

12 Panel

Amphetamines
Cannabinoids
Opiates
Propoxophene
Alcohol
Barbiturates

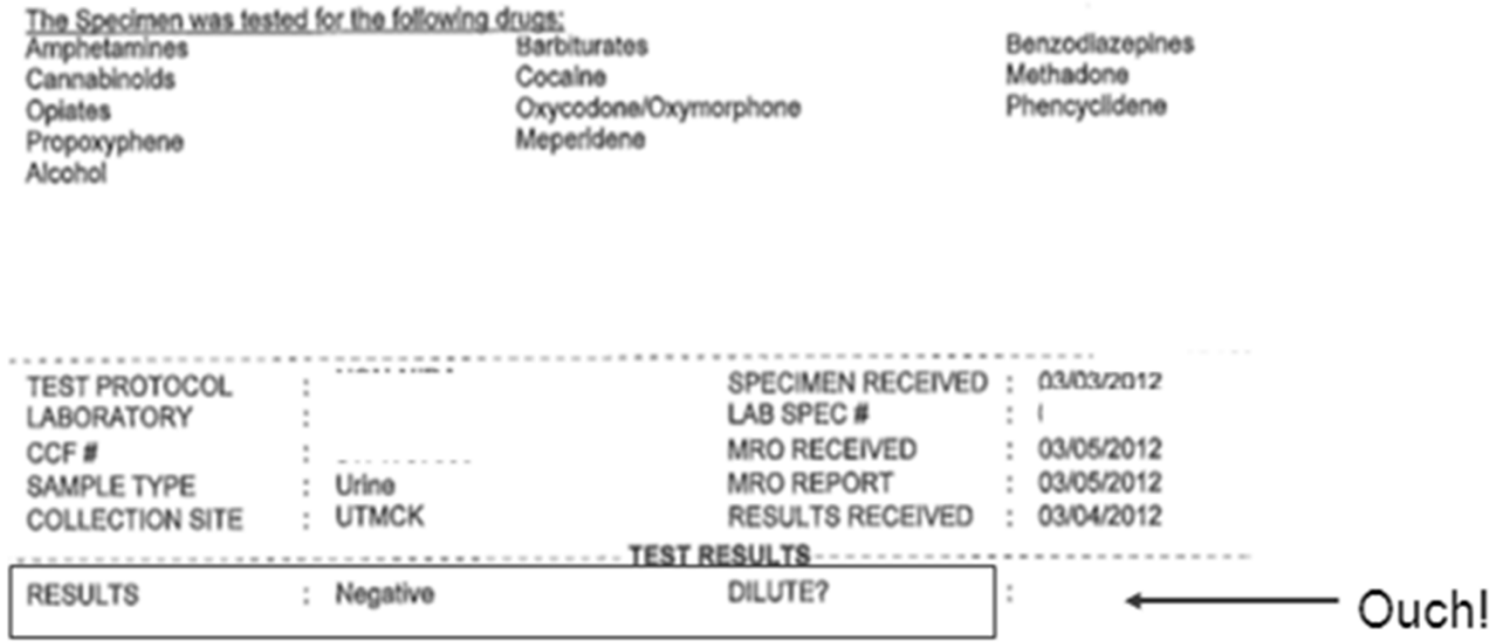
Add fentanyl, zolpidem and others as required

Cocaine
Oxcodone/oxymorphone
Meperidene
Benzodiazepines
Methadone
Phencyclidene



Drug Screen

- Avoid tip-off!



The Specimen was tested for the following drugs:

Amphetamines	Barbiturates	Benzodiazepines
Cannabinoids	Cocaine	Methadone
Opiates	Oxycodone/Oxymorphone	Phencyclidene
Propoxyphene	Meperidene	
Alcohol		

TEST PROTOCOL	:		SPECIMEN RECEIVED	:	03/03/2012
LABORATORY	:		LAB SPEC #	:	I
CCF #	:		MRO RECEIVED	:	03/05/2012
SAMPLE TYPE	:	Urine	MRO REPORT	:	03/05/2012
COLLECTION SITE	:	UTMCK	RESULTS RECEIVED	:	03/04/2012

TEST RESULTS

RESULTS	:	Negative	DILUTE?	:

← Ouch!

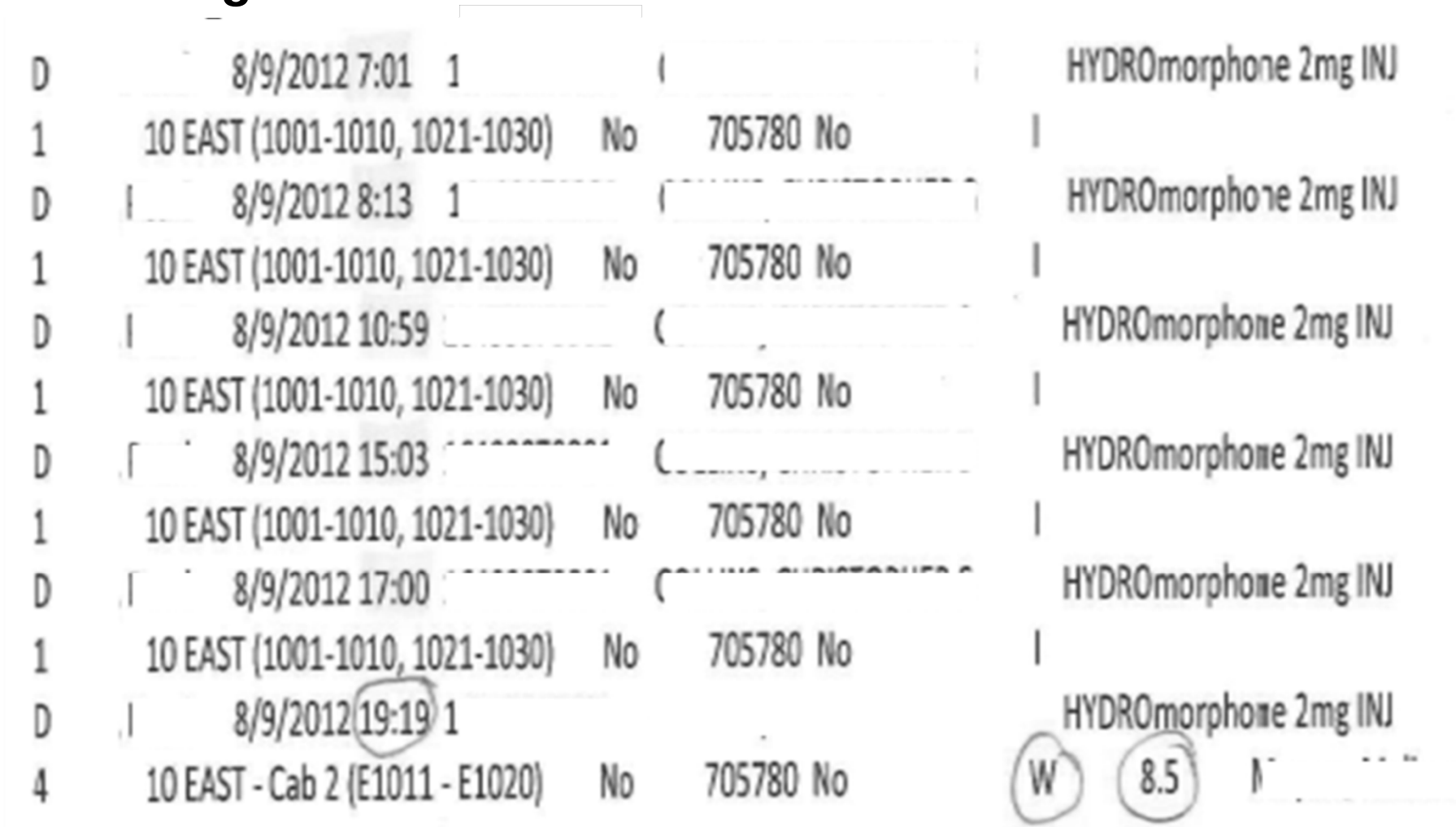
Make sure drug screen is observed and be familiar with testing service and ordering requirements ahead of time!

Diversion confirmed

- Determine employment disposition
- Report to law enforcement and all relevant state and federal agencies
- Consider billing implications and rebill if necessary
- Assist and educate law enforcement and other agencies involved in investigating or prosecuting case
- Notify patients if applicable

Actual Diversion Investigation

8/9/12-PD placed on “watch list” for “bulk wasting”



D		8/9/2012 7:01	1					HYDROmorphone 2mg INJ
1	10 EAST (1001-1010, 1021-1030)		No	705780	No			
D		8/9/2012 8:13	1					HYDROmorphone 2mg INJ
1	10 EAST (1001-1010, 1021-1030)		No	705780	No			
D		8/9/2012 10:59						HYDROmorphone 2mg INJ
1	10 EAST (1001-1010, 1021-1030)		No	705780	No			
D		8/9/2012 15:03						HYDROmorphone 2mg INJ
1	10 EAST (1001-1010, 1021-1030)		No	705780	No			
D		8/9/2012 17:00						HYDROmorphone 2mg INJ
1	10 EAST (1001-1010, 1021-1030)		No	705780	No			
D		8/9/2012 19:19	1					HYDROmorphone 2mg INJ
4	10 EAST - Cab 2 (E1011 - E1020)		No	705780	No	W	8.5	

Diversion Investigation

January 2013-daily surveillance reveals resumed bulk wasting

2/13/2013 13:29:06 **Transactions by User** Page:46

User Name: [redacted]

OmniSupplier: UT10E_1 -- 10 EAST (1001-1010, 1021-1030)

Date/Time	Item ID	Charge ID	Quantity	Item Description	Type	Patient Name /Restock Order #	Login Pos ID
01/10/13 10:06	0756437	0756437	1 ea	oxyCODONE Immed. Rel. 5mg TAB	I-UN	B	N
01/10/13 12:37	0768192	0768192	1 ea	oxyCODONE 15mg LIQ	I-UN	A	N
01/10/13 15:30	0705780	0705780	1.5 mg	HYDROmorphone 2mg INJ	W-WS DP	P	N
Witness Name: [redacted]							
01/10/13 15:30	0705780	0705780	3.6 mg	HYDROmorphone 2mg INJ	W-WS	H W	N
Witness Name: [redacted]							
01/10/13 15:31	0705780	0705780	6.6 mg	HYDROmorphone 2mg INJ	W-WS	C	N
Witness Name: [redacted]							
01/10/13 16:04	0768192	0768192	1 ea	oxyCODONE 15mg LIQ	I-UN	A	N
01/10/13 16:51	0705780	0705780	1 ea	HYDROmorphone 2mg INJ	I-UN	H W	N
01/10/13 16:52	0765099	0765099	2 ea	HYDROcodone/Acetamin 10 1TAB EA	I-UN	H W	N
01/10/13 16:53	0705780	0705780	1.8 mg	HYDROmorphone 2mg INJ	W-WS	H W	N
Witness Name: sa							
01/10/13 16:55	0705780	0705780	1 ea	HYDROmorphone 2mg INJ	I-UN	C	N
01/10/13 18:52	0707208	0707208	1 ea	LORazepam 2mg INJ	I-UN	A	N
01/10/13 18:52	0707208	0707208	1.5 mg	LORazepam 2mg INJ	W-PD	A	N
Witness Name: ca							
01/14/13 09:41	0705780	0705780	1.5 mg	HYDROmorphone 2mg INJ	W-WS	H	N
Witness Name: [redacted]							
01/14/13 17:06	0705780	0705780	4.75 mg	HYDROmorphone 2mg INJ	W-WS	H	N
Witness Name: sa							
01/14/13 17:06	0707208	0707208	1 ea	LORazepam 2mg INJ	I-UN	A	N
01/14/13 17:06	0707208	0707208	1.5 mg	LORazepam 2mg INJ	W-PD	A	N
Witness Name: sa							

Information Key: Please refer to the "Report Abbreviation Key" operational report for a list of all Transfer Types, Misc Codes, Null Types and Inactive Access Types

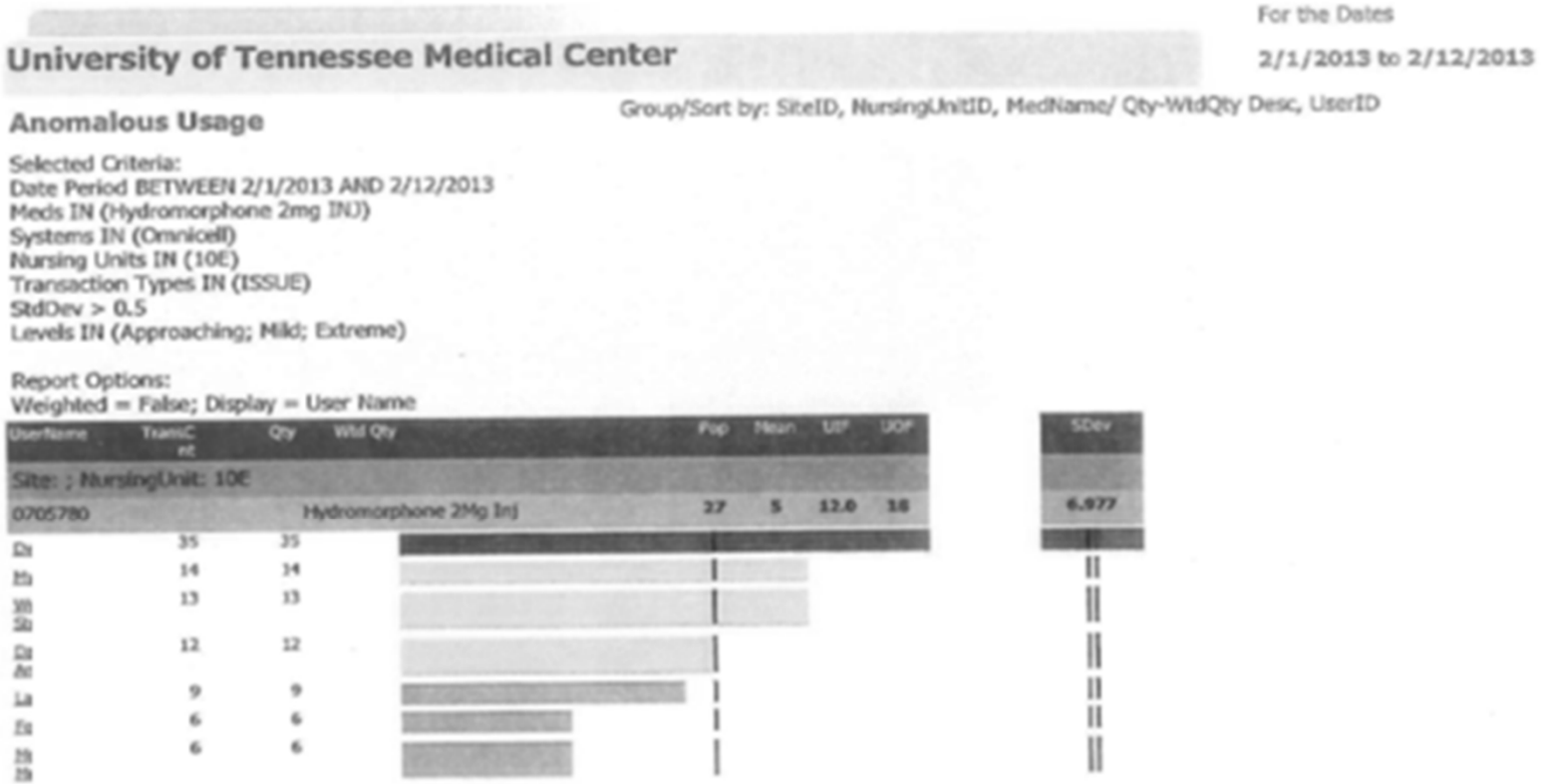
Footnotes: 1 = Item name and ID fields will display Chargeable Procedure name and ID for all transactions of Type = "P"

Note: Transfer Types of "A" are not counted as "Transactions", and are recorded as an "Event" record.

rptranbyuser

Diversion Investigation

February 2013-received alert that PD flagged on Pandora “Anomalous Usage” report for hydromorphone



University of Tennessee Medical Center

For the Dates
2/1/2013 to 2/12/2013

Anomalous Usage

Group/Sort by: SiteID, NursingUnitID, MedName/ Qty-WtdQty Desc, UserID

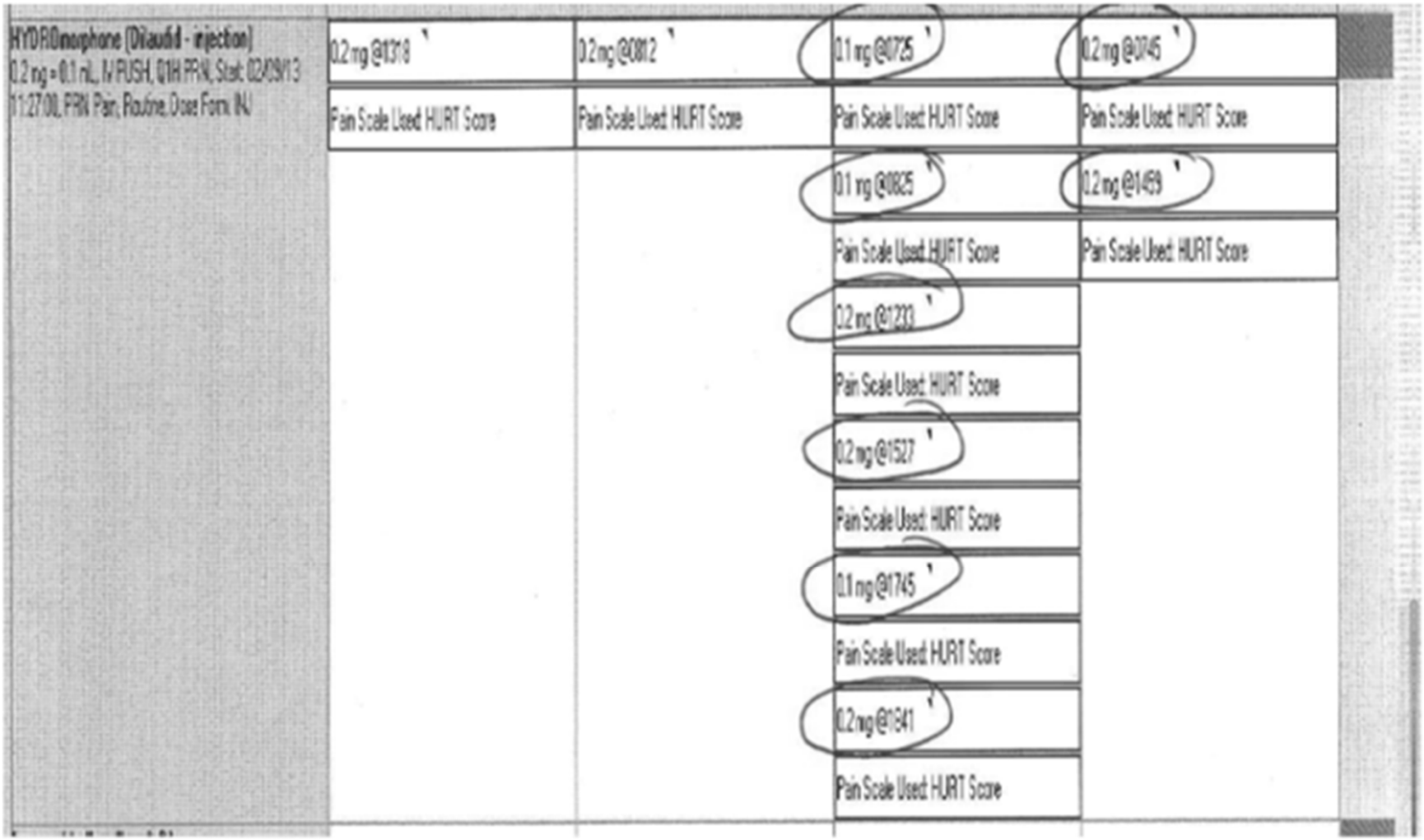
Selected Criteria:
Date Period BETWEEN 2/1/2013 AND 2/12/2013
Meds IN (Hydromorphone 2mg INJ)
Systems IN (Omnicell)
Nursing Units IN (10E)
Transaction Types IN (ISSUE)
StdDev > 0.5
Levels IN (Approaching; Mild; Extreme)

Report Options:
Weighted = False; Display = User Name

UserName	TransCnt	Qty	Wtd Qty	Pop	Mean	UDF	UDP	SDev
Site: ; NursingUnit: 10E								
0705780			Hydromorphone 2Mg Inj	27	5	12.0	18	6.977
Da	35	35						
Ha	14	14						
Wi Sh	13	13						
Da Ar	12	12						
La	9	9						
Ta	6	6						
Ta Ta	6	6						

Diversion Investigation

Review of recent transactions-Patient comatose and on hydromorphone drip. No one else administering hydromorphone except PD.



Diversion Investigation

- PD asks for “one time” orders for hydromorphone extremely often
- Even if patient is on morphine or another CS, PD asks doctor to change order to hydromorphone
- PD only one administering hydromorphone to many of her patients
- PD always administers oral Opioid with hydromorphone if one is ordered

Diversion Investigation

Run report comparing her to her peers on hydromorphone usage

Omnicell®

Dispensing Practices Report

2/12/2013 13:10:21 Page1

Date Range: 1/1/2013 0:00:00.00 - 2/12/2013 23:59:59.99
Site: * -- (All)
Area: 10E
Item: 0705780 -- HYDROmorphone 2mg INJ
Item Control Levels: * -- (0,1,2,3,4,5,6)

Average dose/transaction day: 0.88
Standard Deviation: 0.92

User Name	User ID	Total Doses	[1] Transaction Days	Doses Per Transaction Day	Num of Std Dev Above Avg	[2] % Chance of Type I Error
C	*****	91	16	5.69	5.2	0.00028
F	*****	16	6	2.67	1.93	--
S	*****	2	1	2	1.21	--
M	*****	4	2	2	1.21	--
C	*****	18	14	1.29	0.44	--
M	*****	26	22	1.18	0.32	--
H	*****	20	19	1.05	0.18	--
S	*****	1	1	1	0.13	--
H	*****	2	2	1	0.13	--
F	*****	2	2	1	0.13	--
M	*****	25	25	1	0.13	--
H	*****	2	2	1	0.13	--
L	*****	26	27	0.96	0.09	--
T	*****	21	24	0.88	-1.01	--
M	*****	19	22	0.86	-1.02	--
H	*****	24	29	0.83	-1.06	--
E	*****	22	27	0.81	-1.07	--
W	*****	6	8	0.75	-1.14	--
H	*****	3	4	0.75	-1.14	--
W	*****	20	31	0.65	-1.26	--

Diversion Investigation

Nurse manager questions staff re: comatose patient

Call PD in to meet with her:

- Huge delay
- Allow PD to explain-“I ***medicate*** my patients”
- UDS-dilute
- Suspension

Diversion Investigation

Expanded review of her transactions

- 10.95 mg of Dilaudid identified as missing via failure to waste
- One Percocet 10/325 was also missing

Test her story

- Not statistically significant and way below peers on all other CS on her transaction report

Occurrence report check-no issues

Diversion Investigation

- Removing Dilaudid doses when there isn't any pain documented
- Removing Dilaudid doses when there isn't an order (in anticipation of getting one)
- *Wasting* entire syringes of Dilaudid but *returning* other CS not used
- Dividing one time Dilaudid doses so that more than one syringe can be obtained
- Failing to waste Dilaudid
- Requesting orders for Dilaudid when other medications patient was already on not tried
- Bulk wasting Dilaudid
- Delayed wasting of Dilaudid
- Wasting more Dilaudid than she withdrew and documenting administration of medication when none was obtained (wasting is obviously lax if someone is witnessing this or she is substituting syringes)
- Documenting pain scores inconsistent with colleagues (i.e., two Percocet per day for several days, and then on her 2 consecutive shifts patient gets 5 doses of Percocet and 5 doses of Dilaudid)
- Giving implausible excuses for pulling Dilaudid and not administering ("may be discharged today")
- Documenting administration of IV Dilaudid at time of and after discharge
- Administering Dilaudid to patients for whom it is not appropriate

Diversion Investigation

- Report missing medication to DEA
- Report to TBI and KPD
- Report to Professional Assistance and Board of Nursing
- Report to Pharmacy Board
- Spreadsheet to billing to rebill those with missing medication


Pharmacy diversions continue to increase.
Investigations will continue to be a “hot topic”
Organizations have a DUTY to ensure the safety of their patients AND their staff.
Organizations have a MUST be certain the quality of care provided remains uncompromised.
Early detection and prevention is the KEY to changing behaviors.

Thank you!

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