Pharmaceutical Diversion
Prevention, Detection and Incident Response

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Why I Became Interested in a Narcotics Diversion Rounding Program.

1. Pharmaceutical, including but not limited to, narcotic diversion is a problem in our industry.
2. It has been demonstrated that we are not immune.
3. Having a rounding program such as this is recognized as an emerging best practice in our industry.
4. We have demonstrated the success of a very similar program over the years (HIPAA Roundings.)
5. We have demonstrated the successful collaborative efforts of MSHS' Pharmacy & Audit and Compliance Services Departments in the past.
6. We must do everything reasonable and appropriate to try to get in front of this industry issue.
7. It is the right thing to do.

No, Really, Why?

1. In the wake and aftermath of a significant diversion here at home; and,
2. In the context of the publication of the comprehensive corrective action plan for one of our neighbors, Massachusetts General Hospital; and
3. In the context of the publication of MGH's US$2.3 Million settlement; and
4. While freshly and greatly influenced by a day long seminar sponsored at MSHS and supported by the Pharmaceutical Diversion Education group led by Kim New and John Burke, as well as Bridget G. Brennan, the Special Narcotics Prosecutor for the City of New York; we concluded:
5. It is the right thing to do.

Just one more thing…

Hospital Drug Diversion

Anthony D'Alessandro

Pharmacist Is Accused of Stealing Oxycodone

"The former head pharmacist at a major Manhattan hospital was charged on Tuesday with stealing about 200,000 oxycodone pills — with a street value of $5.6 million — by requisitioning them from his own pharmacy for phantom research projects, New York City's special narcotics prosecutor said."

- **The New York Times, Hartocollis and Moynihan, July 8, 2014**

How did the crime succeed for so long without it being discovered by audit?

1. D'Alessandro personally ordered the narcotics for this "special study."
2. There were no orders or receiving reports from the research pharmacy for these drugs.
3. All audits showed the drugs were "ordered" by the pharmacist specifically for an investigational drug study. No one verified if such a study even existed or how the drugs were stored and utilized.

Creative Drug Diversion

1. Signing onto the electronic prescribing system, writing a prescription, printing it then cancelling it. Taking the written prescription to a pharmacy and having it filled.
2. During the course of a check fraud investigation, requesting physician/victims to audit their prescribing history and uncovering diversion.
3. Victims of all crimes with prescribing practice must check their prescribing history in the state PMP.

Top Ten Ways to Prepare to Respond to a Diversion

1. **Have a team in place.**	2. **Train the team.**
3. **Communicate the written plan with the team.**	4. **Learn from other industry or popular press publicized diversions.**
5. **Collaborate with law enforcement agencies in this specialty and in your area.**	6. A**ddress all legal/human resource issues.**
7. **Encourage whistle blowing.**	8. **Get Management on board.**
9. **Know in advance what evidence could be available to seize and secure.**	10. **Be thorough in investigating the environment of the diversion (audit ADCs, inventory pads, check your state PMP, etc.)**

Diversion Risk

- Addiction is a growing public health issue
- Prescription drug abuse among healthcare providers is higher than in the general population
- Risk Factors
  - Easy access
  - High stress
  - Self diagnosis
  - Potential profit

Pharmaceutical Diversion

- Diversion of controlled substances by healthcare personnel presents an ongoing challenge for healthcare facilities
  - Safety risk to patients
    - Impaired caregivers
    - Infection risk
    - Pain and suffering from withholding treatment
- Regulatory and legal ramifications
- Negative publicity
  - Loss of confidence in the institution by the community

Building a Diversion Prevention Program

1. Create specialized workgroups
   A. Pharmacy narcotic diversion workgroup
      a) Standardize practices of controlled substance management, audit and early detection of diversion
      b) Policy standardization, high user audits, anesthesia reconciliation, staff education

2. Develop rounding program
   A. Administrative support
   B. Multidisciplinary participation
      a) Compliance
      b) Medical staff
      c) Nursing
      d) Pharmacy

Diversion Prevention Rounds

1. A joint effort by the pharmacy department and corporate compliance

2. Conduct on-site rounds at system hospital and community pharmacies, patient care units, and procedure areas
   1. Pro-active
   2. Non-punitive
   3. Transparent
   4. Educational

Diversion Risk Rounds Checklist

1. Develop a checklist to ensure that all areas are assessed
    1. Security
    2. Drug procurement
    3. Storage and transport
    4. Return and waste
2. Observe staff in action
    1. Handoff procedures
    2. Proper documentation
    3. Use of automated dispensing cabinets
3. Evaluate staff awareness and education

Pharmacy Workgroup Activities

Each Occurrence	Daily	Monthly or Quarterly	Annually
• CS return to vendor: confirm receipt and account credit • CS expired: reconcile amounts with reverse distributors	• CS ordered vs received vs stored • Review CS distribution vs Pyxis restock (compare report) • Review/resolve discrepancies • Perform inventory count for non-Pyxis inventory	• Review staff with high volume transactions • Pyxis removal vs admin/waste audit • Review account statements vs invoices • CS transfer audit to other facilities • CS vault inventory • Review CS vault transaction corrections • CS compounding and waste audit logs vs distributions • CS to hospital floorstock reconciliation (*PCA floor sheets, Anesthesia sheets) • Nursing audit: review removal of select CS against the *MAR	• CS High-Level Audit • Physical security audit: test access barriers, locks and alarm systems • Pharmacy staff access review • Pharmacy staff in-service

*PCA: patient controlled analgesia *MAR: medication administration record

** All tasks may be performed more frequently if needed

Recommendations for Preventing Diversion

1. Security and Surveillance
2. Employee Screening
3. Division of Duties
4. Leadership Audits
5. Education and Awareness
6. Controlled Substance Ordering System (CSOS)
7. Optimized use of controlled substance automation

RISK TO PATIENTS

1. 7,200 McKay-Dee and Davis Hospital patients could have been exposed to hepatitis C
2. 5,000 patients in Colorado, Arizona, Washington and California patients offered hepatitis C testing due to diversion scheme by surgical tech
3. More than 200 patients seen at Shore Medical Center notified of potential exposure to hepatitis C

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ESSENTIAL PROGRAM COMPONENTS

1. Diversion Specialist
2. Diversion Oversight Committee
3. Diversion Response Team

PLUS

- Ongoing auditing
- Risk rounds
- Multi-disciplinary effort

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DRUGS OF CHOICE

Injectables:

- Hydromorphone
- Morphine
- Fentanyl
- Propofol

Pills and liquids:

- Hydrocodone
- Oxycodone

Patches:

- Fentanyl

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SECONDARY DRUGS

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

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SURVEILLANCE

Nursing Leadership:

- Monthly statistical comparison (one month of data)
- Daily discrepancies and overrides

Objective Auditor:

- Reports reviewed by nursing leadership
- Focused auditing (PCA, anesthesia multi-dosing, etc)
- Monthly-new privileges
- Cancelled transactions

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Anomalous Usage 10 E

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

Selected Criteria:
Date Period BETWEEN 1/1/2016 AND 1/31/2016
Systems IN (Omnicell)
Nursing Units IN (ER)
Transaction Types IN (WASTE; RETURN; ISSUE)
Med Classes IN (Class 5; Class 4; Class 3; Class 2)
Levels IN (Approaching; Mild; Extreme)
StdDev > 3
Population > 3

Report Options:
Weighted = False; Print Header = False; Display = User Name; My Items Transactions = Transactions/Patient

UserName	TransCnt	Qty	Wtd Qty		Pop	Mean	UIF	UOF	SDev
Site: ; NursingUnit: ER									
0705673		Fentanyl 100Mcg Inj			104	6	9.0	13.5	11.55
B	52	87							
P	29	55							
B A	32	47							
R A	26	34							
V	30	33							
B	12	19							
C Ji	15	18							
D	10	15							
M M	10	11							
K	11	10							
N	9	8							
C	7	8							

UserName	TransCnt	Qty	Wtd Qty		Pop	Mean	UIF	UOF	SDev
Site: ; NursingUnit: ER									
0775064			Midazolam Pf 5Mg Inj		40	4	6.5	9.8	6.99
[	8	6							
E	5	5							
0775122			Morphine Preserv Free 4Mg Inj		120	7	18.0	27.0	5.37
V C	32	32							
S V	25	25							
T M	24	24							
M	22	21							
T M	20	18							
C D	17	16							
C	15	16							
C J	15	15							
D	16	15							
Ji K	15	15							
C L	14	15							
R	15	15							
P B	14	14							
V D	13	13							
D	13	13							
S R	13	13							

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Dispensing Practices Report

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Date Range:
Site: * -- (All)
Area: 7E
Item: 0705780 -- HYDROmorphone 2mg INJ
Item Control Levels: * -- (0,1,2,3,4,5,6)

Average dose/transaction day: 1.2

Standard Deviation: 1.02

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
B	*****	68	12	5.67	4.36	0.00456
D	*****	7	2	3.5	2.24	--
K	*****	14	5	2.8	1.56	--
M	*****	8	3	2.67	1.43	--
G	*****	2	1	2	0.78	--
L	*****	4	2	2	0.78	--
R	*****	35	18	1.94	0.73	--
S	*****	11	7	1.57	0.36	--
Z	*****	3	2	1.5	0.29	--

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Hot List Audit: Total Count

Station	Reason Selected	User Name	Count	Mean	STD	UAM
	Cancelled Transaction Summary		11	2.268	1.924	4.538
	Discrepancy Transaction Summary		15	2.818	3.660	3.328
	Refilled Transaction Summary		82	14.000	20.988	3.240
	Percocet Usage Summary		26	4.512	4.862	4.420
	Hydromorphone Usage Summary		24	4.034	4.851	4.116
	Benzodiazepine Usage Summary		7	2.278	1.565	3.017
	Discrepancy Transaction Summary		55	4.943	9.656	5.184
	Cancelled Transaction Summary		50	7.652	9.452	4.480
	Refilled Transaction Summary		460	39.538	95.456	4.405
	Benzodiazepine Usage Summary		20	3.692	3.896	4.186
	Morphine Usage Summary		23	6.342	5.111	3.259
	Oxycodone Usage Summary		14	3.552	3.334	3.134
	Discrepancy Transaction Summary		37	4.862	8.110	3.963
	Refilled Transaction Summary		204	23.667	46.265	3.898
	Cancelled Transaction Summary		29	4.758	6.865	3.531
	Cancelled Transaction Summary		28	4.758	6.865	3.386
	Wasted Transaction Summary		12	2.913	2.795	3.251

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SURVEILLANCE

Pharmacy:

- Discrepancies over 24 hours
- Discrepancy resolution
- New privileges
- Anesthesia discrepancies
- Closed loop
- Procurement reconciliation
- Temporary patients

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CHALLENGES

1. Infusions-tracking amount infused, closing the loop on patient specific preparations, wasting
2. PCA keys/lock-box keys
3. Use of alias in ED/Trauma patients
4. Discharged patients with active profiles
5. Replenishment for EMS

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CHALLENGES

1. Kits in OR settings
2. Dual sources in OR settings
3. Separate EHR or manual records

AND-Lack of Independent Auditing of Pharmacy

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PRIVACY CONSIDERATIONS

1. Bloodborne pathogen testing of diverting staff
2. After hours drug screening and evaluation of staff in the ED
3. Healthcare personnel who are patients
4. Administrative agency investigations
5. Disclosure to law enforcement

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EVEN WITH CONTINUOUS DILIGENCE…

Diversion can’t be prevented entirely

Goal:

- Prevent
- Detect
- Respond

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Thank You!