

# Drug Diversion in the Hospital Setting

*April 9, 2009*

Karen Bergrud, RPh.  
Assistant Director, Pharmacy Operations  
Mayo Clinic Rochester

# DISCLOSURE

(Nothing to disclose)

# Objectives....

- State the requirements for secure drug storage and documentation.
- Identify gaps or potential failure points in your system.
- Determine surveillance techniques to identify/ward-off potential diversion.

# What's required?

## **Drug Enforcement Agency (DEA):** Security Outline

- Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies, or other persons registered to do research, to dispense, or to use in teaching or chemical analysis a controlled substance in the course of professional practice.
- Controlled substances must be stored in a securely locked cabinet of substantial construction.

# Minnesota Board of Pharmacy

- Minnesota Rule
- *Controlled substances must be accounted for by a "proof-of-use" sign-out sheet where each dose given is accounted for by the nurse administering the drug. No controlled substance may be kept on floor stock unless it is accompanied by the sign-out sheet and each dose is documented by the nurse at the time the drug is procured from the nursing station stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed nurse's signature*
- *Wasted doses must be documented and witnessed by the signature of two individuals who are nurses or pharmacists.*

# MN BoP (con't)

- *Controlled substances must be stored under lock on the nursing stations.*
- *Access to the main supply of Schedule II controlled substances in the pharmacy must be restricted to a limited number of persons in the pharmacy. The main supply of Schedule II controlled substances in the pharmacy must be kept locked when not being used.*

# Who poses a risk?

- Preventing access by the public, patients and their visitors?
- Licensed employees who have authorized access?
- Unlicensed employees?

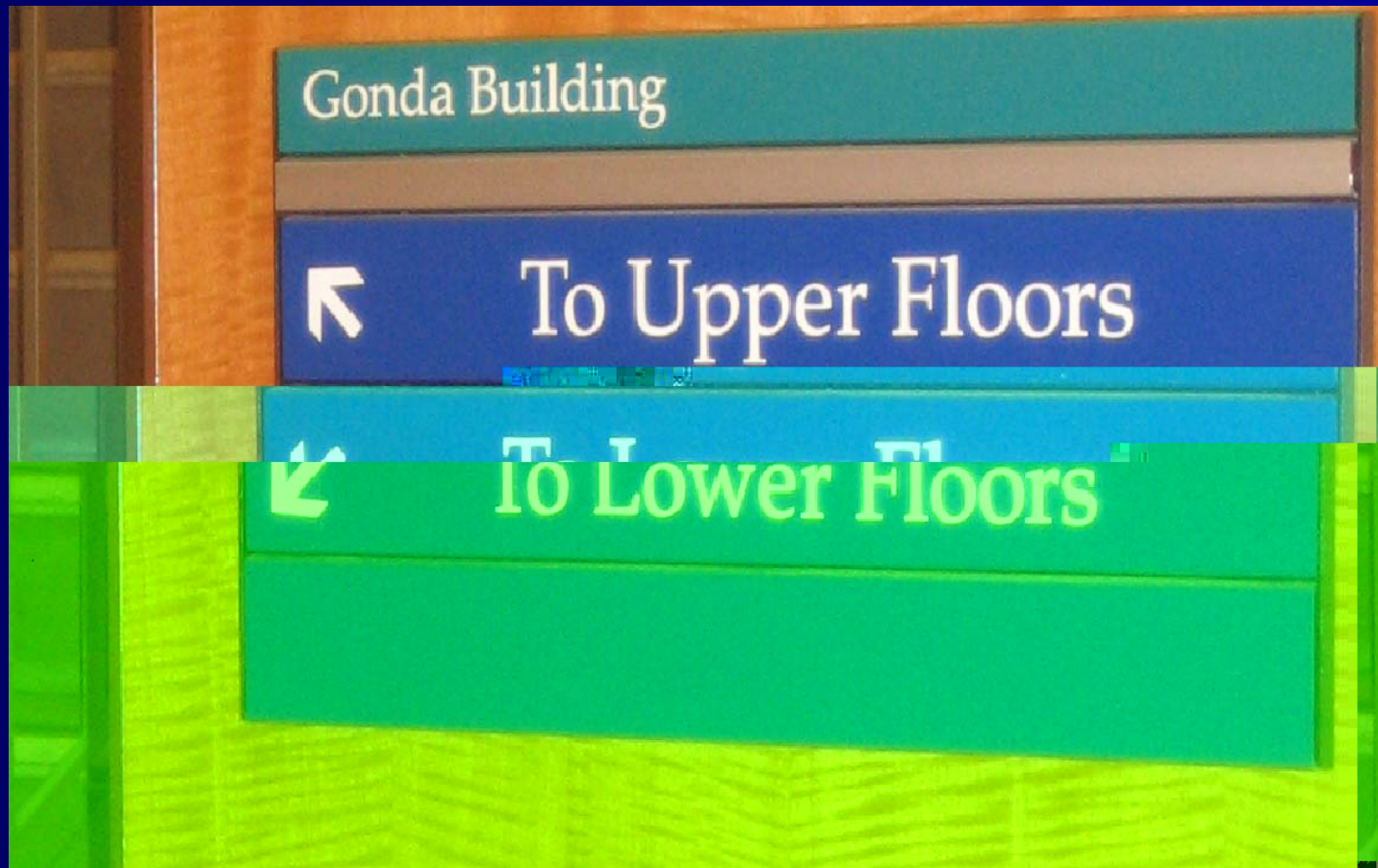
# Gaps in *your* Process?

## Don't assume anything!

- Does the staff know which medications are controlled substances?
- Does your staff understand the security and documentation requirements?
- Do you know who has access today?
- If you haven't seen any problems, it doesn't mean you don't have any.
- Any employee who has access is a potential diverter.
- Be sure your staff know the risks!



**Even Mayo assumes we need direction on the simple stuff!**



# Look for Failure Points...

- First understand your processes
- Include each step from ordering product to final use and/or waste.
- Assure documentation is in place for each point of hand-off. "Chain of Custody"
- Identify the risk points
- Look for ways to minimize those risks
- Determine how to monitor/audit those points of your process.

# Know your process...

- Look at each step from ordering product to final use and/or waste
- Flowchart it with everyone involved in the process.

# Some Steps to Analyze....

- Who determines the need for an inventory & approves it?
- Who is authorized to place an order?
- Who supplies it – single or multiple sources?
- How does it arrive?
- Who receives it?
- How/where is it secured – how about refrigerator security?
- Who can access the supply/background checks?
- When is it inventoried?
- What do you do with the waste, who has access to it, is it secured &/or unusable?
- What about risks if sent to a lab for an assay?

# Can you track the “Chain of Custody”?

- Assure documentation is in place for each hand-off
- Are there steps in the process that are done in isolation or multiple steps done by one individual?

# Identify the risk points

Prioritize the potential risks you've identified

- Frequency or likelihood of occurrence
- Rank the risk if it were to occur
  - Risk to a patient
  - Risk to the institution
  - Risk to the employee
  - High risk/low risk

High likelihood/high risk gets priority!

# Determine how to monitor/audit those points of your process.

Audit the documentation for completeness and accuracy against inventory.

Monitor who has access if possible.  
(terminated/transferred employees?)

Perform assays on waste &/or opened containers still in use. How is the assay process monitored?

# What if there's an "event"?

- Do employees know how to bring forward a discrepancy, a concern or how to share what they may have witnessed?
- Is there an anonymous, confidential route to report?



# Supervisor's Knowledge of the Process?

- Do the supervisors know who they need to involve once they've received a report?
  - Security?
  - Risk Management/Legal Department?
  - Pharmacy/Supplier?
  - Local authorities? DEA?
  - Human Resources?
  - Employee Health Service?
  - Administration?
  - Licensing bodies?

# What do I do with this individual?

- Does the supervisor understand what the next step is with the suspected employee?
  - Confront the employee, do I need a 3<sup>rd</sup> party in the room?
  - Is a drug screen required?
  - Is the employee put on administrative leave?

# Opportunities to consider...

- Secure Storage – limit access, limit times of access, avoid multiple people having keys, or keys leaving the area.
- Automate record keeping, if possible.
- Make it known to staff the processes are monitored, audited, assayed.
- Assume diversion can/does take place at any step of the process.
- Educate, educate, educate!

# Security options:

Automated Dispensing Cabinets  
(examples: Pyxis, Omnicell automation)



# Pros & Cons

- Interfaced with Pharmacy vault to track delivery/receipt.
- Tracks who, what, when for every transaction.
- Access is controlled, password protected.
- Can provide multiple reports on usage
- Can also process patient charges
- Most expensive system
- IS maintenance/oversight

# Security options:

Card Access:



# Pros & Cons

- Capable of limiting who has access
- Can restrict hours of access
- Tracks who entered and when and who attempted access/denied.
- No need for key management.
- Somewhat Costly, More Facility impact
- Requires ownership of approving access.
- Policy restricts sharing of employee cards.

# Security options:

Cypher Lock:





# Pros & Cons

- Less costly than card access entry.
- Allows access only to those who know the code.
- No keys to keep track of.
- Nothing stopping one from sharing/posting the code.
- Code needs to be changed with some frequency.
- No audit trail on who/when it was accessed or who attempted access.

# Key Lock – Cypher box controlled



# Pros & Cons

- Least expensive option
- Staff know where the keys are.
- One set of keys, less likelihood of keys leaving the facility.
- Restricts access to those who know the code.
- Need to change the code frequently.
- Relies on staff returning the key after use.

# NEVER, NEVER, NEVER...

Have several controlled substance  
keys...

Carr3 31645af8af8af8a45af8af8afyeeEMC 1

# Other/additional options...

- Install security cameras in the controlled substance storage area.
- Install *covert* cameras – staff unaware of existence or where they're located.
- Use “tamper-evident” tape on syringes and any opened container – secure the tape!

# Don't forget about waste!

Are these all empty?



# Secure?



# How secure is this?





# Educate Staff

- Which meds are controlled substances
- What are the requirements for this category of medications
- Employee risks
- Policies and Procedures in place
- How to report suspicious activity
- Signs to watch for in co-workers

# "Scorecard" approach...

*Code N: Multidisciplinary Approach to  
Proactive Drug Diversion Prevention*

Used by Ohio State Medical Center, Columbus, Ohio

Hospital Pharmacy, March 2007

Vol.42, Number 3, P244-248

# Things to watch for in co-workers:

- Isolates self from others, eats alone, avoids staff social events
- Frequent unexplained disappearances during shift.
- Shows up on days off to finish work or retrieve forgotten items
- Frequently volunteers to work extra shifts
- Frequently spills/wastes narcotics
- Chaotic personal/home life
- Refused to comply with investigation procedures

# Tips for staff to reduce risks...

Only remove meds with known need.

Only remove amount needed.

Document usage & waste accurately

Don't be a "virtual witness" to waste

Don't share access codes

Report discrepancies &/or suspicious behavior promptly

# Discussion / Questions



# References

1. Security Outline of the Controlled Substances Act of 1970, Controlled Substance Security Manual, DEA Website  
<http://www.dea diversion.usdoj.gov/pubs/manuals/index.html>
2. Minnesota Board of Pharmacy Rules, 2007, Chapter 6800:7520, Subpt 1.S.  
<https://www.revisor.leg.state.mn.us/rules/?id=6800.7520>
3. Siegel, J., O'Neal, B., *Code N: Multidisciplinary Approach to Proactive Drug Diversion Prevention*. Hospital Pharmacy, March 2007; Vol. 42; 244-248