



Preventing Controlled Substances Diversion

Traditionally, controlled substances diversion in hospitals has not been a well-publicized or openly discussed topic. As we embrace new advances in medicine and automation, it is important to address the numerous complex systems of procurement, distribution, and handling of controlled substances. Pharmacy is in a unique position to further the understanding of diversion methods within the hospital as well as build awareness of the new technologies and programs available to assist in preventing diversion. In addition to increased discussion of controlled substances diversion, it also is important to foster a culture of accountability and responsibility that is non-punitive and embraces a Just Culture. A Just Culture is an environment that supports and encourages the reporting of errors and discrepancies without fear of reprisal or blame. A “Just Culture” looks to solve problems, enhance safety, and condone accountability for all health care practitioners so that patients are provided with quality care and a safe healing environment.

Interdisciplinary Approach

Because controlled substances and narcotic diversion can occur in numerous ways, prevention is best achieved by establishing methodical controls and procedures developed by an interdisciplinary team. Involving multiple departments and health care providers will ensure security, compliance, and accountability of controlled substances handling and administration. At St. Joseph’s Healthcare System (comprising St. Joseph’s Regional Medical Center in Paterson, New Jersey, and St. Joseph’s Wayne Hospital in Wayne, New Jersey), a collaborative approach was used to create a team of hospital staff and managers that would help track controlled substances discrepancies and diversion. The team is responsible for managing all procurement, delivery, utilization, accountability, and documentation aspects of the controlled substances process. This team consists of:

Pharmacy Manager: Oversees operations and discrepancy resolutions

Pharmacy Medication Safety Coordinator: Examines medication errors and occurrences, looking for trends, areas for improvement, and status against national benchmarks for safety and security, and then reports this information to the health care team

Evening Pharmacy Coordinator: Pulls controlled substances for the OR for next morning delivery

Senior Staff Pharmacist: Responsible for the daily monitoring activity of the automated controlled substances vault (ACSV) and previews the comparison reports of what was pulled from the ACSV versus what was delivered to the automated dispensing cabinets (ADCs)

Automated Dispensing System (ADS) Pharmacist: In addition to numerous distribution and drug verification responsibilities, the ADS pharmacist is also responsible for pulling the daily controlled substance batch for delivery

Pharmacy Purchasing Coordinator: Receives and confirms controlled substances from the wholesaler

Figure 1. Anesthesia Narcotic Usage Audit

ST. JOSEPH’S REGIONAL MEDICAL CENTER Pharmaceutical Care Division _____ 2009 (month)					
Total number of anesthesia records reviewed: ____					
Compliant anesthesia records: ____					
Compliant wasted thru anesthesia records only: ____					
Non-compliant anesthesia records: ____					
Percentage compliant: ____%					
Percentage compliant wasted thru AR only: ____%					
Percentage non-compliant: ____%					
Date	Narcotic drugs ordered as per anesthesia record drug & dose	Narcotic drugs removed from Pyxis drug & dose	Narcotic drugs wasted or returned to Pyxis and anesthesia record drug & dose	Discrepancy and notes	Health care professional involved

ADS Coordinator: This certified pharmacy technician is responsible for the day-to-day operations of coordinating staff to refill and inventory the unit-based machines, troubleshoot any hardware and minor software issues, monitor and assist patient care area managers with controlled substances discrepancies, and provide surveillance for all medications in the ADS with respect to usage, storage, and diversion

ADS Pharmacy Technician(s): Responsible for the delivery, refilling, and use-by date monitoring of controlled substances in the ADCs

OR Pharmacy Technician: Provides support and monitoring for ADS in the OR and performs audits (see Figure 1) matching anesthesia records with ADS activity

Director of Pharmacy Services: Oversees controlled substances operations and technology, reviews quality and performance improvement monitoring, and pro-

vides administrative oversight with inventory, errors, and diversion issues

Information Technology Resources (ITR) Specialist: Provides software and computer system support for the ADS and monitors the data stream for financial and drug formulary systems

Security: Reviews, investigates, and documents unresolved discrepancies and provides support with legal and law enforcement matters

Nurse Managers: Monitor, review, and resolve discrepancies within a target of 72 hours and aid in the development, education, and enforcement of controlled substances policy and procedures

Designated Nurses: Perform daily inventory and discrepancy checks at the ADCs

Anesthesiology Chair: Actively supports and researches discrepancy issues reported from the OR pharmacy technician

Controlling Access

The ADCs and ACSV are equipped with biometric identification scanners for fingerprint reading. This confirms user identification and provides protection against stolen passwords and unauthorized access.

The process of registering an ADC user requires confirmation from a patient care area manager, information technology resources registration, and pharmacy management approval. The user must also sign an agreement to comply with HIPAA and Corporate Compliance Guidelines regarding patient privacy and appropriate use of the technology.

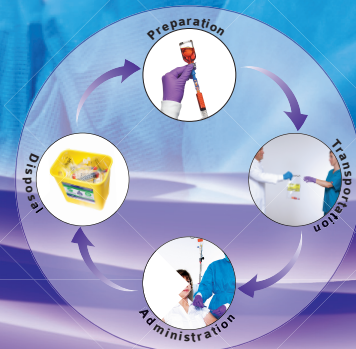
Refrigerated controlled substances are secured using a magnetic locking device that attaches to the refrigerator door. This device releases the door lock when a biometric identification is confirmed. This device also monitors the refrigerator temperature and sends this data to the ADS console.

Diversion Reporting

Controlled substances are monitored by a range of reports and data looking



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Photo courtesy of St. Joseph's Regional Medical Center

St. Joseph's Regional Medical Center secures expired, recalled, or wasted controlled substances in a standard United States Post Office curbside mailbox that serves as a collection box.

at various steps of the distribution and administration process. The reports and data reviews are generated by the ADS and ACSV systems. These reports are key to monitoring and securing controlled substance movement. Some valuable reports include:

CII Safe Pyxis Compare: Matches removal transactions from the ACSV and refill transactions to the ADCs. This is the first step in insuring controlled substances reach their destination.

Proactive Diversion: Creates a calculated standard deviation and highlights higher than average controlled substances access by ADC users.

Open Discrepancies: Visible on the ADC console screen, the report alerts the ADS manager that there is an identified discrepancy occurring at a specific location with a specific drug. The alert gives the time, day, and individuals that either discovered or created the discrepancy.

Documented Discrepancies: With documented discrepancies, it is important to review the reasons entered. This data may point to needed system changes or quality improvement processes. Diversion also occurs when the users put bogus or falsified reasons as a resolution. It is important to review this report to track patterns of questionable activity by users.

Waste and Return: Excessive wasting and cancelling of transactions may be an indicator of diversion. Removing a product and replacing it with another drug or diluent and then returning it back to the pocket is one method of diversion. Constantly removing a larger size product when the exact dose is available is also a red flag.

Override Report: Constant removal of medications without a pharmacist verified order is a source of concern. This report will give you a detailed overview of users' access without appropriate prescriber's orders.

All Station Events/Patient Chart Review: For patient care area managers this report is a snapshot of transactions taking place; on patient care areas. The report is divided up among the different areas; patient care area managers are required to scan the report for questionable activity. The report is compared with the patient's medical record and medication administration record to confirm that the ADC activity matches. Empowering many disciplines to take an active role is an important goal of any diversion prevention program.

Common Diversion Methods

- Pulling narcotics for an excessive amount of patients – For example, critical care nurses pulling narcotics for more than the eight patients assigned to them.
- Pulling larger dose than patient receives – If the dose is 2 mg and the product available is 2 mg and 4 mg, you will see removals of 4 mg with a waste transaction by different witnesses each time.
- Pattern of broken vials and ampoules – Watch for excessive “accidents” and check rubber stoppers for punctures. For example, if a returned bag of controlled substances contains a few broken vials, vials without caps, and intact vials, the broken glass and the intact vials are the decoy; check the vials without the caps for punctures in the rubber stoppers.
- Vial breakage is clean or vials are sheared without fragments – Diverters do not like glass in their veins: If the break is flawless, be concerned.
- Intact narcotics thrown in general trash, and the employee volunteers to take out the trash – Nobody enjoys taking out the trash! Remove trashcans from the controlled substance vault area.
- Pulverized or broken tablets – Pieces of tablets can be removed and the broken pieces are left behind as the decoy.
- Pieces of tablet or powder of capsule missing – Opaque capsules can be refilled with cotton or sugar, giving the appearance of a full capsule.
- Substituting diluent (water, normal saline) for active injectable narcotic in IV bags.
- Substituting look-alike legend drug tablets for active narcotic tablets using bingo cards or blister packs. For example, dicyclomine in an amber blister card may be passed off as oxycodone.
- Passing a heated needle through the bottom of a glass ampoule or IV bag – Watch for leaking IV bags or wet labels in addition to punctured ports.
- Using a curved needle to go between the metal lid and the rubber stopper on vials – Be sure to examine the side of the metal cap for tampering or damage. The surface should be smooth to sight and touch.
- Creating and deleting users in a short period of time in the ADS and upon review, these users are fictitious – Run a report on the ADS once a week and review new users added to the system.
- Employees working and making transactions during off-shifts or unscheduled times.
- Substituting controlled substances with other medications that have CNS side effects (e.g., diphenhydramine, dimenhydrinate, haloperidol, tramadol, and meclizine) and mimic the drowsiness effects of controlled substances.
- Removing controlled substances from the expired, recalled, or wasted bin – St. Joseph's Regional Medical Center secures expired, recalled, or wasted controlled substances in a standard United States Post Office curbside mailbox that serves as a collection box. The mailbox is painted with a simple grey primer and is devoid of any markings. There is a single label on it that reads, “Two pharmacists' signatures are required, please seal the bag.” This message reminds the pharmacists that a co-signature for the paper work is required for all expired medication returns. The signed paper work is sealed in a Ziploc bag and then dropped into the mailbox for security and destruction. Upon destruction, a report is generated from the ACSV that details the entire contents of the mailbox and the contents are physically confirmed with the report.



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Inventory Verification Report: Daily controlled substances inventory is another area where diversion can occur. Excessive count corrections and errors are cause for concern. This report will help track trends and activity during the inventory verification process.

Outdated Inventory Report: Expired, recalled, and returned wasted controlled substances are a commonly overlooked area of diversion. This report will track trends with excessive outdated and returning of controlled substances by users. Always check the returned product for evidence of tampering.

We use an ADS Log (Pyxis Monitoring Log) and a Controlled Substances Discrepancy Log to keep track of all of the reporting results. Copies of these reports can be downloaded online at www.pppmag.com.

At-Risk Employees

In addition to watching for patterns of diversion practices, also be on alert for the following changes in employees' behavioral patterns:

- Changes in work habits, attitude, physical appearance and behavior
- Patients complaining of poor pain management during particular shifts or work schedules
- Patient care record documentation that is poor, vague, and/or demonstrates erratic pain relief
- Numerous requests for witnessing waste transactions, mistakes, or accidents
- Numerous witnesses used by one individual

In a hospital survey conducted by Crowson and Monk-Tutor, over 80% of the respondents indicated that their institution used an ADS, and 62% provided the necessary information to calculate a diversion detection rate of 0.36 per 100 beds pre-automation and 1.12 per 100 beds post-automation (P < 0.001). Out of the 19% of institutions not using ADSs, 60% provided the necessary information to calculate a diversion detection rate that was determined to be 0.76 per 100 beds.¹

A Just Culture Approach

Taking a Just Culture approach to handling a diverter means providing assistance to them rather than immediately seeking criminal penalties. The goal is to get the diverter to admit to a controlled substance abuse problem, remove him/her from the direct patient care setting, and provide the counseling necessary to overcome the problem. This ensures safety for patients, co-workers, and the afflicted employee. Simply ignoring the diversion problem and terminating the employee will only resolve the immediate issue at the affected institution. If the employee moves on and is hired by another institution, the problem will continue and

patients and staff will be at tremendous risk. This pragmatic and non-punitive approach will encourage employees to report potential or actual risks observed. A punitive culture toward drug diversion will discourage communication, prevent disclosure, and stifle continuous quality and process improvement.

Summary

The combined use of automation, manual inspections, and an interdisciplinary team approach will decrease the risk and incidence of controlled substance diversion. Creating multiple levels of reporting and inspection will aid in the discovery of controlled substances diversion. Embracing and promoting a Just Culture will foster cooperation and greater input from the hospital staff for suggestions to improve quality, reduce system failures, and prevent errors. Involve and empower members of your health care team outside of the pharmacy department for improved quality, safety, accountability, and success. ■

Reference:

Crowson K, Monk-Tutor M. Use of automated controlled substance cabinets for detection of diversion in US hospitals: a national study. *Hosp Pharm.* 2005; 40(11):977-83.



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