

Drug Diversion: New Approaches to an Old Problem

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ABSTRACT

Objectives: To familiarize readers with the trends in drug diversion in hospitals and to examine how culture, internal and external to the healthcare organization, will impact successful diversion prevention strategies.

Study Design: The authors drew on their personal experience and expertise, as well as a review of current literature, to introduce new concepts that need to be considered to effectively assess and mitigate risks associated with controlled prescription drug diversion.

Methods: The authors reviewed the most current reports of controlled prescription drug diversion trends and structured approaches for compliance and risk mitigation.

Results: No single approach will mitigate all risks of diversion. A multi-tiered approach that addresses processes, practices, culture, and strategy is recommended.

Conclusions: Controlled prescription drug diversion is a persistent problem in hospitals and healthcare systems. Forces external to the organization, coupled with a lack of urgency to address internal gaps, create a platform for significant drug diversion events. A fresh look at the role of culture and approaches to reduce diversion may help the organization avoid patient harm and financial and reputational risks.

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Drug diversion in hospitals is not a new issue, and the stakes are getting higher for patients, staff, and healthcare organizations. According to the National Drug Threat Assessment Summary (2015), nonmedical use of controlled prescription drugs remains a serious threat, with the majority being opioid drugs.¹ Prescription opioid drug dependence is at epidemic levels in the United States.² The CDC reports that over 5 million individuals are addicted to prescription opioids and 17,000 deaths per year are attributed to opioid overdoses.³ Between 2013 and 2014, there was a 14% increase in opioid overdose deaths—half of which were due to prescription opioid drugs.⁴ The increase in demand for controlled prescription drugs has created an enormous potential for profit from theft, diversion, and prescribing without a legitimate medical purpose. As states enact stronger controls on prescribing and monitoring of controlled prescription drugs, many physicians no longer will see patients with chronic opiate needs, and pharmacies are limiting the number of doses they will dispense. These market forces may place hospitals at even higher risk for diversion events.^{5,6} A new look at an ongoing problem may help the healthcare organization avoid patient harm and prevent financial/reputational risks.

The Regulatory Environment

Regulations for hospitals have changed little since the Controlled Substance Act of 1970. The US Drug Enforcement Agency (DEA) uses a system to ensure that controlled prescription drugs are available to the public and that illegal diversion does not take place. Within that system, the DEA can monitor the production, distribution, dispensing, and security of controlled drugs. DEA investigators conduct scheduled investigations and unannounced visits to DEA registrants, ensuring that correct recordkeeping is being followed. The agency has conducted several high-profile investigations in the last few years, resulting in multi-million dollar fines and



organizationally significant corrective action plans.^{7,8} In each case, the investigation was triggered by reports to the DEA of large quantities of missing or stolen doses of controlled drugs. Upon investigation of the initial report, the DEA found other evidence of noncompliance with the regulations, especially around recordkeeping and supervision. It is important to note that the lack of theft/loss reports may also act as a triggering event for a DEA visit.

Are You Really Secure?

Why do hospitals continue to struggle in preventing drug diversion? The most common cause of drug diversion at any point in the system is access. Controlling access and hard wiring a system of checks and balances is essential to reducing the opportunity for, and improving the detectability of, diversion. There are risk points for diversion whenever controlled drugs are handled, including ordering, receipt, storage, dispensing, administration, and waste. Hospitals rarely audit their controlled drug management plan to assess for changes in practice or gaps in processes; good plans morph over time. Staff may deviate from the established procedures not realizing that they are creating risk. The normalization of deviance is seen by susceptible staff as a flaw that allows them to divert without detection.

The introduction of new technologies, such as automated dispensing cabinets (ADCs) and barcode medication administration (BCMA), often alter work flows without understanding the impact on access to controlled drugs. Hospitals invest substantial amounts of capital dollars in medication dispensing cabinets to ensure that recordkeeping and controls are in place to prevent diversion. However, the use of ADCs may create a false sense of security for the organization. The ADC is a well-established tool to reduce access when appropriately implemented. The staff continually finds ways to work around the built-in controls, and some divert. The ADC programming allows the organization flexibility in how it uses the machine. For example, organizations have many choices with ADCs on how controlled drugs are presented to the user, how much drug is stored in a drawer, and how the user counts the inventory each time the drawer is accessed. If the user is presented with a large number of doses to count and is only required to verify the count instead of performing a “blind count” on the drawer contents, there is a higher likelihood that the user will not count before removing a dose. Each decision is a compromise between efficiency and effective diversion prevention.

Many hospitals have implemented BCMA systems with the goal of reducing medication administration errors

PRACTICAL IMPLICATIONS

Addiction to prescription opioids has reached epidemic proportions and is a major driver for drug diversion. Hospitals are not immune to the growing problem, and the Drug Enforcement Agency is increasing scrutiny of drug diversion in healthcare organizations. Organizations should:

- Conduct a comprehensive diversion risk assessment
- Understand the role of situational awareness in combatting diversion
- Support a culture of safety that extends to diversion prevention

and improving documentation/charge capture. The use of BCMA effectively moves medication preparation from medication rooms to the bedside; however, this creates new risk points when storing and wasting partial doses of controlled prescription drugs. The partial dose is created at the bedside, but the unused portion of the controlled prescription drug must be wasted and documented back at the ADC. Delays between withdrawing of controlled drugs and witnessing the waste of partial doses creates an opportunity for tampering with the partial doses. The chain of control for the unused portion may be broken and diversion never detected.

Hospitals who report infrequent diversion events may be lulled into believing that there is little diversion activity occurring, when, in fact, the reverse may be true. Documentation audits are time-consuming, but necessary, tools to detect activity outside of the automated systems. Diversion detection is dependent on software and analytics to examine usage trends by ADC, location of care, and individual users. Diversion software requires constant vigilance for changes in practice and staff movement. The software user must be aware of how data is pulled and processed in order to accurately interpret report analysis. Most often, these systems fail due to lack of environmental understanding or single point failure whereby only 1 person monitors the system; the latter creates scenarios where analysis is viewed through a single lens or the person may leave the organization, thereby creating a void in monitoring.

We're Not in Kansas Anymore

Hospitals and healthcare systems routinely screen for substance use/abuse as part of the initial employment process, especially for staff that will come in contact with controlled drugs. Screening questions and drug tests are used to assess for the likelihood that an employee may commit a drug security breach. Although this approach may identify candidates not suitable for employment in a healthcare environment, it does not ensure that the employee will not become a diverter once hired.

Essentially, there are 2 employee profiles that the organization should consider. What do we know about the person who diverts controlled prescription drugs for personal use? They tend to be high achievers who are counted on and trusted by their colleagues, and they also tend to work extra shifts—more often the night shift. They tend to work out of staffing agencies, and they may work in areas where there is more autonomy and less supervision, such as the operating room, intensive care unit, or emergency department.⁹ Additionally, they are likely to have significant personal stressors in their lives. In all cases, the common denominator is access. Without active diversion analytics and documentation audits, their diversion activity may not be detected unless their performance at work begins to deteriorate, leading to patient complaints and staff concerns.

Little has been written about the employee who diverts for personal benefit. Diverting for personal benefit typically involves a large number of doses—more than an individual could reasonably use on their own. The changing demographics in society today create new motivation to divert large quantities for sale. One example of large-scale theft was reported in 2014 when the director of pharmacy at Beth Israel Medical Center in New York City, was charged with stealing over \$5.6 million worth of oxycodone.¹⁰ Hospitals may also want to consider the risk in employees who, although they may not handle controlled drugs as part of their routine duties, may have access due to lax procedures. Staff who work in environmental services, supply distribution, and other disciplines may come in contact with not only drugs, but also controlled prescription drug pads used to write prescriptions. Employees with low-paying jobs may be motivated by offers from others outside the organization to steal drugs or prescription pads in exchange for large sums of money. Again, in all cases of large-scale theft/diversion, the common denominator is access.

The socioeconomic and controlled drug use profile of the external community is likely to be replicated inside the walls of the hospital or healthcare organization since this is the labor pool for the employer. Healthcare organizations would be well served to include the community profile into their periodic drug security risk assessment and consider who has intentional and unintentional access.

Culture Versus Strategy

Culture of cater. Healthcare organizations need to ask why access is still the common denominator for controlled drug diversion. The organizational culture, while

well intentioned, has an impact on both the strategies selected to manage access and the effectiveness of these strategies. For example, hospitals and healthcare organizations may make physician satisfaction a priority, aka a “culture of cater.” Decisions that are made to support a culture of cater may include allowing less restrictive access to controlled drugs for anesthesia providers (no time to verify/count inventory) or encouraging nurses to remove, document, and witness waste of controlled prescription drugs from ADCs for anesthesia providers who don’t have time to do so. When nurses are encouraged to focus on physician satisfaction in lieu of patient safety, they are less likely to speak up and disagree; and when culture supports lax procedures for one class of staff, the other classes of staff may be prone to become lax as well.

Culture of trust. Healthcare organizations frequently rely on a “culture of trust” as the foundation for diversion prevention. However, diversion prevention should be built on a foundation of checks and balances, with clear expectations for behavior and accountability. An example of this culture of trust is when the ordering, receipt, and storage of controlled prescription drugs are not segregated between pharmacy staff. This culture is also exhibited when seniority equals honesty. Situational awareness—knowing what is going on around you—can become a victim of this culture of trust. When staff relies on trust, they are not able to recognize inherent risks of simple habits, such as storing ADC keys in open drawers or not securely storing controlled drugs at a patient’s bedside.

Culture of compliance. The “culture of compliance” regarding diversion prevention regulations is similar to compliance with the Federal Conditions of Participation. Healthcare organizations used to be complacent with regulations and only felt a sense of urgency around compliance when faced with a scheduled triennial accreditation survey. Changes in hospital accreditation surveys compelled organizations to adopt a culture of continuous compliance—being ready every day for every patient, not just for a survey. Readiness is assessed on a continual basis through patient observations, audits, and documentation reviews. Accountability for compliance is monitored from the frontline workers to the senior executive leadership. Hospitals could improve diversion prevention and detection through adoption of a similar approach to compliance by using a drug diversion team to provide oversight and accountability.

CONCLUSIONS

To restate the question: why are we still struggling with the same issue of drug diversion? Simply, we have too



many irons in the fire and, unless you have had a major issue, drug diversion hasn't risen to the top of your priority list. Take time to lift your head above the mounds of paper on your desk and take another look at what is happening in your organization. Chances are, the landscape has changed since you last looked at your drug diversion program. Consider the use of external experts to provide an unbiased, periodic fresh look at your controlled drug and diversion control processes. Often, there are simply too many "moving parts" to our programs that people get too close to; having an external review can help uncover gaps that may not be readily apparent to internal staff. Regularly consider the impact of any changes in the medication use process in your organization on the integrity of your diversion control efforts. A proactive diversion control program with regularly invested effort can mitigate the risk of patient harm, significant fines, penalties, and damage to the organization's public image.

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