Detect Diversion Before It Causes Harm

Audits will protect your patients and your facility
By Kim New, JD, BSN, RN

Diversion, the theft of drugs by healthcare personnel, is universal in healthcare facilities in the United States and elsewhere. It is generally believed that 1 in 10 nurses divert drugs. Some of the risks associated with diversion include patient harm, negative publicity, financial loss and civil and regulatory liability.

Every facility should have a formal program to address this continuous challenge. Regular auditing of drug usage for possible diversion is an essential component of any diversion prevention, detection and response program. The internal auditor has an important role in drug diversion surveillance, including in controlled substance transactions in clinical and other high-risk areas.

Be fore the introduction of drug cabinet automation and data analytics, most hospitals treated drug diversion as isolated events. The primary method of auditing was manually counting narcotics at the end of each shift. A more in-depth review of transactions by clinical personnel was time-consuming and cumbersome using paper records. As a result, diversion was mostly identified when concerning behaviors or deteriorating work performance became apparent.

With the arrival of automated drug cabinets and drug transaction analytics, the readily available information and the ease of auditing have increased substantially. Diversion can be detected more quickly, and patients can be protected from the harm that may accompany diversion.

Ideally, diversion events should be detected immediately after they begin, or even be anticipated where heightened opportunity exists. Detecting diversion through transaction irregularities is far preferable to waiting for the diverting personnel to show manifestations of impairment.

Diverters are often high achievers who are capable of appearing perfectly normal, even when they are working under the influence of powerful opioids. Overt signs of impairment often don’t become noticeable until a diversion scheme has continued unchecked over a considerable period.

Why pay attention to diversion?
The risks associated with diversion include harm to patients and others, negative publicity, financial loss and civil and regulatory liability.

The patient safety risk resulting from diversion is receiving attention in the wake of several well-publicized outbreaks of blood-borne infection in hospitals.¹ In one such event in 2012, a radiology technician diverted fentanyl, substituting

¹ Schaefer, MK; Perz, JF. Outbreaks of infections associated with drug diversion by healthcare personnel, United States. Mayo Clinic Proceedings. 2014; 89 (6).

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saline or water and not changing needles before returning the syringes to be used on patients. To date, 45 patients are known to have become infected with hepatitis C from that event, and at least one died as a result.

In another 2011 case, an outbreak of bloodstream infections with Ochrobactrum anthropi, a rare pathogen, led to the discovery of a nurse diverting hydromorphone from bags, and replacing the missing volume with saline, with a breach of sterility.

Other cases have shown a risk to the public. For example, an anesthesia provider severely injured five students while driving under the influence of diverted propofol. In every case that has reached public awareness, there has been substantial adverse publicity for the facility where the diversion took place.

Regulatory foundation
Perhaps because of several recently recognized cases of patient harm from diversion, the Drug Enforcement Agency and other regulatory entities have increasingly focused on diversion within healthcare facilities.

Fines for perceived inadequate diligence are large. In 2014, one California health system settled an accusation of improper handling of controlled medications for $1.55 million, and a burdensome two-year action plan was imposed.

In several instances, hospitals have been placed in immediate jeopardy of losing their accreditation, participation in the Medicare program, or state licensure because of diversion, even in cases where no patient harm occurred. Civil liability for the hospital has been found for injury to patients and has been pursued when there was injury to others more remotely connected to the diversion activity.

A robust auditing program helps ensure compliance with several regulatory requirements relating to controlled medications. Of note, the Medicare Conditions of Participation for Hospitals require:

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

The Interpretive Guidelines² for the above section indicate that a hospital must be capable of quickly identifying loss or diversion of controlled medication and quantifying the loss. The Guidelines state further that facilities must have processes in place to limit diversion.

Assessing routine auditing processes
An effective audit requires knowing what routine auditing is envisioned by the organization and whether that auditing is actually occurring. Many facilities require nurse managers to review a monthly report that includes statistical comparison of drug cabinet transactions among staff. Some institutions have a pharmacy, internal audit or compliance staff member examine the monthly comparison.

Regardless of how the auditing is structured, routine auditing expectations should be set forth in policy (Exhibit 1). It is also essential that all such auditing

<table>
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<th>Exhibit 1 – Essential components of diversion auditing policy</th>
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<td>• What reports will be generated on a routine basis?</td>
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<td>• Who is responsible for reviewing the reports?</td>
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<td>• Within what timeframe will the reports be reviewed?</td>
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<td>• What statistical threshold will require in-depth auditing?</td>
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<td>• How many transactions will be reviewed for each outlier?</td>
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<td>• How will the routine audits be documented?</td>
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² cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospitals.html.
be documented and that the records are accessible in the event of a regulatory investigation.

**Available data**
Internal auditors may be involved in the review of the monthly statistical reports, but may also choose to do an independent audit for diversion. To act effectively as an auditor, you must know how drugs should be handled and understand available transaction and analytics reports (Exhibit 2).

Diverters are often high achievers who can appear perfectly normal, even when they are working under the influence of powerful opioids.

Concerning the handling of medications in clinical settings, the Medicare Conditions of Participation for Hospitals states:

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

Automated drug cabinets typically contain controlled and noncontrolled medications. Controlled medications are kept in single access bins that require a “blind count” each time the bin is entered. The process involves a user typing in the name of the medication he needs and the quantity. The drawer where the medication is stored opens and the specified bin becomes accessible. The cabinet will prompt the user to enter the number of medication units in the drawer. If the count is different from the anticipated quantity, a discrepancy is created.

Perhaps owing to the sophistication of transaction analytics, there has been a shift toward diverting from waste. To reduce the opportunity to divert from waste, at least in nonprocedural areas, users should waste excess medication at the drug cabinet at the time of removal, or as soon as possible after administration. Another authorized user should physically witness all waste.

Medications should never be carried in pockets, and, with the possible exception of procedural areas, should only be removed from the cabinet at the time of need, not in anticipation of pain that might occur at a future time. If a drug is removed for a patient and then is not to be used, it should be returned immediately using a return bin and a witness.

Most institutions review statistical comparison reports for each clinical area on at least a monthly basis. These reports are generated by analytics programs from data gathered from automated dispensing cabinets. Users who are flagged as outliers require more scrutiny, often by review of a sample of their transactions and comparison of those transactions to administrations documented in the medical record.

Monthly statistical reviews are considered a best practice. While the reports are meant to highlight staff that may be higher risk for diversion, many anomalous users are not diverting. I have heard complaints from managers that their monthly review is not valuable because diverters are not often identified. I recommend that all staff should be audited at least annually, however, so I remind managers that

<table>
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<th>Exhibit 2 – Basic reports and their value</th>
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<td><strong>Type of report:</strong></td>
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<td>User activity report</td>
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<td>Cancelled or null transaction report</td>
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<tr>
<td>Medication override report</td>
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<td>Witness buddy report</td>
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<td>Discrepancy report</td>
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the monthly review allows everyone to be reviewed yearly and highlights individuals for additional focus (Exhibit 3).

Controlled medication user transaction reports can be used to audit for many types of suspicious transactions, and are often generated when a nurse has been flagged.

Areas in which patients are transient, such as radiology suites, pose a special risk.

Excessive transactions may point to diversion or just poor practice. Activity reports show all types of transactions including drug removal, wasting, returns, and cancelled transactions. By reviewing activity in conjunction with the medical record, an auditor may identify instances of delay in administration or delay in wasting. Such delays may signal diversion, particularly of injectable medication, but may also reflect noncompliance with medication handling requirements.

Most drug cabinets in a hospital are “profiled,” meaning that an order must be received in the pharmacy and reviewed by a pharmacist before the drug becomes available for withdrawal at the drug cabinet. Some fast-paced units, such as the emergency room or the recovery room, may not be profiled.

In most profiled cabinets, selected drugs that might be needed urgently are accessible through an override process before an order is reviewed. Medication override reports for profiled cabinets are useful for identifying drugs that are removed without an order. Repeated override transactions for the same medication by the same user might reflect diversion, so there is value in reviewing these reports.

Cancelled or null transactions, in which a user enters a bin in the cabinet but indicates the transaction was aborted, occur from time to time for legitimate reasons. If cancelled transactions involve the same drug repeatedly, however, it raises suspicion for diversion.

In one case, a nurse had a pattern of cancelled transactions for morphine 2 mg syringes. Upon further investigation, it was discovered that he had kept used syringes that he filled with saline and then carefully reconstructed to look like unused syringes. Each time he cancelled a transaction for that bin, he was swapping out the saline syringes for unaltered morphine syringes. In this case, patients were denied analgesia and possibly exposed to infection.

In another case, a nurse diverting a strong opioid had begun to suffer from side effects of her drug use. She had repeated cancelled transactions for ondansetron, a noncontrolled medication used for nausea and vomiting. Since ondansetron does not usually require a count each time it is accessed, she was simply going into the cabinet and helping herself to the medication but trying to hide her tracks by canceling the transactions. When the medication bin was finally inspected, much less stock of ondansetron was found than expected.

Perhaps owing to the sophistication of transaction analytics, there has been a shift toward diverting from waste.

In some units, workflow requires that two staff members frequently waste together. In other areas, two staff members wasting together repeatedly may signal diversion. Many individuals who divert from waste have told me that they seek out a gullible staff member willing to sign off as a witness to waste even though they do not actually observe wasting of the medication. A “buddy report,” which shows which individuals waste together, will highlight such schemes.
Because discrepancies in controlled medication count are usually swiftly identified, diversion by removing extra medication is no longer a method often used. Consequently, and because discrepancies can be confusing to resolve, some institutions become lax about addressing discrepancies. Regulatory authorities do expect all facilities to address discrepancies quickly, and most facilities have at least a policy that they will be resolved on each shift.

Medication override reports for profiled cabinets are useful for identifying drugs that are removed without an order.

It is important to run discrepancy reports regularly to ensure that discrepancies are actually being resolved. The reports can also identify users who frequently create discrepancies. Also, be aware that many institutions require a weekly inventory of controlled medications in all drug cabinets. If such a policy exists at your hospital, make sure the inventory is being done. A weekly inventory will help ensure that discrepancies are recognized and appropriately resolved, particularly for medications that are not frequently accessed, since a discrepancy is not created or identified until a subsequent user accesses the bin.

**Special challenges**

It is critical that facilities have a process in place for regular auditing and surveillance of high-risk areas, where tracking medications is difficult and automation may be lacking. Understanding workflow is essential to auditing surgical and procedural areas. Observing processes before undertaking an audit is highly recommended.

The workflow in the operating room and other procedural areas can result in decreased drug security and accountability. Drugs often must be withdrawn in advance of a case. Hand-offs of medication to a colleague may be common. Anesthesia kits may be taken for use on multiple patients throughout a day. Documentation of care or drug transactions may be in paper records.

Best practice for auditing controlled substance usage by anesthesia personnel is to reconcile all activity, comparing what is dispensed with what is documented and wasted. Ideally, activity is reconciled daily or at least weekly. At some facilities, anesthesia providers must submit all procedural waste and documentation to the pharmacy for reconciliation and possible chemical analysis of the waste.

Patient-controlled analgesia (PCA) pumps, controlled medication drips, fentanyl patches, and epidurals require extra attention.

PCA dispensing may be documented manually by the pharmacy and may require a signature of a receiving nurse, who is then responsible for sending the paper record back to the pharmacy after the infusion is concluded. Patients on controlled medication drips may go to surgery and have their drip discontinued by anesthesia personnel prior to the procedure. In some situations, nurses may sign out epidural infusions for anesthesia providers. Anesthesia providers may sign out their own epidural infusions but rely on the nursing staff to waste the residual later. Depending on the process, the time and activity between administration and discontinuation of the medication may confound auditing of wasting from PCAs, epidurals, and fentanyl patches.

Finally, areas in which patients are transient, such as radiology suites, pose a special risk. Staffs in those areas often take advantage of the patients' brief transit to access medications that are not administered. You must pay special attention to the time of withdrawal; if the patient left the area before the drug was accessed, the transaction was probably illegitimate.

**Understanding workflow is essential to auditing surgical and procedural areas.**

Observing processes before undertaking an audit is highly recommended.

In all situations, you must be able to track the medication from the time it is dispensed to the time it is administered, wasted or returned. In the event that tracking is impossible, processes must be improved so that auditing is possible.

**Conclusion**

Drug diversion causes harm to patients, the public and institutions, and is widespread in healthcare facilities. Every institution should have designated and specially trained personnel to discover and respond to diversion. Internal auditors have an important role in detecting diversion where it occurs, and ensuring that facilities have policies and processes to deal with it.