Drug Diversion Prevention

Background

Drug diversion is the illegal distribution or use of prescription drugs for purposes not intended by the prescriber. Diversion is widespread and occurs in many healthcare settings, including but not limited to hospitals, outpatient clinics, ambulatory surgery centers, pharmacies, wholesale distributors, and patient's homes. Commonly diverted medications also vary greatly and include, but are not limited to anabolic steroids, depressants, hallucinogens, opioids (most common), stimulants, chemotherapeutics, Botox injectables, sleep aids, weight-loss medications, and even anesthetic gases.

The ramifications of diversion are devastating to patients, healthcare organizations, and all healthcare workers. Consequences include inadequate patient pain relief, patient exposure to infectious disease, organizational exposure to significant fines and negative publicity, and risk to licensure. Healthcare workers are exposed to increased scrutiny and liability associated with patient safety events and diversion investigations.

According to the 2017 Porter Research Survey, 10 to 15 percent of all healthcare professionals will abuse drugs or alcohol during their careers. Respondents also indicated that they feel most diversion goes undetected, either due to weak diversion detection systems or the total lack of a diversion detection program. These statistics underscore the need for robust diversion prevention programs in all healthcare settings.

Though strategies to detect and prevent diversion can vary across the size and setting of a healthcare institution, the following outlines some basic strategies for all settings, including targeted considerations for acute-care and ambulatory environments. Several resources are cited below and should be evaluated as part of a comprehensive program design.

Strategies

Establishment of a Diversion Program

Diversion mitigation strategies can range from simple to very robust. It is important to begin with strategies that can be fully brought to fruition, then add more strategies as resources allow.

- A drug diversion program should employ an interdisciplinary team to give input into policy and process. The team should continually monitor prevention effectiveness and strive for improvement. This team should have a designated lead from a neutral department such as quality/safety, along with suggested participants of medicine, pharmacy, nursing leadership, anesthesia, security, IT, employee health, human resources, risk management/compliance, and administration. Medication security rounding by team members promotes staff conversation and awareness, as well as effective monitoring of the process.

- A drug diversion policy should detail processes that prevent and identify diversion. Policies should address how to recognize diversion in the organization, how to report suspicions of diversion, steps in the monitoring/surveillance process, and the investigation protocol when there is reasonable suspicion of diversion (such as interviewing the staff member, drug screen, suspension, ensuring the safety of the staff member). Sample policies are listed below in the resources.
- A strong program will monitor and use data in surveillance and improvement activities, as well as integrate with the organization's compliance program. Key metrics should be identified, responsibility for monitoring assigned, and periodic reports made to senior leadership.

Medication Management

Organizations often incorporate customized policies and procedures for medication management. Several aspects of these policies can be used in conjunction with diversion mitigation strategies.

- It is essential that the procurement, receiving, inventory, and stocking processes are detailed by organizational policy, with these duties separated among personnel and requiring two staff to confirm. These steps should also be appropriately documented on file.
- The chain of custody should always be maintained. Be mindful of unique situations such as transport to alternate clinic settings and storage within locations such as anesthesia carts and code carts. The established process should ensure medication security and integrity and be fully auditable.
- Medications are more secure in an automated dispensing cabinet (ADC), and more and more clinics are adopting ADCs. If this is not possible, a locked cabinet in a locked room with limited access (for example, via badge readers or key access with limited disbursement of keys) can be secure. More guidance on the use of ADCs is contained in ISMP's "Guidelines for the Safe Use of Automated Dispensing Cabinets," which covers such topics as biometric access, unit-specific privileges, and locked refrigerators.
- When storage is not automated, regular inventory of controlled medications should be conducted every shift. This should be done by two staff members and documented.
- Medication security can also be enhanced with camera surveillance in key locations such as procurement areas, storage, repackaging/compounding areas, the medication room, hallways that access the medication room, and procedural ADC units. Be mindful of applicable organizational policies or labor contracts regarding video surveillance.
- Organizations and clinicians should stay current on commonly diverted medications. Formularies should contain doses that match common prescribing practices, to minimize waste. Avoid purchasing bulk liquid containers for controlled substances.
- Prescription pads (including printer paper refills) should be tamper-resistant and kept in a locked location, such as a locking printer drawer. Stay mindful that prescribers can also be diverters and watch for suspicious activity such as one prescriber using another's DEA license or frequent calls for prescriptions for family members and/or fictitious patients.
- The most difficult part of the medication lifecycle to monitor for diversion activities is the administrative process. Many behaviors, such as frequent removal of larger-than-necessary doses or frequent discrepancies, can indicate diversion and should be monitored. The disposal of unused medication should involve a witness who observes and documents the observed waste at the time it is disposed of.

- Organizations should have the same controls for unassigned patient medications in the ADC, as well as for expired and recalled medications. There should be separation of duties for the monitoring of medications that are unassigned, expired, or recalled, and these medications should be kept in locked storage. Any expired or recalled controlled medications must be treated as part of the active stock and be inventoried as such until it is tendered to a reverse distributor or destroyed. There should be accurate and complete records of all such transactions.

Human Resources Considerations

- Education of all personnel is one of the most important strategies for diversion detection and should occur in orientation and at least annually. Key components of this education include the organization's commitment to diversion prevention; the organization's receptiveness to reports of suspected diversion, including a mechanism for reporting confidentially and protection from retaliation; signs of substance use and suspicious behavior; and how to report suspected diversion. The education strategy should be in policy, have a specific supervisory component, and be documented.
- Organizations should have policies in place to address employee and clinician substance abuse with avenues for self-reporting, addiction assistance program information, and return-to-work provisions.
- There should be clear drug testing policies for hiring and for-cause incidents, including diversion incidents. There should be provisions for incidents occurring during human resources off-hours.
- Organizations should be ready with a plan to support employees when diversion results in an employee overdose or death in the workplace.

Diversion Investigations

Suspected diversion investigations should be conducted quickly and thoroughly. An organization can best accomplish this with a small, readily available multi-disciplinary team and standard protocol. The following is a summary of investigation points, with more detail contained in the "ASHP Guidelines on Preventing Diversion of Controlled Substances," located in the Resources section of this document.

- An investigation team usually includes representatives from the pharmacy team, the supervisor of the suspected diverter, human resources, and others as detailed in the organization's protocol. Investigations should follow policy and be consistent across roles, practice settings, and the tenure of the suspected diverter.
- After the data/information is reviewed and verified, the suspected diverter should be removed from patient contact and should have their access to medications suspended immediately. If any patients were impacted, they should be notified by staff who have risk management duties. The billing of the diverted substances should be reviewed as well.
- Diversion events must be reported to key internal stakeholders (CEO and pharmacy director) and external stakeholders such as the DEA, state pharmacy board, other licensure boards as applicable, local law enforcement, the department of health for patient-harm events, and the FDA (in the event of tampering). It is helpful for the reporting requirements to be established in organization policies.
- Documentation of the investigation process, outcomes, and reporting should be maintained. The Resources section of this document contains two resources from ASHP for investigations: a team notes tool and incident workflow examples.

Acute Care

The American Society of Health-System Pharmacists (ASHP) provides a comprehensive overview for diversion prevention and can be found in the Resources section of this document. Below are highlighted strategies for acute care.

- Controlled substance infusions should be kept in a secure lockbox with no-port tubing. Keys and access to these boxes should be limited and tracked. Patients should be encouraged to return their own controlled substances to their home, accompanied by a family member when possible. If this is not possible, these medications should be documented, with two healthcare providers verifying the medication and amount. The medications should be stored securely until dispersal. Policy should also define how long abandoned medications can be held, along with the process for their disposal.
- The use of technology for surveillance of diversion is helpful to ensure consistency across roles and individuals, as well as to expedite the investigative process. There are many behaviors to watch for, including:
  - Use of override functionality for controlled substances beyond emergencies and/or to excess. Options for overridden medications should be very limited.
  - Removal of controlled substances without an order, for patients not assigned to the healthcare provider or for recently discharged patients.
  - Frequent discrepancies, frequent dispensation of less medication than ordered but more often than ordered, uncharacteristic patient complaints of pain after medicating, or excessive pulls for as-needed pain medication.
  - Pulling doses that need a larger waste, not documenting waste, failing to waste, or frequently wasting an entire dose.
- Controlled substance discrepancies should be resolved each shift by two staff members. Additionally, inventory should be monitored on a weekly basis by the pharmacy.

Clinic Settings

- The separation of duties for medication procurement, as mentioned above in medication management, can be challenging for small clinics, but it is critical.
- Carefully follow all DEA requirements, including registering all locations that store controlled substances.
- Patient prescriptions awaiting pickup should be monitored carefully, kept in a locked location, and destroyed if not picked up.
- Discrepancies in controlled substances should be resolved the same day, prior to practice closure, by two staff members. Ongoing monitoring of inventory should occur weekly or monthly.
- If your state allows, and you choose to proceed with administering samples of controlled substances, the same monitoring and controls discussed here should be followed. Additional risks associated with sample distribution are covered in our guidance document, "Sample Medication Dispensing in the Outpatient Clinic."
- Clinics should direct patients with unwanted medications to disposal programs. Staff cannot legally accept unwanted medications and should not do so under any circumstances.
- Sharps containers and sewers cannot be used for the disposal of controlled medications. There are controlled waste receptacles available that meet DEA requirements for non-retrievability.

Conclusion

Drug diversion is a serious threat to patients and healthcare organizations alike. The security of controlled substances should be made a priority and monitored diligently by all who interact with these drugs. Comprehensive drug diversion prevention programs include interdisciplinary teams, detailed policies, staff education, surveillance and data monitoring, and expedient investigations.

This information should be modified based on individual circumstances, professional judgment, and local resources. This document is provided for educational purposes and is not intended to establish guidelines or standards of care. Any recommendations contained within the document is not intended to be followed in all cases and does not provide any medical or legal advice.

Resources

American Society of Health-System Pharmacists. "Drug Diversion Core Team Investigation Notes/Report." *Controlled Substances Drug Diversion Pharmacy Technician Toolkit*. Accessed at: https://www.ashp.org/-/media/assets/pharmacy-technician/docs/drug-diversion-core-team-investigation--notes-reports.pdf.

American Society of Health-System Pharmacists. "Drug Diversion Incident Workflow Examples." *Controlled Substances Drug Diversion Pharmacy Technician Toolkit*. Accessed at: https://www.ashp.org/-/media/assets/pharmacy-technician/docs/Example-of-Steps-in-Investigating-a-Potential-Drug-Diversion-Incident.pdf.

Clark J, Fera T, Fortier C, et al. "ASHP Guidelines on Preventing Diversion of Controlled Substances." *American Journal of Health System Pharmacists*. December 15, 2022: Vol. 79, No. 24, 2279 – 2306. Accessed at: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx.

Department of Health & Human Services Centers for Medicare & Medicaid Services. "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid." *Center for Program Integrity*. January 2012. Accessed at: https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaidintegrityprogram/downloads/drugdiversion.pdf.

Institute for Safe Medication Practices. "Guidelines for the Safe Use of Automated Dispensing Cabinets." *ISMP Guidelines*. February 7, 2019. Accessed at: https://www.ismp.org/resources/guidelines-safe-use-automated-dispensing-cabinets.

Kansas Hospital Association. "Sample Policies and Procedures." *Critical Issues.* Accessed at: https://www.kha-net.org/CriticalIssues/QualityandPatientSafety/drug-diversion-prevention-toolkit/sample-policies-and-procedures/.

New K. "Preventing Diversion in Physicians' Offices and Clinics." *Pharmacy Purchasing & Products.* May 2017: Vol. 14, No. 5. Accessed at: https://www.pppmag.com/article/2049.

Porter Research. "Survey Report: Drug Diversion in U.S. Health Systems." *Invistics.* December 2017. Accessed at: https://porterresearch.com/wordpress/wp-content/uploads/2017/12/Survey-Report-Drug-Diversion-in-U.S.-Health-Systems.pdf.

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