Develop a Drug Diversion Prevention Program

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This is the first in a series of two articles on institutional drug diversion.

Traditionally, health care institutions regarded incidents of drug diversion as isolated events. The most basic forms often were discovered through end-of-shift drug counts, and the employee deemed culpable usually was terminated without outside reporting or follow up.

However, over the course of the last 2 decades, our understanding of institutional drug diversion has evolved; now it is recognized as a pervasive threat to both patient and employee safety. As such, it is an issue that requires perpetual vigilance and management expertise to detect and prevent.

Although diversion likely occurs at most institutions where controlled substances are administered, reliable data on its prevalence are lacking, reflecting what is a clandestine activity by nature. Many cases of diversion are never discovered, and those that are identified rarely are reported outside the institution. For example, estimates of the number of hospital nurses that divert vary widely, and few are founded in systematically acquired data. In one of the only published systematic studies available, 6.6% of nurses reported illicit use of prescription-type drugs within the past year.\(^1\) And actual incidence may be much higher. Anecdotally, a 550-bed hospital where I worked previously uncovered an average of two nurses diverting each month.

A Clear Need for Prevention

Several highly publicized incidents have brought the issue of drug diversion to the public’s attention. These have involved situations in which the diverting party introduced pathogens into the provision of care. Since 1985, the media have reported at least five outbreaks of hepatitis C infection and four outbreaks of Gram-negative bacteremia attributable to diversion in health care facilities.\(^2,3\) Each of these outbreaks left as many as 45 patients infected; the number of patients screened for infection has totaled in the thousands, and some of the outbreaks resulted in fatalities. Given the threats posed by diversion to workplace and community safety, instituting a robust drug diversion program is vital.

Comprehensive Safety

In addition to contributing to the risk of infection transmission, diversion results in other hazards to patients, the diverting staff member, co-workers, and even to the public at large. In a 2012 diversion case in Georgia, a nurse who was self-administering propofol drove her car in the wrong direction on a highway and collided with another vehicle containing five teenagers, several of whom, along with the diverter, sustained significant injuries.\(^4\) Diversion also often results in the denial of appropriate care (eg, missing or diluted analgesia for patients in pain), the provision of care by impaired personnel, and falsified documentation of care.

Given these and many other examples of compromised safety due to diversion, a proper detection and prevention program must seek to:

- Reduce the risk of transmission of pathogens and infections
• Ensure the administration of adequate and appropriate concentrations of agents meant to relieve pain
• Reduce the risk of medication and other errors associated with treatment by impaired personnel

Regulatory Compliance
A program to prevent, detect, and respond to diversion also must satisfy various regulatory and accreditation entities, including state agencies that license health care facilities and providers, the Centers for Medicare and Medicaid Services, the Drug Enforcement Administration (DEA), The Joint Commission, and DNV Healthcare. Common regulatory requirements for diversion programs include:

• Drug security from receipt until end use or disposal
• A method of accounting for all scheduled drugs
• Pre-employment screening of applicants
• Procedures for prompt diversion detection
• Documentation and internal and external diversion reporting
• Ongoing process improvement (eg, root-cause analysis)

Program Structure
In order to address the risks and safety issues created by diversion, a prevention, detection, and response program should include certain basic elements.

Staff Education
Widespread staff awareness and engagement are the foundation of any diversion program. While all pharmacy and medication handling staff (technicians, nurses, physicians, anesthesiologists, etc) should receive diversion education at the time of hire (and at least annually thereafter), education also must reach non-clinical staff because evidence of diversion often is discovered by individuals who are not authorized to handle controlled medications. For example, a financial auditor may identify a charge for a duplicate dose; an environmental services worker may discover evidence of sharps container tampering; or a unit secretary may find drug-related equipment in a staff bathroom.

The essential elements to convey in an education program comprise the practical—the risk of harm to patients, co-workers, and the institution—and the didactic—overt and subtle signs of diversion. Actual examples of diversion events best demonstrate the insidiousness of this problem, even in exemplary institutions. Obstacles to proper staff engagement include the belief that diversion is rare or occurs only in remote situations, and the misconception that diverters fit widely held stereotypes of drug abusers (see TABLE 1).
Program Policies
The policy structure of a drug diversion program should, at a minimum, include the following:

**Pre-employment screening.** The DEA expects institutions to undertake employee screening procedures that are sufficient to identify the risk of a drug security breach by a job candidate (21 CFR 1301.90).\(^5\) Include any history of felony conviction or recent misdemeanor charge, as well as any history of illicit drug use.\(^6\)

**Secure medication handling.** The Medicare Conditions of Participation for Hospitals stipulate, “current and accurate records must be kept of the receipt and disposition of all scheduled drugs,” (42 CFR 482.25(a)(3)), and that “all drugs and biologicals must be kept in a secure area, and locked when appropriate,” with access limited to authorized personnel (42 CFR 482.25(b)(2)(i-iii)).\(^7\)

Institutions must maintain secure handling from the moment controlled substances arrive until they are administered to a patient, reverse distributed, or wasted in a manner that renders them irretrievable. To ensure uniform accountability, policies must detail expectations regarding medication administration, wasting, and returns. In general, the following conditions should apply:

- Remove scheduled drugs only at the time of administration
- Waste only at removal or immediately after administration
- Immediately place un-administered drugs in a return bin

Under no circumstances should staff members place controlled medications in pockets, on mobile computer

\(^5\) 21 CFR 1301.90

\(^6\) 21 CFR 1301.90

\(^7\) 42 CFR 482.25(b)(2)(i-iii)
Auditing for diversion. Be explicit about responsibility for diversion auditing and delineate what information will be reviewed, who will review it, and how often. For example, if nursing managers are expected to review drug transaction analytics reports for their department, the policy should specify what reports are to be reviewed and how often the reports are to be generated. Prescribe statistical thresholds requiring further investigation, a uniform method for documenting audits, and a specific time frame within which audits must be completed.

Response to suspected and confirmed diversion. Outline a uniform manner for handling all cases of suspected diversion utilizing a team approach. Describe the mechanism through which response to suspected events will occur at all hours, on all days of the year. Case responses must be consistent and comprehensive in both internal and external reporting, and the individuals tasked with implementing the elements of the response should be designated in the policy.

Program Oversight
Implementation of a diversion program is best handled by a multidisciplinary oversight committee chaired by a diversion specialist (see SIDEBAR). Because diversion is a facility-wide problem, the committee should seek representation from pharmacy, nursing, anesthesia, security, risk management, regulatory and accreditation compliance, human resources, infection prevention, laboratory services, and finance, as well as the chief medical officer. Potential ad hoc committee members include environmental services (eg, if sharps container diversion is an issue) and receiving (eg, if theft is suspected before delivery to the pharmacy).

The committee develops and maintains policies, tracks and analyzes data from diversion events, oversees staff education, considers institutional response to new regulations and requirements, and takes final responsibility for external reporting of diversion and process improvement after the fact. The committee also reviews and addresses results of ongoing and focused auditing.

Diversion Response Team
In addition to the oversight committee, it is useful to maintain a diversion response team to review incidents of suspected diversion as they occur. Smaller than the oversight committee, a typical response team consists of the diversion specialist, the manager of the suspected diverter, and representatives from pharmacy and human resources. Others may be added as needed, but it is essential that the response team remains small and comprises individuals who have the flexibility to meet on an urgent basis.

The response team reviews data that may be indicative of diversion, assesses the risk to patients, and decides whether to intervene or wait and monitor the situation. The team may reconvene after the suspected diverter is interviewed to consider the evidence and make decisions about further action.

Law Enforcement Collaboration
The relationship between health care institutions and law enforcement agencies often is perceived as adversarial in cases of diversion; the reality is law enforcement, regulatory agencies, and health care institutions have the same goals regarding diversion—to prevent it from occurring, to minimize patient harm, and resolve the situation as quickly and efficiently as possible. Thus, a cooperative effort is more easily achieved if a collegial relationship is in place before diversion events occur. Members of local law enforcement, the local DEA field office, the board of pharmacy, and state health-related boards most often are open to overtures from health care institutions to establish and maintain lines of communication before any
diversion is discovered. Reporting and subsequent investigation is more streamlined and productive if outside investigators are familiar with the institution’s culture and policies.

**Routine Risk Assessments**

Incorporate diversion risk rounds—unannounced visits to areas where controlled substances are handled and stored—to make note of actual practices regarding drug security and to question staff about their knowledge of, and investment in, diversion prevention. Risk rounds are as necessary as regular auditing of drug transactions, and they facilitate an ongoing assessment of the implementation of diversion-related policies. The diversion specialist, accompanied by one or two other members of the diversion oversight committee, should conduct rounds in an unobtrusive manner. Although the manager of each unit should be notified when the rounding team arrives, he or she should not accompany the committee on the rounds, so as to promote frank dialogue between the rounding team and the unit staff.

Rounds ideally occur quarterly and always should include the pharmacy and as many clinical areas as possible. If resources are limited, high-risk areas, such as procedural and high-acuity units, should take priority. The goal of diversion risk rounds is to improve performance and compliance and ensure educational programs have the desired effect. They are intended to be a cooperative effort between the rounding team and unit staff, and not punitive in nature.

Pay special attention to areas of enhanced risk for diversion: areas in which staff members have the greatest autonomy and in which patient acuity is highest. In the ED, intensive care units, and especially procedural areas, emergent workflow often necessitates decreased security and accountability. In these areas, staff often must withdraw controlled substances well in advance of administration, colleagues often remove or waste medication on each other’s behalf, controlled substance handoffs occur frequently, and rapid transit of patients may require transportation of drugs from one unit to another. Consequently, risk rounds in such areas constitute an opportunity to find ways of complying with policies without compromising patient care.

**Conclusion**

Diversion is more widespread than is commonly recognized, and diverters often are sufficiently sophisticated to avoid detection by common means. As a result, a carefully crafted and comprehensive diversion program is necessary to prevent and detect diversion and promote patient safety and quality of care. No health care institution should be without a program because diversion occurs, sooner or later, at every institution.

The second article in the series will discuss methods of diversion, detection, investigation of suspected diversion, the partnership between pharmacy and nursing, and the response to diversion once it is identified.

**References**

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**SIDEBAR**

**Value of a Diversion Specialist**

A diversion specialist can direct the daily activities of the diversion program. Primary responsibilities include collecting and reviewing relevant drug transaction data from across the institution, as well as addressing suspicious behavior and incident reports that may relate to diversion or impairment. The diversion specialist also serves as a resource to staff, provides education, performs or oversees the regular auditing of controlled substance transactions, convenes the diversion response team, and serves as a liaison to law enforcement and regulatory agencies.