IDENTIFYING DRUG DIVERSION IN THE HOSPITAL

By Kimberly New, BSN, RN, JD

Introduction:
Drug diversion by healthcare providers occurs in facilities across the United States every day. When diversion occurs, patients are placed at substantial risk of harm. Unfortunately, no facility is immune to diversion issues, and incidents are not reflective of the quality of care or patient safety commitment of a facility. High-profile diversion cases in the recent past have caught the attention of federal and state regulatory agencies, and, as a result, legal and regulatory initiatives are gaining momentum. Due to the danger to patients, to institutions, and to those actually diverting drugs, standards are being proposed which would require facilities to address this issue head on and in a uniform manner via “best practices.” This article will detail recent regulatory initiatives and outline fundamental components of a diversion prevention, detection and response program.

Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Identify the principal structural components of a healthcare facility diversion program
2. Describe drug diversion-related policies each healthcare facility should develop
3. Outline patient safety risks associated with drug diversion by healthcare providers

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HISTORY AND CURRENT CLIMATE

Facilities vary greatly in their approach to diversion by clinicians and other staff. Some have formal programs in place to address the issue, while others take a more reactive approach. Some facilities proactively monitor and audit for diversion activity, while others recognize only the most obvious cases. When diversion is detected, some facilities may allow the diverter to resign, while others may pursue arrest and criminal prosecution.

In February 2011, the Minnesota Department of Health was notified of a cluster of cases at a hospital in St. Cloud, MN, in which several patients had blood cultures that were positive for genetically similar strains of *Ochrobactrum anthropi*, a bacterium associated with soil and water, and an uncommon pathogen. An investigation ensued and drug diversion was identified as the cause of the outbreak. Ultimately a nurse pleaded guilty to stealing narcotic pain medication [hydromorphone]. He admitted to tampering with medication bags by removing the narcotic and replacing it with saline. There are no estimates of the number of patients who may have suffered unrelieved pain as a result of this scheme. The report from the Minnesota Department of Health did, however, note that 25 patients were identified as being infected; six of these patients required treatment in an intensive care setting, three underwent surgical intervention due to symptoms from an unidentified source, and one died. The nurse was ultimately sentenced to two years in prison.

In the fall of 2010, a patient underwent a surgical procedure at a Minneapolis, MN, area hospital and later reported that he had suffered extreme pain during the procedure despite the ostensible administration of fentanyl by a nurse. As it turns out, the nurse skimmed the fentanyl intended for the patient for her own use. The nurse was subsequently charged with drug theft, but in the end entered a plea deal in which she was sentenced to three years’ probation for possession. The terms of the arrangement allowed her record to be expunged if she remained compliant with her probation.

In May 2011, the Minnesota Department of Health and the Minnesota Hospital Association, recognizing these and other recent, widely publicized diversion cases in the state, formed a multidisciplinary coalition of stakeholders to address the issue of healthcare provider diversion in medical facilities. At the outset, the coalition noted that there had been a 325 percent increase in the number of reported instances of diversion by healthcare workers in Minnesota between 2006 and 2010. In March 2012, the coalition published a final report, along with a Road Map and various tools designed to give guidance to healthcare facilities as they face this serious issue.

In May 2012, the New Hampshire Health Department was notified of a possible outbreak of Hepatitis C cases at a hospital in Exeter, NH. Ultimately multiple patients were determined to have contracted hepatitis C as the result of diversion activities by an infected medical technician. He had worked across the country as a traveling agency worker, including in the states of Arizona, Georgia, Kansas, Maryland, Michigan, New York, Pennsylvania and New Hampshire. He began working at New Hampshire’s Exeter hospital 10 months after he was diagnosed with...
The medical technician was suspected of stealing fentanyl syringes drawn up for use on patients, injecting himself with the medication, and replacing it with saline or water. Presumably tainted syringes and needles were used on the patients after he had tampered with them. The medical technician was arrested, charged and eventually “pleaded guilty to seven counts of tampering with a consumer product and seven counts of obtaining controlled substances by fraud in New Hampshire’s U.S. District Court.” In December 2013, he was sentenced to 39 years in prison.

In September 2012, the Minnesota Department of Health published an Investigation Summary (Minnesota Report) outlining the outbreak investigation of the first case noted above. The Minnesota Report contained a list of proposed action steps which were meant to assist the hospital that was the subject of the investigation improve its processes. Other hospitals may use these measures as examples of process improvement steps to avoid similar occurrences under their watch.

In March 2013, the Maryland Department of Health and Mental Hygiene released a Public Health Vulnerability Review (Maryland Report) that analyzed the community health risk and factors involved in the medical technician’s diversion in Maryland. The Department examined his employment history within the state and ultimately concluded that his ability to harm patients was the result of multiple gaps and deficiencies in several systems. In its discussion of the risks to patients, as stated in the Report, “The review team recommends that hospitals and healthcare facilities regard drug diversion as a patient safety issue and standardize their prevention and response efforts.” The Report provided in-depth analysis of system deficiencies and responded with valuable recommendations aimed at avoiding a similar issue in the future.

In June 2013, the New Hampshire Health Department released its final report (New Hampshire Report) addressing the public health impact in and around Exeter, NH. The New Hampshire Report proposals mirrored much of what was contained in the Maryland Report, but also provided a perspective that was unique to the New Hampshire case circumstances.

All of the publications referenced above recognize the public health threat to patients and to the community from healthcare provider diversion. These documents acknowledge that the risks are sufficient to warrant mandating that healthcare facilities develop processes to prevent, recognize and appropriately address this type of diversion. The investigative reports each consider what occurred and identify several suggested action steps that are applicable to this discussion.

The Minnesota, Maryland and New Hampshire reports all contain recommendations facilities are urged to adopt. Below are guidelines for the construction of a diversion program.

Table I: Functions of Diversion Program Components

**Diversion Specialist**
- Responsible for daily operations of diversion program
- Maintains a database of diversion related information and suspicious transactions
- Serves as an institutional resource on diversion related issues
- Convenes and leads diversion response team activities
- Plays a role in the interview of suspected diverters
- Ensures that internal and external reporting occurs
- Convenes and leads diversion risk rounds
- Chairs the diversion oversight committee
- Serves as an institutional diversion liaison to law enforcement, regulatory agencies and the community

**Diversion Response Team**
- Responsible for determining when reasonable suspicion exists to suspect diversion
- Meets on short notice whenever diversion is suspected
- Determines whether to monitor a potential diversion situation or intervene and confront the suspected diverter
- Subset of this team is often involved in interviewing a suspected diverter

**Diversion Oversight Committee**
- Multidisciplinary group that oversees the overall direction of the diversion program
- Meets at least quarterly to review policies, standard operating procedures, track diversion related data, address new diversion issues, and direct and oversee performance improvement measures
RECOMMENDATIONS:
Program Structure
A formal program structure is essential for all diversion programs. Having clearly identified components with delineated functions helps to eliminate program gaps and avoid duplication of tasks. In its general conclusions about the investigation, the New Hampshire Report encourages facilities “to construct a comprehensive and multifaceted program with a formalized approach to decrease the opportunities for drug diversion to occur and identify drug diversion incidents early.”

The Maryland Report recommends standardization of diversion processes, including the formation of a diversion team or committee. The New Hampshire Report suggests a coordinated diversion prevention approach, using one or more designated staff members who have a direct reporting relationship to executive leadership.

The recommended diversion program structure is comprised of three principal components, including a diversion specialist, a diversion response team and a diversion oversight committee. Each component plays a critical role. The overall process includes multidisciplinary involvement, which facilitates appropriate division of labor and comprehensive facilitywide input.

ESSENTIAL PROGRAM COMPONENTS
Policies to Prevent Diversion
Pre-Employment Screening
Healthcare facilities must make every effort to prevent diversion, and this duty begins in the hiring process. It is the position of the Drug Enforcement Agency (DEA) that employers should maintain a “comprehensive employee screening program” to identify employment applicants who might pose a controlled substance security risk.

The New Hampshire Report recognizes the need for a robust pre-employment background check process. The Maryland report addresses the lack of regulation of temporary staffing agencies and potential incentives for agencies to limit background inquiries.

Prior to employing any candidate, facilities should undertake a criminal background check, a drug screen with an appropriately broad testing panel, and primary source verification of licensure. Offers of employment should be conditioned on passing a pre-employment drug screen, and candidates should be required to present for drug testing within 48–72 hours of receipt of the provisional offer. Applicants who have a prior history of diversion will often delay appearing for a drug screen so that any remaining drug in their system will be cleared and undetected. Facilities should also inquire into prior issues with controlled substances that have resulted in the candidate being disciplined or allowed to resign. This inquiry is aimed at identifying drug-related issues that wouldn’t necessarily be revealed by other measures.

While facilities don’t play a role in setting regulatory standards for staffing agencies, it is recommend they carefully examine the employee vetting process of any agencies with which they contract. A facility should not engage any agency that isn’t willing to meet the facility’s own pre-employment review standards. Audits of the agency’s vetting process should be undertaken periodically on randomly selected workers who have been placed within the institution.

Facilities should also ensure that if they do have an agency worker that diverts, they report that individual directly to the relevant professional board or registry and to law enforcement, instead of relying on the agency to report.

Medication Handling
One of the most important prevention efforts a healthcare facility can undertake is the development and implementation of strict medication handling policies. While many institutions have policies, they are often relatively ineffective because they lack specificity. Staff members who handle controlled substances should be advised of the detailed requirements with which they must comply. It is recommended that new staff members undergo medication handling education at hire and that they be required to acknowledge their understanding by signature. Drug cabinet training should be a part of this education process, and staff members should be required to have completed the training prior to acquiring access to the cabinet. All relevant staff members should complete education modules annually.

Policies should address:
• How controlled substances will be ordered
• Where controlled substance orders will be received and how incoming shipments will be processed
• How controlled substances will be stored in the pharmacy and in procedural and other patient care areas
• How controlled substances will be transported within the facility
**IDENTIFYING DRUG DIVERSION IN THE HOSPITAL**

- Rules for dispensing, administering, wasting and returning controlled substances, and time frames within which such actions must occur
- Requirements for witnessing of waste and returns
- Application, documentation and wasting of fentanyl patches
- Requirements for documentation of administration of controlled substances
- Expectations regarding resolution of discrepancies in the controlled substance count

Those institutions for whom the Joint Commission’s Medication Management Standards and the Medicare Conditions of Participation are relevant should be aware that developing policies such as these helps ensure compliance with DEA regulations. Each of these entities has detailed medication handling requirements with which facilities must abide.

To reduce opportunities for diversion, access to controlled substances by override (i.e., when there isn’t a recognized order for the medication) must be strictly limited. Controlled and sustained release medications are not generally used in emergent situations; therefore, they should not be available by override. Many institutions do not allow any oral formulations to be obtained by override, and this is certainly the most desirable arrangement, if it is feasible.

Discrepancies in controlled substance counts can often flag a diversion scheme, yet many institutions grapple with constant unresolved discrepancies. Each facility should examine its discrepancy resolution process to be sure it is working as envisioned. Staff members should be educated on how to resolve discrepancies properly and time frames for doing so should be established. Institutions should require that routine discrepancies be resolved prior to the end of the shift. If discrepancies aren’t addressed immediately, institutions risk missing opportunities to perform effective drug screening on one or more staff members, as appropriate. Discrepancies should be handled uniformly across the institution, including in procedural areas. The steps that are required when a discrepancy can’t be resolved should be detailed by policy. Data reflecting unresolved discrepancies should be continuously tracked, and areas that fail to comply with institutional policy should be required to implement a performance improvement plan.

Because waste is a common source for diversion, wasting should be minimized. Cabinet stock should be evaluated regularly and should contain the smallest practical dosage unit for each clinical area. A policy should require staff members to obtain the dose closest to what is ordered for the patient and should require wasting any excess at the time the controlled substance is removed from the cabinet. When wasting at the cabinet doesn’t occur, a policy should mandate that medication packaging only be opened at the patient’s bedside. Institutions should expect that staff members will return rather than waste any doses that are refused by the patient or are not administered for some reason.

Because of the relatively large amount of controlled substance involved and the degree of accessibility, controlled substance drips and infusions warrant special attention. These are most often used in areas where constant supervision is not feasible. In order to reduce the risk of diversion and to detect any diversion quickly, institutions should use locking cases (which are widely available and relatively inexpensive) as well as portless tubing. Documentation of the rate of infusion and amount infused, even in situations in which dosages are titrated, must be performed frequently and any time there is a change in the rate or when a bolus is administered. Quantities present at the beginning of each shift should be reconciled with what was hung and used during the prior shift.
If a patient complains of unrelieved pain or tampering is otherwise suspected, refractometry should be performed to verify that the drug is present in the infusion as expected.

Badge swipe access to areas where controlled substances are handled is the recommended method of access, since most systems are capable of tracking and producing reports on this type of activity. No one should be allowed access to a controlled substance storage area unless they are authorized to administer controlled substances. Stock items that are unrelated to controlled substances should be stored elsewhere to minimize traffic in locked medication rooms. Key pad access to the storage area is an alternative, but it is generally not capable of being tracked. Since an access code can be more easily shared with others, key pads are less secure. If key pad access is used, the code should be unique to each room, should be sufficiently complex to serve the purpose, and should be changed regularly.

Controlled substance security measures and handling processes should be continuously assessed. In all but one of the diversion events that resulted in a hepatitis C outbreak over the past 10 years, the source of infection was an individual without legitimate access to controlled substances. This illustrates why direct observation for gaps in handling processes is essential. It is advised that facilities regularly conduct controlled substance or diversion risk rounds. These rounds, which are similar to what many institutions employ in anticipation of a visit by The Joint Commission, involve visiting areas where controlled substances are stored and handled and observing processes. The participants in the rounds should report any lapses in security or other issues to the manager with responsibility for the area in question, as well as to the diversion oversight committee. The committee may then consider the matter and direct and evaluate performance improvement activities as warranted.

**Procedural Areas**

Procedural areas are high-risk locations for diversion activities, owing to the nature of patient care in these areas. If cabinets cannot feasibly be placed within procedural areas because of cost or space constraints, facilities should make certain their processes are capable of tracking controlled substances accurately and identifying discrepancies promptly.

Policies should limit access to areas where controlled substances are used, particularly procedural areas where controlled substances may be out of the cabinet for a prolonged time. Staff members present in a procedural area should be limited to those assigned to and working in that unit; others should be kept out of the room except with express authorization. If controlled substances are kept out of a cabinet for any period of time prior to use, they should be labeled and locked in a securely mounted lockbox or placed in a locked drawer. Key access to these temporary storage locations should be unique to each box or drawer. Lucite or opaque mounted storage boxes are ideal in this situation, since the contents are readily visible and controlled substances are less prone to be left there at the end of a shift.

Facilities should prohibit controlled substance “hand-offs” in all areas, including procedural areas. Hand-offs, or passing controlled substances from one provider to another, can foster diversion by diluting accountability. Each time a provider is relieved for a break, the controlled substances being used should be wasted and the relief provider should obtain his/her own controlled substances for use on the patient.
Policies to Detect Diversion

Diversion is universal among institutions in the United States; as a consequence, every institution must have policies in place to detect it. Detection efforts should be aimed at quickly identifying, limiting and quantifying diversion events. Investigating and responding to a diversion event are emotionally charged tasks; therefore, policies should be specific and uniformly applied. Policies that will help achieve the necessary objectivity should speak to:

- Surveillance/auditing methods and who has responsibility for undertaking these reviews
- Frequency of data review or auditing, and statistical thresholds that will trigger a more comprehensive review

Institutions should understand that in order for a surveillance/auditing program to be effective, those performing this task must be familiar with common methods of diversion. Some of the most common methods used by diverters include:

- Removal of medication when the patient doesn’t need it
- Removal of medication for a patient that has already been discharged
- Removal of a duplicate dose
- Removal of and diversion from fentanyl patches
- Removal of medication without an order (override)
- Withdrawal from PCA units and drip lines
- Removal under the sign-on of a colleague or when a colleague steps away from the cabinet prior to logging out
- Substituting a non-controlled substance for a controlled substance during administration
- Pilfering patient medications brought from home

As previously mentioned, controlled substance waste is often a preferred source for diversion, therefore staff member audits should look for patterns that maximize the amount of waste to divert including:

- Removal of larger doses than necessary
- Giving less than ordered more frequently
- Failure to waste
- Frequent wasting of entire doses
- Substituting a non-controlled substance for a controlled substance during waste
- Removal of unspent syringes from sharps boxes

Automated dispensing cabinets are often capable of producing data and reports that assist in detecting diversion, but such technology is not required. It is recommend that facilities develop a method of auditing that is economically feasible, attainable and consistent. If automated dispensing cabinets produce reports, ensure that the reports are actually being reviewed. Auditing should include concurrent review of the patient record, as diversion generally cannot be detected without comparison to what is documented in the record.

Many institutions have clinical managers involved in controlled substance auditing and surveillance. This is a valuable process, but having an objective and uniform review of all data by a single reviewer not associated with a specific clinical area is essential. Clinical managers often have a special bond with their staff members. They know the personal stories of those they supervise. These factors make impartiality difficult. The Minnesota report notes that the investigation into...
the St. Cloud diversion event was impeded by personal relationships of staff members with the diverter.\textsuperscript{32} The report recognizes the critical nature of objectivity in diversion investigations and recommends avoiding the use of staff members who are close to the suspected diverter.\textsuperscript{33}

**Policies to Respond to Diversion**

Every institution should have a policy clearly identifying what constitutes reasonable suspicion and how it will be handled. The most critical factor in responding to diversion is the speed with which the response occurs. Patient safety concerns require prompt attention to reasonable suspicion of diversion. Once reasonable suspicion exists, facilities should remove the suspected diverter from patient contact until an investigation can be completed.

Facilities should consider who will be present when the suspected diverter is interviewed about suspicious activity and where this interview will occur. The location of the interview should afford confidentiality and be quiet and conducive to discussion. The interview goes much more smoothly when the group present at this stage is relatively small and is not comprised of peers of the subject of the interview. The individual leading the interview should understand the drug cabinet reports or drug removal data and should be able to discuss it confidently. The tone of the interview should be businesslike and not hostile.

Drug testing methods should be detailed, including who will administer the test, where it will be administered, whether or not it will be observed, how after hours testing will be accomplished, and how a refusal to be tested will be handled. It is highly recommend that institutions require urine drug screens to be observed, as a diverting individual could attempt to use a device to pass a drug screen. Staff members involved in the drug testing process should be familiar with the organization’s standard drug screen panel and understand when it may be necessary to add additional substances to the panel (such as fentanyl).

Institutions need to consider obtaining consent from all suspected diverters for bloodborne pathogen testing. Employee confidentiality can be maintained if this is handled pursuant to a facility’s occupational exposure protocol. Implementing this process may be done by presenting the suspected diverter with a consent form at the time he/she is completing the urine drug screen paperwork. The consent developed should allow the suspected diverter to consent to all, part or none of the proposed blood testing parameters. Regardless of the decision regarding consent, the suspected diverter should be asked to sign the form. This form may later be used to document the facility’s attempt to fully evaluate the potential risk to patients.

It is also recommended that institutions put into practice a process of notifying the local health department each time a diversion case is confirmed. The health department, along with the institutional infection prevention department, can monitor for any potential outbreaks and potentially make a link to the diversion case. This can help limit patient harm by identifying the source quickly.

Institutions should consider what internal reporting will be undertaken when diversion is confirmed. At a minimum, reporting within the organization should include human resources, risk management, compliance, the pharmacy and

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infection prevention. Security should be contacted for badge access termination and be made aware of the identity of anyone who has been suspended or terminated due to a suspected drug-related crime. Once the investigation is complete, reporting to the governing body and chief executive officer (CEO) should occur either through an existing committee or independently.

A flow chart or checklist is very helpful to ensure that important actions are undertaken when diversion is suspected. Key tasks should be listed, such as discontinuation of badge access to the medication storage room and suspension of drug cabinet access (where relevant).

The pharmacy should have a policy on reporting theft, and it should be understood that diversion is theft, not loss. The Maryland report also recommends having a set definition of what constitutes reportable significant loss.34

As with any crime committed in a healthcare facility, reporting to law enforcement should be undertaken. The New Hampshire report states, “Drug diversion is a criminal activity and as such should be reported to law enforcement.”35 Law enforcement can serve as a valuable resource, and they may have investigatory tools available to them that many institutions don’t possess (such as high quality surveillance cameras or undercover officers). Furthermore, police involvement can immediately result in a discoverable arrest record, while professional board action is often protracted. This means that if the diverting individual tries to obtain employment at another facility, subsequent employers will be put on notice.

Collaborative Relationship Among Key Departments

A robust diversion program can be an overwhelming undertaking. As such, responsibility should be shared among several different departments. Many departments have unique and valuable expertise and areas of responsibility. Departments that should have a role include compliance, nursing, human resources, security, risk management, pharmacy, anesthesia and infection prevention. Additional departments may periodically participate as ad hoc members of the diversion oversight committee (e.g., environmental services, when there are issues regarding the diversion of sharps containers).

Collaborative Relationship With Law Enforcement and Regulatory Agencies

Diversion cases require reporting to many different external authorities. At a minimum, reports of diversion should be made to the DEA, the relevant professional board, the state department of health, the state board of pharmacy and local law enforcement.

Reaching out to law enforcement and regulatory authorities before a diversion event can be extremely valuable. These agencies and others will become involved if a facility has a significant diversion case, so establishing relationships beforehand will enable the facility to know whom to contact and how to contact them. Understanding the expectations on both sides in advance of an event will foster a cooperative approach to diversion investigations. Reaching out to law enforcement and other agencies in advance can also provide facilities with an opportunity to discuss public relations concerns. Many law enforcement agencies understand that facilities may be reluctant to report because of concerns about publicity. They will work with healthcare institutions by, for example, wording arrest documents in a generic fashion, so the press is not tipped off that the drug offense involved diversion at a local institution.

The New Hampshire Report states: Maintaining close working relationships between dedicated drug diversion staff and local law enforcement can assist in coordinating activities to investigate drug diversion suspicions even prior to confirmation.36

Comprehensive Education

Staff member education on diversion and impairment is the most important thing any facility can do to ensure diversion is identified quickly. Comprehensive education also puts employees on notice that the facility takes the issue very seriously — a position that may dissuade some potential diverters.
Training should include real case examples and interactive discussions. Modules should be designed to make it clear to staff members why this topic applies to them. Diversion and impairment education should be mandatory prior to any staff member assuming his/her work duties. All staff members should be required to undergo annual training as part of their mandatory modules. Emphasize the need to include all staff members. There are many cases in which a non-clinical employee has identified suspicious activity indicative of diversion. Providing limited training on diversion and impairment for non-clinical department staff members and more extensive training for clinical staff members is recommended.

Department managers should discuss diversion with their staff members regularly. Clinical managers should involve staff members in diversion audits or controlled substance security evaluations within their department. The goal is for staff members to understand that this is an ever present risk and that everyone must be alert.

All staff members should be apprised of the requirement to report concerns and facilities should have a reporting mechanism that affords anonymity. The goal is to develop a culture in which each employee understands the risks and feels he/she has responsibility for reporting.

CONCLUSION:

The New Hampshire report concludes:

Since drug diversion is a real and constant threat in healthcare settings, the approach to prevention and early detection should be one of active planning, implementation, and oversight rather than being reactive to an event.37

Institutional drug diversion entails risks to patients and their families, to institutions, to staff members and to the diverters themselves. No healthcare institution is immune from drug diversion; every institution should have a program to prevent, detect and respond to diversion. The program must include specific policies and procedures, which must be followed consistently and without prejudice. It should also include clear channels of communication among clinical and non-clinical departments, a collaborative relationship with relevant law enforcement agencies, and a comprehensive program for staff member education. A culture that fosters vigilance and open communication by all staff members and administrators is a key to a successful diversion program. The structure of the program should include an individual with appropriate background and expertise to manage the day-to-day operation of the policies and procedures.

References:

2. Ibid.
4. Ibid.
5. Minnesota Department of Health, Infectious Disease Epidemiology, Prevention and Control Division.
8. Ibid.
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