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Outbreaks of infections associated with drug diversion by US healthcare personnel

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Abstract

Objectives—To summarize available information about outbreaks of infections stemming from drug diversion in U.S. healthcare settings and describe recommended protocols and public health actions.

Patients and Methods—We reviewed records at the Centers for Disease Control and Prevention related to outbreaks of infections from drug diversion by healthcare personnel in U.S. healthcare settings from January 1, 2000, through December 31, 2013. Searches of the medical literature published during the same period were also conducted using PubMed. Information compiled included healthcare setting(s), infection type(s), specialty of the implicated professional, implicated medication(s), mechanism(s) of diversion, number of infected patients, number of patients with potential exposure to bloodborne pathogens, and resolution of the investigation.

Results—We identified six outbreaks over a ten year period beginning in 2004; all occurred in hospital settings. Implicated healthcare professionals included three technicians and three nurses; one of whom was a nurse anesthetist. The mechanism by which infections were spread was tampering with injectable controlled substances. Two outbreaks involved tampering with opioids administered via patient-controlled analgesia pumps and resulted in gram-negative bacteremia in 34 patients. The remaining four outbreaks involved tampering with syringes or vials containing fentanyl; hepatitis C virus (HCV) infection was transmitted to 84 patients. In each of these outbreaks the implicated healthcare professional was infected with HCV and served as the source; nearly 30,000 patients were potentially exposed to bloodborne pathogens and targeted for notification advising testing.

Conclusions—These outbreaks revealed gaps in prevention, detection, and response to drug diversion in U.S. healthcare facilities. Drug diversion is best prevented by healthcare facilities having strong narcotics security measures and active monitoring systems. Appropriate response includes assessment of harm to patients, consultation with public health officials when tampering with injectable medication is suspected, and prompt reporting to enforcement agencies.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Background

In May 2012, the New Hampshire Department of Health and Human Services began investigating a cluster of hepatitis C virus (HCV) infections at a single hospital[1]. This investigation uncovered a large HCV outbreak, spanning several years, involving more than a dozen hospitals, and impacting thousands of patients in eight states. This outbreak was caused by an HCV-infected traveling radiology technician who, in August 2013, admitted to having been addicted to narcotics and diverting medications such as fentanyl away from patients[2]. The mechanism of diversion used by the technician involved a form of tampering that exposed patients to his blood. This outbreak has resulted in multiple lawsuits involving the staffing agencies and institutions that employed the technician[3]. This multi-state outbreak and others like it have identified multiple gaps in prevention, detection, and response to drug diversion in U.S. healthcare facilities[4-6].

The National Association of Drug Diversion Investigators defines drug diversion as “any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient. This can include the outright theft of the drugs, or it can take the form of a variety of deceptions such as doctor shopping, forged prescriptions, counterfeit drugs and international smuggling”[7]. Diversion by healthcare personnel represents one facet of drug diversion that is gaining recognition as a ubiquitous and poorly controlled patient safety risk[8]. Mechanisms of diversion by healthcare personnel can include documentation of a medication dose not actually administered to the patient but saved for use by the healthcare professional, theft by scavenging of wasted medication (e.g., removal of residual medication from used syringes), and theft by tampering (e.g., removal of medication from a medication container or syringe and replacement with saline or other similar-appearing solution that may be administered to patients). Patient safety is compromised whenever diversion by healthcare personnel occurs. Harms can include patients not obtaining adequate pain management, exposure to substandard care from an impaired healthcare professional, and exposure to life-threatening infections[8]. However, when diversion is suspected or identified, the potential for patient harm may be overlooked.

In light of the multi-state outbreak of HCV infections identified in New Hampshire, and the gaps it highlighted, we reviewed reported outbreaks of infections resulting from drug diversion by healthcare personnel in U.S. healthcare settings. In this review, we offer a summary of available information about the types of infections, drugs, mechanisms of diversion and healthcare personnel that have been associated with outbreaks stemming from this activity. We conclude with a summary of recommended standard protocols and public health actions which should be considered when diversion by healthcare personnel is suspected or identified.

Methods

The Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC) frequently assists health departments and institutions with investigations of outbreaks involving healthcare exposures, including drug diversion. We reviewed our internal records and CDC-authored reports related to U.S. outbreaks from drug diversion by

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healthcare personnel for the 14-year period extending from January 1, 2000, through December 31, 2013. A PubMed search was conducted for outbreak investigations occurring during the same time period using combinations of key words including outbreak, diversion, and narcotics. We also examined reference lists from selected publications seeking to identify additional outbreaks meeting our inclusion criteria.

For the purposes of this review, an outbreak was defined as a healthcare-associated infection occurring in two or more patients in whom disease transmission likely resulted from drug diversion by healthcare personnel in a U.S. healthcare facility. We excluded outbreaks occurring prior to January 1, 2000, outbreaks occurring in healthcare settings outside the U.S., as well as reports of drug diversion in which no resulting patient infections were documented.

We compiled the following information for each outbreak identified: year investigated, state(s), healthcare setting(s), specialty of the implicated healthcare professional, implicated medication(s), infection type(s), number of patients with documented or suspected infection, mechanism(s) of diversion, and resolution of the investigation. We relied on case definitions developed by investigators for each specific outbreak when enumerating the number of infected patients. Typically, case definitions were based on results of laboratory testing and temporal associations between healthcare exposures and symptom or infection onset among affected patients.

Patient notification, with recommendations for bloodborne pathogen testing, is often performed when healthcare-associated viral hepatitis transmission risks are identified[9]. For outbreaks of HCV infection, we compiled information about the numbers of facilities performing notification and the numbers of potentially exposed patients, using information from media reports and other sources that were available on-line or in our files.

Results

We identified six outbreaks of infections that resulted from drug diversion by healthcare personnel in U.S. healthcare settings in the past 10 years. Two outbreaks resulted in gram-negative bacteremia in 34 patients; the remaining four outbreaks resulted in HCV infection in 84 patients. All of the outbreaks occurred in one or more hospitals; these facilities were located in eight states. Tampering with injectable controlled substances was documented or suspected in all of the outbreaks; fentanyl was diverted in at least four of these events.

Implicated healthcare professionals included three technicians and three nurses (including one certified registered nurse anesthetist); two of the healthcare professionals were female[10,11] Four of the healthcare professionals were documented to be infected with HCV. Of the remaining two healthcare professionals, one was tested in the midst of the outbreak and did not have HBV, HCV, or HIV[12]; bloodborne pathogen testing was either not performed or not reported for the other healthcare professional[10].

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Summary of Bacterial Outbreaks

IL Hospital, 2006[10]: From January 1 through July 15, 2006, 9 medical-surgical patients at an Illinois hospital had development of *Achromobacter xylosoxidans* bacteremia. All of the infected patients received morphine by a patient-controlled analgesia pump (PCA) before bacteremia developed. Having a PCA pump cartridge started by one nurse was statistically significantly associated with becoming a case-patient. This nurse was the only nurse on the unit who worked during the period from hospital admission to before fever onset for all nine cases. Investigators hypothesized that the nurse may have substituted contaminated water for the morphine or used contaminated needles or syringes to extract the morphine from cartridges. The nurse resigned from the hospital upon being informed of the association with *A. xylosoxidans* bacteremia . The state licensing board was informed, but no disciplinary action was taken.

MN Hospital, 2011: Gram-negative bacteremia developed in 25 surgical patients at a Minnesota hospital between October 2010 to March 2011[12,13]. The predominant pathogens identified in blood cultures from infected patients were *Klebsiella oxytoca* and *Ochrobactrum anthropi*. The six infected patients initially identified all received hydromorphone via a PCA. The identification of the same bacteria in two patients' blood and two hydromorphone bags in use by these patients led to concerns about possible drug diversion as the source of the outbreak. A review of automated dispensing logs identified a nurse who had an access rate several times greater than any other staff during the outbreak period. This nurse admitted to tampering with narcotic bags from locked narcotic boxes. The nurse reported peeling back the foil covering on the ports of bags containing drugs such as hydromorphone, withdrawing narcotic with a syringe, replacing displaced liquid with saline solution, and returning the bags to the lock box. *O. anthropi* was found in a saline bottle collected from the nurse's desk. The nurse was removed from practice and, in 2012, pled guilty to obtaining a controlled substance by fraud and was sentenced to two years in prison.

Summary of Hepatitis C Virus Outbreaks

TX Hospital, 2004: Between July and October 2004, 16 surgical patients at a Texas hospital had development of HCV infection[14,15,16](CDC unpublished data, 2004). All 16 patients had received care from an HCV-infected certified-registered nurse anesthetist (CRNA).The two index patients were detected in September 2004 when acute HCV infection was diagnosed following surgical procedures on consecutive days in August 2004. The infected CRNA was identified early in the investigation as a result of healthcare personnel testing that targeted surgical staff who had cared for the first five infected patients identified. The CRNA denied having engaged in diversion activities but was suspended from clinical care duties and was offered treatment for HCV infection. The CRNA left Texas and went on to practice in other states. In 2009, the CRNA admitted to diverting fentanyl by a variety of methods. One of those methods involved removing portions of fentanyl from vials that were designated for an impending patient procedure; a syringe was used to transfer this fentanyl to a vial kept for personal use, which was likely contaminated with the CRNA's blood. Reportedly, the remainder of the fentanyl in the patient vials was then administered to patients using the same syringe that was used to make the transfer. This mechanism of transmission by indirect syringe reuse, involving accessing contaminated vials or containers,

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has been well-documented in other viral hepatitis outbreaks associated with healthcare and injection drug use[17,18]. Epidemiologic and laboratory evidence indicated that the CRNA became infected, sequentially, with two different strains of HCV from chronically infected patients and subsequently transmitted to susceptible patients. The CRNA pled guilty to aggravated assault and possession of a controlled substance by fraud and, in 2009, was sentenced to 41 months in prison.

FL Hospital, 2008: Five interventional radiology patients at a Florida hospital had development of HCV infection[19.20]. The three initially detected patients were identified between January 2007 and December 2008; none were identified because of symptomatic infection. Rather, two were organ transplant patients identified through routine screening conducted as part of facility protocols, and one was identified through evaluation of an unexplained increase in liver enzymes. All had previously negative HCV RNA test results. Through molecular analysis, the HCV isolates from the patients were found to be genetically related, further supporting the likelihood of healthcare-associated transmission. Record review of these three patients, revealed that all had received fentanyl in the interventional radiology (IR) unit of the hospital. Twenty-one employees assigned to the IR area were recorded as being at work when these patients received fentanyl and submitted blood specimens for testing. A radiology technician was found to be infected with an HCV strain that was genetically related to the patient isolates. The technician reported the following methods of diversion: 1) removing syringes containing residual fentanyl from used sharps containers 2) self-administering fentanyl from a syringe that had been filled in anticipation of patient care, refilling the syringe with saline, and returning the syringe to the patient care area. The technician pled guilty to tampering with a consumer product resulting in death, tampering with a consumer product resulting in serious bodily injury, and stealing fentanyl by deception and, in 2012, was sentenced to 30 years in prison.

CO Hospital, 2009: Hepatitis C virus infection developed in 18 surgical patients at a Colorado hospital[11] (Colorado Department of Public Health and Environment (CDPHE) unpublished data, 2010). Two cases of acute HCV infection were initially reported to the health department in April 2009. Both patients denied traditional risk factors for HCV infection but had undergone surgical procedures at the same hospital during their exposure period and shared a common HCV genotype. An HCV-infected surgical technician, who had recently been terminated for suspicion of narcotics diversion, was identified early in the investigation as a possible source of the infections. Following termination from the hospital, the technician had gained employment at an ambulatory surgical center. The technician reported removing pre-drawn syringes of fentanyl from unattended anesthesia carts, self-injecting the fentanyl, refilling the syringes with saline, and returning the syringes to the cart. The technician pled guilty to tampering with a consumer product and obtaining a controlled substance by deception and, in 2010, was sentenced to 30 years in prison.

NH, KS, MD Hospitals, 2012: Forty-five cardiac catheterization/interventional radiology patients from four hospitals in three states had development of HCV infection[1,2,21]. An HCV-infected traveling radiology technician was part of a cluster of HCV-infected patients reported to the health department by a single New Hampshire hospital in May 2012. The technician was suspected as the source of the outbreak on the basis of factors including:

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review of work schedule and key card access, reports of behavior concerning for drug abuse, suspected duration of the outbreak, and results of molecular testing. The technician eventually admitted to stealing syringes filled with narcotics, self-injecting, refilling them with saline, and placing them back into the procedure area. This act had been repeated at multiple hospitals over several years. The technician pled guilty to tampering with a consumer product and obtaining a controlled substance by fraud and, in 2013, was sentenced to 39 years in prison.

Patient Notification and Bloodborne Pathogen Testing

Patient notification and bloodborne pathogen testing was described for the four HCV outbreaks (Table 1)[1,19,22-25] (CDC unpublished data, 2004, 2013; CDPHE unpublished data, 2010). These activities supported case finding efforts as part of the public health investigations. In each of these instances, additional cases of documented HCV transmission, reflected in the total case counts described above, were identified. In total, nearly 30,000 patients were determined to have been potentially exposed and targeted for notifications advising bloodborne pathogen testing. Of note, the number notified may have been less than the number potentially exposed; for example, patients who had died in the interval between the potential exposure and patient notification were not always included in the actual notifications. In three of the outbreaks, because of concerns about previous or ongoing diversion activities, patient notification expanded beyond the facility where the outbreak was detected to include other facilities where the implicated healthcare professional had worked or was working[1,22-25] (CDC unpublished data, 2004, 2014 and CDPHE unpublished data, 2010).

Discussion

Over the past ten years, outbreak investigations have documented more than 100 infections and nearly 30,000 potentially exposed patients, stemming from drug diversion in U.S. healthcare facilities. The frequency with which these events have been detected appears to have increased; using similar methods, we identified three additional U.S. outbreaks of this type in the previous 20 years[26-28]. For HCV, drug diversion has emerged as the leading cause of healthcare transmission between infected healthcare professionals and patients[29]. All of the outbreaks described herein involved diversion of injectable controlled substances, with contamination and infections resulting from some form of tampering by the implicated healthcare professional. A variety of healthcare professionals were implicated in these outbreaks; three of the six were employed as technicians who lacked authorized primary access to the diverted medication. In most of these events, diversion was not suspected or identified by the affected facilities until many patients had become infected. In several cases, implicated healthcare professionals were able to gain subsequent employment at other healthcare facilities, despite evidence or concerns about diversion. As a result, thousands of additional patients were placed at risk.

These outbreaks highlight gaps in the prevention, detection, and response to drug diversion in U.S. healthcare facilities. Under Title 21, CFR Section 1301.71(a) the Drug Enforcement Administration (DEA) “requires that all registrants provide effective controls and

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procedures to guard against theft and diversion of controlled substances"[30]. In their Conditions of Participation for hospitals, the Centers for Medicare & Medicaid Services requires that "drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area"[31]. Injectable schedule II drugs, primarily fentanyl, were implicated in all of the outbreaks included in this review. In three of the outbreaks, technicians were able to access syringes of fentanyl that had been prepared and left unlocked in an operating room or procedure area in anticipation of a patient's procedure. In these instances, healthcare personnel may have believed these fentanyl syringes did not need to be kept in a locked container while they were outside of their immediate possession, perhaps because they considered the area itself to be secure (i.e., access restricted to healthcare personnel). However, in this period of time, the addicted technicians were able to remove the syringes and replace them with decoy syringes (e.g., syringes they had previously used and filled with another clear solution such as saline or water). Of note, unsafe injection practices involving various forms of syringe reuse represent a well-documented mechanism of bloodborne pathogen transmission in U.S. healthcare settings[17].

In addition to adhering to the basic CMS and DEA controlled substance security requirements, strategies founded on technologic advances hold promise in prevention and early detection of diversion. These include tamper-resistant and tamper-evident syringes, automated dispensing cabinets with security features that allow for control and tracking of drug distribution, algorithmic auditing of pharmacy and other dispensing records, and testing to verify the identity or concentration of wasted drugs (i.e., unused drugs that are returned to pharmacy or discarded by healthcare personnel). Several of the outbreaks involved syringe substitutions; tamper-resistant or tamper-evident syringes may have prevented this type of deception (i.e., passing off syringes that had been used for self-injection as unused fentanyl syringes). Of course, simple actions like preparing medications as close as possible to the time of administration and properly labeling pre-drawn syringes to include patient name can also make it more challenging for healthcare personnel to tamper with or swap pre-drawn syringes. During investigation of the Minnesota outbreak, review of access records from an automated medication dispensing system identified a nurse who had an access rate several times greater than that of other staff[12]. Routine review of access records as a component of diversion prevention programs, absent an identified outbreak, may help detect diversion and prevent further harm.

Healthcare facilities need sound policies and systems to address suspected or confirmed diversion activity, in addition to systems addressing primary prevention (Table 2). Although appropriate personnel actions and treatment referrals are important considerations when responding to diversion events, patient harm and risk mitigation should also be prioritized[8]. To prevent further risk to patients at the facility, initial steps include removing the implicated healthcare professional from the clinical environment and revoking any previously authorized access to controlled substances pending further investigation. In addition, the facility should ascertain the specific types of medications diverted and the mechanisms of diversion used by the healthcare professional. If injectable medications were diverted and tampering is suspected, it is highly recommended that the healthcare facility pursue bloodborne pathogen testing of the implicated healthcare professional. The need for

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patient notification is best assessed in consultation with the local or state health department and guided by information gathered about mechanisms of diversion (e.g., was tampering involved?) and results of the implicated healthcare professional's bloodborne pathogen testing[9,32,33]. In addition, other forms of disclosure or reparations may be warranted (e.g., to ensure that patients and their insurance companies were not improperly billed for medications that were never administered)[34,35].

Early engagement of state and federal regulatory bodies (e.g., DEA, Federal Bureau of Narcotics, Food and Drug Administration Office of Criminal Investigations, pharmacy and licensing boards), as well as local law enforcement, is also critical. Such reporting may facilitate better tracking and identification (e.g., via pre-employment background checks) of healthcare personnel who have diverted, with protection of "downstream" facilities. Current systems such as the National Practitioner Data Bank may require enhancements to better address oversight of all healthcare personnel (including technicians or other categories not holding controlled substances registrations) and the timeliness of action taken to investigate or manage reported concerns[4,36]. The multi-state outbreak of HCV infections identified in New Hampshire is the most recent example of a healthcare professional being able to repeatedly gain employment, even after diversion had been strongly suspected or documented by previous employers[4]. The New Hampshire hospital has filed suit against the staffing agencies that employed the implicated technician alleging that their "actions, including failing to report [the technician] for improper conduct, enabled him to secure employment in [New Hampshire]"[37]. Facilities will benefit from ensuring they are aware of state and federal reporting requirements when diversion is identified (e.g., requirement to notify the DEA Field Division Office in their area, in writing, of the "theft or significant loss of any controlled substance" within one business day of the discovery of such loss or theft[38]) and protections offered (immunity statutes) regarding disclosure of adverse information to prospective employers[4].

The outbreaks summarized in this review are likely an underestimate of the burden of infections resulting from diversion in healthcare settings. We did not include outbreaks occurring outside the U.S. that may have been associated with diversion[39-41]. Further, linking healthcare-associated infections to drug diversion, which itself may be difficult to detect, can be incredibly challenging[19,42]. For example, most patients with HCV infection do not experience symptoms of acute disease, and infections may go undetected for years, making it difficult to identify an exposure window or likely source of their infection[19, 43]. For most of the HCV outbreaks reported herein, confirmed case definitions relied upon advanced molecular testing demonstrating genetic relatedness between the virus of the implicated healthcare professional and infected patients. However, many patients had died or had evidence of resolved infection at the time the outbreak was detected and patient notification was performed. Thus, additional patients may have been part of the outbreak but were not included as confirmed cases

In addition to underestimating the burden of infections resulting from diversion, this summary also does not adequately reflect the frequency of diversion by healthcare personnel or other harms resulting from this act[8,36,44]. There are no reliable national estimates of the prevalence of drug diversion activities by healthcare personnel in the U.S. However, one

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useful data point comes from a recent study which examined substance abuse disorders among anesthesiology residents; the prevalence was nearly one percent, with fentanyl and other intravenous opioids accounting for 57 percent of reports[45]. From a state perspective, a task force in Minnesota identified 345 events of theft or loss of controlled substances reported to the DEA during 2005—2011[46]. These numbers only reflected the events that were actually identified and reported, thus representing a lower bound estimate. Nonetheless, 39 percent of the Minnesota events involved intravenous or intramuscular medications; depending on the methods used to divert, some may have posed risks similar to those in the reported outbreaks.

The outbreaks summarized herein demonstrate some of the devastating and wide-reaching impacts of drug diversion in U.S. healthcare settings. Healthcare facilities should ensure patients safely receive medications as prescribed. This effort includes having systems in place to prevent drug diversion as well as developing protocols for early detection and appropriate response if, despite safeguards, diversion does occur. Appropriate response includes assessment of potential for patient harm, including consultation with public health officials when diversion involving tampering with injectable controlled substances is suspected. Prompt reporting to enforcement agencies and applicable licensure/credentialing bodies should be pursued when any form of diversion is identified to help mitigate risks including exposure to potential liability for subsequent actions by the implicated healthcare professional. Actions by state licensing boards and other legal mechanisms may be required to prevent healthcare professinoal with a history of drug diversion from perpetrating similar acts elsewhere.

Conclusion

Outbreaks of HCV and other infections have highlighted the need for system-wide improvements to address the problem of drug diversion in the healthcare community. Basic patient safety includes effective, reliable safeguards to maintain the security of injectable medication in any healthcare setting.

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Table 1

Summary of patient notification efforts for outbreaks of HCV infection associated with diversion of narcotics by HCV-infected healthcare personnel

Year investigated	State(s) that notified patients	Time period for potential exposure	Number of healthcare facilities that notified patients	Number of potentially exposed patients	References
2004	TX, D.C.	2004-2006	3: Hospital where the outbreak was initially identified, hospital where the CRNA worked at the same time as the outbreak hospital, and hospital where the CRNA worked after the outbreak hospital	1,497: 1,135 patients at the outbreak hospital and 362 patients at the 2 additional hospitals	CDC unpublished data, 2004
2008	FL	2004-2010	1: Hospital where the outbreak was initially identified	6,132	19
2009	CO, NY	2007-2009	3: Hospital where the outbreak was initially identified, ASC where the surgical technician worked after the outbreak hospital, and hospital where the technician worked prior to the outbreak hospital	8,770: 4,748 patients at the outbreak hospital, 1,222 patients at the ASC and 2,800 patients at the additional hospital	22, Colorado Department of Public Health and Environment unpublished data, 2010
2012	AZ, GA, KS, MD, MI, NH, NY, PA	2005-2012	16: Hospital where the outbreak was initially identified and 15 hospitals where the radiology technician worked before the outbreak hospital	>12,000 patients: 4,719 patients at the outbreak hospital and more than 7,500[a] patients from the 15 additional hospitals	1,23-25, CDC unpublished data, 2013

[a] Exact number of patients notified at all 15 hospitals not available.

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Table 2

Steps for healthcare facilities to address patient safety when drug diversion is identified

1. Prevent further risk to patients at the facility
   - **a.** Remove the implicated healthcare professional from the clinical environment and revoke any previously authorized access to controlled substances (e.g., suspend computerized access to automated medication dispensing machines) pending further investigation.
   - **b.** Evaluate security of controlled substances to address gaps in adherence to recommended and required practices.
2. Prevent risk to patients at other healthcare facilities
   - **a.** Engage law enforcement.
     - **i.** Local law enforcement
     - **ii.** Drug Enforcement Administration (DEA)
       - **a.** DEA registrants are required to notify the DEA of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft.
     - **iii.** FDA Office of Criminal Investigation, particularly if product tampering, including substitution, is suspected
   - **b.** File report with applicable licensure agencies (e.g., physician or nursing board, state board of pharmacy).
3. Assess retrospective risk to patients
   - **a.** Attempt to ascertain the mechanism(s) of diversion used by the implicated healthcare professional.
     - **i.** Were injectable medications diverted?
     - **ii.** Was any type of tampering with injectable medication performed? If yes, assess potential for patients to be exposed to the healthcare professional's blood (e.g., through swapping with syringes previously used by the healthcare professional)
   - **b.** If tampering with injectable medication is suspected, pursue bloodborne pathogen testing of the implicated healthcare professional.
   - **c.** Use information from steps 3a-b to determine need for patient notification and testing. This should be performed in consultation with the local or state health department.