March 9, 2023 | Volume 28 ■ Issue 5

ISMP
An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Controlled substance drug diversion by healthcare workers as a threat to patient safety—Part II

In **Part I**, we discussed how drug diversion not only endangers healthcare workers diverting drugs, but also causes harm to coworkers, employers, and can otherwise compromise patient safety. We reviewed the widespread scope of diversion in healthcare, commonly involved medications, barriers to recognition, at-risk behaviors, and other signs associated with possible diversion. In accordance with state and federal laws, consider implementing the following recommendations as a proactive approach to prevent, identify, report, and respond to drug diversion:

PREVENT

- Establish a Controlled Substance Diversion Prevention Program that includes an interdisciplinary diversion response committee (e.g., consider including pharmacy, nursing, anesthesia staff, medical staff, security, human resources, compliance, risk management, administration, legal, media/communications, informatics, and employee health). Ideally, a dedicated diversion officer with a thorough knowledge of medication management systems and technologies (e.g., pharmacist, pharmacy technician, nurse), as well as knowledge of regulatory requirements, should oversee the response team and be the subject matter expert when diversion is suspected.[1,2]
- Have members of the team conduct unannounced quarterly diversion risk rounds in the pharmacy and in key patient care units.[3] During rounds, identify and rectify conditions that might allow diversion (e.g., unsecured controlled substances).
- Support a "trust but verify" approach in relation to controlled substance handling. Leaders must recognize that no news is not good news, as many diverters are never caught.[4] A culture of safety must take precedence in relation to controlled substance diversion.
- During orientation and at least annually, educate staff who handle or may be in proximity to controlled substances about the steps that have been implemented to prevent drug diversion, the signs of drug diversion, and how to report and respond to drug diversion.[4,5,6] Emphasize recognition and reporting, the health and safety of the patient and the diverter, as well as other associated professional and criminal implications. Education of staff is an essential component of any diversion program!
- For patients discharged with prescriptions for controlled substances, provide them with information on the signs and risks of substance use disorder and available resources if help is needed. Discuss the importance of storing the medications in a secure location at home and provide resources for the safe disposal of medications, including information about the Drug Enforcement Administration (DEA) National Prescription Drug Take Back Day (www.ismp.org/ext/3).
- Follow the ***ISMP Hierarchy of Effectiveness of Risk-Reduction Strategies*** (www.ismp.org/node/18343) when considering processes and safeguards to prevent drug diversion, using high-leverage strategies such as forcing functions instead of low-leverage strategies such as rules and policies.[1,7] The American Society of Health-System Pharmacists (ASHP) provides recommendations for preventing diversion throughout the entire life cycle of controlled substance medications.[1] Many of these prevention recommendations are summarized below and categorized by nodes of the medication-use process.

continued on page 2 — Drug diversion >

SAFETY brief

Safety mechanism needed for Evenity syringe needle to prevent needlestick injuries! We continue to receive reports of needlestick injuries involving **EVENITY** (romosozumab-aqqg), risking transmission of blood-borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) to healthcare providers and patients. Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or for patients who have failed or are intolerant to other available osteoporosis therapies. The medication, which is manufactured by Amgen, is supplied in a carton containing two prefilled syringes (both syringes are needed to administer the total dose of 210 mg subcutaneously) and is labeled to be administered by a healthcare provider (**Figure 1**).

Figure 1. A dose of Evenity requires the administration of two subcutaneous injections. The manufacturer, Amgen, packages two prefilled syringes in one carton. The syringe needles do not have safety guards, so the potential for needlestick injuries is high.

In a recent report, a nurse in an outpatient infusion setting experienced an accidental needlestick injury when administering a subcutaneous injection of Evenity to a patient. The needles on Evenity syringes lack a safety device; they are not retractable or even removable, so the nurse was unable to change the needle to one that has a safety guard. Other organizations have reported the same concern about accidental needlesticks with this product, which we wrote about in

continued on page 2 — SAFETY brief >

> Drug diversion — continued from page 1

Procurement

- ☐ Prohibit the purchase of controlled substances by those who are not authorized. Ensure that the person ordering controlled substances is not the same person who receives and verifies the order.
- ☐ Use an electronic controlled substance ordering system (CSOS) instead of paper forms (i.e., DEA Form 222) whenever possible.[1] Archive and back up CSOS files on a routine basis.[2]
- ☐ Require two authorized staff members to check in, count, confirm, and promptly secure delivered controlled substance orders.[1]
- ☐ Purchase ready-to-use dosage forms that do not require manipulation or waste. Rather than purchasing a large product size to cover all doses and reduce the number of items to account for, assess usage and purchase the dosage size(s) most appropriate to the patient population served. This reduces waste and eliminates the opportunity for an individual to inadvertently administer too much medication, rather than the patient-specific dose.
- ☐ Avoid purchasing bulk liquid containers for controlled substances, where doses are removed and recorded over time. Instead, if unit doses cannot be obtained through procurement, aliquot the entire amount into unit doses and add to inventory.

Inventory Management

- ☐ Keep a perpetual inventory of controlled substances, maintaining current, accurate records. In the pharmacy, audit controlled substances monthly by rotating two licensed or otherwise authorized personnel (e.g., pharmacy technician). Complete weekly audits in automated dispensing cabinets (ADCs) by two authorized healthcare workers.[1]
- ☐ Use a "blind count" process during receipt, dispensing from the safe or ADC, and during audits, meaning that staff are not aware of the quantity in the inventory system prior to performing the counts.[2]
- ☐ Never allow resolution of a discrepancy to be completed by a single individual.
- ☐ Analyze ADC data, remove stock that is no longer being used from inventory, and reduce periodic automatic replenishment (PAR) levels when indicated.

Storage

- ☐ Store controlled substances in a secure location such as a safe or storage vault in the pharmacy, profiled ADC, or a locked cabinet or drawer.[2] Whenever possible, use individual locked-lidded drug storage compartments for controlled substances. Store refrigerated controlled substances in a locked compartment, including in the pharmacy.[1] Ideally, limit access to authorized staff by using biometric identification, passwords/codes, and badge swipes.[1,5]
- ☐ Ensure unauthorized staff (e.g., staff transferred to work in another unit, terminated staff) do not have access.
- ☐ Develop a process to maintain security when a controlled substance is removed from the safe or storage vault for compounding and ensure the remainder of any multidose vials are returned as soon as possible. In addition, the person removing the medication from the safe should be different from the person who will be compounding/repackaging the controlled substance.
- ☐ Review the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (www.ismp.org/ext/328) for additional ADC storage recommendations.

Prescribing

- ☐ Use electronic prescribing and, whenever possible, avoid the use of paper prescriptions which can be altered.

continued on page 3 — Drug diversion >

>SAFETY brief

continued from page 1

our July 28, 2022, issue (www.ismp.org/node/33241). All of the reports noted the lack of a safety guard as the contributing factor for potential and actual needlestick injuries and recommended that Amgen add one. A few cases indicated nurses needed an initial needlestick exposure laboratory panel and periodic monitoring to detect any presence of the abovementioned viruses.

It should be noted that the Occupational Safety and Health Act (OSHA) of 1970 requires compliance with OSHA standards to institute safety measures in workplaces where there is occupational exposure to blood or other potentially infectious materials. Under the standard, as revised by the *Needlestick Safety and Prevention Act*, employers are required to evaluate, select, and use engineering controls (e.g., sharps with engineered sharps injury protections or needleless systems) to eliminate or minimize exposure to contaminated sharps (www.ismp.org/ext/1104). Technically, if an injectable does not allow the use of an engineering control such as a needle with a safety guard, then the product should not be used in that facility. Using injectables without safety needles when providing patient care puts organizations at risk, especially with products like Evenity that have labeling stating it should be administered by a healthcare provider.

Some people may think an accidental needlestick is a low-risk situation for a healthcare professional—that it won't happen here or won't cause an infection. Although the actual risk of disease transmission may be low, needlestick injuries can still happen and disease transmission certainly can occur and be devastating. Organization protocols detail steps that address needlestick injuries and have an associated cost, take up precious resources, and cause downtime for nurses and other healthcare workers. There is also a need for postexposure prophylaxis for HBV and HIV, along with associated pretreatment laboratory testing (www.ismp.org/ext/1105).

OSHA requires that employers maintain a log of all work-related needlestick injuries where there may be contamination with another person's blood or other potentially

continued on page 3 — SAFETY brief >

> Drug diversion — continued from page 2

- ☐ Build order sets using a multimodal approach to pain management using medications from different drug classes to control pain effectively and promote clinically appropriate opioid use.
- ☐ Default order sentences to the lowest initial starting dose and frequency and automatically link size-appropriate dosage forms.
- ☐ Limit controlled substance discharge prescriptions to durations and quantities based on the indication.

Preparation and Dispensing

- ☐ Build master formulation records for extemporaneous compounding based on the full vial/bottle volume accounting for expected manufacturer overfill.
- ☐ Consider safety controls (e.g., barcode scanning, weight checks, drug photo identification) when using automated pharmacy dispensing technology.[1]
- ☐ Dispense controlled substances in tamper-evident packaging or use tamper-evident tape.
- ☐ Based on data analysis, dispense products in the smallest syringe/bag/cassette/bottle size feasible.
- ☐ Limit the delivery of controlled substances to authorized pharmacy personnel and use barcode verification for dispensing and delivery.
- ☐ To ensure each controlled substance dispensed from the pharmacy safe or vault is accounted for in the ADC, ensure a closed loop restocking process, and reconcile reports in a timely manner.

Administration

- ☐ According to policy, require staff to obtain controlled substances immediately prior to administration, and promptly waste the amount not needed or return all unused medications to a secure one-way return bin (www.ismp.org/ext/328).
- ☐ To prevent patient harm, do not administer controlled substances removed or prepared by another staff member (except when prepared and labeled in the pharmacy or in emergency situations).
- ☐ Avoid unnecessary dilution.
- ☐ Secure controlled substance infusions in hard locked boxes and avoid the use of tubing with ports for all controlled substance infusions.
- ☐ Do not leave a controlled substance infusion unattended once removed from the ADC.
- ☐ Inspect the integrity of controlled substance packaging prior to administration and during patient handoffs.

Returns, Waste, and Disposal

- ☐ Define who can waste controlled substances, how they are wasted, and how to document the drug, dosage form, and amount wasted. When a medication needs to be drawn up, require a witness to validate the remaining volume that needs to be wasted prior to administration.[1]
- ☐ Verify the product label, volume and/or quantity being wasted, and the physical drug if you are wasting or witnessing the wastage to ensure accurate documentation. Ensure both witnesses are physically present and observant at the point of wastage.
- ☐ Provide secure and tamper-evident containers for controlled substance disposal. Ideally, waste containers should render any controlled substance waste inert.
- ☐ Store unused or expired controlled substances in a secure location and schedule their return regularly through your DEA reverse distributor to avoid excessive product buildup.

continued on page 4 — Drug diversion >

>SAFETY brief

continued from page 2

infectious material. As mentioned in our July 28, 2022 issue, ISMP is aware of other marketed prefilled syringe products without needle safety guards. We do know of another product, **LUPRON DEPOT-PED** (leuprolide acetate for depot suspension), that is labeled "must be administered by a healthcare provider" and it has a safety needle (www.ismp.org/ext/1117).

Much of this safety issue could be avoided if all prefilled syringes had engineering controls that protected people, not just healthcare professionals, against needlestick injuries. ISMP has asked the US Food and Drug Administration (FDA) and manufacturers to address this concern with a requirement for a needle with a safety guard on ALL prefilled syringes. We also spoke with Amgen directly about the need for a needle safety guard for Evenity and hope they will consider adding one. It is the right thing to do! Alternatively, companies can make prefilled syringes available without an affixed needle so that a safety needle can be placed on the syringe before use. This would allow conformance with the OSHA requirement and also help protect people against injury from an uncovered needle after administration, or if any of these products happen to make their way into garbage bins or other forms of common waste which may expose children, animals, and others to unintended needlestick injuries.

Your Reports at Work

Heparin cardboard case label to include concentration

An organization recently reported a mix-up in which the wrong concentration of heparin (25,000 units/500 mL versus 1,000 units/500 mL) was stocked in an automated dispensing cabinet (ADC). A pharmacist discovered that the label affixed to the cardboard case of heparin sodium in 0.45% sodium chloride 25,000 units/500 mL (NDC 63323-518-77) by Fresenius Kabi did not list the concentration of the infusion bags (**Figure 1**, page 4).

continued on page 4 — Reports >

> Drug diversion — continued from page 3

IDENTIFY

- Consider the use of cameras with secure recordings in areas where there is a risk for diversion (e.g., procurement, storage, repackaging/compounding areas, medication rooms, outpatient and procedural ADC stations).[1]
- Monitor controlled substance prescribing rates among similar provider groups.
- Audit the medication administration record (MAR) to determine how often patients have been prescribed opioids and do not receive them. Use this data to look for opportunities to reduce inappropriate opioid prescribing.
- Monitor controlled substance access data (e.g., removals, wastes, returns, cancellations, and discrepancies from ADCs) at least monthly for surveillance; consider secure storage of digital files for a designated time period.[1]
- Monitor for excessive restocking of controlled substances.
- Audit controlled substance administration variances across shifts and monitor for increased dose administration that cannot be linked to the patient's condition, or frequent documentation indicating that a patient refused a controlled substance. Complete regular random audits of doses ordered, removed, and administered to look for discrepancies.
- For defined high-risk areas (e.g., perioperative) and/or specific controlled substances (e.g., fenta**NYL**), reconcile the amount obtained (e.g., ADC dispensing reports), the amount recorded on the MAR as given, and the witnessed amount wasted.
- Consider having the pharmacy use a refractometer or other technology to test random injectable waste samples to confirm it is the expected medication.
- For rapid identification of suspected diversion, consider machine learning diversion monitoring and advanced analytics. These programs use consolidated data sets from multiple informatics technology systems (e.g., ADCs, electronic health records [EHRs], time clocks, inventory systems, wholesalers) to reconcile stock movement and waste documentation, compare clinical data (e.g., pain scores) with dispensing patterns, detect when staff are accessing ADCs when they are not scheduled to work, and trend behavior against other users on the same unit. One study found that the use of machine learning had 96.3% accuracy, 95.9% specificity, and 96.6% sensitivity in identifying high-risk diversion transactions and was able to detect diversion an average of 160 days faster than manual investigations.[8]
- Because many drug diversion schemes cannot be detected with data about controlled substance transactions, personal observations may provide the only clue.[3]

REPORT

- Report and manage all discrepancies immediately upon discovery and as per policy.
- Establish a reporting platform to maintain the confidentiality of staff who report concerns about drug diversion and protect them from retaliation.[1,5]
- Once a worker suspects impairment or diversion, require that they report it immediately due to patient safety concerns. Certainty of impairment or drug diversion is not required, just a good faith concern.[3] Ensure policies are in place and proactively partner with human resources so that if an event occurs, a consistent, rapid response can be ensured.

RESPOND

- Investigate and respond immediately to any reported suspicions of diversion and data discrepancies from surveillance or auditing. Establish a standard process for drug diversion investigations for the committee to use.[4] ASHP provides tools that pharmacies can use when developing this process (www.ismp.org/ext/1001, www.ismp.org/ext/1002). Broadly stated, during investigations, the team should verify the data and analyze the situation, conduct an

continued on page 5 — Drug diversion >

Your *Reports* at *Work*

continued from page 3

Another organization reported that they purchased heparin 25,000 units/500 mL manufactured by Fresenius Kabi because their usual product was on backorder. When the product arrived, the pharmacy buyer placed the case in the heparin 1,000 units/500 mL storage area. A pharmacy technician was restocking the 1,000 units/500 mL product on a cart to deliver to a patient care unit and discovered it was the incorrect concentration.

Figure 1. A cardboard case label does not list the heparin concentration (25,000 units/500 mL).

We reached out to the manufacturer to notify them of this event. We are pleased to share that Fresenius Kabi plans to modify the label to include the heparin concentration. We sincerely appreciate organizations continuing to report these important concerns to us so that we can work together to prevent medication errors and patient harm.

Special *Announcements*

Monthly video series on healthcare issues with our affiliate — ECRI

A new monthly video series featuring healthcare insights from experts within ECRI and ISMP premiered January 11, 2023. Each month, ***ECRI Now*** features interviews with representatives from our team who discuss their experiences and perspectives on some of the biggest issues facing healthcare today. In the first episode, ISMP's Michael Gaunt, PharmD, discussed best practices for safe vaccine administration (www.ismp.org/ext/1107). New episodes are posted the first Wednesday of each month. Each episode includes topics of relevance to healthcare leaders and staff across the continuum. These videos are **FREE** to the public and can be viewed by going to: www.now.ecri.org.

continued on page 5 — Special *Announcements* >

Join us in celebrating Patient Safety Awareness Week — March 12-18, 2023

> **Drug diversion** — continued from page 4

initial interview with the worker, interview peers and departmental managers, review pertinent medical records, run and analyze selective reports for an expanded review of the worker's and peers' medication transactions, and review the worker's prior occurrence reports.[3]

- Determine whether drug diversion occurred, or whether the suspicion or discrepancy is an indication that the wrong product was dispensed, which could require prompt attention, and may be caught prior to reaching a patient.[4,5]
- Plan how to respond if diversion is confirmed. Policies should include notification to impacted patients and any necessary modifications to their care plan as well as recommended monitoring.[3]
- Organizations should avoid stigmatizing language around drug addiction (e.g., drug seekers, frequent flyers), and shift the narrative to view and discuss substance use disorder as a chronic illness (www.ismp.org/ext/1091).
- While there may be a need to comply with reporting to relevant state and federal agencies, establish a culture of recovery, not solely punishment, for a healthcare worker who is diverting drugs. Include a process to determine the worker's employment disposition, and provide resources, such as access to employee assistance programs, for staff who may have a substance use disorder.

CONCLUSION

Healthcare practitioners and organizations must do all they can to stop the diversion of controlled substances. Drug diversion not only causes harm to the healthcare workers diverting drugs, but also to coworkers, employers, and patients. Diversion of controlled substances may result in insufficient treatment of pain or anxiety from receiving a substituted or diluted dose, substandard care from impaired healthcare practitioners, and risk of bloodstream infection from compromised vials and syringes. It can also result in increased hospital costs and significant fines to organizations for inadequate safeguards. Negative publicity from failing to implement effective strategies to prevent diversion can lead to compromised public trust in an organization. ISMP urges organizations to consider the above recommendations to help shine a light on diversion and protect patients.

References:

1) Clark J, Fera T, Fortier C, et al. ASHP guidelines on preventing diversion of controlled substances. *Am J Health Syst Pharm.* 2022;79(24):2279-306. www.ismp.org/ext/1120
2) Tribble DA. How big is the drug diversion problem? Nobody knows! BD. December 2, 2019. Accessed October 11, 2022. www.ismp.org/ext/1005
3) New K. Institutional diversion prevention, detection, and response. Presentation at: National Association of Drug Diversion Investigators (NADDI) Tennessee Chapter Meeting; 2013. Accessed December 15, 2022. www.ismp.org/ext/1067
4) Nyhus J. Drug diversion in healthcare. *American Nurse.* 2021;15(5):23-27. Accessed December 13, 2022. www.ismp.org/ext/1058
5) Michalek C, Fortier C, Haumschild R. Prevention of drug diversion in the healthcare setting. Institute for Safe Medication Practices (ISMP) webinar. May 18, 2020. Accessed March 10, 2022. www.ismp.org/node/14862
6) National Association of Drug Diversion Investigators (NADDI). Drug diversion. 2022. Accessed December 19, 2022. www.ismp.org/ext/1059
7) Institute for Safe Medication Practices (ISMP). Education is "predictably disappointing" and should never be relied upon alone to improve safety. *ISMP Medication Safety Alert! Acute Care.* 2020;25(11):1-4.
8) Knight T, May B, Tyson D, McAuley S, Letzkus P, Enright SM. Detecting drug diversion in health-system data using machine learning and advanced analytics. *Am J Health Syst Pharm.* 2022;79(16):1345-54. www.ismp.org/ext/1047

Special Announcements

continued from page 4

FREE drug diversion webinar – Part II

Drug diversion is a serious problem that affects patients' and health professionals' safety. Patients may suffer from suboptimal therapy, substandard care, or be at risk for adverse reactions or infections. Join us on **March 15, 2023**, for ***Part II: Reducing the Risk and Infection Outbreaks from Drug Diversion***, as our speakers present drug diversion from a risk management and an infection control perspective. For details and to register, visit: www.ismp.org/node/61022. If you missed ***Part I: The Pursuit of Prevention—Confronting Drug Diversion***, which was presented on February 15, 2023, you can view the recording at: www.ismp.org/node/61019.

Reminder to take our survey

We would like to learn from those working in acute care hospitals in California and Arkansas about the **Medication Error Reduction Plan (MERP)** that is required in your states and from others around the country about your thoughts on the MERP requirement. If you have not done so already, please take our short survey and submit your responses by **March 23, 2023**. To take the survey, go to: www.ismp.org/ext/1086.

Become an ISMP Fellow

Applications will be accepted until **March 31, 2023**, for our Fellowship programs that will begin in the summer. For a brief description and directions for applying, please visit: www.ismp.org/node/871.

Virtual MSI workshops

Register for our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshop scheduled for **April 13-14, 2023**. For more details about the program and more dates in 2023, please visit: www.ismp.org/node/127.

Editors: Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Shannon Bertagnoli, PharmD; Ann Shastay, MSN, RN, AOCN; Kelley Shultz, MD. ISMP, 5200 Butler Pike, Plymouth Meeting, PA 19462. Email: ismpinfo@ismp.org; Tel: 215-947-7797.