June 2023 | Volume 21 ■ Issue 6

ISMP
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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 compromises patient safety and causes harm to coworkers and employers. We reviewed the widespread scope of diversion in healthcare, medications most likely to be diverted, barriers to recognition, at-risk behaviors, and other signs associated with possible diversion. In accordance with state (e.g., State Board, Department of Health) and federal laws (e.g., Drug Enforcement Agency [DEA], Centers for Medication and Medicaid Services [CMS]), organizations need to 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 providers, 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, controlled substance syringes in staff's pockets).

- Engage senior leadership to support a "trust but verify" approach and shift towards a culture of safety in relation to controlled substance handling. Leaders must recognize that no news is not good news, as many diverters are never caught.[4]

- During orientation and 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. Staff education is an essential component of any diversion program.[3]

- Follow the ***ISMP Hierarchy of Effectiveness of Risk-Reduction Strategies*** (www.ismp.org/node/18998) 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] Another resource from the American Society of Health-System Pharmacists (ASHP) includes guidelines to prevent diversion throughout the medication-use process.[1]

There are several prevention recommendations that can be implemented throughout the medication-use process (from procurement through administration). Below is a summary of the recommendations that primarily involve nursing practices.

Procurement

- ☐ Pharmacy should 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

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SAFETY wires

Death from air embolism after pneumatic tubing was connected to IV line. The US Food and Drug Administration (FDA) recently added a case to their "Examples of Medical Device Misconnections" webpage, about an event in which a pneumatic (air inflation under pressure) tubing line from a noninvasive vascular diagnostic system was erroneously connected to an intravenous (IV) catheter (www.ismp.org/ext/1109). The case was reported to the FDA earlier this year.

An ultrasound exam is a noninvasive vascular diagnostic system that may involve obtaining a blood pressure measurement to assess the arterial blood pressure differences between a patient's arms and legs. However, a vital sign monitor with attached pneumatic tubing to inflate a blood pressure cuff could also be misconnected. As in the case shared by FDA, the pneumatic tubing used to inflate the cuff during the procedure had a Luer connector that was compatible with the patient's IV catheter (**Figure 1**). The connector was erroneously attached to the patient's IV catheter. As a result, air was injected into the IV line and the patient died from an air embolism.

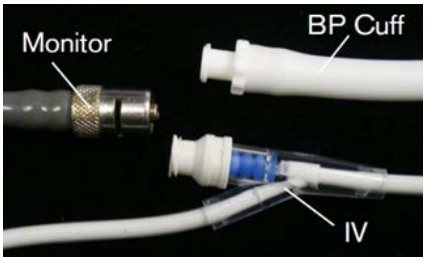

Figure 1. In our May 2004 issue, ISMP showed how blood pressure monitor tubing could connect easily to either the blood pressure (BP) cuff tubing or the Y-site of IV tubing that was being used at the time (changes to the connectors may have been made since then). Note how similar in appearance the IV tubing (with propofol) is to the blood pressure cuff line.

This latest case is similar to others we have written about over the past 20 years. For example, in our acute care newsletter,

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of items to account for, assess usage and purchase the dosage size(s) most appropriate to the patient population served. This reduces the need to waste and eliminates the opportunity for a nurse to inadvertently administer the entire dose rather than the patient-specific dose.

Inventory Management

- ☐ Pharmacy should keep a perpetual inventory of controlled substances, and maintain current, accurate records. Complete weekly audits in automated dispensing cabinets (ADCs) by two authorized healthcare workers.[1]
- ☐ Use a "blind count" process during removal of all controlled substance medications from the 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 at any point in the process to be completed by a single individual.
- ☐ Contact pharmacy if additional resources are needed to investigate a discrepancy.
- ☐ Never share a password to an ADC.

Storage

- ☐ Store controlled substances in a secure location such as a 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.[1] 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.
- ☐ Review the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (www.ismp.org/ext/328) for additional ADC storage recommendations.

Preparation and Dispensing

- ☐ Notify pharmacy if a pharmacy-prepared controlled substance was dispensed without tamper-evident packaging or the use of tamper-evident tape.

Administration

- ☐ According to hospital 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).
- ☐ Policies should define how to administer medications to avoid unnecessary dilution.
- ☐ Secure controlled substance infusions in tamper-evident lock boxes and avoid the use of tubing with ports on all controlled substance infusions (to avoid the unauthorized removal of controlled substances from the infusion line).
- ☐ Do not leave a controlled substance infusion bag unattended once removed from the ADC or the lock box.

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we wrote about tubing from a portable blood pressure monitoring device being inadvertently connected to the patient's IV line, risking, or even causing a fatal air embolism (www.ismp.org/node/65502). A few months later, we wrote about the inadvertent connection of an air supply hose from a sequential compression device (SCD), also referred to as an intermittent pneumatic compression (IPC) device, to a needleless IV tubing port. In that case, the SCD was turned off and the misconnection was found before any patient harm occurred.

The best solution is to eliminate interconnectivity between various medical tubing. Currently, there is an International Organization for Standardization (ISO) standard 80369 that addresses connectors that allow the pneumatic flow of gases via a limb cuff connection (e.g., SCDs, pneumatic tubes to blood pressure cuffs). This ISO standard is the same standard that addresses misconnections by promoting the use of enteral (ENFit), neuraxial (NRFit), and vascular connectors (Luer) to eliminate interconnectivity. The recognized standards have been evaluated by the FDA and manufacturers are encouraged to apply these standards to medical devices, as appropriate.

While connections between pneumatic and vascular systems may be rare, there is no doubt some misconnections are corrected before serious injury occurs and not all incidents (close calls) get reported to the FDA. According to the FDA, misconnections can happen with devices that have not incorporated connector designs conforming to the new standards. Therefore, the FDA encourages providers to report incidents even if the misconnection was corrected before reaching the patient.

In addition, the FDA says they will continue to work with manufacturers, standards organizations, federal partners, professional societies, advocacy groups, patients, and other stakeholders to reduce the chance of medical device misconnections and patient harm. Perhaps FDA could help move this along by developing guidance for industry that more formally requires the use of the

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- ☐ Inspect the integrity of controlled substance packaging prior to administration and controlled substance infusions already infusing during handoffs.

Returns, Waste, and Disposal

- ☐ Policies should define who can waste controlled substances, how they are wasted, and how to document the medication, dosage form, and amount wasted. When a medication needs to be drawn up or partially wasted to achieve the ordered dose, have a second practitioner validate the remaining volume and document the waste prior to administering the medication.[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.
- ☐ Dispose of controlled substances in secure and tamper-evident containers. Ideally, waste containers should render any controlled substance waste inert. Containers should be sealed and discarded before overflowing.

Identify

- ■ Consider the use of cameras with secure recordings in areas where there is a risk for diversion (e.g., medication rooms, outpatient and procedural ADC stations).[1]
- ■ Audit the medication administration record (MAR) to determine how often patients have been prescribed opioids and do not receive them, as well as in the electronic health record (EHR). Consider the use of machine learning diversion monitoring and advanced analytics, to detect diversion.[8]
- ■ Pharmacy should monitor controlled substance access data (e.g., removals, wastes, returns, and cancellations from ADCs) at least monthly for surveillance.[1]
- ■ 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, cardiac catheterization lab) and/or specific controlled substances or diversion-prone medications (e.g., fenta**NYL**, propofol), reconcile amount obtained (e.g., ADC), amount recorded as given on the MAR, and witnessed amount wasted.
- ■ 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 confidentiality of staff who report concerns about drug diversion and protect them from retaliation.[5]
- ■ Once a worker suspects impairment or diversion, require that they report it immediately to their supervisor 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.

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ISO standard when medical devices are being manufactured.

Meanwhile, to protect patients, this is an issue that demands attention. Take the time to work with biomedical engineering to seek out medical equipment that will not connect to vascular systems. When possible, place blood pressure cuffs on a different limb than an IV site and remove IV catheters as soon as they are no longer needed. Appropriately labeled IV lines could help alert staff if they are about to access that line accidentally. Educate staff, including nonclinical staff who work in patient care areas, about this hazard. Before any tubing is connected or reconnected to a patient, verify the access point, and trace the line toward the insertion site/cuff.

While trained licensed practitioners can inadvertently connect the wrong type of tubing to an IV line, especially in a rushed environment or when their view is obstructed, recognize that unlicensed, untrained staff may disconnect or reconnect various tubing, or be inappropriately asked to perform specific tasks such as turning off pumps before patient transport. During orientation, and whenever reiteration is possible, educate unlicensed staff about these risks and to deny requests to connect or disconnect any medical tubing; only trained licensed healthcare professionals should be connecting and disconnecting medical tubing.

SUMAtriptan injection – it's subcutaneous only! **SUMA**triptan injection, indicated for treating migraine and cluster headaches, is administered only as a subcutaneous injection. In a recent case, a prescriber ordered subcutaneous **SUMA**triptan to treat a patient's migraine. A nurse drew up the dose but inadvertently administered it intravenously (IV). The patient experienced flushing without further complications. ISMP previously published (ISMP. Preventing **SUMA**triptan injection wrong route errors. *ISMP Medication Safety Alert! Nurse AdviseERR.* 2018;316[7]:1-2) about similar events. Most errors have occurred while practitioners were administering several IV medications

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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] The team should verify the data and analyze the situation, conduct an 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 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 for how to respond if diversion is confirmed. Policies should include notification to impacted patients, including any necessary modifications in 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 is a need to comply with reporting to relevant state (e.g., Board of Nursing) 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 diverting staff who may have a substance use disorder.

Conclusion

Healthcare practitioners and organizations must do all that 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 a patient's 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 hospitals to consider the above recommendations to help shine a light on diversion and protect patients.

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to patients, but did not notice or forgot that **SUMA**triptan should only be administered subcutaneously. The organization that reported this most recent event has implemented a required field in the electronic health record (EHR) that prompts nurses to document the location of the subcutaneous injection prior to administration.

If pharmacy does not prepare and dispense syringes of **SUMA**triptan as needed, work with them to create a kit that contains the drug vial with an appropriate size syringe and subcutaneous needle (**Figure 1**). Add an auxiliary label to the kit to specify for "subcutaneous use only."

Figure 1. SUMAtriptan kit contains materials for subcutaneous injection, including a subcutaneous needle.

Another option is for the organization to stock the nasal formulation of **SUMA**triptan, which has a similar onset of action. There are also autoinjectors and medication pens available, but these are meant for self-injection by patients at home. Manufacturers should provide subcutaneous medications in prefilled syringes with attached subcutaneous safety needles to facilitate the correct route of administration.

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ISMP Nurse *AdviseERR* (ISSN 1550-6304)

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