ISMP Medication Error Report Analysis

Partially Filled Vials and Syringes in Sharps Containers Are a Key Source of Drugs for Diversion

ISMP Targeted Medication Safety Best Practice #9

Are Patients Who Are Allergic to Antibiotics at Risk for Reactions to Vaccine Ingredients?

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

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PARTIALLY FILLED VIALS AND SYRINGES IN SHARPS CONTAINERS ARE A KEY SOURCE OF DRUGS FOR DIVERSION

A 36-year-old hospital care aide (nursing assistant) who had been diverting discarded drugs died after self-administering what she likely thought was an opioid but was actually a neuromuscular blocking agent.¹⁻³ The aide found an unlabeled syringe containing a clear solution in a biohazard box, injected the solution, and suffered immediate paralysis, respiratory arrest, and then death. This incident happened in Vancouver, Canada, but it should serve as a wake-up call to all US hospitals to take the necessary steps

to detect and prevent the theft and abuse of hospital medications.

The Story

According to news reports,¹⁻³ the aide, Kerri O'Keefe, had worked in the emergency department (ED) for about 15 years. By all accounts, she loved her job and was extremely well liked and respected by her colleagues. She had a long history of drug and alcohol dependence and had been placed on leave twice before, but she was allowed to return to work after stints in rehab. However, she concealed the breadth and depth of her addiction from her family and her colleagues and friends at work. When Kerri

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did not show up for a planned family event, her mother went to her apartment and found her daughter dead and her apartment littered with an arsenal of used syringes, vials, needles, and tourniquets. Many of the syringes included patients' names and dates. Investigators also found stolen urine samples from patients in the refrigerator, which presumably Kerri used if she was asked to provide a urine sample for drug testing.

The hospital had numerous physical controls in place to prevent unauthorized access to controlled substances in automated dispensing cabinets (ADCs), locked cabinets, and pharmacy vaults. The hospital also required periodic counts of controlled substances and documentation when they were removed from storage locations. Kerri was able to gain access to drugs despite the existing safeguards, because she stole discarded syringes, vials, and patches that contained leftover drugs from biohazard boxes. Most boxes were attached to the outside of locked cabinets but could be removed easily.

Based on the drug supplies found in her apartment, it appears that Kerri would collect a stockpile of medications, especially leftover morphine and fentanyl, and then secretly inject the medications at home. It appears that she also self-injected drugs in unlabeled syringes, perhaps hoping the drug was an opioid; on the day of her death, the drug was rocuronium. The unused syringe containing the neuromuscular blocking agent had been discarded in a biohazard box after a planned intubation in the ED was cancelled. According to investigators, the aide had been stealing entire biohazard boxes or emptying the boxes into a backpack or small suitcase on wheels that she routinely took to work.¹⁻³ Despite security cameras, her actions were not discovered prior to her death. Based on news reports, Kerri's death occurred around the time that she was due to take another leave of absence to attend a third round of rehab for her addictions.

Alarming Statistics

Drug overdoses are the leading cause of accidental death in the United States. Opioid addiction is driving this epidemic,⁴ with more than 18,893 overdose deaths in 2014. Of the 21.5 million Americans 12 years or older who had a substance use disorder in 2014, 1.9 million abused prescription pain relievers; far fewer were abusing heroin.⁵ The latest data from the US Substance Abuse and Mental Health Services Administration showed that about 1 in every 10 health professionals is struggling with addiction

or abusing drugs not prescribed for them.⁶ Very few health care workers who are diverting and abusing drugs are caught, often despite clear signs in physical appearance, thoughts and behavior, and performance. The American Nurses Association reports that about 10% of nurses are thought to be abusing drugs and may be caring for patients while impaired.⁷ These incidence rates mirror the general population. Health care workers are not at higher risk of drug abuse than the general population, but the overall pattern of drug abuse and dependency with health care professionals is unique.⁸

Unique Dependency Pattern

Studies have shown disproportionate misuse of prescription drugs by health care professionals when compared to street drugs, primarily because they can access prescription medications easily and often.⁹ Another pattern with health care workers is that drug abuse tendencies arise based on the drugs readily available to the worker.¹⁰ In addition to personal or family stress, dealing with patient illness, harm, death, an unpredictable work pace, heavy work demands, and long hours can make stress alleviation through drug use an attractive and convenient coping mechanism for health care providers.^{10,11} These stresses have led many health care workers to use tobacco and alcohol as a way to relax and unwind after work. But reliance on these legal but addictive substances can be a "slippery slope" leading to prescription drug abuse and subsequent addiction.¹⁰ Some health care professionals have a misconception that their knowledge of the drug will help them "control" its use,¹¹ but for many it is a very short step from misuse to dependence.

Risks to Patients and Workers

Drug diversion and abuse puts patients at risk for suboptimal treatment from diluted or substituted medications, serious infections caused by contaminated needles and syringes, and errors committed by health professionals who are working while impaired. The toll can also be brutal for the impaired health care worker who is abusing prescription drugs.¹² Many health care workers feel guilt and despair, suffer physical and mental health issues, and may be indifferent to the risk of death from an overdose.

The systems for preventing and detecting drug diversion and dealing with workers who are battling a prescription drug dependency are clearly insufficient given the current scope of the problem. Inadequate monitoring systems and lax controls leading

to diversion also result in significant fines levied by the government.¹³ The real challenge is to strike a balance between recognizing addiction as a disease and taking steps to prevent patient and employee harm. Without getting into the controversies about whether to apply a “crime and punishment” model of accountability for drug abusers or remove the stigma of drug abuse so practitioners who need treatment will seek it, the following recommendations can help in the long journey to reduce drug diversion and abuse.

Awareness and Recognition of the Problem

Expect diversion. Given that one in 10 health care workers will abuse drugs, take all the necessary steps to prevent and detect it. No news is not good news when it comes to drug diversion and abuse.

Observe for signs of impairment and diversion. Educate all health care workers to recognize diversion and a drug-impaired coworker. Here are some signs and symptoms:

Changes in behavior¹¹

- Increasing isolation from coworkers and social avoidance at work
- Frequent illness, accidents, emergencies, tardiness
- Complaints from others about poor work performance
- Moody, depressed, irritable, suicidal threats
- Frequent trips to the bathroom, locker room, unexplained absences, long lunches
- Illogical or sloppy charting

Physical signs^{10,11}

- Shakiness, tremors, slurred speech, sweating, unkempt appearance
- Wearing long-sleeve clothing even in warm environments

Signs of diversion

- Frequent incorrect controlled substance counts
- Large or inconsistent amounts of wasted narcotics
- Discrepancies between patient-reported pain and pain medication administration
- Increase in the amount of drugs needed on the unit or in the pharmacy

Report suspicions. Establish an organizational expectation to report suspected drug diversion and worker impairment via a confidential process (eg, hotline).

Educate about resources. Routinely provide staff education regarding the resources available if diversion is suspected or a practitioner wants to seek treatment for addiction.

Drug Security and Chain of Custody

Secure controlled substances at all times:

- Before leaving the medication preparation area, secure vials containing leftover controlled substances yet to be discarded. Walking away to administer a dose or attend to a pharmacy task without securing the vial can invite diversion.
- Prohibit drawing more than a single dose of a controlled substance into a syringe; saving partial doses in syringes exposes the drug to possible diversion.
- Remove controlled substances from an ADC close to the time they are needed for a procedure or for administration. Avoid removing a drug “just in case” it is needed.
- Secure all controlled substance infusions in locked infusion pumps and require a witness to observe the waste once the infusion is removed from the pump.
- Secure the patient’s home medications immediately after collection.
- Secure controlled substances in the operating room, procedural areas, and anesthesia work areas during and between surgical cases.

Manage inventory. Require staff to verify dispensing and receipt of controlled substances. In areas without ADC storage, the person delivering and the person receiving controlled substances should cosign on the appropriate record, and the drugs should be immediately secured. When using an ADC for dispensing and storage of controlled substances, activities should be tracked and reconciled using data available in the vault software.

Use the correct containers. Know the federal, state, tribal, and local laws regarding pharmaceutical waste of controlled substances, hazardous waste, and sharps, and choose the most appropriate and secure containers for safe disposal.

Secure and track sharps/pharmaceutical waste containers:

- In patient care areas, use sharps/pharmaceutical waste containers with small openings that do not easily allow medication devices or waste to be shaken out. Some pharmaceutical waste containers (eg, Cactus Smart Sink) render narcotics unrecoverable, non-retrievable, and unusable.
- When a larger sharps/pharmaceutical waste container must be used (eg, OR, procedural areas), utilize video cameras and regularly observe the monitors.

- Lock sharps/pharmaceutical waste containers to the wall or secure to other stationary equipment that cannot be easily removed from a clinical unit. Secure all keys to replace a container, and limit access to just a few designated staff (or an external company that may collect and replace the containers). Establish a process to track and reconcile all containers to ensure detection of unauthorized removal (some containers have barcodes). Restrict access to the stock of empty back-up containers.
- Place containers in areas where they can be consistently observed or monitored by a video surveillance system. If a container must be removed from a secure wall unit or its usual location because it is full, establish a secure holding area while awaiting proper pick-up for disposal.

Restrict access to controlled substances:

- Establish strict guidelines regarding who can have access to controlled substances in ADCs, pharmacy vaults, treatment kits, and areas where expired drugs are stored.
- Adjust par levels of controlled substances in the pharmacy (including satellites) and on patient care units based on use rates so excess supplies are not available.
- Place each type of controlled substance (including opioid infusions) in ADCs in a separate lidded compartment or area so access is granted only to the intended drug.
- Allow access to medications in clinical areas for current patients on that unit only.
- Limit who can add new patient profiles to the ADC software.

Reduce waste. Provide controlled substances in dose sizes that eliminate or minimize waste (eg, provide a 2 or 5 mg syringe of morphine instead of a 10 or 15 mg syringe).

Monitor prescription pads. Establish a process to secure, track, and reconcile all prescription pads used for controlled substances in patient care units.

Allow no bags. Do not allow purses, backpacks, briefcases, or other personal storage cases in areas where controlled substances are stored or discarded.

Safe Drug Disposal

While following all applicable federal, state, tribal, and local laws and regulations regarding the disposal of controlled substances, consider the following recommendations:

Remaining controlled substance left in a single-use vial.

With a witness present, draw the remaining medication into a syringe, require the witness to verify the volume in the syringe, and then squirt the medication into a pharmaceutical waste box while the witness watches. Do not discard the vial in the sharps box before removing and wasting any leftover medication from the vial. Document the volume and dose of the pharmaceutical wastage, which should be verified and cosigned by the witness. (Note: Squirting a controlled substance into the sink or toilet may not be an option in some states or be safe for the environment. Squirting a controlled substance into a sharps box may not be permitted by the container company or the waste management company that disposes of the sharps containers.)

Extra or remaining controlled substance in a prefilled syringe. Require a witness to verify the volume in a prefilled syringe, then squirt the medication into the pharmaceutical waste box while the witness watches. Do not discard the syringe in the sharps box before removing and wasting any leftover medication. Document the volume and dose of the pharmaceutical wastage, which should be verified and cosigned by the witness.

Unused or expired controlled substance. Return the container of unused inventory to the pharmacy for disposal using a process that verifies delivery and receipt.

Fentanyl transdermal patches. Current manufacturer and US Food and Drug Administration (FDA) guidelines direct users to fold the patch in half with the sticky sides together, and then flush the patch down the toilet. If flushing the patch is not an option, a device that deactivates any remaining drug in the patch should be used prior to disposal. Deactivation and disposal should be documented by a second witness.

Selected high-alert medications. For selected high-alert medications (eg, neuromuscular blocking agents, concentrated electrolytes), follow the same disposal procedures used for controlled substances, although it may not be necessary to witness waste.

Inventory disposal. Establish a witnessed process for disposal of controlled substance inventory in the pharmacy by a pharmacist or by an authorized third party.

Monitoring

Implement monitoring systems:

- Allocate sufficient human resources for an interprofessional team to develop and oversee a controlled substance management and prevention

program. Activities should include ensuring proper documentation, conducting periodic documentation reviews and routine inventory counts, investigating all reports of potential diversion or an impaired worker and unreconciled counts or discrepancies, viewing footage of monitoring, and conducting observations of practices with controlled substances.

- Use recording surveillance cameras in high-risk areas where diversion might take place (eg, narcotic vault, IV room, ADCs) and review the monitors or footage regularly.
- Use software to monitor controlled substance movement in ADCs (eg, Pandora) and pharmacy narcotic vaults (eg, NarcStation, CIISafe).

Periodic documentation review. Establish a system for reviewing the documentation and use of controlled substances, paying particular attention to the following:

- Comparing removal of a controlled substance from an ADC or other storage location to the medication administration record
- Comparing the time of removing a controlled substance to the time of dispensing or administering the drug (delays could signal diversion)
- Comparing pain medication administration time to patient reported pain scales
- Documented pain medication administered to an unconscious patient
- Pain scores much higher when a particular staff member is on duty
- Frequent ADC overrides by a practitioner to gain access to controlled substances
- Irregular usage reports from ADCs and narcotic vaults.

Observe staff. Regularly observe how staff manage controlled substances, including wasting drugs and other security processes. Also observe staff for at-risk behaviors such as badge sharing or unsecured drugs, and coach them to exhibit the desired behaviors.

Investigate immediately. Start an investigation as soon as it is learned that the count of controlled substances does not reconcile with documentation. The investigation should be completed before any staff member on the unit or in the pharmacy leaves the hospital.

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ISMP TARGETED MEDICATION SAFETY

BEST PRACTICE #9

It's critically important to prepare for a serious adverse reaction when administering drugs with a high potential to cause such reactions or when a toxic dose may be inadvertently administered. That's why we have included Best Practice #9 in the new *2016-2017 Targeted Medication Safety Best Practices*

for Hospitals (TMSBPs). Learn more about this best practice at www.ismp.org/sc?id=1659.

As noted in the rationale for this best practice, we've received reports of preventable deaths and serious harm due to a delay in administering an appropriate antidote, reversal agent, or rescue agent (eg, epinephrine for anaphylaxis). These agents must be readily available and, in certain situations, stored in areas where high-risk medications are administered.

We hope your hospital is following through to ensure staff is prepared for these adverse events. One hospital system has coupled rescue/reversal agent orders with their standard order sets so that nurses have appropriate orders available to rescue patients should it be necessary.

Including orders for antidotes, rescue agents, or reversal agents allows a nurse to remove one of these drugs after pharmacy has verified its appropriateness and prevents delays or errors caused by not knowing dosing/administration information. For example, in the hospital system just mentioned, order sets for opioids include a standard set of PRN naloxone orders. All insulin order sets have a hypoglycemia protocol available with associated medication orders. They've also embedded orders for the treatment of anaphylactic reactions (ie, epinephrine, steroids) into order sets for medications that have a high incidence of infusion reactions (eg, rituximab).

ARE PATIENTS WHO ARE ALLERGIC TO ANTIBIOTICS AT RISK FOR REACTIONS TO VACCINE INGREDIENTS?

Several vaccines contain small amounts of antibiotics such as neomycin, streptomycin, polymyxin B,

and gentamicin. They are added to help prevent contamination of the vaccine during manufacturing. For example, the influenza vaccines *Flumist* and *Fluarix* contain small amounts of gentamicin. Still, the antibiotics most likely to cause severe allergic reactions (eg, penicillin, cephalosporins, and sulfa drugs) are not contained in vaccines. Also, only minute quantities of the antibiotics remain in the final vaccination products.

According to a referenced website (www.ismp.org/sc?id=1657) maintained by The Children's Hospital of Philadelphia (CHOP), these small quantities have never been clearly found to cause severe allergic reactions. CHOP says that the possibility of severe allergic reactions caused by the trace quantities remains, at best, theoretical. The website lists the vaccines that contain antibiotics along with the quantities. Not all vaccines have antibiotics, so if there is a concern, you may be able to use an alternate brand.

Another issue is that package inserts often mention contraindications to "vaccine components," but an alert may not appear when an influenza vaccine that contains an antibiotic is selected from a computer listing. We asked a major drug information vendor about this, and the company said that an allergy alert will occur only in a patient with a documented aminoglycoside allergy who is prescribed an influenza vaccine with an NDC that is associated with an ingredient set that contains trace amounts of an aminoglycoside. Regardless of an alert, the risk of an allergic reaction is probably minimal. ■