

ISMP Canada Safety Bulletin

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Unauthorized Access to Methadone in a Community Pharmacy Contributes to Death

- *Ensure that methadone preparation and storage areas are always supervised by pharmacy staff, with no opportunity for unauthorized patient access.*
- *Store methadone in a secure manner, out of public view.*
- *Reconcile narcotic inventory more often than every 6 months, and conduct daily inventory counts and reconciliation for frequently dispensed controlled substances, such as methadone.*
- *Educate staff to recognize an individual experiencing a mental health crisis and empower them to follow up their concerns with the patient and relevant health care providers.*
- *Ensure accessibility to an emergency preparedness protocol to guide staff in circumstances such as an opioid overdose and/or a patient presenting with suicidal ideation.*

Methadone, a full opioid agonist, is most frequently used as an evidence-based pharmacotherapy for individuals living with an opioid use disorder. Methadone has a narrow therapeutic index and an inappropriate dose can lead to serious harm.^{1,2} As part of an ongoing collaboration with a provincial death

investigation service, ISMP Canada received a report describing the death of an individual who ingested a large amount of methadone that had been inappropriately accessed in a community pharmacy. This bulletin highlights the contributing factors identified in the incident analysis and suggests strategies to improve methadone security in community pharmacies.

INCIDENT DESCRIPTION

A patient was receiving buprenorphine-naloxone (available as Suboxone or a generic) from his regular community pharmacy for opioid use disorder treatment. On the day of the incident, the patient jumped over the dispensary counter into the unattended staff-only area, took a bottle containing methadone, and began drinking the methadone liquid directly from the container. Pharmacy staff immediately called police and emergency medical services (EMS) and attempted to stop the patient from drinking more methadone.

During transport to the hospital, the patient was alert and conversing with paramedics. Once at the hospital, the patient's condition began to deteriorate rapidly. Despite intubation, administration of naloxone, and other interventions, the patient died the next day because of multi-organ failure due to acute methadone toxicity.

CONTRIBUTING FACTORS

Many factors were identified as having contributed to this incident and the resultant harm; those most relevant to community pharmacy practice are described below.

Storage and Dispensing of Methadone

According to the *Narcotic Control Regulations* of the federal *Controlled Drugs and Substances Act*, “a pharmacist shall take all reasonable steps that are necessary to protect narcotics on his premises or under his control against loss or theft”.³ Although the regulations do not specify the exact procedures or policies to be undertaken by a pharmacy, provincial and territorial colleges of pharmacy have developed a variety of resources to support their members in complying with this provision.⁴⁻⁷

In the incident described above, methadone storage, preparation, and dispensing occurred in an alcove off to the side of the pharmacy’s main dispensary. This alcove had a private entrance for patients and was visible in the main dispensary by means of mirrors and security cameras. The methadone containers were physically secured to a shelf at the back of the alcove behind a half-wall barrier, which was used as the service counter.

A few weeks before the incident, the patient had made a comment to the pharmacist indicating possible suicidal ideation. This patient (and others) had also “joked” about self-serving their methadone doses, because the methadone container was stored on a shelf within the dispensary that was easily viewed by anyone standing outside the dispensary counter. Although pharmacy staff had taken some reasonable steps to secure the methadone stock, the comments made by this patient and others indicated that the storage area was perceived as accessible to the public. In hindsight, these comments represented a missed opportunity for pharmacy staff to store methadone more safely, in an area out of public view.

Commercially available 10 mg/mL oral liquid is the format most often used to prepare doses for patients who are receiving methadone opioid agonist treatment. Methadose, a product commonly stocked

in pharmacies that dispense methadone, is supplied in 1-litre⁸ opaque plastic bottles; a clear vertical strip down one side of the bottle, with gradation markings, provides a view of the volume remaining in the bottle (Figure 1). Best practice guidelines for the dispensing of methadone require the use of a device that measures volume as accurately as possible.⁹ One commonly-used device is a dispensing pipette, which can be attached to the mouth of the bottle (Figure 2). Pharmacies that dispense methadone usually do not remove the dispensing pipette from the bottle after each patient’s dose is measured, and the bottle-pipette combination may be left on the dispensing counter for extended periods. Furthermore, with the pipette attached, the height of the bottle-pipette combination (Figure 2) may exceed the space available inside a narcotics cabinet, leading to safe-storage challenges.

Figure 1:

Clear strip with gradation marks on a 1-litre bottle of Methadose, showing the volume of solution remaining.



Figure 2:

Methadose 1-litre container with a pipette dispensing device attached.



With the pipette device attached, the lightweight plastic bottle may be top-heavy, especially when the bottle is nearly empty, and there is a risk it will topple over. To prevent this instability, the pharmacy involved in the incident described had combined and repackaged methadone from multiple opened bottles into a 4-litre amber glass bottle. Pharmacies that frequently dispense methadone may combine the contents of several small containers into a single large one to avoid the need for frequent recalibration of the measurement device. Storage of the large container within view of patients may have contributed to the observation that a large quantity of drug was accessible.

Inventory Management

Community pharmacists are required to conduct a complete reconciliation, including a physical count, of their inventory of controlled substances (i.e., narcotics, controlled drugs, and targeted substances) at least every 6 months although some jurisdictions require the reconciliation to be done more frequently.^{10,11} Daily counts of frequently dispensed narcotics can facilitate the reconciliation process and support a rigorous and thorough inventory management system. If methadone has been transferred from containers with gradation marks into larger containers lacking these marks, accurate inventory counts and reconciliation are more difficult. In the incident described above, the quantity of methadone in the container accessed by the patient was unknown, as there had been no recent inventory count or reconciliation. As a result, the pharmacist could not quickly relay to the paramedics an estimate of the quantity of methadone ingested.

Recognition of Mental Health Concerns

Pharmacists are expected to regularly perform complete patient assessments, including mental health status, to gather relevant information needed to provide optimal care. The patient involved in the incident described above had previously made a comment to the pharmacist indicating possible suicidal ideation. Documentation, follow-up communication with the patient and contact with the prescriber about this comment might have

prompted a more in-depth mental health assessment and subsequent intervention.

Emergency Preparedness

Pharmacies should have a protocol to train and support staff in responding to a patient expressing suicidal ideation as well managing an opioid overdose. In the incident described above, pharmacy staff called 9-1-1 to request help from police and EMS, and both arrived onsite within minutes. It is unknown whether the pharmacy had a defined emergency protocol, including administration of naloxone, for management of a patient experiencing a possible opioid overdose.

RECOMMENDATIONS

Pharmacy Teams Practising in Community Pharmacies that Dispense Methadone

Review the Preparation, Storage, Security, and Inventory Management of Controlled Substances

- Ensure that methadone storage and preparation areas are always locked and supervised by pharmacy staff, with no opportunity for unauthorized patient access. If possible, patients should not have a direct view of the process when stock containers are retrieved from or returned to storage.
- Avoid transferring commercially available methadone products into another bulk-storage container.
- Calibrate and routinely clean commercial methadone dispensing devices according to manufacturers' recommendations, to minimize the risk of inaccurate dose measurements and poor inventory control.
- Reconcile the narcotic inventory more often than every 6 months.¹¹ To facilitate the reconciliation process, consider keeping a daily dispensing log for methadone liquid and conducting daily counts for other frequently dispensed (high-volume) narcotics.
- Install secure storage cabinets that are configured to accommodate upright storage of methadone containers with the dispensing device attached.

Collaborate with Other Practitioners

- Communicate with other practitioners in the patient's circle of care when concerns arise regarding the patient's well-being.
- Document all interactions with other health care providers in a timely manner.

Prepare for Emergency Situations

- Educate staff to recognize patients who might be experiencing a mental health crisis.^{12,13}
- Ensure that policies and protocols are readily available to and understood by staff members, to support them in responding to emergency situations such as patients expressing suicidal ideation, and about how to recognize when a patient is exhibiting signs and symptoms of opioid overdose.
- Document concerns identified by pharmacy staff on the methadone dosing log sheet to facilitate follow-up and referral for intervention if necessary.
- Inform pharmacy team members about where naloxone and/or naloxone kits are stored within the dispensary. Train them on the administration of naloxone should a patient need it prior to the arrival of medical assistance.
- Assist paramedics and hospital staff in opioid overdose management by advising them of critical information such as the estimated amount of opioid ingested and the approximate time it was taken (if known) as well as details about the pharmacology of the medication (e.g., methadone has a delayed onset and long duration of action). Providing the pharmacist's contact information can help facilitate this process.

Manufacturers of Commercially Available Methadone Solutions

- Consider including a dose-dispensing device together with each bottle of methadone (to be attached to the mouth of the bottle, once it is opened) that does not add height or cause the bottle to become unstable and fall over once attached. Glass bottles are heavier than plastic and may be more suitable for large volumes.

Pharmacy Regulatory Authorities

- Develop guidelines or direct regulated pharmacy staff to resources that outline best practice protocols for responding to an emergency situation (e.g., assessment and support for patients expressing suicidal ideation or suspected of experiencing an opioid overdose) and the immediate steps to be taken while awaiting medical assistance.

CONCLUSION

Pharmacy staff who work in community pharmacies that dispense methadone should regularly assess the layout of dispensing areas and implement appropriate safeguards to minimize the risk of loss or theft of this high-alert medication. Previously published bulletins and newsletters describe key medication management considerations to further optimize the management of methadone.^{1,14-21} This bulletin highlights several strategies that pharmacies can implement to improve the safe storage and security of their methadone inventory and suggests a proactive approach to prepare pharmacy staff who may be faced with an emergency situation, such as a patient experiencing an opioid overdose.

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This segment of the bulletin describes a recent SafeMedicationUse.ca publication from ISMP Canada's Consumer Program.

January 2020 - Newsletter:

Who Keeps the Box? Are Your Prescriptions Properly Labelled?

SafeMedicationUse.ca received several reports describing prescription labels that were placed only on the outer box of a medication, without a label on the product contained inside. In one case, a consumer reported that her child's liquid antibiotic was supplied in a bottle with no pharmacy label. The label had been placed on the outer box, but the box had been discarded in the pharmacy, before the medication was given to the parent.

In other cases, the outer box, with a label, was given to the patient but was thrown away when the consumer got home. As a result, the patient did not have important information about how to properly use the medication.



Tips for Practitioners

The containers for some medication formulations, such as topical products, oral solutions, and inhalers, can be difficult to label. As a result, pharmacy staff may be tempted to label only the outer box and not the interior container from which the medication will be administered. Whenever possible, it is important to label the inner container as well.

- When filling a prescription for which the outer box will be dispensed to the patient, affix 1 prescription label to the inner container (e.g., tube, bottle, inhaler) and another label to the outer box. It is recognized that this approach is not always feasible for products such as sachets or blister-packaged tablets. For these items, advise patients to keep the outer box or container.
- During product verification, open every box to confirm that the product inside is appropriately labelled. Consider whether dispensing the outer box provides any additional value to the patient.
- Use the prescription pick-up interaction for both new and repeat prescriptions as an additional opportunity for verification. Show the medication to the patient, highlighting the information on the label. Open every box in front of the patient, to provide final confirmation that the product inside is appropriately labelled.

For more information, read the full consumer newsletter:

<https://safemedicationuse.ca/newsletter/labels.html>



The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.



The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.



The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

Online: www.ismp-canada.org/err_index.htm

Phone: 1-866-544-7672

ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

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Contact Us

Email: cmirps@ismpcanada.ca

Phone: 1-866-544-7672

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