

ISMP Canada Safety Bulletin

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Lack of Standardized Documentation Contributes to a Mix-up between Methadone and Buprenorphine-Naloxone

- Standardize documentation templates for opioid agonist treatment to include the medication name, dose, and unit of measure.
- Implement independent double-check processes for dispensing methadone and buprenorphine-naloxone. Use more than 1 record to verify the medication name and dose to be dispensed.
- Ensure that doses of opioid agonists are recorded in **milligrams (mg)** and that entries for buprenorphine-naloxone include the amount of each component, to help clearly differentiate doses of the combination product from doses of methadone.

Opioid use disorder is one of the most challenging forms of addiction facing the Canadian healthcare system; almost 4000 Canadians lost their lives to an opioid-related overdose in 2017.^{1,2} The ability to treat opioid use disorder using opioid agonist treatment with methadone or, more recently, buprenorphine-naloxone (brand name Suboxone), has played an integral role in addressing Canada's Opioid Crisis.³ In 2018, the recommended medication for first-line treatment of opioid use disorder was changed from methadone to buprenorphine-naloxone, because of the latter's superior safety profile.¹ Also in 2018,

restrictions related to the prescribing of methadone were eased, in a measure intended to facilitate the prescribing and dispensing of this medication when buprenorphine-naloxone is not the preferred option.⁴ This bulletin shares a report of a medication incident in which nonstandardized documentation of opioid agonist treatment led to preventable harm.

INCIDENT DESCRIPTION

A patient presented to the pharmacy to receive the prescribed daily dose of opioid agonist. The pharmacist on duty, who worked relief shifts at several community pharmacies, was unfamiliar with the methadone and buprenorphine-naloxone dispensing procedures at this pharmacy and was not aware that procedures were not standardized between pharmacies. The relief pharmacist checked only the medication administration log in the patient's file, which did not specify the name of the medication that had been dispensed previously (i.e., methadone or buprenorphine-naloxone). Instead, the entry for the last observed dose read simply "8", without specifying either the unit of measure or the dosage form. As a result, 8 mL (80 mg) of liquid methadone was inadvertently dispensed, whereas the patient should have received buprenorphine 8 mg / naloxone 2 mg. The pharmacist requested and received verbal confirmation from the patient that the expected medication was methadone, and then gave 8 mL (80 mg) to the patient. Immediately after ingesting

the methadone, the patient realized that it was not the correct medication, and the pharmacist directed the patient to the emergency department for monitoring. Fortunately, the patient did not experience serious adverse effects and was able to resume buprenorphine 8 mg / naloxone 2 mg therapy without interruption.

BACKGROUND

Buprenorphine is a partial opioid agonist that is indicated for the treatment of opioid use disorder,⁵ and as an analgesic for the treatment of severe pain for which alternative treatment options are inadequate.^{6,7} Naloxone is an opioid antagonist that is used to reverse the effects caused by an opioid.⁸ As indicated above, the combination product (buprenorphine-naloxone; available as a tablet for sublingual administration) is now recommended as the first-line opioid agonist treatment for adults with opioid use disorder.¹ An advantage of the 2-drug combination, in addition to its more favourable safety profile, is the deterrence of drug diversion: if the medication is injected instead of being taken sublingually, the naloxone will reverse the opioid effects of the buprenorphine.⁹ Buprenorphine-naloxone is available in multiple fixed-ratio strengths (e.g., 2 mg / 0.5 mg; 8 mg / 2 mg); however, prescribers and pharmacists often refer only to the strength of the buprenorphine component of the combination product (e.g., “8” rather than “8 mg / 2 mg”).

Methadone in liquid form, diluted in Tang or juice, is an opioid agonist used in the treatment of opioid use disorder. Because methadone is a full opioid agonist with a narrow therapeutic index, treatment with this medication is complicated and requires frequent patient monitoring during dose initiation and titration.¹⁰

DISCUSSION

In the case described above, multiple factors contributed to the medication error, including:

- A relief pharmacist who was not familiar with the methadone and buprenorphine-naloxone dispensing and documentation protocols at the pharmacy failed to check the original prescription.

Instead, the pharmacist checked only the medication administration log, which did not specify the medication that the patient was to receive.

- The pharmacy had not implemented an independent double-check process for the provision of opioid agonist treatment.
- The pharmacist asked a closed-ended question to confirm what the patient was expecting to receive (i.e., “Are you expecting methadone?”), which might have contributed to confirmation bias on the part of both the pharmacist and the patient.
- The dose entry for the combination product was abbreviated to indicate only the amount of the buprenorphine component, not the naloxone component, resulting in incomplete information in the dose field of the administration log.
- The unit of measure for buprenorphine-naloxone was not stated in the dose administration log, which led to confirmation bias. As a result, the number “8” recorded in the administration log was interpreted as a volumetric dose (i.e., 8 mL), which in turn led to the assumption that the required medication was methadone, since only methadone is available as a liquid.

Methadone and buprenorphine are regulated federally by Health Canada. Regulatory authorities in each province and territory have imposed additional mandatory training, standards, and guidelines regarding the provision of these medications. Although the general description of the processes to be followed are the same, there is no uniform standard for the specific documentation or procedures (e.g., dispensing protocols) required for pharmacies and clinics within each province and territory.¹¹ This variability in practice is especially challenging for relief pharmacists who work at multiple pharmacies.

With the exception of “carry” or take-home doses of methadone or buprenorphine-naloxone, the pharmacist is required to directly observe the patient ingesting the medication as a deterrent to diversion and to ensure that the entire dose has been taken. The pharmacist is also required to document the patient's name, medication dose, and the date, time, and place of the observed administration. Despite these common best-practice requirements, each jurisdictional guideline provides a different template

for dose administration documentation (or “logs”), with variation in the document title, required information, and format. A review of these template logs showed that log titles did not consistently include the medication name(s), and many of the templates did not require specification of dosing units. Two examples of more complete templates are included from the Centre for Addiction and Mental Health (Figure 1)¹² and of the opioid use disorder treatment guidelines of the Alberta College of Pharmacy (Figure 2).¹³ Both logs include the name of

the medication, 2 patient identifiers, a staff identifier, the date of administration, the dose ingested, and the number of “carries” (if any) to be supplied. The log from the Centre for Addiction and Mental Health also includes the prescription number, and the dose ingested specifies the unit of measure in milligrams. The log from the Alberta College of Pharmacy also includes the time of administration, and although not specified, the dose ingested is intended to be captured with the unit of measure.

Figure 1: Sample medication administration log for methadone and buprenorphine-naloxone. Reproduced, with permission, from Opioid Agonist Maintenance Treatment: A Pharmacist’s Guide to Methadone and Buprenorphine for Opioid Use Disorders, published by the Centre for Addiction and Mental Health.¹²

Special notes:

Patient Name: _____ DOB: _____ Health Card #: _____

Sheet #: _____ Medication: _____

RX#	DATE	DAY	OBSERVED QUANTITY	CARRY QUANTITY	TOTAL DAILY DOSE (MG)	DISPENSED BY/ TIME	COMMENTS

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Figure 2: Sample medication administration log for methadone and buprenorphine-naloxone. Reproduced, with permission, from Medication-Assisted Treatment for Opioid Dependence: Guidelines for Pharmacists and Pharmacy Technicians, published by the Alberta College of Pharmacy.¹³

Patient record of drug administration

Staff name (please print)	Initials (for file)	Staff name (please print)	Initials (for file)	Special instructions

Date	Time of ingestion	Drug (Methadone or Suboxone)	Dose ingested	Witnessed by (initials)	# of carries	Date carry received	Patient signature	Notes (# of carry bottles returned)

RECOMMENDATIONS

Pharmacy Regulatory Authorities

- Provide standardized documentation templates for opioid agonist treatment, for use in all pharmacies and clinics within the province or territory. Ensure that these templates include the medication name, the dose, and the unit of measure.
 - The unit of measure for any medication entered on the form should be milligrams (mg). For methadone, the dose can be expressed in both milligrams and millilitres (mL); this minimizes the need for the pharmacy team to recalculate the volume each time the medication is dispensed.
 - Dose entries for the buprenorphine-naloxone combination product should specify the strength of each component.
- Actively promote the use of the standardized documentation, beyond offering guidelines, examples, or options.

Pharmacy Managers

- Wherever possible, modify the pharmacy management software to display the methadone dose in milligrams (with or without the volume in millilitres) for consistency between the patient's profile, printed prescription label, and standardized documentation for opioid agonist treatment.
- To minimize the risk of confusion, clearly differentiate methadone and buprenorphine-naloxone logs and store these records separately.
- Ensure that all pharmacy team members (full-time, part-time, and relief) are appropriately trained in the pharmacy's dispensing processes for methadone and buprenorphine-naloxone. A copy of these protocols should be readily accessible to all team members.
- Implement independent double-check processes for dispensing methadone and buprenorphine-naloxone. Checks should include a review of the patient's profile and the original prescription (which needs to be readily retrievable and viewable), and verification of the measured amount, before the medication is provided to the patient. In situations where pharmacists work alone, the patient could be actively involved in this process to serve as an independent double check.

Pharmacists

- When dispensing a refill for methadone or buprenorphine-naloxone, check the patient's profile to identify the medication required and ensure that the medication is still appropriate for the patient. Do not rely solely on the administration log to determine the medication to be dispensed, nor its appropriateness.
- When dispensing methadone or buprenorphine-naloxone, conduct an independent double check with another pharmacy staff member or the patient, when possible. Such a process is important for high-alert medications like methadone, which have a heightened risk for harm if dosed incorrectly.
- Using open-ended questions, ask the patient to state the expected medication and dose (e.g., "What is the name of your medication?" "What dose are you on?"). Repeat the medication name and dose back to the patient for confirmation before providing the medication and witnessing its ingestion.
- Advise patients to keep their most recent medication receipt handy (e.g., in a wallet), to provide an additional verification record. The patient can also sign the documentation to confirm the dosing details.

CONCLUSIONS

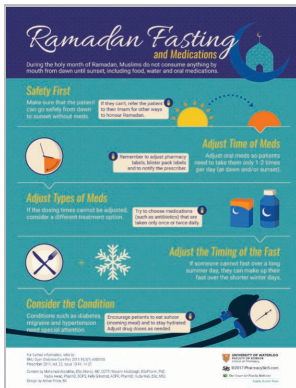
Methadone and buprenorphine-naloxone are important treatment options for opioid use disorder. Standardized protocols for prescription intake, processing, dispensing, administration, and documentation are valuable and can help to reduce the risk of errors. Pharmacy regulatory authorities can support safe dispensing practices by actively promoting a standardized documentation template that captures essential and legislated medication information. Incorporation of this template into the local workflow by the pharmacy team, along with independent double checks and relevant training of all pharmacy staff, will further the safety of these medications as a critical aspect of opioid agonist treatment.

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Supporting Safe Medication Use during Periods of Fasting

Patients fast for many different reasons, including religious observances. This year, from May 5 to June 4, adults who observe Ramadan will not eat or take any oral medications between dawn and sunset. As a result, medication administration times will need adjustment to avoid putting patients' health at risk. [Pharmacy5in5](#), an online learning tool to help pharmacists stay up to date with pharmacy practice, includes resources for supporting patients in managing their medications during the fasting period.

More information about managing medications during Ramadan is available at the [Pharmacy5in5](#) website or from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5415064/pdf/10.1177_1715163517700840.pdf

Figure used with permission from [Pharmacy5in5.ca](#)



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.



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Report Medication Incidents

(Including near misses)

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

Phone: 1-866-544-7672

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