

ISMP Canada Safety Bulletin

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Oral Opioid Agonist Therapy: A Multi-Incident Analysis of Reports from Community Pharmacies

Opioid agonist therapy (OAT) is the first-line pharmacological treatment for individuals with moderate to severe opioid use disorder.¹ Buprenorphine/naloxone, methadone, and slow-release oral morphine (24-hour formulation) are the oral OAT options available in Canada.¹ All of these medications are considered to be high-alert products. Methadone has previously been identified as a leading cause of harm among medication incidents reported in the community pharmacy setting over a recent 5-year period.² Injectable OAT products are also now available, and learning will be shared as their use is monitored. This safety bulletin describes an analysis of incidents involving oral OAT reported by community pharmacies and presents strategies to prevent harm.

METHODOLOGY

Medication incidents associated with OAT in the community pharmacy setting were extracted from the National Incident Data Repository for Community Pharmacies (NIDR)* for the 3-year period between April 1, 2020, to March 31, 2023. Search criteria included the generic and brand names for buprenorphine/naloxone and methadone, as well as the brand name Kadian to capture slow-release oral morphine (the only 24-hour oral formulation marketed in Canada).

Reports were excluded if they described indications other than opioid use disorder such as pain management, or if the incident description was unclear or absent. The multi-incident analysis was conducted according to the methodology outlined in the Canadian Incident Analysis Framework.³

QUANTITATIVE FINDINGS

A total of 1261 medication incidents were extracted and screened for inclusion. After applying the exclusion criteria, 1169 incidents remained for the final analysis. Figure 1 shows the proportion of incidents by type of OAT medication. For some added perspective, Methadose (methadone) was the second most frequently dispensed medication in Canada in 2022, after Synthroid {levothyroxine}.⁴ Most of the incidents (92%) were reported as near misses or as resulting in no harm. Mild to severe harm to patients was reported in the other 8% of reports (Figure 2). All moderate to severe harm cases involved methadone. These findings align with a recognition that relative to other treatment options methadone poses an increased risk of harm from overdose.^{5,6} Previous Safety Bulletins also describe risks of error with methadone.^{2,7-10}

QUALITATIVE ANALYSIS

Three main themes and associated subthemes were identified in the multi-incident analysis (Figure 3).

* It is recognized that it is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems.

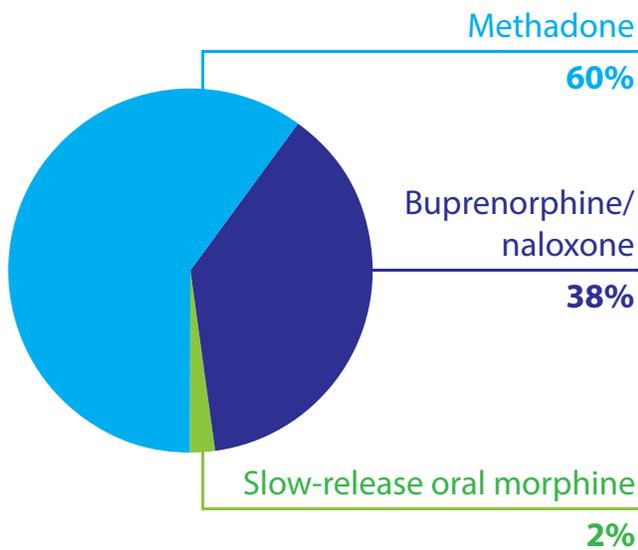


FIGURE 1. Proportion of incidents reported for each oral opioid agonist therapy medication.

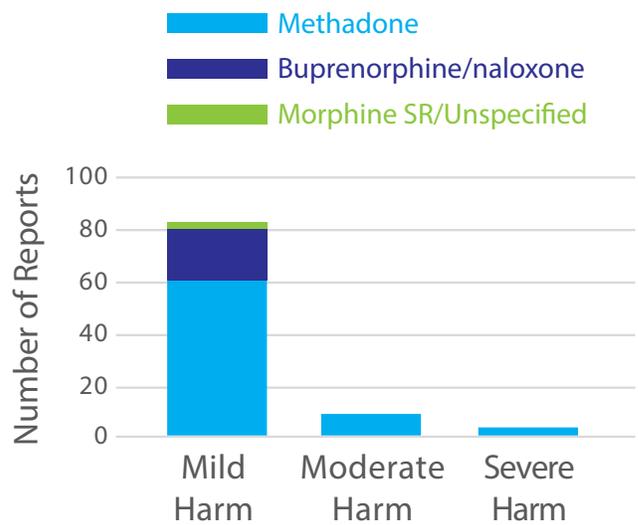


FIGURE 2. Distribution of harm incident reports by opioid agonist therapy medication (note some reports cited more than one OAT medication).

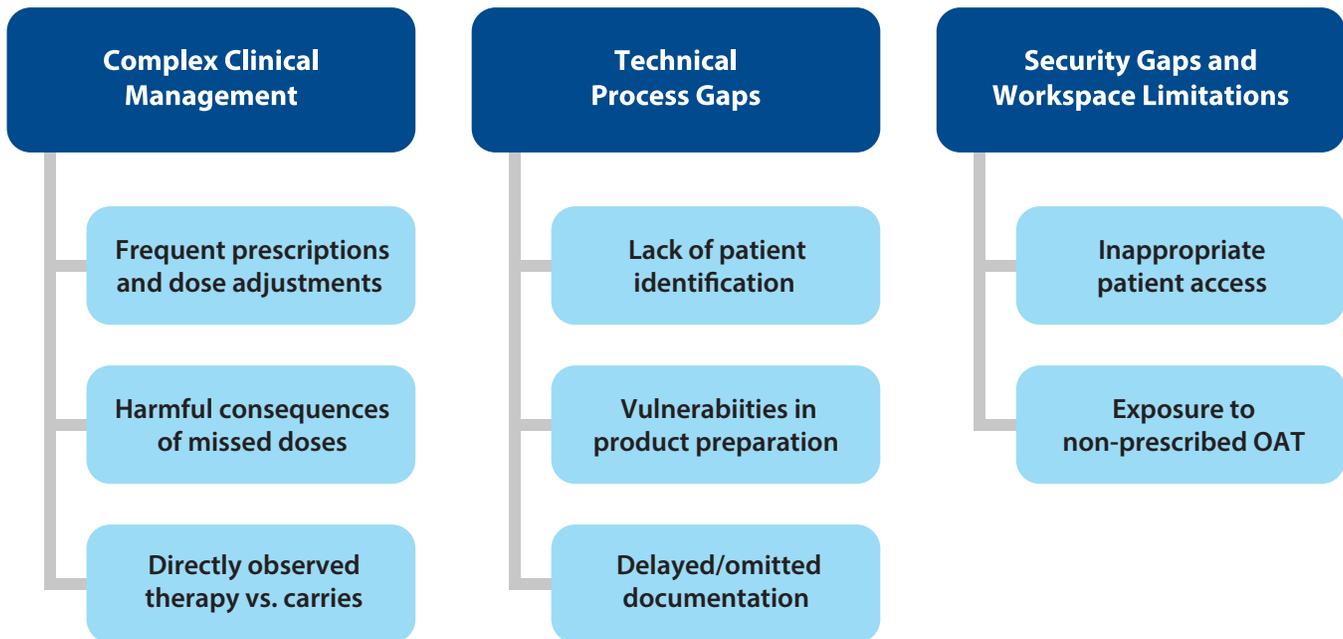


FIGURE 3. Themes and subthemes identified in the multi-incident analysis of reports pertaining to opioid agonist therapy (OAT).

THEME: Complex Clinical Management

Frequent Prescriptions and Dose Adjustments

The use of medications to treat opioid use disorder involves close monitoring and frequent dose changes in each of the treatment phases (induction, titration and stabilization, maintenance), as well as during dose tapering.¹ Dosing errors and missed doses can cause harm, including symptoms of toxicity or withdrawal.

Contributing factors identified in this subtheme included a lack of up-to-date patient medication profiles, a lack of provider communication with the patient related to the need for frequent dose changes,¹¹ and using the “copy” function to collect details from previous prescriptions without making specified changes.⁷

Incident Example: *A patient’s medication was being switched from methadone to slow-release oral morphine with concurrent weekly tapering (methadone dose decreases) and titration (morphine dose increases). On the day of the incident, the prescriptions for both medications were filled with an incorrect dose for that day because of misinterpretation of the regimen. The errors were recognized later when staff double checked the dispensing software and administration log.*



TIP: Use 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 opioid agonist therapy and witnessing its ingestion.¹²

TIP: Do not use the “copy” function during order entry for OAT because each prescription involves a change in one or more information fields, including the start and stop dates. Ensure inactivation of previous prescriptions.

TIP: Enter the complete titration/tapering schedule into the pharmacy software system upon receiving the prescription, including the start/end dates and the corresponding doses. Do not leave future schedules to be entered at a later time, as this can lead to missed/wrong doses.

Harmful Consequences of Missed Doses

Even a few missed OAT doses can lead to withdrawal effects and loss of tolerance to opioids.¹ In these cases, a lower dose may be required upon restarting the opioid to minimize risk of overdose. Documentation and communication of missed doses and subsequent clinical management are time sensitive. The key contributing factors in these incidents were an underappreciation of the importance of documenting missed doses, missed follow-up with prescribers, and knowledge gaps about how best to care for patients when doses are missed.



TIP: Create a checklist to support pharmacists in documenting and addressing missed doses of OAT. This checklist should include expectations for documentation in the patient’s profile and medication administration log, templates for communication with prescribers, and a readily accessible clinical resource to support practice.

TIP: Check the medication administration log to confirm the previous directly observed dose before providing the next OAT dose.

Directly Observed Therapy versus Carries

Upon initiating OAT, directly observed therapy is often provided as part of patient care. Once the patient’s condition has been stabilized, take-home doses (commonly called “carries”) are provided to support continuity of care. A key factor contributing to errors identified within this subtheme was a misunderstanding of prescription details that resulted in an incorrect number of doses being dispensed for both directly observed therapy and carries.



TIP: Post a sample OAT prescription highlighting key areas for checks where errors can potentially occur. For example, start and stop dates, strength/dose, directly observed doses vs. carries.

THEME: Technical Process Gaps

Lack of Patient Identification

In many incidents, a patient's identity was assumed but not confirmed with 2 identifiers, resulting in a different patient's OAT dose being selected. Contributing factors included confirmation bias relating to the patient's identity and similarity of patients' names on labels, as well as environmental distractions.



TIP: At pickup, confirm the patient's identity with 2 identifiers, as is the process for any medication. The name and date of birth are preferred identifiers. To support rigorous identity checks as a part of dispensing protocols, consider scanning the patient's photo ID into their profile and attaching the ID with their OAT administration log, or use dispensing technology with fingerprint identification.¹²

TIP: Before dispensing a dose of OAT medication, confirm the previous day's documented dose with the dispensing record and ask the patient what dose they are expecting to receive today.

TIP: Remove pre-prepared doses of methadone from the pick-up area when patients do not come for their doses; this prevents staff from inadvertently providing the dose to another patient. Follow a standardized process to dispose of the dose(s) or re-integrate back to inventory if allowed by provincial requirements.

Vulnerabilities in Product Preparation

During preparation of the OAT medication, a systematic process is needed to ensure accuracy of the dispensed product. Examples of reported errors at this step included wrong medication, wrong dose, and wrong quantity. Factors that contributed to these errors included a lack of independent double checks (e.g., for calculations) and workflow interruptions.

Incident Example: *The pharmacist prepared a patient's methadone dose the day before (without adding juice). The next day, the pharmacy technician noted that the volume of methadone seemed very low. The pharmacist had prepared a partial dose of methadone and was interrupted before the remaining portion of the final dose could be added.*



TIP: Conduct independent double checks to ensure correct product selection, dose calculation, and dose measurement for OAT medications.

TIP: Always work on one patient's OAT prescription at a time, and follow through to completion, to reduce the risk of errors due to interruptions.

TIP: Ensure all pre-prepared doses are correctly labelled, before storing.

Delayed/Omitted Documentation

OAT requires additional documentation (e.g., for missed doses and communication with prescribers) relative to other prescription medications. This subtheme describes incidents that could have been prevented or mitigated through enhanced documentation.

Often, pharmacies keep separate records for OAT documentation, which include the patient's photo identification, treatment agreement (if used), and a medication administration/dispensing log. A previous safety bulletin titled [Lack of Standardized Documentation Contributes to a Mix-Up between Methadone and Buprenorphine-Naloxone](#) provides examples of standardized administration logs.⁸



TIP: Ensure the pharmacy’s OAT dispensing policies and procedures include documentation practices for directly observed OAT doses in the medication administration log. For example, review log BEFORE dispensing medication and document in log immediately after observed ingestion or dispensing of carries. At the end of day, document “MISSED” if there is a missed dose.

TIP: Document prescription changes in the medication administration log with clear communication for dose INCREASES and dose DECREASES. Consider attaching a copy of the most recent prescription to the log.

THEME: Security Gaps and Workspace Limitations

Inappropriate Patient Access

OAT medications must be stored securely in accordance with the *Narcotic Control Regulations of the Controlled Drugs and Substances Act*.¹³ Included in the analysis were reports of incidents in which patients were able to inappropriately access OAT medications. Factors identified as contributing to these incidents included unsecure storage, limited space, poorly designed dispensing processes for OAT medications, and high workload.

Incident Example: *A patient presented in a hurry for their daily directly observed dose. The wrong patient’s methadone bottle had been taken from the fridge and left on the cluttered counter while the pharmacist retrieved the medication administration log to double check the patient’s name and dose. The patient grabbed the bottle and drank the dose, which was higher than their prescribed dose.*



TIP: Store prepared OAT prescriptions out of reach and out of view of patients.⁹

Exposure to Nonprescribed OAT

A few incidents were reported in which OAT prepared for one patient was inadvertently given or almost given to a patient for whom OAT was not prescribed. These errors were attributed to clutter in the workspace or storage areas (e.g., safe, refrigerator) leading to label mix-ups and overlap of workflow processes involving OAT and non-OAT prescriptions.



TIP: Create a designated and separate workspace for OAT preparation. Keep documentation and required supplies in this area.

CONCLUSION

This multi-incident analysis of errors with oral OAT (reported from 2020 to 2023) identified several vulnerable processes in the care of patients receiving this treatment. While it is recognized that during this period, the pandemic affected both pharmacy teams and patients with opioid use disorder,¹⁰ this analysis provides valuable learning to support ongoing quality improvement initiatives. Community-based health care teams, including prescribers and regulated pharmacy staff, are encouraged to review their own processes and associated incidents and consider how learning from this analysis can help to support the safe delivery of OAT to patients and continuous quality improvement.

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