

ISMP Canada Safety Bulletin

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Deaths Associated with Medication Incidents Occurring Outside Regulated Healthcare Facilities

Increasingly, the provision of health-related services in a person's own home forms an important part of medical care.¹ This trend reflects a desire on the part of governments, healthcare organizations, and families to maintain independent living as long as possible. It also recognizes the risks of hospital-based care (beyond those associated with the presenting illness), such that expediting safe discharge of patients back to their own environments increases the likelihood of maintaining independence.^{2,3} Additionally, fiscal challenges to the Canadian healthcare system have moved the focus of care from acute care facilities into the community.⁴ This shift towards increased provision of services in the community has not been limited to strictly medical care. Some mental health services that were once delivered only in institutional facilities are now being provided in the community. Social services and correctional services organizations also coordinate and deliver community-based care (e.g., in group homes, homes for special care, and halfway houses). With the movement of all these healthcare activities into the community comes an increased potential for medication incidents, as individuals without healthcare training or experience undertake the complex process of safe medication management. As a priority focus of a collaborative project between the Institute for Safe Medication Practices (ISMP) Canada and 4 provincial Offices of the Chief Coroner or Chief Medical Examiner,⁵ a multi-incident analysis of medication incidents associated with deaths in the community setting was undertaken. The goal of this

analysis was to better understand the challenges faced by unregulated personnel and consumers when managing medications. This bulletin shares the findings of the analysis, highlighting the major themes and associated contributing factors, as well as opportunities for system-based improvements.

Methodology

Completed investigations of 122 deaths associated with medication incidents from 4 provincial Offices of the Chief Coroner or Chief Medical Examiner spanning a 5-year period (January 1, 2007, to December 31, 2012) were reviewed by an interdisciplinary analysis team at ISMP Canada and were abstracted into a secure database. From this dataset, 45 incidents were identified that occurred in an individual's home, a group home, or other residential setting. In all cases, medications were administered by the patient, family members or unregulated providers. The analysis was conducted using the multi-incident analysis technique outlined in the Canadian Incident Analysis Framework.⁶

Findings of the Multi-Incident Analysis

The overarching theme identified was that of knowledge deficit leading to various patient safety risks. Three key areas of knowledge deficit were identified, each of which was divided into subthemes (see Figure 1). Increased understanding of how these incidents occurred may assist healthcare providers to

proactively identify potential areas for system improvement and thereby decrease the potential for similar tragic events in the future.

Main theme: Knowledge deficit related to misperceptions associated with taking medications

Analysis of the incidents revealed misperceptions on the part of care providers and consumers about the use of medications, including an under-appreciation of the general risks associated with taking medications, both prescription and non-prescription. Fourteen of the deaths involved the following subthemes:

- Intentional therapeutic overdose; “If one is good, two will be better.”
- Therapeutic sharing; “What works for me will work for you.”

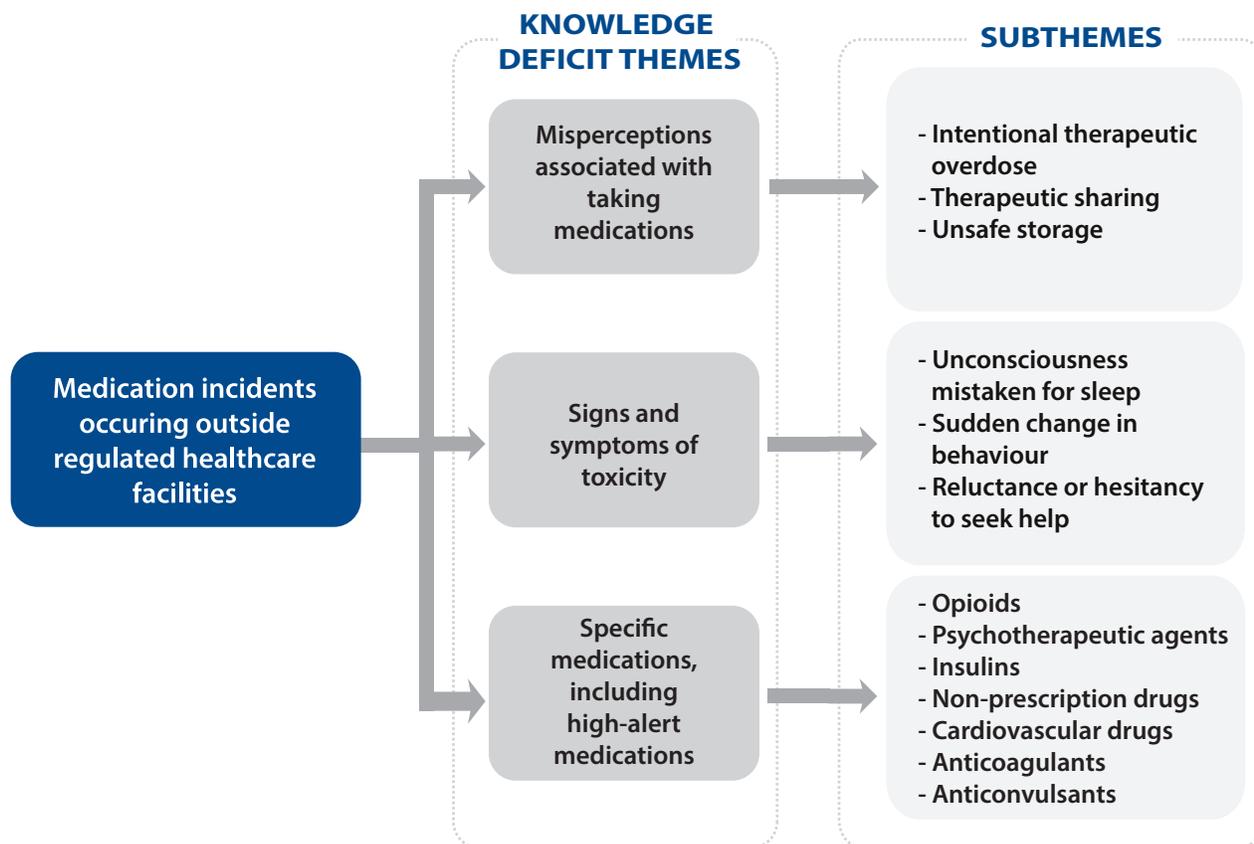
- Unsafe storage; “Does it really matter where I keep my medications?”

Subtheme: Intentional therapeutic overdose; “If one is good, two will be better.”

Medication incident analysis revealed a number of situations in which a prescribed or over-the-counter medication was taken or given at a higher dose than prescribed or recommended on the package. The narratives revealed that extra doses were sometimes taken, that doses intended for “as needed” use became routine, and that sometimes instructions were disregarded.

One of the contributing factors identified in this theme was a lack of awareness of increased risk of side effects or serious toxicity with an increase in dose. For cases in which medications intended for “as needed” use were administered regularly, one

Figure 1: Main themes and subthemes from the multi-incident analysis



contributing factor was an increase in dose without proper assessment of symptoms (e.g., based on an assumption that the symptom observed was due to worsening pain).

Incident example

An elderly individual died because of complications from overuse of a non-prescription Chinese herbal medication containing methyl salicylate. This medication was intended to be used once or twice daily on the legs to provide relief from arthritic pain. The decedent was frequently seen using the medication at least 3 or 4 times daily, and would hide the medication from the rest of the family after being reminded that it should be used only once or twice daily. Overuse of this product led to multiple medical problems, which were complicated by peripheral vascular disease and which contributed to her eventual death.

For various reasons, patients may choose not to follow medication instructions. Communication problems between prescribers and patients, as well as difficulties interpreting labelled instructions, may contribute to improper dosing. Taking extra doses of a medication may reflect poor pain control and the need for better assessment and symptom management. Over-the-counter medications may be perceived as having a high margin of safety, although this is not always the case.

Subtheme: Therapeutic sharing; “What works for me will work for you.”

In a few instances, the decedents intentionally took opioid medications that were prescribed for someone else (e.g., when a well-intentioned person recommended and supplied an opioid analgesic to a friend). In some of these cases, the narratives suggested that the decedents felt their symptoms were not being appropriately addressed by their care team, which may have led them to consider the recommendations of a friend.

Incident example

An adult man was found dead at home. He had a history of chronic pain related to a work injury and

a history of chronic alcohol use. At the time of the postmortem examination, a fentanyl 100 mcg/hour patch was noted on his body. His spouse had noticed the patch on his arm the evening before his death; on questioning, her husband told her the patch had been provided by a friend. No patch medication had ever been prescribed for the decedent. The death was attributed to fentanyl and alcohol toxicity in an apparent opioid-naive person.

Medications may be shared with the best intentions, i.e., to help others. However, people are often unaware that the effect of a medication is highly dependent upon the individual’s own medical conditions, his or her tolerance to the medication, and the pharmacologic properties of the compound itself. Many drugs require individual assessment, dosing, and monitoring and cannot be safely shared from one person to another.

Subtheme: Unsafe storage; “Does it really matter where I keep my medications?”

Severe patient harm, including death, can occur when medications are accessed and taken by people who should not be receiving them. The incidents reviewed confirmed that pre-pouring and unsafe storage of medications are risky practices. In particular, opioids are likely to cause harm if they are inadvertently used by the wrong person.

Incident example

A young child died as a result of ingesting some of her father’s liquid methadone dose. The child’s father had taken part of the dose and mixed the remainder with additional orange juice in a cup and placed it in a location that was accessible to the child. The child was later observed drinking what appeared to be juice. The following morning, the child could not be awakened and subsequently died in hospital.

Proper storage of medications in homes and residential facilities is an often-overlooked safety issue. Poor storage practices can contribute to changes in potency or effect of the drug, can result in one drug being mistaken for another, or can lead to inadvertent consumption of a medication, as in this

case. The safe disposal of unused medication is another aspect of medication storage safety that is frequently neglected.

Main theme: Knowledge deficit related to signs and symptoms of toxicity

Opportunities to mitigate harm or prevent death may exist even after the occurrence of a medication incident. Unfortunately, in many of the incidents considered for this analysis, caregivers or family members did not know or recognize warning symptoms of toxicity, which hindered timely recognition of trouble and resulted in missed opportunities to rescue the decedent. Analysis revealed that the majority of deaths falling under this theme involved the following situations:

- Unconsciousness mistaken for sleep
- Sudden change in behaviour
- Reluctance or hesitancy to seek help

Subtheme: Unconsciousness mistaken for sleep

In numerous incidents included in this analysis, family members reported thinking that the decedents were sleeping when in fact they were unconscious. Many recalled hearing the person snore or make gurgling or groaning noises. Typically, the family members had not tried to waken the person until it was too late. In many cases, it appeared that there was an assumption that “sleep is good”, so timely attempts to rouse the decedent were not undertaken.

Incident example

A resident of a halfway house died from accidental oxycodone toxicity. The decedent was taking morphine sulfate and gabapentin prescribed by his family physician to manage chronic pain. Because of continued pain, the resident was referred to a pain specialist, who suggested a change to a long-acting oxycodone product. The written recommendation from the specialist was misinterpreted by the family physician, who prescribed a high dose of oxycodone. After confirming the dose with the pharmacy (and the pharmacy in turn confirmed with the prescriber), the medication was given for 3 days by staff at the halfway house. On the day of death, the resident

was “sleeping” when a staff member came to provide the medication; the resident was left to sleep. Staff returned 2 hours later and found that the resident was not breathing.

If unconsciousness is detected in a timely manner, there may be an opportunity to intervene and rescue the person from harm. In particular, unusual and irregular snoring is often a sign of dangerous stupor. The need to take action in this situation cannot be overstated.

Subtheme: Sudden change in behaviour

The incident analysis identified cases of a noted change in the decedent’s behaviour, which might have represented an opportunity for timely intervention. An associated contributing factor was failure to realize the seriousness of the change in the behaviour, as indicated in the example below.

Incident example

An adult with a history of mental illness and of taking multiple medications, including an opioid, was found dead at home. A family member commented that two days before the death he had been very groggy and did not seem like himself.

Behaviour changes can be caused by drug toxicity. Although this problem is often associated with psychiatric drugs, there are many other medications for a variety of conditions that can cause irregular behavior if given too frequently or at a higher dose than required. Drug toxicity can also result if one medication affects the metabolism of another, leading to accumulation of the drug in the body and signs of overdose.

Subtheme: Reluctance or hesitancy to seek help

In a number of the cases reviewed, the decedent’s condition or pain had worsened, and they may have made changes in their medication regimen without seeking advice from a healthcare professional. In some instances, the decedent had told friends or family members of new or worsening symptoms lasting anywhere from 3 days to 3 weeks before death but had never reported these concerns to the care team.

It is crucial that patients be aware of the need to communicate any unusual or changing symptoms related to their medication regimen. The care team must be aware of these concerns if they are to appropriately assess and treat symptoms and protect against harm. In addition, a plan should be in place to assess symptoms and medication effects at regular intervals appropriate to the clinical situation. For medications with known symptoms of toxicity, patients should be informed of warning signs, and an emergency plan should be drafted to outline the steps to take in the event of impending harm.

Other narratives, like the one below, illustrate reluctance to seek help, even when an incident was known to have occurred.

Incident example

An adult male lived in a communal house for people with various mental health issues. The owner of the house was responsible for distributing medications to the tenants at mealtimes. On the day of the incident, the owner was unwell and asked a family member to oversee the medication routine. Instead of receiving his usual medications, the decedent was given someone else's medications, including amitriptyline, quetiapine, loxapine, and olanzapine. When the family member realized the error, he immediately notified the owner of the house, who indicated that the medications the tenant had received were not significant enough to warrant medical attention. The decedent went to bed that evening and was found dead in his room the following morning.

This incident further illustrates the need for a general understanding that medications have the potential to cause harm if used incorrectly.

Main theme: Knowledge deficit related to specific medications, including high-alert medications

The following were the top 7 medication classes most frequently identified in this analysis, based on the medication categories of the American Hospital Formulary Service Pharmacologic–Therapeutic Classification System⁷ (with the exception of “non-prescription drugs”):

- opioids (20 cases)
- psychotherapeutic agents (17 cases)
- insulins (5 cases)
- non-prescription drugs (5 cases)
- cardiovascular drugs (4 cases)
- anticoagulants (3 cases)
- anticonvulsants (2 cases)

Several of the incidents involved known high-alert medications. High-alert medications are those that carry a heightened risk of causing significant patient harm when they are used in error.⁸ Illustrative examples from the top 4 high-alert drug classes most commonly involved in incidents in this dataset, and the associated knowledge deficits are highlighted in Table 1. It is noted that these identified knowledge deficits may not be generalizable to all the incidents reviewed in the drug class.

The healthcare team must ensure that patients and their caregivers understand the proper use of medications. Equally important is confirming that patients are aware of the potential side effects of their medications, know how to differentiate potentially dangerous effects from more benign ones, and know what actions to take to mitigate harm.

Conclusion

This bulletin has highlighted several underlying knowledge deficits or misperceptions that may have contributed to preventable deaths outside regulated healthcare facilities. The themes and subthemes identified in this analysis illustrate the need to ensure that sufficient information is effectively communicated to consumers, families and unregulated caregivers. This information includes the importance of following labelled instructions (for both prescription and over-the-counter medications) and also the signs and symptoms of toxicity necessitating intervention by regulated healthcare providers. High priority should be given to safeguards for known high-alert medications.

It is hoped that the contributing factors identified here will provide insights that healthcare providers can use in developing and implementing safeguards to support consumers and unregulated care providers. This information should also be helpful for local quality improvement and education initiatives.

Table 1: Selected Incident Examples and Associated Knowledge Deficits

Drug Class	Incident Example	Knowledge Deficits Identified
Opioids	An adult was found dead at home due to fentanyl overdose, as a consequence of incorrect application of fentanyl patches. At autopsy, 2 fentanyl 100 mcg/hour patches were observed on the body. The decedent's prescription was for fentanyl 100 mcg patches. After the decedent had been using the patches for some time, a prescription was filled using patches from a different manufacturer that were half the previous size. The decedent assumed that the size of the patch indicated a reduction in dose and started using two patches.	<ul style="list-style-type: none">- Lack of knowledge about the narrow therapeutic range of opioids- Perception that a small patch may be less effective than a large one
Psychotherapeutic agents	A resident of a home for persons with mental health issues was taking multiple medications. The resident suffered a fatal arrhythmia, likely secondary to multiple factors, including clozapine and protriptyline therapy and sleep apnea.	<ul style="list-style-type: none">- Lack of knowledge of drug-drug interactions and drug-disease interactions
Insulins	An older adult died of inadvertent insulin overdose. He and his family were recent immigrants, and there was a language barrier with healthcare providers. Day-to-day care was the responsibility of the adult children, who prepared meals and administered medications, including insulin. They believed that additional insulin was needed to treat low blood sugar and continued to give insulin when blood sugar readings were low.	<ul style="list-style-type: none">- Lack of knowledge regarding the function of insulin in diabetes management.
Non-prescription drugs	A patient was brought to an emergency department by ambulance. On assessment, the patient was found to have an acetaminophen level of more than 1100 mcg/mL (therapeutic range 66-199 mcg/mL). The patient described taking a dose of acetaminophen of approximately 5 grams most days of the week and drinking alcohol once or twice per week.	<ul style="list-style-type: none">- Lack of knowledge that significant toxicities and drug-drug or drug-food interactions can occur even with over-the-counter medications

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

February 2014 - Newsletter:

Acetaminophen – Harm from Overdose Can Be Prevented

Acetaminophen is safe and effective when used correctly. However, taking too much acetaminophen can harm the liver, possibly leading to liver failure or even death. Through its work with provincial coroners and chief medical examiners, ISMP Canada has become aware of 2 fatal incidents involving inadvertent overdose of acetaminophen. In one of these cases, the consumer had been taking about 10 extra-strength acetaminophen tablets most days of the week and also drank alcohol, which increases the chances of liver damage.

The newsletter advises consumers of the importance of not exceeding the maximum daily dose of acetaminophen and also recommends that consumers avoid taking more than one product containing acetaminophen at the same time. The newsletter advises practitioners to ask patients about their use of other products before prescribing or recommending any product containing acetaminophen, and to be sure that patients understand the importance of adhering to the recommended dosage schedule.

For additional recommendations for both consumers and practitioners, read the complete newsletter at:

www.safemedicationuse.ca/newsletter/newsletter_Acetaminophen.html



**Consumers Can Help Prevent
Harmful Medication Incidents**

SafeMedicationUse.ca

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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)

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