ISMP Canada Safety Bulletin

Analysis of Harmful Medication Incidents Involving Psychotropic Medications

Psychotropic medications are among the most commonly prescribed therapeutic classes of medications. In 2007, this class of drugs accounted for 53 million (12.5%) of the 422.6 million prescriptions dispensed by community pharmacies in Canada, second only to cardiovascular agents.[1] This bulletin shares information about incidents involving psychotropic medications that have been voluntarily reported to ISMP Canada, specifically incidents related to the following categories of drugs: antidepressants, antipsychotics, benzodiazepines, anxiolytic-sedative-hypnotics, and antimanic drugs. These categories are based on the American Hospital Formulary Service Pharmacologic-Therapeutic Classification System.[2] The bulletin includes an overview of incidents with an outcome of harm or death and highlights the major themes identified through an aggregate analysis. Specific incident examples are provided, along with opportunities for system-based improvements.

Background and Overview of Findings

Reports of incidents involving psychotropic drugs with an outcome of harm,[3] including reports submitted by consumers to the SafeMedicationUse.ca pilot program, were extracted from the ISMP Canada medication incident database. The data reviewed for this analysis spanned a period of about 11 years (Oct. 7, 2000, to Sept. 29, 2011).

Of the 79,539 incidents in the ISMP Canada database, including near misses and hazardous conditions, 5850 (7.4%) involved psychotropic medications. Of these 5850 medication incidents, 137 (2.3%) were associated with an outcome of harm.[*] Three incidents were excluded from the analysis because of insufficient detail, and 1 incident was excluded because it was determined to be a nonpreventable adverse reaction, which left 133 incidents for aggregate analysis.

Findings of Qualitative Analysis

Qualitative analysis of the 133 incidents identified a number of recurrent themes, which were classified according to 3 main practice settings: community, long-term care, and hospitals. The themes for each setting were associated with certain contributing factors, as shown in

Table 1. There was some overlap among the settings in terms of themes and contributing factors identified (Table 1). In addition, it can be anticipated that other points of overlap in themes among settings may exist, even if not revealed by this analysis. Therefore, all of the various themes and associated contributing factors may be of interest to practitioners in all settings. Examples of incidents are provided below, along with opportunities for system improvement.

Community Setting

Multiple Medications Theme

Incident example: A patient was receiving multiple psychotropic medications, including methotrimeprazine. The patient experienced a number of symptoms, including tremors and difficulty walking, which were interpreted as a worsening of the underlying illness. The daily dose of methotrimeprazine was increased. A few weeks later, the patient died. It was subsequently determined that toxic levels of methotrimeprazine were present in the blood at the time of death.

Comments: The adverse effects of a number of psychotropic medications may mimic the signs and symptoms of the condition for which the patient is being treated. For patients with complex mental health and wellness needs, particularly those who require multiple medications and/or escalation in therapy because of continuation or exacerbation of symptoms, additional consultation with specialists may be required. The difficulty that some patients have in communicating their symptoms to their caregivers may compound the problem.[4]

Incorrect Medication Theme

Incident example: A patient received a medication refill and noticed that the pills looked different. The patient assumed that the change in the appearance of the tablets was due to a brand change and did not bring the issue to the attention of pharmacy staff. At the next refill, 3 months later, the patient shared concerns about new symptoms experienced since the last refill, including diarrhea, fatigue, and dizziness, as well as several minor mishaps while driving. It was discovered that lorazepam had been dispensed instead of loperamide.

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

Table 1: Themes and Associated Contributing Factors from Qualitative Analysis of Harmful Incidents Involving Psychotropic Medications Submitted to a Voluntary Reporting Program

Theme*	Associated Contributing Factors
Community setting	
Multiple medications	▪ One or more adverse effects of a psychotropic medication mimicking and misinterpreted as signs and symptoms of underlying disease, leading in turn to escalation of drug therapy (i.e., dose increase or addition of a new medication) ▪ Lack of comprehensive medication reviews
Incorrect medication	▪ Medication names that sound or look similar ▪ Lack of quality checks (e.g., bar-coding, DIN check, visual check of tablets in vial) in community pharmacy ▪ Assumption that changes in appearance of a medication relate to a change in brand rather than an incorrect drug
Incorrect patient	▪ Lack of a systematic patient identification and verification process
Incorrect dose	▪ Errors in placement of decimal point ▪ Lack of quality checks (e.g., DIN check, consideration of clinical appropriateness) in community pharmacy ▪ Assumption that changes in appearance of a medication relate to a change in brand rather than an incorrect dose
Long-term care setting	
Multiple medications	▪ Duplicate therapies, increasing the likelihood of drug interactions or additive effects
Incorrect patient	▪ Lack of a systematic patient identification and verification process ▪ Interruptions during medication administration ▪ Prepouring of medications ▪ Mixing of medications into food, rendering them unidentifiable
Incorrect dose	▪ Administration of medications without documentation in the MAR, leading to administration of extra doses
Hospital setting	
Multiple medications	▪ Duplicate therapies, increasing the likelihood of drug interactions or additive effects ▪ Lack of comprehensive medication reviews ▪ Patients taking their own medications in hospital without caregivers' knowledge
Transitions of care	▪ Lack of a systematic medication reconciliation process
Incorrect patient	▪ Prepouring of medications ▪ Lack of a systematic patient identification and verification process
Incorrect medication	▪ Medication names that sound or look similar
Incorrect dose	▪ Misinterpretation of order (e.g., mg vs. mL) ▪ Mix-ups between different drug concentrations ▪ Lack of standardized confirmation process for verbal orders in urgent situations (e.g., acute psychotic episode) ▪ Transcription errors ▪ Lack of a systematic medication reconciliation process
Dose omission	▪ Transcription errors ▪ Medications left at patient's bedside ▪ Medications not provided for patients with day pass ▪ Lack of awareness about nonformulary drugs or drugs unavailable in the inpatient pharmacy
Change of order	▪ Lack of a systematic process for order to discontinue a medication at a future date (e.g., cross-tapering of antidepressants) ▪ Mix-ups between scheduled and PRN orders for the same medication

DIN = Drug Identification Number, MAR = medication administration record, PRN = as necessary.

*Some themes and associated contributing factors overlap from one setting to another. Other points of overlap may exist among these settings, even if not revealed by this analysis, which was based on voluntarily reported incidents.

Comments: This particular incident revealed several areas of concern:

1. Patients should be encouraged to question unexpected changes in their medications (e.g., when the name of the medication or the medication itself looks different) by alerting the pharmacy that filled the prescription. Similarly, pharmacy staff should take seriously and investigate all such concerns that are raised by patients. Several reported incidents were identified in which either the patient or pharmacy staff assumed that a change in the appearance of a medication was related to use of a different brand, when in fact the wrong drug or the wrong dose had been dispensed.

2. The period between the occurrence of an incident and its discovery may be relatively long. It is therefore extremely important to inform patients about their medications and to engage them in their own care throughout all stages of therapy. Informed patients can and do help to prevent errors or identify errors before they lead to harm, and several such examples have been highlighted by ISMP Canada's pilot consumer reporting and learning program, SafeMedicationUse.ca.[5,6]

3. Finally, medication names that sound or look similar are prone to mix-ups; the risk of this type of error may be greater when the dosage ranges are similar or overlap. Table 2 highlights examples of medication pairs that were involved in harmful mix-ups voluntarily reported by community pharmacies.

Table 2: Examples of Medication Pairs Involved in Reported Mix-ups	
Seroquel 400 mg	sertraline 400 mg
Apo-Doxy 100 mg	Apo-Doxepin 100 mg
lithium carbonate 150 mg	lamotrigine 150 mg
Artane 2 mg	Ativan 2 mg
trifluoperazine 2 mg	trimethoprim 200 mg
loperamide 2 mg	lorazepam 2 mg

Incorrect Patient Theme

Incident example: Spouses with the same family name had their medications mixed up at the pharmacy. The spouse who was supposed to receive the anticoagulant warfarin was given trazodone, and the spouse who was supposed to receive trazodone was given the anticoagulant.

Comments: The aggregate analysis included several reported incidents in which medications were taken by the incorrect patient, including mix-ups of spouses' medications both at the pharmacy and in the home. The Medication Safety Self-Assessment for Community/Ambulatory Pharmacy program[7] provides guidance on medication system safeguards for the community pharmacy setting. Similarly, information in the SafeMedicationUse.ca newsletters[8,9] and

at its website[10] provides prevention strategies that consumers can use in the home.

Long-Term Care Setting

Multiple Medications Theme

Incident example: A long-term care resident was given a PRN dose of lorazepam 1 mg for agitation. Thirty minutes after the lorazepam was administered, clonazepam was started. A short time later, the patient fell. The patient was disoriented and required transfer to a hospital emergency department. The incident report stated that concurrent use of the 2 medications led to the patient's disorientation and fall.

Comments: Elderly patients may be more susceptible to the harmful effects of psychotropic medications. The Safer Medication Use in Older Persons initiative provides information about medications that are poorly tolerated by elderly patients.[11] Sharing this information can help to raise awareness among healthcare practitioners and also among patients and their families.

Incorrect Patient Theme

Incident example: Staff in a long-term care facility prepared quetiapine and lithium for a long-term care resident by incorporating the medications into the resident's cereal. However, the cereal was not given to the resident immediately and was inadvertently eaten by another resident. The resident who ingested the medications became increasingly lethargic, suffered some loss of consciousness, and was transferred to the emergency department.

Comments: Some patients have difficulty taking capsules or tablets. Facilities should have a process to alert pharmacy staff about these situations, so that alternative dosage forms (e.g., oral solutions, suspensions) or therapeutic alternatives can be considered. If mixing a medication in food is determined to be appropriate, the medication should be mixed in a minimal amount of food and administered promptly. It is important that the food itself then be treated as a medication, not only to confirm that the drug has been administered in full but also to ensure that it is not accidently eaten by or given to someone else.

Hospital Setting

Multiple Medications Theme

Incident example: A hospital inpatient became drowsy as a result of taking medications brought from home. More specifically, the patient took doses of lorazepam prescribed for home use, as well as other medications that had been prescribed in the hospital. [A report received after initiation of this aggregate analysis identified a similar incident in which the patient required transfer to critical care.]

Comments: Patients and family members may bring medications to hospital to assist in sharing information about home medications. Ideally, home medications that are not required during the hospital stay should then be returned to the patient's home or placed in a secure area, as patients' ability to recall or comprehend instructions may change during the course of their hospital stay. An important step is for hospitals to ensure that healthcare practitioners have direction (e.g., a policy or protocol) on how they are expected to safely deal with patients' own medications.

Transitions of Care Theme

Incident example: A patient admitted to hospital experienced extreme drowsiness after receiving bromazepam 3 mg. The bromazepam dose had been obtained from the label of the patient's prescription vial from home. When asked, the patient informed the pharmacist that she had been taking only half of the prescribed 3 mg tablet while at home.

Comments: This incident highlights problems associated with relying on information from prescription labels. Dosing information on labels should not be considered accurate or complete without verification from the patient or alternative information sources. For example, prescribers may adjust medication dosing without writing a new prescription. Medication reconciliation is a critical step during transitions in care such as from home to hospital. A systematic medication reconciliation process uses multiple sources of information to identify the best possible medication history. It is recognized that obtaining an accurate medication history can be a challenge if the patient has cognitive impairment.[4]

Incorrect Dose Theme

Incident example: A physician verbally prescribed lorazepam 2 mg IM for an agitated patient. Because the environment was noisy and chaotic, the dose was misheard as 10 mg, and the patient received lorazepam 10 mg IM. The error was identified shortly after the order was written in the patient's chart.

Comments: Verbal orders can be problematic in any setting, and certain doses are prone to mix-ups. If verbal orders are necessary, as may be the case in urgent situations, repeating and confirming the dose before administration, using a single-digit format, can help to prevent errors. For example, if a dose of "10 mg" is heard, the practitioner preparing the medication for administration would repeat back the order as "one-zero, ten milligrams". This approach to verbal orders can facilitate detection of an incorrect dose before it reaches the patient.[12]

Dose Omission Theme

Incident example: Venlafaxine was omitted from a patient's regimen when the medication was inadvertently crossed off the patient's medication administration record. Consequently, when the patient was transferred to chronic care, the medication continued to be omitted, and the patient experienced discontinuation syndrome (characterized by nausea, vomiting, and delirium).

Comments: This incident example demonstrates that dose omission errors involving psychotropic agents may result in withdrawal reactions. These reactions may mimic other disease states and lead to patient harm. A systematic medication reconciliation process can help to identify medication discrepancies. Medication reconciliation during transitions of care (such as discharge) can prompt recognition of errors and prevent or limit the extent of harm.

Conclusions

It is recognized that about 1 in 5 Canadians will experience some form of mental health need.[13] The use of psychotropic medications is increasing among all age groups, including the pediatric population.[14] As such, reporting and aggregate analysis of medication incidents involving these drugs is an important step toward enhancing safe medication use.

Very few studies have examined medication errors in the psychiatric setting. One such study demonstrated the need for vigilance by healthcare practitioners to identify medication errors. In that study, for every medication error that was self-reported by a patient, healthcare practitioners were able to identify 244 medication errors.[15] Engaging patients who are experiencing mental health and wellness needs can be challenging. In particular, some patients do not have insight into their condition, which may affect medication management (including adherence with prescribed therapy) and communication with their multiple caregivers.[4] However, limited specific research to guide practice and care delivery is leading to increased interest in improving patient safety in mental health.[1]

The aggregate analysis reported here is intended to provide insights into incidents involving psychotropic medications that have been voluntarily reported, particularly those associated with harm. The analysis identified themes and associated contributing factors, as well as opportunities for system improvements. It is hoped that the findings from this aggregate analysis will support and augment local, provincial, and national quality improvement initiatives. ISMP Canada also incorporates learning from incidents such as those described above into its various medication safety programs, to facilitate the enhancement of medication-use systems.

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