

Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis

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Abstract

Background: Quality-related events are defined as medication errors that reach the patient (e.g., incorrect drug, dose and quantity), in addition to medication errors that are intercepted before dispensing (i.e., near misses). The aim of this study is to quantify and characterize such events as reported by community pharmacies in a Canadian province.

Methods: A retrospective analysis was conducted on quality-related events reported to the Community Pharmacy Incident Reporting system from 301 community pharmacies in Nova Scotia between Oct. 1, 2010, and June 30, 2017. We performed a descriptive analysis on these events with respect to the discoverer, patient outcome, medication system stages and type.

Results: We identified 131 031 events reported by community pharmacies in Nova Scotia over the study period, 98 097 of which were quality-related events. Overall, 82.0% ($n = 80\,488$) quality-related events did not reach the patient, and 0.95% ($n = 928$) were associated with patient harm. Incorrect dose or frequency, incorrect quantity and incorrect drug were the most common types of quality-related events reported. Most of the quality-related events occurred at order entry, followed by preparation and dispensing, and prescribing.

Interpretation: Quality-related events reported by community pharmacies differ from those reported in institutional settings with respect to patient outcome, medication system stages and type. This analysis provides valuable information to guide quality improvement initiatives to strengthen medication safety in community pharmacies.

Community pharmacies in Canada dispense more than 600 million prescriptions each year; however, little is known about the quality-related events associated with this process.¹⁻⁴ Quality-related events are defined as medication errors that reach the patient, such as incorrect drug, dose or quantity, in addition to medication errors that are intercepted before a drug is dispensed (i.e., near misses).² These events occur when vulnerable medication-use systems or human factors affect prescribing, transcribing, dispensing, administration, and monitoring practices.⁵ When an event reaches a patient and causes harm, it is defined as an adverse drug event.⁶ Adverse drug events are estimated to be responsible for 12% of emergency department visits and 24% of all adverse events that occur in hospitals in Canada.^{7,8}

In an effort to address factors that lead to quality-related events, health care organizations and governments have developed and implemented reporting systems. Aside from providing data for large-scale aggregate analysis, reporting systems enable health care stakeholders to better understand

the contributing factors that may have led to quality-related events, and have been associated with improvements in patient safety culture and better organizational learning.⁹ The implementation of reporting systems in community pharmacies in Canada has been limited, but previous research involving analyses of quality-related events from community pharmacies in Europe showed differences from institutional settings with respect to patient outcome, stage of medication use and type of quality-related event.^{10,11} The aim of our study was to characterize quality-related events reported to an independent third-party national medication safety organization by community pharmacies in a Canadian province.

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Methods

The Nova Scotia College of Pharmacists Standards of Practice for Continuous Quality Assurance require community pharmacies to anonymously report all quality-related events to a national incident data repository at the Institute for Safe Medication Practices Canada through the Community Pharmacy Incident Reporting system.¹² The Community Pharmacy Incident Reporting system was developed and validated with community pharmacists in Ontario and Nova Scotia.¹³ The provincial pharmacy regulatory authority regularly audits and ensures pharmacies' adherence to these standards.

Study cohort

All community pharmacies in Nova Scotia were included in the study.

Data sources

The quality-related event reporting form was developed in collaboration with Nova Scotia and Ontario community pharmacy professionals; it consists of 7 mandatory fields: (1) date quality-related event occurred, (2) type of event, (3) who the event was discovered by, (4) medication system stages involved, (5) medication(s), (6) patient outcome associated with the event, and (7) a free-text description field (Box 1). All members of the pharmacy team (e.g., owner, manager, pharmacist, technician, assistant) can report a quality-related event through the online Community Pharmacy Incident Reporting system.

Statistical analysis

All 7 mandatory fields of reported quality-related events from Nova Scotia community pharmacies that occurred between Oct. 1, 2010, and June 30, 2017, were extracted from the Community Pharmacy Incident Reporting system (by A. Boucher and C. Ho). Single-item and cross-tabulation search statements were developed to further extract relevant data for analysis (by A. Boucher and C. Ho). Descriptive analyses were performed on events with respect to discoverer, patient outcome, medication system stages involved and type (by A. Boucher and C. Ho). All analyses were performed using IBM SPSS version 24.

Ethics approval

This study does not involve human subjects.

Results

A total of 301 community pharmacies (Table 1) in Nova Scotia reported 131 031 events to the Community Pharmacy Incident Reporting system during the study period. Of these events, 98 097 were reported as quality-related events and were included in our analysis. A mean of 14 533 quality-related events were reported annually. The mean number of reported quality-related events for each pharmacy during the study period was 326 (standard deviation [SD] \pm 439). We found a large variability between pharmacies, with between 1

and 2806 quality-related events reported per pharmacy during the study period. Furthermore, 10% ($n = 30$) of the pharmacies accounted for 42.7% ($n = 41\ 926$) of all reported quality-related events.

Community pharmacies in Nova Scotia

Most (55.2%; $n = 166$) of the community pharmacies in Nova Scotia are chain pharmacies, and 48.2% ($n = 145$) are located in a geographic region with a population of between 5000 and 49 999 (Table 1).

Discoverer

Pharmacists discovered 75.2% ($n = 73\ 739$) of quality-related events. Pharmacy technicians or assistants and patients discovered 10.3% ($n = 10\ 094$) and 9.9% ($n = 9728$), respectively. The remaining 4.6% ($n = 4536$) were discovered primarily by other health care practitioners (Appendix 1, available at www.cmajopen.ca/content/6/4/E651/suppl/DC1).

Patient outcome

Analysis of outcomes showed that 82.0% ($n = 80\ 488$) of reported quality-related events did not reach the patient (i.e., near misses), and 0.95% ($n = 928$) were reported as harm events (Table 2).

Medication system stage

Of all analyzed quality-related events, 17.5% ($n = 17\ 135$) were reported as occurring in multiple medication system stages. The medication system stage most frequently associated with quality-related events was prescription order entry (58.7%; $n = 69\ 856$), followed by prescription preparation and dispensing (29.3%; $n = 34\ 859$) and prescribing (9.0%; $n = 10\ 658$) (Table 3). Among harm events, there was a more even distribution across the medication system stages, with prescription preparation and dispensing (38.1%; $n = 571$) accounting for the largest proportion, followed by order entry (27.4%; $n = 411$) and administration (15.2%; $n = 228$). Administration and monitoring or follow-up were associated with the highest potential for patient harm.

Type of quality-related event

The most frequently reported types of quality-related event were incorrect dose or frequency (25.6%; $n = 25\ 089$), followed by incorrect quantity (20.0%; $n = 19\ 619$) and incorrect drug (14.2%; $n = 13\ 951$) (Table 4). For harm events, the highest number of quality-related events was associated with incorrect dose or frequency (27.4%; $n = 254$), followed by incorrect strength or concentration (20.2%; $n = 187$) and incorrect drug (19.9%; $n = 185$). Adverse drug reactions were associated with the highest potential for patient harm.

Interpretation

We identified 98 097 quality-related events reported during the study period. Despite variability in reporting between pharmacies, 100% of community pharmacies in Nova Scotia ($n = 301$) reported at least 1 such event during the study period,

Box 1 (part 1 of 2): Mandatory fields of the Community Pharmacy Incident Reporting system

1. Date quality-related event occurred
2. Type of quality-related event*
 - Incorrect patient
 - Incorrect prescriber
 - Incorrect drug
 - Incorrect dose/frequency
 - Incorrect strength/concentration
 - Incorrect dosage form/formulation
 - Incorrect route of administration
 - Incorrect duration of treatment
 - Incorrect quantity
 - Incorrect storage
 - Omitted medication/dose
 - Incorrect third-party billing
 - Drug therapy problem
 - Contraindication
 - Adverse drug reaction
 - Documented allergy
 - Drug–drug interaction
 - Drug–food interaction
 - Drug–disease interaction
3. Quality-related event discovered by (i.e., Discoverer)*
 - Pharmacist
 - Pharmacy technician/assistant
 - Pharmacy student
 - Patient
 - Patient’s family member/relative
 - Patient’s caregiver/home aid/assistant
 - Patient’s friend/visitor
 - Community Care Access Centre home care coordinator
 - Physician
 - Medical student
 - Paramedic
 - Nurse
 - Nursing student
 - Social worker
 - Dentist
 - Midwife
 - Chiropracist/podiatrist
 - Respiratory therapist
 - Dietician
 - Physiotherapist
 - Occupational therapist
 - Veterinarian
 - Other
4. Medication system stage involved†
 - Prescribing
 - Prescription order entry
 - Prescription preparation/dispensing

Box 1 (part 2 of 2): Mandatory fields of the Community Pharmacy Incident Reporting system

4. Medication system stage involved (continued)†
 - Administration
 - Monitoring/follow-up
 - Not applicable
5. Medications‡
6. Degree of harm (i.e., patient outcome)*
 - No error (medication not dispensed/near miss/medication discrepancy) — Circumstances or events that have the capacity to cause harm
 - No harm (medication dispensed) — No symptoms detected; no treatment required
 - Mild harm — Symptoms were mild, temporary and short-term; no treatment or minor treatment was required
 - Moderate harm — Symptoms required additional treatment or an operation; the incident kept the patient in hospital longer than expected; or caused permanent harm or loss of function
 - Severe harm — Symptoms required major treatment to save the patient’s life; the incident shortened life expectancy; or caused major permanent or long-term harm
 - Death — There is reason to believe that the incident caused the patient’s death or hastened the patient’s death
7. Quality-related event description

*The reporter may only select 1 option from this field.

†The reporter may select more than 1 option from this field.

‡Reporters have the option to report an event that is not medication-related by unchecking “Is this medication related” next to the “Medications” field. The “Medications” field will auto-populate if a drug identification number (DIN) is entered. A DIN is an 8-digit unique identifier located on the label of prescription and over-the-counter drugs that have been approved for sale in Canada. Reporters may also select the medication from a drop-down menu when the reporter begins typing the medication name, or they may choose to manually enter a free-form medication name.

Table 1: Pharmacy characteristics

Characteristic	No. (%) of pharmacies <i>n</i> = 301
Type of pharmacy*	
Chain	166 (55.1)
Banner	111 (36.9)
Independent	24 (8.0)
Population served by the pharmacy	
< 1000	31 (10.3)
1000–4999	70 (23.3)
5000–49 999	145 (48.2)
50 000–99 999	16 (5.3)
> 100 000	39 (13.0)

*Chain pharmacies are typically directed by a corporate office, with respect to its professional programs, marketing, ordering, etc. Banner pharmacies are independently owned pharmacies that are affiliated with a central office; they pay fees for the banner’s benefit in centralized buying, marketing and professional programs. Independent pharmacies are not affiliated with any corporately run chains or banners. The owner of an independent pharmacy has complete control over the business (e.g., ordering and marketing strategies).

Table 2: Quality-related events reported by patient outcome

Event reached patient	Patient outcome	No. (%)	Harm QRE
No	No error (i.e., near miss)	80 488 (82.0)	No
Yes	No harm	16 681 (17.0)	No
Yes	Mild harm	839 (0.86)	Yes
Yes	Moderate harm	80 (0.1)	Yes
Yes	Severe harm	7 (0.00)	Yes
Yes	Death	2 (0.00)	Yes
Total		98 097 (100)	

Note: QRE = quality-related event.

Table 3: Total number of QREs, number of harm QREs and proportion of harm QREs for each medication system stage

Stage	No. (%)		% Harm QREs*
	QREs	Harm QREs*	
Prescribing	10 658 (9.0)	159 (10.6)	1.5
Prescription order entry	69 856 (58.7)	411 (27.4)	0.6
Prescription preparation/dispensing	34 859 (29.3)	571 (38.1)	1.6
Administration	2167 (1.8)	228 (15.2)	10.5
Monitoring/follow-up	704 (0.6)	90 (6.0)	12.8
Not applicable	743 (0.6)	39 (2.6)	5.2
Total	118 987† (100)	1498† (100)	–

Note: QRE = quality related event.
 *Harm QREs are associated with a patient outcome of mild harm, moderate harm, severe harm or death (Table 2).
 †The reporter can select multiple options for "Medication System Stages Involved" field; hence the total number of QREs and the number of QREs with harm are greater than those shown in Table 2.

suggesting universal compliance with the reporting program. Most of the events were discovered by a pharmacist and did not reach the patient. Quality-related events most frequently occurred in the order entry stage and were most commonly categorized as incorrect dose or frequency, or incorrect quantity.

Most of the events reported were caught by pharmacy staff and did not reach the patient. This result is in contrast to previous analyses of reported events from community pharmacies and hospitals where, in general, less than 60% of quality-related events did not reach the patient.¹⁰ This discrepancy may be due to several factors. First, in addition to anonymous reporting, the Nova Scotia Continuous Quality Assurance program also requires community pharmacies to perform an annual medication safety self-assessment and conduct quarterly staff meetings to implement and

monitor ongoing quality improvement initiatives.¹² These additional quality improvement components help facilitate quality-related event reporting by addressing several common barriers to incident reporting, including lack of feedback on action taken as a result of reporting, insufficient justification for reporting a “near miss” and the belief that reporting is unlikely to lead to system changes.^{14,15} Second, adherence to all required components of the Standards of Practice for Continuous Quality Assurance are regularly audited and enforced by the provincial pharmacy regulatory authority. As a result, our data and analysis may provide a more representative view of quality-related events and associated outcomes that occur in community pharmacies.

The most common medication system stages involved in the reported quality-related events were prescription order entry and prescription preparation and dispensing. Previous studies in community pharmacies have found similar results,^{10,11} but studies in hospitals generally report a higher frequency of quality-related events related to prescribing and administration.^{16–19} In addition, we found that quality-related events that occurred during administration or monitoring and follow-up were more likely to result in patient harm, probably because there are fewer opportunities to catch quality-related events in later stages of the medication-use process, and patients are more likely to identify and report events that cause harm.²⁰ The most frequent types of reported quality-related events (e.g., incorrect dose or frequency, incorrect quantity, incorrect drug) were generally in agreement with results from previous studies conducted in community pharmacies and hospitals.^{11,16,17,21} However, other types of quality-related events were often reported in different proportions in hospital studies.^{16,17} We found that adverse drug reactions may convey a higher risk of harm to patients compared with other types of quality-related events, which aligns with previous research that identified adverse drug reactions to be the most common cause for drug-related emergency department visits.⁷

Limitations

We found significant variability in the reporting rates among community pharmacies. This finding is in line with results from previous research and may imply under-reporting of quality-related events to some extent.^{10,22} In addition, our findings represent quality-related events reported from a single reporting system in a single province. Because community pharmacies are largely governed by provincial pharmacy regulatory authorities, our results may not be generalizable to the rest of Canada. Nonetheless, our findings will provide important comparative data for other provincial pharmacy regulatory authorities in Canada, which are mandating quality-related event reporting in the coming years.^{23,24}

Conclusion

We aimed to characterize quality-related events reported from community pharmacies in Nova Scotia. We found that these events differ from those reported in institutional settings

Table 4: Total number of QREs, number of harm QREs and proportion of harm QREs for each type

Type	No. (%) of QREs	No. (%) of harm QREs*	Proportion of harm QREs*, %
Incorrect dose or frequency	25 089 (25.6)	254 (27.4)	1.0
Incorrect quantity	19 619 (20.0)	19 (2.0)	0.1
Incorrect drug	13 951 (14.2)	185 (19.9)	1.3
Incorrect strength or concentration	10 508 (10.7)	187 (20.2)	1.8
Incorrect prescriber	8454 (8.6)	0 (0)	0.0
Incorrect patient	5685 (5.8)	32 (3.4)	0.6
Incorrect duration of treatment	5048 (5.1)	18 (1.9)	0.4
Incorrect dosage form or formulation (including not splitting tablets as per patient's request)	3281 (3.3)	32 (3.4)	1.0
Omitted medication or dose	1919 (2.0)	58 (6.23)	3.0
Incorrect route of administration	1121 (1.1)	7 (0.8)	0.6
Incorrect storage	857 (0.9)	3 (0.3)	0.4
Incorrect third-party billing	803 (0.8)	1 (0.1)	0.1
Drug therapy problem — drug–drug/OTC/natural health product interaction	506 (0.5)	19 (2.0)	3.8
Drug therapy problem — documented allergy	447 (0.5)	31 (3.3)	6.9
Drug therapy problem — contraindication	356 (0.4)	12 (1.3)	3.4
Expired medication	191 (0.2)	9 (1.0)	4.7
Drug therapy problem — adverse drug reaction	188 (0.2)	56 (6.0)	29.8
Drug therapy problem — drug–disease interaction	63 (0.1)	3 (0.3)	4.8
Drug therapy problem — drug–food interaction	11 (0.0)	2 (0.2)	18.2
Total	98 097 (100)	928 (100)	–

Note: OTC = over the counter, QRE = quality-related event.
 *Harm QREs are associated with a patient outcome of mild harm, moderate harm, severe harm or death (Table 2).

with respect to patient outcome, medication system stages and types of event. Although our findings provide an important first step in describing quality-related events in community pharmacies, they are unable to provide insight into the various factors that may contribute to these events. Future research should focus on the medications involved and qualitative analysis of the event description to better understand the potential contributing factors associated with quality-related events in community pharmacy practice. Combined with quantitative analysis, such research will provide a comprehensive view of key safety risks and trends, thus allowing for the development of recommendations to improve medication safety.

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