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Title	Quality-related events reported by community pharmacies in Nova Scotia: a 7-year descriptive analysis
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Reviewer 1	Cheryl Sadowski
Institution	Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, Edmonton, Alta.
General comments (author response in bold)	<p>Introduction</p> <p>Some definitions are required, including "medication system stages" - does this mean a particular set of processes in the pharmacy? The DIN is one example that is defined, but other terms need equal description. Another term that is in the mandatory fields to report is 'prescribing'. Most people assume they know what this is, but it does need to be clarified if it is the writing (transcription) of an order, or the thought process on deciding on a medication. In table 1 "no error" should also be defined. I would assume if a QRE happened an error took place?</p> <p>The "medication system stages" and "quality related events" are defined in the first paragraph of the "Introduction" section. We also included definitions of other terms (e.g. "no error") in Figure 1. If a QRE happens, it does not necessarily mean that an error has taken place. Please refer to our definition of QRE in the first paragraph of the "Introduction" section.</p> <p>Methods</p> <p>For this new process was there validation that the staff entering the data were accurate? For example, were test cases given, or is there a sampling process for auditing? It's unclear for example, if every pharmacist would rank the severity of an event equally.</p> <p>The last sentence of the first paragraph explains that the provincial pharmacy regulatory authority regularly audits and ensures pharmacies' adherence to the Standards of Practice for Continuous Quality Assurance, which include the reporting of quality related events into the Community Pharmacy Incident Reporting system. Pharmacy professionals in Nova Scotia received training and support on how to report QREs to the reporting system. The patient outcome (i.e. severity) of a QRE is usually determined by the pharmacy professionals based on their professional/clinical judgement.</p> <p>I had originally assumed the study was about human subjects, but a veterinarian discovering QRE's means that the products were also dispensed for animals, correct? If so, it would be helpful to state that, and perhaps a reference about what percentage of scripts in a pharmacy are for vet patients.</p> <p>Prescriptions for animals can be ordered by veterinarians and dispensed by community pharmacies in Canada, although the majority of prescriptions dispensed by community pharmacies are for human patients. Since only 0.01% of QREs were discovered by a veterinarian, the proportion is too low to warrant any mentioning or elaboration of this finding in the manuscript.</p> <p>Please comment on compounded prescriptions and if they were included.</p> <p>Compounded prescriptions are often dispensed in community pharmacies in Canada. Therefore, they were included.</p> <p>Please explain the difference between pharmacy technicians and assistants. In some provinces technicians are regulated healthcare professionals, but assistants are not. In this study they are combined in the analysis, but the role each could play in addressing QRE's would be different.</p> <p>Under the subheading "Data Sources", we mentioned that all members of the pharmacy team (e.g., owner, manager, pharmacist, technician, assistant) could report a QRE through the online Community Pharmacy Incident Reporting system. It is expected that regardless of the role, each pharmacy team member would report QREs for the purpose of shared learning and improving medication safety. Therefore, all pharmacy team members should address QREs in a similar way.</p> <p>Results</p> <p>The tables generally provide additional information but it would help the reader if table 3 had subgroups instead of a long list of data. The same for supplemental 3 table - grouping would be easier to follow.</p> <p>Table 3 is now Table 4 in our manuscript. Figure 1 illustrates the various types of QREs in the reporting system. Therefore, it is not necessary to create subgroups in Table 4. Supplemental 3 table has been removed from our manuscript.</p> <p>Tables 5 and 6 are really products of the volume of these drugs being dispensed, versus complexity in ordering or preparing these prescriptions. I might suggest that these tables could be supplemental as well.</p> <p>Tables 5 and 6 have been removed. Our initial analysis pertaining to medications has been removed.</p> <p>Interpretation</p> <p>The content that is present is appropriate. Although this is a descriptive analysis, there are some further steps that could be elaborated on. For example, on table 4 it shows that medications involve a large group or team of people, health professionals and non-professionals, across public and private sectors of the healthcare system. I had originally thought it was a pharmacy-focused problem, but it's actually very broad, meaning that the implications for prescribers and all other health professionals supporting those patients need to be thinking about this issue. The discussion could highlight the importance of communication, responsibility, inter-professional care, etc. The role of interventions or changes in policy that would be desirable could be added as well.</p> <p>Table 4 is now Supplemental 1 table in our revised manuscript. As mentioned above, regardless of the type of "Discoverers", the purpose of QRE reporting is for shared learning and improving medication safety. We compared our findings with previous studies in community and hospital pharmacy settings with respect to patient outcome, medication system stages, and types of QRE reported. We recommended in the "Conclusions" section that future research should focus on the medications involved and qualitative analysis of the event description in order to better understand the potential contributing factors associated with QREs in community pharmacy practice. If these contributing factors are identified in future studies, then comments regarding communication, professional responsibility, and inter-professional care may be more relevant. It may be too premature for us to comment on</p>

	<p>these aspects based on our current findings.</p> <p>I was looking for a bit of commentary on why some drugs are associated with more harm than others, despite lowering rates of dispensing, or why some drugs did not have many QREs. Was there any thought about the formulation, or names of the drugs sounding similar, or other factors? (This would provide insight into supplemental 3 table.)</p> <p>Supplemental 3 table has been removed from our manuscript. Our initial analysis pertaining to medications has been removed.</p>
Reviewer 2	Ali Elbeddini
Institution	University of Colorado Anschutz Medical Campus, Aurora, Colo.
General comments (author response in bold)	<p>Results</p> <p>1- Please change wording on page 9, lines 26-27: "...prescription preparation/dispensing accounting for the largest proportion of harm reports..." Remove the words "harm reports" and replacing it with "QREs". The wording may lead readers to confuse proportion of QREs with proportion of QREs with harm.</p> <p>This is reviewed and addressed in the revised manuscript.</p> <p>2- Please explain how QREs are caught at administration and monitoring/follow-up stages. Could there be under-reporting at these stages? Is there any bias in the sample of these events since they consists of the highest proportion of QREs with harm, although order entry and prescription preparation/dispensing has the highest number of QREs?</p> <p>The medication system stages involved in a QRE were determined by the discoverer. There could be under-reporting is any reporting system and this was addressed in the "Limitations" section.</p> <p>In the third paragraph of the "Interpretation" section, we mentioned that there were fewer opportunities to catch QREs that occur in later stages of the medication-use process, and patients are more likely to identify and report QREs that cause harm. Therefore, this may result in QREs that occurred during administration or monitoring/follow-up having a higher likelihood of resulting in patient harm.</p> <p>3- If possible, would you please clarify which medications results in higher levels of harm for the 20 medications associated with harm (table 6) since the range of harm is broad spanning from mild to death.</p> <p>Table 6 has been removed. Our initial analysis pertaining to medications has been removed.</p> <p>4- Antibiotics have different indications. With no indications written on the prescription, it may be difficult for the community pharmacy to decipher incorrect duration of treatment. Could you please comment on how tetracycline's incorrect durations of treatment were identified (page 10, lines 8-9)? Is this unrelated to incorrect dose/frequency and quantity?</p> <p>Our initial analysis pertaining to medications has been removed.</p>