Expansion of patient safety regulatory requirements in community pharmacy in Canada: The Melissa Sheldrick effect?

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OVER THE PAST 2 DECADES, THE PATIENT SAFETY MOVEMENT has had a large impact on health care in Canada and beyond. Twenty years ago, the Institute of Medicine's report, *To Err Is Human: Building a Safer Health System*, drew worldwide attention to the problem of errors in health care.¹ Here in Canada, the 2004 Canadian Adverse Event Study described the magnitude of errors in Canadian hospitals for the first time.² Other research estimated the annual cost of preventable drug-related morbidity and mortality in older adults in Canada to be \$11 billion.³ By the early 2000s, the Canadian Patient Safety Institute and the Institute for Safe Medication Practices (ISMP) Canada were established, and there was widespread participation in national patient safety campaigns such as Safer Healthcare Now!

Despite this flurry of interest and the development of a national health care movement, much of the activity on medicine error and patient safety remained confined to the institutional setting. Accreditation Canada focused on reducing harm in Canada's hospitals. Requirements for patient safety practices related to pharmacy departments and the medication-use system were developed for hospitals and long-term care facilities. An editorial published in this journal in 2006 stated that "one gets the sense that community pharmacy, as a whole, has fallen behind in the patient safety movement."⁴ One could argue that nearly a decade later, little had changed. An investigative report by the CBC National and CBC Marketplace in January 2015 was highly critical of the safety of community pharmacy practice across Canada.⁵

The one exception to this lack of movement and to the criticism by the CBC investigative report was community pharmacy practice in Nova Scotia. In 2008, 13 pharmacies in the province participated in a patient safety pilot project in partnership with

the provincial pharmacy regulatory authority, the Nova Scotia College of Pharmacists (NSCP). SafetyNET-Rx, a research, evaluation and training collaboration, was established by researchers at Dalhousie University and St. Francis Xavier University to evaluate this pilot project and other patient safety activities in community pharmacy. Input from the pharmacists and technicians in these 13 pharmacies was used by ISMP Canada to create the national Community Pharmacy Incident Reporting system (known as CPhIR). In 2010, based in part on the findings from the pilot study, the NSCP adopted new Standards of Practice for Continuous Quality Assurance, which contained a number of mandatory patient safety practices for community pharmacies.⁶ In the subsequent years, numerous studies by the SafetyNET-Rx team demonstrated the value of these practices in changing the structures and processes of patient care and improved perceptions of safety by pharmacy staff.⁷⁻¹⁶ A recently published study evaluating the first 7 years of the mandatory anonymous reporting by 301 Nova Scotia pharmacies documented 131,031 quality-related events reported by these pharmacies, 98,097 of which were medication related.¹⁷

Despite Nova Scotia's pharmacy regulatory authority adopting these comprehensive patient safety requirements in 2010 and the evidence supporting their use, there was little uptake across the country until very recently. Only in 2017 did a second province, Saskatchewan, adopt similar requirements as Nova Scotia. Since that time, however, every province and territory in Canada has adopted, or is in the process of exploring adoption of, similar standards of practice, as can be seen in Figure 1. What is the reason for this sudden uptake? From what we can discern, it is because of one individual: Melissa Sheldrick.

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FIGURE 1 Components of patient safety requirements for community pharmacies by province/territory

Provinces	Does the province have CQI legislation/standards for practice?	Monitor staff performance, equipment, facilities, and adherence to standards of practice	Manage known, alleged, and suspected medication errors that reach the patient	Report errors/incidents	Report near misses	Report anonymously	Report to an independent, objective third-party organization	Support a national database for sharing learnings arising from trends and patterns	Review pharmacy's aggregate data quarterly	Document quality improvements made resulting from the quarterly meetings of staff	Complete a medication safety self-assessment annually	Educate pharmacy staff on best practices in error/incident management	Encourage open dialogue about errors and other activities to support patient safety culture	Other
Alberta														Accessing and using Netcare, using Chat, Check, Chart model
British Columbia														
Manitoba														New pilot program contains all elements currently missing
New Brunswick														Publishing a practice directive for handling near misses/errors
Newfoundland & Labrador														
Northwest Territories														
Nova Scotia														Scheduled audits + randomly occurring audits
Nunavut														
Ontario														Supplemental standards of practice for each profession
Prince Edward Island														In 2019, mandatory incident reporting, safety self-assessments
Quebec														Encourage an active risk management culture
Saskatchewan														Safety culture assessments, plan to implement "medskim" tool
Yukon

The province does have this requirement in their CQI standards
 The province does not have this requirement in their CQI standards (provinces with all yellow cells have a plan to implement CQI standards or are exploring it)

BOX 1 Survey of patient safety requirements for community pharmacies across Canada

A survey was developed and sent electronically to the 13 registrars of the provincial and territorial pharmacy regulatory bodies or their equivalents in August 2018. The survey asked about the adoption of patient safety/continuous quality improvement requirements for community pharmacies and, if legislation was enacted, the various components of the legislation. Upon receipt of completed surveys and compilation of the initial findings, the registrars were contacted again in September 2018 and asked to verify the initial findings.

We received responses from 11 of 13 provinces and territories (84.6% participation rate). The information for the 2 provinces/territories that did not respond was captured from various online documents, and all results were sent back to these jurisdictions for feedback and approval. The majority of the surveys were completed by the registrars themselves, while a few chose to delegate the survey completion to another position (i.e., director of professional practice). Two provinces (British Columbia and Newfoundland & Labrador) and the 3 territories indicated that they did not yet have legislation/standards but were currently in the process of implementation. The other responding provinces all have existing legislation/standards. As Figure 1 demonstrates, there are considerable differences between these provinces and territories on the specifics of the legislation.

In 2016, Ms. Sheldrick's 8-year-old son Andrew died after a medication error at a compounding pharmacy in Ontario.¹⁸ A coroner's report found that the wrong medication had been included in the compound and was directly responsible for his death. Following the release of the report, Ms. Sheldrick became a forceful advocate for improving the safety of Canada's community pharmacies. She met with the Ontario Minister of Health who, in turn, charged the Ontario College of Pharmacists to engage the issue. She appeared on national media and spoke at provincial pharmacy conferences and at the Canadian Pharmacists Conference in June 2018. In 2 short years, she accomplished what the evidence from Nova Scotia could not: she persuaded all of the provincial pharmacy regulatory bodies to implement or explore implementing new standards of practice.

This is an interesting case study in the eventual widespread adoption of a health policy affecting community pharmacy practice in Canada that seems to have occurred as more of a social movement rather than because of the evidence. We applaud Melissa Sheldrick for being a voice for change and for the provincial pharmacy regulatory authorities for finally implementing new standards of practice and regulations. However, we still have considerable work ahead in optimizing and standardizing medication error reporting and continuous quality improvement/assurance (CQI/A) practices across Canada.

As seen in Figure 1, there remains considerable variation in reporting and CQI/A practices across the provinces and

territories. Potentially, harmonization of legislation, including reporting practices for medication incidents and near misses, could help ensure continuity and standardization for safe community pharmacy practice across Canada. We also recommend additional research into the evaluation of these practices as has been done so successfully in Nova Scotia. Differences across available error reporting systems constitute a further issue, and ideally, we should work toward creating one central database of all medication incidents and near misses or, failing that, a commitment and process for sharing information about these events so pharmacies can learn from each other.

While community pharmacy has trailed the patient safety movement in institutional settings, this essential public health service has moved a long way forward in just the past 2 years. Not all medication incidents can be prevented, but the Nova Scotia experience has taught us that the reporting of errors by community pharmacists can help identify the requisite conditions pharmacists need to enhance safety in their practice. Melissa Sheldrick's strong advocacy has shown us that pharmacy patients across Canada stand to benefit as a result of enhanced reporting.

The movement toward Canada-wide community pharmacy error reporting and the integration of CQI/A practices to enhance patient safety is now well under way. That is an outcome of which we can all be proud and for which we can credit Melissa Sheldrick. ■

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Washington (DC): National Academies Press; 1999.
2. Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170(11):1678-86.
3. Kidney T, MacKinnon NJ. Preventable drug-related morbidity and mortality in older adults: a Canadian cost-of-illness model. *Geriatrics Today* 2001;4:120.
4. MacKinnon NJ. Is community pharmacy falling behind in the patient safety movement? *Can Pharm J* 2006;139(5):23-24, 27.
5. Pharmacists fail to catch drug interactions by Megan Griffith-Greene. January 19, 2015. Available: www.cbc.ca/news/business/pharmacists-fail-to-catch-drug-interactions-1.2917327 (accessed Dec. 14, 2018).
6. Nova Scotia College of Pharmacists. *Standards of practice: continuous quality assurance programs in community pharmacies*. Halifax: Nova Scotia College of Pharmacists; 2010. Available: https://www.nspharmacists.ca/wp-content/uploads/2018/01/SOP_ContinuousQualityAssuranceProgramsInCommunityPharmacies.pdf (accessed Dec. 14, 2018).
7. Boyle TA, Mahaffey T, MacKinnon NJ, Deal H, Hallstrom LK, Morgan H. Determinants of medication incident reporting, recovery, and learning in community pharmacies: a conceptual model. *Res Social Adm Pharm* 2011;7(1):93-107.
8. Boyle TA, MacKinnon NJ, Mahaffey T, Duggan K, Dow N. Challenges of standardized continuous quality improvement programs in community pharmacies: the case of SafetyNET-Rx. *Res Social Adm Pharm* 2012;8(6):499-508.
9. Boyle TA, Scobie AC, MacKinnon NJ, Mahaffey T. Implications of process characteristics on quality-related event reporting in community pharmacy. *Res Social Adm Pharm* 2012;8(1):76-86.
10. Scobie AC, Boyle TA, MacKinnon NJ, Mahaffey T. Head office commitment to quality-related event reporting in community pharmacy. *Can Pharm J (Ott)* 2012;145(3):e1-6.
11. Boyle TA, Scobie AC, MacKinnon NJ, Mahaffey T. Quality-related event learning in community pharmacies: manual versus computerized reporting process. *J Am Pharm Assoc* 2012;52(4):498-506.
12. Boyle TA, Ho C, MacKinnon NJ, Mahaffey T, Taylor JM. Safety implications of standardized continuous quality improvement programs in community pharmacy. *J Pharm Pract* 2013;26(3):228-36.
13. Boyle TA, Bishop AC, Duggan K, et al. Keeping the "continuous" in continuous quality improvement: exploring perceived outcomes of CQI program use in community pharmacy. *Res Social Adm Pharm* 2014;10(1):45-57.
14. Boyle TA, Bishop AC, Mahaffey T, et al. Reflections on the role of the pharmacy regulatory authority in enhancing quality related event reporting in community pharmacies. *Res Social Adm Pharm* 2014;10:387-97.
15. Boyle TA, Bishop AC, Overmars C, et al. Uptake of quality-related event standards of practice by community pharmacies. *J Pharm Pract* 2015;28(5):442-9.
16. Boyle TA, Bishop A, Morrison B, et al. Pharmacist work stress and learning from quality related events. *Res Soc Admin Pharm* 2016;12(5):772-83.
17. Boucher A, Ho C, MacKinnon NJ, et al. Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis. *CMAJ Open* 2018;6(4):E651-6.
18. Russell A. How widespread are prescription errors in Canada? We don't really know. *Global News*. December 4, 2016. Available: <https://globalnews.ca/news/3103260/how-widespread-are-prescription-error-problems-in-canada-we-dont-really-know/?sf44799285=1> (accessed Dec. 14, 2018).