Risk Management in Community Pharmacy

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INTRODUCTION

Similar to high-risk industries like aviation and the operation of nuclear power plants, the medication distribution system has a potential to cause harm as well as benefit. For example, the following medication incident was voluntarily reported to ISMP Canada.

"A patient received a prescription for digoxin 0.25 mg to be taken once daily. At the pharmacy, both the technician and the pharmacist misread the numeral "2" as "7" and therefore misinterpreted the prescription as "digoxin 0.75 mg po daily". When a drug information reference was consulted to verify appropriateness of the dose, the dosage used in "rapid digitalization" was misinterpreted as an appropriate daily dose for digoxin. Several days later, after taking daily doses of 0.75 mg, the patient experienced nausea and dizziness, and admission to hospital was required." [1]

Incidents like the one above are not unique. They likely occur every day in pharmacies across Canada. Is there anything that pharmacists can do in order to prevent the above from happening? At a minimum, risk management strategies should be in place in order to help reduce the risk of errors. Literature related to risk management in community pharmacy practice covers topics ranging from development of a culture of safety to actual measures that improve safety such as bar-coding and clinical support tools. Fortunately, most of these topics have been incorporated into continuous quality improvement (CQI) tools, which are mostly readily accessible to pharmacy practitioners.

In this article, we will focus on selected CQI tools that can facilitate risk management within the community pharmacy practice setting. In order to implement changes in a pharmacy, a culture of safety must first

TABLE 1. SUMMARY OF CONTINUOUS QUALITY IMPROVEMENT (CQI) TOOLS [2-6]

Authors / Organization	Purpose of CQI Tool	Focus of CQI Tool
UK: Manchester Patient Safety Assessment Framework (MaPSAF) [2]		
University of Manchester, Manchester, UK	• To facilitate reflection and raise awareness on patient safety. • To stimulate discussion about strengths and weaknesses of patient safety culture. • To reveal any differences in perception on patient safety among staff members. • To identify areas for improvement. • To evaluate safety interventions and monitor progress over time. • To develop a mature safety culture.	Illustrate dimensions of patient safety and risk management culture that are applicable to community pharmacy practice: 1. Commitment to patient safety 2. Incident reporting 3. Investigating causes of incidents 4. Learning from incidents 5. Communication 6. Staff management 7. Staff education and risk management training 8. Teamwork
UK: Pharmacy Safety Climate Questionnaire (PSCQ) [3]		
University of Manchester, Manchester, UK	To seek pharmacy staff members' viewpoints on patient safety issues and incident reporting in their community pharmacy practice setting.	This 34-item questionnaire correlates to dimensions of patient safety and risk management culture in the MaPSAF (see above). This tool was developed by the University of Manchester and validated in several European countries [8]. See Table 2 for relationship between MaPSAF and PSCQ.
US: Pathways for medication safety®: Looking collectively at risk [4]		
American Hospital Association, Health Research and Educational Trust, and ISMP (US)	Help hospital personnel assess and act on medication risks. Selected components can be applied to community pharmacy practice.	Describe processes to enable implementation of medication safety initiatives. Offer assessment tools to evaluate and monitor progress of risk reduction strategies.
US: Improving medication safety in community pharmacy: Assessing risk and opportunities for change (AROC) [5]		
ISMP (US)	To educate pharmacists on error prone processes and strategies to reduce risks and enable self-assessment	Recommend strategies that can reduce errors from occurring in 10 Key Elements of medication use processes: 1. Patient information 2. Drug information 3. Communication of drug orders and other drug information 4. Drug labelling, packaging, nomenclature 5. Drug standardization, storage, distribution 6. Medication device acquisition, use, monitoring 7. Environmental factors, workflow, staffing patterns 8. Staff competency and education 9. Patient education 10. Quality processes and risk management AROC also includes useful information in appendices such as dangerous abbreviations and look-alike drug names with recommended tall man lettering.
Canada: Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy™ (MSSA-CAP) [6]		
ISMP Canada	Identify and assess safe medication practices in community/ambulatory pharmacy; and monitor improvements in safe medication practices via the online interface	Categorize known medication safety strategies into 10 Key Elements (see below) and 20 Core Distinguishing Characteristics. 1. Patient information 2. Drug information 3. Communication of drug orders and other drug information 4. Drug labelling, packaging and nomenclature 5. Drug standardization, storage and distribution 6. Use of devices 7. Environmental factors 8. Staff competence and education 9. Patient education 10. Quality processes and risk management The MSSA-CAP is being updated in 2012 in order to accommodate the expanding scope of pharmacy practice in Canada and a new online interface is currently under development.

Recommended Use of CQI Tool
Encourage individual staff member to honestly assess the pharmacy practice setting on the various aspects of risk management culture. This exercise will take approximately 1 hour to complete. Discuss individual ratings with the rest of the pharmacy team. Identify areas for improvement; discuss strategies, evaluate interventions, and track changes or progress over time. **Available at:** http://www.pharmacy.manchester.ac.uk/cip/resources/MaPSAF
Encourage individual staff member to complete the questionnaire honestly; to indicate his/her agreement or disagreement with the statements or items about the community pharmacy in which he/she works. This exercise will take approximately 10 to 15 minutes to complete. Then, as a team, discuss and identify areas for improvement, implement interventions, evaluate, and track changes over time. **Available at:** http://www.pharmacy.manchester.ac.uk/cip/resources/pscq/
Pharmacy managers can use this manual as a guide for fostering a culture of safety in the practice setting. Section 2.1 – Building Blocks for Assessing Risk and Section 2.2 - Failure Mode and Effects Analysis can serve as a universal educational tool for all pharmacy practitioners. **Available at:** http://www.medpathways.info/medpathways/tools/tools.html
Pharmacy staff members can consult this document and reflect on current practices and identify areas for improvement. **Available at:** http://www.ismp.org/communityRx/aroc/
Pharmacy members can complete the MSSA-CAP items as a team during 2 to 3 one-hour meetings. Use the MSSA-CAP online interface to track trends and monitor progress or improvements in safe medication practices. **Available at:** https://www.ismp-canada.org/amssa/index.htm

be in place that encourages blame-free reporting and shared learning. The CQI tools *Manchester Patient Safety Assessment Framework (MaPSAF)* [2] and *Pharmacy Safety Climate Questionnaire (PSCQ)* [3] are a good starting point to evaluate the culture of safety in your pharmacy. Once a patient safety culture is established, the *Pathways for Medication safety®: Looking Collectively at Risk* [4] document can facilitate a top-down approach (from management to frontline staff) to enhance the culture of safety and assist the investigation of a near-miss or a medication incident.

Finally, tools such as ISMP (US) *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change (AROC)* [5], and the ISMP Canada *Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy TM (MSSA-CAP)* [6] can be used to improve existing medication distribution systems and encourage shared learning from peers.

Further information regarding the above CQI tools can be found in Table 1 and Table 2.

CULTURE OF PATIENT SAFETY: EMBRACING CHANGE, INCIDENT REPORTING, AND SHARED LEARNING

The ability for an organization to develop risk management strategies starts with voluntary incident reporting by healthcare professionals. Unfortunately, fear of punitive action often hampers practitioners' willingness to report. [4] To encourage reporting and shared learning, organizations must move from the culture of "blame and shame" to a culture of patient safety that embraces the possibility of human errors and focuses on developing more resilient systems. For instance, the following incident was voluntarily reported to ISMP Canada by a practitioner for the purpose of shared learning:

"In a community pharmacy, bisoprolol 5 mg tablets were dispensed to a patient instead of bisacodyl 5mg tablets. The error was discovered when the pharmacist was returning the stock bottles to the shelf and realized that although a prescription had been prepared from the stock bottle of bisoprolol, no bisoprolol prescriptions had recently been processed by the pharmacy." [7]

TABLE 2. RELATIONSHIP BETWEEN MAPSAF AND PSCQ [3]

Dimensions of Patient Safety and Risk Management Culture in MaPSAF	Items in PSCQ
(1) Commitment to patient safety (Correspond to 3 items in PSCQ)	7, 17, 22
(2) Incident reporting (Correspond to 6 items in PSCQ)	4, 10, 14, 20, 25, 30
(3) Investigating causes of incidents; and (4) Learning from incidents (Correspond to 8 items in PSCQ)	3, 11, 13, 19, 23, 28, 32, 34
(5) Communication (Correspond to 6 items in PSCQ)	1, 6, 9, 16, 21, 27
(6) Staff management (Correspond to 5 items in PSCQ)	2, 12, 24, 29, 31
(7) Staff education and risk management training (Correspond to 3 items in PSCQ)	8, 18, 33
(8) Teamwork (Correspond to 3 items in PSCQ)	5, 15, 26

The shared learning from the above incident is as follows:

"Because both "bisoprolol" and "bisacodyl" begin with the letters "bis", these medications may be stored side by side in both community and hospital dispensaries. Cues may or may not be present to alert healthcare professionals to the potential for a mix-up. In this particular incident, the medications had been obtained from the same generic manufacturer. In such circumstances, the potential for a mix-up may be increased if the labelling and packaging are similar, and also because the drugs' brand names have the same prefix (the abbreviated manufacturer's name) followed by the name "bisoprolol" or "bisacodyl"." [7]

What can we do to develop a more resilient medication distribution system? With respect to the above incident, the following risk management strategies can be considered.

1. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION

"Review pharmacy storage areas to determine if look-alike/sound-alike products are stored in close proxim-

ity. Consider the following strategies to enhance differentiation:

– Purchase look-alike/sound-alike products from different manufacturers.
– Place warning labels on look-alike/sound-alike products and/or in their storage areas (regardless of whether they are stored separately or in close proximity)." [7]

2. QUALITY PROCESS AND RISK MANAGEMENT

Consider the use of bar-coding technology to allow for automated verification of the dispensed drug or conduct independent double checks (for example, by marking or verifying the Drug Identification Number on the prescription hard copy) during the dispensing process. [7]

As mentioned above, the *Manchester Patient Safety Assessment Framework (MaPSAF)* and the *Pharmacy Safety Climate Questionnaire (PSCQ)* are CQI tools that pharmacists can use to evaluate and monitor the culture of safety in the pharmacy. The MaPSAF was developed by the University of Manchester and is based on the notion that a culture

of safety enables safe medication practices. [2] It includes a matrix that describes the 8 dimensions of patient safety culture. [2] To further assess a pharmacy's safety culture, pharmacies can use the PSCQ, a 34-item questionnaire to generate staff feedback, reflection, and discussion for CQI purposes. [3] Each of the 34 items directly correlates to the 8 dimensions of patient safety in the MaPSAF. Table 2 illustrates the relationship between the PSCQ and the MaPSAF.

While cultural limitations can be identified relatively easily, implementation of change is a more challenging task. The existing culture may make pharmacy staff members feel insecure when they are involved in a near-miss or a medication incident. Therefore, senior management or pharmacy managers should be the driver and leader in embracing and enhancing the culture of safety. [4] Staff will report and hence discuss a near-miss or an incident only if they feel comfortable to do so. Pharmacy managers can refer to the *Pathways for Medication Safety®: Looking Collectively at Risk* [4] or http://www.justculture.org/ for strategies about embracing

change and fostering a culture of patient safety in the practice setting.

MEDICATION SAFETY SELF-ASSESSMENT AND LEARNING FROM PEERS

Policies and procedures of individual pharmacies may differ, but elements of patient care and pharmacy workflow should be similar to a certain extent. This allows pharmacists and pharmacy technicians to learn from their peers. Consider the bisoprolol and bisacodyl mix-up incident described above, it is conceivable that similar incidents could occur at any pharmacy. [7] By reporting this medication incident to ISMP Canada, the pharmacist offered the opportunity to other health care practitioners to learn from this event. In an effort to summarize shared learning from reported near misses and medication incidents, ISMP US and ISMP Canada developed the *Improving medication safety in community pharmacy: Assessing risk and opportunities for change (AROC)* and the *Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy TM (MSSA-CAP),* respectively. These risk assessment tools categorize known medication safety strategies into 10 Key Elements and 20 Core Distinguishing Characteristics. Pharmacists can use them to assess the safety of medication practices in their work settings and identify opportunities for continuous quality improvement.

CONCLUSION

As pharmacists in Ontario take on additional responsibilities, we must first ensure that we have an adequate risk management system in place to strive for patient safety and medication safety. Pharmacies can first use the MaPSAF and PSCQ to assess their safety culture. Pharmacy managers can subsequently use *Pathways for Medication Safety®: Looking Collectively at Risk* to devise a plan for embracing change and enhancing the cultural competency of the practice setting. Finally, medication safety self-assessments such as the AROC from ISMP US and the MSSA-CAP from ISMP Canada can help pharmacists learn from each other and improve the medication distribution system as a whole. Risk management is a collaborative and iterative process. We recommend using the above CQI tools with all staff in the pharmacy at least annually in order to ensure continuous quality improvement.

REMARKS

ISMP Canada Safety Bulletins (https://www.ismp-canada.org/ISMPCSafetyBulletins.htm) are designed to disseminate timely, targeted information to reduce the risk of medication incidents. The purpose of the bulletins is to confidentially share the information received about medication incidents which have occurred and to suggest medication system improvement strategies for enhancing patient safety. The bulletins will also share alerts and warnings specific to the Canadian market place. Complimentary subscription is available at https://www.ismp-canada.org/subscription.htm.

Additional relevant Continuing Education (CE) opportunities can be found on page 57.

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