

COMPASSTM
(Community Pharmacists Advancing Safety in Saskatchewan)
Continuous Quality Assurance (CQA) Pilot Project
Concept Paper

Introduction

Patient safety has become a critical concern throughout the healthcare system in Canada. No sector of health care is immune to the occurrence of errors which puts patient's safety at risk. Research in the area of medication related errors has primarily been focused on the incident rates in hospitals, with very little research being done on rates in community pharmacies. However, some limited research that was done in the UK (Ashcroft, et al) showed that QRE's (quality related events) occurred at a rate of 26 errors for every 10,000 prescriptions dispensed in community pharmacies, with the majority of these being potentially preventable. Currently, there is no central repository for the recording and tracking of the occurrence of medication errors in community pharmacies within Saskatchewan. Pharmacies may have systems to report their errors, but their systems don't go far enough in evaluating the error for the root cause, implementing a plan to address the error, or allowing pharmacists to learn from each other's errors.

The Ministry of Health has included in its health system planning, a focus on a culture of safe patients and safe workplaces; with some of their goals focusing on medication safety. Any actions focused on enhancing the safety of the medication system early in the health care process is a preventative approach and has significant potential to beneficially impact patient safety. Given community pharmacy's key role in this early area of the health care process, an effective continuous quality improvement (CQI) process for community pharmacies that is both proactive and responsive, and that enables enhancement of the safety culture of the pharmacy as well as its practices, can be expected to have a substantial impact on patient safety and therefore align with the Ministry of Health's health system planning.

Continuous Quality Improvement – Proactive Assessment

The safety culture of a pharmacy refers to the values, attitudes, and behavioral norms that exist in a pharmacy in the form of both its personnel (management and staff) and its policies (written and unwritten), that predict the pharmacy's ability to effectively deal with potential and realized safety issues for continual improvement of patient safety.ⁱⁱ A culture that is predominantly one of "blame and shame" hinders acknowledgement and reporting of incidents and errors, preventing the opportunity to learn from them.ⁱⁱⁱ The evolution of a pharmacy's safety culture such that pharmacy team members no longer deny or hide incidents because of shame, but rather acknowledge that as humans, all practitioners are capable of erring - but "good" or "responsible" practitioners manage them properly, would provide the conducive environment needed to realize the adoption of optimal patient safety activities into practice.^{iv}

In order to transform the safety culture of a pharmacy so that incidents and errors are seen as an opportunity to learn and minimize reoccurrence, its current state must be assessed, acknowledged and understood.^{v,vi} By self-assessing its safety culture through the attitudes and perceptions of its workforce at a given point in time, a pharmacy can proactively develop plans to address identified issues.^{vii} Similarly, regular self-assessment of the safety of its practices enables a pharmacy to proactively identify and address weaknesses in its system, rather than wait for a failure in the system to identify areas for improvement. Therefore, ongoing proactive assessment of both the safety culture of the pharmacy and the safety of its medication system are important components of an effective continuous quality improvement program.

Continuous Quality Improvement – Learning from Quality Related Events

In addition to proactive self-assessment of the safety of its practices, a community pharmacy has a valuable opportunity to identify and address areas for improvement through analysis of its medication incidents and “near hits”. These events, plus those that originate from a point in the medication system prior to a prescription entering the sphere of community pharmacy and which are identified and subsequently rectified by the pharmacist (e.g. those that arise during assessment and prescribing, etc.) are collectively known as Quality Related Events (QREs). QREs represent one of the most frequently occurring and serious issues impacting patient safety.^{viii} Quality related events not only pose direct significant health risks to Canadians; when made public, such events also indirectly negatively impact health outcomes indirectly through distrust in the medication system and resultant poor compliance. However, if managed properly, QREs provide a valuable opportunity to identify changes which can enhance the safety and quality of the medication system both within a specific pharmacy and if shared, across the profession.^{ix}

Unfortunately, despite their frequency of occurrence, their potential implications to both the pharmacy and public, and the presence of national standards, provincial legislation and corporate policies requiring pharmacies to document and report these errors, the under-reporting of QREs in the community pharmacy setting is high.^x The negative connotation associated with QREs for many pharmacy staff, including inferred messages of diminished self-efficacy, and the fear of retribution see many staff reluctant to openly discuss and admit to QREs. Studies have identified that a key to enhancing the reporting of QREs is the creation of a culture where staff feel confident to report without fear, and where this is solidified by the ability to report QREs anonymously.^{xi xii} In addition, given the lack of shared learning from in-house reporting systems, improvement to the medication system as a whole through shared learning from QREs across the profession will only be realized if the QREs are reported to an independent, objective third party organization.^{xiii} Finally, a unified effort is required to create an open dialogue on QREs between pharmacy staff and management, regulatory bodies, and researchers of patient safety, healthcare management, and business (e.g., information systems, quality management) to achieve enhanced patient safety.

COMPASS™ CQA Pilot project – The Impetus

The Saskatchewan College of Pharmacists (SCP) requires pharmacies in Saskatchewan to establish and maintain a quality management program as per the NAPRA Model Standards of Practice, 2009. SCP recognizes the importance of continuous quality improvement (CQI) process which evaluates and ensures both medication safety (keeping patients safe as they use medications) and safe medication practices (processes that are in place that assures patients safe access to medications) in order to enable pharmacies to provide optimal patient care. However, routine audits of pharmacies undertaken by SCP identified that many pharmacies were uncertain of what a quality management program entailed, or where they could access information or resources to assist them in meeting this requirement. Furthermore, SCP does not have specific criteria against which quality management programs established by some pharmacies could be assessed.

Another impetus of the pilot project is the focus on quality in Saskatchewan by the Ministry of Health and the health system goals. Pursuit of a culture of safety is an expectation of everyone in the health system, including those who are not within the publicly funded system.

Along with the above issues, an increasing number of complaints of drug related adverse events were being reported to SCP, leading to elevated costs associated with the complaints and discipline process. Therefore, the SCP Council wanted to explore a strategy that would allow for a CQI process that would serve as a resource for pharmacies requesting assistance in meeting their standards of practice requirement, and a standard against which the SCP inspectors could assess CQI programs in community pharmacies across the province. As well, as potentially have the impact of decreasing complaints, align SCP with the strategic directions of the Ministry of Health, and ultimately make the medication system safer.

Therefore, the SCP Council invited Certina Ho, of ISMP Canada to provide a presentation highlighting medication safety initiatives and a method to ensure continuous quality assurance (CQA) in community pharmacies in Sask. The SCP council heard about the components of an effective Continuous Quality Improvement (CQI) process and how these components could be used to develop and implement a CQA pilot project in Saskatchewan. The resultant

process that was determined will be used in the Sask. pilot project; named COMPASS™ (Community Pharmacists Advancing Safety in Saskatchewan) was modeled after the very successful SafetyNET-Rx project in Nova Scotia and a similar CQA pilot project in Prince Edward Island and Newfoundland and Labrador.

COMPASS™ Pilot Project – A Continuous Quality Improvement Program

The COMPASS™ (Community Pharmacists Advancing Safety in Saskatchewan) pilot project proposes to recruit a representative sample of at least 10 pharmacies to participate in the pilot project. The specific goals of the COMPASS™ pilot project include:

- providing an open dialogue between pharmacy staff, community pharmacies, regulatory bodies, on quality related events;
- disseminating the knowledge needed to enable community pharmacies to assess and benchmark their own quality management and improvement practices in a systematic and validated way;
- assessing the feasibility of implementation and/or adaption of the Safety-NET-Rx process in order to have a standardized, and packaged process that pharmacies can adopt to identify, report, and manage QREs;
- partnering with a growing community within pharmacy concerned with medication safety;
- identifying the major organizational culture and change management issues that may promote or hamper the use of a CQA program, and QRE reporting;
- assessing the feasibility as a performance measurement system for compliance with our standards of practice.

The COMPASS™ pilot project that will be conducted in Saskatchewan will be a partnership between the Saskatchewan College of Pharmacists, the Institute of Safe Medications Practices (ISMP Canada)) and SafetyNET-Rx.

The COMPASS™ pilot project will be modeled after the SafetyNET-Rx pilot project conducted in Nova Scotia from 2010 to 2011 due to the great deal of promise it showed in changing the culture of safety in Nova Scotia in community pharmacies. SafetyNET-Rx provided the tools and support for pharmacists and pharmacy technicians to anonymously report errors, proactively evaluate the safety of their systems, respond to errors that occurred and develop action plans to better their systems, with the goal of continually trying to improve.

Safety-NET-Rx encouraged pharmacies to apply a set of standardized business processes, quality management (QM) practices (e.g., continuous quality improvement, business intelligence iterative improvement cycle, root-cause analysis), and integrated information technologies (IT) to identify, report, analyze and learn from QREs. In addition to providing a complete quality management program, SafetyNET-Rx also presented recommendations to community pharmacies on how to address organizational culture, resistance to change, and business process redesign issues that may impact its adoption and success. The recommendations and lessons learned during the SafetyNET-Rx pilot projects will be incorporated into the COMPASS™ pilot project.

The same components will be used that were used during the SafetyNET-Rx program, which were designed to enhance the safety of the medication system in community pharmacies in Nova Scotia.

The key components of the COMPASS™ pilot project are:

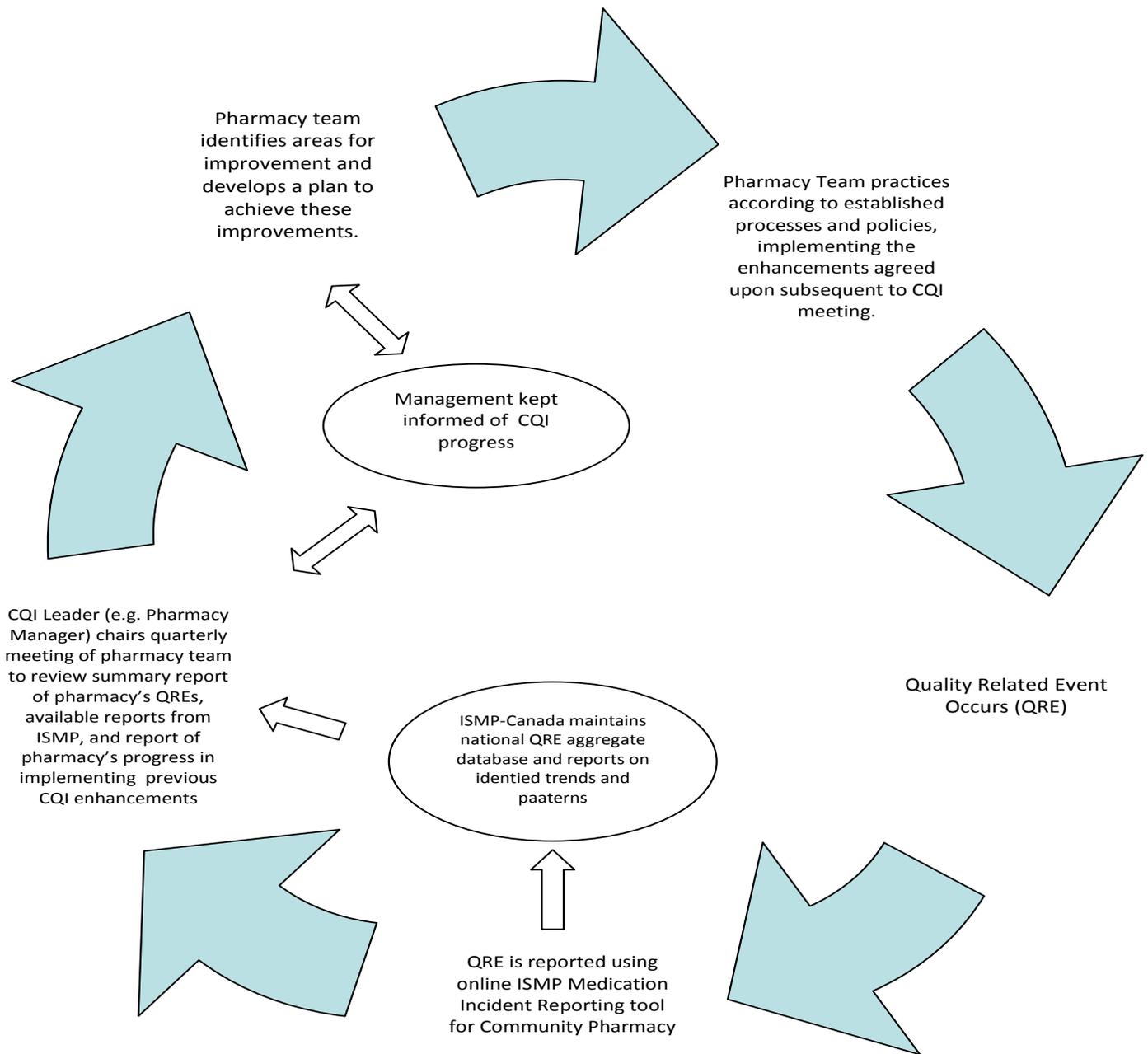
- Ongoing proactive self-assessment of both the safety culture of the pharmacy and the safety of its medication system using ISMP Canada's Medication Safety Self-Assessment (MSSA) tool. The purpose of self-assessment is to inform the pharmacy's continuous quality improvement process on an ongoing basis, outside of any incident or event.
- reporting and learning from QREs through anonymous reporting of QREs to an objective, national organization Community Pharmacy Incident Reporting (CPhIR) program for population of a national aggregate database;

- quarterly meetings in which there is regular reflection on reports specific to an individual pharmacy by the pharmacy's team for identification of areas for improvement, development of a plan to achieve these improvements, and ongoing monitoring of the success in realizing these improvements (Figure 1).

The quality related events (QRE) reporting cycle that will be used during the COMPASS™ pilot project was developed by the SafetyNET-RX research team and industry partners, and is called the SafetyNET QRE Reporting Cycle (Figure I). It combines key elements of Quality Management (e.g., Shewhart-Deming cycle, COI) with the latest in integrative information systems. The cycle provides pharmacy staff with the technology, processes, and autonomy to identify, report, and learn from QREs.

Other key pilot project elements include: open discussions on safety culture issues including QREs; access to store-level, provincial, and national aggregate data on QREs for identification of trends and patterns; training sessions on using the electronic tools for reporting QRE's, research on attitudes and perceptions of pharmacy team members with respect to reporting of QRE's, guidance by the technology provider, and provincial regulatory body.

Figure 1: SafetyNET QRE Reporting and Learning Cycle



Evaluation of the COMPASS Pilot Project

Part of the evaluation of the COMPASS™ pilot project will be completed by the SafetyNET-Rx research team. SafetyNET-Rx will be conducting two surveys during the pilot and one post-pilot survey. One of two pilot surveys will be conducted to identify key factors impacting the reporting and learning from quality related events (QREs) in community pharmacies. The second survey that will be conducted will be asking the public for their attitudes and opinions on how safe they feel their community pharmacy is, with respect to quality related events (QREs). The SafetyNET-Rx team will be providing SCP with aggregate results of the findings of the surveys periodically throughout the pilot.

The post-pilot survey will be an exit survey and will identify if there has been any improvement in the key factors that impact reporting and learning from quality related events (QREs).

An evaluation of the process and tools used will also be completed to identify any issues that will need to be addressed when implementing a standard CQI process.

Next Steps

A steering committee will be used to guide the pilot. The steering committee will also review the results of the pilot project evaluation and make recommendations to SCP who will determine the next steps. Those next steps may include a second phase of the pilot project to include additional pharmacies in Saskatchewan. The second phase of the project would include assessing adoption and adherence to the program, and working with the pharmacies to address identified challenges.

Alternatively, the next step may be full implementation of the CQA program in all Saskatchewan pharmacies. Full implementation would include the adoption of and the requirement to comply with the Bylaws and Standards of Practice for CQA programs in all pharmacies in Saskatchewan.

The implementation plan may include using the aggregate data obtained from ISMP-Canada to identify common safety issues amongst pharmacies and implementing plans to help pharmacies address these issues. Common safety issues may also be identified through collaboration with other health care agencies, where strategies will be developed to help Saskatchewan pharmacies address and resolve these issues.

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