

DETERMINANTS OF MANDATED CQI PROGRAM DIFFUSION BY CANADIAN RETAIL PHARMACIES

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Abstract

To proactively address issues of adverse drug event (ADE) reporting and learning, the Nova Scotia (Canada) pharmacy regulatory authority is exploring mandated use by retail pharmacies of a standardized ADE continuous quality improvement (ADE-CQI) program, entitled SafetyNET. This research explores various pre-adoption issues related to this initiative, including current ADE reporting and learning processes, activities that may improve ADE reporting and learning, and the factors that may impact the success of a mandated ADE-CQI program.

Keywords: Quality Management, Health Care Management, Retail Pharmacy, Patient Safety

INTRODUCTION

With a significant aging population, patient safety has become a critical concern throughout the health care system in Canada. A large volume of academic research has highlighted that medication errors and “near misses”, collectively known as adverse drug events (ADEs), represent one of the most frequently occurring and serious issues impacting patient safety. Yet, despite their implications for both the pharmacy and the public, the under-reporting of ADEs in the retail pharmacy setting is high (Kelly, 2004; Ashcroft, Morecroft, Parker, & Noyce, 2006). Recognizing the significant human aspect of their core work flow processes, it is expected that pharmacy staff will eventually make mistakes. Despite potentially negative implications to both the business and patient, such mistakes do however, present opportunities for the entire pharmacy staff, including pharmacists, technicians, and management, as well as the provincial regulators, to learn from these mistakes, and take steps to reduce the likelihood that they reoccur. Subsequently, the underreporting of ADEs, not only places patients and the Canadian health care system at risk, but also represents a lost opportunity for the pharmacy to learn from ADEs

and take steps as an organization (e.g., work flow/dispensing changes) to reduce the likelihood of a similar ADE occurring again. Moreover, due to the unique nature of retail pharmacy practice where multiple pharmacy technicians and pharmacists may work together and where even a patient who frequents the same pharmacy may see different pharmacists at each encounter, the issue of handoffs and transitions of care merits special consideration.

In response to the need for better ADE reporting and organizational learning, the Nova Scotia (Canada) College of Pharmacists (i.e., provincial regulatory body that protects public safety related to pharmacy practice) is exploring mandated use by retail pharmacies within its jurisdiction of a standardized regulatory authority-approved adverse drug event continuous quality improvement (ADE-CQI) program, entitled SafetyNET. SafetyNET applies standardized business processes, integrated information systems (e.g., web-based reporting and analytics), and commonly used continuous quality improvement practices (e.g., root-cause analysis, Shewhart-Deming Cycle) to reduce, better report, and learn as an organization from ADEs. To explore the issue of mandated ADE-CQI program diffusion by retail pharmacies, this research reports initial results (i.e., pre-adoption perceptions) of an 18-month pilot project focused on the adoption of the SafetyNET CQI program by 13 pharmacies in Nova Scotia. More specifically, this study reports pharmacy staff (i.e., management, pharmacists, technicians) perceptions of the sources of ADEs, activities that they believe will improve ADE reporting and learning, and potential determinants of mandated ADE-CQI program diffusion.

ADVERSE DRUG EVENTS IN RETAIL PHARMACIES

Increasing open incident reporting is recommended by the Australian Council for Safety and Quality in Health Care (2001) as well as by the UK Department of Health (2000) in order to develop an increased understanding of ADEs and their causes. Despite this need for better reporting, the bulk of the research on ADEs in retail pharmacies have instead focused on the causes of errors. A US Pharmacopeia report ranked performance deficit (38%), referring to an administrative mistake, as the most common cause for dispensing errors (Santell, et al., 2003). Staffing shortages, lack of patient information, noisy workplace settings, inexperienced staff, and poor lighting are all highlighted by the literature as reasons for an administrative mistake as well as causes of dispensing errors themselves (Malone, Abarca, Skrepnek, et al., 2007; Davidhizer & Lonser, 2003; Szeinbach, Seoane-Vazquez, Parekh, et al., 2007; Moeller, 2003; Wilkins & Shields, 2008). Other commonly reported causes of dispensing errors as ranked by a US Pharmacopia report include policy or procedure not being followed (20%), transcription inaccurate or omitted (15%), incorrect or insufficient documentation (12%), computer entry (11%), lack of communication (10%) and knowledge deficit (10%) (Santell, et al., 2003).

While analysis of ADEs for contributing causes can identify actions to reduce the likelihood of recurrence, this can only occur when they are reported and subsequently managed appropriately. However, there is little research on what motivates pharmacy staff to report ADEs despite the considerable literature on the sources of ADEs in retail pharmacies. Ashcroft et al. (2005a) generate five ascending levels of a safety culture and hence the likelihood of ADE reporting and learning, comprising of: pathological, reactive, calculative, proactive, and generative. Ashcroft et al (2005a) define the generative culture as one where errors are unavoidable and are seen as

learning opportunities where the pharmacies increase the overall quality of health care by sharing the knowledge obtained from error reporting. The generative culture can be considered the greatest manifestation of organizational learning as it integrates risk management in every business process as well as puts a focus on CQI. Ashcroft et al, (2005a) highlight that all UK pharmacies should be striving for a generative culture, but interviews with pharmacy staff confirm that in reality most pharmacies have a pathological culture, the lowest of the stages of safety culture development (Ashcroft et al, 2005b). The pathological culture, as defined by Ashcroft et al, (2005a), is one where error reporting may pose a threat to a pharmacy's reputation or to the job security of pharmacy staff, thus reporting ADEs is avoided whenever possible. In retail pharmacies where a pathological culture prevails, the costs of error reporting are perceived to outweigh the benefits (Ashcroft et al, 2005b). The need for recommendations, best practices, and formal CQI programs are emphasized by the prevalence of the pathological culture in retail pharmacies. A formal CQI program may help encourage a retail pharmacy to move towards a generative culture, as the pharmacy would be providing a safe and supportive environment for learning from ADEs; making reporting more desirable and less of a threat.

Although few studies have explored the determinants of ADE reporting and subsequent procedures within the context of a retail pharmacy, by expanding the scope of the literature search, far more studies have explored this issue within the hospital context. Evans et al. (2006), for example, attempts to determine the barriers to reporting healthcare incidents as well as the familiarity doctors and nurses had with the current incident reporting system. The study found that nurses were more familiar with the incident report forms than doctors (99.8% vs. 93.6%). Evans et al. (2006) also found that nurses completed incident reports far more frequently than doctors (89.2% vs. 64.6%). Various self-perceived barriers to reporting are identified by Evans et al. (2006) with the most common barrier cited being lack of feedback on action taken as a result of reporting. Other common barriers cited by Evans et al. (2006), which have also found individual support in other studies (e.g., Osborne, Biais & Hayes, 1999; Wakefield, et al 1996; McArde, Burns, & Ireland, 2003) include system design (e.g. not enough time to complete forms, forms take too much time to fill out), lack of justification for reporting a "near miss", and delaying filling out a report and ultimately forgetting. Self-perceived barriers to incident reporting pertaining to the workplace culture were less commonly reported but included concern regarding confidentiality, a belief that speaking to the person involved is all that is necessary, a belief that adverse incident reporting is unlikely to lead to system changes, threat of litigation, and lack of support of coworkers.

Force, Deering, Hubbe et al., (2006) highlight in a hospital context that in addition to systems and outcome oriented determinants, a major cause of low ADE reporting is the culture of the hospital. In a case study of a hospital attempting to improve ADE reporting, Force et al. (2006) found that fears of professional humiliation, punitive actions, and retribution were major barriers to ADE reporting. The hospital studied by Force et al. (2006) was able to increase incident reporting significantly to an average of 72.5 reports per month versus the previous average of 14.3 reports per month by allowing the reports to be confidential, redesigning the ADE forms and where they could be found, as well as improving feedback mechanisms. The level of incident reporting increasing significantly can be attributed to the culture of blame within the hospital setting being reduced.

Within the pharmacy, Ashcroft et al. (2006) found that the probability of an ADE being reported was at best on a level of indifference. Though they are different, there are many similarities between hospitals and retail pharmacies in terms of barriers to reporting ADEs. Concerns regarding firm reputation and job security are a high priority to staff, as well as confidentiality of reporting ADEs because of aversion to blame. Also important factors for both pharmacies and hospitals in making a ADE reporting system worthwhile are feedback and organizational learning (Ashcroft & Parker, 2008; Evans, Berry, Smith et al., 2006; Force, et al., 2006).

CQI & SAFETYNET: NOVA SCOTIA'S RESPONSE TO ADEs

Widely used in manufacturing and service organizations, continuous quality improvement (CQI) is a philosophy, encapsulating a set of techniques and principles, focused on continually addressing the root cause of errors, empowering employees to report problems without negative consequences, developing open and seamless information flows, and continually focusing on improving overall levels of quality at all levels of the organization. Despite the widespread use of CQI in both manufacturing and service areas, the adoption of formal CQI programs (along with associated principles and techniques) in the retail pharmacy setting is low; yet its potential in reducing ADEs is significant.

Studies have shown that even some attempt at formally improving quality at the pharmacy can have a significant positive impact. For example, Wiederholt *et al.* (2002) highlight that goal setting and feedback were useful in increasing capacity to detect errors. A control group of participants, who set goals to *maintain* their performance, detected 22% more process errors than they did before goal-setting. Pharmacists who set a personal goal to *improve* performance increased their detection of process errors by 103% by becoming more mindful of their actions on the job (Grasha, 2004). By simply tracking performance, individuals can become more aware of any challenges they face, while cultivating knowledge to overcome these challenges and identify areas to improve. In addition to reducing ADEs, individuals through such efforts, can become more aware of any challenges they face, cultivating knowledge to overcome these challenges, and identify areas to improve. As highlighted by Salsman (2007), “an important avenue for improving the safety of medication-use systems lies in collecting information on incidents, examining the underlying factors, communicating the lessons learned, and implementing change”.

SafetyNET is a regulatory-approved CQI process and support program focused on reducing, analyzing, and learning from ADEs. At the heart of SafetyNET is the SafetyNET Cycle (Figure 1) which combines key elements of quality management (e.g., Shewhart-Deming cycle, root-cause analysis) with the latest in integrative information systems (i.e., web based reporting and analytics). The cycle provides pharmacy staff with the skills, through trained in-store CQI facilitators (i.e., a pharmacist and pharmacy technician), technology, processes, and autonomy to identify, report, and learn from ADEs.

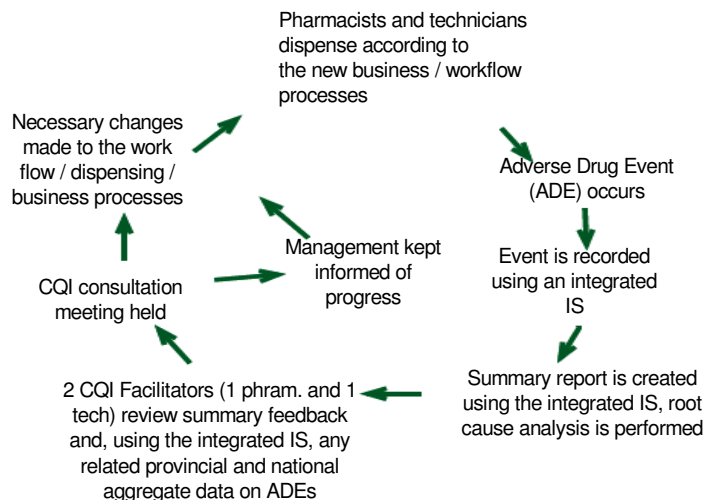


Figure 1 – The SafetyNET Cycle

In addition to the SafetyNET Cycle, other key elements of SafetyNET include: on-line reporting of ADEs to a central repository; completion of a medication safety self-assessment questionnaire; quarterly staff meetings in the pharmacy to discuss reported ADEs; access to store-level, provincial, and national aggregate data on ADEs for analysis of root causes; and training sessions on CQI, business process redesign, and resistance to change.

RESEARCH METHOD & DATA ANALYSIS

This paper reports the results of a pre-SafetyNET assessment of the current ADE reporting and learning processes in retail pharmacies, pharmacy staff’s (i.e., pharmacy management, pharmacists, pharmacy technicians) perceptions of the activities that may improve ADE reporting and learning, and the factors that may promote or limit the success of a mandated ADE-CQI program in their pharmacy.

To explore these issues, a survey was administered to pharmacy staff members from 13 pharmacies in Nova Scotia Canada, who agreed to pilot the SafetyNET program for 18 months. The questionnaire was divided into five sections, capturing: (1) basic descriptive data (e.g., position, size of pharmacy, pharmacy services offered); (2) activities that may reduce ADEs in their pharmacy; (3) current ADE reporting and learning processes in place; (4) factors that may promote or limit their use of a mandated ADE-CQI program; and (5) open-ended question where participants could comment on the general issue of ADE reporting and learning in their pharmacy. A web-based version of this questionnaire was administered to pharmacy staff from the 13 SafetyNET pilot stores in the summer of 2008. Of the 72 staff completing the survey 26 (36.1%) were pharmacists, 18 (25%) pharmacy managers, and 28 (38.9%) pharmacy technicians.

To explore the determinants of mandated ADE-CQI program diffusion, participants were asked a series of questions regarding items that they felt may promote or limit the success of SafetyNET in their pharmacy. Results of performing

MANOVA highlights no mean differences between staff groups (Wilks' Lambda = .295, F (50, 78) = 1.311, p = .140). As a result, the data from all staff members were combined and analyzed collectively. These items were placed into initial groups based on a review of the literature. To determine how well the items encapsulate each group/factor Cronbach's Alpha was applied, with all factors achieving an alpha value greater than the commonly cited 0.7 threshold. Table 1 presents pharmacy staff perceptions of the determinants of mandated CQI-ADE program diffusion.

Table 1- Proposed factors influencing mandated ADE-CQI program diffusion

Factor (Cronbach's Alpha)	Measures (Mean value on 5-point Likert-type Scale)
Individual (.711)	Degree of uncertainty about the longevity of the CQI process (3.07); guaranteed autonomy for reporting errors (3.39); a sense of ownership of the new process (2.82); destigmatization for discussing ADEs (3.28)
Process & Technology (.834)	Ability of the CQI process to actually reduce ADEs at the pharmacy (4.13); impact on day-to-day operations (3.58); difficulty of using the new process (3.61); time required to use the process (3.75); degree of procedural changes needed (3.45); quality of error reporting and tracking tools (3.73); technical support for use (3.76); extent of training on the new process (3.87)
Member Support (.847)	Willingness to commit their time to use the new program (4.01); willingness to try new ideas (3.99); willingness to talk more openly about ADEs (4.03); overall support for the new program (4.01)
Management Support (.899)	Recognize staff who participate (3.96); provide needed financial resources (4.01); reward full disclosure (3.64); enthusiasm about improved reporting / analysis of ADEs (3.98); provide time for staff to participate (3.92)
Regional & National (7.42)	Adoption by other local pharmacies (2.99); improved reputation of the pharmacy (3.51); extent of use by other pharmacies in the province (3.57); feedback from other pharmacies that have used the CQI program (3.51); public awareness of the new CQI program (2.73); extent of provincial support for the new program (3.39)

DISCUSSION

To explore perceptions of the existing ADE learning and reporting processes in retail pharmacies, a variety of questions were asked, ranging from the extent that the process is modern and up-to-date, to the extent the process treats ADEs as a “taboo” subject. Analyzing the data using MANOVA highlights no differences in perceptions between pharmacy managers, pharmacists, and pharmacy technicians (Wilks’ Lambda = .384, $F(34, 78) = 1.408$, $p = .108$). Characteristics of the current in-store ADE process that scored high included the time needed to complete the process (mean = 3.26 on a 5-point Likert-type scale) and the extent that the process is cost effective (mean = 3.14). Characteristics of the process that were considerably lacking include the extent that the process is periodically updated (mean = 2.31), allows errors to be reported unanimously (mean = 2.42), and is reinforced and openly discussed at meetings (mean = 2.51).

To examine actions that can be undertaken by the individual pharmacy or the regulatory authority to increase ADE reporting, a wide variety of questions dealing with store, regional, and national initiatives were presented to respondents. Analyzing the data using MANOVA highlighted differences in perceptions of such initiatives between pharmacy managers, pharmacists, and pharmacy technicians (Wilks’ Lambda = .544, $F(22, 104) = 1.684$, $p = .043$). Examining the data further highlights that group differences exist between not punishing those who report and commit drug errors ($p \leq 0.05$) and mandating error reporting to a provincial centre ($p \leq 0.05$), with the individual group means presented in Table 2.

Table 2 - Differences between managers, pharmacists, and technicians

Staff position	Not punishing those who report and commit ADEs	Mandating ADE reporting to a provincial centre
Pharmacists	3.77	3.58
Pharmacy managers	3.13	3.50
Pharmacy technicians	3.00	2.96

The most critical element for improving ADE reporting within retail pharmacies is ensuring anonymity for pharmacists and technicians for reporting ADEs (mean = 3.75), sharing “learnings” from errors with colleagues (mean = 3.74), and creating a safe reporting environment (mean = 3.46). Actions that ranked low include celebrating the reporting of errors (mean = 2.64) and establishing a provincial centre of patient safety (mean = 3.00).

As evident from the data analysis and literature review, there are a wide variety of items that may influence the diffusion of a mandated ADE-CQI program by retail pharmacies. These items span a wide variety of pharmacy stakeholders ranging from individual pharmacists to regulatory authority. Transposing the items and factors in Table 1 to a graph involving various pharmacy stakeholders and the ability of the pharmacy to reduce or promote each item, a proposed classification framework is developed and presented in Figure 2.

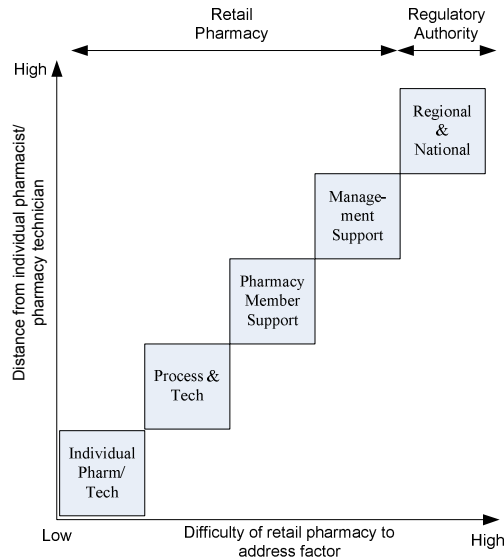


Figure 2 – Factors influencing mandated CQI Program adoption

The various determinants of mandated ADE-CQI program diffusion can be grouped into five factors: (1) Individual pharmacy staff member (e.g., uncertainty about the longevity of the CQI process, guaranteed autonomy for reporting errors, a sense of ownership of the new process); (2) Process and technology (e.g., time required to use the process, degree of procedural changes needed, quality of error reporting and tracking tools); (3) Internal member support (e.g., willingness to commit time to the new program, willingness to try new ideas, willingness to talk more openly about ADEs), (4) Management support (e.g., recognize staff who participate, provide needed financial resources, reward full disclosure); and (5) Regional and national issues (e.g., extent of diffusion by other local pharmacies, improved reputation of the pharmacy, extent of diffusion by other pharmacies in the province, feedback from other pharmacies that have used the CQI program). The degree to which the pharmacy can address each determinant depends upon the group. Issues stemming from pharmacy staff, process & technology, internal member support, and management are within the ability of the retailer to reduce/promote. Items stemming from regional and national issues are outside of the immediate control of the retailer, with responsibility for reducing such items instead falling to government or the regulatory authority. Instead of reducing/promoting items from this latter group, the best a pharmacy can do is to reduce their impact by making changes to internal operations. Internal changes may, however, present new issues. Therefore, pharmacies need to undergo periodic self-assessments to identify current factors that may be limiting their full use of a mandated ADE-CQI program, and to develop, not only in-store strategies, but also collective and regional strategies, in order to address policy and regulatory issues.

IMPLICATIONS AND CONCLUSION

This framework (i.e., Figure 2) presents a starting point in examining the issue of ADE reporting and learning within Canadian retail pharmacies. However, much more work is needed in this area. Although the literature from the information systems, innovation diffusion, quality/lean management, and public policy domains present a potential list of determinants; a core list of determinants needs to be further identified and empirically validated. In addition, one cannot assume that all determinants will

influence ADE reporting and learning equally. Research is needed to determine those determinants that may, for instance, be associated with low ADE reporting but not with low ADE learning once an error is reported. To help retail managers better prioritize what areas to address first, research is needed to determine the relative influence of each determinant on ADE-CQI program diffusion. And finally, because the regulatory authority represents both a supporter and deterrent for ADE-CQI program diffusion, more research is needed to better understand how various characteristics of the regulatory authority may influence the success of a mandated ADE-CQI program. These latter three issues can be addressed by developing and testing a structural equation model of how the factors presented in Figure 1 and the items in Table 2 influence under what conditions errors are reported, extent of immediate recovery activities, and impact on longer term organizational learning initiatives.

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