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REFLECTIONS ON THE ROLE OF THE PHARMACY REGULATORY AUTHORITY IN ENHANCING QUALITY RELATED EVENT REPORTING IN COMMUNITY PHARMACIESⁱ

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Abstract

Background—Given the demanding nature of providing pharmacy services, coupled with the expanded scope of practice of the professions in jurisdictions around the world, greater commitment to continuous quality improvement through adoption of quality related event (QRE) reporting is necessary to ensure patient safety. Pharmacy regulatory authorities (PRAs) are in a unique position to enhance QRE reporting and learning through the standardization of expected practice

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Objective—This study aims to better understand the perceived roles of PRAs in enhancing QRE reporting and learning in community pharmacies and identifying regulatory best practices to execute such roles.

Methods—A purposive case sampling approach was used to identify PRA staff members from two groups (deputy registrars and pharmacy inspectors) in 10 Canadian jurisdictions to participate in focus groups in the fall of 2011. Focus groups were used to explore perceptions of the role of PRAs in enhancing and promoting QRE reporting and learning, and perceived barriers to effective implementation in practice. Thematic analysis was used to analyze the qualitative data.

Results—Two focus groups were conducted, one with seven deputy registrars/practice managers and one with nine pharmacy inspectors. Five themes were identified, including (1) defining QRE reporting and compliance, (2) navigating role conflict, (3) educating for enhanced QRE reporting and learning, (4) promoting the positive/removing the fear of QREs, and (5) tailoring QRE reporting and learning consistency.

Conclusions—Overall, participants perceived a strong role for PRAs in enhancing QRE reporting and learning and providing education for pharmacies to support their compliance with reporting standards. However, PRAs must navigate the conflict inherent in both educating and promoting a process for achieving a standard while simultaneously inspecting compliance to that standard. Ensuring pharmacies have autonomy in operationalizing standards may help to mitigate this conflict. Finally, greater education for PRAs themselves to better inspect compliance and in order to better communicate the benefits of QRE reporting and learning to pharmacies would be beneficial.

Keywords

Quality assurance; pharmacy administration; reporting; qualitative research

INTRODUCTION

Increasing time pressures, professional demands, and accountability, combined with the expanding scope of pharmacy practice, makes the need for enhanced quality related event (QRE) reporting and learning in community pharmacies both timely and critical. Quality related events have been defined as medication errors that reach the patient, as well as errors that are intercepted by pharmacy staff or others prior to dispensing such medication (e.g., near miss),¹ and may arise, for example, from the processing of a prescription for the incorrect drug, dosage, quantity, or patient. Quality related events can have devastating consequences to all those involved including the individual staff member, pharmacy, patient and the patient's significant others.

Pharmacy regulation in Canada falls under provincial, not national, jurisdiction. The National Association of Pharmacy Regulatory Authorities (NAPRA) is an umbrella association of the provincial pharmacy regulatory authorities that was created to enable provincial regulatory authorities to take a national approach in addressing common issues in Canada.² While it has provided national leadership to a variety of initiatives including the establishment of model standards of practice for Canadian pharmacists and a professional competencies document, there has been no work done at a national level to establish an

agreed upon regulatory approach related to continuous quality improvement (CQI) or QRE reporting and learning in community pharmacies. As such, standards regarding QRE reporting and learning have fallen to the jurisdiction of the provincial pharmacy regulatory authorities (PRAs) in Canada. Recently, four provinces in Canada have adopted regulations requiring QRE reporting within community pharmacies with varying degrees of requirements for additional CQI processes. At a foundational level, minimum standards require that each pharmacy have a process for the documentation of all suspected or known medication incidents, with some jurisdictions also requiring quarterly review of documented incidents to identify trends and improvements. These reporting and analysis requirements are similar to regulations mandated by a number of jurisdictions in the US, including Florida, California, and Oregon.

With the changing landscape of QRE reporting requirements in Canada, other provinces are now looking to adopt similar regulations and standards. Pharmacy regulatory authorities have the potential to help community pharmacies enhance QRE reporting and learning through actions such as developing standardized continuous quality improvement (CQI) programs and explicitly communicating standards and expectations with respect to QRE reporting and learning, including requiring pharmacies to provide opportunities for pharmacy staff to discuss QREs in a non-punitive manner. However, in doing this, pharmacy regulatory authorities are advocating for a shift from a punitive approach to QRE management, while they themselves may be required to sanction practice that may have contributed to the QRE (should they be so informed) as part of their responsibility in governing the practice of pharmacy in the health interest of the public. These can reasonably be seen as contradictory positions, and as such, the perceived role of the PRA in enhancing QRE reporting and learning can be unclear and confusing for both PRAs and community pharmacies. This research aimed to capture PRA staff reflections on their role in enhancing QRE reporting and learning, as summarized by the following research questions:

- What are the perceived roles of pharmacy regulatory authorities in enhancing quality related event reporting and learning in community pharmacies?
- What are the perceived barriers and challenges that pharmacy regulatory authorities face in executing such roles?

METHODS

To explore the roles of the PRA in enhancing QRE reporting and learning in community pharmacies, focus groups were conducted with staff members from Canadian pharmacy regulatory authorities. According to Huston and Hobson, “at their most basic form, focus groups are structured or semi-structured meetings with a small group of individuals (i.e., “informants” or “participants”) that allow for the exchange of information, opinion, and feedback related to a single topic.”³ There are a number of advantages of focus groups when compared to individual interviews, including: (1) participants are provided with a “safe place” to discuss topics, as they can choose the extent they want to provide input on specific questions; (2) the sense of community that focus groups offer may increase participants willingness to discuss sensitive topics; (3) participants can “feed-off” the ideas of one another, allowing participants to remember situations that they may not have otherwise

recalled; (4) participants are in a better position to frame their views, by comparing or contrasting them to those of others; and (5) common issues are more likely to be discussed the most during focus groups, and these issues will appear to be the most important.³⁻⁶ In recent years, focus groups have been used to explore a wide variety of important community pharmacy issues, such as healthcare quality, health service utilization, prescription intervention practices, and e-prescribing.⁷⁻¹⁰ As a result, a purposive case sampling approach was used in order to capture the full range of PRA approaches to addressing QRE-related issues in community pharmacies, including PRAs that currently have regulations in place and those that do not. Staff members from all of Canada's 10 autonomous provincial PRAs were sought for participation in the focus groups.

To obtain multiple viewpoints and perspectives, focus groups were conducted with two staff groups from Canadian provincial PRA, each group with distinctly different roles with respect to pharmacy practice and their interaction with community pharmacies. The first group was comprised of pharmacy inspectors (labeled as inspectors for this study) who assess compliance to existing rules of professional practice (e.g. legislation, standards of practice, policies). The second focus group was comprised of individuals involved in the development of the legislation, standards of practice, and policies, that community pharmacies are expected to follow (labeled as deputy registrars for this study).

Focus groups were arranged by email and were scheduled and conducted in Halifax, Nova Scotia, prior to the annual meeting of the Canadian Pharmacy Inspectors (CANPI) group. Working with the Nova Scotia College of Pharmacists, email contact was made with deputy registrars (or those with a similar title) and pharmacy inspectors who were attending the CANPI annual meeting. The invitation to participate email introduced the purpose of the study, provided details regarding when the focus groups would be occurring, and outlined data confidentiality and privacy. All who were contacted agreed to participate in the focus groups.

Questions posed to both focus groups centered on the roles of the PRA in enhancing QRE reporting and learning and included: (1) the perceived relationship (pro-active/reactive, supportive/punishing, strict/lax) between PRAs and community pharmacies in their jurisdiction; (2) the PRAs role with respect to QRE reporting and learning; (3) what PRAs believe are the regulatory and community pharmacy factors that may impact QRE reporting and learning in community pharmacies; and (4) examples of regulatory initiatives, strategies, and standards of practice that may help address the risk factors or promote the success factors. The St. Francis Xavier University Research Ethics Board provided ethics approval for the study.

A thematic analysis approach was used to conduct the analysis of the focus group data. Thematic analysis involves the coding of qualitative data to produce themes, which are defined as a "pattern found in the information that at a minimum describes and organizes the possible observations and at a maximum interprets aspects of the phenomenon."¹¹ Thematic analysis involves a number of steps from raw qualitative data to the identification of codes and themes. Braun and Clarke have identified six phases that constitute thematic analysis:

(1) immersion/familiarization; (2) generating initial codes; (3) searching for themes; (4) reviewing themes; (5) defining and naming themes; and (6) producing the report.¹²

Both focus groups were audio recorded and transcribed verbatim. Once accuracy of the verbatim transcripts was established, both the inspector and deputy registrar transcripts were read together as one complete data set. Once a complete reading had taken place, each individual focus group transcript was then read again individually. During this second reading, initial notes and thoughts regarding the data were recorded in a journal. The next phase of analysis was the generation of initial codes for the data. Coding was done by hand due to a small dataset size. Once the initial list of codes was created, the next phase of analysis was to analyze the codes to identify possible themes. For the purpose of this research, themes were generated inductively and were semantic in nature, meaning that participant responses were analyzed based on what was said, not on underlying meanings and conceptualizations.¹² These themes were then reviewed against all data extracts to determine their presence by two researchers. Finally, each theme was named and defined using the data to provide a description for future use.

RESULTS

Two focus groups were conducted in the fall of 2011. A total of 16 individuals representing Canada's 10 provincial PRAs participated in the focus groups, with the size of the focus groups following the recommended 5 to 10 participants per focus group.³ Table 1 summarizes the demographic characteristics of each focus group.

Results of the thematic analysis highlighted five key roles of the PRA in enhancing QRE reporting and learning, as summarized in Table 2 and discussed in detail below.

Defining QRE Reporting and Learning Compliance

Defining QRE process compliance encompasses the discussions regarding how a regulator or pharmacy can assess whether QRE standards are being achieved. The challenges identified within the context of QREs and quality assurance included environmental and cultural factors, defining a minimum standard, applying a benchmark, and understanding what needs to be communicated or documented. For both inspectors and deputy registrars, the first step is in defining compliance itself. There were differing opinions on what would be needed to assure compliance with QRE reporting and quality assurance requirements, with a consensus that PRAs should be able to confirm that activities are taking place without requiring the knowledge of specific QREs. For example, setting up a system "whereby we require them to have a log – the date, what happened, how you fixed it, and whether the fix worked" (*Pharmacy Inspector*). Participants spoke to the need to see "markers" of participation or documentation that would show inspectors that QRE learning activities were taking place, such as reports and checklists. This was captured in one inspector's comments:

"And we really don't want to know what the incidents are unless we have to through discipline but we want to know they have a system. So when we go in, we look at the system. And I tell them I like the log because I can look at it. I don't have to look at the incidents themselves. I look and see that you're doing your job

and go on from there. So actually the way our system is set up, we don't really want to know how many there are. We just want to know you have a system that's working and that you're taking care." (*Pharmacy Inspector*)

Overall, regulators had a hard time assessing if community pharmacies were effectively practicing QRE reporting and learning, given the lack of such markers. This ultimately made it difficult to assess whether or not learning was taking place:

"I really have no idea whether or not they are doing a good job because we have nothing. It seems from what they tell us that they have a process to look at the errors that they have truly identified. But we have no idea how many errors they're actually making and whether they are able to learn from that." (*Pharmacy Inspector*)

The need to document formalized processes for QRE reporting and learning to show compliance and implementation of appropriate policies was an issue brought forth in both the inspector and deputy registrar discussions. This formalization was seen as important in ensuring that pharmacists were aware of their mistakes and ensuring that formal learning processes took place following disclosure:

"Because when we talk to them, you know, we'll say okay, in the event that you have an error, what's your process? So we go through that. But I mean 7 out of 10 of them will say, "I don't even know when I made a mistake the last time or I have never made a mistake". And I think, okay, none that you have actually identified. (*Pharmacy Inspector*)

Participants also acknowledged the presence and influence that corporate policies may have on pharmacy compliance to QRE-related policies and standards, including the detrimental effect of duplicate regulator-corporate QRE reporting mechanisms. It was suggested that if the reporting processes needed to meet the requirements of corporate policy and the regulatory standards could be coordinated, this activity would be less onerous.

Navigating Role Conflict: The "Telling" and "Selling" of QRE Reporting and Learning

Related to issues regarding defining compliance, participants also identified the role conflict inherent in the number of hats they must wear when dealing with issues surrounding QRE reporting and learning. For both inspectors and deputy registrars, roles ranged from teacher and mentor to investigator and police. Participants felt there was an overall difficulty in fulfilling all of these roles in the context of establishing relationships with pharmacies and enhancing QRE reporting and learning. Inspectors further highlighted the conflict inherent in their having to report identified QRE standards related issues or healthcare quality deficiencies of the pharmacy when they become aware of them, even if the primary purpose of their visit at the pharmacy was not inspection related. This was contextualized as the difficulty that regulators face when attempting to bridge being a regulatory body, and thus having to police and discipline, with also encouraging pharmacies to fearlessly disclose, examine and discuss QREs: "One of the conflicts we have as regulatory authorities, if you know about something, you've got to act on it. If you think there's something there, you've got to act on it whether you have the resources or not. So if we have access to information that says someone is not doing it properly, we have to act. Otherwise we're liable. And

therefore if the pharmacies know that, why would they want to report? Why would they set themselves up?” (Pharmacy Inspector)

Some participants felt that these roles were difficult to navigate and decreased opportunities for enhanced QRE reporting and learning to occur. Both inspector and deputy registrar discussions also touched on the importance of differentiating between advocacy and regulatory activities, with conflicting views on which group providing continuing education on QREs and self-assessing for compliance would fall:

“I don’t think that [education] is necessarily our role but, our role has changed a lot. It’s very much more let’s coach you, let’s help you as opposed to an adversarial role. When we go into a pharmacy, we really do try and make it more of a let’s learn, let’s coach, let’s help, let’s make your practice better. Because I think some of that may have come from practice because you could tell somebody, ‘You need to do that.’ But if you say, ‘Let me help you. I’ll show you how to make that better,’ it works better.” (Pharmacy Inspector)

In some instances, regulators felt that their role has significantly changed from that of regulatory authority to educator on practice, with one inspector noting “as far as pharmacists are concerned, that’s who we are more so than the regulatory side” (Pharmacy Inspector). In addition to individual role conflicts, deputy registrars also noted role conflict emerging from the need to be sensitive to business sustainability on the one hand and the need to take disciplinary measures on the other hand. Participants noted that pharmacists were often unclear on the regulator’s primary role of protecting public interest and safety: “we are invisible until something, usually bad, happens... They still don’t understand why we’re there as protection of the public, the safety of the whole procedures, the dispensary processes and [other regulatory focuses]”. (Deputy Registrar). Overall, this conflict was primarily seen as the result of the dual roles of policing and educating that many regulatory bodies play. Inspecting was described as those activities that assure compliance related to quality and safety, and being available for advice when pharmacies are unsure of how to comply; however, investigating was often seen as punitive.

Educating for Enhanced QRE Reporting and Learning

Educating for improvement highlights the narratives around the importance of providing proactive education regarding QRE-related best practices, policies, and procedures for all stakeholders involved, including pharmacies, inspectors, and registrars. Discussions ranged from improving awareness, to coaching to ensure quality and safety, to demonstrating the importance of QRE-related policies. Throughout the conversations there was the understanding that broad-based QRE-related education must be conducted before policy and standards implementation, to help ensure understanding of goals and provide opportunities for discussion. One pharmacy inspector noted “I think as a group in pharmacy, what we fail to do is to set up an appropriate structure for the staff. And I think there’s a tremendous vacuum of need and want.” (*Pharmacy Inspector*). Demonstrating the positive outcomes that can come with the inclusion of QRE reporting and learning and quality and safety standards was seen as essential to ensuring that pharmacies “get it.”

Educating for improvement also meant providing the necessary education for pharmacies to see the value that QRE reporting and quality and safety standards can have on overall efficiency:

“I think even the banners where you have your independent pharmacies, they don’t see the benefit of improved efficiency either. They see that [QRE reporting] as one more thing I’ve got to do. And they don’t see that okay, if I make a mistake in the middle of the process, now it’s back to the beginning of the process and start again. And now I’ve just added twice as much work. Education could be a benefit.”

(Pharmacy Inspector)

Participants also saw the need for greater training of PRAs in how to better inspect and investigate pharmacies when significant QREs or safety violations did occur, including how to better identify the contributing factors to the event. Outlining the learning process needed to ensure compliance with QRE and quality-related standards was also seen as an important aspect of assuring a learning approach. Interestingly, discussion also touched on the need to ensure training and education of PRAs themselves in the area of QRE reporting and overall quality:

“It would not be a bad thing for me as an inspector to learn more about actual things that we could do to help pharmacies learn... It would be a real strength to have education for me to help them learn from some of their mistakes.”

(Pharmacy Inspector)

In this way, education was seen as everyone’s job so as to ensure that both parties are knowledgeable in their role and understand pharmacy standards related to QRE reporting and learning, and overall quality improvement.

Promoting the Positive/Removing the Fear of QREs

Promoting the positive and removing the fear of QRE reporting relates to the experiences that inspectors and deputy registrars have when interacting with pharmacies on the sensitive topic of QREs. Discussions included helping pharmacies to interpret positive QREs, providing support when incidents occurred, ensuring that communication around quality standards is patient-focused, and demonstrating cost-savings. Fear was perceived as stemming from internal and external pressures that pharmacies often face, including an unsupportive corporate culture, fear of punishment if a QRE is reported, and distrust that anonymous QRE reporting may not really be anonymous:

“We do not have any kind of a formal form or anything like that. There is a place that you can report them anonymously. But to be honest, I think that most pharmacists don’t think that they are anonymous, and they are just so afraid of something happening to them. When I go in, I talk about the incidents. I certainly don’t ask to see the incident form. And I have told them I don’t want to see them. I just want to know if you have them. Then they’re okay. But they really don’t believe it’s going to be anonymous. They are really afraid.”

(Pharmacy Inspector)

Communicating positive aspects of QRE reporting was seen as imperative to ensuring that pharmacies implement quality-related standards and understand the associated benefits.

Participants spoke to instances where pharmacists fear reaching out to inspectors and regulatory bodies with questions about new standards, as they did not want to risk being found non-compliant or punished for deficiencies. Inspectors and deputy registrars suggested ways of dealing with fear, including encouraging pharmacies to report positive QREs such as correcting an error originating from the prescriber, and re-framing possible negative situations into learning opportunities.

Fear was also perceived as originating from uneasiness with reporting quality issues to a regulatory authority. One participant noted that often PRAs are “invisible until something, usually bad, happens” (*Deputy Registrar*), and as such standardizing QRE reporting, and related quality and safety expectations of pharmacies, could cause some pharmacies to question regulator motives. To help promote the positive benefits of quality-related standards, participants spoke of the need to frame the issue as a patient-focused initiative, explicitly tying such standards to improving patient outcomes “if you just tell them to do something, and ... you don’t explain the reason why it’s important to do something and translate it into patient safety, then they don’t get it” (*Deputy Registrar*). Furthermore, deputy registrars thought it was important to ensure that QRE-related standards be communicated within a business model, demonstrating cost savings and improved efficiencies and risk management to ensure uptake by pharmacy and corporate management “because it costs you money when you make an error if you have to pay a patient” (*Deputy Registrar*).

Tailoring QRE Reporting and Learning Consistency

Tailoring QRE consistency underscores discussions regarding the need to create QRE standards while also understanding site-specific differences that may limit the adoption of common, province-wide QRE processes. Participants noted the need to recognize differences between independent and corporate pharmacies, adopt standardized language, and outline expected care across Canada. Overall, tailoring consistency meant providing a standardized QRE reporting and learning process for pharmacies, while understanding that pharmacies can and should operationalize processes differently to suit their individual needs:

“One of the problems you find is that most pharmacist managers, especially independents who do not have a support system from a head office, have difficulty operationalizing any type of policies that are sent to them...And that’s where I find that we do spend a lot of our time during the inspection process to help them operationalize, to comply with these things.” (*Pharmacy Inspector*)

However, participants expressed the need to treat QRE reporting and quality assurance like any other standard, meaning that there must be a requirement for certain minimum processes and policies to be in place in order to allow audits to occur:

“So if they are not doing the standard on continuous quality improvement, continuous quality assurance, that is just one part of the audit that is required for you to extend. So then it’s no different than if you don’t comply with counseling, if you don’t comply with any other of our policies and standards.” (*Pharmacy Inspector*)

In addition to the need to enforce standards at the store level, deputy registrars also spoke to a much broader interpretation of consistency; in the respect that there should be a minimum standard of care expected across all pharmacies “I don’t think we should expect a different set of care whether you’re a corporation or an independent or a sole proprietor. There should be a minimum set of standards” (*Deputy Registrar*). Participants saw the importance of a national body overseeing minimum standards of care and safety across Canada (which would encompass QRE reporting and learning), with provincial jurisdictions able to tailor standards to the needs of their distinct populations, “I guess I’d like to see [the national regulatory body] sort of be the umbrella. That’s sort of what it is where it provides protection for us all. So the big guys may be holding the umbrella but we’re under them so the rain is not falling on us” (*Deputy Registrar*).

DISCUSSION

The research results point to a wide range of issues. At the most basic level, participants noted that the actual definition of QRE compliance needs attention. What constitutes compliance and how can it be measured are foundational issues. Moving beyond definitions and into implementation, participants pointed to the need for PRAs to consider how they will encourage pharmacies to openly discuss QREs, while at the same time holding pharmacy staff members accountable by disciplining unsafe practices; and how to do both in a manner that doesn’t undermine the outcome either.

It is essential that pharmacies “buy in” to the importance and value of continuous quality improvement (CQI) and the criticalness of QRE reporting and learning to this process, in order for the intended outcome of the standard to be realized (i.e. improved safety and quality of pharmacy practice). As such, regulators must not only “tell” pharmacies that they must perform QRE reporting and learning activities, they must also “sell” them into wanting to do so. Given this constant balancing act and the need to both “tell” and “sell,” understanding and clearly communicating the PRA’s role in enhancing QRE processes, while intentionally being shielded from the details of the reporting and learning processes, may help to alleviate confusion and remove some of the fear inherent to QRE reporting. Fear of reprisal from reporting QREs is present in Canadian community pharmacies and has been highlighted as limiting QRE learning activities and the extensive use of formal CQI programs.^{13,14} Indeed, the findings highlight the need for such clarity not only for community pharmacies, but also for PRAs themselves. Without such clarity, community pharmacies may be unsure of what should or should not be discussed when speaking with a regulatory body regarding QREs, thus impairing meaningful learning.

The apprehension of Canadian PRAs in navigating this narrow road is exacerbated by increasing pressures on self-regulated professions to be faithful to their mandate to serve the public’s best health interest and as such, to ensure that their activities are free from any real or perceived advocacy purposes or influence. This increased scrutiny creates unease for regulators when they consider activities that could be seen as being advocacy in nature. This is especially pronounced in the area of QRE processes given that they involve issues of practice quality and patient safety often related to members of the profession. Developing national minimum standards for QRE reporting and learning and broad stakeholder

education and training on QRE issues were viewed as the next steps in addressing this issue. The literature has shown the importance of having effective leadership when engaging in significant pharmacy practice change.¹⁵ Due to the inherent diversity in the practice of pharmacy, national leadership support may be needed to achieve consistency across jurisdictions. However, although there were strong views on the need for a set of minimum national standards related to QREs, who should be tasked with preparing community pharmacies to meet such standards remains unclear.

All participants realized the need for education related to QRE and quality assurance issues, and a number of studies highlight that for the adoption of quality assurance programs and standards within healthcare to be successful, greater emphasis needs to be placed on employee empowerment, problem-solving techniques, and education and training.^{16,17} However, whose bears the responsibility to do this is not yet agreed upon. Some participants rationalized that since education and training on QRE reporting and learning are designed to protect public safety, such activities fall well within the mandate of PRAs. Research has begun to explore the role that self-regulation and inspection can have in community pharmacy. Wiederholt et al., for example, provide an argument in favor of a reduced role for pharmacy regulators in the penalization of pharmacies through greater use of pharmacy self-inspection, with results from their pilot study showing greater pharmacy compliance with regulations and adoption of improvements when pharmacies self-inspected.¹⁷ These findings suggest that regulators may be able to play more of an active role in educating and supporting, rather than inspecting, in the future.

Some deputy registrars and inspectors, however, voiced the opposing view that it is more appropriate for professional associations to help educate their members on how to be in compliance. In their view, it is the job of the PRA to set the standard; it is then the job of the advocacy bodies to educate members on how to meet the standard. In some Canadian jurisdictions, advocacy bodies are large and fully engaged in educating their members. In other jurisdictions, the separation of the advocacy and regulatory roles is still embryonic and advocacy bodies are smaller and less established. Responsibility for education, especially for independent pharmacies, which operate without corporate, behind-the-scenes support for regulatory compliance, is less a priority for some professional associations.

Other participants suggested that universities should assume the responsibility for continuing education. It appears, however, that QRE reporting and learning issues are not a priority for many such groups. For example, Bradley, Steven and Ashcroft, focusing on three schools of pharmacy, found that reporting and learning from adverse incidents was absent from the curricula from all three schools.¹⁸ Overall, with continuing professional development for pharmacists being recognized as an important component of improving patient health outcomes, a more integrated and well-defined approach to achieving continuing education needs to be identified.¹⁹

An additional note regarding the need for thoughtful consideration when establishing required QRE processes comes from the ongoing, and increasing, tension between financial sustainability of the pharmacy business model and increased regulatory reporting. Regulations typically pose costs to pharmacies. Standards including those around QRE

reporting, require pharmacists' time and effort, and may be both difficult to interpret and operationalize. Pharmacies have indicated to the PRAs in this study that such reporting may be onerous and can impede the viability of their business model. PRAs can respond to such concerns with a hard line, "pay to play" attitude, or they can attempt to find a balance between regulations and sustainability. Finally, participants spoke to inter-pharmacy differences and the issue, when setting and enforcing regulations, of differences in capacity. While deputy registrars noted that the public deserves proper care and safety regardless of where they live, inspectors noted significant differences in the capacity of pharmacies to comply with new regulatory standards. Requirements that do not allow accommodation for inter-pharmacy differences risk being too onerous. However, such accommodation poses the risk of a lowest common denominator approach to standard setting.

Limitations

The use of focus groups as a research method has several inherent limitations. Focus groups can have a tendency to produce "groupthink" in which normalized behaviors and opinions emerge more frequently or to be more biased towards responses from dominant participants, with more reserved participants having reduced opportunities to contribute to the discussion.^{20,21} Practices aimed at reducing bias in this study included the use of standardized moderator guides, asking for differing views or opinions, and ensuring that all participants had an opportunity to join the discussion.

In addition, this study elicited views from two major pharmacy stakeholders, specifically pharmacy inspectors and deputy registrars. However, there are a number of additional stakeholders not addressed in this study that may have been able to provide additional insight into how PRAs can assist with enhancing QRE reporting and learning. Future research should focus on interviewing or surveying a broader group of pharmacy stakeholders in order to address such issues and support or deconstruct the key findings of this study.

CONCLUSION

Exploring the perceived roles and issues that regulatory authorities have in implementing and promoting QRE reporting and learning is integral to understanding best practices in the wide adoption of quality assurance in this area. This study shows that PRAs are often required to function within the context of seemingly competing interests and priorities. There is no "one size fits all" on the horizon. While many regulatory authorities perceive their role as encouraging the use of QRE reporting and learning, many also perceive inherent role conflicts between wider education and policing of such policies. Furthermore, this study identified a perceived need for regulatory bodies to provide greater education to community pharmacies with respect to QRE reporting and learning and allow for some autonomy for the implementation of such activities at the pharmacy level.

In addition, this study has demonstrated that PRAs have to establish rules related to QRE processes in consideration of business sustainability and inter-pharmacy differences in the interest of achieving compliance. Greater training of regulatory authorities regarding QRE reporting and learning, as well as how to inspect for QRE process standards, is required in

order to further establish QRE reporting and learning in Canada. Using QRE reporting as a model to improve quality of care, patient safety and business efficiency may ultimately improve the appeal of reporting for community pharmacies and help to establish standardized guidance by regulatory bodies.

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Table 1

Focus Group Participants

	Inspector Focus Group	Deputy Registrar Focus Group	Total Study
Number of Participants	9	7	16
Primary Role	Pharmacy Inspector	Acting Registrar, Deputy Registrar, Assistant Registrar, Pharm Practice Director, Pharm Practice Manager, Investigations.	
Length of Focus Group	84 min	70 min	154 min
Canadian PRAs Represented	7	6	10
Small PRAs Represented (500 community pharmacies)	3	4	6
Large PRAs Represented (> 500 community pharmacies)	4	2	4
Number of Canadian community pharmacies regulated by the PRAs	7,576	5,337	8,854
Percentage of Canadian community pharmacies regulated by the PRAs	85.4%	60.2%	99.8%

(Abbreviations: PRA – Pharmacy Regulatory Authority)

(Community pharmacy numbers based on National Association of Pharmacy Regulatory Authorities (NAPRA), 2012)

Table 2

Perceived Role of the Pharmacy Regulatory Authority in Enhancing Quality Related Event Reporting and Learning

Key Role	PRA QRE-related Challenge	Regulatory Role/Issue
Defining QRE reporting and learning compliance	How PRAs and pharmacies know when QRE-related standards are being achieved, without requiring the details related to actual errors.	Participants emphasized the need for documented and formalized processes for QRE reporting and learning in order to show compliance and operationalize policies. As such, there was an identified need for PRAs to communicate clearly defined “markers” of participation that would show inspectors that QRE learning activities were taking place.
Navigating role conflict	Conflict surrounding the number of different roles the PRAs may have when dealing with issues surrounding QRE reporting and learning.	Roles ranged from teacher and mentor to investigator and disciplinarian; not only ensuring compliance related to safety but also being available for advice when pharmacies are unsure of how to comply. Balancing the two roles (i.e., compliance vs. advice) was viewed as difficult and decreased the likelihood that meaningful QRE learning would occur.
Educating for enhanced QRE reporting and learning	The provision of education regarding QRE-related issues for all the key stakeholders involved in QRE reporting and learning (e.g., pharmacies, inspectors, and registrars).	Participants highlighted that PRA-led QRE-related education must be conducted before policy and standards implementation, in order to ensure mutual understanding of goals and provide opportunities for stakeholder discussion. Participants also identified the need for greater training of PRAs in how to better inspect and investigate pharmacies when significant QREs or safety violations did occur.
Promoting the positive/removing the fear of QREs	How PRAs can remove the fear from QREs; including how to: help pharmacies interpret positive QREs; provide support when incidents occur; ensure that communication around QRE standards is patient-focused; and demonstrate cost-savings.	Communicating positive aspects of QRE reporting were seen as imperative to ensuring that pharmacies implement any new QRE standards. To remove the fear of QRE reporting and learning, participants highlighted the need for PRAs to communicate QRE activities as both patient-focus initiatives (e.g., standards tied to improving patient outcomes) and within a business model, demonstrating cost savings and improved efficiencies and risk management (e.g., ensure pharmacy and corporate management support).
Tailoring QRE reporting and learning consistency	The need to create QRE standards while understanding the differences that may limit the adoption of common, PRA-wide, QRE reporting and learning processes.	Participants highlighted the need for PRAs to develop a common QRE reporting and learning process for pharmacies in their PRA, but emphasized that pharmacies can and should operationalize processes differently to suit their individual needs. The need for a minimum standard of care (which would encompass QRE reporting and learning) across all PRAs was identified.

(Abbreviations: PRA – Pharmacy Regulatory Authority; QRE - Quality Related Event)