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The Role of Community Pharmacists in Pharmacovigilance, R&D, Quality Assurance, Regulatory Compliance, and Risk Management in Pharmaceutical Management: A Systematic Literature Review

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Abstract:

Background: The goal of this systematic review was to investigate the existing literature on community pharmacists' knowledge, attitudes, roles, and practices concerning pharmaceutical management strategies.

The goal was to understand various attributes that influence the engagement of community pharmacists in their support and involvement on pharmacovigilance, research and development (R&D), quality assurance, regulatory compliance, and risk management pharmaceutical management practices.

Methods: The researchers searched five scholarly databases, Medline, EMBASE, ProQuest, PubMed, and Scopus for articles to review. The process entailed the use of a wide range of key words and a search string to identify and select suitable studies. The entire study methodology was based on the PRISMA guidelines. A total of 2110 studies emerged on the primary search, and after screening for suitability of inclusion 21 studies were reviewed.

Results: Findings showed that community pharmacists possess substantial knowledge on the different pharmaceutical management strategies; pharmacovigilance, research and development (R&D), quality assurance, regulatory compliance, and risk management. Community pharmacists have some knowledge, commitment, and positive attitude for supporting different pharmaceutical management strategies. However, there is still room for improvement as in some areas the knowledge and attitudes that community pharmacists is not sufficient for optimal healthcare outcomes.

Conclusions: Stakeholders such as higher education institutions, government agencies, and management teams in pharmacy have a role to play to support better knowledge and attitude to enable community pharmacists to fully engage in roles that support different pharmaceutical managerial strategies.

Keywords: Community Pharmacists, Pharmaceutical Management Strategies, Pharmacovigilance, Risk Management, Research and Development, Quality Assurance, Regulatory Compliance.

1. Introduction

The Community pharmacists plays an important role across the healthcare setting, notably positioning readily available professionals within the system and who have primary responsibility in providing medication-related services to patients (Newman et al., 2019). Pharmaceutical management strategies, primarily regulatory compliance, risk management, quality assurance, research and development (R&D), and pharmacovigilance are all crucial for ensuring the safe, effective, and also in the efficient use of medications (Hagar et al., 2020; Agomo et al., 2020; Dineen-Griffin et al., 2019). According to Kumar (2021), pharmaceutical strategic management activities revolve around the systematic planning, implementation, and control of strategies and initiatives within the pharmaceutical industry to achieve the long-term goals and objectives of a pharmaceutical company. These activities are crucial for staying competitive in the rapidly evolving and highly regulated pharmaceutical sector. Notably, pharmaceutical strategic management is an ongoing process that requires adaptation and adjustment as the industry evolves, new technologies emerge, and regulatory environments change.

Companies in this sector must navigate a complex landscape of scientific, regulatory, and commercial challenges to bring innovative medicines to market and achieve sustainable growth (Kumar, 2021). The knowledge, attitudes, roles, and practices that community pharmacists have in relation to these pharmaceutical management strategies are vital for the successful delivery of the healthcare services they are tasked with providing (Jackson et al., 2014). Pharmacovigilance is an essential part of a community pharmacist's role as they do monitor and report adverse drug reactions, assess medication effectiveness, and contribute to medication safety databases (Mahmoud et al., 2014). They are also responsible for dispensing prescriptions, ensuring that medications comply with regulatory standards and guidelines, and verifying the accuracy and safety of each prescription, and they also engage in the verification of the quality and integrity of medications, checking for proper storage; appropriate labeling, and expiration dates (Winslade & Tamblyn, 2017). These important professionals have in their core tasks around pharmacy services delivery the identification of potential risks like drug interactions or adverse effects and the providing of counseling to patients to minimize these risks (Duarte et al., 2016). While they may not directly engage in R&D activities, community pharmacists have important input in ensuring proper procedures in practices like those that lead to new medications, evidence-based practices, and emerging therapeutic approaches (Goode et al., 2019; Moussa et al., 2021).

Given the critical roles that community pharmacists play around these important pharmaceutical management strategies, it is important that they have the right knowledge and attitudes to allow them engage in roles and practices that support these strategies. Consequently, this systematic review aimed at examining community pharmacists' attributes influencing their engagement for involving and supporting pharmacovigilance, quality assurance, research and development, regulatory compliance, and risk management pharmaceutical management strategies.

2. Materials and Methods

2.1 Protocol

The knowledge, attitudes, roles, and practices of community pharmacists in regards to pharmacovigilance, risk management, quality assurance, research and development, and regulatory compliance as core pharmaceutical management strategies was undertaken and reported on the framework and principles provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

2.2 Search Process

A comprehensive search strategy was developed and implemented across relevant electronic journals, including EMBASE, PubMed, ProQuest, Scopus as well as Medline. The search terms included variations of community pharmacists, pharmaceutical management strategies, knowledge, attitudes, roles, practices, pharmacovigilance, risk management, research and development, quality assurance, regulatory compliance. The particular strategy used in the search process was the Boolean method, and the primary search string was community pharmacists OR pharmaceutical management strategies AND knowledge OR attitudes OR roles OR practices OR pharmacovigilance OR risk management OR research and development OR quality assurance OR regulatory compliance. In the process, only articles that were published from 2014 to early 2023, and which had copies in English, were included. In order to supplement the main results of articles from the online search process in the five academic databases, the researchers also conducted further research in platforms, particularly Google Scholar, and screened the emerging studies for their suitability for inclusion in this study. The researchers asked two researchers to help with screening the articles, and they carried out the work of reading the full-text articles published in English and selected those suitable for inclusion in the final list of articles to be reviewed.

2.3 Inclusion and Exclusion Criteria

The flow chart that guided the identification and selection of the included studies is shown in figure 1. Articles were selected based on predetermined inclusion and exclusion criteria. Included studies were those that focused on community pharmacists' knowledge, attitudes, roles, or practices regarding pharmaceutical management strategies in either one or more of the pre-identified pharmaceutical management strategies of pharmacovigilance, risk management, quality assurance, research and development, and regulatory compliance. Studies employing qualitative, quantitative, or mixed-methods approaches were considered, and most important was that the included studies were ones that were full studies written in the English language and with peer-reviewed credibility.

Exclusion criteria encompassed studies not directly related to community pharmacists knowledge, attitudes, roles, and practices or pharmaceutical management strategies including pharmacovigilance, risk management, quality assurance, research and development, and regulatory compliance.

2.4 Data Extraction

Data extraction was performed independently by two assistant reviewers to the lead researcher using a standardized form. Extracted data included study author and publication date information, country where the study was carried out, area of the pharmaceutical management strategies, sample size, and key findings.

2.5 Quality Assessment

Before inclusion, each article selected was evaluated for its quality by two assistant researcher to the lead researcher using the Mixed Methods Appraisal Tool (MMAT). Any differences that emerged in the quality assessment process was discussed with the lead researcher and a conclusion was reached through discussion on what studies were to be included for review. In line with the MMAT guidelines for quality assessment, each included article was first evaluated on the basis of whether there was a clear research question and second, whether the collected data was useful to allow the answering of the research question(s). Once this test was passed, the reviewing researchers then went on to answer five additional questions for each article. These questions, flowing from the MMAT quality assessment tool, were on the appropriateness of the study design to answer the research question, appropriateness of the research method to answer the research question, whether the findings derived directly from the collected data, whether the interpretation of the results was sufficiently substantiated by the data, and whether there was coherence between the methodology data sources, collection of the data and its analysis, as well as interpretation.

2.6 Data Processing

In cases where there were disagreements on articles to be included for review, the lead researcher discussed with the assistants to reach a consensus on whether an article should be included or not.

Results

The initial search identified 2110 articles. After screening and applying inclusion/exclusion criteria, 21 studies were included in the review. Figure 1 presents the PRISMA flow chart for the selected articles for inclusion in the systematic review.

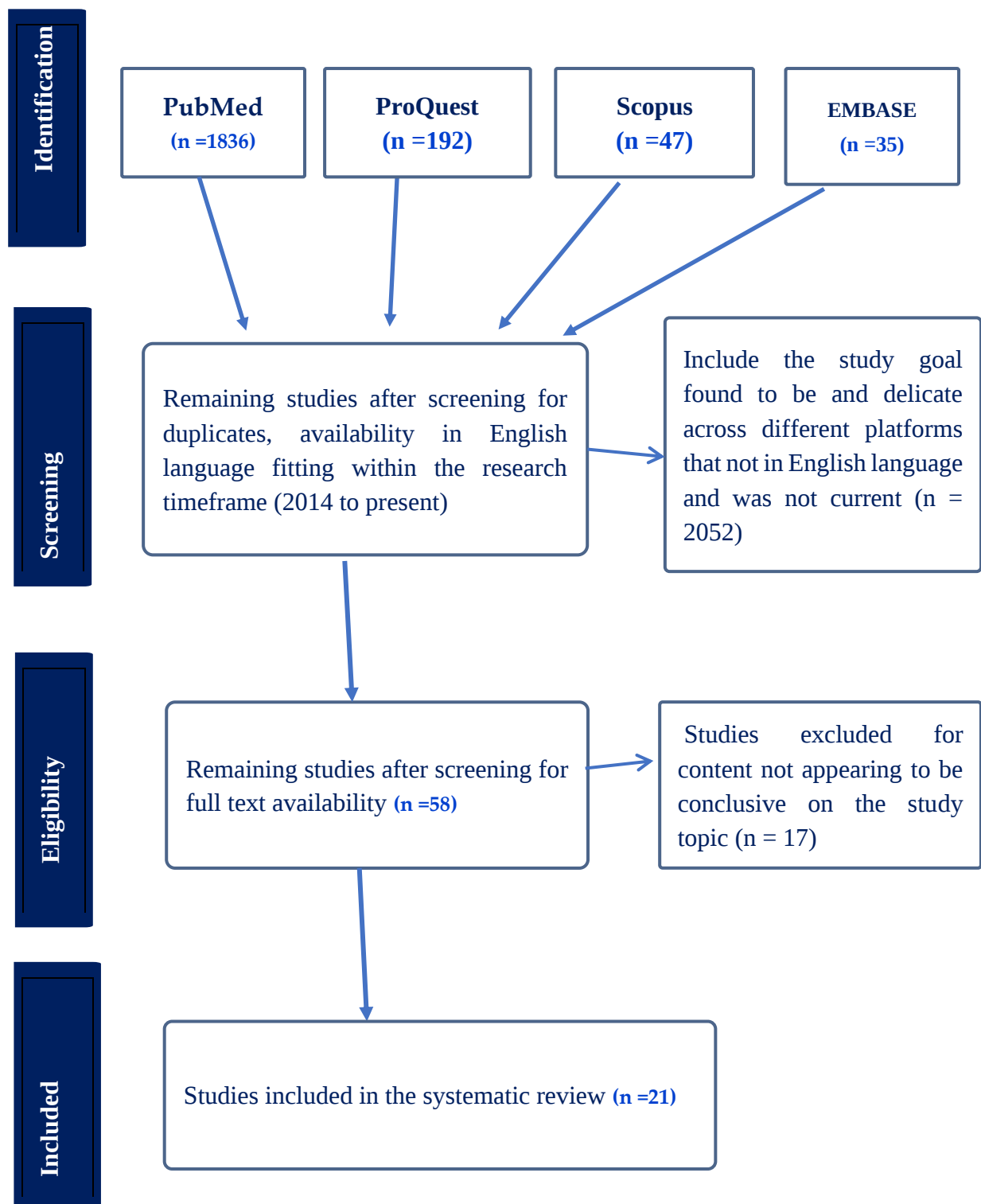


Figure 1. PRISMA Flow Chart for the Selection of the Included Studies

The studies were from different countries including the Saudi Arabia (3 studies), United Arab Emirates (1 study), India (2 studies), Pakistan (2 studies), Malaysia (2 studies), Australia (1 study), U.K (2 studies), Finland (2 studies), Portugal (1 study), Slovakia (1 study), Lithuania (1 study), U.S (1 study), Canada (1 study), and Egypt (1 study). Five studies investigated concepts related to pharmacovigilance, five were on risk management, four were on quality assurance, three were on regulatory compliance, two were on research and development, one was on quality assurance and regulatory compliance, while another was on quality assurance and risk management. The findings of the review of these studies are captured in Table 1.

Table 1. Summary of studies.

Author(s)	Country	Area of focus in Pharmaceutical Management Strategies	Number of participants	Study Type	Key Findings
Mahmoud et al. (2014)	Saudi Arabia	Pharmacovigilance	104 community pharmacists	Quantitative survey	A lot of community pharmacists are not familiar with the process of reporting adverse drug reactions, which is a key aspect of the pharmacovigilance strategy for managing pharmaceuticals.
Valinciute-Jankauskiene and Kubiliene (2021)	Lithuania	Pharmacovigilance	12 interviews with general practitioner community pharmacists	Qualitative	Several barriers prevent community pharmacists from being effectively involved in pharmacovigilance, such as insufficient information and education, high workloads, complex ADR reporting procedures, limitations in the e-health system, organizational culture, and a lack of trust in authorities.
Hussain (2021)	Pakistan	Pharmacovigilance	11 interviews with community pharmacists	A qualitative case study	Community pharmacists play a vital role as key sources of information for effective pharmacovigilance.
Kallio et al. (2020)	Finland	Risk management	56 online surveys with community pharmacists	Quantitative survey	Pharmacists seldom utilize the full range of risk management tools available to them for supporting pharmaceutical risk management strategies.

Kallio et al. (2021)	Finland	Risk management	574 pharmacists	National online cross-sectional survey	Pharmacists are well-versed in risk management strategies like verifying patient medication doses and identifying drug-drug interactions. However, they lack adequate expertise in areas related to ADRs, such as serotonergic load and anticholinergic load. While they have access to various tools for assessing risks in pharmacy, they express a need for additional training on the methods used in the ADR reporting process.
Duarte et al. (2016)	Portugal	Risk management	271 pharmacies and 10 community pharmacists	A cross-sectional survey and a Focus Group study.	Around 50% of community pharmacists in the study area consider their knowledge of risk management strategies in pharmacy to be poor.
Hagar et al. (2020)	United Arab Emirates	Risk management	322 pharmacists	A cross-sectional study	Community pharmacists displayed positive attitudes towards identifying risks within the pharmacy industry.
Abubakar et al. (2022)	Saudi Arabia	Quality assurance	130 community pharmacists	A cross-sectional study	Most pharmacists have a strong understanding of quality assurance and are eager to support pharmaceutical management strategies to improve service delivery.
Ting et al. (2017)	Malaysia	Regulatory compliance	Community pharmacists and General Practitioners in Sarawak state Pharmaceutical Enforcement Division (PED).	Observation study	Community pharmacists generally demonstrate good compliance with established laws on pharmacy practices, with a compliance rate of 53% observed in this study between 2012 and 2014.
Jeyamani et al. (2018)	India	Regulatory compliance	95 community pharmacists	A cross sectional survey	Many community pharmacists lack a deep understanding of current regulatory laws related to pharmaceutical practices, which may hinder their involvement in supporting initiatives aimed at ensuring regulatory compliance.

Duban et al. (2017)	Slovakia	Regulatory compliance	181 community pharmacists and 347 general practitioners		Community pharmacists are willing to support regulatory compliance practices within their organizations, but their limited knowledge of all relevant areas in this field prevents them from fully engaging in roles that promote regulatory compliance.
Rajiah et al. (2021)	India	Quality assurance	19 studies	Systematic review	One common way community pharmacists contribute to quality assurance is by interacting with patients.
Winslade & Tamblyn (2017)	Canada	Quality assurance and risk management	1742 pharmacies	Population based cohort study	Pharmacy management plays a crucial role in equipping pharmacists with the necessary knowledge to uphold quality assurance and reduce risk incidents in the field, especially those associated with improper drug dispensing.
Parekh et al. (2023).	U.K	Risk management	Data from 165244 patient cases	Quantitative	Community pharmacists support risk management strategies by referring patients to prescribers for medication reviews.
Goode et al. (2019)	U.S	Research and development	-	Review	Community pharmacists enhance healthcare delivery by leading and advancing team-based patient care services within communities, ultimately improving the quality of care.
Moussa et al. (2021)	Australia	Research and development	Six community pharmacists serving as change implementation facilitators	Observational study	Community pharmacists play a key role in pharmacy research and development by acting as change facilitators and identifying barriers to implementing new practices.
Kho et al. (2017)	Malaysia	Quality assurance	20 pharmacists	Qualitative study with semi-structured interviews	In their pursuit of quality assurance, community pharmacists encounter various challenges, including market competition, customer knowledge and expectations, legal complexities, and macroeconomic factors.

Abdulsalim et al. (2023)	Saudi Arabia	Pharmacovigilance	209 community pharmacists	A quantitative cross-sectional study	Community pharmacists possess strong knowledge of pharmacovigilance and demonstrate a positive attitude toward reporting adverse drug reactions.
Jawad (2016)	Pakistan	Quality assurance and regulatory compliance	1003 drug stores	Observational study	Many drug stores, including those involving community pharmacists' practices in compliance and quality assurance, fail to meet regulatory standards.
Aziz et al. (2022)	Egypt	Pharmacovigilance	37 pharmacists	A quantitative cross-sectional study	Pharmacists are willing to support pharmacovigilance initiatives, but organizations must foster an enabling environment to facilitate their involvement.
Latif et al. (2021)	U.K	Quality assurance	333 community pharmacists	Qualitative case study with focus groups	Community pharmacists acquire valuable knowledge for supporting quality assurance through effective collaboration between higher education institutions and local community pharmaceutical committees.

Discussion

4.1 Engagement of Community Pharmacists in Pharmacovigilance

Pharmacovigilance is an important undertaking among the key management strategies in pharmacy. According to Mahmoud et al. (2014), majority of community pharmacists working within Riyadh have poor knowledge on the procedures for ADR reporting, and it is in this regard vital for appropriate pharmacovigilance authorities to come up with strategies and programs that are meant to increase the knowledge of community pharmacists on this vital pharmacovigilance activity, and improve their attitudes and role in ensuring proper reporting as well as the practices they engage in for better patient care. These results were substantiated by Valinciute-Jankauskiene and Kubiliene (2021) who explain that most of the community pharmacists in Lithuania have basic knowledge on areas related to pharmacovigilance, and that main barriers to this are lack of information and education, heavy workload, complicated ADR reporting procedure, limitations of the e-health system, organizational culture, and lack of trust in authority. Hussain (2021) focused on the role of the community pharmacist in regards to pharmacovigilance, and the findings showed that the community pharmacist is an important person in the pharmacovigilance system in that they serve as a source of information for the effective early detection of ADRs, and other

issues that could affect the overall medication process of patients. In regards to the knowledge and attitude towards pharmacovigilance, Abdulsalim et al. (2023) found that most community pharmacists have an understanding of pharmacovigilance as an important pharmaceutical management strategy, and they also portray positive attitude towards reporting cases of ADRs. A similar positive attitude among community pharmacists was reported in the study by Aziz et al. (2022) who also noted the need for pharmacy management teams to support this attitude for better pharmacovigilance through putting in place measures that create an environment where community pharmacists are supported in their willingness to support pharmacovigilance goals and initiatives.

4.2 Engagement of Community Pharmacists in Pharmaceutical Risk Management

The healthcare environment has many possible events and activities that could result into risks and injuries to patients and possibly litigations pharmacies. The right knowledge and attitude is for this reason important for better risk management among community pharmacists. According to Kallio et al. (2020), pharmacists not only have a positive attitude in relation to the risk management pharmaceutical strategy but also possess a wide range of tools for enabling them in supporting risk management practices within their organizations. However, these tools are rarely used, pointing to a need for top management stakeholders to come up with and enforce systems that can allow community pharmacists to participate fully in the risk management strategies in pharmacy. In a study where the authors investigated the competency of community pharmacists in risk management in medication during routine dispensing, Kallio et al. (2021) found that while pharmacists have good knowledge in practices such as dosage confirmation and the identification of drug-drug interactions, they do lack sufficient knowledge on other important measures such as serotonergic load and anticholinergic load utilized in ADR reporting. Consequently, the authors recommended the need for the design of training programs that can equip community pharmacists in enhancing their knowledge for enabling them to serve their role in risk management strategies better. The notable lack of sufficient knowledge in risk management strategies among community pharmacists was also echoed in the findings by Duarte et al. (2021) who found that about 50% of pharmacists in the Lisbon area in Portugal rated themselves as having poor knowledge in risk management strategies in pharmacy. The participants indicated that primary causes of this lack of sufficient knowledge in pharmaceutical risk management strategies was due to the concept of risk management as a vital pharmaceutical management strategy not being fully addressed in graduation training for pharmacists, poor professional's attitude on concept, and lack of communication among key stakeholders. Contrary to the findings by majority of the authors whose studies focused on knowledge, attitudes, and the roles of community pharmacists in risk management, Hagar et al. found that pharmacists have positive attitude towards helping in the identification of risks within their organizational setting, and that they also have good willingness towards embracing proposed measures for better support in risk management strategies as a core pharmaceutical management strategy. Community pharmacists also support

risk management through referring patients with notable risk sickness conditions to prescribers for review (Parekh et al., 2023).

4.3 Engagement of Community Pharmacist on Regulatory Compliance

Regulatory compliance is an important aspect for effective operation in the pharmacy industry, and the reviewed literature shows that community pharmacists have good level of knowledge and engage in practices that show support for pharmaceutical management activities geared towards supporting regulatory compliance. Ting et al. (2017) found that on average, about 53% of community pharmacists comply with government laws and regulations set in place for ensuring safety pharmacy practices. On a study with differing findings, Jeyamani et al. (2018) found that most of community pharmacists do not have sufficient knowledge on regulatory compliance, and that this situation worsens when there are new laws in place towards compliance. These results are supported by those by Jawad (2017) who found that many drug stores are non-regulatorycompliant, implying possible lack of the appropriate knowledge among community pharmacists for regulatory compliance. According to Duban et al (2017), community pharmacists have the will and commitment to support regulatory compliance initiatives within their organizations, but barriers such as lack of supportive workplace environment for them to collaborate with other stakeholders minimizes the impact that they can have on their organizations for effective and full regulatory compliance.

4.4 Engagement of Community Pharmacists in Quality Assurance

Quality assurance is an equally important management aspect in the pharmaceutical industry., with Latif et al. (2021) found positive benefit for community pharmacists towards supporting quality assurance as an important pharmaceutical management strategy, noting that a significant knowledge that community pharmacists gain in this area is from effective collaboration between higher education institutions and local community pharmaceutical committees. Winslade and Tamblyn (2017) also found an important role played by managerial pharmacists in supporting the acquiring of relevant professional skills and knowledge for community pharmacists to support both quality assurance and risk management in pharmacy. The authors noted that when organizational management is in the fore front in ensuring a conducive work environment that is supportive of community pharmacists in their work, the pharmacists stand a chance to gain both professional knowledge and skills to engage in practices that support not only quality assurance but also help minimize occurrences of risk events in pharmacy. Similarly, Abubakar et al. (2022) found that most community pharmacists have positive knowledge around quality assurance and also demonstrate willingness to support initiatives set up by pharmacy management towards proper quality assurance management. Interactions between community pharmacists and patients are a major approach through which these professionals support quality assurance (Rajiah et al., 2021). Abubakar et al. (2022) found that most of the community pharmacists in Saudi Arabia have positive knowledge in regards to pharmaceutical management strategies meant for quality assurance, but noted that they experience lack of space and privacy as notable challenges for allowing them to deliver on their

mandate in this area. Investigating the challenges faced by community pharmacists in ensuring effective strategies for quality assurance, Kho et al. (2017) established that problems like unfair competition in the market, unclear regulations, and changes in macroeconomic forces are substantial barriers.

4.5 Engagement of Community Pharmacists in Pharmaceutical Research and Development

As new technologies emerge in different areas, health care services delivery is also witnessing shifts in practices for better healthcare, and community pharmacists have the knowledge and initiative to support these practices through innovative methods that lead to development of new service delivery methods. According to Goode et al. (2019), community pharmacists support the development of new methods in pharmacy and health care service delivery services by leading team-based patient care activities. Community pharmacists also support research and development in pharmacy through engaging in change implementation projects where they serve as facilitators of the change implementation and also help in the identification of barriers to successful change implementation (Moussa et al., 2021).

Conclusions

Community pharmacists serve a vital role of being sources of information and reporting on pharmacovigilance related issues, but do lack adequate knowledge to effectively perform this role, with barriers preventing their effectiveness in this area ranging from lack of information and education to heavy workload, and poor organizational culture. Community pharmacists have notably poor attitude on risk management strategies in pharmacy, and they also lack sufficient knowledge to enable them to serve the role of supporting risk management initiatives within the pharmaceutical industry. Ultimately, this systematic review points to a substantial lack of knowledge among community pharmacists in all five areas of risk management, pharmacovigilance, quality assurance, regulatory compliance, and research and development, all of which are integral strategies within the wide docket of pharmaceutical management strategies. The shortcomings are due to failure on different levels and different stakeholders, from curriculum design to organizational culture and individual personality traits among community pharmacists. Consequently, it is recommended that resolving the shortage of knowledge among community pharmacists which hinders them from effectively playing their roles in the different pharmaceutical management strategies requires a collaborative effort that includes all stakeholders, from curriculum designers to pharmacy organizational management teams, and to the individual pharmacists. Such collaboration is also vital for fostering positive attitude among community pharmacists on the different pharmaceutical management strategies and ensure that they are better committed to serving their roles in the context of pharmaceutical management strategies.

Important to note, there are several limitations for this review, and some recommendations are appropriate for future research. One of the limitations is that this study included only English-language studies, a limitation that has the potential to have resulted in the exclusion of relevant studies published in other languages.

Also, the review focused primarily on community pharmacists other than in two studies where general practitioners were included as part of the participants. The time frame for the included studies, 2014 to 2023, could also have prevented the inclusion of studies outside this timeframe and which could contain useful insights on the study topic. Consequently, the findings of this study may not fully capture the perspectives of other healthcare professionals involved in pharmaceutical management strategies which could also be useful in helping relevant stakeholders understand the issues around this area better, as well as it could have left out important findings in studies published outside of the studies timeframe. Consequently, future research could explore the views of other key professionals to help stakeholders understand the topic better for the enhancement of quality of not only pharmacy delivery services but also general healthcare outcomes

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