Review

Expanding the role of community pharmacists: Policymaking in the absence of policy-relevant evidence?

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ABSTRACT

Background and objectives: Policies to expand the traditional role of community pharmacists have been implemented or at least considered in a number of countries, as advocated by academics, professional organizations, and governments. Such reforms come on the heel of pressing system-wide challenges. At a time of growing interest in evidence-based policymaking, what is the policy-relevant evidence base in support of this new expanded role for community pharmacists?

Methods: An umbrella review was conducted to identify published systematic reviews of evidence on the effectiveness of community pharmacist interventions. Findings of the identified reviews were documented according to Pharmaceutical Care and Total Pharmacy Care models, and evaluated on the basis of internal and external validity. The internal validity of identified reviews was evaluated in terms of the comparability of populations, interventions, and outcomes. External validity was based on the reproducibility and generalizability of review findings.

Results: Thirty-three systematic reviews published since 2000 evaluated the evidentiary support for the expanded role of community pharmacists, which focuses on two primary objectives: (1) to encourage the effective, safe and appropriate use of medicines and (2) to promote the prevention and management of chronic diseases. The results of most systematic reviews were mixed, with unclear policy relevance. Important methodological drawbacks were found in terms of study identification and selection, and comparability of interventions and outcomes. In addition, the external validity of the findings was inconclusive on the basis of reproducibility and generalizability.

Conclusions: There is inconclusive evidence in support of expanding the role of community pharmacists. This raises an important question: should the pharmacy profession only undertake tasks for which there is strong policy relevance with evidence of economic and public health benefits? In spite of this tension between the necessity to formulate new policies during a period of economic constraints and the level of corresponding evidence, several countries have begun entertaining policies to equip community pharmacists with patient-centered responsibilities. As implementing such expanded roles requires significant changes in the wider health care system, further research is needed to evaluate country-level policy developments.

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1. Introduction

The increasingly orthodox approach to formulating policies is to “do what the science says.” Many now believe that policy-making should be evidence-based in order to...
remove its “political” components [1]. The principle of evidence-based policymaking has indeed permeated all areas of public policy, including the health sector [2].

The increasing interest in evidence-based policymaking has implications for the community pharmacy profession. Recently, experts from academia and professional organizations have advocated in favour of devising policies to equip community pharmacists with expanded roles and responsibilities [3,4]. Several international and national reviews on the role of community pharmacists have concluded that pharmacists could adopt an expanded, patient-centered role and could contribute to safe, effective and economic use of drugs [5,6].

Triggering this patient-focused role two decades ago, Hepler and Strand defined pharmaceutical care as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life” [7]. Going beyond pharmaceutical care, Holland and Nimmo defined the Total Pharmacy Care Model as the combination of five existing practice models: drug information, self-care, clinical pharmacy, pharmaceutical care, and distribution [8]. As such, total pharmacy care is “the delivery of a comprehensive range of services that result in the maximum possible contribution to the health of a nation’s population within the limits of the health care delivery structure.”

Indeed, community pharmacists have the potential to improve patients’ outcomes and reduce the costs of care by promoting health, preventing illness and avoiding adverse events [9]. Pharmacists are the third largest health care professional group in the world after physicians and nurses [10]. Community pharmacists are at times patients’ first and only contact with the health care system [11] and are often described as the most accessible of all health professionals [12]. Consequently, patient-centered responsibilities would be commensurate with the profession’s extensive training and expertise.

Some governments appear to share the enthusiasm for expanding the role of community pharmacists. Across a number of countries, the emerging (albeit slowly) comprehensive role for community pharmacists implies a reconfiguration of the role of community pharmacists within the health system (see Fig. 1). With this understanding, pharmacists’ existing responsibilities towards patient welfare serve as a basis for policies, which grant them greater oversight over the proper and cost-effective use of medicines. The expectation is that, taken together, these activities will encourage care delivery that is coordinated across the health system. This will help to reduce drug-related adverse events and complications associated with long-term chronic conditions (e.g., cardiovascular disease and diabetes). In turn, it should also minimize office visits, hospitalizations and readmissions, and emergency department visits, all of which have considerable economic, clinical, and humanistic consequences.

Although expanding the role of community pharmacists is becoming an important policy objective, the evidence base for such policies has not been comprehensively evaluated. Numerous systematic reviews exist but whether these are adequate for policymaking is not clear. Distinguishing between evidence that is experimental in nature and evidence that is relevant for policymaking, it is important to assess the policy-relevance of the existing evidence on the basis of both its internal validity (“trustworthiness”) and external validity (“transferability”).

Our paper is consequently guided by the following research question: What is the policy-relevant evidence base in support of the new expanded roles for community pharmacists advocated by academics, professional organizations, and governments? To address this research question, we first briefly review the emerging comprehensive roles and responsibilities advocated by academic experts, professional organizations, and governments. We then critically review the scope, quality, and relevance of the corresponding systematic review evidence currently available to inform such policies.

In the next section, we outline the methods used to identify the relevant policy materials and corresponding
systematic review evidence. In the third section, we report the findings of our review of systematic reviews and highlight the variability across reviews in terms of their findings. As we discuss in the final section of the paper, the drawbacks of most existing reviews raise an important question: should the pharmacy profession only undertake tasks for which there is strong policy relevance with evidence of economic and public health benefits?

2. Methods

First, we performed a review of academic publications as well as policy documents from governmental agencies and professional associations. The objective of this non-systematic, exploratory review was to compile a list of new roles and responsibilities for community pharmacists across Europe and North America. This was based on reviewing the Pharmaceutical Care and Total Pharmacy Care models, and searching governmental agency and professional association websites [17–21]. All authors reviewed and discussed the identified materials to compile a comprehensive list of community pharmacist roles and responsibilities, documented to broadly parallel the domains of Total Pharmaceutical Care [8] and Pharmaceutical Care models [7]. Specific national examples and experiences were excluded as they are beyond the scope of this review.

Second, we conducted a review of published systematic reviews, which evaluated the effectiveness of community pharmacist interventions on humanistic, clinical, and economic outcomes. To identify relevant systematic reviews, we searched (1) the University of York Centre for Reviews and Dissemination Database for Systematic Reviews and (2) the Cochrane Collaboration's Database for Systematic Reviews. In addition, supplementary searches were performed on PubMed (MEDLINE) and Google Scholar. Search terms used in PubMed and Google Scholar were “community pharmacy” and “systematic review”. In the case of PubMed, the term ‘community pharmacy’ was exploded to allow for different iterations (e.g., pharmacist, pharmacies). Finally, the citation-tracking feature of Google Scholar was used to manually identify any potentially relevant recent publications that cited older references.

In terms of the inclusion and exclusion criteria, we included reviews examining community pharmacists working in outpatient settings (high street, local, and rural pharmacists). We filtered the search for reviews published in the English language after 2000 (up to December 2012) and excluded those exclusively focused on clinical pharmacist interventions. Clinical pharmacists were defined as pharmacists working in clinics and hospitals.

Data extraction from the identified systematic reviews focused on the following elements: patient population characteristics, study design features (inclusion of randomized vs. non-randomized studies), and the nature of pharmacist interventions. The findings of the identified systematic reviews were documented as humanistic, clinical and economic outcomes.

First, the included systematic reviews were evaluated in terms of their methodological quality using the AMSTAR (assessment of multiple systematic reviews) 11-item questionnaire [22]. In an attempt not to duplicate previous work in the literature, we updated the systematic review by Melchior and colleagues that adopted the same quality assessment tool to evaluate the systematic reviews of pharmacist interventions [23]. For the 21 studies that were included in both umbrella reviews, we used the AMSTAR scores as reported by Melchior and colleagues. For the remaining 12 systematic reviews that were included in our review, we used the 11-item AMSTAR questionnaire to measure the methodological quality of the systematic reviews. We assigned one point for each “yes” and no points for any other score (“no”, “can’t answer” and “not applicable”) to calculate the overall AMSTAR score ranging from 0 to 11. A score of 0–4 indicated “poor”; 5–8 “moderate”; and 9–11 “good” quality.

Included systematic reviews were then evaluated on the basis of their policy relevance. Our definition of policy relevance had two components: (1) internal validity (trustworthiness of evidence), measured in terms of methodological quality and (2) external validity (transferability of evidence), measured in terms of the reproducibility and generalizability of findings across settings.

First, to evaluate internal validity, identified reviews were individually evaluated in terms of the comparability of populations, interventions, and outcomes. In particular, the following limitations were evaluated:

(a) Population heterogeneity: Were the study populations adequately comparable in terms of study setting (inpatient, outpatient, community)?
(b) Intervention heterogeneity: Did the reviewers describe the interventions and whether the interventions were similar and consistently implemented across studies?
(c) Outcome heterogeneity: Were the outcomes consistent across studies included in the review?

Second, identified systematic reviews were collectively reviewed in terms of their reproducibility and generalizability. Reproducibility was defined as the consistency of findings across settings and patient populations. Generalizability was defined as the relevance of a review's findings to real-world settings and the confidence with which the results could be applied from a specific study setting to other populations and settings. To evaluate generalizability, we qualitatively reviewed the experimental nature of the studies (i.e., randomized vs. non-randomized designs) and whether there was adequate detail about the intervention characteristics and external factors (e.g., training of community pharmacists, implementation strategy, and incentive mechanisms) to make a judgement about its applicability to other settings.

3. Results

Table 1 provides a list of expanded roles and responsibilities of community pharmacists as identified in governmental and professional association publications, and categorized to reflect the Pharmaceutical Care and Total Pharmacy Care models. Within this expanded role, community pharmacists have two primary objectives: (1)
Expanded role of pharmacists, policy objectives, evidence from systematic reviews, and limitations of this evidence. In addition to overarching limitations that apply to all reviews within each role, the table reports a number of specific limitations for each systematic review.

<table>
<thead>
<tr>
<th>Envisaged role of pharmacists</th>
<th>Policy objectives</th>
<th>Evidence from systematic reviews</th>
<th>Limitations of existing reviews</th>
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<tbody>
<tr>
<td><strong>Positive findings</strong></td>
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<tr>
<td>Effective, safe and appropriate use of medicines</td>
<td>Avoid office visits</td>
<td>Prevent hospitalizations</td>
<td>Overarching limitations</td>
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<tr>
<td>- Monitor medication</td>
<td>- Avoiding medication errors</td>
<td>- Minimizing adverse reactions</td>
<td>Weak or no evidence on the effectiveness of monitoring of dosage; emergency prescription refill; renewing or extending medication; and advising patients on over-the-counter medications.</td>
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<tr>
<td></td>
<td>- Avoiding drug interactions</td>
<td>- Monitoring of dosage</td>
<td>Specific limitations</td>
</tr>
<tr>
<td></td>
<td>- Emergency prescription refill</td>
<td>- Renewing or extending medication</td>
<td>1. Population heterogeneity. Not specifically focused on community pharmacists; difficult to elicit to which patient population or pharmacist setting the results would apply.</td>
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<td></td>
<td>- Advising patients with over-the-counter medications</td>
<td></td>
<td>2. Intervention heterogeneity. Included interventions varied in scope and intensity; not clear whether negative findings were due to differences in study methodology, comparison groups, setting, intervention targets, and outcomes.</td>
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</table>

**Mixed or inconclusive findings**

- Castillo et al. included 12 randomized controlled trials (RCTs) evaluating the effect of pharmacist interventions on suboptimal prescribing (overuse, misuse, underuse) in individuals 65 years or older; most studies showed a positive effect [29] (specific limitations: 1, 2, 3) (AMSTAR score: 6, moderate).
- Royal et al. reviewed 17 randomized and non-randomized studies evaluating the effect of pharmacist-led interventions to reduce medication-related adverse events and hospital admissions; meta-analysis showed significant reduction in hospital admissions [27] (specific limitations: 2) (AMSTAR score: 6, moderate).
- Robertson et al. included 21 RCTs and quasi-experimental studies evaluating the effect of computerized clinical decision support systems targeting pharmacists on prescribing, clinical and patient outcomes in terms of safety and quality use of medicines; results were consistently positive on safety outcomes [30] (specific limitations: 1, 2) (AMSTAR score: 6, moderate).
- Koshman et al. reviewed the findings of 12 RCTs evaluating the effect of pharmacist interventions on outcomes for patients with heart failure; meta-analysis showed reductions in all-cause and heart-failure hospitalizations and no effect on mortality [61] (specific limitations: 1, 2, 3) (AMSTAR score: 9, good).
- Chisholm-Burns et al. reviewed 298 randomized and non-randomized studies evaluating the effect of US pharmacists as team members on patient care; most studies showed a positive effect on mortality, adverse drug events, medication errors, length of hospital stay; no clear results for hospitalizations and emergency department visits [26] (specific limitations: 1, 2) (AMSTAR score: 10, good).
- Roughhead et al. reviewed 22 RCTs evaluating the impact of community and outpatient pharmacists; findings were positive in terms of medication use, inconclusive and mixed results in terms of reducing drug-related problems [45] (specific limitations: 1, 2, 3) (AMSTAR score: 7, moderate).
- Fish et al. reviewed 16 RCTs evaluating the impact of general practice based pharmacists in providing medication monitoring interventions; findings were inconclusive [62] (specific limitations: 2, 3) (AMSTAR score: 7, moderate).
- Rollason and colleagues reviewed 14 randomized and non-randomized studies evaluating the effectiveness of pharmacist interventions in reducing polypharmacy in the elderly; the quality of identified studies was weak with mixed and inconclusive findings in terms of reducing the number of medications [84] (specific limitations: 1, 2) (AMSTAR score: 5, moderate).
- Von Gunten et al. reviewed 43 controlled and uncontrolled studies evaluating the impact of pharmacist interventions; findings were positive in terms of reducing costs with mixed or negative results in terms of reducing hospital length of stay, length of therapy, mortality rate, and readmission rates [32] (specific limitations: 1, 2) (AMSTAR score: 4, poor).
Table 1 (Continued)

<table>
<thead>
<tr>
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<tr>
<td><strong>Negative findings</strong></td>
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<tr>
<td>Holland et al. reviewed the findings of 32 RCTs evaluating the effect of pharmacist-led medication review interventions in individuals aged 60 or older; meta-analysis showed no effect on all-cause emergency hospitalizations and mortality, and modest reductions in the number of prescriptions [28] (specific limitations: 1, 2, 3) (AMSTAR score: 11, good).</td>
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<td>Hanlon et al. reviewed 14 RCTs of pharmacist interventions designed to improve medication-use process measures and health outcomes in the elderly; community pharmacist interventions had no effect on drug-related problems [31] (specific limitations: 2, 3) (AMSTAR score: 5, moderate).</td>
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<td><strong>Positive findings</strong></td>
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<td>Von Guntenet al. reviewed 43 controlled and uncontrolled studies evaluating the impact of pharmacist interventions; findings were consistently positive in terms of appropriateness of indication [32] (AMSTAR score: 4, poor).</td>
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<tr>
<td><strong>Mixed or inconclusive findings</strong></td>
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<td>Robertson et al. included 21 RCTs and quasi-randomized studies evaluating the effect of computerized clinical decision support systems targeting pharmacists on prescribing, clinical and patient outcomes in terms of safety and quality use of medicines; inconsistent and weak findings on quality use of medicines in terms of recommending additional or alternative drug for chronic conditions [30] (AMSTAR score: 6, moderate).</td>
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<tr>
<td><strong>Overarching limitations</strong></td>
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<td>Robertson et al. reviewed 6 RCTs evaluating the effect of pharmacist interventions in the improvement of adherence to antidepressant medications; results showed a significant benefit from pharmacist interventions [52] (specific limitations: 1, 2, 3) (AMSTAR score: 7, moderate).</td>
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<td>Morrison et al. reviewed 32 RCTs evaluating the effect of counseling of patients, counseling of physicians, or both, in outpatient, hospital, and community pharmacy settings; findings were primarily positive [54] (specific limitations: 1, 2, 3) (AMSTAR score: 4, poor).</td>
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<tr>
<td>Holland et al. reviewed the findings of 32 RCTs evaluating the effect of pharmacist-led medication review interventions in individuals 60 or older; positive findings on drug knowledge and adherence [28] (specific limitations: 1) (AMSTAR score: 11, good).</td>
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<tr>
<td>Chisholm-Burns et al. reviewed 298 randomized and non-randomized studies evaluating the effect of US pharmacists as team members on patient care; 48% to 57% of studies showed favourable findings in adherence, satisfaction, and knowledge [26] (specific limitations: 1) (AMSTAR score: 10, good).</td>
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<tr>
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<tr>
<td>Al-Jumah et al. reviewed 12 RCTs evaluating the effect of pharmacist interventions (patient education and drug monitoring) on adherence to antidepressant medications; positive findings on adherence with no clear impact on depressive symptoms [33] (specific limitations: 1, 2, 3) (AMSTAR score: 5, moderate).</td>
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<td>Van Wijk et al. reviewed 18 randomized and non-randomized studies evaluating the effect of community pharmacist interventions on patient adherence to chronic medication; results were unclear and inconsistent [34] (specific limitations: 1, 3) (AMSTAR score: 6, moderate).</td>
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</table>

### Safety, accuracy and quality

- Managing drug distribution systems
- Ensuring careful purchasing of medications to prevent counterfeit use
- Adopting quality management systems for timely and effective procurement and storage

Maintain high quality across the drug distribution system

Systematic reviews could not be identified

### Promotion, prevention and disease management

- Health promotion and awareness building
  - Performing individual patient assessments
  - Undertaking smoking cessation counselling
  - Weight management counselling
  - Promoting immunization and other public health initiatives

Promote healthy behaviours through printed materials and interventions

Positive findings

Sinclair et al. reviewed 2 RCTs investigating the effectiveness of community pharmacy-based interventions to assist patients to stop smoking; the limited evidence found suggests that these interventions can have a positive effect on smoking cessation rates [35] (AMSTAR score: 11, good).

Blenkinsopp et al. reviewed 11 randomized and non-randomized studies evaluating the effectiveness of community pharmacy-based interventions in reducing the risk behaviours and risk factors for coronary heart disease; positive findings were found for smoking cessation and lipid management [36] (specific limitations: 1, 2) (AMSTAR score: 6, moderate).

Dent et al. reviewed 5 RCTs and 10 non-randomized studies assessing the effectiveness of tobacco-cessation services delivered by pharmacists in the US; the evidence found strongly suggests that pharmacists are effective in helping their patients to quit smoking [37] (specific limitations: 1, 2) (AMSTAR score: 2, poor).

Santschi et al. reviewed 30 RCTs evaluating the impact of pharmacist care on the management of cardiovascular risk factors among outpatients; the evidence found showed that the pharmacist intervention was associated with a reduction in the risk of smoking [38] (specific limitations: 1, 2) (AMSTAR score: 10, good).

Mixed or inconclusive findings

Gordon et al. reviewed 10 randomized and non-randomized studies looking at the extent to which community pharmacies can increase capacity for weight management; the evidence found was insufficient to assess the effectiveness and cost-effectiveness of community pharmacy-based weight management initiatives [39] (specific limitations: 1, 2) (AMSTAR score: 8, moderate).

### Overarching limitations

- There was no systematic review evidence regarding the effect of weight management counselling, promoting immunization and other public health initiatives.

### Specific limitations

1. **Population heterogeneity.** The setting of the studies included was not always clear, making it difficult to assess the respective role of community pharmacists.

2. **Intervention heterogeneity.** The nature of the intervention – whether through printed materials or active engagement of community pharmacists – was not clear in most studies.
Table 1 (Continued)

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptom management and continuity of care</strong></td>
<td>Foster collaboration and appropriate care delivery across the wider health system</td>
<td>Positive findings</td>
<td><strong>Overarching limitations</strong></td>
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<tr>
<td>◦ Advising patients with minor ailments</td>
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<td>Holland et al. reviewed 30 RCTs assessing the impact of multidisciplinary interventions on hospital admissions and mortality in heart failure; evidence of reduction in all cause admission, all-cause mortality and heart failure admission was found, with most consistent findings found for interventions delivered at least partly in the home. [63] (Specific limitations: 1, 2) (AMSTAR score: 11, good)</td>
<td>○ No systematic review evidence on the effectiveness of community pharmacists in advising patients with minor ailments.</td>
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<td>◦ Referring patients to other health professionals</td>
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<td>Elliet et al. reviewed 21 randomized and non-randomized studies evaluating the effectiveness of pharmacist interventions in ensuring continuity of care (ongoing care); findings were positive in patients with diabetes; dyslipidemia; hypertension; and depression [40] (specific limitations: 1, 2, 3) (AMSTAR score: 9, good).</td>
<td><strong>Specific limitations</strong></td>
</tr>
<tr>
<td>◦ Presenting drug regimens to a care team or physician</td>
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<td>Geurts et al. reviewed 83 non-randomized studies to assess the impact of collaboration between pharmacists and general practitioners on patient’s health; the results were contradictory and not statistically significant [41] (specific limitations: 1, 2) (AMSTAR score: 4, poor).</td>
<td>1. <strong>Population heterogeneity.</strong> Not specifically focused on community pharmacists; multidisciplinary interventions did not distinguish between professions, making it difficult to assess the specific contribution of pharmacists.</td>
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<tr>
<td>◦ Developing a care and follow-up plan</td>
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<td>2. <strong>Intervention heterogeneity.</strong> The nature of the intervention differed across studies; pharmacists received considerable training in some instances.</td>
</tr>
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</table>

**Mixed or inconclusive findings**

| | | | 3. **Outcome heterogeneity.** The definition of continuity of care differed across individual studies included in systematic reviews. |
| | | | **Specific limitations** |
| | | | 1. **Population heterogeneity.** Not specifically focused on community pharmacists; difficult to elicit to which patient population or pharmacist setting the results would apply. |
| | | | 2. **Intervention heterogeneity.** Most of the interventions assessed were complex and multifaceted. Due to the complex nature of the interventions, it was difficult to precisely identify which (aspect of the) intervention was responsible for positive or negative findings. |

**Disease management and self-care**

Help prevent and manage costly chronic diseases

| | | Positive findings | **Specific limitations** |
| | | Collins et al. reviewed 14 RCTs evaluating the effect of pharmacist intervention on glycemic control; the results showed a positive and consistent association between pharmacist interventions and improvements in glycemic control [47] (specific limitations: 1, 2) (AMSTAR score: 6, moderate). | 1. **Population heterogeneity.** |
| | | Santchi et al. reviewed 30 RCTs evaluating the impact of pharmacist care on the management of cardiovascular disease risk factors among outpatients; pharmacist interventions were associated with reductions in blood pressure, total cholesterol and low density lipoprotein cholesterol [38] (specific limitations: 2) (AMSTAR score: 10, good). | Not specifically focused on community pharmacists; difficult to elicit to which patient population or pharmacist setting the results would apply. |
| | | Morgado et al. reviewed 15 randomized and non-randomized studies evaluating the effect of pharmacist interventions in enhancing blood pressure control and adherence to antihypertensive therapy; pharmacist interventions significantly improved medication adherence, systolic blood pressure, diastolic blood pressure and blood pressure control in patients with essential hypertension [42] (specific limitations: 1, 2) (AMSTAR score: 10, good). | 2. **Intervention heterogeneity.** Most of the interventions assessed were complex and multifaceted. |
| | | Machado et al. reviewed 36 randomized and non-randomized (controlled and uncontrolled) studies evaluating the effect of pharmacist interventions on diabetes management; education and medication management interventions resulted in positive effects on Hb A1C levels, blood pressure, with fixed results in lipid parameters, and adherence outcomes [48] (specific limitations: 1, 2) (AMSTAR score: 9, good). | Due to the complex nature of the interventions, it was difficult to precisely identify which (aspect of the) intervention was responsible for positive or negative findings. |
to encourage the effective, safe and appropriate use of medicines and (2) to promote the prevention and management of chronic diseases. This expanded role involves monitoring medications by ensuring that patients receive appropriate medications for a given indication; promoting adherence; encouraging healthy behaviours and building health awareness; managing chronic conditions; and supporting the continuity of care. Through medication review practices, pharmacists play a part in avoiding medication errors and minimizing adverse reactions and drug interactions. To ensure the clinical and economic appropriateness of medication therapy, pharmacists have a role in recommending additional or alternative drugs and promote generic medication use. To improve adherence, pharmacists reinforce prescribing instructions; educate and provide counselling services; and inquire about satisfaction with therapy. Finally, in an attempt to prevent and manage chronic conditions, pharmacists are responsible for coordinating with other health care providers and develop a care and follow-up plan, and order and interpret tests for conditions such as asthma, diabetes, hypertension, and heart disease.

In total, 33 systematic reviews published since 2000 evaluated the effectiveness of community pharmacist interventions in achieving these expanded roles and responsibilities (Table 1). In the proceeding section, the total number of systematic reviews is higher than 33 as a number of systematic reviews focused on more than one role for community pharmacists, and are counted more than once.

The identified list of systematic reviews spanned a large body of evidence assessing the effectiveness of community pharmacist interventions on economic, clinical, and humanistic outcomes. Eleven systematic reviews evaluated the effectiveness of community pharmacist interventions on medication monitoring activities with the objective of avoiding medication errors, minimizing adverse reactions, and avoiding drug interactions. Two
systematic reviews explored whether community pharmacist interventions were beneficial in ensuring appropriate use of medications. Eight systematic reviews focused on the existing evidence on improving medication adherence in terms of improving adherence outcomes and patient health outcomes in the elderly [31]. Regarding appropriate indications, the evidence was mixed – although with important methodological limitations. Five systematic reviews evaluated the role of community pharmacists in health promotion and awareness building, and in particular smoking cessation counselling, weight management counselling, and promoting immunizations. Three reviews focused on symptom management and continuity of care in terms of referring patients to other health professionals and presenting drug regimens to care teams or pharmacists. Finally, eleven systematic reviews evaluated the effectiveness of community pharmacist interventions on disease management and self-care by reviewing and synthesizing the existing evidence on preventing and managing chronic conditions. Based on the AMSTAR scores, the methodological quality of most included systematic reviews ranged from poor to moderate, with nine reviews scored as ‘good’ methodological quality (Table 1).

According to one of the most comprehensive reviews of the literature performed by the Cochrane Collaboration in 2000, community pharmacists’ involvement in patient counselling and physician education activities had a positive impact on health services utilization, costs, and patient outcomes [24]. In an update of this Cochrane review, pharmacist services targeted at patients were associated with reductions in the incidence of therapeutic duplication and resulted in a decrease in the total number of medications prescribed [25]. There were also clear improvements in clinical outcomes across the identified list of randomized trials.

However, as Table 1 shows, the results of most systematic reviews of community pharmacist interventions are mixed. According to some reviews, community pharmacists are highly effective in ensuring the safety of medication use by preventing the occurrence of drug related medication errors [26] and avoiding hospitalizations [27]. According to others – the majority – the findings are either inconsistent or inconclusive with no clear implications for expanding the role of community pharmacists in health care delivery [28].

The first area of practice considered in Table 1 is the effective, safe and appropriate use of medicines. In terms of monitoring medication, most of the evidence reviewed is inconclusive or mixed. Keeping in mind the limitations described in the next section, positive effects were found in the areas of suboptimal prescribing in individuals aged 65 years and older [29]; reduction of hospital admissions [27]; and computerized clinical decision support systems’ impact on patient safety outcomes [30]. Negative outcomes were reported for pharmacist-led medication review interventions [28] and for interventions used to improve medication-use process measures and health outcomes in the elderly [31]. Regarding appropriate indication, the evidence was mixed – although with important methodological limitations. Mixed or inconclusive findings were found for the effect of computerized clinical decision support systems on recommending additional or alternative drugs for chronic conditions [30], whereas positive findings were reported in terms of appropriateness of indication [32]. The evidence on the effect of pharmacists’ interventions was broadly positive, with mixed findings reported in the areas of adherence to antidepressant medications [33] and adherence to chronic medications [34].

The second area of practice reviewed in Table 1 is the promotion, prevention and management of diseases. There was considerable evidence in support of the role of community pharmacists for health promotion and awareness building. Positive effects were found in four studies investigating the impact of pharmacist interventions for smoking cessation [35–38] and lipid management [36], while inconclusive findings were reported for weight management [39]. Findings were broadly positive for symptom management and continuity of care [40], with mixed findings reported for the impact of collaboration between general practitioners and pharmacists [41]. Finally, in the area of disease management and self-care, positive evidence was found supporting community pharmacist interventions for improving glycemic control [38,42–46], management of cardiovascular risk factors, diabetes, hyperlipidemia, asthma, blood pressure control, adherence to antihypertensive therapy and prescribing for mental health conditions.

3.1. Internal validity

The existing systematic reviews of the literature evaluating the effectiveness of pharmacist interventions had a number of drawbacks. As shown in Table 1, the included systematic reviews had a number of overarching limitations, which applied to all reviews identified within a category. In general, there was weak or no evidence on the effectiveness of community pharmacist interventions in monitoring of dosage; emergency prescription refill; renewing or extending medication; and advising patients with over-the-counter medications. Similarly, there was no systematic review evidence on the effectiveness of pharmacist interventions on promoting generic use. In terms of disease promotion and symptom management, there was no systematic review evidence regarding the effect of weight management counselling, promoting immunization and other public health initiatives. In particular, methodological limitations of the identified systematic reviews were evaluated on the basis of three dimensions: population, intervention, and outcome heterogeneity. An important observation that arose from Table 1 was the absence of a pattern associating the methodological quality of a given systematic review with its outcomes. Reviews reporting mixed findings did not necessarily suffer from more methodological limitations.

First, in terms of the comparability of populations, although the majority of the included studies evaluated community pharmacists, it was still difficult to elicit the applicability of findings to community pharmacy settings due to the lack of setting-specific sub-groups. In many cases, multidisciplinary interventions did not distinguish...
between professions, making it difficult to assess the specific contribution of pharmacists. This limitation applied to almost all of the identified reviews (Table 1).

Second, the nature of the community pharmacist interventions differed across studies (Table 1). For example, systematic reviews that evaluated the effectiveness of community pharmacist interventions on symptom management and continuity of care activities included studies where pharmacists received considerably more training in some cases as opposed to others [40,41]. In a number of studies, there were co-interventions, making it difficult to clearly delineate the different types of interventions. This was particularly the case among the systematic reviews evaluating the impact of interventions on health promotion and awareness building where reviewers pooled studies with complex and multifaceted interventions [42,43,47–50]. In other cases, systematic reviews included studies that employed heterogeneous interventions whether through printed materials or active engagement of community pharmacists [36–39].

Finally, there was also considerable outcome heterogeneity across the included set of studies (Table 1). For instance, in systematic reviews evaluating the effectiveness of community pharmacist interventions on medication adherence, adherence was measured differently across the set of included studies, ranging from subjective measures such as self-report to objective assessments such as pharmacy records, pill counts and blood plasma concentrations. In particular, these reviews employed a wide diversity of endpoints ranging from knowledge and compliance to clinical outcomes such as blood pressure and blood sugar level control [33,51–54]. In cases where systematic reviews achieved comparability on the basis of more than one dimension, considerable heterogeneity was present in terms of the third dimension. For example, a number of systematic reviews focused on ensuring consistency and comparability across the included studies in terms of populations and outcomes (e.g. pharmacist intervention studies were eligible for inclusion if they reported the outcome of interest in a given group of therapeutically defined individuals), rather than interventions. Elias and colleagues reviewed the findings of 25 randomized and non-randomized studies that examined pharmacist interventions in osteoporosis management [55]. Bennett and colleagues reviewed the findings of randomized trials that evaluated the impact of pharmacist interventions on pain-related outcomes in individuals suffering from chronic pain [56]. Similarly, Pickard et al. included studies if they focused on health-related quality of life endpoints in certain therapeutic areas. In these reviews, a variety of pharmacist interventions were considered (independent or as part of teams) ranging from computerized decision aid systems to comprehensive pharmaceutical care. As a result, the nature of the intervention and its setting were considerably different across the included list of studies.

3.2. External validity

Given the geographic variability in the existing evidence base for pharmacist interventions (where evidence of effectiveness varied considerably both between and within countries) the condition of reproducibility was not met. While there was strong evidence in support of an expanded role for community pharmacists in the US [57,58], much of the evidence stemming from the UK was negative. For instance, in the UK offering advice during a medication review to old patients did not result in improved outcomes [59]. Similarly, home visits for heart failure patients in the UK did not achieve the intended effects [60].

In terms of generalizability, an important limitation of existing systematic reviews was the clear preference for assessing randomized controlled trials (RCT) to other study designs, which was the case in 14 reviews [28,29,31,33,35,38,44,45,47,52,54,61–63]. Another limitation of the included reviews in terms of their generalizability was the lack of detail around the intervention. A large number of systematic reviews did not report the care setting of interventions of the primary studies while some reviews did not define the target population in the methods [23]. In addition, the ‘dose’ of the intervention was not reported in many of the studies [64]. Dose refers to the intensity of the intervention, including the way it is implemented, and followed up. There was minimal or no information on the training regimens that the community pharmacists underwent prior to the study; whether the intervention was successfully implemented; and what other factors may have contributed to the success or failure of the intervention.

4. Discussion

In this study, we reviewed the systematic review evidence in support of policy developments in expanding the role of community pharmacists. We included 33 systematic reviews of the literature published since 2000. According to some reviews, community pharmacists were highly effective in promoting the effective, safe, and appropriate use of medicines. According to others, the findings were either inconsistent or inconclusive with no clear implications for expanding the role of community pharmacists in health care delivery.

From a methodological standpoint, our conclusions parallel and extend those of previous umbrella reviews. Charrois and colleagues provided a critical evaluation of systematic reviews of pharmacy practice research [64]. Although the review by Charrois and colleagues did not identify specific systematic reviews, it provided a general assessment of the evidence base and highlighted some important methodological issues, including searching, interpreting, and evaluating the available evidence. More recently, Melchior and colleagues found that the quality of systematic reviews of pharmacist interventions ranged from moderate to low [23]. Their review was focused on the use of a quality assessment tool, AMSTAR, which specifically evaluates the conduct of the systematic review on a number of domains including (but not limited to) study inclusion criteria, protocol development, literature search strategy, and assessment of publication bias. Importantly, these previous umbrella reviews did not focus specifically on community pharmacists. Also, the scope of their assessment was limited to the methodological quality of the systematic reviews. Our umbrella
review consequently differs from previous examples in important ways. First, this umbrella review is the first to comprehensively review the findings (in addition to methods) of published systematic reviews. Second, the focus of our review was on community pharmacists. As such, the list of systematic reviews included in our study differed from those in previous reviews. Third, in addition to critically reviewing the identified systematic reviews in terms of their methodological rigour (and complementing the AMSTAR assessment undertaken by Melchiors and colleagues), we interpreted the findings in terms of their policy relevance.

In terms of the comparability of populations, interventions, and outcomes, the identified systematic reviews had important limitations. The majority of the reviews included studies undertaken in settings other than community pharmacists, with study populations ranging from those in facility settings to the community. Outcomes and interventions varied widely across studies, making the interpretation of their findings difficult. This lack of comparability made the findings of existing systematic reviews difficult to interpret. In essence, the high level of heterogeneity in the existing evidence base made it difficult to determine to which population, intervention, and outcome the findings apply. Taken together, without a clear exploration of consistent outcomes of interventions in homogenous populations, the existing body of evidence may not be adequate to inform policy.

Equally important, there was no detail around the nature of the interventions, the setting in which they were devised, and how they were implemented. These factors, termed ‘support factors’ by Cartwright and Hardie, are essential to understand why a given intervention worked or failed in a given experiment, and to evaluate whether those factors are transferable across settings [65].

A large number of reviews exclusively included RCTs. RCTs are considered the ‘gold-standard’ for evaluating an intervention’s effectiveness [66]; however, they have important limitations when evaluating pharmacist interventions. Van Wijk and colleagues discuss the potential in RCTs to experience the Hawthorne effect, whereby participants alter their behaviour as a result of being part of an experiment [34,67]. In addition, the high regard placed on RCTs stems from its success in clinical research. However, few of these techniques (e.g., blinding and treatment concealment) are suited for community pharmacy service research. In light of these limitations, a viable alternative to the RCT design may be an observational study. Observational studies may better reflect actual pharmacy practice. Systematic reviews evaluating the effectiveness of pharmacist interventions should consider evidence that is both valid and relevant, irrespective of study design [68].

Surprisingly, none of the systematic reviews focused specifically on evaluations of policy interventions. In this regard, the majority of the included studies in systematic reviews were academically focused experimental studies, seemingly undertaken in isolation from wider policy changes at the regional or country level. Reflecting the experimental nature of the literature on pharmacy practice research, systematic reviews did not explore whether interventions were implemented with appropriate and adequate incentive mechanisms. Financial reimbursement was only rarely evaluated [28].

In sum, doubts about the external validity of the included systematic reviews (in terms of their reproducibility and generalizability), coupled with their methodological limitations (the poorly defined interventions, and the lack of appropriate assessments for comparability in terms of populations and outcomes) indicate that the existing evidence is not adequate to forecast the likely effect of expanding the role of community pharmacists. In light of the available evidence (or the lack thereof) on the effectiveness of pharmacist interventions, should decision makers devise and implement policies to expand the role of community pharmacists within the health care system?

Despite the limitations of the existing evidence, there is a continuing discussion around expanding the role of community pharmacists. Significant changes in national health care systems are fuelling a critical examination of the role and contribution of each health profession, and particularly community pharmacists. Several countries are in the early to mid-stages of reforming and expanding the role of community pharmacists (Fig. 1). These efforts highlight an apparent paradox between the necessity of formulating new policies and the level of corresponding evidence. It begs the question whether policy-makers can account for changing demographic, economic and public health circumstances [69,70] when reforming the role of community pharmacists or do they simply base their policy decision on the limited, available evidence.

Albeit the existing evidence, policymakers seem to adopt the view that equipping community pharmacists with patient-centered responsibilities is justified on the grounds of pressing system-wide challenges that span demographic, economic, and public health issues. Population ageing has been recognized as one of the drivers of the demand for medical technologies (e.g., pharmaceuticals, devices, diagnostic and surgical procedures) and consequently, of the annual growth in national health spending in most countries. Caring for chronic conditions that emerge as the patient ages is costly. For instance, across the 27 member states of the European Union, cardiovascular disease is estimated to cost €169 billion annually, with health care services accounting for 62% of these expenditures [71]. Similarly, increases in costs can be attributed to other chronic conditions such as obesity and diabetes.

Medications contribute disproportionately to these rising health care expenditures. A growing number of people receive medications for an increasingly complex mix of conditions [72]. The use of multiple medications, termed “polypharmacy”, is becoming common among older patients and represents a risk factor for morbidity and mortality [73,74]. Medication-related adverse events resulting in complications and hospitalizations are common and costly [75–77]. An estimated 7 percent of hospitalizations are attributable to medication-related adverse events [78]. Spending on medications accounts for about 18% of total health spending on average across European Union countries [79]. In the UK alone, prescription costs
totaled £8.6 billion in 2010 [80]. Between 1990 and 2010, the average spending per capita on medications has risen by almost 50% in real terms, although with considerable cross-country variations [79]. This trend partly results from the ageing of the population as well as the increase in the price of medicines and the change in the mix towards newer and more expensive products [81,82].

As some countries move towards equipping community pharmacists with an expanded patient-centered role, their efforts will necessitate a reconfiguration of the health system and will require philosophical, organizational, and functional changes in the practice of community pharmacy and in the wider health care system. The envisioned policy change (see Fig. 1) supposes the following conditions are met: the integration of community pharmacists within the wider health care system; a public informed about the new role of pharmacists; performance-based incentive structures; and – among other practical issues – the implementation of information systems. For example, when asked about their role in the public health system, pharmacy students in France listed a number of barriers preventing these innovations, including working time, remuneration and organizational problems such as the need to create a space devoted to consultations [83].

These attempts to redefine the community pharmacy practice are similar in their aim to legitimize pharmacists as health professionals. However, achieving such a patient-centered role may put community pharmacists at odds with other professions who seek to maintain and enhance their existing professional status. Thus, a system-wide policy agenda is needed to align the roles, objectives, and incentives of health professionals and devise an expanded role for community pharmacists.

5. Conclusions

Scientific evidence is essential for informing health policy decisions. The notion of evidence-based policymaking has important implications for the community pharmacy profession as it is moving towards a more patient-centered role. A number of countries are introducing policies to formally expand the role played by community pharmacists in their respective health systems. The systematic review evidence in support of this transformation is mixed and inconclusive. Moreover, there are important limitations to the existing systematic reviews of evidence concerning community pharmacist interventions. In addition to methodological concerns with individual systematic reviews, the lack of generalizability and reproducibility pose challenges to guiding evidence-based policies. Despite the limitations of the evidence base, future policy efforts to expand the role of community pharmacists should be considered in light of the pressing demographic, economic, and public health challenges. Although the policy enthusiasm for equipping community pharmacists with patient-centered roles may not reflect the existing evidence, system-wide considerations may justly moving in this direction. Future research efforts should evaluate the latest policy developments in a selected number of countries that offer an emerging patient-centered role for community pharmacists.

References


[34] Van Wijk BL, Klungel OH, Heerdink ER, de Boer A. Effectiveness of community pharmacy interventions for preventing diabetes mellitus: a systematic review. Cochrane Database of Systematic Reviews 2004 (1).


[38] Sinclair Hazel K, Bond Christine M, Stead Lindsay F. Community pharmacy personnel interventions for smoking cessation. Cochrane Database of Systematic Reviews 2004 (1).


