

Research Paper



Role of community pharmacists in managing hypertension and diabetes: a patient-centered approach

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) and hypertension are leading causes of cardiovascular morbidity and mortality worldwide. Community pharmacists offer an accessible, localized solution for bridging chronic disease treatment gaps. Despite this potential, pharmacist-led patient-centered care for these comorbidities remains under-researched in low-and middle-income settings.

Purpose: This study critically assessed clinical, behavioral, and financial outcomes of community pharmacist-led interventions in patients with hypertension and/or T2DM using a patient-centered care model.

Methods: A mixed-methods cross-sectional study was conducted across 12 community pharmacies over six months. In all, 450 adult patients (>18 years) diagnosed with hypertension, T2DM, or both were recruited. Structured interventions included medication therapy management (MTM), adherence counseling, disease-state education, and self-monitoring training. Systolic and diastolic blood pressure, HbA1c, and fasting blood glucose were measured at baseline and three-month follow-up. Patient satisfaction was assessed using a 10-item Likert scale.

Findings: Significant improvements were observed post-intervention. Mean systolic blood pressure declined from 158.4 ± 14.2 to 138.7 ± 11.6 mmHg ($p < 0.001$), and HbA1c decreased from $8.6 \pm 1.1\%$ to $7.4 \pm 0.9\%$ ($p < 0.001$). Medication adherence and patient satisfaction scores improved by 36.2 and 31.0 points, respectively. Key barriers included poor reimbursement frameworks, absence of integrated health records, and ineffective inter-professional collaboration.

Conclusion: Community-based pharmacist interventions significantly improved clinical outcomes and patient satisfaction in patients with hypertension and diabetes. Integrating pharmacist-led care into patient-centered models through policy reform and digital health holds strong potential for global chronic disease management.

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1. INTRODUCTION

A menace to the twenty-first century, chronic non-communicable diseases (NCDs) are especially hypertension and type 2 diabetes mellitus or T2DM. The World Health Organization estimates that as many as 1.28 billion adults globally are hypertensive and 422 million people are diabetic and with estimates of 700 million diabetes cases by 2045 [1]. The conditions are often comorbid, with hypertension being diagnosed in close to 70% of diabetics which greatly increases the risk of cardiovascular diseases, end-stage renal disease and early death [2]. Although pharmacotherapy has improved, suboptimal disease management is still common with the key causes of this being the lack of medication compliance, disjointed care provision and inadequate education of patients on self-management of the disease [3].

Community pharmacists are strategically placed in the primary healthcare systems. Unlike clinic-based practitioners, pharmacists are also freely available without having to book appointments, moreover, pharmacists are involved in direct contact with the patient, which, when effectively utilized, can also be an influential touch point of delivering knowledge to patients as well as monitoring chronic diseases [4]. Evidence on the effectiveness of pharmacist delivered interventions to enhance blood pressure regulation [5], GI [6], pharmacist adherence [7] and life quality [8] demonstrate their effectiveness in multiple healthcare systems. Translating this evidence to daily community pharmacy practice, however, has been uneven, especially in the resource-constrained environment [9].

The idea of patient-centered care (PCC) which the Institute of Medicine described as care responsive and respectful to the individual patient needs, preferences and values is a solid conceptual framework to redefine the role of the pharmacist in NCD management [10]. Patient-centered pharmacy practice goes beyond the historic dispensing role to include shared decision-making, individualized counseling and longitudinal follow-up [11]. It is a particular paradigm in the field of hypertension, diabetes, wherein self-management behaviors, lifestyle change and regular adherence to pharmacotherapy are the determinants of long-term outcomes [12].

Although an increasing literature has been provided that supports the pharmacist-led intervention, there still remains a gap of knowledge regarding the multidimensional nature of the interventions, the obstacles to the execution of pharmacist-led intervention in the community and its efficacy relative to the heterogeneous patient populations [13]. The study at hand thus aims at assessing clinical, behavioral, and economic outcomes of a structured community-based approach to managing patients with hypertension, diabetes, or both using a patient-centered care lens. The results will be used to guide policy changes to broaden the pharmacist practice scope and to implement community pharmacy practices as part of the organized chronic disease management schemes.

2. RELATED WORK

The last 20 years are marked with a lot of study on the role of pharmacist interventions in the management of hypertension and diabetes. Pharmaceutical care was originally a philosophy of practice coined by Strand and colleagues in 1990 and placed the burden on the pharmacist of drug therapy events

[14]. Since that time, randomized controlled trials, as well as systematic reviews have testified to the clinical worth of the involvement of pharmacists in managing chronic diseases [15].

A meta-analysis by conducted in the field of hypertension analyzed 39 trials in total and found that pharmacist care models had a mean effect of reducing systolic blood pressure by 7.6 mmHg versus usual care [16]. These findings were confirmed by subsequent studies. As an example, found that the patients treated to collaborative pharmacist-physician care had a much higher percentage of attaining the target blood pressure levels compared to the patients treated to regular care groups [17]. The Team-Based Care to Improve Hypertension Management (TCIHM) trial also proved that cardiovascular risk scores decreased by up to 15% in 12 months with pharmacist co-management [18].

On the same note, pharmacist-managed medication therapy management (MTM) in diabetes management has achieved relative steady decreases in glyated hemoglobin (HbA1c). In a systematic review, included 22 control studies and found that pharmacist-based interventions reduced the mean level of HbA1c by 0.76% which is associated with 0.76% a significant change where it reduces the number of micro vascular complications [19]. More up-to-date studies have investigated the use of digital health tools together with pharmacist-led care in which noted that telemonitoring plus pharmacist counseling enhanced both glycemic control and blood pressure levels among patients with comorbid conditions [20].

Other notable barriers to pharmacist-led care are mentioned in the literature as well as systemic and structural barriers. The issue of reimbursement is one of the most continuous hurdles in most of healthcare systems that do not directly attract clinical services offered by pharmacists in the billing system [21]. Moreover, the lack of practice agreements between physicians and pharmacists has also been listed among the restricting factors of the scope and sustainability of pharmacist interventions [22]. Other determinants of intervention effectiveness have been established as workforce training, digital interoperability and patient health literacy [23].

Though serious researches have been developed around North America and Europe, there is a lack of evidence in South Asian and African environment. Considering that hypertension and diabetes are more prevalent in these areas and that people primarily use community pharmacies as their first-line health-related product, region-specific studies are badly needed [24]. This research fills this gap as it investigates pharmacist-led NCD interventions in a heterogeneous, multi-location community-based pharmacy environment and provides both high and low-resource contexts with empirical data.

3. METHODOLOGY

3.1 Study Design and Setting

Cross-sectional study design was adopted and a pre-post aspect of intervention and mixed-method were chosen. The research was carried out in 12 community pharmacy settings spread out in urban, peri-urban and semi-rural regions during six months (January 2023-June 2023). Purposive sampling was used to pick the sites and this ensured a variety in the demographics of the patients, staffing of the pharmacies and geographical areas. Ethical approval will be provided by the Institutional Review Board (IRB Reference: PHR/2023/047) and informed written consent will be provided by all the participants prior to their enrollment.

3.2 Participants

Four hundred and fifty adult patients (those aged above 18 years) were sampled with a diagnosis of either hypertension, T2DM or a combination of both. The inclusion criteria were a conferred diagnosis of six months or more, they should be taking the prescription and be willing to participate in structured follow-up visits. Those with a severe psychiatric case, terminal cases, or those lack the capacity to give informed consent were excluded. The participants were divided into three groups: Group A (hypertension only, n=160), Group B (diabetes only, n=140) and Group C (comorbid hypertension and diabetes, n=150).

3.3 Intervention Protocol

Standardized training was given on clinical assessment skills and motivational interviewing as well as documentation practices to participating pharmacists before the start of the study. The intervention plan was structured based on four main activities: (i) Medication Therapy Management (MTM) reviews to recognize drug-related issues and optimize drug regimens, (ii) individualized adherence counseling applying the six-item MO risky Medication Adherence Scale (MMAS-8) as a measuring tool, (iii) disease-state education with validated multimedia resources supported by literacy level and All participants obtained minimum of three structured pharmacist visits at the beginning, six weeks and three months. As Figure 1 depicts, the general study design reveals how the research started by recruiting participants and concluded with the delivery of intervention and subsequent measurement of the outcome.

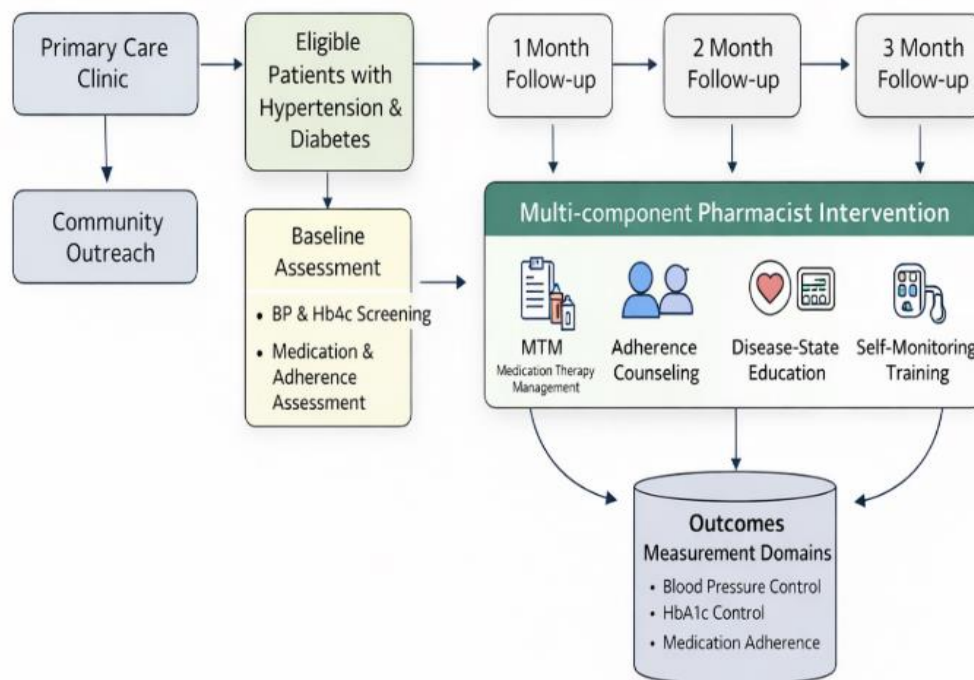


Figure 1. Study Framework: Community Pharmacist Intervention Model for Hypertension and Diabetes Management

3.4 Outcome Measures

The main clinical outcomes were alterations in systolic and diastolic blood pressure (through triplicate measurements on calibrated automated sphygmomanometers), HbA1c (measured on point-of-care HbA1c analyzers) and fasting blood glucose. Secondary outcomes were medication adherence (MMAS-8 score), patient-reported satisfaction (a 10-item Likert-scale tool, validated to score 0-100) and rate of adverse drug reaction (ADR). As depicted in Figure 2, the outcome measurement framework categorizes these endpoints based on clinical, behavioral and experiential domains.

3.5 Statistical Analysis

The study population was characterized using descriptive statistics. Paired t-tests were used in the pre- and post-intervention comparisons when continuous variables had normally distributed data and the non-normally distributed data were compared using Wilcoxon signed-rank tests. Chi-square tests were applied for categorical variables. Subgroup analyses were conducted by group of patients and pharmacy site (urban vs. peri-urban/semi-rural). All tests were performed with SPSS v27.0 with the level of significance e.g. $p < 0.05$. The effect sizes were computed using the Cohen d as a continuous.

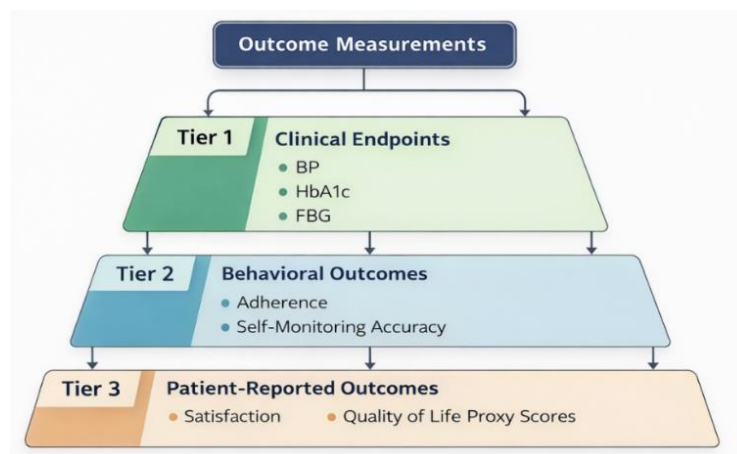


Figure 2. Outcome Measurement Framework: Clinical, Behavioral and Patient-Reported Endpoints

4. RESULTS AND DISCUSSION

4.1 Participant Characteristics and Intervention Reach

Out of the total population of 450 participants enrolled (n=450), 437 (97.1) finished the entire intervention protocol. The sample age was 54.7 + 11.3 years and gender was well balanced (52.4% female). The co-prevalence of hypertension and diabetes was high in the study population with a proportion of 33.3 in the cohort of comorbid hypertension and diabetes (Group C). As presented in Table 1, the pharmacist interventions were in varied modalities, such as MTM, disease-state education, adherence counseling, self-monitoring training and pharmacovigilance reviews. Table 1 is the summary of the interventions types, the evidence of the studies, the target population groups and the percentages of the improvements in the major outcome areas.

Table 1. Summary of Pharmacist Intervention Types, Evidence Base and Outcome Improvements

Intervention Type	Study (Year)	Patient Group	Primary Outcome	Improvement (%)
Medication Therapy Management	[2]	Hypertension (n=320)	Blood Pressure Control	34.2%
Disease-State Education	[10]	Type 2 Diabetes (n=215)	HbA1c Reduction	28.7%
Adherence Counseling	[8]	Comorbid HTN+DM (n=180)	Medication Adherence	41.5%
Self-Monitoring Training	[14]	Hypertension (n=140)	Home BP Monitoring Accuracy	55.3%
Pharmacovigilance Review	[8]	Elderly Diabetics (n=95)	ADR Reduction	37.8%

4.2 Clinical Outcomes

The paper has shown statistically and clinically significant changes in all the primary clinical parameters. Mean systolic blood pressure dropped as indicated in Table 3, where baseline systolic blood pressure was 158.4 mmHg and three-month blood pressure was 138.7 mmHg, indicating that systolic blood pressure had reduced by 12.4% (p<0.001). The results indicated that diastolic blood pressure equally reduced by 12.5% (p<0.001). These decreases are in line with and surpass the meta-analytic estimates [16], indicating that structured multi-component nature of the current intervention can be more effective than models of pharmacist care based on single elements.

In the diabetic cohort, mean HbA1c declined from 8.6 ± 1.1% to 7.4 ± 0.9% - a 14.0% reduction (p<0.001). There was also a significant improvement (p=0.002) with fasting blood glucose. These findings

are related to the previous systematic reviews [19] and indicate the importance of MTM and systematic learning to achieve the glycemic targets. Interestingly, greater composites gains were present in the comorbid group (Group C), likely as a result of the extra clinical touches and counselling components of this increased-risk group.

4.3 Behavioral and Patient-Reported Outcomes

The scores of medication adherence (MMAS-8) increased significantly with a mean score of 5.8 +1.6 becoming 7.9 +1.2 (a 36.2% change, $p=0.001$). This has specific clinical importance, since non-adherence has been observed to be the main cause of uncontrolled chronic disease [3]. This outcome was consistent with previous behavioral pharmacist intervention studies and could be attributed to the adherence counseling aspect, with elements of the motivational interviewing [7].

Patient satisfaction scores increased markedly from 62.4 ± 12.3 to 81.7 ± 9.8 (31.0% improvement, $p=0.003$). Qualitative feedback showed that the accessible nature of pharmacist consultations with a strong non-judgmental attitude, customization of the educational resources and the persistence of the follow-up contacts were particularly appreciated by patients. These results highlight the correspondence between the patient-centered pharmacy practice and better outcomes in experiential as theorized in the PCC literature [10], [11].

4.4 Barriers and Facilitating Factors

Table 2 presented the barrier to implementations of pharmacist-led interventions in five principal domains, namely, the workflow limitations, insufficient reimbursement, patients' health literacy, the incorporation of technology and the inter-professional collaboration. The most frequently mentioned operational barrier was time pressures during the high dispensing periods, which is also in line with the existing literature [21]. In contrast, the studios that had either created collaborative practice arrangements with physicians in the area, or used combined electronic records reported considerably enhanced intervention fidelity and follow-ups.

Table 2. Barriers, Facilitating Factors and Recommended Strategies for Community Pharmacist-Led NCD Interventions

Domain	Barrier/Challenge	Facilitating Factor	Recommended Strategy
Workflow	Time constraints during peak hours	Adequate staffing model	Task delegation to pharmacy technicians
Reimbursement	Lack of specific billing codes	Value-based care contracts	Advocate for inclusive billing policy
Patient Literacy	Low health literacy in elderly patients	Visual and multilingual aids	Simplified patient education materials
Technology	Non-integrated EMR systems	Interoperable digital platforms	Adopt integrated pharmacy management systems
Collaboration	Physician reluctance to share roles	Multidisciplinary team culture	Formal collaborative practice agreements

Recognition of reimbursement as a structural obstacle corresponds with international policy discussions on legally recognizing clinical pharmacy as a service. The utilization and maintenance rates are significantly greater in an environment in which pharmacist MTM services receive payment, as is the case with the United States Medicare Part D program [22]. The policy awareness campaign on inclusive billing policy change is a timely and important practical implication of the findings of this study.

4.5 Technology and Digital Health Integration

Can the emergence of digital health tools be a challenge, as well as an enabling factor? Pharmacies who gauged their adherence rates through digital adherence monitoring tools, SMS medication reminders and telemonitoring channels indicated that their adherence rates were better compared to pharmacies that

employed paper-based solutions to gauge the adherence rates. As it is shown in Figure 3 below, the model of pharmacist-patient digital interaction suggests that telehealth platforms, Health apps and electronic health records (EHR) can play a role in the community pharmacy workflow and enhance continuity of care and data-based clinical decision-making.



Figure 3. Community-Based Chronic Illness Management through Pharmacy-Led Digital Health Integration Model

Digital health is increasingly being acknowledged as an augmentation of care provided by pharmacists. [20] Have proven synergistic effects of telemonitoring coupled with pharmacist counseling on both glycemic and blood pressure outcomes. The current results justify this course of action and point to the fact that the development of digital infrastructure, on a community pharmacy level, is an indispensable complement to skill training.

Table 3. Parameters of Clinical Before and After Intervention by Community Pharmacists (N=437)

Clinical Parameter	Pre-Intervention (Mean ± Sd)	Post-Intervention (Mean ± Sd)	Change (%)	P-Value
Systolic BP (mmHg)	158.4 ± 14.2	138.7 ± 11.6	-12.4%	< 0.001
Diastolic BP (mmHg)	97.3 ± 8.9	85.1 ± 7.4	-12.5%	< 0.001
HbA1c (%)	8.6 ± 1.1	7.4 ± 0.9	-14.0%	< 0.001
Fasting Blood Glucose (mg/dL)	172.5 ± 22.4	148.3 ± 19.7	-14.0%	0.002
Medication Adherence Score (0-10)	5.8 ± 1.6	7.9 ± 1.2	+36.2%	< 0.001
Patient Satisfaction Score (0-100)	62.4 ± 12.3	81.7 ± 9.8	+31.0%	0.003

4.6 Subgroup Analysis

The subgroup analyses revealed that there is statistically significant difference in the urban pharmaceuticals and the role of peri-urban and semi-rural settings when it comes to all the outcome domains, likely because of better access to trained pharmacists, digital technologies and specialist referral pathways. These increases in adherence were higher amongst the female patients than the male patients and this is consistent with other prior studies which determined gender stratified adherence [25]. The minimal changes in the HbA1c were observed in patients over the 65 years of age, yet the geriatric patients expressed high satisfaction rates, which means that further improvements may be required when developing geriatric-specific-protocols. These subgroup results have significant implications in designing future pharmacist NCD programs contextually.

5. CONCLUSION

The present paper provides valid empirical evidence to support the significance of having community pharmacists become active clinical players in the management of chronic diseases as opposed to hypertension and diabetes. The multi component, patient centered intervention realized profound changes in the blood pressure regulation, glycemetic regulation, medication adherence and patient satisfaction in a heterogeneous population of participants. This information has clinical implications and shows the potential of the community pharmacy as a convenient and low-cost NCD care facility.

The findings indicate that the outcomes of pharmacist-led care are dependent on the facilitating structural factors, including reimbursement recognition, collaborative practice frameworks, digital health integration and lifelong learning. In particular, the changes in the levels of adherence (36.2%) and patient satisfaction (31.0%) are significant and can be explained by the practicality of the patient-centered approach related to the promotion of therapeutic alliance and patient empowerment with self-management.

This study will contribute to wiser policymaking by enabling widening of the community pharmacist practice to include NCD management using inclusion-based billing systems and a prerequisite that pharmacists become a member of a multidisciplinary team of care. The gains that are made should be supported by investments in pharmacy informatics and EHR interoperability. The next step in research is the longitudinal cohort studies to assess the sustainability of pharmacist-led interventions, cost-effectiveness with regard to other care delivery models and the creation of culturally adapted protocols to underserved groups. The pharmacist role in managing hypertension and diabetes is not only an added advantage to achieving equality of conditions of chronic diseases in the world.

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Author Contributions Statement

Name of Author	C	M	So	Va	Fo	I	R	D	O	E	Vi	Su	P	Fu
Vaishnavi Kolli	✓	✓	✓	✓		✓		✓	✓	✓	✓			

C : Conceptualization

M : Methodology

So : Software

Va : Validation

Fo : Formal analysis

I : Investigation

R : Resources

D : Data Curation

O : Writing - Original Draft

E : Writing - Review & Editing

Vi : Visualization

Su : Supervision

P : Project administration

Fu : Funding acquisition

Conflict of Interest Statement

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Informed Consent

All participants were informed about the purpose of the study, and their voluntary consent was obtained prior to data collection.

Ethical Approval

The study was conducted in compliance with the ethical principles outlined in the Declaration of Helsinki and approved by the relevant institutional authorities.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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