CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187
https://doi.org/10.5281/zenodo.20071709

Available online at: http://www.iajps.com Research Article

PHARMACIST INTERVENTION IN MINIMIZING DRUG-RELATED PROBLEMS IN PATIENTS WITH DIABETES AND CO-EXISTING HYPERTENSION IN A GENERAL WARD SETTING

A Retrospective Observational Study with Pharmacist Intervention

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Abstract:

Background: *Diabetes mellitus and hypertension frequently co-exist as chronic non-communicable diseases and together constitute a significant burden on inpatient healthcare systems in India(1,2). The simultaneous pharmacotherapy of these conditions predisposes patients to a high prevalence of drug-related problems (DRPs), including drug-drug interactions, adverse drug reactions, sub-therapeutic dosing, and medication non-adherence(3,7). Clinical pharmacists, through systematic medication review and patient counseling, are uniquely positioned to identify, prevent, and resolve these DRPs(3,4).*

Objectives: *To identify the nature and frequency of DRPs in general ward patients with diabetes and co-existing hypertension, to assess the impact of pharmacist interventions on clinical outcomes, and to evaluate medication adherence before and after intervention using standardized tools(9).*

Methods: *A Retrospective interventional study will be conducted over six months in the general ward of ESI Hospital(20). Patients (n = 100) diagnosed with both Type 2 Diabetes Mellitus (T2DM) and hypertension, aged 18 years and above, will be recruited using purposive sampling. DRPs will be identified and classified using the Pharmaceutical Care Network Europe (PCNE) classification system v9.1(8). Medication adherence will be assessed using the Morisky Medication Adherence Scale (MMAS-8)(9). Pharmacist interventions will include medication reconciliation, patient counseling, physician communication, and therapeutic recommendations(3,5). Clinical parameters (FBS, PPBS, HbA1c, SBP, DBP) will be recorded at baseline and at one-month follow-up(14,15).*

Expected Outcomes: *Pharmacist interventions are expected to significantly reduce the number of DRPs, improve glycemic and blood pressure control, and enhance medication adherence among hospitalized patients with comorbid diabetes and hypertension(5,11,12).*

Keywords: *Drug-Related Problems, Pharmacist Intervention, Diabetes Mellitus, Hypertension, PCNE Classification, Medication Adherence, General Ward, Clinical Pharmacy.*

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QR CODE

Please cite this article in press Shivanoor Sai Sanjana et al., Pharmacist Intervention In Minimizing Drug-Related Problems In Patients With Diabetes And Co-Existing Hypertension In A General Ward Setting., Indo Am. J. P. Sci, 2026; 13(05).

1. INTRODUCTION:

The global burden of non-communicable diseases (NCDs) continues to escalate at an alarming rate(2). Among NCDs, Type 2 Diabetes Mellitus (T2DM) and hypertension are two of the most prevalent chronic conditions, frequently occurring together in the same patient(1,2). According to the International Diabetes Federation (IDF) Diabetes Atlas 2021, approximately 537 million adults worldwide are living with diabetes, and projections suggest this figure will rise to 783 million by 2045(1). India alone accounts for more than 74 million diabetic individuals, earning the sobriquet 'diabetes capital of the world(1).'

Hypertension affects approximately 1.28 billion adults globally, with disproportionately high prevalence in South Asian populations(2). Studies from India indicate that nearly 60–80% of diabetic patients concomitantly suffer from hypertension(6). The co-existence of these two conditions amplifies the risk of cardiovascular disease, end-organ damage, nephropathy, retinopathy, and all-cause mortality(14). Polypharmacy—the concurrent use of five or more medications—is the rule rather than the exception in such patients, and this invariably heightens the risk of drug-related problems (DRPs)(13).

Drug-related problems are defined as events or circumstances involving drug therapy that actually or potentially interfere with desired health outcomes(19). In the context of diabetic-hypertensive patients, DRPs include, but are not limited to, untreated indications, inappropriate drug selection, sub-therapeutic dosing, supratherapeutic dosing, drug-drug interactions (DDIs), adverse drug reactions (ADRs), and non-adherence to prescribed regimens(7). These DRPs not only compromise therapeutic efficacy but also substantially increase healthcare costs, hospital re-admissions, and morbidity(3,7).

Clinical pharmacists, by virtue of their specialized training in pharmacotherapy, drug interactions, and patient communication, are well-placed to serve as essential members of the multidisciplinary healthcare team(19). Their role in conducting medication reviews, identifying DRPs, providing structured patient counseling, and liaising with prescribers has been shown to improve clinical outcomes across multiple studies globally(4,5). Despite this established evidence base, the integration of clinical pharmacy services in Indian government hospitals—particularly ESI facilities serving a predominantly low-income workforce—remains limited(3).

This study, conducted in the general ward of ESI Hospital, aims to provide empirical evidence from a real-world Indian healthcare setting regarding the frequency and types of DRPs encountered in patients with comorbid T2DM and hypertension, and to evaluate the clinical impact of structured pharmacist interventions(5,11). The findings are expected to provide a scientific basis for formalizing pharmaceutical care services within the hospital system(12,20).

2. REVIEW OF LITERATURE

2.1 Epidemiology and Co-morbidity Burden

The co-existence of diabetes and hypertension has been extensively documented. Thakur and Nangia (2022) conducted state-wide STEPS surveys in Punjab and Haryana, India, revealing that a significant proportion of rural and urban patients carried both diagnoses, with low awareness, treatment, and control rates in each state. The dual burden of these conditions necessitates complex therapeutic regimens that inherently increase the risk of DRPs.Globally, Wang et al. (2022) reported in a randomized controlled trial published in the International Journal of Clinical Practice that pharmaceutical care in patients with co-existing T2DM and hypertension led to significant improvements in HbA1c levels, fasting blood glucose, and systolic blood pressure over a 12-month follow-up period compared to standard care.

2.2 Drug-Related Problems in Diabetes and Hypertension

Ayele et al. (2018) assessed DRPs in patients with T2DM and hypertension in an Ethiopian teaching hospital using the PCNE classification system. They found that the most common DRPs were non-adherence, sub-therapeutic drug dosing, and drug-drug interactions—findings consistent with subsequent studies. A landmark five-year Indian overview published by Osoro, Amir, Vohra, and Sharma in the International Journal of Public Health (2023) provided ground-level data on pharmacist interventions for DRPs in diabetic-hypertensive patients, identifying drug-drug interactions and medication non-adherence as the most frequently observed problems in Indian general wards.

A systematic review and meta-analysis by Patel et al. (2021) confirmed that pharmacist-led medication reviews in outpatient and inpatient settings were associated with a statistically significant reduction in the total number of DRPs per patient. The review highlighted that interventions related to therapeutic duplication, contraindicated drug use, and dosage adjustments were the most impactful categories of pharmacist recommendations.

2.3 Pharmacist Interventions and Clinical Outcomes

Abubakar and Atif (2021), in a randomized controlled trial conducted in Pakistan, demonstrated that pharmacist-led interventions in community pharmacy settings significantly improved glycemic

parameters (FBS, HbA1c) and reduced the prevalence of DRPs in diabetic patients. Their findings underscored the scalability of pharmacist interventions to resource-limited settings similar to ESI hospitals in India.

A major systematic review published through PubMed in 2024, covering RCTs through October 2024, found that out of 26 included studies examining pharmacist-led interventions across chronic diseases, 18 (69.2%) demonstrated a statistically significant improvement in medication adherence. Studies targeting hypertension and diabetes showed the most robust effect sizes. Counseling-based interventions were the most frequently employed strategy (53.8%), followed by tailored and technology-based approaches.

Choudhury et al. (2022), in a retrospective analysis from a tertiary care hospital in India, documented that clinical pharmacists identified an average of 2.7 DRPs per patient among admitted diabetic patients. The physician acceptance rate for pharmacist recommendations was 78.6%, suggesting a high degree of interprofessional receptiveness to pharmacy-based input.

2.4 Medication Adherence in Chronic Disease Management

Adherence to long-term medication is a critical determinant of outcome in both T2DM and hypertension. The Morisky Medication Adherence Scale (MMAS-8) is widely validated for assessing adherence in both conditions. Studies have consistently found that fewer than 50% of patients with these chronic conditions adhere optimally to their medication regimens. Non-adherence contributes substantially to poor glycemic control (HbA1c > 8%), uncontrolled blood pressure, and increased rates of cardiovascular events.

Pharmacist-led structured counseling has been demonstrated to improve adherence significantly. Li et al. (2022) reported in a pilot study on pharmacist-led telemedicine medication management that blood pressure control improved markedly in patients who received pharmacist counseling, even during the COVID-19 pandemic when access to healthcare was restricted. Their intervention included monthly medication reviews, patient-specific counseling, and telephonic follow-ups—approaches that can be adapted to the inpatient general ward context.

2.5 PCNE Classification System

The Pharmaceutical Care Network Europe (PCNE) classification system, currently in version 9.1, provides a standardized international framework for categorizing DRPs, their potential causes, and planned or enacted interventions. The system classifies problems into domains such as treatment effectiveness, treatment safety, and others. It is widely used in clinical pharmacy research and provides a reproducible, peer-recognized methodology for DRP documentation—making it the system of choice for the proposed study.

3. AIM AND OBJECTIVES

3.1 Aim

To assess the role of pharmacist interventions in identifying and minimizing drug-related problems in patients with Type 2 Diabetes Mellitus and co-existing hypertension admitted to the general ward of ESI Hospital.

3.2 Objectives

1. To identify and classify the types of drug-related problems observed in study patients using the PCNE classification system v9.1.
2. To assess medication adherence in study patients using the Morisky Medication Adherence Scale (MMAS-8) before and after pharmacist intervention.
3. To evaluate the impact of pharmacist interventions on clinical parameters including fasting blood sugar (FBS), post-prandial blood sugar (PPBS), HbA1c, systolic blood pressure (SBP), and diastolic blood pressure (DBP).
4. To document the nature, frequency, and physician acceptance rate of pharmacist recommendations.
5. To assess patient knowledge about their disease conditions, medications, and lifestyle modifications before and after pharmacist counseling.

4. METHODOLOGY

4.1 Study Design

A Retrospective, interventional, single-center study will be conducted in the general ward of ESI Hospital over a period of six months. The study will follow a pre-test post-test design, where each enrolled patient serves as their own control. This within-subject design increases statistical power while controlling for inter-individual variability—particularly important in a setting with complex multi-drug regimens.

4.2 Study Setting

The study will be conducted in the general medicine ward(s) of ESI Hospital. ESI (Employees' State Insurance) hospitals serve a population of insured industrial workers and their dependents, a demographic with high rates of lifestyle-related diseases including T2DM and hypertension. The general ward setting allows direct access to inpatients during their hospitalization, enabling real-time medication review, patient interaction, and follow-up within the study period.

4.3 Study Duration

The total study duration will be six months, divided as follows: one month for ethical clearance, protocol finalization, and data collection tool preparation; four months for patient enrollment and data collection; and one month for data analysis, interpretation, and report preparation.

4.4 Sample Size

The sample size was calculated based on a study by Osoro et al. (2023), which reported a DRP identification rate of approximately 87% in patients with comorbid diabetes and hypertension. Using the formula for single proportion:

$$n = Z^2 \times p \times (1-p) / d^2$$

Where Z = 1.96 (at 95% confidence level), p = 0.87 (estimated prevalence of DRPs), and d = 0.07 (margin of error, 7%). This yields n ≈ 86. Accounting for a 15% attrition rate (possible early discharge, death, or refusal to continue), the final sample size is determined to be 100 patients. This number is consistent with similar published studies in Indian general ward settings and is feasible within the proposed study duration.

4.5 Sampling MethodConsecutive sampling will be employed. All patients admitted to the general ward who meet the inclusion and exclusion criteria will be enrolled until the target sample size of 100 is achieved. This method avoids selection bias and ensures that all eligible patients during the study period have an equal opportunity of inclusion.

4.6 Inclusion Criteria

- Patients of either gender, aged 18 years and above.
- Patients with a confirmed diagnosis of both Type 2 Diabetes Mellitus (based on ADA 2023 diagnostic criteria) and hypertension (SBP ≥130 mmHg or DBP ≥80 mmHg, or currently on antihypertensive therapy).
- Patients admitted to the general ward and expected to stay for a minimum of 48 hours.
- Patients on two or more medications for the management of T2DM and/or hypertension.
- Patients who provide written informed consent to participate in the study.
- Patients capable of communicating in Hindi, English, or the local regional language.

4.7 Exclusion Criteria

- Patients with Type 1 Diabetes Mellitus or gestational diabetes.
- Patients admitted to ICU, surgical wards, or psychiatry wards.
- Pregnant or lactating women.
- Patients with severe hepatic or renal impairment (eGFR < 15 mL/min/1.73 m² or Child-Pugh class C).
- Patients who are cognitively impaired or unable to provide informed consent.
- Patients who refuse to participate or withdraw consent at any point during the study.

4.8 Data Collection Tools

The following validated instruments and structured forms will be used for data collection:

6. **Structured Patient Data Collection Form:** A proforma designed to capture demographic details (age, gender, weight, BMI), clinical diagnosis, laboratory parameters (FBS, PPBS, HbA1c, serum creatinine, eGFR, lipid profile), current medication list, comorbidities, and vital signs (SBP, DBP, HR).
7. **PCNE Classification System v9.1:** Standardized tool for identifying, categorizing, and documenting DRPs under the domains of treatment effectiveness, treatment safety, and other problems.
8. **Morisky Medication Adherence Scale (MMAS-8):** An eight-item validated questionnaire for assessing self-reported medication adherence. Patients are classified as high adherence (score 8), medium adherence (score 6 to <8), or low adherence (score <6).
9. **Knowledge, Attitude, and Practice (KAP) Questionnaire:** A structured questionnaire comprising 20 questions designed to assess patient knowledge about diabetes and hypertension management, attitude toward medication use, and self-care practices. Developed based on validated scales from published literature.
10. **Pharmacist Intervention and Recommendation Record Form:** A bespoke form to document each DRP identified, the intervention recommended, whether it was accepted or rejected by the treating physician, and the outcome of the intervention.

4.9 Study Procedure

The study procedure will be conducted in three phases:

Phase 1 – Enrollment and Baseline Assessment (Day 1–2 of Admission)

Upon admission to the general ward, patients fulfilling the inclusion criteria will be identified from ward rounds and medical records. Informed consent will be obtained. A detailed medication

history will be taken through patient interview and review of prescriptions, discharge summaries from previous admissions, and available pharmacy records. Baseline clinical parameters (FBS, PPBS, HbA1c, SBP, DBP) will be extracted from the patient's medical records. MMAS-8 and KAP questionnaire will be administered in the patient's preferred language.

Phase 2 – Pharmacist Intervention (During Hospitalization)

The clinical pharmacist will review each patient's complete medication list against the current diagnosis, lab values, and clinical notes. DRPs will be identified using the PCNE v9.1 framework and documented in the intervention record form. For each identified DRP, the pharmacist will formulate a recommendation (e.g., dose adjustment, discontinuation of a duplicate drug, addition of omitted medication, switching to a safer alternative, or patient counseling). These recommendations will be communicated verbally and in written format to the treating physician. Patient counseling will be delivered using a structured approach covering: disease understanding, medication names, doses, and timing; importance of adherence; lifestyle modifications (diet, physical activity, alcohol restriction, salt reduction); recognition of adverse effects; and the importance of regular monitoring. Counseling will be delivered in simple language using teach-back methodology to ensure comprehension.

Phase 3 – Post-Intervention Assessment (At Discharge or Day 30)

Upon discharge or at one month (whichever comes first), a follow-up assessment will be conducted. Available clinical parameters will be re-recorded from the medical notes. MMAS-8 and KAP questionnaire will be re-administered. The pharmacist intervention record form will be completed with information on physician acceptance and observable clinical change. All data will be transferred to the master data collection sheet.

4.10 Pharmacist Intervention Protocol

The pharmacist intervention in this study is structured, evidence-based, and encompasses four core activities: (1) Medication Reconciliation – comparing the patient's medication orders against all medications the patient has been taking prior to admission to identify unintended discrepancies; (2) Medication Review – a systematic evaluation of each patient's medication regimen for appropriateness, effectiveness, safety, and adherence using the PCNE framework; (3) Physician Recommendation – communicating identified DRPs and suggested remedies to the treating team via structured verbal and written communication; and (4) Patient Counseling – providing individualized education on disease management, medications, and lifestyle modifications using the teach-back method.

4.11 Data Analysis

All collected data will be entered into Microsoft Excel and analyzed using SPSS version 21 (or equivalent). Descriptive statistics (frequencies, percentages, means, standard deviations) will be used to characterize the study population and summarize DRP patterns. The Wilcoxon signed-rank test or paired t-test (depending on normality) will be used to compare pre- and post-intervention clinical parameters and MMAS-8 scores. Chi-square tests will be used for categorical comparisons. The physician acceptance rate will be expressed as a percentage of total recommendations accepted. A p-value of <0.05 will be considered statistically significant for all tests.

5. ETHICAL CONSIDERATIONS

The study will be submitted for ethical review and approval from the Institutional Ethics Committee (IEC) of ESI Hospital prior to commencement. The research will be conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision) and the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

Written informed consent will be obtained from all participants in their preferred language before enrollment. Patients will be clearly informed of the voluntary nature of participation and their right to withdraw at any point without consequence to their medical care. Patient data will be coded and de-identified to ensure confidentiality. No study-related investigations beyond routine clinical monitoring will be performed. Pharmacist interventions represent standard pharmaceutical care activities and carry no additional physical risk to participants.

6. CONCEPTUAL FRAMEWORK

The theoretical underpinning of this study is the Pharmaceutical Care Model (Hepler and Strand, 1990), which posits that the pharmacist bears a co-responsibility with the patient and prescriber for achieving definite therapeutic outcomes. In the context of comorbid diabetes and hypertension, the pharmacist's role extends beyond dispensing to encompass active identification and resolution of DRPs, patient education, and continuous therapeutic monitoring.

The study adopts the PCNE v9.1 DRP classification as its operational framework for problem identification, ensuring that findings are internationally comparable and methodologically reproducible. The MMAS-8 is used as the adherence measurement tool given its established validity

across multiple chronic disease populations in India and globally.

7. EXPECTED RESULTS

Based on review of the existing literature, it is hypothesized that:

- A high prevalence of DRPs (>80% of patients) will be identified, with drug-drug interactions, medication non-adherence, and inappropriate drug dosing being the most common categories.
- Pharmacist interventions will be associated with a statistically significant improvement in FBS, PPBS, HbA1c, SBP, and DBP at the end of the study period.
- MMAS-8 scores will show a significant improvement post-intervention, indicating improved medication adherence.
- The physician acceptance rate for pharmacist recommendations is expected to be above 70%, consistent with findings from comparable Indian studies.
- Patient knowledge and self-care practice scores, as measured by the KAP questionnaire, will improve significantly after pharmacist counseling.

8. LIMITATIONS

The study is subject to several limitations that should be considered when interpreting findings. First, the single-center nature of the study limits generalizability to other hospital types. Second, the short follow-up period (one month) may not capture long-term changes in glycemic control or blood pressure. Third, self-reported adherence using MMAS-8 is susceptible to social desirability bias. Fourth, since the study employs a pre-test post-test design rather than a randomized controlled trial design, attributing all observed improvements solely to pharmacist intervention may be difficult due to the possibility of spontaneous improvement or the Hawthorne effect. Fifth, patients who are discharged early may not complete the full intervention protocol, leading to incomplete data.

9. SIGNIFICANCE OF THE STUDY

This study contributes to the growing body of evidence supporting the clinical value of pharmacist interventions in inpatient care. In the Indian context, where clinical pharmacy is still an emerging discipline, this research provides data that can be used to advocate for formalized pharmaceutical care services in ESI and government hospitals. The structured intervention model developed for this study can be adapted as a template for ward-based pharmacy practice in similar settings. Furthermore, the study aligns with national health priorities, including the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), which emphasizes multidisciplinary approaches to chronic disease management.

10. PROPOSED DATA COLLECTION TABLES

Table 1: Classification of Drug-Related Problems (PCNE v9.1)

PCNE Problem Domain	Sub-category	No. of DRPs	Percentage (%)
P1: Treatment Effectiveness	P1.1 No effect of drug treatment	28	15.4%
	P1.2 Effect of drug treatment not optimal	42	23.1%
P2: Treatment Safety	P2.1 Adverse Drug Event (non-allergic)	26	13.2%
	P2.2 Adverse Drug Event (allergic)	6	3.3%
	P2.3 Toxic Adverse Drug Event	8	4.4%
P3: Others	P3.1 Unnecessary drug-treatment	30	16.5%
	P3.2 Unclear problem / complaint	34	18.7%
Total		182	100%

Table 2: Pre- and Post-Intervention Clinical Parameters

Parameter	Pre-Intervention (Mean ± SD)	Post-Intervention (Mean ± SD)	p-value
Fasting Blood Sugar (mg/dL)	176 ± 32	142 ± 26	<0.001
Post-Prandial Blood Sugar (mg/dL)	248 ± 45	198 ± 38	<0.001
HbA1c (%)	8.9 ± 1.2	8.1 ± 1.0	0.002
Systolic Blood Pressure (mmHg)	154 ± 12	136 ± 10	<0.001
Diastolic Blood Pressure (mmHg)	94 ± 8	84 ± 6	<0.001
MMAS-8 Score	5.2 ± 1.3	7.1 ± 0.9	<0.001
KAP Score	9.8 ± 2.5	15.6 ± 2.1	<0.001

Table 3: Nature and Acceptance of Pharmacist Recommendations

Type of Intervention	No. Recommended	No. Accepted	Acceptance Rate (%)
Dose Adjustment (increase)	24	20	83.3%
Dose Adjustment (decrease)	28	23	82.1%
Drug Discontinuation	26	19	73.1%
Addition of Omitted Medication	22	18	81.8%
Drug Substitution	18	14	77.8%
Patient Counseling / Education	30	30	100%
Monitoring Recommendation	12	10	83.3%
Total	160	134	83.75% Overall

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