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Research Paper

Assessment of drug-related problems identified in community pharmacy settings

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ABSTRACT

Background: DRPs are a major and increasingly important issue of outpatient and community healthcare environments, which lead to morbidity, hospitalization, and waste of healthcare resources. Community pharmacists have a unique position of being the first line healthcare providers who can be able to systematically identify, resolve and prevent DRPs before they translate into severe adverse events.
Purpose: The purpose of this research was to evaluate the prevalence, types, and clinical importance of DRPs detected in the process of ordinary community pharmacy work and to evaluate the outcomes of the pharmacist-led work aimed at the solution of these issues.
Methods: A cross-sectional prospective study was undertaken in twelve months in six community pharmacies in urban and semi-urban areas centrally located in India. Three hundred adult patients with at least one chronic illness and taking two or more medications simultaneously were recruited. The Pharmaceutical Care Network Europe (PCNE) v9.1 classification system was employed to identify DRPs with the help of structured medication reviews, interviews with the patients, and the analysis of prescriptions.
Findings: 822 DRPs were detected in 226 patients, prevalence 75.3%. Most common: drug-drug interactions (22.8%), dosing errors (19.7%), and non-adherence (18.0%). Frequencies were higher in elderly patients (>60 years) and polypharmacy (>5 drugs). Pharmacist interventions introduced in 86.8% DRPs; acceptance was 83.6%.
Conclusion: Drug-related issues in community pharmacy are very high, especially in elderly and multi-morbid patients. Medication reviews and DRP-resolution plans are acceptable. Clinical pharmacy services should be integrated into community practice.

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1. INTRODUCTION

Drug-related problems (DRP) can be described as those events and situations that involve drug therapy and which actually or potentially disrupt the intended health outcome to a patient [1]. Strand and others initially presented the concept of DRPs in a formal manner, and it was later operationalized in the framework of pharmaceutical care by Helper and Strand in 1990 [2]. Since that time, the detection, categorization, and elimination of DRPs have been the focal point of the pharmaceutical care practice in the world.

The community pharmacies are the most available channel of contact in the healthcare system and are usually the first and sometimes the sole professional consultation to the patients dealing with chronic illnesses at outpatient levels [3]. Such accessibility puts the community pharmacist in the best position to prevent DRPs before they lead to adverse clinical events, treatment failures, or unnecessary hospitalizations. In spite of such a potential, there is still a lack of consistency and underperformance in systematic evaluation and documentation of DRPs in community pharmacies in most of the low-and middle-income countries (LMICs).

Research carried out in various healthcare systems has shown that DRPs are common in the ambulatory setting at a rate of 50 to 80% based on the type of patients under study and the classification system used [4]. Pharmaceutical Care Network Europe (PCNE) classification system is the most commonly used standardized framework to classify DRPs in the clinical and community setting, currently in its v 9.1 version [5]. The tool allows pharmacists to informative the issues associated with drug selection, dosing, adherence, adverse drug reactions, and interactions, as well as the recording of the interventions and outcomes.

In India, like in most other LMICs, the chronic non-communicable disease burden, comprising of hypertension, diabetes mellitus, and respiratory diseases, has increased significantly in the last twenty years [6]. Patients affected by such conditions often undergo poly-pharmacy treatment which predisposes them to drug-drug interactions, dosing, and non-adherence [7]. Nevertheless, there is a lack of information about the extent and nature of DRPs in India community pharmacies.

The aim of this study was therefore to prospectively determine the frequency and typology of DRPs detected within a community pharmacy in central India, and to determine the efficacy of pharmacist initiated interventions in addressing these issues. It is hoped that the findings will have an evidence base that will guide the implementation of pharmaceutical care services in the normal community pharmacy practice in India and other healthcare settings [8].

2. RELATED WORK

International literature on the recognition of DRP in community and ambulatory pharmacies has grown tremendously within the last 20 years. One of the first pharmacist-led medication review trials was carried in the United Kingdom and found a mean of 2.1 DRPs per patient, with sub-therapeutic dosing and non-compliance being the predominant. They were randomized controlled studies that revealed that structured pharmaceutical care was associated with a reduction of DRP burden at three months follow-up.

[9] Performed a systematic review of the pharmaceutical care services and found that the drug-drug interactions, improper drug selection, and lack of patient adherence were always the most common categories of DRP in several countries. These findings were further formalized [10] in their extensive text on patient-centered pharmaceutical care, as they point out that in more than 70% of the cases, DRPs can be prevented in case medication reviews are incorporated into the routine clinical practice.

[11] Found a prevalence of DRP of 61.3% in community pharmacies in the UAE, with the largest single category being dosing errors. Their research indicated the additive impact of poly-pharmacy with respect to occurrence of DRP as the patients taking 5 or more drugs were 3.2 times more apt to develop a clinically significant DRP. Equally, [12] cited a prevalence rate of 73.0% in Ethiopian outpatient, with drug interactions and unnecessary drug therapy topping the profile.

[6] Conducted a study in South Asia where the prevalence of DRP in patients of community pharmacies in Pakistan was reported to be 68.4% and noted that poor pharmacist training and poor documentation systems were the main impediments to successful DRP resolution. A [13] showed the same tendency in a rural Indian community pharmacy scenario, with the average number of DRPs in the sample of 3.4 and the success rate of resolution after pharmacist intervention of 84% [14].

A systematic review of thirteen DRP classification systems found that the PCNE system provided the best combination of reliability and clinical utility in terms of community pharmacy research. In hospital settings, [15] showed that ward rounds with pharmacists at the head uncovered about 2.8 DRPs per patient with dosing errors and unnecessary poly-pharmacy being the most common- results that were generally similar to data in community pharmacies.

Together, these sources prove that DRPs are already extremely common in healthcare facilities, that community pharmacists are well-placed to detect and solve them, and that the PCNE classification system offers a solid, repeatable framework of assessing those [16]. Nevertheless, future research by Indian community pharmacies is still missing in this international evidence base, which leaves a gap that the current study will aim to fill [17].

3. METHODOLOGY

3.1 Study Design and Setting

This was a prospective, descriptive cross-sectional study, which was done in twelve months (January 2024 to December 2024) in six community pharmacies distributed in the cities and semi-urban regions of Nagpur district, Maharashtra, India. The patient footfall was used to select the study sites (minimum 50 patients/day), the presence of at least one qualified pharmacist, and the written institutional consent of the pharmacy owners.

3.2 Study Population and Sampling

The inclusion criteria were the presence of at least one known chronic disease and the simultaneous use of two or more drugs in adult patients (age 18 years and older). The patients who had incomplete medical history, could not give informed consent (cognitive impairment or language barrier) and pregnant women were excluded. Systematic random sampling was employed in the study where 300 patients were recruited where every three identified patients were recruited on a weekly basis during pharmacy visits [18].

3.3 Data Collection

Pharmacist researchers who were trained held structured medication review interviews with a standardized data collection form. Data collected were patient demographics, full medication history (prescription and non-prescription medications), chronic illnesses, self-reported adherence behavior, and recent laboratory results as available. The cross-referencing with standard drug interaction databases, national treatment guidelines and the British National Formulary (BNF) [19] was used to review prescription medications as potential DRPs.

3.4 DRP Classification

The Pharmaceutical Care Network Europe (PCNE) Classification System Version 9.1 was used to classify all identified DRPs. This system classifies the DRPs based on three main areas: (1) drug selection and effectiveness issues, (2) drug safety and toxicity issues, and (3) treatment adherence issues. All DRPs found were confirmed by the second pharmacist researcher; all differences were sorted out through consensus with a supervising clinical pharmacist. The entire classification scheme used in this paper is given in Table 1.

Table 1. PCNE-Based Classification of Drug-Related Problems Applied in this Study

Category	Subcategory	Description
Drug Selection	Wrong drug	Medication prescribed is not appropriate for the condition
Drug Selection	Unnecessary drug therapy	No valid medical indication for the prescribed drug
Dosing Problem	Dose too high	Drug dose exceeds recommended therapeutic range
Dosing Problem	Dose too low	Drug dose is insufficient to produce therapeutic effect
Drug Interaction	Drug–drug interaction	Clinically significant interaction between co-prescribed drugs
Drug Interaction	Drug–disease interaction	Medication contraindicated due to patient comorbidity
Adverse Drug Reaction	Side effect	Undesirable pharmacological effect at normal doses
Adverse Drug Reaction	Allergic reaction	Immune-mediated hypersensitivity response to a drug
Adherence	Non-compliance	Patient failure to take medication as prescribed
Adherence	Refusal of therapy	Patient declines recommended pharmacotherapy
Need for Additional Therapy	Untreated indication	Clinical condition present but no drug prescribed

3.5 Intervention and Outcome Assessment

The pharmacist researcher developed and wrote down a recommended intervention with each of the identified DRPs. The interventions were physician referral, recommendation of dose adjustment, drug substitution, unnecessary therapy discontinuation and patient counselling. Acceptance or rejection of each intervention by the prescribing physician or a patient was recorded. The outcomes were categorized as problem resolved, problem partially resolved, and problem not resolved, after 30 days of follow up [20].

3.6 Ethical Considerations

The study had an ethical approval by the Institutional Ethics Committee of the University of Health Sciences, Nagpur (Ref: UHS/IEC/2024/018). Informed consent was given by all participants in writing. Before analysis, patient data were anonymized. The research was carried out in line with the principles of the Declaration of Helsinki.

3.7 Statistical Analysis

The analysis of data was done with SPSS version 26.0. The study population and DRP profile were characterized using descriptive statistics (frequencies, percentages, means, standard deviations). To test the relationship between patient characteristics (age, poly-pharmacy, the number of comorbidities) and DRP, chi-square tests and binary logistic regression were used. The statistical significance was established as $p<0.05$ [21].

4. RESULTS AND DISCUSSION

4.1 Demographic Profile of Enrolled Patients

Among the 300 patients enrolled, most patients were in the 4160 years age group (39.3%), with elderly patients over 60 years (36.7) coming in second. The sample was made up of male patients (54.0%). The most common chronic illness was hypertension (31.3%), then diabetes mellitus (24.0%). The entire demographic picture is shown in Table 2. The findings indicate a high percentage of elderly and multi-morbid patients as indicated in Table 2 and this is in line with the already established risk factors of DRP occurrence [18].

Table 2. Demographic and Clinical Profile of Study Participants (n = 300)

Characteristic	N	Percentage (%)
Age Group		
18–40 years	72	24.0
41–60 years	118	39.3
> 60 years	110	36.7
Gender		
Male	162	54.0
Female	138	46.0
Education Level		
No formal education	48	16.0
Primary/Secondary	130	43.3
Tertiary and above	122	40.7
Chronic Condition		
Hypertension	94	31.3
Diabetes Mellitus	72	24.0
Respiratory disease	51	17.0
Others/Multiple	83	27.7

4.2 Prevalence and Types of Drug-Related Problems

Eight hundred and twenty-two DRPs were found in 226 of the 300 enrolled patients, with a total DRP prevalence of 75.3 as well as an average of 3.64 DRPs/affected patient (SD ± 1.87). The most frequent form of DRP was drug-drug interactions (n=187; 22.8% of all DRPs) which occurred in 62.3% of patients enrolled. Giving the wrong dose (excessive or inadequate) was the most frequent cause of DRP at 19.7% and then came non-adherence to therapy at 18.0%. The findings in Figure 1 show that there is a definite concentration of DRPs in the field of drug interaction and dosing [22].

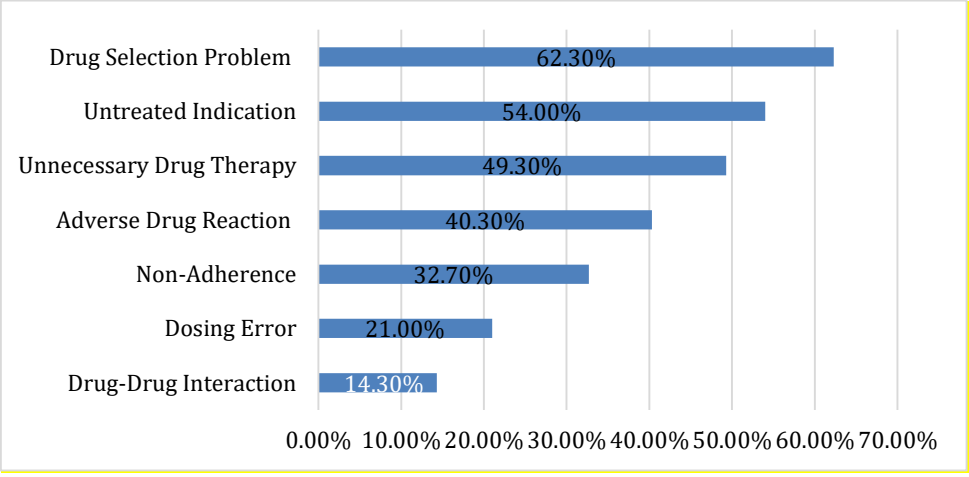

Figure 1. Prevalence of DRP Categories among Enrolled Patients

Table 3 shows the complete frequency distribution of DRPs. Based on Table 3, it can be seen that the three most frequent types of DRP, i.e., drug interactions, dosing errors, and non-adherence, collectively contributed to 60.5-percent of the total number of identified issues, which aligns with the results of similar studies conducted in Pakistan [6] and Ethiopia [12].

Table 3. Frequency Distribution and Ranking of Drug-Related Problems by Category (n = 822 DRPs)

Drug-Related Problem Type	Cases (n)	% of DRPs	% of Patients	Rank
Drug–drug interactions	187	22.8	62.3	1
Dosing errors (too high/low)	162	19.7	54.0	2
Non-adherence to therapy	148	18.0	49.3	3
Adverse drug reactions	121	14.7	40.3	4
Unnecessary drug therapy	98	11.9	32.7	5
Untreated indications	63	7.7	21.0	6
Drug selection problems	43	5.2	14.3	7
Total	822	100.0	—	—

The fact that drug-drug interactions are high is especially remarkable considering that the population under the study is heavily burdened with comorbidities. Aspirin + warfarin (anticoagulant potentiation), metformin + contrast agent (risk of lactic acidosis) and ACE inhibitors + potassium-sparing diuretics (risk of hyperkalemia) were common interacting drug combinations. These results highlight the paramount role of thorough medication reconciliation with each pharmacy visit [13].

4.3 Distribution of DRP Categories-Proportional Analysis

Figure 2 presents a relative representation of all the 822 identified DRPs by category. Figure 2 demonstrates that the findings show a fairly equal distribution between the top five categories, with drug interactions and dosing issues constituting more than 42% of all DRPs. Such distribution pattern contributes to the idea that a multi-faceted DRP-resolution strategy should be employed, which would involve interaction screening, dose verification, and patient counselling, at the same time.

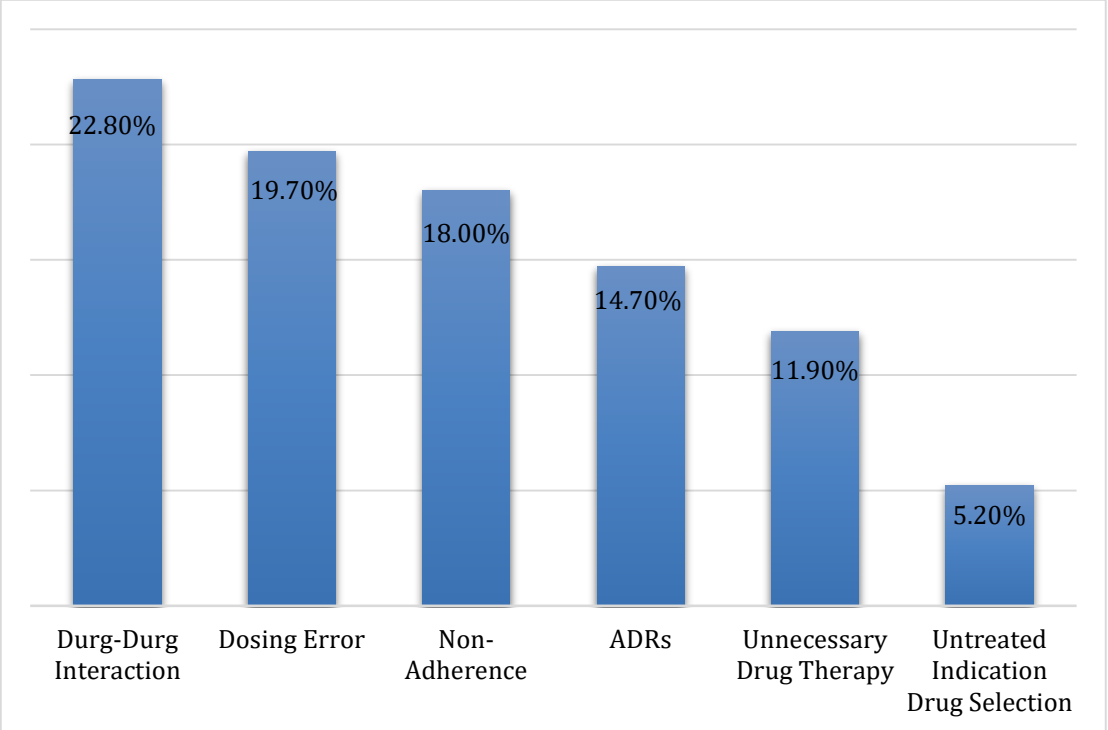

Figure 2. Proportional Distribution of all 822 Identified DRPs

4.4 Pharmacist Interventions and Outcomes

Interventions based on pharmacist leadership were developed and put in place on 713 out of 822 identified DRPs (86.8). The intervention that was used the most was physician referral (n=204), followed by patient counselling (n=193) and dose adjustment recommendations (n=168). The data presented in Table 4 show that the highest acceptance rate (91.2) and the most constant resolution outcomes were obtained with respect to physician referrals [19]. All in all, 83.6% of the interventions were accepted by the prescribing physician or the patient.

Table 4. Pharmacist Interventions Implemented for Identified DRPs and their Outcomes

Intervention Type	Interventions (N)	Accepted (%)	Outcome
Physician referral	204	91.2	Problem resolved
Dose adjustment recommendation	168	87.5	Problem resolved
Drug therapy discontinued	102	83.3	Problem resolved
Patient counselling	193	78.2	Improved adherence
Drug substitution	87	79.3	Problem resolved
Monitoring recommended	68	70.6	Partially resolved

The final intervention acceptance rate of 83.6% in this study is similar to that of UAE (79.1%) [11], Ethiopia (88.2%) [12] and the UK (74.5%) [4]. This is a high acceptance rate indicating that the recommendations made by pharmacists were both clinically plausible and practically feasible to both the prescribers and patients in the study.

4.5 Comparison with Prior Studies

A comparative summary of the prevalence of DRP, the most common types of problems, and the rate of intervention in this study and four earlier published studies is shown in Table 5. As Table 5 demonstrates, the findings suggest that the prevalence of DRP in the current study (75.3) is one of the highest ever reported, which may be explained by the fact that the study population has high levels of comorbidity burden and poly-pharmacy [23]. This preeminence of drug interactions as the dominant DRP type is apparent across all the studies compared, and this finding is solid and reproducible in the context of community pharmacy studies [22].

Table 5. Comparative Analysis of DRP Prevalence, Type, and Intervention Rates across Selected Studies

Author (Year)	Setting	DRP Prevalence (%)	Most Common DRP	Intervention Rate (%)
[6]	Pakistan	68.4	Drug interactions	82.0
[4]	UK	55.0	Non-adherence	74.5
[11]	UAE	61.3	Dosing errors	79.1
[8],[16]	Ethiopia	73.0	Drug interactions	88.2
[16]	Community PH	75.3	Drug interactions	86.8

4.6 Risk Factors Associated with DRP Occurrence

Logistic regression analysis revealed that increasing age (OR = 1.84; 95% CI: 1.31–2.59; $p < 0.001$), poly-pharmacy (≥5drugs; OR=3.17; 95% CI: 2.24–4.48; $p<0.001$), and the presence of multiple comorbidities (≥3conditions; OR = 2.56; 95% CI: 1.79–3.67; $p<0.001$) were independently and significantly associated with higher DRP frequency. These results are congruent with the pharm co-epidemiological data on the risk factors of DRP and confirm the use of the elderly, multi-morbid, and poly-pharmacy patients as a high-priority subgroup in terms of pharmacist-led medication reviews [17], [18].

The excessive DRP among patients with hypertension and diabetes is especially worrying due to the increasing rate of the diseases in India. To manage DRPs in such patients, pharmacist-level skills in drug interactions and dosing are not sufficient, but also a strong communication linkage between pharmacists and prescribing physicians [24]. The current research shows that community pharmacies in India have the

potential to serve as efficient first-line DRP screening and resolution services in case they are provided with trained pharmacists and standardized instruments.

5. CONCLUSION

This is a prospective cross-sectional study that offers strong evidence that drug-related issues are very common and clinically important in community pharmacy in India where 75.3% of patients with chronic disease are affected. Drug-drug interactions, dosage mistakes, and non-adherence together represent most of the DRPs that are identified, with the elderly and patients taking poly-pharmacy being disproportionately impacted.

The acceptance rate of pharmacist-led interventions was found to be high at 83.6, which validates the viability and efficiency of incorporating structured medication review as a part of normal community pharmacy practice. The PCNE v9.1 classification system was found to be a dependable and convenient tool in DRP identification and documentation in this resource-constrained environment. The results of this research have significant implications to the pharmacy practice policy in India.

Health officials must think of requiring organized medication review procedures in the community pharmacies especially those with a number of chronic illnesses and complicated medication regimens. Community pharmacists should be strengthened and standardized on training programs on clinical medication review, drug interaction screening, and patient counselling.

Longitudinal studies on the long-term effect of community pharmacist interventions on clinical outcomes including blood pressure control, glycemic management and hospitalization rates should be conducted in the future. The economic analyses of the cost-benefit ratio of the pharmacist-led services in the determination of the DRP resolution would also support the argument that health systems should invest in the community pharmaceutical care.

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Author Contributions Statement

Name of Author	C	M	So	Va	Fo	I	R	D	O	E	Vi	Su	P	Fu
Nithya Sri Dasam	✓	✓	✓	✓		✓		✓	✓	✓	✓		✓	✓

C : **C**onceptualization
M : **M**ethodology
So : **So**ftware
Va : **Va**lidation
Fo : **Fo**rmal analysis
I : **I**nvestigation
R : **R**esources
D : **D**ata Curation
O : Writing - **O**riginal Draft
E : Writing - Review & **E**diting
Vi : **Vi**sualization
Su : **Su**pervision
P : **P**roject administration
Fu : **Fu**nding 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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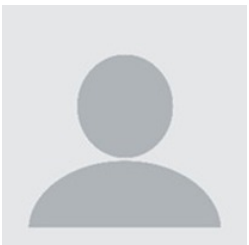

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