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Original Article

Prevalence and Determinants of Antibiotic Dispensing Practices without Prescription in Community Pharmacies of Gadag City, India

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ABSTRACT

Background: Pharmacists play a crucial role in healthcare, ensuring the safe and effective distribution of medicines. However, the practice of dispensing antibiotics without prescriptions, particularly in India, raises significant concerns. This study aims to determine the extent of antibiotic dispensing practices without prescriptions across all drug outlets in Gadag City. **Materials and Methods:** A cross-sectional study was conducted in Gadag City, India, using semi-structured questionnaires. Universal sampling was employed, covering all 91 pharmacies, of which 83 participated. Data was analyzed using Excel and SPSS. **Results:** The study revealed that 92.7% of pharmacists dispense antibiotics without prescription. Patient demand for brand-specific antibiotics was high, with 79.5% of pharmacists noting patient insistence on particular brands, and the condition for which the antibiotics are most frequently dispensed is common cold and flu (92.8%). **Conclusion:** The findings reveal a significant disconnect between pharmacists' knowledge of legal restrictions on dispensing antibiotics and their actual practices, with a large proportion still providing antibiotics without prescriptions. Pharmacists concern over losing business and patients' financial constraints are key motivators for this practice. These findings underscore the urgent need for national-level policy enforcement and targeted educational programs to mitigate the risks of antimicrobial resistance.

Keywords: Antibiotic Prescription, Antimicrobial Resistance, Community Pharmacy, Non-Drug Prescriptions.

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INTRODUCTION

Antibiotics are used to prevent, diagnose, and cure diseases.[1] However, inadequate use may cause health problems due to adverse drug effects and ineffectiveness.[2] In India, most patients don't prefer to visit their doctors until their health issues get worse,[3] so they simply manage their symptoms/illness with medications from pharmacies directly, without a valid prescription which may have serious long-term consequences.[4] All drugs that come under Schedule H and Schedule X of the Drugs and Cosmetics Rules, 1945, legally require a prescription for their sale.[5] All other drugs are "non-prescription drugs" Antimicrobial agents fall under Schedule H and H1. Though antibiotics are to be sold only with a valid prescription, this rule is not enforced, and in India, antibiotics are freely available without a prescription.[6] In India, pharmacists are permitted to sell drugs without a prescription if they are not listed as prescription-only drugs under the Drugs and Cosmetics Act of 1940. However, this provision is often misinterpreted and exploited by pharmacists, who may sell prescription-only drugs without a valid prescription.[7,8]

The practice of dispensing antibiotics without a prescription is not only illegal but also poses a significant risk to patient safety. Patients may receive the wrong medication, incorrect dosage, or inappropriate advice on medication use, which can lead to serious health consequences.[9] In recent years, there have been calls for stricter regulation of the dispensing of antibiotics without a prescription in India. The government has taken some steps to address this issue, such as implementing a centralized drug tracking system and increasing penalties for pharmacists who violate drug laws.[7] Despite the growing concerns over the illegal dispensing of antibiotics without prescriptions in India, there is limited research focused on the extent of this practice in smaller cities. Most studies have concentrated on larger urban areas, leaving a gap in understanding the local factors influencing this issue, hence this study aims to determine the prevalence, factors, and pharmacist perceptions regarding antibiotic dispensing without prescriptions in Gadag City.

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MATERIALS AND METHODS

Study Design

A cross-sectional research design was employed to assess the dispensing practices without a prescription in drug retail outlets of Gadag City. The study aimed to assess pharmacies in Gadag City, with a total of 91 pharmacies, as reported by the Assistant Drug Controller. Using Cochran's formula for finite populations, the sample size was calculated to be 74 pharmacies with a 95% confidence interval and 5% margin of error. However, 83 pharmacies consented to participate, exceeding the calculated minimum sample size. The formula used was:

$$n = \frac{\mathrm{NZ^2pq}}{(N-1)E^2 + Z^2pq}$$

Where: n=sample size, N=total number of pharmacies in Gadag City (91), Z=Z value for a 95% confidence level (1.96), p=estimated proportion of pharmacists dispensing antibiotics without prescriptions (assumed 0.5 for maximum variability), q=1-p, E=margin of error (5% or 0.05).

Inclusion and Exclusion Criteria

All registered community pharmacists were considered eligible to participate in our study, provided they are willing to participate. All community pharmacists were required to hold at least one pharmacy degree (either D. Pharm, B. Pharm or Pharm D).

Data Collection Tool

A semi-structured questionnaire was developed by the researchers, based on an extensive literature review and previous publications on antibiotic dispensing without a prescription. The questionnaire included sections on sociodemographic characteristics, perceptions, dispensing practices, and pharmaceutical care provision.

Data Collection

Data was collected through self-administered questionnaires, which were distributed to pharmacists at the participating pharmacies. The respondents were asked to complete the forms independently.

Statistical Analysis

The data were analyzed using Microsoft Excel and Statistical Package for the Social Sciences (SPSS). Categorical data were presented as frequencies and percentages. Data were classified based on different independent variables and tabulated in Microsoft Excel. Descriptive analysis was performed using SPSS software.

RESULTS

The study was conducted among pharmacists in 83 community pharmacies. The majority of the participants were male (93.9%), and the most common education qualification was D. Pharma (91.5%). Regarding the age distribution, (60.2%) pharmacists were in the age group of above 40 years. The work experience of the participants varied, with the highest (30.1%) having more than 15 years of experience as shown in Table 1.

The study found that a majority of pharmacists (92.7%) dispense antibiotics without a prescription, and (79.5%) reported that patients insisting pharmacist to dispense on brand names. However, only (65.06%) of pharmacists think that dispensing without a prescription may cause serious health issues. On the other hand, (87.9%) pharmacists reported warning their patients about the potential side effects of a antibiotics. In terms of the differences between prescription-only drugs (non-OTC) and Over-the-Counter drugs (OTC), only (69.8%) of participants had an idea as shown in Table 2.

The most common patient complaints for which antibiotics were dispensed without prescription are common cold and flu (92.8%), fever (90.4%), headache (86.7%), and stomach pain (84.3%) The main reason cited for dispensing antibiotics without a prescription was the concern on which (85.5%) agreed that if one pharmacist refused, the patient would simply go to another pharmacist to get the medication, also (69.9%) of pharmacists responded with the reason of patients inability to afford consultation in various cases. In the assessment of pharmacists' roles in providing pharmaceutical care, our findings reveal a diverse range of perspectives among the respondents as shown in Table 3. While a majority (55.4%) believe that pharmaceutical care can positively impact dispensing practice. Additionally, 56.6% of pharmacists recognize the necessity of continuous pharmaceutical education for effective practice. It is noteworthy that the majority (80.7%) engage in offering advice and counseling during drug dispensing. Moreover, a substantial percentage (84.3%) perceives pharmaceutical care as positively influencing patients' health outcomes.

The analysis revealed significant associations between various demographic and professional factors and pharmacist's practices and perceptions as shown in Table 4. Belief in the impact of pharmaceutical care on dispensing practices was significantly associated with educational qualification (p=0.031). Offering advice and counseling during drug dispensing showed significant relationships with age group (p=0.018), job designation (p=0.038), and work experience (p=0.019). Additionally, perceptions of pharmaceutical care's impact on patient health outcomes were significantly influenced by age group (p=0.048) and work experience (p=0.020).

Table 1: Distribution of responses according to Socio-demographic Characteristics.

Sl. No.	Variable (*n*=83)	Frequency (n)	Percentage (%)
1	**Age group**		
	20-29	16	19.20
	30-39	17	20.40
	40-49	35	42.10
	50-59	15	18.0
2	**Gender**		
	Female	5	6.10
	Male	78	93.90
3	**Education Qualification**		
	B Pharm	4	4.80
	D Pharm	76	91.50
	Other	3	3.60
4	**Job Designation**		
	Both Owner and Manager	17	20.40
	Owner	50	60.20
	Staff Pharmacist	16	19.20
5	**Work Experience**		
	1-5 years	23	27.70
	6-10 years	15	18.0
	11-15 years	20	24.0
	above 15 years	25	30.10

Table 2: Distribution of responses on pharmacist's perception about dispensing antibiotics (*n*=83).

Variables	Responses	Frequency (n)	Percentage %
Dispensing antibiotics without prescription.	Yes	77	92.70
	No	06	7.30
Patients insisting pharmacist to dispense on brand names.	Yes	66	79.50
	No	17	20.40
Problems like ADR, AMR, or any other may arise if dispensed without prescription.	Yes	54	65.00
	No	29	34.90
Warning patients about the potential side effects of particular drugs.	Yes	73	87.90
	No	10	10.80
Encouraging the patient to consult a physician and get a prescription.	Yes	50	60.20
	No	33	39.70
Differentiating between prescription only medicines (non-OTC) and Over the Counter medicines (OTC).	Yes	58	69.80
	No	2	30.10

DISCUSSION

The issue of inappropriate dispensing of antibiotics is a significant problem in many countries, including India. Several studies have highlighted the prevalence of this issue in community pharmacies, where pharmacists are often the first point of contact for patients seeking medication.[10]

The findings of these studies have shown that dispensing practices in community pharmacies in India are often suboptimal, with a significant proportion of pharmacists dispensing antibiotics without a prescription, particularly for common ailments such as the common cold and flu. Furthermore, there is a lack of consensus among pharmacists regarding their responsibilities towards providing pharmaceutical care. In this study conducted in Gadag, Karnataka, the study found that only 69.8% of pharmacists could

Table 3: Distribution of responses according to pharmaceutical care provision. (*n*=83).

Sl. No.	Variables	Responses	Frequency (n)	Percentage (%)
1	Primary responsibility of pharmacist is to provide pharmaceutical care	Yes	46	55.40
		No	37	44.50
2	Continuous pharmaceutical education is necessary for community pharmacists to practice pharmaceutical care	Yes	47	56.60
		No	38	45.70
3	Patient knows that how and when to take or use the product	Yes	50	60.20
		No	33	39.70
4	Offering the advice and counseling during drug dispensing	Yes	67	80.70
		No	16	19.2%
5	Proper pharmaceutical care will decrease the unnecessary and frequent dispensing practices without prescription?	Yes	70	84.3%
		No	13	15.6%

Table 4: Significance between the questions and the comparing variables (*n*=83).

Questions with their comparing variables	Significance (*p* value)
Belief in impact of pharmaceutical care on dispensing practices. against educational qualification.	0.031*
Offering the advice and counselling during drug dispensing. against Age group.	0.018*
Offering the advice and counselling during drug dispensing. against Job designation of respondent.	0.038*
Offering the advice and counselling during drug dispensing. against Work experience.	0.019*
Perception of Pharmaceutical Care on Patient Health Outcomes. against age group.	0.048*
Perception of Pharmaceutical Care on Patient Health Outcomes. against Work experience.	0.020*

* Significance level is *p* value<0.05.

differentiate between prescription-only drugs (non-OTC) and Over-the-Counter drugs (OTC). This awareness level was higher in Belagavi City of Karnataka (82.5%), Saudi Arabia (70.5%), and Tanzania (81.2%).[3,10,11] Hence there is a need for more training and awareness about the differences between these two types of drugs. The study found that (92.7%) of pharmacists dispense antibiotics without a prescription. This percentage was much higher than the study conducted in North Nigeria (39.7%).[12] There is a need for more strict regulations and enforcement regarding dispensing without a prescription. The study found that (79.5%) of patients insisted on brand names when dispensed by pharmacists. This percentage was much higher than the study conducted in Tamil Nadu (40.0%) but similar to Saudi Arabia (93.3%).[6,11] The study found that 65.0% of pharmacists think that dispensing antibiotics without a prescription may cause serious health issues. This percentage was lower than the study conducted in Belagavi (71.3%) but much lower than Tanzania (90.0%).[3,10] Pharmacists in Gadag Karnataka, have a lower perception of the potential health risks associated with dispensing without a prescription. The study found that (87.9%) of pharmacists warned their patients about potential side effects of antibiotics. This percentage was much higher than the study conducted in North West Ethiopia (59.0%) and similar to Saudi Arabia (81.0%).[1,13] This indicates that pharmacists in Gadag city are proactive in warning patients about the potential side effects of antibiotics. Indian pharmacists dispense antibiotics without a prescription at a much higher rate than pharmacists in other countries. Patients in India heavily rely on brand names and the advice of pharmacists. Indian pharmacists have a lower perception of the potential health risks associated with dispensing without a prescription. However, they are proactive in warning patients about potential side effects.[14] But there is a need for more strict regulations and enforcement regarding dispensing without a prescription. The study found that the most common patient complaints were common cold and flu (92.7%) for which antibiotic were dispensed without prescription. This percentage was much higher than the study conducted in Belagavi for common cold (37.5%) and similar to Saudi Arabia (68.0%).[1,3] Common cold and flu are the most common patient complaints in Gadag Karnataka. The study found that the main reason cited by pharmacists for dispensing without a prescription was the fear of losing business to other pharmacists (85.5%). This indicates that pharmacists are more concerned with losing business than following regulations and ethical practices. These findings suggest a need for more strict regulations and enforcement regarding dispensing without a prescription, as well as increased education and awareness among pharmacists and patients about the potential health risks associated with this practice. One notable finding regarding, belief in Impact of pharmaceutical care on dispensing practices showed that (55.4%) of the pharmacists believe that pharmaceutical care has significant impact on dispensing practices. This is lower than the findings of similar studies conducted in Poland and Vijapur Karnataka, where (76.0%) and (78.0%) of respondents

considered it their responsibility, respectively.[15,16] Furthermore, only (56.6%) of pharmacists in this study believed that continuous pharmaceutical education is necessary to practice pharmaceutical care. However, the study also found that (80.7%) of pharmacists provided advice and counselling during antibiotics dispensing. This is higher than the percentages reported in the north west Ethiopia (81.2%), Poland (45%).[16,17] Another important finding was that 84.3% of the pharmacists believed that pharmaceutical care has significant impact on patients health outcomes. Overall, this study suggests that while a majority of pharmacists in India provide advice and counselling during drug dispensing, there is a need to increase awareness and responsibility among pharmacists regarding pharmaceutical care. Continuous education and training programs may be beneficial in this regard. Additionally, there is a need for policies and regulations to reduce the practice of dispensing antibiotics without prescription and to promote the safe and effective use of antibiotics. A key drawback of this research was that the study exclusively focused on registered pharmacists within pharmacy establishments, excluding employees and pharmacy assistants who work within these pharmacy settings.

CONCLUSION

The findings reveal a significant disconnect between pharmacist's perception of legal restrictions on dispensing antibiotics and their actual practices, with a large proportion (92.7%) still providing antibiotics without prescriptions. Patients commonly request antibiotics for conditions like the common cold and flu, often showing a preference for brand-name medications, which pharmacists accommodate. Pharmacists' concerns over losing business and patients' financial constraints are key motivators for this practice, despite their awareness of the associated health risks. To address these issues, there is a clear need for policy measures to enforce stricter compliance with prescription guidelines and continuous training programs to reinforce the differentiation between prescription-only and over-the-counter medications. Enhanced regulatory oversight, alongside ongoing education for pharmacists, is essential to promote ethical dispensing practices and ensure safer use of antibiotics in community pharmacies.

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CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **AMR:** Antimicrobial Resistance; **B. Pharma:** Bachelor of Pharmacy; **D. Pharma:** Diploma in Pharmacy; **GPP:** Good Pharmacy Practices; **OTC:** Over-the-Counter; **PMBJAK:** Pradhan Mantri Bhartiya Janaushadhi Kendra; **SPSS:** Statistical Package for the Social Sciences; **WHO:** World Health Organisation.

ETHICAL APPROVAL

The study obtained ethical approval from the Institutional Ethics Committee of Karnataka State Rural Development and Panchayat Raj University (Approval No: RDPRU/SEP/IEC/4/2021/16).

CONSENT TO PARTICIPATE

Oral informed consent was obtained from the study participants.

SUMMARY

This cross-sectional study examines the prevalence of non-prescription antibiotic dispensing across all drug outlets in Gadag City, India. 92.7% of pharmacists dispense antibiotics without a prescription, largely influenced by patient demand and financial constraints. The most frequently dispensed antibiotics without a prescription are for conditions such as the common cold and flu (92.8%) and fever (90.4%). While 87.9% of pharmacists inform patients about potential side effects, only 44.5% maintain records for Schedule H1 and X drugs, highlighting gaps in regulatory compliance.

Key drivers of non-prescription antibiotic sales include patient insistence (79.5%), concerns over business loss (85.5%), and the financial burden of medical consultations (69.9%). The study also evaluates pharmacists' roles in pharmaceutical care, revealing that 80.7% provide guidance during dispensing, and 84.3% perceive pharmaceutical care as beneficial to patient outcomes. Significant associations were identified between pharmacists' educational qualifications, age, job designation, and work experience with their perceptions and practices related to pharmaceutical care.

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