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Original Research Article

Evaluation of antibiotic dispensing without prescription by community pharmacies: a simulated patient study

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ABSTRACT

Background: Antibiotics are widely used, but using them without a prescription remains problematic. In India, Despite Schedule H regulations, antibiotics are available in community pharmacies without a prescription, leading to inappropriate use and contributing to the rise of antibiotic resistance. This study aimed to evaluate antibiotic dispensing practices and influencing factors in community pharmacies for Adult Upper Respiratory Tract Infections (URI) and Uncomplicated Acute Diarrhea (UAD) using a simulated patient (SP) approach.
Methods: A cross-sectional observational study was conducted at 200 community pharmacies across Coimbatore city, Tamil Nadu, using SPs presenting symptoms of URI and UAD. Chi-square test, unpaired T-test, and binary logistic regression were employed to analyze factors like scenario, location, pharmacy type, and interaction time on antibiotic dispensing.
Results: Antibiotics were dispensed without prescription in 76% of pharmacies, with a higher rate for URI (82%) than UAD (70%, p=0.047). Dispensing was more common in pharmacies within a 1–10 km radius (92%) than those farther away (60%, p=0.032). Interaction time averaged 3.8 minutes when antibiotics were dispensed versus 2.3 minutes when not. Erythromycin (33%) and norfloxacin (32%) were the most commonly dispensed antibiotics. Scenario (OR=8) and locality (OR=5) significantly influenced dispensing practices, while pharmacy type had minimal impact.
Conclusions: Antibiotic dispensing without prescription is high with higher rates for URI compared to UAD. Factors like locality, symptom enquiry, and interaction time influenced dispensing. Targeted interventions like training, audits, and public awareness are essential to promote rational use and mitigate antimicrobial resistance.

Keywords: Antimicrobial resistance, Community pharmacies, Diarrhea, Patient simulation, Upper respiratory tract infection

INTRODUCTION

The modern era is facing a significant global health threat in the form of antimicrobial resistance (AMR). The spread of resistant bacteria has been accelerated by the misuse and overuse of antibiotics, particularly in outpatient settings, making infections that were once treatable more challenging to handle.[1] In 2022, an estimated 4.9 million deaths were linked to bacterial AMR, with 1.27 million of those deaths directly caused by resistant infections. Without immediate and coordinated action, AMR is expected to result in over 10 million deaths annually by 2050, surpassing cancer as a leading cause of mortality.[2] Pharmacies are often the first, and sometimes the only place where individuals seek treatment for common infections. However, this accessibility has led to the inappropriate use of antibiotics. Studies have shown that 40-60% of inappropriate antibiotic use occurs in outpatient settings,

such as community pharmacies, where antibiotics are dispensed without prescriptions.[3] India is one of the largest populations and highest burdens of infectious diseases has a crucial role in the global effort against AMR.[4] The country has seen a significant increase in antibiotic consumption, which has doubled from 2000 to 2022.[5] Being one of the world's largest consumers of antibiotics, this overuse has had severe consequences. In 2022, almost 700,000 deaths in India were due to AMR-related complications, with a significant portion linked to inappropriate antibiotic usage.[6] Despite strict regulations under Schedule H, which require antibiotics to be sold only with a valid prescription, the availability and use of antibiotics in community pharmacies remain high.[7,8] Pharmacies play a crucial role in controlling antibiotic use.[9] However, many pharmacies face pressure to maintain sales, especially due to the increasing competition from online pharmacies. This pressure often results in prioritizing profits over patient care, leading to the over-dispensing of antibiotics.[10]

Given these challenges, this study aims to assess the dispensing of antibiotics without a prescription by community pharmacies in an urban city using the simulated patient technique. Specifically, on Upper Respiratory Tract Infections (URI) and Uncomplicated Acute Diarrhoea (UAD), comparing outcomes across different geographical areas in the city, identifying the most frequently dispensed antibiotics, evaluating the differences across the types of pharmacies and analyzing the factors influencing antibiotic dispensing practices.

METHODS

A community-based cross-sectional observational study was conducted using the Simulated Patient (SP) technique over a period of six months, from March, 2024 to August, 2024. This study was approved by the Institutional Human Ethics Committee (IHEC) of PSGIMS&R (Approval No. Exp/062, March 05, 2024) to evaluate antibiotic dispensing without prescription by community pharmacies in Coimbatore city, Tamil nadu, India. Coimbatore is a city that serves as a prominent healthcare and a well-established network of community pharmacies. As per the Coimbatore District Administration Statistical Reports, there are 1,000 allopathy pharmacies present; a subset of 20% (200) was incorporated into the study. The selection process involved dividing the Coimbatore city map into four zones (Northwest, Northeast, Southwest, and Southeast), with 50 pharmacies randomly selected from each zone. The randomization was performed using EpiTools, online randomization software.

Simulated patient technique

The Simulated Patient (SP) technique is a reliable method for assessing healthcare practices, particularly when direct prescription audits are not feasible.[13]A Simulated Patient (SP) is a trained individual who acts as a real patient to evaluate healthcare practices.[14] In this study, the SPs will enact scenarios specifically designed to assess the dispensing of antibiotics without prescriptions, offering unbiased insights into dispensing habits. Four male students, aged 20, from PSG College of Pharmacy, Coimbatore were selected to serve as SPs. All were local resident's familiar with the district geography and fluent in Tamil and English language.

Each simulated patient (SP) was assigned two clinical scenarios in two different zones. Northwest: SP1 presents URI and SP2 presents UAD. Northeast: SP3 presents URI and SP4 presents UAD. Southwest: SP1 presents UAD and SP3 presents URI. Southeast: SP2 presents UAD and SP4 presents URI.

Training of simulated patients

The research team set up a supervising committee for SP training, which included a community pharmacist and a layperson. The training started with discussions about the importance of the cases, followed by creating scripts for the SPs. After mastering the scripts, the SPs participated in supervised dry runs at local pharmacies, where the supervisor pretended to shop while the SP carried out the interaction. This was followed by unsupervised practice visits to ensure that SPs remembered all the details of the case presentation and interaction without being detected.

Selection of scenarios represented by SPs

Two clinical scenarios were selected for the study, namely Upper Respiratory Tract Infection (URI) and Uncomplicated Acute Diarrhea (UAD). URI is a common condition that is generally of viral etiology, and for the symptoms of the common cold such as runny nose, sore throat, cough, and nasal congestion, only symptomatic treatment is required (American Centres for Disease Control)[15]. Symptomatic treatment includes the use of antihistamines, decongestants, cough suppressants, and non-steroidal anti-inflammatory drugs (NSAIDs).[15] Similarly, guidelines for the treatment of UAD have been published by the WHO, recommending oral rehydration salts (ORS) and antimotility drugs as the appropriate management.[16]

Therefore, in both scenarios, the use of antibiotics is not recommended, as these are self-limiting conditions where antibiotics provide no clinical benefit, as referred in Table 1.

Statistical analysis

All data were analyzed using IBM SPSS Statistics version 28.0. The Chi-Square Test and Binary Logistic Regression were used to assess the relationship between antibiotic dispensing and influencing factors. The Unpaired T-Test was utilized to evaluate the relationship between antibiotic dispensing and the interaction time between the Simulated Patient (SP) and the pharmacies.

Table 1: Clinical condition scenarios represented by SP.

Description of the case scenario	Clinical condition		Expected management
Upper respiratory tract infection (URI)	Individual with 2 days history of runny nose, sore throat, cough, pain during swallowing and fever. Family members have similar symptoms. No medical history. No medication history. No social history. No allergic status.	Sir/Ma'am, I am having runny nose, cough and fever. Can you give me some medicine? If requested by the pharmacist, the SP's will be revealing the other symptoms/ history.	Acceptable: Not dispensing antibiotics, with or without referral to a doctor;Symptomatic treatment includes the use antihistamines, decongestants, cough suppressants, and non-steroidal anti-inflammatory drugs (NSAIDs) Not acceptable: Dispensing antibiotics, other prescription only medications (bronchodilators).
Uncomplicated acute diarrhoea (UAD)	Individual with 2 days history of watery diarrhoea. No medical history. No medication history. No social history. No allergic status.	Sir/Ma'am, I am having diarrhoea. Can you give me some medicine? If requested by the pharmacist, the SP's will be revealing the other symptoms/ history.	Acceptable: Not dispensing antibiotics, with or without referral to a doctor. Dispensing oral rehydration salts (ORS), antimotility drugs (Loperamide) Not Acceptable: Dispensing antib iotics, antiemetics, antacids.

RESULTS

The study included 200 community pharmacies evenly distributed across the four regions of Coimbatore City: Northwest, Northeast, Southwest, and Southeast. Of these, 100 pharmacies were observed to manage URI cases, while the remaining 100 focused on UAD cases. To further enhance the analysis, the pharmacies were categorized into two geographical zones: 50% (n=100) were located within a 1-10 km radius and the other 50% (n=100) within an 11-20 km radius. The analysis also revealed that 42% (n=85) of the pharmacies were chain pharmacies, while 58% (n=115) were independent pharmacies as shown in Table 2.

Table 2: Distribution of community pharmacies.

	Characteristics	Frequency (N)	Percentage (%)
Scenario	URI	100	50
	UAD	100	50
Locality	1-10 km radius	100	50
	11-20 km radius	100	50
Type	Chain pharmacy	85	42
	Independent pharmacy	115	58

Table 3: Allocation of scenarios to community pharmacies.

	Characteristics	URI (N)	UAD (N)
Locality	1-10 km radius	50	50
	11-20 km radius	50	50
Types	Chain pharmacy	38	47
	Independent pharmacy	62	53

Table 3 shows that each scenario URI and UAD was allocated to 100 community pharmacies, with 50 pharmacies within a 1–10 km radius and 50 within an 11–20 km radius. Among pharmacy types, 38 chain and 62 independent pharmacies were assigned to URI, while UAD was assigned to 47 chain and 53 independent pharmacies, ensuring balanced representation across both distance and type.

Among the 200 pharmacies surveyed, 76% (n=152) dispensed antibiotics, while 24% (n=48) did not dispensed any antibiotic. Within these 152 pharmacies, 42% (n=64) provided antibiotic counselling, 58% (n=88) did not offer such counselling. 37% (n=57) emphasized completing antibiotic courses, while 63% (n=95) did not highlight this important aspect. 45% (n=68) provided non-pharmacological counselling, while 55% (n=84) did not.79% (n=120) enquired further about patients illnesses, 21% (n=32) did not engage in such inquiries as shown in Table 4.

Table 4: Counselling and communication practices among pharmacies that dispensed antibiotics (n=152).

	Characteristics	Frequency (N)	Percentage (%)
Antibiotic counselling	Provided	64	42
	Not provided	88	58
Reinforced course completion	Yes	57	37
	No	95	63
Enquired more about illness	Enquired	120	79
	Not enquired	32	21
Non pharmacological counselling	Provided	68	45
	Not provided	84	55

Table 5: Comparison of antibiotic dispensing practices by scenario, distance, and pharmacy type.

Variable	Categories	Antibiotic dispensed (N)	Percentage (%)	P value
Scenario	URI	82	82	0.000
	UAD	70	70	
Distance to Pharmacy	1-10 km	92	92	0.032
	11-20 km	60	60	
Pharmacy type	Chain pharmacy	79	79	0.289
	Independent pharmacy	74	74	

Table 6: Comparison of average interaction time based on antibiotic dispensing.

Pharmacies Dispensed antibiotic	Mean of interaction time (SP and pharmacist) in minutes	P value between two groups (p<0.05)
Yes	3.8	0.01
No	2.3	

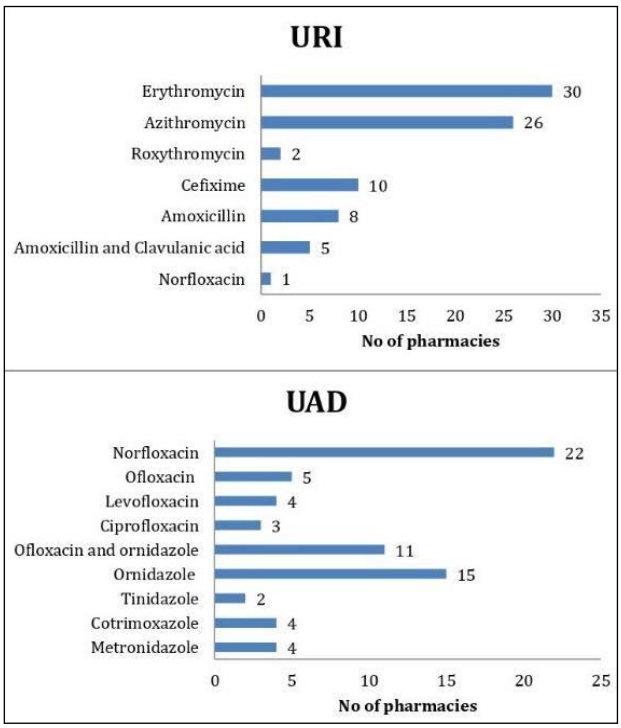

Figure 1: Antibiotics commonly dispensed for URI and UAD.

The analysis revealed key differences in antibiotic dispensing practices across the two scenarios. Antibiotics were dispensed more frequently for URI (82%) than for UAD (70%) (p=0.045). Pharmacies located within a 1–10 km radius dispensed antibiotics at a significantly higher rate (92%) compared to that 11-20 km away, where only 60% of cases received antibiotics (p=0.032). Antibiotic dispensing was similar between chain pharmacies (79%) and independent pharmacies (74%) (p=0.289) as shown in Table 5. SPs had longer interaction times when antibiotics were dispensed (3.8 minutes) compared to when antibiotics were not dispensed (2.3 minutes) (p=0.01) as shown in Table 6.

Erythromycin (a macrolide antibiotic) was the most frequently dispensed antibiotic for URI (30 pharmacies), while norfloxacin (a fluoroquinolone antibiotic) was the most dispensed antibiotic for UAD (23 pharmacies), as shown in Figure 1.

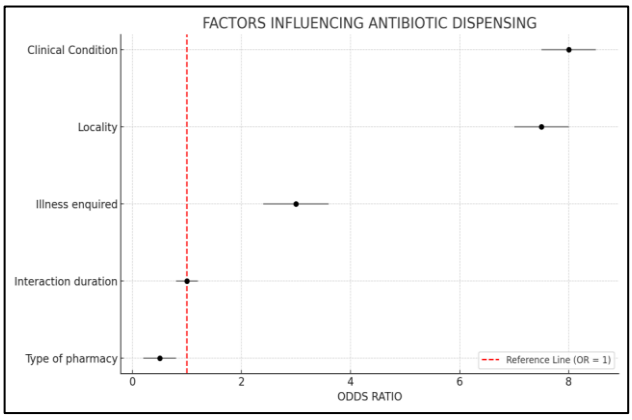

Figure 2: Odds ratio of factors influencing the pharmacist dispensing.

The odds ratios (OR) for factors influencing antibiotic dispensing are shown in Figure 2. The most prominent factors are the clinical condition (OR=8) and locality (OR=5). The pharmacies enquiry about the illness (OR=3) and the interaction time with the SP (OR=1) also play a role. However, the type of pharmacy shows minimal effect (OR=0.5).

DISCUSSION

The dispensing of antibiotics without prescription in community pharmacies poses significant risks in contributing to antimicrobial resistance (AMR). This inappropriate use leads to the emergence of drug-resistant bacteria, complicating the treatment of common infections.

Alarmingly, the study revealed that 76% of pharmacies in Coimbatore city dispensed antibiotics without a prescription. Such widespread non-compliance exacerbates the threat of AMR, underscoring a critical global health challenge.

The use of the SP technique was essential for gathering authentic data on dispensing practices without influencing pharmacies behavior. By simulating real world patient interactions for conditions like URI and UAD, the SP approach offered valuable insights while mitigating the Hawthorne effect. This ensured unbiased observations regarding whether pharmacies asked relevant questions, or provided adequate counselling.

The study highlighted two case scenarios: URI and UAD, both of which, according to clinical guidelines, should not warrant antibiotic treatment. However, findings showed that 82% of pharmacies dispensed antibiotics for URI, indicating a potential misunderstanding of the condition. This finding aligns with research by Gaurav Nepal et al, which reported that 79.6% of pharmacies in Nepal dispensed antibiotics for URI without a prescription.[17] Similarly, 70% of pharmacies dispensed antibiotics for UAD, this reflects misconceptions about the necessity of antibiotics for treating diarrhea, consistent with findings by Basak et al, which indicated that 80.4% of pharmacies in India dispensed antibiotics for acute diarrhea without a prescription.[18]

Geographically, the study revealed significant differences in antibiotic dispensing practices across localities. Pharmacies within a 1-10 km radius dispensed 92% of antibiotics compared to 60% in pharmacies located within a 11-20 km range (p=0.032). This disparity may arise from established relationships with regular customers in residential areas, leading pharmacies to be more lenient with antibiotic dispensing. This observation parallels findings by Nga et al in Vietnam, which noted that pharmacies in residential areas were more likely to dispense antibiotics without a prescription than those in rural settings.[19]

Interestingly, the study found no statistically significant difference in antibiotic dispensing practices between chain and independent pharmacies (p=0.289). This suggests that the issue of factors such as patient pressure, profit motives may influence dispensing practices in both types of pharmacies. This aligns with a study by Nafisah et al in Saudi Arabia, which found no significant differences in antibiotic dispensing practices between chain and independent pharmacies.[20]

Longer interactions with SP (3.8 minutes) were associated with a higher likelihood of antibiotic dispensing compared to shorter interactions (2.3 minutes) (p=0.01). This finding aligns with research by Zhang et al in China, which indicated that increased interaction time with patients led to a higher likelihood of pharmacies dispensing antibiotics.[21]

This study found significant gaps in patient counselling practices. Only 42% of pharmacies that dispensed antibiotics offered antibiotic counselling, and just 37% emphasized the importance of completing the full antibiotic course. This lack of guidance is concerning, as proper counselling is essential to ensure antibiotics are taken correctly and for the full prescribed duration.

The findings indicate that the clinical condition and the pharmacies locality were the most significant factors influencing antibiotic dispensing. Moderate factors included the pharmacies enquiry about the illness and interaction time with SP, suggesting that antibiotics were dispensed when the interaction was brief. However, the type of pharmacy (independent or chain) had little effect on dispensing practices.

This study has a few limitations. Since the SP method was used, Information about the pharmacists such as their qualifications, age, or experience could not be collected, which might also influence antibiotic dispensing. Additionally, it focused only on two clinical conditions: URI and UAD so the findings may not be applicable to other commonly encountered conditions.

CONCLUSION

Antibiotics were dispensed without prescription in 76% of community pharmacies in Coimbatore city, with higher rates observed for URI than UAD, reflecting both high availability and inappropriate use. Antibiotic dispensing was influenced by factors such as locality, symptom enquiry, and interaction time, while pharmacy type showed minimal effect. To address these concerns, implementing targeted interventions such as scenario-based training for pharmacy staff, stricter audit procedures, and patient awareness programs can help promote more responsible antibiotic dispensing practices, ultimately supporting the fight against AMR and protecting public health.

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