Over-the-counter sales of antimicrobials and factors associated with it among private pharmacies in ward-32 of Kathmandu Metropolitan City: a pilot study

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ABSTRACT

Introduction: Over-the-counter sales of antimicrobials are contributing to the increasing burden of anti-microbial resistance. This mixed-method study aims to assess the practice of over-the-counter sales of antimicrobials by private pharmacies and factors associated with it from the perspective of both the private pharmacy staff and the community people to produce more enriched and valid findings through triangulation of results from quantitative and qualitative studies.

Method: A cross-sectional, concurrent triangulation mixed method approach was used. Participants were selected purposively, including 30 exit interviews from 5 pharmacies and 6 qualitative interviews. Descriptive statistics and Fisher's exact test were done for quantitative analysis. Braun and Clarke's six steps of thematic analysis were followed for qualitative data analysis.

Result: Qualitative findings illuminated the repercussions of antibiotic misuse, stressing the imperative need for patient education, responsible prescribing, and regulatory measures. Identified factors included self-medication practices, familial influence, profit-driven pharmacies, easy access, healthcare system challenges, prescription barriers, and unregulated OTC sales. Quantitative results validated these, with 53.3% obtaining antibiotics without prescriptions. Key factors contributing to this trend included profit-motivated pharmacies (p=0.014), self-medication (p=0.014), the presence of a doctor in the pharmacy (p=0.005), and fear of losing customers (p=0.046).

Conclusion: The integrated findings underscore urgent need to address antimicrobial misuse to curtail unnecessary expenses, adverse health effects, and the looming threat of antibiotic resistance. Comprehensive interventions are crucial to mitigate unwarranted costs, health risks, and the emergence of antimicrobial resistance, emphasizing the significance of a multifaceted approach in safeguarding global public health.

Keywords: antimicrobial, Nepal, over-the-counter, pharmacies

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INTRODUCTION

Globally, antimicrobial resistance is responsible for an estimated 700,000 deaths per year, which could increase to as much as 10 million by 2050 if this problem is not addressed.[1] Approximately 93% of access to antimicrobials comes from community pharmacies.[2] Pharmacists serve as the final line of defense with the ability to prevent misuse of antimicrobials.[3] In Nepal, there are a huge number of formal as well as informal pharmacies.[4] The Drug Act 1978 AD has mentioned that antimicrobials fall under group 'B' drugs that require a prescription for dispensing.[5] Despite this, the private pharmacies in Nepal are largely unregulated and the private pharmacy staff fail to adhere to good pharmacy practice.[6]

The literature review showed that most studies focused on antibiotics prescription from pharmacies' perspective. [4, 9, 10 ,11, 14] The studies were quantitative and the factors associated were found out based on the structured questionnaire. There was a gap in exploring other possible reasons for over-the-counter sales of antimicrobials as a whole including community perspective.

This mixed method study aims to assess the practice of over-the-counter sales of antimicrobials by private pharmacies and factors associated with it from the perspective of both the private pharmacy staff and the community people to produce more enriched and valid findings through triangulation of results from quantitative and qualitative studies. In this study, if the pharmacy staff has given the medicine or the patient has self-medicated, it has been defined as over-the-counter sales of antimicrobials. The medicines bought through a valid prescription from a doctor and the medicines prescribed by a doctor in the pharmacy have not been defined as over-the-counter sales.

METHOD

This cross-sectional study employed a concurrent triangulation mixed-method design, emphasizing both qualitative and quantitative data. Conducted in Ward 32 of Kathmandu Metropolitan City from September 20 to 23, 2023, the research involved 30 exit interviews and 4 in-depth interviews (IDI) with patients, along with 2 key informant interviews (KII) with pharmacy staff. Five pharmacies were purposively selected, and from each, 6 exit interviews were conducted. The study aimed to integrate quantitative and qualitative findings to uncover convergent, divergent, and expansive insights regarding antimicrobial use.

A structured questionnaire was used for exit interviews. IDIs and KIIs were conducted following respective guidelines. Face validity of the questionnaire and guideline was maintained through pre-test. Participants provided voluntary written informed consent, signed digitally in Kobo Toolbox. Ethical approval (Ref: PHP2312011822) was obtained from the Institutional Review Committee of Patan Academy of Health Sciences. The study included individuals visiting the pharmacy to buy antimicrobials for themselves or their children. Exclusions comprised individuals buying on behalf of others, as well as those below 18 years of age.

Quantitative data, gathered through Kobo Toolbox, underwent cleaning in MS Excel and analysis using EZR software. Descriptive analysis encompassed frequency, percentage, mean, standard deviation. Inferential analysis utilized Fisher's Exact Test for the association between dependent and independent variables, with a two-sided p-value as the significance criterion. For qualitative study, the audio recordings of qualitative interviews were first transcribed into Nepali and then translated into English for analysis purposes. The data was analyzed manually using MS Excel. For thematic analysis, Braun and Clarke's six steps of thematic analysis were followed.[7] The findings were presented based on themes with their sub-themes, codes, and verbatim.

RESULT

The mean age with standard deviation of the respondents was 40.33±14.125. Among 30 respondents, 56.67% were 40 years of age or below and 56.67% were male. The majority, 56.67%, had education beyond the secondary level. Twenty percentage of respondents were unemployed and 36.67% occupied semi-professional positions. The socio-economic status was classified based on the Kuppuswamy scale in the context of Nepal.[8] Majority (60%) fell into the upper-middle-class category.

In Table I, the presence of doctors in pharmacies was only 20%. Combining self-medication and pharmacy staff prescriptions, total over-the-counter (OTC) sales of antimicrobials reached 53.33%. The majority of antimicrobials were antibiotics 24 (80%).

Azithromycin emerged as the most commonly dispensed antimicrobial, reported by 6 (20%) of respondents, followed by Cefixime, Amoxycillin, and Metronidazole.

Table 1. OTC sales of antimicrobials, N=30

Variables	N (%)	Variables	N (%)
Presence of doctor in the pharmacy		**Source of antimicrobials**	
No	24 (80%)	Self-medicated	5 (16.67%)
Yes	6 (20%)	Prescribed by a doctor	14 (46.67%)
Class of antimicrobials		Prescribed by the pharmacy staff	11 (36.67%)
Antibiotics	24 (80%)		
Antifungal	6 (20%)		

Table 2. Factors associated with over-the-counter sales of antimicrobials, N=30

Variables		OTC sales of antimicrobials		p-value
		No	Yes	
		N (%)	N (%)	(Fisher's exact)
Age group	≤40	8 (47.1%)	9 (52.9%)	0.96
	>40	6 (46.2%)	7 (53.8%)	
Sex	Female	7 (53.8%)	6 (46.2%)	0.49
	Male	7 (41.2%)	10 (58.8%)	
Education				
Basic Education		2 (66.7%)	1 (33.3%)	0.48
Secondary Education		3 (30.0%)	7 (70.0%)	
More than secondary		9 (52.9%)	8 (47.1%)	
Occupation				
Unemployed		1 (16.7%)	5 (83.3%)	0.35
Unskilled worker		3 (75.0%)	1 (25.0%)	
Skilled worker		1 (50.0%)	1 (50.0%)	
Clerical, shop owner, farmer		1 (25.0%)	3 (75.0%)	
Semi-professional		7 (63.6%)	4 (36.4%)	
Professional		1 (33.3%)	2 (66.7%)	
Socio-economic status				
Upper class		0 (0%)	1 (100%)	0.92
Upper middle class		8 (44.4%)	10 (55.6%)	
Lower middle class		5 (50%)	5 (50%)	
Upper lower middle class		1 (100%)	0 (0%)	
Presence of doctor in the pharmacy				
No		8 (33.3%)	16 (66.7%)	**0.005***
Yes		6 (100%)	0 (0%)	
Class of antimicrobials				
Antibiotics		12 (50%)	12 (50%)	0.66
Antifungal		2 (33.3%)	4 (66.7%)	

Table 3. Association between OTC sales and motivators

Variables		OTC sales of antimicrobials		p-value
		No	Yes	(Fisher's exact)
		N (%)	N (%)	
Profit	No	3 (21.4%)	11 (78.6%)	**0.014***
	Yes	11 (68.8%)	5 (31.2%)	
Fear of losing customers	No	7 (33.3%)	14 (66.7%)	**0.046***
	Yes	7 (77.8%)	2 (22.2%)	
Practice of self-medication	No	3 (21.4%)	11 (78.6%)	**0.014***
	Yes	11 (68.8%)	5 (31.2%)	
Weak law of country	No	10 (41.7%)	14 (58.3%)	0.34
	Yes	4 (66.7%)	2 (33.3%)	
Easy access to pharmacies	No	10 (58.8%)	7 (41.2%)	0.16
	Yes	4 (30.8%)	9 (69.2%)	
Time saving	No	11 (50.0%)	11 (50.0%)	0.69
	Yes	3 (37.5%)	5 (62.5%)	
Money saving	No	14 (51.9%)	13 (48.1%)	0.23
	Yes	0 (0%)	3 (100%)	
Weak health system of Nepal	No	11 (50.0%)	11 (50.0%)	0.69
	Yes	3 (37.5%)	5 (62.5%)	

Table 4. Themes, sub-themes, and codes of the thematic analysis

SN	Themes	Sub-Themes	Codes
1	Understanding of antimicrobials		Meaning of antibiotics
			Limited knowledge on antimicrobials
2	Habit of visiting private pharmacies		Reasons for pharmacy visits
			Previous practice of visiting pharmacies
3	Experience during pharmacy visit		Obtaining antibiotics without prescription
			Lack of medication counseling
			Proper counseling by pharmacy staff
4	Reasons for OTC sales of antimicrobials	Reasons concerning individuals	Lack of awareness
			Self-medication practices
			Influence of family and friends
			Seeking quick relief
		Reasons concerning pharmacies	Profit-motivated pharmacies
			Fear of losing customers
			Easy access to pharmacies
			Incompetent pharmacy staffs
		Challenges in Nepal's government	Health care system and access challenges
			Inadequate laboratory facilities
			Poor regulation on OTC sales
		Barriers to obtaining prescriptions	Lack of access to doctors
			Limited access to health care services
			Economic factors
			High opportunity cost
5	Consequences of OTC sales of antimicrobials		Limited knowledge on AMR
			Unwarranted expenses
6	Suggestions for improvement	Role of government	Enforcement of regulations
			Strengthen health system
			Monitoring and regulation
		Role of pharmacies	Maintaining records
			Adhere to the regulation
			Competent pharmacists needed
		Role of individuals	Make effort to get prescription

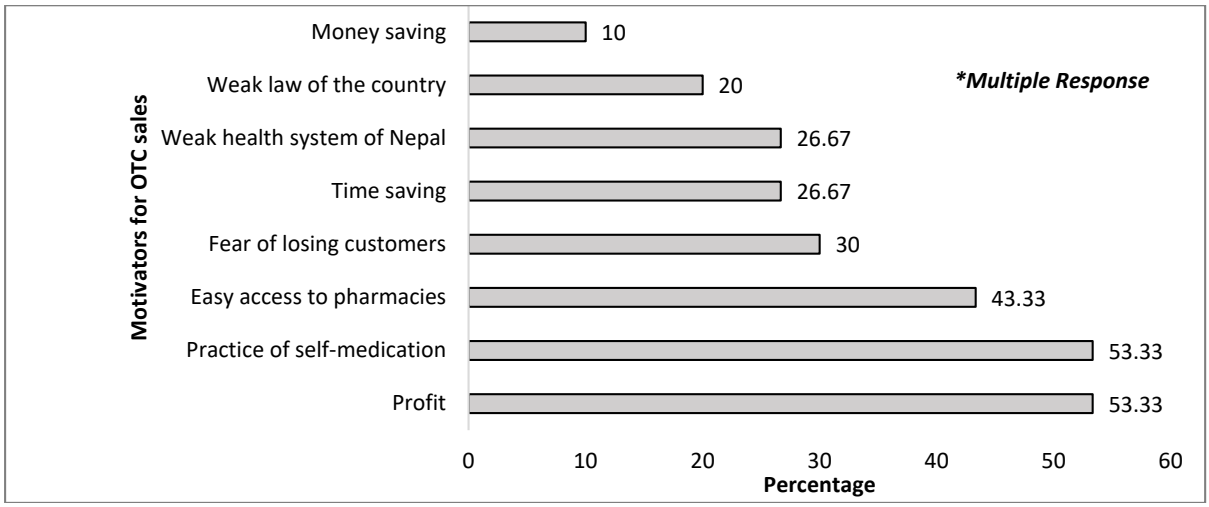

Figure 1. Motivators for OTC sales of antimicrobials, N=30

The primary reasons for pharmacy visits included cough (26.67%), and other respiratory problems (20%). OTC sales were primarily driven by profit and self-medication, as reported by 53.33% of respondents (Figure 1).

The findings from Tables II and III suggest that the presence of a doctor in the pharmacy, profit, fear of losing customers, and the practice of self-medication are key factors associated with OTC sales of antimicrobials. The variable presence of doctors has been added to the study to address the fact that there are instances in Nepal where doctors visit certain pharmacies on certain days of the week for some hours. Other demographic and

contextual factors did not demonstrate significant associations with OTC sales.

Reasons for OTC sales of antimicrobials

Sub-theme 1- Reasons Concerning Individuals

On an individual level, the reasons for OTC sales of antimicrobials included lack of awareness, self-medication practices, the influence of family and friends, and the habit of people seeking quick relief.

"They go to the pharmacy, get the medication without a prescription, and then take it without knowing it's an antibiotic. They often take it without proper knowledge."

- IDI_1(39 years, Male, Bachelor's Degree)

People also tend to seek quick relief than going through the standard procedure of getting a prescription from a doctor.

"When they have a slight fever or minor discomfort, they might visit a pharmacy and when they get a lower dose, if their symptoms don't improve within 2-3 days or if they get worse, they may go to another pharmacy. It happens because people want quick relief."

- IDI_2 (27 years, Female, Bachelor's Degree)

Sub-theme 2- Reasons Concerning Pharmacies

From the level of pharmacy, the reasons for OTC sales of antimicrobials included pharmacies treating it more as a business, profit-motivated pharmacies, easy access to pharmacies and incompetent pharmacy staff. When a pharmacy prescribes strong medication that leads to quick relief of symptoms, more customers are attracted.

"When you get a fever, you go to a medical pharmacy, and within two days, you'd get your fever down. They don't investigate the cause; they just treat it. Pharmacies, too, often follow the practice of prescribing high doses for the sake of effectiveness."

- IDI_3 (52 years, Male, Master's Degree)

Sub-theme 3- Challenges in Nepal's Government

The respondents showed a gap in the existing government system which is playing a huge role in increasing OTC sales of antimicrobials. The reasons identified in this study were: inadequate laboratory facilities and poor regulation of OTC sales. The ambiguous policies of Nepal are also hindering the regulation according to one of the pharmacy staff.

"Despite these guidelines, it's not feasible to have strict monitoring because someone needs to enforce it. It would have been effective if the government enforced rules and regulations regarding the prescription and sale of medicines, including detailed record-keeping for pharmacies, both at the inlet and outlet levels."

- *IDI_1* (39 years, Male, Bachelor's Degree)

Sub-theme 4- Barriers to obtaining a prescription

Uneasy and limited access to doctors, limited access to health care services, economic factors, and high opportunity cost were identified as barriers to obtaining a prescription.

"There's also a lengthy process involved in getting a prescription, and sometimes people can't afford it. So, for someone who earns 800 rupees a day, going to a hospital and buying medicines for 200 rupees after taking a day off work might not be practical. Not everyone can seek immediate medical attention, even when they have a severe condition. They may visit a pharmacy first."

- KII_2 (48 years, Male, Pharmacist)

Convergent Findings

Both data sources converge on the prevalence of OTC sales of antimicrobials. The quantitative survey showed a 53.3% prevalence of OTC sales. This problem was also acknowledged in the qualitative part. From both qualitative and quantitative findings, the factors associated with OTC sales of antimicrobials were identified as profit as the motivator of OTC sales for pharmacies, widely accepted self-medication practice in the community, and fear of losing customers. These findings were significant in quantitative survey as well as widely mentioned in qualitative interviews.

"Right now, pharmacies are primarily focused on making money. They're driven by profits. But we need to monitor how far these pharmacies have progressed and grown, to what level they've improved their services, and how they're thinking about their own."

- IDI_3 (52 years, Male, Master's Degree)

Divergent Findings

In quantitative findings, limited access to healthcare services, poor regulation on OTC sales of antimicrobials, expensive hospital costs, and saving time by going to the pharmacy were not significant. However, they were emphasized in the qualitative interviews.

"Yes, economic factors do play a role. For example, when you go to the hospital or clinic, the fees are

quite high. They charge around 7/800 rupees, and then when you go to the pharmacy to buy the prescribed medicines, the cost adds up. People try to save money, and that's why they opt for the easier and cheaper option, which is buying medicines directly from pharmacies. The high cost of medical consultations and prescribed medications at hospitals and clinics often drives people to look for more affordable options, like buying medicines directly from medical halls. It's a way for them to save money."

- IDI_4 (56 years, Female, Basic Education)

Expansive Findings

The consequences of OTC sales and suggestions for improvement came under expansive findings which were only found through qualitative interviews. The role of government included enforcement of regulations, strengthening the government system, strengthening the health system, monitoring and regulation, and conducting awareness programs.

"The government should indeed play a role by strictly enforcing these laws. It's necessary to clamp down on those who openly sell antibiotics without a prescription or any oversight. The relevant authorities should take strict actions."

- KII_1 (42 years, Male, Pharmacist)

DISCUSSION

In our study, the overall OTC sales of antimicrobials were found to be 53.3%. A similar study with the same methodology conducted in the Rupandehi district of Nepal also showed a similar prevalence of 44.8%.[9] The commonly appearing disease conditions in this study were fever (6.67%) and cough (26.67%) which was also the same in the Rupandehi study, fever (18.1%) and cough (5.3%).[9] Our study showed that azithromycin was most widely used antimicrobial. This finding contradicts the findings of the study by Nepal et.al, where the most used antimicrobial was cefixime followed by amoxicillin. Since most of the patients came with the problem of cough, the drug of choice could have been azithromycin in our study. It also treats a wide range of infections compared to amoxycillin which could be another reason for its higher use.

In this study, the profit motive of the pharmacists was identified as a factor responsible for OTC sales of antimicrobials. In a qualitative study done in the central, eastern, and western regions of Nepal among patients, clinicians identified commercial interest in selling medicines as a factor for OTC sales of antimicrobials, as well.[10]. A similar result was obtained from another qualitative study in western Nepal.[11]

Another factor significant in both qualitative and quantitative studies was the fear of losing customers by the pharmacies or the intention to gain goodwill from the customers. There are a few national and international articles that have shown this as a reason for OTC sales of antimicrobials.[10–13] Similarly, there are a few studies done in Nepal that have shown self-medication to be one of the socially acceptable and rooted practices that have been contributing to OTC sales of antimicrobials.[10,11] This finding is similar to our study. The age of the patients was seen as significant in other similar studies done in Nepal.[9,14,15] Our study showed no association of the socio-economic status of the patients with the practice of OTC sales of antimicrobials. In spite of that, there are studies that have shown association between OTC sales of antimicrobials specially self-medication practice with the socio-economic status.[16] However, these factors were not found significant in this study. This can be because of the small sample size of this study.

Our study and previous research shed light on the challenges within Nepal's healthcare system. The qualitative data underscored issues such as limited access to healthcare services and inadequate laboratory facilities. Similarly, a study by Adhikari et al. discussed the challenges of healthcare access in rural Nepal, emphasizing the need for improved healthcare infrastructure [10]. The poor regulation of OTC sales of antimicrobials and inadequate enforcement of existing laws were also highlighted in both our study and research by Adhikari et al.[10] Our study identified an association between the presence of doctors in the pharmacy and OTC sales of antimicrobials which has not been explored in other studies.

CONCLUSION

The study indicates that over-the-counter sales of antimicrobials are linked to the absence of a doctor, profit motives of pharmacists, self-medication, and fear of losing customers. Qualitative analysis corroborated these findings and extended on other important factors related to service seekers like the habit of sharing medication, limited access to health centers and doctors and expensive health care of Nepal. The participants revealed concerns about antibiotic misuse, including financial burdens and health risks. Participants highlighted the need to urgently address antibiotic misuse to prevent unnecessary

expenses, adverse health effects, and the risk of antibiotic resistance.

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Conflict of interest
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