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Original Article

Dispensing Practices of Antibiotics among Community Pharmacies of Bharatpur, Nepal: A Simulated Patient Cross-Sectional Study

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ABSTRACT

Background: The practice of community pharmacies dispensing antibiotics without a prescription is widespread, and improper use of these medications is associated with the emergence of resistance. Hence, this study aimed to evaluate the dispensing practices of antimicrobials in community pharmacies of Bharatpur city, Nepal. **Materials and Methods:** A cross-sectional study involving 101 community pharmacies of Bharatpur Metropolitan city was conducted for a duration of six months starting from 1st January 2022 till 30th June 2022. A simulated patient method was used to determine the antimicrobials dispensing practices using a case scenario of acute diarrhea. Using a simple random method, the community pharmacy was chosen as the study site from among the community pharmacies that were registered with the Department of Drug Administration (DDA). A trained pharmacists posing as a simulated patient gathered data, and the data was then analyzed using chi-square test to find out the association. **Results:** Ninety-three percent of the 101 community pharmacies dispensed antimicrobials without prescription. Among the most frequently dispensed medications were antimicrobials (53.5%), gastrointestinal agents (44.4%) and mineral supplements (2%). Moreover, the trend of dispensing antimicrobials was significantly higher among non-pharmacy professionals (p=0.014), including Health Assistants (64%), Community Medical Assistance (55.6%) and those with orientation training (42.9%). **Conclusion:** The study findings indicate that there is unquestionably irrational dispensing of antimicrobials in cases of acute diarrhea. To reduce this, it is necessary to prioritize awareness campaigns about the responsible use of antimicrobials, and to ensure that relevant policies, rules and regulations are implemented promptly.

Keywords: Antibiotic resistance, Community pharmacy, Dispensing practice, Simulated patient.

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INTRODUCTION

Antimicrobial resistance has increased significantly, leading to a complex public health issue globally with a major effect on quality of life (WHO, 2021). It increases morbidity, mortality, delayed treatment process, prolonged hospitalization and healthcare cost. Due to antimicrobial resistance, easily curable minor ailments could lead to become more lethal (Morrison & Zembower, 2020).

As per the report of the Center for Disease Control and Prevention (CDC) in 2019, more than 2.8 million antimicrobial resistances occur in US each year and more than 35,000 people die in the same year (CDC, 2019). The research had estimated that approximately 700,000 people die by antimicrobial resistance with the possibility of emerging 10 million deaths annually by 2050 if no forward actions are taken to reduce it (de Kraker *et al.*, 2016). The irrational use of antimicrobials is a major driver in emergence of antimicrobials resistance (Soltani *et al.*, 2020). Likewise, disproportionate drug pressure is also one of the main factors for antimicrobial resistance. Among antimicrobials, 50% of patients received at least one antimicrobial in low- and middle-income countries (Adhikari *et al.*, 2021). Dispensing practices of antimicrobials without a diagnosis and medical prescription are still common worldwide (Chang *et al.*,2019).

Community Pharmacies (CPs) are the main sources for dispensing antimicrobials worldwide (Showande & Adelakun, 2019). A multi country public awareness overview by WHO in 2015 reported that 93% of antimicrobials were mostly dispensed from community pharmacy outlets. In Low- and Middle-Income Countries (LMICs), where public cannot afford to visit the

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physician and purchase medicines, community pharmacies are the first point of contact to seek health-care (Saleem *et al.*, 2020). In LMICs, despite the availability of laws and regulations, dispensing antimicrobials without a prescription is common in practice (Belachew *et al.*, 2022). Inappropriate dispensing may be due to unavailability of qualified pharmacists, patient pressure, lack of knowledge regarding rational use of antimicrobials, and lack of regulatory practices (Chang *et al.*, 2019). Likewise, economic gain, desire to meet the customer demands, fear of losing customer, and insufficient monitoring system are among the prime reasons to dispense antimicrobials without prescription by most of community pharmacies (Husaini *et al.*, 2021; Acharya & Wilson, 2019). In Nepal 67-97% of antimicrobials are dispensed without prescription from the community pharmacies and they are utilized irrationally (Jha *et al.*, 2020; Ansari, 2017; Nepal *et al.*, 2019). Although Antimicrobial Resistance (AMR) surveillance was started in Nepal in 1999 by the National Public Health Laboratory, the country fails in implementing the efforts successfully. According to the Nepalese drug act, the Department of Drug Administration (DDA) is the regulatory body to supervise the community pharmacies. Furthermore, the "Drug Act 2035" classifies drugs into three categories i.e. group (Ka, Kha and Gha). Antimicrobials come under the group 'Kha' which can be dispensed only with valid prescription of the registered medical practitioner. Earlier, DDA with the help from Global Antimicrobials Resistance Partnership Nepal has created a community pharmacies training schedules focusing on prescription and dispensing of antimicrobials though use of various activities including electronic boards and audio- visual materials. However, the DDA could not succeed to spread these activities at national levels due to lack of formal schedule or process (WHO, 2018).

In the past, health professionals other than pharmacists such as Health Assistant (HA) and Community Medical Assistance (CMA) operated community pharmacies, but most of the community pharmacies are now in the court of pharmacists. So, it had become necessary to find out whether there is any change in dispensing practices in context to previous scenario. As per the country report based on the Global Burden of Disease 2017 study, diarrheal diseases was ranked as third leading cause of mortality in Nepal (NHRC, 2019). A study conducted in Nepal reported that 97% of community pharmacies dispensed unnecessary antimicrobials in case of diarrhea (Wachter *et al.*, 1999). Therefore, this study aims to assess the antimicrobials dispensing practices among community pharmacies in Bharatpur Metropolitan City, Chitwan Nepal in diarrhea case scenario through using simulated patient method.

MATERIALS AND METHODS

Study design and duration

This cross-sectional study was conducted among community pharmacies of Bharatpur Metropolitan city for a duration of six months starting from 1st January 2022 until 30th June 2022. Bharatpur is the fourth largest city of Nepal with a total population of approximately 579,984, and is located in south-western part of province number three (City population). This district was chosen as the study area due to the dearth of research of this kind and the area's rapid growth in comparison to other cities of Nepal. The DDA Directory was used to gather the list of Community Pharmacies (DDAb). The community pharmacies that were included in DDA's directory and signed the written consent form were eligible to participate in the study. Similarly, community pharmacies that were closed after two visits and pharmacists who were not cooperative were not included in the study.

Sample size

The sample size of 92 was calculated using the prevalence of 91.3%, from the study conducted in Rupandehi district Nepal (Nepal *et al.*, 2019), and a margin of error of 0.05, and confidence interval of 95%. However, keeping in mind of drop rates in participation, an additional 10% community pharmacy were enrolled in the study representing a total sample size of 101 for this study.

Sampling techniques and data collection procedure

The data was collected using a Simulated Patient (SP) method. This method is more reliable and is considered as the gold standard to evaluate the suppliers' practice, and the method was used in India and LMICs, where medicines review is not possible (Nafade *et al.*, 2019). Furthermore, SP method minimizes the Hawthorne effects, a bias that occurs when people are aware that they are being observed (Hamadouk *et al.*, 2021). The adult acute diarrhea was taken as fictitious disease scenario to visit the selected community pharmacies. The typical symptoms of acute diarrhea include passing of abnormally loose and watery stool (i.e., no blood on stool) three times a day, with absence of nausea, vomiting, stomachache and fever.

Adequate training was provided to the simulated client having a problem with acute diarrhea, and the data collection process was divided into two sections. The first section includes the first visit, where informed consent of the participants was taken. After taking consent from the participants, socio-demographic information of the same participants was taken. Likewise, the second section includes the second visit (after a week) to the same pharmacies and pharmacists who were approached in first visit. A gap of one week was maintained to collect the data by using simulated patient method. For the simulation, a 35-year-old male was trained properly about the case of acute watery diarrhea along with the sign and symptoms to be presented to the pharmacies at the time of data collection. The simulated patient

strictly followed the predesigned fictitious case of diarrhea and presented the same scenario in all the visits. The case scenario of diarrhea was taken from the WHO manual (Womack, 1924) and world gastroenterology guidelines (Farthing *et al.*, 2013). The detailed case scenario of diarrhea which was acted by the simulated patient is attached on (Annexure 1).

At the beginning, the community pharmacy's setup and surrounding were observed and noticed. The simulated patient entered into the pharmacy only when the environment was quiet and then he presented his symptoms. Two demand levels were used for data collection. Demand level 1 commenced with making a symptom-relieving request.

Level 2 demand began when the first level of demand for medications was met. Thus, Level of Demand 2, which is requesting something more powerful than Level 1. Our visit came to an end once we had taken the medications they had prescribed. During each visit after leaving the community pharmacies, the information exchanged between pharmacy employees and fictitious patients was committed to memory and recorded in a data collection form. The data collection form along with the fictitious case scenario of diarrhea scenario is attached in Annexure-1.

Data analysis

The complete data were entered in MS-Excel and then exported to Statistical Package for Social Sciences version 11.5 (SPSS Inc., Chicago, IL, USA) for descriptive and inferential analysis. Descriptive analysis was performed for participant's socio-demographic information like age, gender, education, ask history, and referred to visit physician. Similarly, dispensing patterns of antimicrobials at various levels (Categorical variables) were summarized using frequency and percentage. Pearson's chi-square test was used to determine the association between the qualifications of participants and dispensing practices of antimicrobials at various levels of demand. The p-value of <0.05 was considered as statistically significant throughout the analysis.

Ethical approval and informed consent

The study received ethical approval from the Institutional Review Committee of Purbanchal University, School of Health Science (IRC-PUSHS) Nepal with reference number of 045-078/79, dated 27th January 2022.

RESULTS

Most of the participants (43.56%, n=44) represented the age group of 26-35 years followed by 26 (25.74%) in age group of 36-45 years. Although dispensing practices were mainly accomplished by pharmacy professional with a diploma in pharmacy degree (47.52%, n=48), there were others including CMA (25.74%, n=26), HA (15.84%, n=16) and those with orientation short course (2.97%, n=3) to cover 52% of dispensing practices. Surprisingly, none of the community pharmacies asked about prescription before dispensing medicines. On the other hand, it was common in practice to take history in most of the cases (94.06%, n=95), but referring the patients to visit physician in case the symptoms do not subside, was rare in practice (29.70%, n=30). Surprisingly, it was pervasive (93.07%, n=94) for community pharmacies to dispense antimicrobials at first level of demand. Considering the therapeutic class of medicines dispensed, antimicrobials were among the highly dispensed medications (53.54%, n=164) compared to gastrointestinal medicines (44.44%, n=88) and mineral supplements (2.02%, n=4). Moreover, metronidazole was more frequently dispensed (44.44%, n=88) (Table 1).

In this study, Health Assistants (HAs) have been found more prone to dispense antimicrobials (64%) followed by CMA (55.56%), diploma in pharmacy (52.87%), and orientation short course (42.86%) (Table 2).

In our study, no significant association was found between numbers of antimicrobials dispensed and gender with the p-value 0.222. However, the statistically significant association was found between education level of participants with antimicrobials dispensing at level 1 and level 2 with p-value of 0.014 and 0.024 respectively. Likewise, a statistically significant association was found between education level of participants with referring the patients to visit physicians and number of antimicrobials dispensed with p-value of 0.05 and 0.006 respectively. Besides, no any significant association was found between education levels of participants with asking history before dispensing antimicrobials with p-value of 0.261.The association between the various variables with antimicrobials dispensing practices is clearly depicted on the Table 3.

DISCUSSION

This is the first simulated study to be carried out in Nepal's Chitwan District's Bharatpur Metropolitan City. Using a simulated approach, actual case scenario procedures were seen in Bharatpur's community pharmacies. This study reveals how antimicrobials are dispensed at community pharmacies without a prescription or a doctor's diagnosis. Patients in LMICs who cannot afford to see a doctor and buy medications instead opt to buy medications from community pharmacies (Saleem *et al.*, 2020). The simulated patient in our study asked for medications for the diarrheal scenario while acting as though he knew nothing about medications. According to our research, 93.07% of neighborhood pharmacies gave the fictitious patient antibiotics without a prescription. The main cause of the rise in antibiotic resistance is the illogical antimicrobial dispensing procedures.

The percentage of antimicrobials dispensed was found 53.54%. According to a study done in Pakistani community pharmacies, the results are consistent with 67.1% (Malik *et al.*, 2021). The fact that a significant portion (44.55%) of community pharmacies are run by non-pharmacy professionals (such as HA and CMA) who

are neither properly trained in pharmaceuticals nor permitted to dispense medications may be the cause of the higher rate of antimicrobial dispensing through these outlets. Additional studies showed that education level and antibiotic dispensing behaviors are significantly correlated (p=0.014), which is corroborated by a study conducted in Ethiopia that also identified a strong correlation (p=0.028) (Belachew *et al.*, 2022). Additionally, because there aren't enough medical experts or graduate pharmacists in the right places, non-pharmacy professionals have the opportunity to work in community pharmacies to help with diagnosis and prescription dispensing (NPC, 2000). A study conducted in Western Nepal also highlighted a similar trend of operating community pharmacies by non-pharmacy professionals (38.88%) (Sah *et al.*, 2024). The distance between community pharmacy and the hospital is another factor that is related to the dispensing of antimicrobials. Our study also showed that, in comparison to pharmacies close to the hospital, community pharmacists farther away from the hospital dispensed more antimicrobials in response to patient demand rather than sending patients to see a doctor. This could be because of the concern that the patient might go straight to the local hospital to make a claim.

Table 1: Characteristics and practices of visited community pharmacies (*n*=101).

Variables	Category	Frequency (%)
Gender	Male	82 (81.19%)
	Female	19 (18.81%)
Age (in years)	18-25	13 (12.87%)
	26-35	44 (43.56%)
	36-45	26 (25.74%)
	46-55	10 (9.90%)
	56-65	5 (4.95%)
	66-75	3 (2.97%)
Education	CMA	26 (25.74%)
	HA	16 (15.84%)
	Diploma in Pharmacy	48 (47.52%)
	Bachelor in Pharmacy	8 (7.92%)
	Orientation short course	3 (2.97%)
Response	Ask about prescription	0 (0%)
	Ask about history	95 (94.06%)
	Advised to visit physician	30 (29.70%)
Antimicrobials dispensed	Level 1 demand single	94 (93.07%)
	Level 2 demand double	12 (11.88%)
Therapeutic class	Antimicrobials	106 (53.54%)
	GIT	88 (44.44%)
	Mineral supplements	4 (2.02%)
Generic Antimicrobials	Metronidazole	88 (44.44%)
	Ciprofloxacin	10 (5.05%)
	Ornidazole	4 (2.02%)
	Secnidazole	3 (1.52%)

Dispensing antimicrobials without asking for a valid medical prescription is another important concern. More than 93% of the community pharmacies dispensed antimicrobials without demanding a valid medical prescription. This finding is corroborated by comparable results from research conducted in Tanzania (92.3%) and Nepal's capital city (97%) (Wachter *et al.*, 1999; Horumpende *et al.*, 2018). Additionally, more than 70% of the surveyed community pharmacies in our study did not refer the simulated patient to visit physician if symptoms did not subside. This finding is congruent with the results of studies conducted in Pakistan (79.8%) (Malik *et al.*, 2021) and Turkey (85.1%) (Okuyan *et al.*, 2017). This indicates that referring the patients by the community pharmacies to visit physician if symptoms do not subside is quite infrequent in practice, and is significantly associated with educational qualification (Malik *et al.*, 2021). All these practices could facilitate irrational use of antimicrobials, which leads to the development of antimicrobial resistance, and devastating the resources.

In addition to antimicrobials, metronidazole, which is a member of the antiprotozoal/antimicrobial class, was one of the most often prescribed medications (44.4%). But, according to the standard treatment guidelines suggested by the World Gastroenterology Organization, Oral Rehydration Solution (ORS) is the first choice of treatment for adult acute diarrhea, and not the metronidazole (Farthing *et al.*, 2013).

Despite the implementation of the guidelines, only 28.8% of community pharmacies in this survey distributed ORS, which is a relatively low percentage. Similarly, the study carried out in North West Ethiopia revealed a comparable rate of administering fewer

Table 2: Education-wise antimicrobials dispensed at various levels of demand (*n*=101).

Education status	Drug Classification	Percentage (%) of drug dispensed
Community Medical Assistant (CMA)	Antimicrobials	55.56
Health Assistant (HA)	Antimicrobials	64.00
Diploma in Pharmacy	Antimicrobials	52.87
Bachelor in Pharmacy	Antimicrobials	25.00
Orientation short course	Antimicrobials	42.86

Table 3: Factors associated with dispensing of antimicrobials without prescription (*n*=101).

Independent Variables (IDVs)		Number (%)	Dependent Variables (DVs)	*p*-value
Gender	Female	81.19	Number of antimicrobials dispensed	0.222
	Male	18.81		
Type of Education	Non-pharmacy profession	44.56	Antimicrobials dispensed at Level 1	0.014*
	Pharmacy profession	55.44		
	Non-pharmacy profession	44.56	Antimicrobials dispensed at Level 2	0.024*
	Pharmacy profession	55.44		
	Non-pharmacy profession	44.56	Referring patients to visit physician	0.05*
	Pharmacy profession	55.44		
	Non-pharmacy profession	44.56	Taking patient history	0.261
	Pharmacy profession	55.44		
	Non-pharmacy profession	44.56	Number of antimicrobials dispensed	0.006*
	Pharmacy profession	55.44		

Note: *indicates the significant association i.e. *p*-value <0.05, Pharmacy professions include (diploma in pharmacy and bachelor in pharmacy), Non-pharmacy professions include (CMA, HA, Orientation short course).

Annexure 1: image1Case Scenario: A 35 years male with fictitious case of passing abnormally loose and watery stool three times a day will go to the community pharmacy for demanding the antimicrobials at various levels of demands with community pharmacy personnel. Other signs and symptoms if asked: No nausea and vomiting, no stomachache and no fever.

Pharmacy Name:					Date:	
Did medical retailer ask for prescription?					Yes	No
Did medical retailer ask for history?					Yes	No
Did medical retailer refer simulated patient to visit physician for the diagnosis and prescription?					Yes	No
Level of demands	Name of Drug Dispensed	Qty	Frequency	Regimen	Antimicrobials Dispensed at Level 1,2	
Remarks:						

Name of data collector: ……. Principal Investigator: ……...
Signature: …….. Signature: ……..

ORS (10.5%) (Wondimsigegn *et al.*, 2021). This is most likely because metronidazole is thought to be more effective than ORS at controlling diarrhea. Actually, unless the diarrhea is contagious, metronidazole and antibiotics are rarely needed for its treatment. However, the percentage of mineral supplements dispensed in cases of diarrhea was low (2.02%), and a comparable study carried out in Iraq showed an even lower tendency of mineral supplement administration in cases of diarrhea (1.3%) (Ibrahim *et al.*, 2018). This suggests that giving mineral supplements for diarrhea is not given much attention.

Although this study highlights an important issue in the country, it does have some limitations as well. This study was conducted in only one city. Thus, the results cannot be generalized to all of the community pharmacies working in the entire district or the country. Additionally, this study only focuses on antimicrobials dispensing without prescription but did not consider the prescribing behavior of antimicrobial in community pharmacies.

CONCLUSION

This simulated patient approach indicates that community pharmacies in Bharatpur, Chitwan, Nepal, engaged in a significant rate of malpractice when it comes to prescribing antibiotics for acute diarrhea. The Department of Drug Administration and other regulatory bodies must immediately monitor community pharmacies' dispensing practices, especially with regard to antimicrobials, since careless use of these drugs can result in resource waste and the emergence of antibiotic

resistance. In order to encourage the prudent use of antibiotics, the study further urges the relevant authorities to emphasize the stringent implications of the legislation and to enhance awareness campaigns and trainings, such as those on antibiotic stewardship. The following relevant recommendations are sent out in light of the study's findings. Firstly, there should be enforcement of laws in the country to limit the dispensing of antimicrobials without prescription. Secondly, it is highly recommended for multifaceted educational interventions in the form of media, TV, internet, display of printed material and regular inspection of community pharmacies by the regulatory bodies such as DDA. Thirdly, there should be heavy penalty in the breach of the regulations. Our findings recommend for further studies among larger population at national level.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

LMICs: Low- and Middle-Income Countries; **CDC:** Centre for Disease Control and Prevention; **WHO:** World Health Organization; **RDU:** Rational Drug Use; **OTC:** Over the Counter; **DDA:** Department of Drug Administration; **GARP:** Global Antibiotic Resistant Partnership; **SP:** Simulated Patient; **CP:** Community Pharmacy; **HA:** Health Assistant; **CMA:** Community Medical Assistant; **SPSS:** Statistical Package for Social Sciences.

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