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# Antibiotics Sold Over-the-Counter at Drug Stores in Mizan-Aman Town, Southwest Ethiopia: A Cross-Sectional Simulated Customer Visit Investigation

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## Article Info

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### 1. Introduction

In addition to being essential for numerous medical interventions, antibiotics have lessened the burden of common infectious diseases [1]. These medications are essential, especially in underdeveloped nations where infectious diseases are a major cause of mortality [2]. Additionally, because individual use of antibiotics has a significant impact on other people in the community and environment, they are uniquely regarded as societal medications [3]. Additionally, antimicrobial

Global public health is increasingly threatened by resistance, which calls for action from all branches of government and society at large [3]. Antibiotic-resistant bacteria are a result of antibiotic misuse and overuse, which also reduces the effectiveness of these medications [4].

Research has shown a correlation between antibiotic usage grades and the prevalence of antibiotic-resistant illnesses. The use of these improper medications provides a hint for professionals to believe that the prescription of antibiotics to treat viral infections is contributing to the issue [5].

The overall volume of antibiotic consumption, particularly incorrect diagnosis, indiscriminate prescribing, and dispensing errors, is one of the main causes of the rising resistance [6]. In addition to having a higher risk of worse clinical outcomes, people infected with drug-resistant bacteria also incur higher healthcare costs than those infected with nonresistant strains of the same bacterium [7]. Outpatient care costs for infections caused by antibiotic-resistant bacteria were estimated to be around EUR 10 million, and productivity losses from infected patients' absences from work were estimated to be over EUR 150 million annually, according to a study done in the European Union. Infections caused by the chosen antibiotic-resistant bacteria were also expected to cost society EUR 1.5 billion annually in Europe [8].

One significant regulatory concern is the sale of prescription-only medications without a prescription. More than half of antibiotics are sold worldwide without a prescription. Antibiotics are frequently sold over-the-counter in affluent nations, but in developing nations like Ethiopia, where regulatory measures are insufficient, this practice is more obvious [9, 10]. 65.4% of community pharmacies in Alexandria, Egypt, have sold antibiotics without a prescription, according to a research [11].

Due to either the incorrect medication or a subtherapeutic dosage, the comparatively unrestricted availability and consumption of antibiotics in poor nations has resulted in an excessively high rate of inappropriate use and higher levels of resistance than in industrialized nations [12]. The majority of antimicrobial use takes place outside of hospitals in every nation [13]. Due to restricted access to physicians, pharmacists in underdeveloped nations become the main provider of healthcare, and patients frequently seek their services directly. Because of this, it is difficult to strictly implement laws governing the over-the-counter administration of antibiotics [14]. Few local investigations have been done to date to look into and report antibiotic sales without a prescription. In order to evaluate the professional practice of OTC antibiotic sales at community drug retail stores located in Mizan-Aman town, the investigators set out to do just that.

## **1. Approaches**

From March 14–28, 2018, a cross-sectional simulated client visit study was carried out among community drug retail establishments located in Mizan-Aman town, Southwest Ethiopia. The administrative center of the Bench Maji zone, one of the 13 SNNPR zones, is Mizan-Aman town. The settlement lies 582 kilometers from Ethiopia's capital, Addis Ababa. The study was conducted on all of the community drug retail establishments in Mizan-Aman town, which now has eighteen commercially licensed locations. Additionally, the study covered every drugstore that was open at the time of data collection. A questionnaire created by the authors was used to gather data. The questionnaire was revised several times to make it clearer and more in line with the study's objectives. Three sections comprised the questionnaire:

The discussion that was anticipated to take place between the pharmacy professional and the simulator (data collector) regarding the simulated clinical case was included in the third section. The first section contained general information, which was followed by a number of the assigned clinical scenarios and the pharmacy professional's response, either by agreeing or refusing to dispense an antibiotic. Generally speaking, the data collector noted the type of antibiotic and the level of demand (first, second, or third) in which the pharmacy professional administered the medication. Additionally, the data collector recorded whether or not the pharmacy professional gave instructions on how to take it, mentioned the length of treatment, inquired about any drug allergies, other symptoms, concurrent use of other medications, or the female client's pregnancy status, and suggested that she see a doctor. However, if a pharmacist declined to dispense an antibiotic, the data collector was supposed to provide a potential explanation.

Three distinct clinical scenarios were selected: severe diarrhea, sore throat, and urinary tract infection (UTI) in women of reproductive age with no sequelae. The antibiotic was obtained in each of the three situations using three different amounts of demand. The first level of demand was to ask the pharmacy specialists if there was anything that might be administered to alleviate the disease's symptoms. The actor employed the second level of demand if the antibiotic was not administered: "Can't you give me something stronger? This medication isn't very strong." The actor publicly declared, "I would like an antibiotic," which was regarded as the third grade of demand, if the pharmacy staff had yet to supply the medication.

If they declined to sell an antibiotic, they were asked to explain why. If the only legal or regulatory reference made in the response was that the antibiotic could not be sold without a prescription, that response was deemed administrative. On the other hand, a response may be considered health-related if

the pharmacists voiced concerns about the following: the patient's health was not well, an antibiotic cannot be used to treat viral infections, or selling an antibiotic in this situation could cause resistance to spread.

Three levels of demand were used by sims to seek pharmacy professionals in an effort to obtain antibiotics:

Level 1: Making a request to have their symptoms lessened

Level 2: Requesting a more potent drug

Level 3: When the first two levels of demand are not met, a definite request for an antibiotic is made.

Three clinical pharmacists gathered the data. Three major investigators/simulators participated in our investigation. Investigators visited each drugstore once, simulating a clinical scenario based on pharmacy surveys using the simulated client approach. In order to standardize the information provided to the pharmacists, data collectors received training on data gathering procedures and participated in several rehearsal meetings. Descriptive statistics were also created and presented using the collected data. Finally, as this study was a minimum risk study, it was deemed ethically appropriate to use the simulated client method, which involved deceit and incomplete disclosure to study participants.

could not have been carried out with full admission of the investigator's true identity. Data was anonymized and kept private.

TABLE 1: Antibiotic prescribing practices by pharmacy professionals without a prescription in relation to demand at pharmacies in Mizan-Aman town, Southwest Ethiopia, March 14–28, 2018.

Degree of  
A sore throat  
UTI  
Diarrhea acute

1.1. Definition of Terms and Operational Definitions  
Resistance to antibiotics. It is the situation in which newly discovered strains of bacteria or other microorganisms have been shown to either resist conventional antibiotic exposure or to become resistant to antimicrobial medications.  
Pharmacy. It is a retail establishment that sells miscellaneous items and medications.  
The scenario of a sore throat. For the past 24 hours, a 24-year-old male relative has been suffering from a sore throat, trouble swallowing, and a mild fever.  
The scenario of acute diarrhea. A 23-year-old male cousin in good condition had a loose bowel movement, four to five episodes of diarrhea, mild weakness, and a little fever for one day.  
The UTI Situation. For three days in a row, a 24-year-old female relative complained of burning when she urinated.

2. Outcomes  
A total of eighteen pharmacies were the subject of the study. Clinical scenarios were distributed equally across the many pharmacies that were part of this investigation. 14 (78%) of the dispensers were men, making up the majority.

2.1. The Dispensing of Antibiotics. Out of the 18 drug stores that were given all three clinical scenarios, the majority, 17 (94.4%), gave out antibiotics without a prescription with three different demand levels. The UTI simulation was linked to the highest percentage of antibiotic dispensing. The majority of 17 (94.4%) out of 18 pharmacies that displayed a clinical scenario for a urinary tract infection dispensed antibiotics without a prescription. Of the three clinical settings examined in this study, this was the highest percentage of sales. Accordingly, just one druggist sold the antibiotics when more potent agents were requested, but 16 pharmacy professionals received the antibiotics under the first level of demand. Similarly, 16 (88.9%) pharmacies sold antibiotics for acute diarrhea without a prescription. Antimicrobial medications were acquired from 14 (77.8%) pharmacies without a prescription for the sore throat simulation. When the simulated requested any medication to relieve his or her symptoms, the majority of the antibiotics—47, or 87.2%—were given out without a prescription. With varying levels of demand for the simulated scenarios, Table 1 summarized the distribution of the percentage of pharmacies that distribute antibiotics without a prescription. Since the researcher requested something to reduce the symptoms, Level 1 demands are the lowest level.

demand Level	n	=	14	n	=	17	n	=	16.
Level 1	14		(100%)	16		(94.1%)	11		(68.75%)
Level 2:	0		percent	1		(5.9%)	3		(18.75%)
Level 3:	0		percent	0		(0%)	2		(12.5%)

Figure 1: From March 14 to 28, 2018, antibiotics were prescribed for a UTI clinical scenario at pharmacies located in Mizan-Aman town, Southwest Ethiopia.

Level 2 stands for something more powerful. By requesting an antibiotic directly from the pharmacy professional, Level 3 indicates the highest level of demand. The most often prescribed antibiotic in cases of urinary tract infections was ciprofloxacin (7, 38.9%), which was followed by norfloxacin (six drug stores, 33.3%) (Figure 1). In that simulated situation, metronidazole was the most frequently recommended antibiotic (50%) for severe diarrhea, while amoxicillin was most frequently administered (10, 71.4%) for sore throat (Table 2). The majority of the druggists, nine (64.2%), gave the simulator instructions on how to take the antibiotics, but only one distributor warned the investigators about the potential negative effects of the medication. The primary interview elements and the proportion of antibiotics prescribed in each case scenario are summarized in Table 3.

2.2. An additional question regarding a simulated clinical scenario from a pharmacy professional. When the client was simulated for sore throat, the majority of pharmacy professionals questioned the simulator for other symptoms (11 [61.1%]), followed by acute diarrhea (8 (44.4%) and UTI, respectively. On the other hand, none of the pharmacy personnel had questioned the simulator regarding concurrent medication use and potential drug allergies. The investigator's true identity was disclosed. Data was anonymized and kept private.

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TABLE 2: Antibiotics dispensed for acute diarrhea and sore throat clinical scenarios at drug stores found in Mizan-Aman town, Southwest Ethiopia, March 14-28, 2018.

Clinical scenarios	Antibiotics	Frequency (%)
Acute diarrhea (N=16)	Metronidazole	8 (50.0%)
	Rifampicin	4(25.0%)
	Tinidazole	2(12.5%)
	Ciprofloxacin + Tinidazole + Metronidazole	2(12.5%)
Sore throat (N=14)	Amoxicillin	10(71.4%)
	Azithromycin	3(21.4%)
	Amoxicillin + Azithromycin	1(7.2%)

TABLE 3: Pharmacy professional counseling and explanation to simulated clinical scenarios at drug stores found in Mizan-Aman town, Southwest Ethiopia, March 14-28, 2018.

Pharmacy professional Statements	Number (%) of drug stores providing antibiotics		
	Clinical case presented		
	Sore throat (n= 14)	UTI (n=17)	Acute diarrhea (n=16)
Only explained how to take the	9(64.3%)	15(88.2%)	5(31.2%)
Explained both how to take the antibiotics	1(7.1%)	-	4(25%)
Explained only instruction on side effects antibiotics and duration of treatment	1(7.1%)	1(5.9%)	1(6.2%)
Providing no counseling regarding of dispensed antibiotic(s)	3(21.4%)	1(5.9%)	3(18.7%)
Other(s)* dispensed antibiotics	-	-	3(18.7%)

\*Explained how to take the antibiotics as well as duration and side effects and explained how to take the antibiotics and side effects.

Only one (5.56%) pharmacy professional asked the female simulator about her pregnancy status when she was simulated for UTI clinical scenario.

From all drug stores in which the clinical scenarios were presented, eight (44.4%) for acute diarrhea, six (33.3%), and four (22.2%) were not asked for any additional inquiry about presented clinical scenarios (Table 4).

1.1. *Antibiotic Dispensing Refusal.* Out of 18 drug stores, merely a single drug store refused to dispense antibiotics for entirely three simulated clinical scenarios. Regarding each clinical scenario, the majority (22.2%) of this repudiation response came from sore throat cases. Accordingly, two (11.1%) of them were rationalized as their concern related to health issues and antibiotic resistance, whereas one pharmacy professional (5.6%) cited purely administrative reasons for not selling the drug in referring to the prohibition of selling an antibiotic without an official prescription signed by a physician. Also, the remaining one druggist (5.6%) refused to sell antibiotics due to fear of misdiagnosis.

Only one dispenser (5.6%) for UTI scenario and two professionals (11.1%) for acute diarrhea case refused to dispense antibiotics without prescription due to fear of misdiagnosis. In all drug stores in which they refused to dispense antibiotics, they recommended simulator to visit the physician.

**2. Discussion**

Our study revealed over the counter sale of antibiotics at drug stores found in Mizan-Aman town with neither a prescription nor a diagnosis from a physician. The investigators simulated for UTI, sore throat, and acute diarrhea to obtain antibiotics by using various levels of demand. This cross-sectional simulated client visit study has shown that almost all (94.4%) of drug stores sold antibiotics without a prescription. This finding is similar to the study done in Pune, India, by S.d. salunkhe *et al.*, in which over the counter sale of antibiotics was 94.56% [15]. Besides, our finding is also comparable with the finding of the study done in Addis Ababa, Ethiopia, by Daniel Asfaw *et al.*, which reported a very high rate of dispensing of prescription-only medicines without a prescription [16].

On the other hand, our result is too higher than the finding of Lebanese study, which revealed that 32% of drug retail outlets sold antibiotics without a medical prescription [17]. This discrepancy might be due to differences in study design, since their study design was descriptive, cross-sectional, in which they simply assess pharmacists’ attitudes and knowledge about over the counter sale of antibiotics. In contrary, we assessed the actual practical aspect of professionals because we conducted a cross-sectional simulated client visit study. Furthermore, variation in sample size and study participants might also be the possible reasons.

TABLE 4: Pharmacy professionals’ additional inquiry about simulated clinical scenario at drug stores found in Mizan-Aman town, Southwest Ethiopia, March 14-28, 2018.

Pharmacy professional inquiry	Simulated clinical scenarios		
	Sore throat	UTI	Acute diarrhea
Only asked for further symptoms	11(61.1%)	8(44.4%)	8(44.4%)
Asked about prior drug allergy	0(0%)	0(0%)	0(0%)
Asked only concomitant use of another drug	0(0%)	0(0%)	0(0%)
ASKED pregnancy status of the female simulator for UTI	-	1(5.56%)	-
Other*	1(5.56%)	1(5.56)	2(11.1%)
No additional inquiry	6 (33.3%)	8 (44.4%)	8(44.4%)

\* Asked further symptoms and about environmental sanitation, further symptoms, and dose.

According to present study, regarding each clinical scenario, the percentage of drug stores dispensing antibiotics without a prescription for the urinary tract infection scenario was 94.4%, followed by acute diarrhea (88.9%), and 77.8% was for sore throat scenario. This study is comparable with the study done in Jordan by Ammar Almaaytah *et al.*, which showed the percentage of pharmacies dispensing antibiotics without a prescription for the sore throat scenario to be 97.6%, followed by urinary tract infection (83.3%) and diarrhea (83%) [18]. In addition, the finding of study done in Riyadh also shows equivalent results, in which simulated cases of sore throat and diarrhea resulted in an antibiotic being dispensed in 90% of encounters and 75% for UTI [19]. On the other hand, our finding is not in line with study piloted in Catalonia, Spain, in which antibiotics were obtained from 79.7% of pharmacies when a urinary tract infection was simulated and from 34.8% of pharmacies when a sore throat was simulated [20]. This inconsistency might be attributed to variation in study setting and disparities in healthcare systems affecting access to healthcare.

The results of our study clearly demonstrated that antibiotics could be easily acquired and sold without the need to supply a medical prescription to the pharmacy professional. From the clinical scenarios simulated in this study, sore throat is mainly caused by viral cause rather than bacterial pathogen, which did not require antibiotic utilization. Moreover, since acute watery diarrhea is self-limited, antibiotics should not have been prescribed without stool tests to identify the likely pathogen. Therefore, using antibiotics for nonbacterial or viral pathogen will expedite antibiotic-resistance, which is the major potential sequelae associated with this practice. As a result, antibiotic-resistance in turn leads to an extra cost burden to the patient owing to the need for broader-spectrum antibiotics, additional prescriptions, and hospitalizations for antibiotic failures. Dispensing of antibiotics for nonbacterial diseases that actually do not require antibiotics could be terrible [21]. Our study had shown that Fluoroquinolones were the most commonly dispensed antibiotics for presumed UTI in a child-bearing-age woman without verifying the pregnancy status. Consequently, they could subject the fetus to hazardous congenital abnormalities, since quinolones are contraindicated in pregnancy.

In our finding, antibiotics were dispensed without a prescription with three different levels of demand. Most (87.2%) of antibiotics were dispensed without a prescription when the simulator asked for any medication to alleviate his/her symptoms (first level of demands). Only one drug store refused to dispense antibiotics without a prescription with all three level of demands. This finding is almost similar to the study done in Riyadh, Saudi Arabia, which reported that 90% were dispensed with first level demands and only one drug store denied dispensing with all three-level requests [19]. On the contrary, the study done in Jordan reported that 59.2% of antibiotics were obtained by first level of demands [18]. This disparity might be due to difference in study setup and sample size.

Obtaining antibiotics without a prescription will not only promote antimicrobials resistance but can also be associated with significant adverse events including drug adverse effects, high cost, and complications. According to our study, none of the pharmacy professionals asked about prior history of drug allergy and concomitant drug use.

### 3. Limitation of the Study

Sample size considered was small. Additionally, since three levels of demand were used consecutively until an antibiotic was bestowed, the simulators claimed obtaining an antibiotic when the pharmacy professional denied so as to show the effect of perseverance on obtaining an antibiotic when it is not clearly required. We were aware of the fact that this technique could have augmented the number of offers of antibiotics by the dispensers.

### 4. Conclusion

The results of this study demonstrate that nonprescription sales of antibiotics were highly pronounced in contrary to national guidelines regarding this practice. Commonly dispensed antibiotics were Amoxicillin, Metronidazole, and Ciprofloxacin to treat complaints of sore throat, acute diarrhea, and UTI, respectively. Most of antibiotics were dispensed without a prescription when the simulator asked for any medication to alleviate his/her symptoms.

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