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Research Article

# Dispensing of Antibiotics Without Prescription in Southern Benin, West Africa, 2018

**Areine Gracidie AGBO, Assad BIO-SYA, Géraud PADONOU, Bawa BOYA and Aurel Constant ALLABI***

*Faculty of Health Sciences, Laboratory of Pharmacology and Toxicology, University of Abomey-Calavi and Teaching Hospital of Abomey-Calavi/ Sô-Ava*

***Corresponding Author:** Aurel Constant ALLABI, Faculty of Health Sciences, Laboratory of Pharmacology and Toxicology, University of Abomey-Calavi and Teaching Hospital of Abomey-Calavi/ Sô-Ava.

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## Abstract

The over-the-counter sale of antibiotics is recognized as a basis for antibiotic abuse and thus represents a global threat. This study aimed to determine the frequency of dispensing of certain antibiotics without prescription in the city of Cotonou. This was a cross-sectional study with descriptive and analytical aims. Data were collected in randomly selected pharmacies in Cotonou. A pseudo client visited some pharmacies to request the delivery of certain antibiotics and clinical scenarios were simulated to assess the attitudes and practices of professionals. Investigative staff visited 55 pharmacies and requested either amoxicillin/clavulanic acid, ciprofloxacin, gentamycin or ceftriaxone without providing a prescription or any other justification for the request. The frequencies of antibiotics dispensed without prescription during the visit of the pseudo-client were Amoxicillin-clavulanic acid cp (100%), Gentamycin 80 mg inj (60%), Ciprofloxacin 500 mg cp (72, 73%), and Ceftriaxone 1 g inj (58,18%). In the diarrhea scenario, only 4% of the pharmacies visited offered oral rehydration. For the bronchopulmonary clinical case, the most proposed antibiotics were: Amoxicillin-clavulanic acid (50%), Amoxicillin (28.57%) and Azithromycin (21.43%). The dispensing of antibiotics without prescription in pharmacies is high. There is an urgent need for regulatory measures and public awareness to limit this practice.

***Keywords:*** *Antimicrobial Use; Antimicrobial Resistance; Non-Prescription Dispensing; Pharmacy Practice; Benin; West Africa*

## Introduction

The development of antimicrobial resistance, which is partially attributable to the overuse and/or misuse of antibiotics in health care, is one of the world's greatest public health concerns [1]. Total global antibiotic consumption has increased by 65% in just 15 years (2000 - 2015), and is also expected to be much higher by 2030 [2]. This increase is mainly due to growing consumption in low- and middle-income countries [2,3]. As a result of economic growth and improved access to pharmaceuticals, the rate of antibiotic consumption in many low- and middle-income countries is now comparable or even higher than of high-income countries [2,4]. The increase in antibiotic consumption in sub-Saharan African countries is no different from that of other low- and middle-income countries, and may even be worse, since this region has one of the highest infectious disease burdens in the world [5]. This high consumption of non-prescription antibiotics has become a growing public health concern, as it has been strongly implicated in the development of antimicrobial resistance [6,7].

Despite prohibitive regulation, there is ample evidence that antibiotics are commonly dispensed without prescription and/or appropriate counseling in many low- and middle-income countries [8]. Over-the-counter medications containing antibiotics can delay hospital admission, mask the diagnosis of infectious diseases, and facilitate the development and spread of resistant pathogens. The willingness of providers to make antibiotics available without prescription is itself one of the factors that drive over-the-counter medication [9]. Indeed, their use follows clinical, bacteriological, pharmacological, and economic criteria. Knowledge of these criteria is essential for judicious prescription of antibiotics. In Benin, doctors are authorized to prescribe antibiotics, and they are insured by a state-registered nurse within the limits of his/her competence [10].

More specifically, over-the-counter sales in pharmacies also need to be reformed in order to limit abuse and inappropriate self-medication, thus reducing the causes of resistance. The client and pharmacy professionals (assistants, pharmacy students, and pharmacists) are the main actors in this practice. Socioeconomic and environmental factors, as well as characteristics related to both customers and pharmacy professionals, will determine the level of this practice. However, there is a lack of data on the level of this practice of dispensing antibiotics without a prescription in West Africa and in particular in pharmacies operating in Benin in order to propose appropriate solutions. It is of paramount importance to know the antibiotics involved in this practice.

The objective of this study was to quantify the extent of non- prescription dispensing of antibiotics in southern Benin by determining, for example, the frequencies per antibiotic. In addition, we assessed the attitudes and practices of this dispensation in the face of two common clinical situations in our context to better identify on which pillar to tackle and what to do efficiently.

## Study methods

### Type of study

This is a cross-sectional study with descriptive and analytical purposes. The ongoing study took place from August 05, 2018, to December 09, 2018, in the pharmacy dispensaries of Cotonou.

### Sampling

A stratified random survey with proportional probability was carried out to select the pharmacies in each regional zone defined by the National Council of the Pharmacists Order. Indeed, on the pharmaceutical map, cities are split into zones and each zone is assigned a given number of pharmacies.

During the visit there was no way to differentiate pharmacy employees from pharmacist, and the voluntary agents did not attempt to do this as it might have compromised the aim of the study. Investigative agents purchased the antibiotic and the number of pharmacies that dispensed the antibiotics was recorded. In addition, the ground of sale refusal of the requested drugs and any comments made by the pharmacist/pharmacy employees were recorded. Investigative staff visited 55 pharmacies and requested either amoxicillin-clavulanic acid 500/62.5 mg cp or gentamycin 80 mg inj or ceftriaxone 1 g inj or ciprofloxacin 500mg cp without providing any prescription or any other justification for the request. These antibiotics were chosen considering the rate of bacterial resistance against these different antibiotics evaluated between 2016 - 2017 in Benin [11].

For the clinical scenarios, we used the algorithms prepared for this purpose for each of the two cases. We appropriated them before simulating them in the pharmacy. The questions that could be asked by the providers and the answers given by the actor interviewers are presented in the Appendix. The first simulated clinical case involved a 4-year-old child who had been experiencing diarrhea for two days. The bronchopulmonary clinical case involved a 4-year-old child who had been suffering from a cough, cold and fever for 4 days.

## Ethical Considerations

The confidentiality of the information collected and the anonymity on the identity of the different pharmacies and agents surveyed were respected.

### Data processing and analysis

Descriptive statistical analyses of the results were performed. The frequency of dispensing each antibiotic without a prescription was calculated by counting the number of pharmacies that suggested it. The total number of pharmacies visited for non-prescription antibiotics requests was 55. The number of pharmacies visited for the simulation of the two clinical cases was 25. The relative frequencies were calculated by considering 55 or 25 as the denominator, depending on the case.

## Results

### Dispensing of certain antibiotics without a prescription

The dispensation of antibiotics without prescription was delivered at 100% for amoxicillin + clavulanic acid 500/62.5 mg cp. Some pharmacies had not delivered certain antibiotics. The antibiotics concerned by this refusal were ciprofloxacin 500 mg cp (26.79%), gentamycin 80 mg inj (39.29%) and ceftriaxone 1g inj (41.07%) (Figure 1). The reasons for non-dispensing were rarely the absence of a prescription. These reasons for non-dispensing were listed in table 1 below. Only one pharmacy out of 55 visited had required a doctor's prescription before dispensing antibiotics and this was for gentamycin inj and ceftriaxone inj.

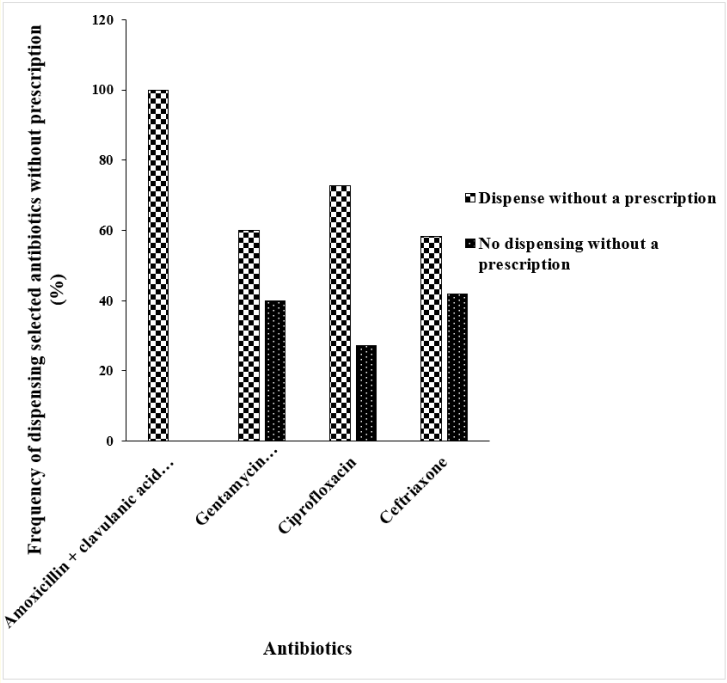


***Figure 1:*** *Proportion of pharmacies that dispensed the antibiotic without a prescription.*

| Reasons for Not Dispensing Antibiotics | Gentamycin | Ciprofloxacin | Ceftriaxone |
|---|---|---|---|
| Breaking | 68.18% | 93.33% | 86.95% |
| Out of stock | 27. 27% | 6.67% | 8.70% |
| No prescription | 4 .54% | - | 4.35% |

***Table 1:*** *Reasons for not dispensing antibiotics.*

NB: The antibiotic is "out of stock" means that the product is not available at the pharmacy or at the wholesalers. On the other hand, "out of stock" means that the product is finished in the pharmacy visited.

## Clinical case simulation on diarrhea

For this simulation 25 pharmacies were visited. For proper management, the following questions should have been asked: How many stools per day? Fever? Stomach ache? Is the child eating? drinking? Lost appetite? Stool color? Presence of blood or mucus? Only 36% of the pharmacies visited had asked all the questions listed on our survey form. Table 2 below summarizes the questions asked by providers in this scenario and their relative and absolute frequencies.

| Questions asked | Relative frequency (n=absolute frequency) |
|---|---|
| How many bowel movements per day? | 60% (15) |
| Fever? | 32% (8) |
| Stomach ache? | 16% (4) |
| Is the child eating ? drinking ? has he lost his appetite ? | 12% (3) |
| Stool color? | 16 % (4) |
| Presence of blood and/or mucus? | 28% (7) |
| What medicines have you given him? | 20% (5) |
| Have you been to see the doctor? | 4% (1) |
| Have you been to see the doctor? | 4% (1) |

***Table 2:*** *Questions asked by respondents about the clinical case of diarrhea and their frequencies.*

Figure 2 shows the proportions of different antibiotics advised during this scenario.

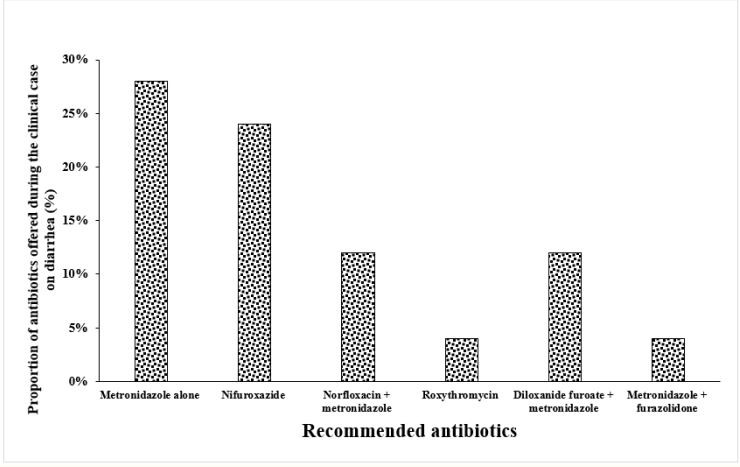


***Figure 2:*** *Frequency of antibiotic recommendations by providers during the clinical case on diarrhea.*

During the scenario, 84% of the treatment profile proposed by providers was antibiotic therapy. The Figure 2 below summarizes the medications suggested by the providers. Metronidazole was the most commonly proposed antibiotic (28%) by providers. In monotherapy or in combination (Metronidazole + Norfloxacine, Metronidazole + Diloxanide furoate, Metronidazole + Furazolidone), metronidazole was offered in 56% of cases. Nifuroxazide was proposed in 24% of cases and metronidazole + norfloxacin in 12% of cases (Figure 2). Oral rehydration was proposed in only 4% of cases.

### Bronchopulmonary disease clinical case simulation

For this simulation 25 pharmacies were also visited. The questions asked by providers and their frequency are provided in the table 3.

| Questions Asked | Relative Frequency (Absolute Frequency) |
|---|---|
| Since when? | 84% (21) |
| High temperature? | 48% (12) |
| Headache? | 40% (10) |
| Symptoms? | 28% (12) |
| Since when has he been dewormed? | 12% (3) |
| Type of cough? | 4% (1) |

***Table 3:*** *Questions asked by the providers on the bronchopulmonary scenario and their frequency.*

Table 4 shows the proportions of the therapeutic profiles proposed during the bronchopulmonary scenario. Of the 25 pharmacies visited, antibiotic therapy was suggested in 56% of cases. We were referred to the hospital only in 8% of the cases. The table below provides information on the proportions of the treatment profile proposed by the providers.

During the bronchopulmonary scenario, the combination of amoxicillin + clavulanic acid was the most advised with a rate of 50% followed by amoxicilin (28.57%) and azithromycin (21.43%).

| Therapeutic Profile | Relative Frequency (Absolute Frequency) |
|---|---|
| Symptomatic treatment | 36% (9) |
| Symptomatic treatment + antibiotic therapy | 52% (13) |
| Antibiotic therapy only | 4% (1) |
| Referred to hospital | 8% (2) |

***Table 4:*** *Frequencies of therapeutic profiles proposed during the bronchopulmonary scenario.*

During the bronchopulmonary scenario, the combination of amoxicillin + clavulanic acid was the most advised with a rate of 50% followed by amoxicilin (28.57%) and azithromycin (21.43%).

## Discussion

Our study unveiled that antibiotics were sold over-the-counter in pharmacies in the southern part of Benin without any prescription or diagnosis by a physician. Investigators simulated obtaining antibiotics for bronchopulmonary infection and acute diarrhea using different levels of demand. This cross-sectional pseudo-client simulation study showed that 100% of pharmacies sold amoxicillin + clavulanic acid without any prescription. This result is superior to the study conducted in Pune, India, by Salunkhe., *et al,* [12] in which the over-the-counter sale of antibiotics was 94.56%. Moreover, our result is also comparable to the study conducted in Addis Ababa, Ethiopia by Erku.,

*et al*, [13] which reported a very high rate of over-the-counter sale of medicines. On the other hand, our result is too high compared to the Lebanese study, which found that 32% of drug outlets sold antibiotics without any prior prescription [14]. Belachew., *et al,* [1] found that the overall pooled proportion of non-prescription antibiotic requests or consultations that resulted in the provision of non-prescription antibiotics was 69%. This discrepancy could be due to differences in the study design, as their design was descriptive, cross-sectional, in which they simply assessed pharmacists' attitudes and knowledge regarding over-the-counter antibiotic sales. On the contrary, we assessed the current practicality of the professionals because we conducted a cross-sectional customer visit simulation study.

More than half of gentamycin 80 mg injection (60%) were sold in pharmacies and 68.18% were out of stock indicating that the current dispensing rate of gentamycin inj is much higher than the 60%. Ceftriaxone 1 g inj was dispensed by 58.18% of pharmacies. Only one pharmacy did not comply with dispensing antibiotics for lack of prescription for injectable. Ciprofloxacin 500 mg cp was dispensed without prescription by 72.73% of pharmacies. These results indicate the facility of our pharmacy system in dispensing antibiotics, including injectable, without a prescription. This easiness of dispensing without any prescription is due to regulatory weaknesses or a lack of supervision and control of the above-mentioned activity. The consequences of this practice are multiple.

Our results regarding the delivery of ciprofloxacin cp are quite similar to those obtained by Zawahir., *et al,* [15]. In the latter survey, ciprofloxacin cp was served in 70% of pharmacies. A lower rate of 53% dispensing without prescription for ciprofloxacin was obtained in 2007 in Greece by Plachouras., *et al* [16]. This low rate is thought to be related to a restriction on the use of fluoroquinolones in Greece, requiring them to be served only on prescription with justification from the prescriber.

The rate of dispensing amoxicillin + clavulanic acid without any prescription is 100% in both studies (Benin and Greece) [16]. A lower rate of 52% was found in Sri Lanka by Zawahir et al, [15] for amoxicillin alone. In this last case, the presence of the pharmacist at the counter helped to mitigate dispensing.

As regards the pharmaco-therapeutic analysis of the treatment proposed for bronchopulmonary clinical cases, a symptomatic treatment was proposed in 36% of the cases and a symptomatic treatment + an antibiotic therapy in 52% of the cases. Only 8% of the cases were referred to hospital. In the majority of cases (80%), the management of cough was not done according to the evidence: based of medicine. These signicant gaps between what expectations and findings for therapeutic conseling in this case highlight the gap that need to be bridged in agent training.. The treatment of colds depends on whether the nose is runny or blocked. In both cases the treatment is not the same. Rhinitis is viral in the majority of cases. Purulent rhinitis due to streptococcus A or pneumococcus may also occur. It could be due to an allergy and in this case systematic antibiotic therapy would not be justified [17].

The most suggested antibiotic to surveyors during this scenario was the combination of amoxicillin + clavulanic acid 50% followed by amoxicillin (28.57%). Azithromycin was moderately recommended at 21.43%.

Our results are opposite to those obtained by Shet., *et al,* [19] in a study conducted in India. The antibiotics obtained in the bronchopulmonary disease scenario were amoxicillin (51.2%), azithromycin (12.2%) and ciprofloxacin (12.2%). The results obtained in China are also against ours. In their study, antibiotics were suggested in 77.7% of bronchopulmonary scenario cases [20].

For the clinical case on diarrhea, the treatment profile proposed by the dispensers was 84% antibiotic therapy. This result is similar to that of the study conducted in Jordan by Almaaytah., *et al*, [21] which showed that the percentage of pharmacies dispensing antibiotics without any prescription for diarrhea (83%). In addition, the results of a study in Riyadh are lower, where simulated cases of diarrhea resulted in the dispensing of an antibiotic in 90% of cases [22]. In contrast, our results are higher than those of a study in Catalonia, Spain, in which antibiotics were obtained in 79.7% of pharmacies [23]. This discrepancy could be attributed to variation in the study setting and health system disparities affecting access to care. Metronidazole was the most commonly offered antibiotic (28%) by providers, followed

by nifuroxazid (24%). Moderate combinations were metronidazole + norfloxacin (12%), diloxanide furoate + metronidazole (12%). The least proposed (4%) for treatment were the combination of metronidazole + furazolidone and roxythromycin. Thus in combination or standalone metronidazole was proposed in 56% of cases. The causes of diarrhea incude gastroenteritis, allergy to antibiotics or food poisoning. In general, the WHO suggests using rehydration as treatment for acute diarrhea, taking into account the age of the child [17]. We came up with only one pharmacy offered oral rehydration among the twenty five visited. Our results are similar to those obtained by Shet. *et al,* [19]. The combination of metronidazole+ norfloxacin was the most recommended (41.3%) followed by metronidazole (15.2%). These results are not far from those obtained by Chang J. *et al* in China in 2017, where antibiotics were proposed in 55.9% of cases [20].

Our results clearly demonstrated that antibiotics could be easily acquired without the need to provide a medical prescription to pharmacy professional.. In general, no bacteriological examination is performed during this process. The use of antibiotics for viral infections will fast-track microbial resistance to antibiotics, the main consequence associated to this practice. This practice induces financial burdens on the patient and the community. These additional costs are due to the use of more specific and expensive antibiotics, additional care and prescriptions, and hospitalizations or prolonged hospital stays due to the ineffectiveness of antibiotics. Dispensing antibiotics for non-bacterial diseases that do not require antibiotics could be nefarious for the patients [24].

This study highlights the need to ensure compliance with regulations to prevent deviant behaviour related to the dispensing of antibiotics without any prescription in pharmacies. Interventions such as public education, continuing education of pharmacy professionals, and strict enforcement of existing regulations, especially regarding antibiotic dispensing, and periodic monitoring of antibiotic dispensing should be implemented. It is the responsibility of national drug regulatory authorities to ensure that strategies are implemented at the national level to prevent or mitigate microbial resistance. Eliminating the dispensing of antibiotics without any prescription could be a very useful measure to limit unnecessary overuse of antibiotics and thus limit microbial resistance. Following these and other data, more restrictive regulatory measures for the dispensing of antibiotics have been effectively implemented at the national level.. The data from this study will serve as a baseline for evaluating the impact of the regulatory measures put in place since 2019.

## Conclusion

We have been able to evaluate the practice in real situation thanks to a pseudo-client requesting the dispensing of some antibiotics without any prescription and the simulation of the two clinical cases. These findings pinpoint the issue of inappropriate dispensation of antibiotics in pharmacies. Overall, antimicrobials dispensation without any prescription is a widespread practice in the study area and contributes to antibiotic overuse. To mitigate this practice, it will be pivotal to implement a continued education program on antibiotic therapy for both auxiliaries and pharmacists irrespective of their level of responsibility. Outreach campaign is needed on self-medication and antibiotic therapy in particular.

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## Conflict of Interest

The authors declare there is no competing interest about the publication of this manuscript.

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