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Current pattern of antibiotic use in community pharmacies in Lagos state Nigeria

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Abstract
Background: Antibiotic resistance has become a global pandemic. The rapid emergence of resistant bacteria worldwide endangers the efficacy of antibiotics. The antibiotic crisis has been attributed to the misuse of medications among other factors.
Objectives: The objective of the study was to document the current pattern of antibiotic use in community pharmacies in Lagos state.
Methods: An observational cross-sectional prospective study was employed using a detailed indicator encounter form in 20 community pharmacies in Lagos state.
Main outcome measure: Percentage antibiotic encounters, name, dosage, quantity and cost of antibiotics dispensed, percentage of antibiotics dispensed per prescription source and health problems encountered.
Results: A total of 1980 patient encounters were observed giving rise to 600 antibiotic drug items dispensed. Percentage antibiotic encounter was 27.5%. The class of antibiotics with the highest frequency were the penicillins at 35%. The antibiotic most frequently used was amoxicillin+clavulanic acid at 12.2%. Tablets and capsules were the highest dosage form dispensed. Of the antibiotics dispensed, 26% were on the strength of a doctor's prescription, 59% of the antibiotics were dispensed as brands and 82% were purchased as full courses. Typhoid fever was the most frequent health problem encountered. Significant association was found between prescription source and dose dispensed, prescription source and dispensing of brands or generic, prescription source and cost of antibiotics and between prescription source and class of antibiotics.
Conclusion: Antibiotic use in community pharmacies in Lagos State does not follow the available legislation on prescription only medicine in Nigeria and needs to be attended to by the appropriate regulatory and professional bodies.

Keywords: Prescription pattern, antibiotics, community pharmacies, percentage antibiotic encounter

1. Introduction
An antibiotic refers to any substance of natural, semi synthetic or synthetic origin that inhibits the growth and replication of a bacterium (bacteriostatic) or kills it out rightly (bacteriocidal) [1]. The discovery of antibiotics determined a new era in the treatment of infections and diseases and in the quality of life. However, the irrational use of antibiotics has resulted in the rise of multidrug resistance bacteria called superbugs [2]. Antibiotic resistance has become a global pandemic and a well-recognized public health threat in recent years. The rapid emergence of resistant bacteria is occurring worldwide endangering the efficacy of antibiotics. The antibiotic crisis has been attributed to the overuse and misuse of these medications among other factors [3]. The overall volume of antibiotic used in the public is one of the foremost causes of antimicrobial resistance [4].
Despite WHO efforts in halting the overuse of antimicrobials, antibiotics are considered one of the most common medicines purchased by people globally [5]. The issue is of more concern in developing countries or places where antibiotics can be dispensed or purchased with or without prescription from many different quarters as it is the case in Nigeria. Prescription only medicines (POMs) including antibiotics are sold without demand for prescription in pharmacies and patent and proprietary medicines vendor outlets and even by drug hawkers [6]. By law in Nigeria, POMs which include antibiotics are not to be sold over the counter [7]. Only pharmacies are licensed to dispense POMs against a valid prescription [8].
Self-medication with POMs is an important driver of irrational use of medicines which is highly prevalent in Nigeria [9]. High accessibility of community pharmacies gives it strategic advantage to promote responsible self-medication and rational use of medicines [9].

Community pharmacies are considered as the most accessible healthcare facilities providing the community with easy access to their medication and advice about health. Patients access health services in pharmacies without paying consultation fee or booking in advance [10].

Patients access counselling and consultation services freely and only part with their money when a product is purchased. The average Nigerian reasoning is that going to the physicians consulting room or clinic requires additional money to be spent on registration and consultation while at the pharmacy, access to the pharmacist is easier, faster and costs little or nothing [11].

There is not much data available regarding detailed information of behaviour on antibiotic use in Community Pharmacies. This is of particular significance in developing a suitable and sustainable intervention programme to promote rational use of antibiotics [4].

1.1 Aim of the study

The aim of the study was to document the current pattern of antibiotics use in community pharmacies in Lagos state.

2. Materials and Methods

2.1 Study site

The study was carried out in community pharmacies in Lagos State using the modified WHO detailed indicators encounter form [12]. The study sites were 20 community pharmacies in four of the 20 local government areas (LGAs) in Lagos State. The four local governments were chosen using convenience sampling to reflect both the cosmopolitan and residential nature of Lagos State.

The sites are

1. Ikeja Local Government Area
2. Amuwo Odofin Local Government Area
3. Ojo Local Government Area
4. Alimosho Local Government Area

2.2 Study population

The study population was the 1193 licensed community pharmacies in Lagos state as at 31st December 2018

2.3 Sample size

A sample size of 20 community pharmacies is in line with the WHO recommendation of the minimum number of health facilities to be involved in a basic cross-sectional study to measure drug use indicators in a representative group of facilities [11]. Five Pharmacies were selected from each LGA to make up the required number.

2.4 Sampling Method

The study involved sampling on two levels: Community pharmacies and patient encounters

Community pharmacies included in the study were selected using stratified random sampling. The Pharmacies in each local government areas were further classified into zones based on the local council development areas. Pharmacies were randomly selected from each zone based on the proportion of number of pharmacies available in each zone.

2.5 Sample size calculation

For the patient encounters, the sample size, N was calculated using Fisher's formula

$$N = \frac{Z^2PQ}{D^2}$$

Where Z= a constant which is 1.96 at 95% confidence interval

Estimated percentage antibiotic encounter for Nigeria = 48% [13].

Q=100-P, D= absolute precision, or sampling error tolerated =5%

A minimum sample of 383.54 was obtained.

A sample size of 384 antibiotic encounters is necessary to study pattern of antibiotic use in the 20 community pharmacies involved in the study.

The inclusion criteria were evidence of registration by Pharmacists Council of Nigeria and retail pharmacy practice while exclusion criterion was wholesale pharmacy practice.

2.6 Data collection

The data collection tool used was the detailed indicator encounter form. This form was adapted from the WHO standardized detailed indicator encounter form recommended for use in the WHO manual on "How to investigate drug use in health facilities" [12]. The detailed indicator form was validated by conducting a pilot study using it in a community pharmacy not included in the study for 2 days. The indicator form was adjusted as required after the pilot study. Drug encounters for patients less than 12 years old were recorded as for children. Health problem for which antibiotics was prescribed was determined through interaction with patient. The detailed indicator encounter forms were filled in each pharmacy over a period of one week until 30 antibiotics were dispensed. All drug encounters were recorded and antibiotics included numbered until 30 antibiotics have been dispensed. The forms were filled by the Superintendent Pharmacist or the staff on ground after appropriate training. The entire data collection for the 20 pharmacies took place over a period of 2 months (August-September 2019).

2.7 Ethical approval

This observational cross-sectional prospective study was approved by Lagos University Teaching Hospital Health Research Ethics Committee with Approval number No. ADM/DCST/HREC/APP/2867).

2.8 Consent to participate

Informed consent was obtained from all participants involved in the study.

2.9 Statistical analysis

Total numbers of patient encounters until 30 antibiotics were dispensed was computed. Percentage antibiotic encounter for the 20 pharmacies enlisted in the study was computed. Percentage encounter with an antibiotic (PEA) is the total number of patients who received one or more antibiotics divided by the total number of encounters with patients for which data were collected in a given period multiplied by 100. Brand names, generic names and strength of antibiotics dispensed were computed. Prescription source of the antibiotic dispensed were listed. Dosage forms of the antibiotic dispensed were computed. All drugs recorded by their brand names were regarded as dispensed as brand while those recorded with their chemical names were regarded as dispensed as generic. Purchase of full doses of antibiotics or less was computed from quantity of antibiotic dispensed. Cost of antibiotics purchased was computed. Data were collated into excel tables and chi square analysis was carried out using SPSS analysis tool. A *p-value* of ≤ 0.05 was regarded as significant.

3. Results

3.1 Analysis of encounter forms and demographics of patients who received antibiotics

A total of 4252 drugs were dispensed during the period of the study to 1980 patients out of which 600 were antibiotics. The total number of antibiotic encounters was 544. This resulted in a recovery rate of 141.67%

Average percentage antibiotic use was 14.11% while Percentage Antibiotic Encounter was 27.47% (Table 1). The numbers of male patients who received antibiotics were 310 (57%) while the numbers of females were 234 (43%). The number of adults (12 years and above) encountered were 442(81.3%) while number of children were 102(18.7%).

Table 1: Analysis of encounter forms: Distribution by location

Location of Pharmacy	Number of antibiotics dispensed	Number of patient encountered during period of study(patient encounters)	Number of patients who received antibiotics (antibiotic encounters)	Number of all drug items dispensed during period of study	*% Antibiotic use	% Antibiotic encounter
Alimosho	30	62	26	204	14.71	41.94
Alimosho	30	68	25	223	13.50	36.76
Alimosho	30	68	28	221	13.57	41.18
Alimosho	30	62	30	156	19.20	48.39
Alimosho	30	76	28	110	27.27	37.33
Ojo	30	84	28	117	16.95	33.33
Ojo	30	76	28	188	15.95	36.84
Ojo	30	76	29	250	12.00	39.46
Ojo	30	60	22	147	20.41	36.6
Ojo	30	72	21	285	10.52	29.16
Ikeja	30	120	29	266	11.28	24.16
Ikeja	30	40	29	120	25.00	72.5
Ikeja	30	96	27	140	21.43	28.13
Ikeja	30	90	30	160	18.75	33.33
Ikeja	30	168	28	306	9.80	16.6
Amuwo	30	183	24	304	9.87	13.1
Amuwo	30	208	30	338	8.86	14.42
Amuwo	30	136	27	234	12.82	19.85
Amuwo	30	112	28	204	14.70	25.0
Amuwo	30	123	27	219	13.70	21.95
Total	600	1980	544	4252		

$$\text{Percentage antibiotic use} = \frac{\text{Number of antibiotics}}{\text{Number of all drugs dispensed}} \text{ X } 100$$

$$\text{Average Percentage antibiotic use} = \frac{\text{Number of antibiotics}}{\text{Number of all drugs dispensed}} \text{X } 100 = \frac{600}{4252} \text{X} 100 = 14.11\%$$

$$\text{Percentage antibiotic encounter} = \frac{\text{Total number of patients who received antibiotics}}{\text{Total number of patient encounters}} \text{X} 100$$

$$= \frac{544}{1980} \text{X } 100 = 27.47\%$$

There was a wide range of health problem for which antibiotics were prescribed. Typhoid fever was the health problem with the highest frequency of presentation on interaction with the patients at 7%. A total of 13 classes of antibiotics were dispensed. Amoxicillin +clavulanic acid had the highest frequency of 73(12.2%) out of the 600 antibiotics dispensed (Figure 1). The class of antibiotics dispensed most frequently were the Penicillins (35.1%) while the class of drugs with the highest type of drugs dispensed were the cephalosporins (Table 2).

Table 2: Classes and types of antibiotics dispensed

Class of Antibiotics	Types of drugs dispensed in that class	Percent of prescriptions in the class	Generic name of antibiotics	Frequency	%
Penicillins	7	35.1%	Amoxicillin	65	10.8
			Amoxicillin+clavulananic acid	73	12.2
			Ampicillin	8	1.3
			Ampicillin+cloxacillin	59	9.8
			Penicillin	3	0.5
			Procaine penicillin	2	0.3
			Flucloxacillin	1	0.2
Tetracyclines	2	2.5%	Tetracycline	6	1.0

			Doxycycline	9	1.5
Cephalosporins	9	12.1%	Cefixime	5	0.8
			Cefixime+clavulanic acid	4	0.7
			Cefpodoxime	6	1.0
			Cefpodoxime +clavulanic acid	4	0.7
			Ceftadizime	1	0.2
			Ceftriaxone	3	0.5
			Cefuroxime	43	7.2
			Cefuroxime +clavulanic acid	3	0.5
			Cephalexin	3	0.5
Quinolones	6	14.7%	Ciprofloxacin	66	11.0
			Ciprofloxacin +tinidazole	3	0.5
			Levofloxacin	7	1.2
			Moxifloxacin	2	0.3
			Ofloxacin	9	1.5
			Pefloxacin	1	0.2
Lincomycins	2	2.6%	Clindamycin	5	0.8
			Lincomycin	11	1.8
Macrolides	4	10.1%	Azithromycin	28	4.7
			Clarithromycin	10	1.7
			Clarithromycin+tinidazole	1	0.2
			Erythromycin	21	3.5
Sulphonamides	4	3.8%	Cotrimoxazole	17	2.8
			Phthayl sulfathiazole	3	0.5
			Sulfathiazole	1	0.2
			Silver sulphadiazine	2	0.3
Chloramphenicol	1	3.7%	Chloramphenicol	22	3.7
Aminoglycosides	5	2.4%	Gentamycin	7	1.0
			Gentamycin +clioquinol	1	0.2
			Neomycin	3	0.5
			Neomycin sulphate+polymycin B	3	0.5
			Tobramycin	1	0.2
Carbapenem	1	0.2%	Meropenem	1	0.2
Nitroimidazoles	3	11.4%	Metronidazole	54	9.0
			Secnidazole	10	1.7
			Tinidazole	4	0.7
Carboxylic acid	1	1.2%	Mupirocin	7	1.2
Nitrofuran	1	0.3%	Nitrofuratoin	2	0.3
Total	46	100		600	100

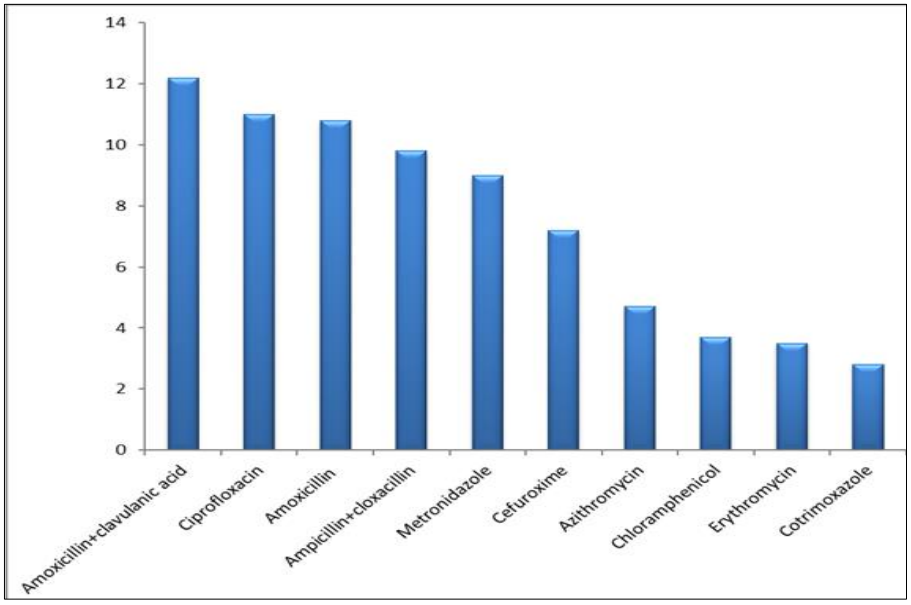

Fig 1: Distribution of top 10 antibiotics dispensed

Amoxicillin+clavulanic acid was the antibiotic with the highest frequency of use at 12.2%

4. Pattern of antibiotic dispensing in community pharmacies: Tablets and capsules were the highest dosage forms of antibiotics dispensed. Of the antibiotics, 26% were given out on prescription by a medical doctor, 40% on pharmacist's recommendation and 32.5% by self medication. Of the antibiotics used, 59% were dispensed as brands, 41% as generic forms and 82% were given out as full doses (Table 3). Ciprofloxacin, cefuroxime and azithromycin were dispensed as full doses each time they were used (Figure 2).

Table 3: Pattern of antibiotics dispensing in community pharmacies

Item	Variable	Frequency (n=600)	Percent (%)
Dosage form of antibiotics	Tablets	293	48.7
	Capsules	163	27.2
	Suspension	82	13.7
	Creams	18	3.0
	Eye drops	13	2.2
	Injections	12	2.0
	Ear drops	5	0.8
	Ointments	5	0.8
	Oral drops	4	0.7
	Infusions	2	0.3
	Nasal drops	1	0.2
	Pessaries	1	0.2
	Syrups	1	0.2
Prescription source	Doctors	156	26
	Pharmacist	240	40
	Nurse	9	1.5
	Self-medication	195	32.5
Distribution of antibiotics dispensed	Brands	354	59
	Generic	246	41
Dose of antibiotics dispensed	Full dose	492	82
	Less than full dose	108	18

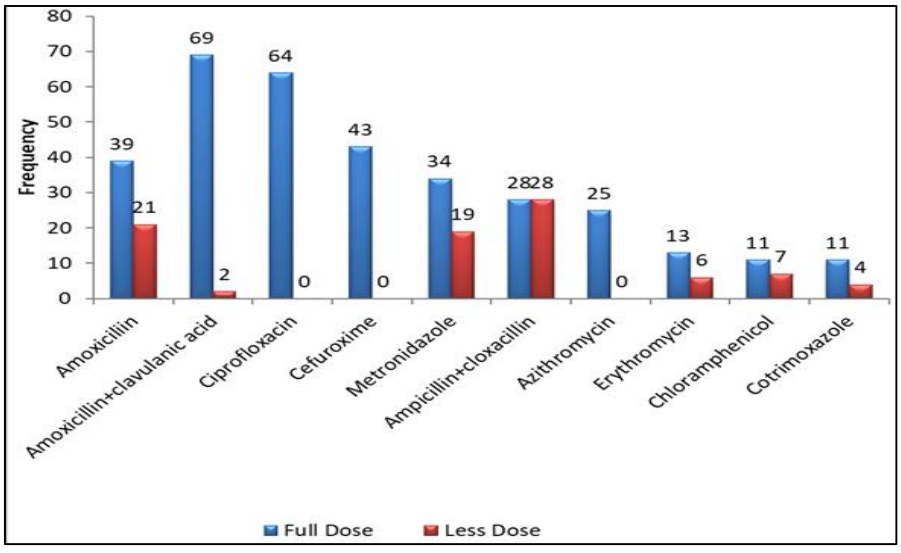

Fig 2: Distribution of antibiotics and dose dispensed

Ciprofloxacin, cefuroxime, azithromycin were all dispensed as full doses each time they were used.

Different brands of the same drug were found to come with different costs. Ampicillin + cloxacillin was the antibiotic with the highest frequency of use by those self-medicating, amoxicillin + clavulanic acid had the highest frequency by pharmacists' recommendation while cefuroxime had the highest frequency for those prescribed by physician.

5. Test of association between antibiotics used and different parameters in the study: There was a statistically significant association between the prescription source and if the antibiotic was dispensed as a generic or branded product (*p-value*=0.025), dose of antibiotic dispensed (*p-value* =0.001) and the cost of antibiotics used (*p-value* <0.00001) (Table4). In addition, a statistically significant association exists between class of antibiotics and age of the patient (*p-value* <0.0001), if it was dispensed as a full dose or less (*p*< 0.0001), if it was dispensed as generic or brand (*p-value* <,0.0001), prescription source (*p-value<0.0001)* and cost of

the antibiotic (*p-value* <0.00001) (Table 4).

Table 4: Test of association between different parameters in the study

Parameter 1	Parameter 2	Chi square X^2	df	P value
Prescription source	Distribution of antibiotics (Brand/generic)	9.2	3	0.025
Prescription source	Dose dispensed (full dose/less than full dose)	66.633	3	0.001
Prescription source	Cost of antibiotics	81.9	18	<0.00001
Prescription source	Class of antibiotics	83.0	30	<0.0001
Class of antibiotics	Cost of antibiotics	598.2	72	<0.00001
Class of antibiotics	Age of patient	40.9	12	<0.0001
Class of antibiotics	Dose dispensed(full dose /less than full)	93.5	24	<0.0001
Class of antibiotics	Distribution of antibiotics (Brand/generic)	96.7	12	<0.0001

6. Discussion

The Percentage Antibiotic Encounter (PEA) of 27.47% found for this study is much lower than the 48% PEA found in Nigeria in the study carried out among 12 developing countries in 1993 [13] though that study was conducted in hospitals and not community pharmacies. A drug use and antibiotics prescribing pattern at a General hospital in Nigeria in 2002 found that the percentage antibiotic encounter was 50.3% for outpatients [14].

The class of antibiotics with the highest frequency were the penicillins followed by the quinolones and the cephalosporins. This is in line with previous study on antibiotic dispensing in community pharmacies in Egypt where penicillins and quinolones were the two major classes of antibiotics most commonly dispensed on prescription while the two most commonly dispensed antibiotics on pharmacist recommendation were the cephalosporins and the quinolones [15]. Likewise, in a study carried out in India, the antibiotic classes with the highest percent of prescription in the private retail pharmacies were the cephalosporins, quinolones and penicillins respectively while amoxicillin+clavulanic acid was the highest dispensed penicillin [16]

In this study, only the extended spectrum penicillins were mainly used i.e. amoxicillin+clavulanic acid, amoxicillin and ampicillin+cloxacillin. Ampicillin and penicillin were of limited use at 1.3% and 0.5% respectively. The is at a variance with the study carried out by Babalola and Lamikanra in 2002 in Nigeria on the pattern of antibiotic purchase by customers patronizing 800 community pharmacies in five states in the south western Nigeria [17]. It found that the most frequently purchased antibiotics were the ones with the lowest cost e.g. tetracycline at 22%, ampicillin at 21%, cotrimoxazole at 18%. This suggests a change in the pattern of antibiotic use in community pharmacies based on perceived resistance to older and lower costing antibiotics [17]

In terms of dosage forms, tablets were the most frequently utilized form which is comparable to the percentage of tablets and capsules found by Babalola and Lamikanra in their study [17]. They found that 87% of the antibiotics dispensed were in the form of tablets or capsules

Of the antibiotics dispensed, only 26% were dispensed on the strength of a doctor's prescription, 40% were dispensed on pharmacist's recommendation while 32.5% were self-prescribed (Table 3). On comparing this with the study by Babalola and Lamikanra in Nigeria, it was found that fewer prescriptions get to the pharmacy than in 2002 when 40% of the antibiotics were bought on a doctor prescription, 29% recommended by the pharmacist and 31% were self-prescribed [17]. The fact that prescriptions do not flow to community pharmacies is an issue that needs to be addressed.

The percentage of self-medication with antibiotics found in this study (32.5%) is in line with that found by Babalola and Lamikanra in their study at 31% [17]. A study on prevalence of self-medication in Jos city, Nigeria in 2011 showed 22.3% prevalence of self-medication in the use of antibiotics one month before the survey while evaluation of the extent of non-prescription antibiotics use in Nsukka, Nigeria showed that 86% of respondents use non prescribed antibiotics for treatment or prevention or both [18,19]. There is an urgent need to discourage the practice of self-medication of antibiotics using a multifaceted approach.

In this study, 59% of antibiotics were dispensed as brands. Comparing this with the result of an assessment of prescribing practices in selected rural pharmacies in India, only 2.5% of the drugs were prescribed as generic name while earlier studies on drug use in Nigeria hospitals gave percentage generic prescribing as 58% [13].

Of the antibiotics used, 82% were dispensed as full doses while 18% were dispensed as less than full dose. This is a much higher percent of antibiotics dispensed as a full course compared to that found by Babalola and Lamikanra where only 15% of the customers purchased a full course of antibiotics [17].

Significant associations were found between prescription source and dispensing as brand or generic, dispensing of full dose or less, cost of antibiotics; and class of antibiotics (Table 4). This is similar to the result found in a study conducted in a community pharmacy in India where significant associations were found between prescriber and duration of antibiotics and prescriber and frequency of daily antibiotic use [20]. We found no study assessing association between class of antibiotics and cost, dose dispensed or dispensing as brands or generic

It was noticed that ciprofloxacin, cefuroxime and azithromycin were all usually sold out as full doses. The reason may be attributed to the mode of packaging of the antibiotics. When full doses are packaged as single sachets, patients tend to purchase full doses. This is in line with the study on common antibiotic packaging and guidelines for their use in Australia which found that mismatch between common antibiotic packaging and the guidelines recommended for their use contributes to a shortfall or excess of doses compared to recommended antibiotic treatment protocols thus implying that this mismatch is contributing to antibiotic resistance in the community [21].

In some countries, long established antibiotics with proven safety profile have been rescheduled as over the counter products as bacterial infections present acutely and patients may benefit from easier and quicker access to certain antibiotics. In some European Union countries such as Sweden, Norway, Hungary, Romania, Italy Spain and Belgium, antibiotics such as metronidazole, topical gentamycin, ciprofloxacin, azithromycin, chloramphenicol etc. and combination products such as bactracin+neomycin, oxytetracycline+polymycin combination have been

reclassified as over the counter product under certain conditions. A study in the European Union identified 20 countries where such classification exists [22]. Though no reclassification has been done in Nigeria, nonetheless antibiotics are widely available in a large variety of sources without prescription and without an authorized person selling them [6].

The Ministry of Health and Pharmacist Council of Nigeria needs to undertake a careful review of the pharmacy laws which regulate the practice of the profession in order to reclassify or provide a legal framework to support community pharmacists to have a minor ailments program where some common minor illnesses are treated in the pharmacy and antibiotics can be provided legally by the pharmacist. Measures must also be in place to ensure adequate monitoring of usage and antimicrobial resistance. Interventions that discourage irrational antibiotic use should be embarked upon by the Association of Community Pharmacists of Nigeria as embarked upon in other countries [23]. This could include campaigns for example targeting antibiotic stewardship, health education and continuing education programmes for pharmacists.

Some of the limitations encountered during the study were pharmacist's unwillingness to be involved in the study, poor documentation culture, unwillingness to disclose details of transaction such as cost, health problems not known by pharmacist and patient's unwillingness to disclose. The sample size was increased to overcome some limitations encountered in the study.

7. Conclusion

Pattern of antibiotic use in community pharmacies in Lagos State does not conform to the available legislation on prescription requirement for antibiotics thus confirming this fact with literature evidence. Appropriate steps to be taken by the regulatory bodies on both flow of prescriptions from clinics to community pharmacies as well as enforcement of this prescriptive requirement. However, the percentage antibiotic encounter found in this study was lower than that previously estimated for Nigeria. Appropriate antibiotic stewardship programmes should be mounted for community pharmacists to enable them contribute to curtailing the antimicrobial resistance that is a current global menace.

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10. Conflict of interest: None

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