

Original Research Article

Patent Medicine Vendors in Rural Areas of Lagos Nigeria: Compliance with Regulatory Guidelines and Implications for Malaria Control

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Abstract

Purpose: To determine the compliance of patent medicine vendors (PMVs) in rural areas of Lagos State, Nigeria with set guidelines to regulate their practice and its implications for malaria control.

Methods: A baseline cross-sectional study was conducted as part of an intervention study in two rural local government areas (LGAs) of Lagos State Nigeria. One hundred and eighty PMVs were randomly selected and interviewed using structured questionnaire. In addition, an observational checklist was used to monitor the drug shops for compliance with regulatory guidelines. Indicators of compliance used include proportion of PMVs with valid practicing license and proportion of shops with duly registered anti-malaria drugs.

Results: Most 148 (82.2 %) of the respondents were shop owners with 170 (94.4 %) aged ≥ 21 years (the minimum age required by law) and a mean of 30.9 ± 8 years (range 16 - 67years). Only two (1.1 %) PMVs had a valid annual practicing licence and only three (1.7 %) of the drug shops had specified signposts. The shops stocked various kinds of anti-malaria drugs including those that are no longer recommended. All the sampled drugs were duly registered with NAFDAC and within expiry dates.

Conclusion: There was poor compliance with regulatory guidelines. A strict enforcement of the guidelines by the regulatory agency is recommended to ensure that only licensed persons sell appropriate anti-malaria drugs.

Keywords: Patent medicine vendors, Compliance, Guidelines, Malaria, ACTs.

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INTRODUCTION

Patent Medicine Vendors (PMVs) are important informal community-based providers of health care [1-4]. Many countries, recognizing their role and contribution to ensuring equitable access by the population to essential drugs, permit them to sell certain over-the-counter (OTC) drugs, including anti-malaria drugs and other drugs for treatment of common ailments [5-7].

The activities of PMVs are usually regulated by agencies of government [6,7]. In Nigeria, Pharmacists Council of Nigeria (PCN) regulates PMVs' activities as established in Pharmacy Council of Nigeria Decree 91 of 1992 [8]. PCN specifies eligibility criteria for operating as a PMV, stipulates licensing requirements, and gives guidelines for operators to follow. While PCN regulates the activities of PMVs, drug registration and regulation are within the purview

of National Agency for Food and Drug Administration and Control (NAFDAC) [5].

Malaria remains a leading cause of morbidity and mortality in Nigeria as in other sub-Saharan Africa countries [9]. According to the new antimalarial treatment policy, trained PMVs are categorized in level 1 of malaria management [10]. At this level, a health care provider is expected to diagnose malaria symptomatically and administer artemisinin-based combination therapy (ACTs) for uncomplicated cases or give pre-referral treatment and promptly refer patients with severe febrile illness. PMVs will continue to play a major role in malaria treatment especially those in the rural areas where the burden of malaria is higher [11,12]. Not much is known about PMVs operating in the rural areas of Lagos and their level of compliance with PCN and NAFDAC guidelines, hence this study.

METHODS

Study setting

Lagos State is one of the 36 states of the Federal Republic of Nigeria. It is located in the southwestern zone of Nigeria and is the commercial nerve centre of the country. It is divided into 20 Local Government Areas (LGAs); 16 are classified as urban and four as rural. The rural LGAs are Ikorodu, Epe, Ibeju-Lekki and Badagry. The study was carried out in Ikorodu and Ibeju-lekki.

The Ikorodu branch of the Lagos State Medicine Dealers Association (LSMDA) had 482 registered PMVs in its four zones in the LGA and they were distributed thus: Ikorodu South (82), Ikorodu Central (75), Odogunyan (184) and Igbogbo (141). The Ibeju-Lekki branch of LSMDA had 157 registered PMVs.

There were two independent umbrella associations for PMVs in Lagos state: Lagos State Medicine Dealers' Association (LSMDA) and National Association of Patent and Proprietary Medicine Dealers (NAPPMED). We first established contact with LSMDA; it was much later while pre-testing the data collection instruments that the parallel group was discovered. We decided to limit the study to LSMDA to avoid the complexity of involving the two bodies. Lagos State Medicine Dealers' Association (LSMDA) had a branch in each LGA and for ease of administration, big LGA branches were further divided into zones. The state and the LG branches all had executive committees running the association.

Study design and study population

This was a cross-sectional study to determine the compliance with relevant regulatory guidelines by PMVs operating in rural LGAs of Lagos state. The study population comprised LSMDA-registered PMVs operating in Ikorodu (Odogunyan zone) and in Ibeju-Lekki LGAs of Lagos state. Only PMVs who had their patent medicines shops registered with the LGA branch of LSMDA were included in the study. Where the shop owner was not the one actively involved in operating a selected shop, the person in charge, either an apprentice or a sales attendant who usually sold drugs to clients, was interviewed.

Sample size estimation

The minimum sample size for the main study (intervention) was estimated using the formula for comparison of two proportions [13] and a sample size of 90 for each LGA was computed.

Sampling methodology

The proposed intervention study was designed to take place in two rural LGAs (one to serve as intervention and the other as control LGA). Using simple random sampling method by balloting, Ikorodu and Ibeju-Lekki LGAs were selected. In Ikorodu, only Odogunyan zone (the largest zone) was involved in the study. The methodological and logistic challenge of involving all the zones informed the purposive selection of Odogunyan zone where it was most certain that the required number of PMVs for Ikorodu would be obtained. Simple random sampling method was used to select 90 PMVs from each of the study areas.

Ethical considerations

Ethical approval for the study was obtained from the Research and Ethics Committee of the Lagos University Teaching Hospital. Meetings were held with the executive bodies of LSMDA at the state and LGA levels. We also attended the monthly meetings of the two LGAs and explained the purpose of the study to members. Informed consent was obtained from the respondents and they were further assured of the confidentiality of the information they would provide.

Data collection and analysis

Data were collected between July and September 2009. Executive members of LSMDA in each LGA helped to locate the selected shops and assure respondents of the association's approval. One of the authors and two trained research assistants administered the pretested

structured questionnaire and observational checklist to respondents and their shops. The questionnaire elicited *inter alia* information on the socio-demographic characteristics of the PMVs and their work history. The observational checklist was used to check the shop premises, the types of antimalaria drugs in the shops, and the expiry date and registration status of the drugs. All the antimalaria drugs (AMDs) in stock for sale were identified, and one of each type of the drugs shown was arbitrarily selected by the interviewer and checked for NAFDAC number and expiry date. The Epi Info 2002 (Windows version 3.5.1) was used for data entry, cleaning, and analysis. Chi-square test (with Yates correction) and Fisher exact test were used to determine associations between qualitative variables. A p-value of < 0.05 was considered statistically significant.

RESULTS

Table 1 shows that most 148 (82.2%) of the respondents were shop owners. Respondents' ages ranged from 16 to 67 years, with a mean age of 30.9 ± 8 years, and 94.4% were ≥ 21 years (21 years is the minimum age required by PCN

to be licensed to operate as a PMV [8]). The highest level of education attained by the PMVs was secondary education 144 (80%). There were more females 95 (52.8%) than males 85 (47.2%) and most are married 107 (59.4%). Most of the PMVs were of Igbo 85 (47.2%) ethnic extraction and the dominant religion was Christianity 156 (86.7%). Some significant differences exist between the two LGAs.

Training and work history

About a third 57 (31.7%) of the respondents had health-related training background and majority of them were trained as auxiliary nurses. The PMVs had been in practice for a mean duration of 5.4 ± 4.7 years. About two-third 114 (63.3 %) of the PMVs mentioned attending a continuing education programme (CEP) in the previous 24 months, less than a half 75 (41.7 %) attended one specifically on malaria. Significantly more PMVs in Ikorodu attended CEPs than their counterparts in Ibeju-Lekki. Only 10 (6.3 %) of shop owners claimed having a practising licence and for most of them 163 (90.6%), operating their shop was their only job (Table 2).

Table 1: Socio-demographic characteristics of respondents

Characteristic	Ikorodu (n=90) Freq (%)	Ibeju-Lekki (n=90) Freq (%)	Total (n=180) Freq (%)	χ^2	P-value
Respondent					
Shop owner	78 (86.7)	70 (77.8)	148 (82.2)	4.38	0.112
Sales attendant	6 (6.7)	5 (5.6)	11 (6.1)		
Apprentice	6 (6.7)	15 (16.7)	21 (11.7)		
Age group (yrs)					
<21	2 (2.2)	8 (8.9)	10 (5.6)	7.11	0.068
21-29	32 (35.6)	40 (44.4)	72 (40.0)		
30-39	43 (47.8)	35 (38.9)	78 (43.3)		
≥ 40	13 (14.4)	7 (7.7)	20 (11.1)		
Mean age	32.2 ± 7.4	29.6 ± 7.9	30.9 ± 7.8		
Sex					
Female	58 (64.4)	37 (41.1)	95 (52.8)	8.92	0.003
Male	32 (35.6)	53 (58.9)	85 (47.2)		
Education					
Primary	7 (7.8)	9 (10.0)	16 (8.9)	2.16	0.339
Secondary	70 (77.8)	74 (82.2)	144 (80.0)		
Tertiary	13 (14.4)	7 (7.8)	20 (11.1)		
Marital status					
Married	68 (75.6)	39 (43.3)	107 (59.4)	19.38	<0.001
Single	22 (24.4)	51 (56.7)	73 (40.6)		
Ethnic group					
Igbo	30 (33.3)	55 (61.1)	85 (47.2)	18.37	<0.001
Yoruba	39 (43.3)	30 (33.3)	69 (38.3)		
Others	21 (23.3)	5 (5.6)	26 (14.5)		
Religion					
Christianity	76 (84.4)	80 (88.9)	156 (86.7)	0.43	0.511
Islam	14 (15.6)	10 (11.1)	24 (13.3)		

Table 2: Practice-related information and attendance of continuing education programme

Variable	Ikorodu Group Freq (%)	Ibeju-Lekki Group Freq (%)	Total Freq (%)	χ^2	P-value
Previous health training					
Yes	33 (36.7)	24 (26.7)	57 (31.7)	1.64	0.200
No	57 (63.3)	66 (73.3)	123 (68.3)		
Total	90 (100.0)	90(100.0)	180 (100.0)		
Health training received					
Auxiliary Nursing & Others	23 (69.7)	21 (87.5)	44 (77.2)	1.59	0.207
General Nursing/midwifery	10 (30.3)	3 (12.5)	13 (22.8)		
Total	33 (100.0)	24(100.0)	57 (100.0)		
Duration of practice (yrs)					
1-5	54 (60.0)	70 (77.8)	124 (68.9)	7.36	0.025
6-10	19 (21.1)	13 (14.4)	32 (17.8)		
≥11	17 (18.9)	7 (7.8)	24 (13.3)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		
CEP* attendance in the last 24 months					
Yes	72 (80.0)	42 (46.7)	114 (63.3)	20.12	<0.001
No	18 (20.0)	48 (53.3)	66 (36.7)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		
CEP attendance on malaria in the last 24 months					
Yes	55 (76.4)	20 (47.6)	75 (65.8)	8.52	0.004
No	17 (23.6)	22 (52.4)	39 (34.2)		
Total	72 (100.0)	42 (100.0)	114 (100.0)		
Licence status of shop owner					
Yes	3 (3.6)	7 (9.3)	10 (6.3)	0.193*	
No	81(96.4)	68 (90.7)	149 (93.7)		
Total	84 (100.0)	75(100.0)	159 (100.0)		
Job status					
Only job	82 (91.1)	81 (90.0)	163 (90.6)	0.00	1.000
Main/Part-time job	8 (8.9)	9 (10.0)	17 (9.4)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		

*Fisher exact p-value

Table 3: Findings from observation of patent medicine shops

Variable	Ikorodu group Freq (%)	Ibeju-Lekki group Freq (%)	Total	χ^2	P-value
Presence of sign post					
Yes	3 (3.3)	4 (4.4)	7 (3.9)		1.000*
No	87 (96.7)	86 (95.6)	173 (96.1)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		
Wording in business name					
Patent medicines shop	1 (33.3)	2 (50.0)	3 (42.9)		1.000*
Others	2 (66.7)	2 (50.0)	4 (57.1)		
Total	3 (100.0)	4 (100.0)	7 (100.0)		
Nature of shop					
Drug shop only	8 (8.9)	4 (4.4)	12 (6.7)	0.80	0.370
Drug shop/provision store	82 (91.1)	86 (95.6)	168 (93.3)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		
Annual practising licence					
Displayed/presented on request	1 (1.1)	5 (5.6)	6 (3.3)	1.55	0.211
Not available	89 (98.9)	85 (94.4)	174 (96.7)		
Total	90 (100.0)	90 (100.0)	180 (100.0)		
Status of licence					
Expired	1 (100.0)	3 (60.0)	4 (66.7)		1.000
Not expired	0 (0.0)	2 (40.0)	2 (33.3)		
Total	1 (100.0)	5 (100.0)	6 (100.0)		

*Fisher exact p-value

Table 4: Types of antimalarial drugs found in the observed patent medicine shops

Antimalarial	Ikorodu group n=90 Freq (%)	Ibeju-Lekki group n=90 Freq (%)	Total n=180 Freq (%)	χ^2	p
ACTs	39 (43.3)	67 (74.4)	106 (58.9)	16.73	<0.001
Artemisinin monotherapies	66 (73.3)	70 (77.8)	136 (75.6)	0.27	0.603
Chloroquine	80 (88.9)	87 (96.7)	167 (92.8)	2.98	0.084
Amodiaquine	17 (18.9)	10 (11.1)	27 (15.0)	1.57	0.210
Sulphadoxine-pyrimethamine	81 (90.0)	77 (85.6)	158 (87.8)	0.47	0.495
Quinine	4 (4.4)	7 (7.8)	11 (6.1)	0.39	0.534
Pyrimethamine	3 (3.3)	10 (11.1)	13 (7.2)	2.98	0.084
Halofantrine	2 (2.2)	10 (11.1)	12 (6.7)	4.38	0.036
Others	0 (0.0)	3 (3.3)	3 (1.7)		0.246*

* Fisher exact p-value

Observational findings on drug shops

Only seven (3.9 %) shops had sign-post announcing their premises and only three out of the seven contained the required wordings. Of all, only six (3.3 %) of the stores had the shop owners' annual practising license conspicuously displayed or presented on request. Majority of the shops surveyed functioned as both a drug shop and a provision store (Table 3). All the antimalarials examined had NAFDAC number and none had expired.

Different types of antimalarials were stocked in both areas (Table 4). "Others" were herbal products called "M & T" capsule labeled as "...for malaria treatment" and carried NAFDAC number. In only one shop was an injectable antimalarial (quinine) found.

DISCUSSION

This study describes the people operating as PMVs in rural Lagos and reports their status as regards compliance with regulatory bodies' (PCN and NAFDAC) guidelines. Other studies in Nigeria found a lower proportion of respondents as shop owners [10, 14]. This may be attributable to the fact that running the shop was the only source of income for most of the PMVs in this study as opposed to the cited studies where respondents had other sources of income. The finding of apprentices or sales attendants selling antimalarials calls for concern. They may not have adequate knowledge of malaria treatment compared to the shop owners and may not be able to sell appropriate drugs in the correct doses to their clients, a practice that may result in poor treatment with consequences such as recrudescence, drug resistance, progression from uncomplicated to severe malaria and ultimately avoidable death. This finding also shows that any capacity building programme for

PMVs may be more effective if apprentices and sales attendants are involved since they interface with clients in a number of shops. The finding of respondents younger than 21 years was due to the participation of apprentices and sales attendants. When both were excluded from the data, the age range was 22 - 67 years. This complies with PCN's minimum requirement of 21 years for a PMV to be licensed [8]. Maturity is essential in the business as a PMV is not just a seller; s/he needs to counsel clients and often has to make treatment decisions for them, a task that can only be successfully performed by an adult.

About a third of the PMVs in the study had previous health-related training. This proportion is higher than that found in other studies in Nigeria [14-16], but much lower than what was reported in studies in Tanzania where 93-97% of PMVs had formal health training [6,17]. This disparity is not unexpected as it is mandatory for PMVs in Tanzania to have formal health training before they can be licensed to practise [6], while in Nigeria the educational requirement is just being able to read and write in English language [8]. Basic health training would no doubt expose PMVs to rudiments of malariology and the understanding of other common ailments including the basic pharmacology of drugs meant to treat those ailments, thus enhancing appropriate treatment.

For majority of the vendors, operating their drug shops was their only business. The study in Kaduna, Nigeria also reported a high figure of about 80% operating their shops as their sole business [14]. Organizing a programme that would enhance the malarial treatment practice and increase patronage and sales by PMVs would probably have a great appeal since their shops were the only business concern most of them had. At the same time since most of them

were shop owners, it might be difficult to call them out for long sessions of training. This should be factored into any training that would be organized for them; multiple short sessions rather than long sessions would probably yield better result. [18,19]

About two-thirds of the PMVs attended some form of continuing education programme (CEP) in the previous two years - a prerequisite for licence renewal by the PCN [8]. It is the duty of the PCN to organize such CEPs for licensed PMVs [8], but since majority of the PMVs were unlicensed, PCN could not have been the organizer of the attended CEPs. This implies that the largely unlicensed PMVs had not been officially exposed by the regulatory body to any formal lecture/training to improve their practice in the last two years prior to data collection, despite new policies and developments in the management of some of the common ailments for which they are consulted by the community. For malaria, less than half of the PMVs had attended at least one CEP. Some of the programmes attended, especially those organized by pharmaceutical companies, may just be drug presentations where adequate knowledge about the disease may not be passed. This underscores the importance of government taking the lead in organizing CEPs for both licensed and unlicensed PMVs. If the PCN has failed in stopping unlicensed PMVs from operating, it will be disastrous to pretend they do not exist and exclude them from orientation and education programmes that can enhance their contribution to appropriate malaria treatment.

There was worrisome violation of guidelines set by the PCN for operating as a PMV and for owning a drug shop. An insignificant number had a sign-post and out of those that had, only a few carried the prescribed wordings. Without a signpost it would be difficult for the PCN and other legal and relevant agencies that may want to monitor their activities to identify their business premises. Almost all the vendors were operating without practising license from the PCN. Many claimed they had applied and were in the process of being licensed. As explained by officers of the association in a preliminary discussion with them, the licensing process is long and may take several months or years. There was a long period when issuance of licence to PMVs was suspended because of conflict among the stakeholders in the regulation of their practice [20]. This could partly explain why most of them did not have licence. Nonetheless, the fact that many of them had been in practice for many years without licence (not even expired one) reflects a weak

enforcement by the PCN. A similar study among PMVs done in Kaduna, Nigeria reported a much higher figure of 56% displaying their licenses, though the status of the licences was not mentioned [14]. The PMVs in the Kaduna study belonged to NAPPMED (we worked with LSMDA members), a parallel body of PMVs. Could there be a fundamental difference in the way both bodies comply with rules? Unlicensed businesses are more difficult to regulate and this creates room for malpractices and corruption. Infringements of this kind are common with vendors as studies in Tanzania and Uganda showed similar violations [6,17]. In the study in Tanzania, 11 of the 30 shops studied lacked valid permit and none of the serving drug sellers met the qualification requirements for practising [6]. In Uganda, only 39% of the drug shops were registered [21].

In this study, all the drugs checked were duly registered, none had expired and there was almost a universal absence of injectable antimalarials. This contrasts with findings from similar studies in Tanzania where 63% stocked unregistered and 13% stocked expired antimalarials [6], and in Kenya where many unapproved and unregistered antimalarials were found and less than half of the recommended ones were registered [7]. Absence of unregistered or expired antimalarials in the observed shops was some evidence that the ongoing campaign against counterfeit drugs by NAFDAC was yielding result. Alternatively, could it be due to concealment of incriminating drugs by PMVs as has been reported in an earlier study [6]?

Chloroquine (CQ) and sulphadoxine-pyrimethamine (SP), the former first and second line AMDs had the lion's share of the market despite that they are no longer recommended except SP that is reserved for intermittent preventive treatment of malaria in pregnancy (IPTp) [9]. CQ and SP were replaced because of their reduced effectiveness occasioned by resistance of malaria parasite to them. Their dominance in drug shops means people are still exposed to inadequate treatment with consequences. Another worrisome finding was the wide availability of artemisinin monotherapies. The WHO recommended their withdrawal from the market because of evidence of resistance to them and the danger they pose to the ACTs [22]. Immediate withdrawal of these drugs and other non-artemisinin monotherapies, particularly CQ and SP should be pursued with vigour.

Limitations of the study

As noted earlier, the zone in Ikorodu LGA was purposively selected and might theoretically not be representative of the entire LGA. However, there is little doubt that it is similar in all respect to the other zones as they shared the same *modus operandi* being in the same LGA. NAPPMED members were not involved in the study. This limits generalization of the findings to all vendors in the reference population.

CONCLUSION

This study shows poor compliance with regulatory guidelines and some significant differences of programmatic importance between the two study LGAs, even though both are rural. The ubiquitousness of PMVs can help to get ACTs to remote areas where formal health care providers may not be present. However, given their poor compliance with some regulatory guidelines and the consequences of this for malaria treatment in the communities, there is a need for the authorized government agency to redouble its effort to enforce compliance and supervise their activities. Government should revise the list of antimalarials PMVs are permitted to sell to reflect the policy change and prevent the sale of ineffective antimalarials.

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