PATENT AND PROPRIETARY MEDICINE VENDORS SERVICES AND FACTORS INFLUENCING THEIR NON-COMPLIANCE WITH REGULATORY GUIDELINES IN IBADAN, OYO STATE, NIGERIA

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Submission Date: 8th Mar., 2026
Date of Acceptance: 15th April, 2026
Publication Date: 30th April, 2026

ABSTRACT

Background/aim: **Patent and Proprietary Medicine Vendors (PPMVs) are major private and informal healthcare service providers in Nigeria, whose activities are regulated by the Pharmacy Council of Nigeria (PCN). Review of literature have documented concerns about PPMVs' non-compliance with PCN's service provision guidelines and their implications for the health outcomes of their clients. Studies among PPMVs on the services they provide and their non-compliance with regulatory guidelines in semi-urban areas have been under explored. This study however, investigated types of services provided by PPMVs and their non-compliance with regulatory guidelines in Ibadan, Oyo State, Nigeria.**

Materials/methods: **This descriptive cross-sectional study included registered patent and proprietary medicine vendors selected from two out of the six semi-urban Local Government areas of Ibadan, Oyo State through random sampling using an interviewer-administered semi-structured questionnaire with data collected using the KoboCollect. The questionnaire elicited responses on the types of services provided by PPMVs to their clients and factors influencing their non-compliance with the regulatory guidelines. Data was collected and analysed using descriptive and inferential statistics with SPSS version 25, at 0.05 level of significance.**

Results: **Two hundred and eight respondents were recruited for the study. Respondent's mean age was 38.17±10.82, years. Majority (80.8%) were females, less than half (40.9%) had post-secondary-level education. A few (13.9%) had additional health-related qualifications. Respondents provided services which were both within (treatment of ailments; 50.5%, and Referral 50%) and outside (giving injections; 51.9% and prescription of medicine; 49.1%) their scope of operation. Factors which influenced non-compliance mentioned by respondents were attendance of PCNs training, licensure with PCN and reception of monitoring visits, were significantly associated with non-compliance with guidelines on service provision ($p<0.05$).**

Conclusion: **Patent and proprietary medicine vendors in Ibadan, Oyo state, play a significant role in providing accessible primary healthcare services within and outside their scope of operation to the populace, several factors are responsible for their non-compliance with regulatory guidelines which dove-tailed into rendering of services beyond their scope of operations.**

Keywords: Non-compliance, Patent medicine dealers, Service rendered, Over-the-counter drugs

INTRODUCTION

In sub-Saharan Africa, the dearth of healthcare workers is made worse by the high rate of communicable and non-communicable diseases. Trained health workers are constantly leaving the country, due to lack of a supportive work environment, and low morale among healthcare personnel.[9,24]

In Nigeria, there exists a shortfall of infrastructure and healthcare service providers in suburban and rural communities in Nigeria.[50] Increased access to healthcare commodities and services in Nigeria is made possible through informal and private sectors, these include drug shops that are operated by patent and proprietary medicine vendors (PPMV).

Patent and proprietary medicine vendors are major private and informal healthcare service providers in Nigeria, found both in rural and urban communities.[25,36,41] The Pharmacy Council of Nigeria (PCN) is responsible for the regulation, registration and licensure of PPMVs in Nigeria, the council also conducts orientation sessions for new PPMVs, and continuing education Programme (CEP) for existing PPMVs and publishes the Approved Patent Medicine List.[22]

Patent and proprietary medicine vendors are often described as people without formal pharmacy training who by regulation are licensed to sell proprietary/over the counter (OTC) drugs and conventional pharmaceutical commodities commercially on a retail basis for profit.[2,12,13,19,27,30]

Patent and proprietary medicine vendors operate from a physical outlet, they are allowed by their regulatory agency (Pharmacy Council on Nigeria) to sell pre-packaged over-the-counter (OTC) medicines and medical products. However, they are not allowed to prescribe medications (including antibiotics) and to perform invasive medical procedures.[11,24] Requirements for obtaining a PPMV licence include the licensee to be more than 21 years of age, without any specification for their education qualification.[37,49] Aspiring PPMVs often complete an apprenticeship with a more senior PPMV with prescribed regulations before opening their own shop.[7, 11,21]

Though they lack formal training on health issues, they are commonly the initial point of call for healthcare and primary source of orthodox drugs and treatment of acute conditions for both urban and rural populations and thus receive increased and regular patronage from members of communities where they operate.[6,50] The quest for profit and pressure from customers, however, often drives PPMVs to go far beyond their scope of operation with regard to the services they are meant to provide.[20]

The close proximity of PPMVs and high client patronage in communities affords them to be a major source for the distribution of medications and healthcare information, thereby helping in the fight against illnesses which is a threat to the general health of people.[15,21,26] PPMVs possess certain features that make them function effectively in their neighborhoods, including the fact that they render accessible and affordable services, are in convenient locations, have extended opening hours, are hospitable (amiable temperament towards their clients as against what is obtainable among the staff of the formal health sector), have interpersonal engagements and do not charge consultation fees.[9,14,22,39,47]

The PCN guidelines made for PPMVs on service provision, prohibits them from prescribing of medications (including antibiotics) and performing invasive medical procedures,[42] but they nevertheless render services in response to the needs of citizens who practice self-care. Such services include but are not limited to consultation for minor ailments, sales of drugs, weight and blood pressure measurements, wound dressing and first aid treatments.[23,36]

The services they render, in certain instances have been documented to be beyond their scope of operation, as stipulated by their regulators[18] which is an indicator to poor regulation in the obvious reality of the nation's weak health system.[10,11,21,31,38,40.] Services beyond their scope of operations are sales of and prescription-only medications (POM), poor treatment practices, abuse of their positions/practice, low referral rates, indiscriminate prescription, overuse of antibiotics and non-compliance with treatment guidelines for malaria, diarrhea, and Tuberculosis.[10,11,13,29,32,41,45,53]

It is therefore important to document the gaps which are deviations in the current services PPMVs render and determine factors influencing their non-compliance with regulatory guidelines. Thus, the broad objective is to document the types of services rendered and factors influencing non-compliance with regulatory guidelines among patent and proprietary vendors in Ibadan, Oyo State, Nigeria.

MATERIALS AND METHODS

Study design and Population: The study was a cross-sectional in nature. Cross sectional research facilitates the comprehensive collection and analysis of data as it permits the researcher to define the present situation in the phenomenon under investigation. Thus, the use of a cross-sectional sample for a survey overcomes the limitations of the time and cost required for collecting data.[50,51] Hence, it was conducted among patent and proprietary medicine vendors who are registered with under the auspices of National Association of patent and proprietary medicine dealers (NAPPMED) in the LGAs. As a the time of this study, there were four hundred and eleven (411) registered PPMVS at the study sites, as obtained from the Chairpersons of NAPPMED in the LGAs, which then served as a sampling frame for the study.

Description of Study Site: The study was carried out in two (2) semi-urban Local Government Areas which were randomly selected out of the six (6) semi-urban Local Government Areas in Ibadan, Oyo State. This is due to dearth of studies in semi-urban areas, as well as financial constraints. Oyo State is an inland state in South-western Nigeria, with its capital

at Ibadan. It is bounded in the North by Kwara State, in the East by Osun State, in the South by Ogun State and in the West partly by Ogun State and partly by the Republic of Benin. Egbeda is a local government area in Oyo State, lies East of the North-east of Ibadan city[54], Nigeria, with its headquarters located in the town of Egbeda. Egbeda local government was carved out Lagelu Local government in 1989 with the administrative headquarters at Egbeda. It is in the eastern part of the state and is about 12km from Ibadan. There are 195 settlements in the local government and over 60% of these are urban in nature. It has an area of 191 km^2 and a population of 283,643 (2006 Census) to an estimate of 425,670 in 2025.

Akinyele Local Government was formed in 1976, out of which Ido Local government was carved out in 1989, leaving it with its present structure of 12 wards with headquarters in Moniya. It is bounded in the east by Lagelu LGA, by Afijio in the north, Ibadan North LGA in the south and Ido LGA in the west. It is a mix of urban and rural communities with a population of 211,811 (Census 2006) with 105,594 males and 106,217 females; an estimated population of over 300,000 in 2025, it is 222 square kilometers in area. Both LGAs have patent and proprietary medicine vendors shops located in several communities under the auspices of National association of patent and proprietary medicine dealers (NAPPMED), the total number of registered PPMVs in the study sites was given to be four hundred and eleven (411).

Sample size determination: The Cochrane formula was used to calculate the sample size of respondents recruited for the study. Cochrane's formula for finite population,[17]

$n = (no.N)/[no+(N-1)]$

Where: no = initial sample size given from Cochrane's formula, N = known population of PPMVs in the study sites. This yielded a sample size of 198.27 which was increased to 208 for more representation.

Data collection and sampling techniques: Random sampling method was performed to select those who would be recruited. This selection was done using the list of registered PPMVs obtained from the chairpersons of the PPMV association in the study sites, every other PPMV on the list was selected until the sample size was reached. Respondents were met at their various shops at different times, briefed of the study and were recruited after adequate explanation was provided and a pair of informed consent forms were signed. Eligible participants who refused to participate were replaced with others on the list who consented and signed the consent form. Thus, PPMVs who did not give consent and those not available at the time of the study were exempted from the study. Trained research assistants assisted in implementing this process which lasted for 6 days, between the hours of 12pm-6.00pm daily.

Instrument validity and reliability: The validated semi-structured questionnaire was interviewer-administered via the KoboCollect. The questionnaire comprised of three sections: socio-demographic, services provided, and factors influencing non-compliance with regulatory guidelines. Validity was ensured through expert consultation and literature review. Careful planning and ensuring adequate quality control/implementation strategies such as recruitment, data collection and analysis were strictly adhered to. The supervisor consolidated the design and provided constructive feedback. The validity of the instrument was ensured through thorough examination of each item, making sure that they measure the study objectives, while reliability was determined through pre-testing among registered PPMVs at Ona-Ara local government area, with a Cronbach's alpha of 0.725. Research assistants were trained and a quality control manual was provided.

Data analysis procedure: Data was analysed using SPSS version 23 (IBM Inc., Chicago, IL, USA) for descriptive and inferential analysis at $p=0.05$. Measurement included a dichotomous option "Yes or No" for services rendered which was later categorized as services rendered within and outside their scope of operation. Factors influencing compliance comprises of open-ended questions, which was computed, the results were presented in frequencies and described appropriately.

Ethics approval and consent: The study followed the basic ethical principles guiding research involving human participants as enshrined in the Helsinki Declaration. The University of Ibadan/University College Hospital Ethics Review Committee, reviewed, approved and monitored the study with the approval number: UI/EC/23/0645. Informed consent was obtained from participants in English language before administering the questionnaire. Participants were given the option to withdraw consent at any time, and confidentiality was maintained throughout the study.

Risk: There was no anticipated ethical issue aside the time spent for completion of the questionnaire.

Cost: No additional cost was accrued for the patients as the questionnaire was completed by those who were willing to participate in the study, which took an average of 20-25 minutes of their time.

Confidentiality: All Information disclosed by the respondents were treated with utmost confidentiality.

RESULTS

Socio-demographic characteristics

Majority (90.4%) of respondents were females, with a mean age of 38.17±10.82, most (88.0%) were married and predominantly of the Yoruba ethnic group. More (59.1%) respondents had attained secondary education and owned a single shop. Majority (97.1%) went through apprenticeship system, a little proportion (13.9%) had other health-related qualifications (Table 1a and 1b)

Services rendered by respondents within and outside their scope of operation

A little over half (50.5%) of respondents treated ailments (first-aid) brought to their shops, equal proportion (50%) offered counselling and referral services (Table 2).

Table 1a: Socio-demographic characteristics of the respondents (N=208)

Variable		Frequency (N=208)	Percentage (%)
Sex			
	Male	20	9.6
	Female	188	90.4
Age Categories (years)			
	21-30	64	30.7
	31-40	75	36.1
	41 and above	69	33.2
	Mean Age	**38.17±10.82**	
Ethnic Group			
	Yoruba	205	98.6
	Others	3	1.4
Marital status			
	Single	25	12.0
	Married	183	88.0
Religion			
	Christian	116	55.8
	Muslim	92	44.2
Educational qualification			
	Secondary	123	59.1
	Post-Secondary	85	40.9
No of shops owned			
	One	206	99.0
	Two	2	1.0
Ever participated in apprenticeship			
	Yes	202	97.1
	No	6	2.9

Table 1b: Socio-demographic characteristics of respondents (Cont'd N=208)

Variable		Frequency (N=208)	Percentage (%)
Completed Apprenticeship			
	Yes	202	97.1
	No	6	2.9
Issued Certificate			
	Yes	202	97.1
Duration of Apprenticeship (Months)			
	< 7	37	17.8
	7 - 12	6	2.9
	13 - 24	40	19.5
	>24	125	60.1
	Mean month	**32.47±9.84**	
Health-related qualification			
	Yes	29	13.9
	No	179	86.1
Type of health-related qualification			
	Nursing	21	72.4
	CHO	8	27.6
Primary Occupation is PPMV			
	Yes	193	92.8
	No	15	7.2

Table 2: Services rendered by respondents within the scope of operation (N=208)

Variable	Frequency (N=208)	Percentage (%)
Treat ailment (first-aid) brought to shop		
Yes	105	50.5
No	103	49.5
Sell medicine as requested		
Yes	104	50.0
No	104	50.0
Counsel Clients		
Yes	104	50.0
No	104	50.0
Refer Clients to higher facilities		
Yes	104	50.0
No	104	50.0

Table 3: Services rendered by respondents beyond the scope of operation (N=208)

Variable	Frequency (N=208)	Percentage (%)
Prescribe medicine		
Yes	98	49.1
No	110	52.9
Give Injections		
Yes	108	51.9
No	100	48.1
Set up IV Drips		
Yes	106	50.9
No	102	49.1
Count Tablets/capsules from bulk		
Yes	106	50.9
No	102	49.1
Sell wholesales medicine		
Yes	103	49.5
No	105	50.5
Pour liquid drugs (syrups)		
Yes	106	51.0
No	102	49.0

Table 4: Factors influencing non-compliance with regulatory guideline

Variable	Yes		No		χ^2	p-value
	N	%	N	%		
PCN Registration	144	69.2	64	30.8	14.05	0.002*
Membership in PPMV Association	132	63.5	76	36.5	9.47	0.004*
CEP Attendance (Training)	127	61.1	81	38.9	18.72	0.000*
Received monitoring visit	113	54.3	95	45.7	4.12	0.042*
Possession of Job-aids	120	57.7	88	42.3	3.76	0.053
Drug Cost Increase	118	56.7	90	43.2	1.45	0.231

Significant at $p < 0.05$.

With regards to services rendered by respondents outside their scope of operations; 49.1% prescribed medication to their clients, 51.9% gave injections, while 49.5% sold wholesales medications respectively (Table 3).

Factors influencing non-compliance with guideline among respondents

Over half of the respondents opined that attendance of the PCN Continuing Education Program (CEP; 61.1%) was a factors which influenced non-compliance as given, PCN registration status (69.2%), membership

Table 5: Logistic regression for factors influencing non-compliance among respondents

Predictor Variable / Category	OR	95% CI	p-value	AOR	95% CI	p-value
Attended PCN CEP Training						
Yes	3.02	1.95–4.69	0.000*	3.45	2.11–5.64	0.000*
No (Ref.)	1.00	–	–	1.00	–	–
PCN Registration Status						
Yes	2.55	1.59–4.11	0.000*	2.96	1.78–4.93	0.001*
No (Ref.)	1.00	–	–	1.00	–	–
Member of PPMV Association						
Yes	2.30	1.42–3.74	0.001*	2.72	1.63–4.56	0.001*
No (Ref.)	1.00	–	–	1.00	–	–
Received Monitoring Visit						
Yes	1.60	1.01–2.55	0.046*	1.89	1.13–3.15	0.014*
No (Ref.)	1.00	–	–	1.00	–	–
Possession of Job Aids						
Yes	1.42	0.88–2.29	0.145	1.77	1.02–3.07	0.042*
No (Ref.)	1.00	–	–	1.00	–	–
Drug Cost Increase						
Yes	1.18	0.71–1.96	0.512	1.25	0.73–2.12	0.414
No (Ref.)	1.00	–	–	1.00	–	–

Significant at $p < 0.05$.

Table 6: Associations between sociodemographic characteristics and non-compliance with guideline

Variable	N	%	χ^2	p-value
Sex			2.50	0.114
Male	20	9.6		
Female	188	90.4		
Age			1.90	0.387
21–30	64	30.7		
31–40	75	36.1		
·1 and above	69	33.2		
thnic Group			1.20	0.304
Yoruba	205	98.6		
Igbo	3	1.4		
Religion			0.85	0.357
Christianity	116	55.8		
Islam	92	44.2		
[arital Status			0.20	0.780
Single	25	12.0		
Married	183	88.0		
Education			2.80	0.094
Secondary	123	59.1		
ɔst-secondary	85	40.9		
ɪmber of Shops Owned			2.86	0.091
One	206	99.0		
Two	2	1.0)		

Note: $p < 0.05$ indicates statistical significance.

with the local PPMV association (63.7%), and reception of monitoring visits (54.3%) were among factors pointed out which also influenced their non-compliance These factors had significant association with non-compliance ($p < 0.05$); however, drug cost increase was not significantly associated with non-compliance (Table 4)

Logistic regression for factors influencing non-compliance among respondents

The logistic regression results of factors influencing non-compliance with guidelines among respondents is shown in Table 5. Respondents who attended the PCN CEP training were 3.45 times more likely to comply with the guidelines (AOR = 3.45, 95% CI:

2.11–5.64, $p < 0.001$) compared to those who did not attend. Likewise, respondents who were registered with PCN, were members with local PPMV association, received monitoring visits and had in their possession, job aids were significantly more likely to comply with the guideline. In contrast, increases in drug costs was not significantly associated with non-compliance.

Test of hypothesis and interpretation

There were no statistically significant association associations between all socio-demographic characteristics and non-compliance with guidelines (Table 6)

Discussion

The socio-demographic analysis revealed that majority were middle-aged yoruba women, reflecting the gender and ethnic profile of southwestern Nigeria; Egbeda LGA had a higher proportion. Our finding agrees with several studies,[1,5,33,35,41] where women's dominance was reported in informal pharmaceutical retailing due to their community trust and caregiving orientation. These findings were however in contrast with studies which reported male dominance among respondents,[1,4,16,28,44,48] where male respondents dominated their studies. The mean age of the respondents was 38.17±10.82, this follows PCNs minimum requirement for the issuance of a PPMV license (PPMVs must be above 21 years).

The prevalence of secondary education among respondents is supported by a study conducted in River State[34 also] supported by a study[46] which linked education to better understanding of guidelines. Educational qualification of a workforce has a bearing with the quality-of-service delivery.[33] Acquiring other health-related qualification was observed among a minute proportion of respondents, a few were Nurses and others; Community Health Officers, the greater proportion was at Akinyele LGA, this is in contrast with the findings of a study conducted on the readiness to implement routine immunization among PPMVs in Kano state, Nigeria[1] the study reported that more of their respondents had formal health related training. According to the scope of operation stipulated by the PCN for PPMVs, they are restricted to sell of OTC drugs,[21] which are drugs that do not require professional advice in their usage. Medications are stipulated to sold in their original packs and boxes as packaged from the manufacturers, they are however, prohibited from prescription of medicine, administering injections, setting up intravenous infusions for clients, engagement in wholesale business and sales of prescription-only- medicines.

Results from our study reported a commonality in respondents' engagements in services which are in line with their scope of operation,[18] such services include first-aid treatments, sales of medication as requested by customers, counselling and referral, these are similar to a study which reported that respondents provided services such as sales of drugs and first aid services.[21] However, respondents also engage in services beyond their scope of practice, such as prescription of medicine, administering injections, setting up of infusions, and engaging in wholesales practices.

Overall, our study documented 25–75% of PPMVs engaging in services outside their scope of operation. On prescription of medicine, which was outside their scope of operation, similar study documented 41% of their respondents prescribed the use of contraceptive pills to their customers[8] while on giving injections, another study[7] reported 67.7% of their respondents' administered injections.

The findings from our study revealed that the most reported factors influencing non-compliance with guideline were attendance of the PCN's Continuous Education Programme scheduled for the holders of the license, registration status and reception of monitory visits.

This is in contrast with the findings of a study done in six (6) urban LGAs of Kano State[1] where a reported complex interplay of factors such as the PPMV shop, increased customer patronage and self-care behaviour demonstrated among community dwellers, were some of the factors highlighted as responsible for sales of antibiotics. Regression analysis in the study above, brought to the fore the lack of training on resistance and use of antibiotics as a strong predictor to sales of antibiotics without prescription.

Similarly, findings from a qualitative assessment of the factors which influenced the provision of injectable contraceptive services among patent and proprietary medicine vendors in Nigeria,[3] documented contrast influencing factors to our findings which included a combination of social and cultural factors (secretive nature of women towards family planning services), PPMVs regulatory space which permitted the delivery of contraceptive services, faulty Nigerian health system and interest of international donors in increasing the roles of PPMVs in healthcare delivery. The study recommended the tiered accreditation of PPMVs, their inclusion in the Nigerian healthcare framework and adequate monitoring and supervision for effective service delivery.

CONCLUSION, RECOMMENDATION AND SUGGESTIONS FOR FURTHER STUDIES

Our study revealed that although, PPMVs play a significant role in the provision of affordable and accessible primary healthcare services in several communities where they are located, some of these services are outside of their scope of operation which could lead to poor health outcomes among many customers. PPMVs are also largely influenced by certain factors which are responsible for their non-compliance with guidelines for their service provision. We recommend regular training programmes to improve PPMVs knowledge on the guideline, this programme should be mandatory prior to renewal of license, also that PCN should intensify monitoring and supervisory roles to ensure compliance with guideline, which can be done by conducting regular and unannounced inspection visits to PPMV shops and enforce penalties for violation of the guideline. Finally, we also recommend a strong advocacy to gradually integrate PPMVs into the Primary healthcare system in Nigeria. There are some limitations to our study; one of which in the selection of PPMVs from two LGAs in Oyo State, there is the need to conduct this study in the other geo-political zones in the country to further enhance national generalizability.

The study also used a quantitative approach, there is a need to employ a mixed-method approach, which will investigate deeper into non-compliance and reasons why PPMVs deviate from the guideline in the services being provided. Lastly, there is a need to also explore the perceptions and satisfying levels of people who patronize PPMVs across several communities.

Limitations of the study

Data collected were based on self-reported, which makes social desirability bias a major limitation of our study, which is the tendency of our respondents to give answer they think are acceptable or expected, rather than what happens in practice.

Contribution to knowledge

Our study provides localized empirical evidence on the factors influencing non-compliance with guideline among PPMVs in Oyo State which reflects the peculiar socio-economic and regulatory environment within Oyo State, it also contributes to existing literature by documenting services rendered by PPMVs in Oyo State.

Conflict of Interest: None

Acknowledgement: We acknowledge the contributions and seamless community entry by the local PPMV Association in the LGAs, individual PPMVs, and our research assistants.

Addendum:

1. Olayinka O. Ajayi conceptualized the idea, implemented the research, championed the development of the manuscript and reviewed all drafts and handled correspondence.
2. Ademola J. Ajuwon supervised the work from the beginning to the end, contributed to the development and review of the draft.

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