

Response of patent medicine vendors in rural areas of Lagos state Nigeria to antimalarial policy change

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Abstract:

Background: Patent medicine vendors (PMVs) play an important role in the treatment of malaria, especially in the rural areas. Nigeria recently changed her antimalarial treatment policy from chloroquine to artemisinin-based combination therapy (ACT).

Objectives: To determine the response of PMVs to the new policy.

Methods: A baseline study was conducted in two local government areas (LGAs) of Lagos state Nigeria as the first phase in an intervention study aimed at improving the malarial treatment practices of PMVs in rural Lagos. A mixed method design involving a questionnaire survey of 180 PMVs and four key informant interviews were used. An antimalarial drug (AMD) audit was also performed.

Results: More than 80% of respondents were aware of the policy change in malaria treatment, but only 23.9% sold an ACT for the last case of malaria treated in an under five child. The main determining factor of the particular AMD sold was PMV's personal choice (70.6%). About half (58.9%) of the shops stocked ACTs, the newly recommended antimalarials.

Conclusions: The high awareness of the policy change did not translate to a commensurate increase in the sale of the new drugs. Factors beyond the PMVs need to be addressed for a successful adoption of the new policy.

Key words: Patent Medicine Vendors, ACTs, policy change, malaria, artemisinin monotherapies, non-artemisinin therapies

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Introduction

Malaria remains a leading cause of morbidity and mortality in Nigeria as in other sub-Saharan Africa countries.¹ Appropriate treatment of uncomplicated malaria currently means the use of artemisinin-based combination therapies (ACTs) as recommended by World Health Organization (WHO).² Nigeria adopted ACTs as the drugs of choice for the management of uncomplicated malaria in 2004 following drug therapeutic efficacy trials which confirmed widespread resistance to the

erstwhile drugs of choice and demonstrated adequate response to selected ACTs.³ Artemether-Lumefantrine (AL) is the preferred ACT, while Artesunate-Amodiaquine (AA) is the alternate treatment.³

Patent Medicine Vendors (PMVs) are important informal community-based providers of health care, who by law are permitted to sell only patent (nonprescription) medicines in their original prepackaged forms.^{4,6} They operate in both urban and rural areas where they sell drugs by simply filling prescriptions, prescribe and then sell, instruct/advise clients on the use of drugs sold, and refer clients to formal health facilities.⁷⁻⁹ Many countries, in their bids to ensure equitable access of the population to essential drugs, permit PMVs to sell over-the-counter (OTC) drugs, including antimalarials drugs (AMDs).^{10,11} Studies across Africa have shown that between 15% and 82% of recent childhood illnesses (most of which are malaria) are managed by PMVs as the first provider of care.^{5,6,12,13} This is supported by recent studies in Nigeria^{14,15} including the Nigeria malaria indicator survey (2010)¹⁶ which reported that 57.4% of household members with fever used PMVs as the first treatment point. The burden of malaria is known to be

heavier in the rural areas^{15,17} and it was estimated that 58% of malaria deaths occur in the poorest 20% of the world's population, most of who reside in the rural areas.¹⁸

Studies have shown that despite change in antimalarial drug policy, both providers and consumers continued to use the erstwhile drugs for a long time for various reasons.¹⁹⁻²² This slow adoption is not without consequences as the problems that necessitated the change remain.

PMVs' shops belong to Level 1 in the three-level hierarchy of disease management facilities in Nigeria. Others at this level are primary health care centres, dispensaries and health posts.³ The PMVs are permitted to treat uncomplicated malaria with ACTs in the new policy.³ This study aimed to assess the response of the dominant providers of AMDs in the rural areas after about five years of change in the antimalarial treatment policy.

Methods

Study setting

The study was conducted in Lagos State, which is one of the 36 states of the Federal Republic of Nigeria. It is located in the southwestern zone and had an estimated population of 10,016,807 for 2009 as projected from the 2006 census.²³ 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.²⁴ The study was carried out in Ikorodu and Ibeju-lekki LGAs.

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). The authors first established contact with LSMDA; it was much later while pre-testing the data collection instruments that the parallel association was discovered. A decision was made to limit the study to LSMDA to avoid the complexity of involving the two bodies. LSMDA had a branch in each LGA and for ease of administration; it subdivided its large LGAs into zones.

Ikorodu had an estimated population of 580,236 for 2009.²³ The Ikorodu branch of the Lagos State Medicine Dealers Association (LSMDA) had 482 registered PMVs in its four zones and they were distributed thus: Ikorodu South (82), Ikorodu Central (75), Odogunyan (184) and Igbojbo (141). Ibeju-Lekki is another ru-

ral LGA in the state with an estimated population of 129,467 for 2009.²³ The Ibeju-Lekki branch of LSMDA had 157 registered PMVs operating in the LGA.

Study design

This report is from the pre-intervention phase of an intervention study designed to improve the malarial treatment practices of PMVs operating in rural Lagos. A mixed method design was used and it involved a questionnaire survey and key informant interviews. The study population comprised only LSMDA-registered PMVs operating in Ikorodu and in Ibeju-Lekki LGAs of Lagos state. 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 intervention study was estimated using the formula for comparison of two proportions.²⁵ A study conducted in Oyo state, which is in the same geopolitical zone with Lagos found that 79.5% of PMVs were aware of the new policy.²⁶ We expected our intervention to raise the awareness to at least 95%. At alpha of 5% and power of 80%, and allowing for attrition and uncompleted interviews, 20% of the size calculated was added and rounded up to 90.

Sampling methodology

Ikorodu and Ibeju-Lekki LGAs were randomly selected (by balloting) out of the four rural LGAs in the state. In Ikorodu, for methodological and logistical reasons, Odogunyan zone was purposively selected out of the four zones in the LGA but the respondents were randomly selected using a table of random numbers. The table of random numbers was also used to select the respondents in Ibeju-Lekki. A list of all registered PMVs in each study location constituted the sampling frame.

Data collection

Data collection, which took place in July /September 2009, was done using a pretested structured interviewer-administered questionnaire, key informant interview guide and an observational checklist. One hundred and eighty PMVs (90 in each LGA) were interviewed and their shops were observed. One of the authors and two trained research assistants administered the instruments. The questionnaire elicited information on the socio-demographic characteristics of the PMVs, their knowledge of the new policy on malaria treatment and

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their treatment practice. As an indicator of the current treatment practice, the PMVs were asked to mention the AMD sold for the last case of malaria treated in an under-five child. Drug audit was performed using a checklist. All the AMDs in stock for sale were identified. One of each type of the drugs was arbitrarily selected by the interviewer and checked for NAFDAC number and expiry date. The presence of NAFDAC number is an indication that the product is duly registered. The chairperson and the secretary of the association in each LGA were interviewed as key informants. The two were purposively selected as they were expected to have a good knowledge of the subject matter and be able add depth to the interview.

Data analysis

The Epi Info 2002 (Windows version 3.5.1) was used for data entry, cleaning, and analysis. The drugs with their different proprietary names were classified into the following broad generic groups: ACTs, artemisinin monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into those containing artemether-lumefantrine (AL), artesunate-amodiaquine (AA) and others. Chi-square test (with Yates correction in 2 x 2 tables) and Fisher's exact test were done to find association between categorical variables. Multiple logistic regression analysis was done

to determine predictors of ACT sale. A p-value < 0.05 was considered statistically significant. The key informant interviews were tape-recorded, transcribed and organized under thematic headings. Content analysis²⁸ was employed to identify responses and findings were presented under major themes. The main outcome measures were awareness of the policy change, stocking and sale of the recommended ACTs.

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 and they gave their consent for the study. Informed consent was also obtained from individual respondents and this included consent for tape recording at the key informant interview.

Results

Sociodemographic characteristics

Table 1 shows that most of the respondents (148/82.2%) were shop owners and their ages ranged from 16 to 67years. More than 90% had secondary education and 31.7% had health training background, mainly auxiliary nursing. Statistically significant differences exist between the two LGAs in some characteristics.

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)		

Knowledge of current malaria treatment policy

Majority of the PMVs (150/83.3%) reported being aware of change in the malaria treatment policy but further questions to establish their knowledge of relevant components as it affects their practice showed only 10 (5.6%) had good knowledge, 74 (41.1%) had fair knowledge and 96 (53.3%) had poor knowledge of the policy.

Sale of antimalarials and reasons for the sale

About a quarter (43/23.9%) of respondents sold an ACT for the last case of malaria treated in an under-five child, AMTs were sold by 37/20.6%, while NATs were the most frequently sold AMDs (100/55.6%) (Figure 1). Figure 2 shows that 14/32.6% of the ACTs sold were AL while 27/62.8% were AA combination. In 127/70.6% of AMD sales, the PMV made the choice (Figure 3). A further analysis of the three determinants of drug sale shows that NATs were the most frequently sold AMD by PMVs (67/52.8%) and also the most

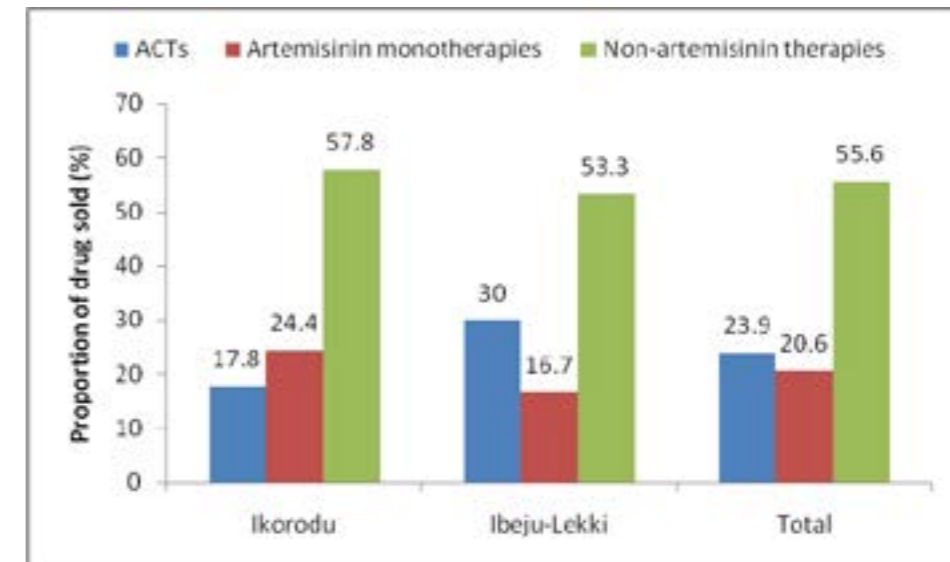


Figure 1: Antimalarial drug sold for the last under-five child treated for malaria

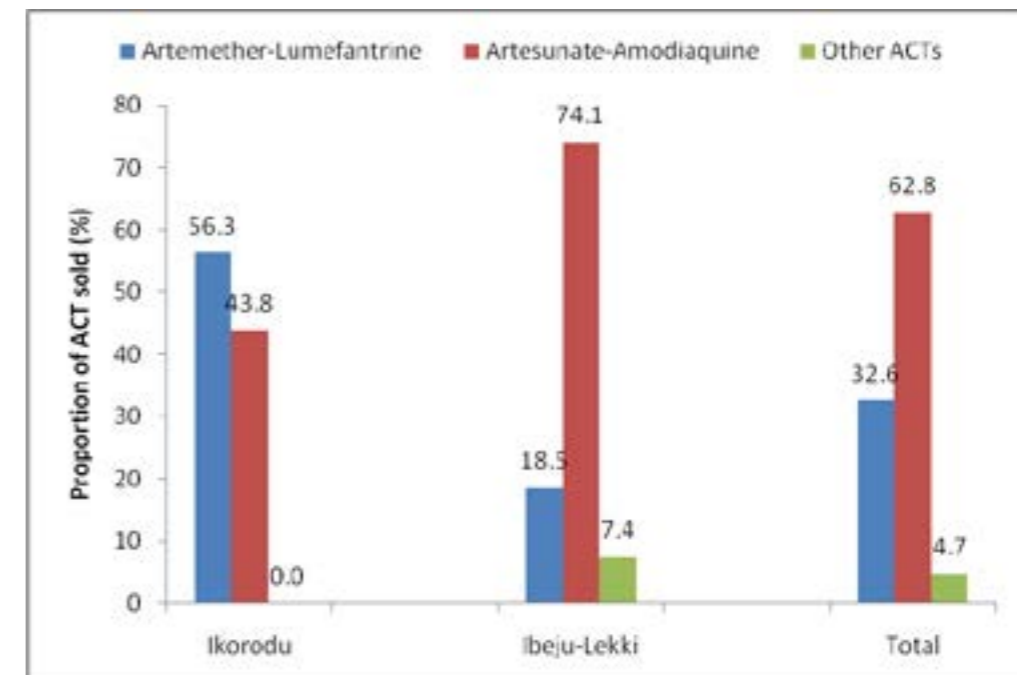


Figure 2: Types of ACT sold for the last under-five child treated with an ACT

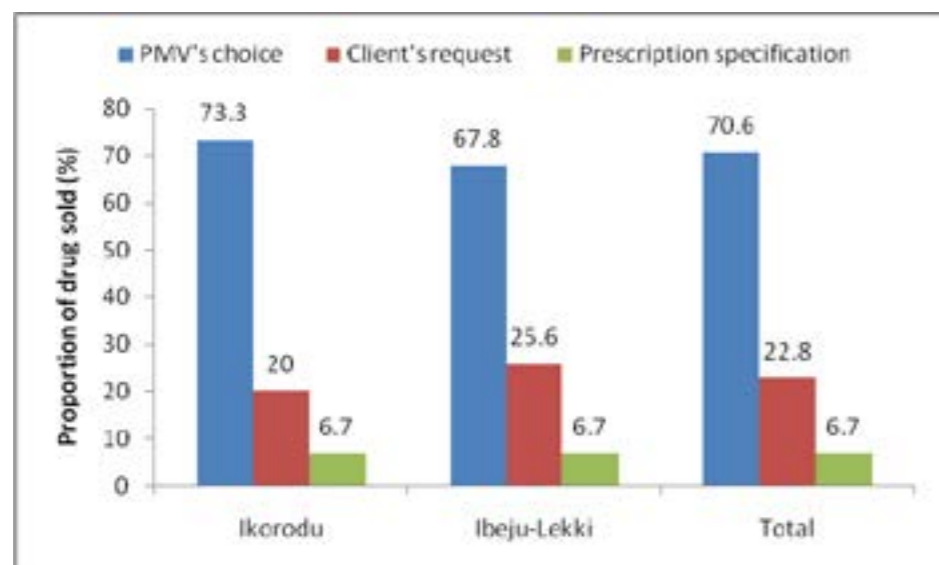


Figure 3: Determinant of antimalarial drug sold for the last under-five child treated for malaria

Table 2: Analysis of drug sold by the three determinants of sale

Antimalarial	Ikorodu Freq (%)	Ibeju-Lekki Freq (%)	Total Freq (%)	χ^2	p-value
Drug sale by PMV's choice					
ACTs	12 (18.2)	23 (37.7)	35 (27.6)	7.24	0.027
Artemisinin monotherapies	17 (25.8)	8 (13.1)	25 (19.7)		
Non-artemisinin therapies	37 (56.1)	30 (49.2)	67 (52.8)		
Total	66 (100.0)	61 (100.0)	127 (100.0)		
Drug sale by client's specific demand					
ACTs	1 (5.6)	2 (8.7)	3 (7.3)	0.648*	0.648*
Artemisinin monotherapies	2 (11.1)	5 (21.7)	7 (17.1)		
Non-artemisinin therapies	15 (83.3)	16 (69.6)	31 (75.6)		
Total	18 (100.0)	23 (100.0)	41 (100.0)		
Drug sale by prescription specification					
ACTs	2 (33.3)	3 (50.0)	5 (41.7)	0.567*	0.567*
Artemisinin monotherapy	2 (33.3)	3 (50.0)	5 (41.7)		
Non-artemisinin therapy	2 (33.3)	0	2 (16.7)		
Total	6 (100.0)	6 (100.0)	12 (100.0)		

*Fisher exact p-value

frequently demanded by clients (31/75.6%) (Table 2).

Antimalarial drug audit

Table 3 shows the various types of AMDs found in the drug shops. All the antimalarials examined had NAF-DAC number and none had expired. ACTs were found

in 58.9% of the shops but a significant difference exists between the two groups ($p < 0.001$). The NATs, mainly chloroquine (92.8%) and sulphadoxine-pyrimethamine (87.8%) dominated the shops followed by AMTs (75.6%).

Table 3: Antimalarial drugs found in the observed patent medicine shops

Antimalaria	Ikorodu n=90 Freq (%)	Ibeju-Lekki n=90 Freq (%)	Total N=180 Freq (%)	χ^2	p-value
CQ	80 (88.9)	87 (96.7)	167 (92.8)	2.98	0.084
SP	81 (90.0)	77 (85.6)	158 (87.8)	0.47	0.495
AMTs	66 (73.3)	70 (77.8)	136 (75.6)	0.27	0.603
ACTs	39 (43.3)	67 (74.4)	106 (58.9)	16.73	<0.001
Amodiaquine	17 (18.9)	10 (11.1)	27 (15.0)	1.57	0.210
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
Quinine	4 (4.4)	7 (7.8)	11 (6.1)	0.39	0.534
Others	0 (0.0)	3 (3.3)	3 (1.7)		0.246*

*Fisher exact p-value

Predictors of ACT sale by PMVs

Multiple logistic regression analysis was done to identify predictors of ACT sale among PMVs who made the choice of AMD for their clients. Independent variables in the model were respondent status, education, previous health-related training, previous CPD on malaria, years of practice, and awareness of change in the treatment policy. None of the factors was predictive of ACT sale.

Key informant interview

Knowledge of the current antimalarial treatment policy

The four officials interviewed were aware of change in the policy but none of them knew the year the new guidelines came into effect.

New drugs for treating malaria: All said ACTs are now the recommended drug for treating malaria in children and adults. A chairperson explained, "Chloroquine is so abused and is no longer effective. Combination is needed now, AL or AA". A secretary said, "we were told in Eko FM seminar that chloroquine and fansidar (an SP) are no longer active, that ACTs are the active ones."

Availability and affordability of the new drugs: they all agreed that the drugs were available but the prices were high compared with CQ and SP. A chairperson said, "... the prices of the new drugs are on the high

side. For example fansidar is N130 – N150 (\$0.93 - \$1), Amatem (a brand of AL) is N500 (\$3.8), not in favour of the poor masses." Another chairperson added, "initially so expensive, we don't stock them. SFH (Society for Family Health) came in and subsidized just for children. They supply only those who attended the seminar they organized." The drugs according to them were widely acceptable to buyers, only that many still could not afford them. Ikorodu secretary said, "they rely on what we tell them and they are convinced."

Discussion

This study examined the response of PMVs in rural Lagos regarding malaria treatment about five years after change in policy from chloroquine to ACTs for the treatment of uncomplicated malaria. The erstwhile first-line and second-line non-artemisinin therapies (NATs), i.e., chloroquine (CQ) and sulphadoxine-pyrimethamine (SP) respectively, were still the most commonly sold AMDs for the treatment of uncomplicated malaria in under-five children, a finding which is at variance with the new policy recommendation. The sale mirrors the stock of AMDs found on drug audit, which showed that CQ and SP still had dominion of the market. These findings are in consonance with other studies in Nigeria^{21,26,27} and elsewhere^{19,22} where, despite change in treatment policy, formerly used AMDs were still on

sale in drug shops even years after the change. The wide availability and sale of CQ and SP implies that many cases of uncomplicated malaria were still receiving inappropriate treatment with consequences including progression to severe illness, increased mortality and growing drug resistance.

Artemisinin monotherapies (AMTs) were the second most common group of antimalarials in stock while ACTs were the third with a significant difference between the two LGAs. Regarding sale, overall, ACTs came a distant second to the NATs in the type of AMDs sold but the pattern of sale was different in the two LGAs. The type of ACT sold also varies in the two LGAs and even though AL is the first line ACT, overall AA was the highest in sale volume. Both AA and AL are taken over three days but while AA is taken once daily, AL with a somewhat complex dosage regimen and more pills/syrup to swallow is taken twice daily. This may make AA more appealing to both the user (who would prefer a light drug burden) and the drug seller (who would have to explain how to use the drug). The differential ACT penetration and sale in the two LGAs shows that even in supposedly similar settings (both rural areas) diverse factors might be at play, including differences in drug supply chain and preferences of clients.

The continued presence of AMTs in the shops is worrisome. Suspected resistance to artemisinins has been identified²⁹ and there is growing concern that this may spread if AMTs continue to be used. WHO has recommended their withdrawal and replacement with ACTs but they are still widely on sale in many countries, most of which are in Africa.²⁹ The Pharmacists Council of Nigeria (PCN), which is the government regulatory agency that monitors the practice of PMVs³⁰ has not revised the approved list of antimalarials PMVs are allowed to sell³¹ to reflect the policy recommendation as at the time of this study. The continued presence of the previously recommended drugs on the approved list may thereby create confusion and weaken adoption of the new policy. In addition, the availability of non-approved AMDs in many shops is a pointer to weak regulation, enforcement and monitoring of the practice of the PMVs by PCN.

In this study, three factors determined malaria treatment options. First, many clients simply approached the medicine sellers without any predetermined drug and the choice was left to the PMVs. Second, some

buyers asked for a particular drug, and third a few came with a prescription. Just like a typical patient in a hospital leaves treatment decision for the clinician, more than 70% of the clients considered the PMV as the doctor whom they believed knew what was best for them. That only 27.6% of these PMVs sold ACTs despite more than 80% of them being aware of the change suggests that factors beyond their knowledge played a significant role. None of the hypothesized provider factors was predictive of ACT sale by the PMVs. The officers of the PMVs' association stated that many people could not afford the ACTs, though the drugs were acceptable to the communities. The PMVs seemed to respond to this by simply offering what they knew the people could afford i.e., CQ and SP. This was similar to the experience of PMVs in the in-depth study in Enugu Nigeria.³² All the respondents said they had heard of artemisinin derivatives but none had it in their shops. One of them captured their reason thus, "we cannot stock because of the high cost. If you do, no villager will buy it from you because they are very poor."

Majority of the clients who bought AMD from the PMVs specifically demanded NATs. This suggests low level of awareness of the new drugs by the caregivers. Community based studies revealed poor awareness of ACTs among households.^{15,21} This underscores the need for consumer education about the new treatment policy.

Limitations of the study

Odogunyan zone in Ikorodu LGA was purposively selected out of the four zones and might theoretically not be representative of the entire LGA. NAPPMED members were not involved in the study. This limits generalization of the findings to all vendors operating in the rural areas of Lagos state. Since information about the indicator of drug sale was retrospectively collected, recall bias cannot be completely ruled out.

Conclusions

Five years after change in antimalarial treatment policy, the high awareness among PMVs was yet to translate to a commensurate increase in the sale of the new drugs (ACTs). NATs and AMTs continued to dominate the market with dire consequences for malaria control. Factors beyond the PMVs like clients' knowledge of the policy change, exorbitant prices of the ACTs and continued availability of older antimalarial drugs in the market need to be addressed in order to optimize the

use of ACTs. The authors recommend that the government should implement sustainable initiatives that will make ACTs more affordable to the people; government and other stakeholders in malaria control should enlighten the citizenry on the new drugs and discourage demand and use of drugs that are no longer effective; the PCN should without further delay revise the approved list of antimalarial drugs PMVs are allowed to sell; and government should initiate effort to withdraw non-ACT antimalarials from the market.

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