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 the availability of the drug in the shop. Though there was high awareness of the new treatment policy at the grass root level, few PMVs were actually following it.

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.

Keywords: Patent Medicine Vendors, AMDs, policy change, malaria, artemisinin monotheophanises, non-artemisinin therapies

Introduction
Malaria remains a leading cause of morbidity and mortality in Nigeria as well as in other sub-Saharan African countries.1 Appropriate treatment of uncomplicated malaria currently means the use of artemisinin-based combination therapies (ACTs) as recommended by the World Health Organization (WHO).2 Nigeria adopted ACTs as the firstline treatment drugs (AMDs).10,11 Studies across Africa have shown the complexity of involving the two bodies. LSMDA and NAPPMED. The study 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 Medicine 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 2009.12 The Ikorodu branch of the Lagos State Medicine Dealers Association (LSMDA) had 482 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.13 A study conducted in Oyo state, which is in the same geopolitical zone with Lagos found that 79.3% of PMVs were aware of the new policy.14 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 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 2009.12 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 Igboho (141). Ibeju-Lekki is another rural LGA in the state with an estimated population of 129,467 for 2009.12 The Ibeju-Lekki branch of LSMDA had 157 registered PMVs operating in the LGA.

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
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 presence of NAFDAC number was verified 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 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 monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs). The ACTs were further classified into monotherapies (AMTs), and non-artemisinin therapies (NATs).

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 67 years. 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.

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 12/70.6% 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Ikorodu (n=90)</th>
<th>Ibeju-Lekki (n=180)</th>
<th>Total (n=270)</th>
<th>χ²</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respondent</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shop owner</td>
<td>78 (86.7)</td>
<td>70 (77.8)</td>
<td>148 (82.2)</td>
<td>4.38</td>
<td>0.112</td>
</tr>
<tr>
<td>Sales attendant</td>
<td>6 (6.7)</td>
<td>5 (5.6)</td>
<td>11 (6.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apprentice</td>
<td>6 (6.7)</td>
<td>15 (16.7)</td>
<td>21 (11.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age group (yrs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;21</td>
<td>2 (2.2)</td>
<td>8 (9.0)</td>
<td>10 (5.6)</td>
<td>7.11</td>
<td>0.008</td>
</tr>
<tr>
<td>21-29</td>
<td>32 (35.6)</td>
<td>40 (44.4)</td>
<td>72 (40.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>43 (47.8)</td>
<td>35 (38.9)</td>
<td>78 (43.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥40</td>
<td>13 (14.4)</td>
<td>7 (7.7)</td>
<td>20 (11.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean age</strong></td>
<td>32.2 ± 7.4</td>
<td>29.6 ± 7.9</td>
<td>30.9 ± 7.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>58 (64.4)</td>
<td>37 (41.1)</td>
<td>95 (52.8)</td>
<td>8.92</td>
<td>0.003</td>
</tr>
<tr>
<td>Male</td>
<td>52 (56.6)</td>
<td>53 (58.6)</td>
<td>85 (47.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>7 (7.8)</td>
<td>9 (10.0)</td>
<td>16 (8.9)</td>
<td>2.16</td>
<td>0.339</td>
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<tr>
<td>Secondary</td>
<td>70 (77.8)</td>
<td>74 (82.2)</td>
<td>144 (80.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>13 (14.4)</td>
<td>7 (7.7)</td>
<td>20 (11.1)</td>
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<td></td>
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<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Married</td>
<td>68 (75.6)</td>
<td>39 (43.3)</td>
<td>107 (59.4)</td>
<td>19.38</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Single</td>
<td>22 (24.4)</td>
<td>51 (56.7)</td>
<td>73 (40.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethnic group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Igbo</td>
<td>30 (33.3)</td>
<td>55 (61.1)</td>
<td>85 (47.2)</td>
<td>18.37</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Yoruba</td>
<td>39 (43.3)</td>
<td>30 (33.3)</td>
<td>69 (38.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>21 (23.3)</td>
<td>5 (5.6)</td>
<td>26 (14.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Christianity</td>
<td>76 (84.4)</td>
<td>80 (88.9)</td>
<td>156 (86.7)</td>
<td>0.43</td>
<td>0.511</td>
</tr>
<tr>
<td>Islam</td>
<td>14 (15.6)</td>
<td>10 (11.1)</td>
<td>24 (13.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Socio-demographic characteristics of respondents

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

![Figure 1: Antimalarial drug sold for the last under-five child treated for malaria](image)

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

![Figure 2: Types of ACT sold for the last under-five child treated with an ACT](image)
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 NAFDAC 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**

<table>
<thead>
<tr>
<th>Antimalaria</th>
<th>Ikorodu n=90 Freq (%)</th>
<th>Ibeju-Lekki n=90 Freq (%)</th>
<th>Total N=180 Freq (%)</th>
<th>χ²</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CQ</td>
<td>80 (88.9)</td>
<td>87 (96.7)</td>
<td>167 (92.8)</td>
<td>2.98</td>
<td>0.084</td>
</tr>
<tr>
<td>SP</td>
<td>81 (90.0)</td>
<td>77 (85.6)</td>
<td>158 (87.8)</td>
<td>0.47</td>
<td>0.495</td>
</tr>
<tr>
<td>AMTs</td>
<td>66 (73.3)</td>
<td>70 (77.8)</td>
<td>136 (75.6)</td>
<td>0.27</td>
<td>0.603</td>
</tr>
<tr>
<td>ACTs</td>
<td>39 (43.3)</td>
<td>67 (74.4)</td>
<td>106 (58.9)</td>
<td>16.73</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Artemisinin monotherapies</td>
<td>17 (18.9)</td>
<td>10 (11.1)</td>
<td>27 (15.0)</td>
<td>1.57</td>
<td>0.210</td>
</tr>
<tr>
<td>Non-artemisinin therapies</td>
<td>3 (3.3)</td>
<td>10 (11.1)</td>
<td>13 (7.2)</td>
<td>2.98</td>
<td>0.084</td>
</tr>
<tr>
<td>Pyrimethamine</td>
<td>2 (2.2)</td>
<td>10 (11.1)</td>
<td>12 (6.7)</td>
<td>4.38</td>
<td>0.036</td>
</tr>
<tr>
<td>Quinine</td>
<td>2 (2.2)</td>
<td>7 (7.8)</td>
<td>11 (6.1)</td>
<td>0.39</td>
<td>0.534</td>
</tr>
<tr>
<td>Others</td>
<td>0 (0.0)</td>
<td>3 (3.3)</td>
<td>3 (1.7)</td>
<td>0.246*</td>
<td></td>
</tr>
</tbody>
</table>

*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 and elsewhere where, despite change in treatment policy, formerly used AMDs were still on...
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 up 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 identified26 and there is growing concern that this may spread if AMTs continue to be used. WHO has recommended their withdrawal and replacement with ACTs. NATs and AMTs continued to dominate in supposedly similar settings (both rural areas) diverse factors might be at play, including differences in drug supply chain and preferences of clients. The authors recommend that the government should enlighten the citizenry on the new drugs and government should initiate effort to withdraw non-ACT antimalarials from the market.

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.16,30 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 differentiate 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.

References
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