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Preface

The aim of the Future Health Systems (FHS) Research Programme Consortium Future Health Systems is to find ways to translate political and financial commitments to meet the health needs of the poor. The consortium addresses fundamental questions about the design of future health systems, and work closely with actors who are leading the transformation of health systems in their new realities. This consortium addresses fundamental questions about the design of future health systems, and works closely with people who are leading the transformation of health systems in their own countries. Our research themes are:

- Protecting the poor against the impact of health-related shocks
- Developing innovations in health provision
- Understanding health policy processes and the role of research

Working papers are intended to make available initial findings and ideas from the research of members of the consortium. These are scholarly inquiries aimed at provoking further discussion and investigation. Comments and suggestions on these papers are welcome, and can be directed to the authors.

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Malaria treatment and policy in three regions in Nigeria: The role of Patent Medicine Vendors

Summary

Malaria is a major cause of illness and death in Nigeria, and a significant drain on its economy and the poor. Yet most Nigerians do not obtain appropriate treatment for malaria, and depend on informal private providers for anti-malarial drugs (AMDs), largely through patent medicine vendors (PMVs). Little is known about PMVs, or the poorly regulated market in which they operate. Increasing levels of substandard or fake drugs is a major concern about the drugs supplied to Nigerians. Understanding this market is particularly important, as rising malarial drug resistance has prompted changes in government malaria treatment guidelines, which now recommend the use of more expensive and less available artemisinin-combined therapy (ACT). Yet the reality for most Nigerians is that the market has been little affected by these policies, and access to quality malaria treatment remains low. This study seeks to better understand the role played by PMVs in the provision of AMDs in Nigeria, and to explore ways to improve the regulation and delivery of AMDs.

This scoping study involves cross-sectional surveys of 110 PMVs and 113 households using a multi-stage random selection of respondents from 6 urban and 6 rural local government areas in three states (Oyo, Kaduna, and Enugu States), each representing a different geographic and linguistic-ethnic region of the country. These were supplemented by key informant interviews with 54 community leaders, 55 PMV Association officers, 31 government and health officials, and observations of 106 drug shop inventories from the same communities.

In addition to describing characteristics about PMVs and PMV associations that have not been previously documented, this study focused on the role they play in malaria treatment. Although PMV demographic characteristics, knowledge, attitudes, and sources of drugs varied considerably across study sites, in each of the states examined, PMVs were the major source of malaria treatment (39% overall), followed by self-treatment (25%), which in many cases also utilize the PMVs. Less than one quarter of all PMVs interviewed knew about the change in recommended malaria treatment from chloroquine and to=ACTs. PMVs still recommended and provided drugs whose efficacy is highly questionable: 92% of shops had sulfadoxine-pyrimethamine in stock, 72% had chloroquine (both not recommended), whereas only 9% had ACTs. More shops (32%) had monotherapy artesunates than ACTs, even though monotherapy is not recommended due to the risk of promoting drug resistance to artemisinins. Another common finding among all types of informants was the high level of concern about the quality of

the drugs. Although more government regulation was suggested by all parties, PMV Associations were also identified as potentially playing important roles in providing information, influencing PMV behaviour, and procuring drugs. Community involvement in drug regulation was also viewed as highly desirable by PMVs (92%).

Further research topics are discussed in the paper, along with areas where action is needed to address the problems of inappropriate treatment and poor quality drugs. Interventions need to reduce the opportunities for PMVs to knowingly supply sub-standard drugs, which is likely to involve a combination of more effective government regulation and self-regulation by PMV associations. An active role for communities and introduction of new technologies to facilitate monitoring and communications are also worth investigating.

Background

Malaria is a major cause of illness and death in Nigeria, and a significant drain on its economy and the poor. Yet most Nigerians do not obtain appropriate treatment for malaria, and depend on informal private providers for anti-malarial drugs (AMDs), largely through patent medicine vendors (PMVs). PMVs comprise a poorly understood and badly regulated market in Nigeria. Government policies have tried to keep pace with rising malarial resistance to conventional AMDs and increasing counterfeit and substandard drugs. Yet the reality for most Nigerians is that the market has been little affected by these policies, and access to quality malaria treatment remains low. Given the central importance of malaria and PMVs in the treatment of malaria, this study seeks to better understand the role played by PMVs in the provision of AMDs in Nigeria, and to explore ways to improve the regulation and delivery of AMDs.

Burden of Malaria in Nigeria

The burden of malaria in Nigeria has been well documented. According to the Nigeria Demographic and Health Survey (NDHS) of 2003, 32% of children below five years of age suffered from an episode of malaria in the two weeks prior to the interview (National Population Commission and ORC Macro, 2004). The overall childhood mortality in Nigeria is 194 per 1000 births (WHO, 2007), much of which can be attributed to malaria. Salako *et al.* (2001) reported that 26% of under five mortality in three rural communities in Nigeria was due to malaria, as verified through verbal autopsy. This is similar to the situation reported over 30 years ago, when 27% of child deaths in another rural community in Oyo State were attributed to malaria (Ola-Fadunsi *et al*., 1981). This is also supported by the Federal Ministry of Health Situation Analysis (FMOH, 2000) which claimed that malaria accounts for 30% of childhood mortality. If one assumes that 25% of childhood mortality is due to malaria, this translates to 48.5 deaths per 1000 live births annually. According to the Nigerian government, “Malaria impedes human development and is both a cause and consequence of under development. Every year, the nation loses over 132 billion Naira (over US$1 billion) from cost of treatment and absenteeism from work, schools and farms” (Federal Republic of Nigeria, 2005). Despite limitations in estimating the true prevalence of malaria, it has been estimated that malaria causes a loss of between 1-5% of total GNP annually in Nigeria (Leighton *et al*., 1993). At the household level, it is estimated that between 3-11% of annual household income could be lost due to malaria from both lost workdays and treatment and control expenditures (Leighton *et al*., 1993).

Changing Efficacy of Anti-Malarial Drugs and National Treatment Policies

The problem posed by malaria has worsened in recent years as resistance to conventional drugs has changed. Prior to the adoption of the current Nigerian National Antimalarial Treatment Policy in 2005, drug efficacy testing found significant resistance to the medicines that had been used for treating malaria in Nigeria. Of the six geopolitical zones of the country, the levels of resistance to chloroquine (CQ) was above 75% in all but the Northwest zone, with the therapeutic efficacy ranging from 4%-77% (Federal Government of Nigeria, 2005). The therapeutic efficacy of sulfadoxine-pyrimethamine (SP) ranged from 9%-94%, with levels of resistance above 75% in the South-South, Northeast and Southeast zones. In contrast, the efficacy for two artemisinin-based combination therapy (ACT) drugs, artemether-lumefantrine (87%-100%) and artesunate-amodiaquine (82.5%-100%), was very high. These findings led to the adoption of the current national treatment guidelines listing artemether-lumefantrine as the drug recommended for first line use, and artesunate-amodiaquine as a second line choice. The national treatment policies on ACTs are in keeping with the WHO Treatment Guidelines (WHO, 2006) which recommends ACTs as the first line antimalarial drugs, and that monotherapy artesunate drugs should not be used anywhere due to the risk of promoting drug resistance.

The job of convincing health workers and the general population that previous treatment guidelines were correct but that they now needed to be changed substantially has been a major challenge. The introduction of the national policy favouring ACTs was not without controversy and confusion, as reported in the popular press in Nigeria. *This Day* reported on February 12, 2005, that: “Worried by the negative public reaction to the purported ban of chloroquine as a frontline drug for malaria in the country, Minister of Health, Professor Eyitayo Lambo, has allayed fears,” by explaining that although chloroquine was not banned, it had lost its effectiveness (Haruna, 2005). The *Vanguard* of February 06, 2005, quoted the Chairman of the Lagos State branch of the Pharmaceutical Society of Nigeria as saying that the new malaria treatment policy “may not achieve its desired purpose except there is complete sanitization of the nation’s chaotic drug distribution system” (Ogundipe, 2005). The problem persisted over a year later. The *Daily Trust* of June 16, 2006 reported that “Doctors are prescribing anti-malarial drugs which experts say are ineffective because alternatives are too expensive for the average Nigerian” (Mohammad *et al*., 2006). The Daily Trust explained that doctors would ignore the policy and that government had done little to improve the living conditions of Nigerians.

Patent Medicine Vendors as the Primary Source of Malaria Treatment

Several studies have demonstrated that PMVs are the most common source of malaria treatment in Nigeria. For example, a survey in three rural communities found that PMVs were the first choice for malaria medicines for 49% of children below five years of age (Salako *et al.*, 2001). The next most common choices were private clinics (14%), government clinics (11%), and herbs concocted at home (11%). A study of urban malaria in Lagos also found that PMVs were the most common source of malaria treatment (36%), followed by government (29%) and private (22%) clinics (Brieger *et al.*, 2001). A recent study in Edo State reported that medicine shop was used for child malaria treatment by 44%, followed by public or private hospital/clinic (28%) (Enato & Okhamafe, 2006).

Despite their prominence, relatively little is known about PMVs and how they work. PMVs are known to belong to PMV associations, yet there are virtually no published studies on how PMV associations operate. The Pharmacy Law of Nigeria specifies that PMVs should sell only pre-packaged patent medicines, and requires that the licensee be at least 21 years of age and submit the names of two referees (Egboh, 1984). The educational level is not specified as a requirement, but by convention, the minimum educational attainment of PMVs has been primary schooling (Ojuawo & Oyaniyi, 1993). Yet upon entering a medical shop, one is likely to fine the actual owner in about two-thirds of the shops, and a clerk or apprentice in the remainder (Ajayi *et al.,* 2003). Within their shops, PMVs have been observed to behave primarily as commercial salesmen, since around 75% simply sell what a customer requests, and on other rare occasions, fills a prescription (Brieger *et al*., 2004). Yet the remainder of the time, the PMV responds to customer requests for advice or a description of symptoms.

Access and Quality Problems with Malaria Treatment

Most Nigerians have difficulty obtaining the correct treatment for malaria. The NDHS noted that only one-third (34%) of children who reported an episode of malaria were actually given an antimalarial drug (National Population Commission & ORC Macro, 2004). Another survey in five states found that only 23% of children aged 0-23 months who reported symptoms consistent with malaria two weeks prior to the survey received appropriate antimalarial therapy (Keating, 2005). Even if the child gets an AMD, the treatments provided may not be effective. A rapid assessment of 40 pharmacy and medicine shops conducted in four states just prior to the launching of the national policy on malaria treatment found that only 15% of outlets stocked the recommended first line treatment (artemether-lumefantrine), less than those that had non-recommended artesunates (30% had artesunate monotherapies) (Tetteh and Adeya, 2005). On

the other hand, conventional AMDs that are no longer efficacious were widespread, as nearly all shops had chloroquine and sulfadoxine-pyrimethamine tablets, and many had other antimalarial drugs such as halofantrine (38%) and proguanil hydrochloride (23%).

In addition to having the wrong AMD, the problem of obtaining effective care for malaria is further compounded by rising problems with drug quality. Taylor and others (2001) investigated the quality of different drugs obtained from 53 retail pharmacies and in Nigeria, and showed that 48% of the drugs analyzed did not comply with set pharmacopoeia limits. A more pessimistic view was presented by Hewlett-Packard (2003), which estimated in 2003 that 80% of drugs on the Nigerian market were counterfeit, and identified a major enforcement problem with the lack of secure packaging, labelling and coding of products.

Regulation of Malaria Drugs

The malaria drug regulatory environment in Nigeria is complex, and has several key stakeholders (Tetteh and Adeya, 2005). The Federal Ministry of Health (FMOH) through its National Malaria Control Program (NMCP) determines the scientific basis for recommending appropriate treatment. A National Malaria Control Committee of experts supports the NMCP for this purpose. In addition the FMOH has developed an essential drugs list for the various levels of care in the public health service. The National Agency for Food and Drugs Administration and Control (NAFDAC) is the formal regulatory body that tests, approves and registers medicines, as ultimately indicated by a NAFDAC number on the packet. NAFDAC also inspects manufacturing premises, regulates advertising and oversees pharmaco-vigilance. It issues a registration number that manufacturers must put on each package. Its inspectors have concentrated on monitoring the products supplied by wholesalers and open markets. The inspectors also visit retail facilities to check that products have a registration number and a sample of them for efficacy. Although the national malaria treatment policy recommends ACTs as the main treatments for malaria, NAFDAC has registered a wide variety of antimalarial drugs.

The Pharmaceutical Council of Nigeria (PCN) is responsible for registration and regulation of all pharmaceutical premises, and the regulation of the professional practices at pharmacies. Until recently, the role of the PCN in regulating PMV premises has been unclear. Traditionally PMV licenses were issued by the respective State Ministries of Health (SMOHs). If PMVs are found guilty of an offence, such as selling prescription drugs or substandard or out-of-date products, they may lose their license. For the past few years there has been a continuing struggle among the FMOH, SMOHs and PCN that has resulted in a suspension of issuance of

PMV licenses until the issue of authority can be resolved. This is clearly a period of transition with poorly defined lines of regulatory authority with respect to PMVs.

Purpose of the Study

Given the massive and complex challenges of providing appropriate and quality treatment for malaria in the Nigerian context, it is important to better understand how the largest market for malaria treatment actually works, and identify options for the future. The scoping study reported here is intended to provide insights on malaria treatment provided in representative areas of Nigeria, and particularly to understand the knowledge, attitudes, and practices of PMVs and their associations, and how they relate to communities and government agencies. Although these studies provide a small snapshot of conditions at one point in time in three areas of Nigeria, they are intended be a basis for future interventions and research to improve the quality of malaria treatment, particularly for the poor. The specific research questions to be addressed in the three geographic areas of Nigeria, from the perspective of community members, PMVs, PMV associations, and government officials, include:

1. What is the potential role of PMVs in improving the provision of effective anti-malarial drugs?
2. What are the barriers and opportunities for providing good quality and appropriate anti-malarial drugs?

Methodology

Sampling and Instruments

The study used multiple instruments (see Table 1) and followed a multi-stage random sampling scheme. Three states were purposively selected to represent each of the major geographic and linguistic-ethnic areas of Nigeria: Oyo State (Southwest, Yoruba), Kaduna State (Northcentral, Hausa), and Enugu State (Southeast, Igbo). Local Government Areas (LGAs) were stratified to urban and rural LGAs, with two LGAs randomly sampled from each strata, yielding 2 urban and 2 rural LGAs in each state (12 LGAs in total). In urban LGAs, 1 ward was randomly sampled for each urban LGA, and in rural LGAs, one community was randomly selected from a list of all communities in the LGA.

Each study instrument was used as follows:

1. Household Survey: In each sampled site, the research team went to the central crossroads of the village/ward, randomly selected one quadrant, and with a random starting point, and random direction, and fixed sampling interval, selected 10 households per site. If more than one household was found in a building, one household was selected randomly. The head of household was chosen as the respondent in the household, but if he/she was not in, a random selection of one adult, alternating between male and female respondents. The response rate was 94%. The survey included questions concerning malaria treatment, the role of government and PMVs, quality of anti-malarial drugs, and poverty concerns.
2. Community Key Informant Interviews. Upon entering each of the randomly selected communities/wards, researchers asked community members to identify five key opinion leaders: community leaders, religious leaders, women leaders, and youth leaders in the community. These were selected for individual in-depth interviews. The interviews covered topics related to malaria practices, poverty, and the role of government and PMVs.
3. PMV Survey. In each selected site, a listing was made of all the PMVs in each sampled ward/community, constructed by information provided by the PMV association, community health workers, and community leaders. Of the 111 PMVs identified in the study, interviews were completed with 110 (99% response rate). Questions explored their knowledge and practices about malaria treatment, drug quality, and regulation.

4. PMV Association Interviews. In each of the 12 randomly selected LGAs, a PMV association was identified. For each PMV association, the 4-5 principal officers were identified (chairman, secretary, treasurer and/or public relations officer) and interviewed. The response rate was 100%. The topics included descriptions of their membership and activities, and particularly their role in regulation.
5. Government and Regulatory Body Key Informant Interviews. A list was constructed of key officials from federal drug regulatory agencies, State health officials, and LGA political and health and malaria officials. The topics addressed malaria and drug policy and regulation.
6. Medicine Shop Inventory Observations. In each of the randomly selected communities/wards, medicine stores were identified from a list of all the PMV stores. Respondents were asked to show all the drugs used for malaria at their shop, and the stocks were the physically examined according to a checklist. Of the drugs shown to be used for malaria, one of each type was selected and examined for price, dosage form, expiry date, and NAFDAC number.

The two survey instruments (Household and PMV surveys) were translated from English to the local language (Yoruba, Hausa and Igbo) and later back translated into English with a view to ensure accuracy of translation. The key informant interviews were conducted in the local language, the notes were taken in the local language, and then translated into English when transcribed into word processing software.

Ethical approval for the study was provided by the University College Hospital **-** University of Ibadan joint Institutional Review Committee. Verbal informed and voluntary consent was obtained from each study participant.

Table 1: Study Instruments and Sample Sizes

			Number of respondents			
Instrument	**Content**	**Type of respondent**	**Oyo**	**Kaduna**	**Enugu**	**Total**
1. Household Survey	Malaria treatment seeking behaviours; AMDs used; knowledge and perceptions on AMD policies	Household Heads	38	37	38	113
2. Community Key Informant Interviews	Malaria treatment seeking; mechanisms for AMD quality and regulation	Community leaders (elders, religious, women, youth leaders)	20	14	20	54
3. PMV Survey	Socio-demographic characteristics; Knowledge, opinions and practices about AMDs, government AMD policy, and regulation	PMVs	40	34	36	110
4. PMV Association Interviews	PMV Association drug regulatory functions and networking	PMV Associations PMV Association officers	4 24	4 9	4 22	12 55
5. Government and Regulatory Body Informant Interviews	Malaria and AMD policy formulation and implementation	LGA, State, and Federal principal officials	16	8	7	31
6. Medicine Shop Inventory Observations	Types of AMDs stocked, presence of NAFDAC number, expiry dates	Medicine shops Malaria brands	48 315	40 113	18 153	106 581

Analysis

For the survey instruments, data were analyzed with frequencies and cross-tabulations, using Chi-square test to detect statistically significant differences (p value<0.05) between state samples. For the key informant interviews, all the data generated were transcribed daily on return from the field. These were later edited and typed using a standard word processing format. Edited reports of each of the interviews were prepared theme by theme. Key findings that cut across various groups were noted and sorted. General and specific responses were identified using content analysis.

Results

PMVs are Largest Source of Malaria Treatment

The household survey confirmed that PMVs are the largest source of treatment for malaria across all the study sites (Table 2). The second most common source of treatment was self treatment with modern medicine, which could have been obtained from PMVs or taken from treatment left over from previous illnesses. Public clinics or hospitals comprised only 16 percent of all treatment of malaria, providing the most care in Kaduna State (24%), and the least in Oyo State (6%). Among those who used a PMV or self-medication, the most popular drugs were two brands of sulfadoxine-pyrimethamine and chloroquine.

Table 2: First Source of Care for Treatment of the Most Recent Episode of Malaria (Percent)

	Oyo	Kaduna	Enugu	Total
Patent Medicine Vendor	47.2	37.9	30.6	38.6
Government clinic or hospital	5.6	24.1	19.4	15.8
Private clinic or hospital	8.3	10.3	19.4	12.9
Self-treatment with modern medicine	27.8	17.2	27.8	24.8
Self-treatment with herbs and concoctions	8.3	10.3	2.8	6.9
Households (n)	*(36)*	*(29)*	*(36)*	*(101)*

Source: Household Survey

Characteristics of Patent Medicine Vendors

Table 3 shows the socio-demographic characteristics of the 110 PMVs identified in the three states. There were relatively equal numbers of PMVs from urban and rural areas, but there was a large difference in the gender of PMVs across states, with about 75% of the Oyo State sample being female, compared to only 18% in Kaduna State ($p<0.001$). Educational levels of PMVs were similar across the states, with the vast majority (81%) having at least secondary school education. Most of the PMVs reported receiving some training, though there were significant differences between the states, with nearly all (94%) of PMVs from Enugu State having some training, whereas only 62% in Kaduna had some training ($p=0.002$).

Table 3: Background Characteristics of Patent Medicine Vendors (Percent)

Characteristic	Oyo	Kaduna	Enugu	Total	P Value
Sex					<0.001
Female	75.0	18.2	25.0	41.9	
Male	25.0	81.8	75.0	58.1	
Location					0.2
Urban	55.0	57.6	38.9	50.5	
Rural	45.0	42.4	61.1	49.5	
Education Level					0.6
Primary	2.6	6.1	11.4	6.5	
Secondary	84.6	78.8	80.0	81.3	
Tertiary	12.8	15.2	8.6	12.1	
Any In-service Training	85.0	61.8	94.4	80.9	0.002
Patent Medical Vendors (n)	*(40)*	*(34)*	*(36)*	*(110)*	

Source: PMV Survey

Malaria Treatment by Patent Medicine Vendors

In the PMV survey, all PMVs were able to identify chloroquine as an AMD. They were also familiar with two of the most common brands of sulfadoxine-pyrimethamine, *Fansidar* (91%) and *Amalar* (89%). Most had heard about the ACTs. *Coartem* brand was identified by 65%, while 62% identified other artesunate-amodiaquine drugs. When asked about other AMDs they knew, other brands of sulfadoxine-pyrimethamine were most commonly mentioned (25%).

Visits were also made to 106 PMV shops in the same sites in the three states that identified the types of malaria drugs they provide (Table 4). Stores carried an average of 5.5 brands of drugs which they said were for treating malaria. Sulfadoxine-pyrimethamine was the most common drug in all shops (92% of shops), followed by chloroquine (72%). Only 9% had ACTs in stock, while 32% had monotherapy artesunate drugs. Shops in Enugu were more likely to carry ACTs (28%) and other types of antimalarials (67%).

Table 4: Type of Malaria Drugs Found in Shops (Percent of Shops with at Least One Type of the Drug)

Malaria Drug	Oyo	Kaduna	Enugu	Total
ACTs	2.1	7.5	27.8	8.5
Monotherapy artusenates	29.2	27.5	50.0	32.1
Chloroquine	81.3	60.0	72.2	71.7
Sulfadoxine-pyrimethamine	89.6	95.0	88.9	91.5
Other	27.1	7.5	66.7	26.4
None	35.8	5.0	5.6	23.6
Number of Shops (n)	(48)	(40)	(18)	(106)

Source: PMV Shop Inventory Survey

The recommended drugs for treating malaria, ACTs, were also the most expensive, averaging 504 Naira (US$ 4.03) for a treatment dose, whereas chloroquine was the cheapest at 83 Naira (US$ 0.66) per treatment dose. Artesunate monotherapy drugs, which are not recommended, cost on average 393 Naira (US$ 3.14), less than the cost of the recommended ACTs. Sulfadoxine-pyrimethamine had a mean price of 91 Naira (US$ 0.73) and the others cost on average 272 Naira (US$ 2.18). Among the 548 actual antimalarial packs/doses investigated, 28% were specifically packaged as child doses. None of the ACTs were available in child doses.

Patent Medicine Vendor Knowledge and Information on Malaria Drug Treatment and Regulation

Since the recommended guidelines for malaria treatment has changed in recent years, it is important also to understand how well these changes are known. Although nearly all (90%) local government officials were aware of the new government guidelines regarding the use of artemisinins, they doubted whether PMVs were following them. They reported very low levels of compliance with these guidelines, especially by private providers. There was a general agreement that substantial efforts are needed to inform these providers and also the general public about the new treatment guidelines. The research team was unable to assess the volume of activities underway to achieve this.

The survey of PMVs was able to provide some insights on how effectively information on the new treatment guidelines has been communicated to them (Table 5). Relatively few PMVs were aware of the new government policy on AMDs, though there are large differences between states. About 43% of PMVs claimed to know about new government policy on AMDs, ranging from 80% in Oyo State to 16% in Enugu State ($p<0.001$). However, much fewer were able to

identify that the new government policy included a change in the treatment guidelines for chloroquine and ACTs, with PMVs in Kaduna and Enugu States having much lower levels of knowledge (p<0.001).

Table 5: Patent Medicine Vendor Awareness of Government Drug Regulations and Policies on Anti-Malarial Drugs (Percent)

Response	Oyo	Kaduna	Enugu	Total	P Value
Aware of New Government Policy on AMDs	79.5	25.8	15.6	43.1	<0.001
Knowledge of Change in Policy Concerning Chloroquine or ACTs	51.3	9.7	6.3	24.5	<0.001
PMVs reporting the following sources of information on drug regulation					<0.001
Government (%)	2.6	54.5	36.4	29.8	
Drug Company (%)	81.6	30.3	21.2	46.2	
Patent Medicine Vendors (n)	*(40)*	*(34)*	*(36)*	*(110)*	

Source: PMV Survey

Information about drug regulations is also important if good quality AMDs are to be provided. The patent medicine vendors reported different sources of information on drug regulations, which also varied considerably between states. In Kaduna State, more participants cited government (55%) than drug companies (30%) as a source of information about drug regulation. Although PMVs in Oyo State were more likely to be aware of government policies on AMDs, they were less likely to get their information on drug regulation from the government (3%) compared to drug companies (82%). The pattern in Enugu was intermediate between the other two states.

Source of Medicines for Patent Medicine Vendors

Patent medicine vendors in different states procure their drugs from different sources (Table 6). Open markets are large commercial centres found in urban areas where many drug wholesalers congregate to sell drugs in bulk. Overall, most PMVs procured their drugs from the open market, particularly in Oyo State, whereas those in Kaduna State tended to rely on dealing separately with manufacturers or individually with their agents. There were also large differences in how satisfied PMVs are with their source of drugs procurement. Although most rated their experience as satisfactory or highly satisfactory, PMVs in Oyo State tended to be highly satisfied (72%), whereas only about a fifth of respondents in Kaduna and Enugu were equally satisfied (p<0.001).

Table 6: Source of Drugs for Patent Medicine Vendors

Source(s)	Oyo	Kaduna	Enugu	Total	P Value
Type of Source					<0.001
Open Market	74.4	25.0	51.5	51.9	
Manufacturers/Distributors/Agents	0.0	40.6	12.1	16.3	
Both	25.6	34.4	36.4	31.7	
Satisfaction with the Source					<0.001
Highly Satisfactory	71.8	21.9	20.6	40.0	
Satisfactory	28.2	56.3	50.0	43.8	
Fairly Satisfactory	0.0	18.8	14.7	10.5	
Not Satisfactory	0.0	3.1	14.7	5.7	
Patent Medicine Vendors (n)	*(40)*	*(34)*	*(36)*	*(110)*	

Source: PMV Survey

Patent Medicine Vendors Associations: How They Work

Patent medicine vendors are organised in associations, most of which have been operating for many years. In the PMV Association Interviews, it was found that all of the nine associations in Oyo and Enugu States were established at least 25 years ago, and four have been in existence for over 50 years. In Kaduna State, on the other hand, two of the associations were less than 20 years old. All 12 of the ward level PMV associations had 100 or more members, except for two in Kaduna and two in Enugu, which had between 30 and 75 members. These ward associations are also affiliated to PMV associations at LGA, state and federal levels.

Of the 55 association officers interviewed, 46 had been in their post for three or more years. The officers said that the objectives of their association were to defend members' interests, help when problems arise and provide opportunities to improve their knowledge. Most associations do not assist members with the sourcing of drugs, although a few said they provide this kind of service. The ward associations commonly hold monthly meetings.

The ward associations reported that they have the power to fine members for bad practices, such as selling sub-standard drugs, selling antibiotics, refusing to pay association dues, failing to refer patients, missing association meetings and operating without a license. The officials suggested that these fines were effective in reducing undesirable behaviour as well as providing a source of revenue to the association.

The informants were asked about the problems their association members face. The most commonly mentioned problem involved harassment by regulatory agencies (52% of informants), followed by problems with financial constraints (33%) and other problems relating to difficulty in finding good quality drugs and in securing licenses from government. Although

PMVs are rarely examined by NAFDAC or licensing authorities, there are problems with police visits. The police visit shops to check that they have an up-to-date license and that they are not stocking prescription drugs or out-of-date products. However, according to the PMV associations, these visits are often motivated by an attempt to extract money from the shop owners. There are also incidences when officers of the Nigeria Drug Law Enforcement Agency (NDLEA), whose responsibility is to control the distribution of illicit drugs, arrest PMVs or ask for bribes. The PMVs are highly vulnerable to these visits, since they risk losing their license if convicted of an offence.

The PMV association officials also discussed their relationships with government. On the one hand, they complained of unfair enforcement of licensing rules and extortion of money from their members. On the other hand, they reported cordial relations with regulatory agencies and local state health facilities. From time to time they need to consult state-level officials to sort out a problem of an association member. They also spoke of cooperative relationships with the LGA health department.

Concerns about the Quality of Anti-Malarial Drugs

In all the surveys and interviews, the quality of anti-malarial drugs was identified as an important concern. The in-depth interviews with Community Leaders enumerated the following problems with drug quality: prevalence of fake and substandard drugs, side effects or adverse body reactions, drug resistance, and too many different antimalarial drugs in the market. Officers of PMV associations also cited drug quality as an important issue, and focused on initiatives that could be taken to address the problem of low quality drugs.

In the household survey, community members were asked how they identify good quality drugs. Most (62%) of the respondents judged quality to be when someone uses the drug and it is effective. Other common ideas about quality include presence of NAFDAC registration numbers and manufacturing dates (20%), a recognizable brand/manufacturer's name (11%), high cost (5%), and recommended or sold by reputable doctor or pharmacist (4%). When asked more specifically what they would look for as evidence of quality, household survey respondents cited examples such as the presence of an expiry date (43%) and a NAFDAC number (42%). Other common responses included having a trade mark (10%), presence of a manufacturer's name (8%), being sold in a chemist's shop (4%) and experience of other users (4%). When asked specifically about modern antimalarial drugs, 12% stated clearly that these drugs were not as effective as before, and 6% were concerned about side effects. The remainder had a positive opinion on AMDs.

Patent medicine vendors were also asked about several dimensions of the problem of sub-standard AMDs. When asked how they identified "fake" drugs, they identified them as having the following characteristics: lack of NAFDAC number (43%), rough packaging (27%), no manufacturer's name (12%) and no expiry date (8%). A variety of other ideas included "drugs from Onitsha town", cheap drugs, and characteristics such as unusual smell, colour, taste and "breaks easily". On the other hand, genuine drugs are recognized by having a NAFDAC number (55%), neat packaging (33%), clear manufacturer's name and address on packet (20%), an expiry date (21%), and being costly (9%).

Yet according to PMVs, knowledge about fake drugs may not be the most important factor in the selling of fake drugs. When asked why some PMVs sell fake AMDs, a large proportion said the primary reason was due to greed (78%), and the remainder cited ignorance (Table 8). The fact that so many of them attributed the selling of fake AMDs to unethical practice suggests the existence of un-stated norms of behaviour. This view is underlined by the strong support for some form of regulation to reduce negative opportunistic behaviour. The proportion citing greed was much higher in Oyo, where a much larger percentage of PMVs buy drugs in open pharmaceuticals markets.

Actions to Reduce Fake Drugs

Suggestions to prevent the sale of fake drugs were offered by 92% of the PMVs interviewed in the PMV survey. Arrest was suggested by 19%, and resist buying drugs without NAFDAC numbers was suggested by 17%. Monitoring by a government agency was mentioned by 15%, while 9% suggested not buying drugs without manufacturer's name and address. Many other responses involved buying drugs that had the characteristics of genuine drugs as mentioned above.

A substantial proportion of PMVs (64%) said that stronger government regulation was needed to reduce the availability of fake drugs, while nearly a quarter called for PMV self-regulation through the associations (Table 7). Only six percent said that drug companies could play an important role in drug regulation. The proportions varied between states, reflecting the very different market arrangements. The highest proportion advocating stronger government regulation was in Kaduna (85%) and the lowest proportion was in Oyo (51%). In Oyo State, 42% called for PMV self-regulation. Despite the call for stronger government regulation, around a fifth of people expressed concern that corruption would impede the appropriate enforcement of drug regulations.

Table 7: Patent Medicine Vendor Attitudes on Low Quality Drugs (Percent)

	Oyo	Kaduna	Enugu	Total	P Value
Primary reason cited for prescribing low quality drugs					0.04
Ignorance (%)	8.3	33.3	25.8	21.6	
Profit/Greed(%)	91.7	66.7	74.2	78.4	
PMVs citing different potential sources of regulation to reduce the availability of low quality anti-malarial drugs					
Government Regulation (%)	50.0	84.8	60.6	64.4	0.008
PMV Self Regulation (%)	42.1	6.1	21.2	24.0	0.02
Drug Company Regulation (%)	2.6	6.1	9.1	5.8	0.5
PMVs citing corruption as a serious constraint to the regulation of fake anti-malarial drugs	8.3	26.7	33.3	22.2	0.04
PMVs in favour of community involvement in drug regulation	97.4	87.5	88.2	91.4	0.2
Patent Medicine Vendors (n)	*(38)*	*(33)*	*(33)*	*(104)*	

Source: PMV Survey

PMV association officers proposed actions that involve informing PMVs about the problem of fake drugs, particularly through the state-level task force and local activities to inform members. Some advocated more frequent visits to shops and more stringent enforcement of rules concerning drug quality. Some also said they visit shops and remove out-of-date products from the shelves. All three state associations have established a task force to close the business of anyone selling fake drugs.

The study team also explored the views of PMVs and of members of the community concerning the involvement of community people in monitoring the quality of drugs. Over 90 percent of PMVs thought it was a good idea (Table 8). Some informants specifically suggested this would discourage people from selling fake drugs. A substantial number of community people expressed a willingness to be involved in some form of regulating the quality of drugs. This could involve checking for NAFDAC registration numbers. However, some people expressed concern that this would require efforts to inform people about the impact of low quality drugs and the reasons for the monitoring activities.

Discussion

This study has documented the problems that people have in getting access to appropriate treatment for malaria. They have little knowledge of the changing patterns of drug resistance and the consequent changes in the drugs that are effective. They must rely either on traditional practices or on the advice of the people who provide the drugs. Since patent medicine vendors provide anti-malarial treatment in a substantial proportion of cases, their knowledge and practice strongly influence people's wellbeing. This study made two major findings about this knowledge and practice. First, patent medicine vendors have little knowledge about new guidelines for drug use and they still recommend that people use drugs whose efficacy is doubtful. Second, there is a lot of concern about the quality of the drugs they supply. Action is needed to address these problems.

Study Limitations

Scoping studies of this kind are intended to provide insights for further investigation and intervention, and are limited in what they are able to conclude. Although the study used representative sampling techniques, it had very small sample sizes, and therefore may not be capturing the full range of experiences of PMVs, PMV associations, or of communities and government officials in Nigeria. Given the large differences that were found between study sites, it will be important that future studies include sufficiently large sample sizes from across different parts of Nigeria, particularly since there is a concern to assess how vulnerable groups are affected by policies and the market. The study involved cross-sectional assessments, later studies will need to capture changes over time to better identify factors that are causally related to better knowledge or treatment of malaria. The inferences in this study were derived from interviews and observations of medical stores. Future studies may want to include direct observation of the treatments received by patients, and chemical testing of drug products. Notwithstanding these limitations, these studies allowed us to identify more focused questions for research and intervention, which remains challenging in a weakly regulated environment.

Possible interventions

Actions to improve the present situation will have to address a number of inter-related factors. One set of interventions needs to address the lack of knowledge about appropriate treatment, which will require training of PMVs and educating the public. This will involve the design of strategies for communicating with a variety of audiences including government regulators, patent

medicine vendors and community members. These strategies will have to take into account the fact that a substantial proportion of patent medicine vendors obtain information from drug suppliers, rather than government. They also need to take into account the many inter-state differences in the characteristics of patent medicine vendors and the market within which they operate. This may require innovative approaches to explain reasons for radical changes in what has been proposed as appropriate treatments for malaria.

Other interventions need to reduce the opportunities for patent medicine vendors to knowingly supply sub-standard drugs. This is likely to involve a combination of more effective government regulation and self-regulation by patent medicine vendor associations. A lot of work will be required to promote effective partnerships between government regulators and these associations. There was strong support by patent medicine vendors, government policy-makers and members of the community for an increased role of communities in monitoring drug quality. This will involve training people to undertake these tasks, which could include looking for NAFDAC registration and expiry dates. New simple technologies for testing drugs or scanning product identification, or for utilising information and communications technology to be able to provide real-time support to PMVs and regulators could also be considered.

The study documented a considerable amount of concern by households about the high cost of anti-malarial treatment. One approach to this problem would for patent medicine vendors to be supplied with anti-malarial drugs for children at a subsidised price. In exchange, they would have to charge an agreed retail price. One option would be to require eligible shops to meet certain quality standards in a form of franchising. This could draw on the lessons from the experiments with social marketing of anti-malarial medications that BASICS and Society for Family Health have undertaken in Nigeria (Greer *et al.* 2004; Salami & Brieger, 2003).

Although a case can be made for subsidizing ACTs in Nigeria in order to make them more affordable, others have argued for a global subsidy (Laxminarayan *et al.* 2006; Arrow *et al.* 2005). Resistance to AMDs are not bound by national boundaries, suggesting that global action is needed if ACTs are to remain effective. Even partial subsidies of ACTs, preferably for two or more different ACTs, would be useful in crowding out monotherapies from the market, delaying the arrival of resistance to artemisinins, and saving lives due to malaria mortality, and cost between $400 to $1500 per death averted (Laxminarayan *et al.* 2006). Another effect of a global subsidy is that it may allow chloroquine to become effective again (Kaufer & Plowe 2004). Yet the cost of a global subsidy has been estimated at about $500 million per year, and though it is suggested that a subsidy would be most effective if introduced at the top of the distribution chain, no consensus has yet been reached on how to proceed (Arrow *et al.* 2005). Our results

suggest that there are considerable variations in information flows and local market conditions, so that effects may be quite different in different markets. At least in the medium term, any changes in global or national policy should merit closer attention to how they influence local markets, and particularly the behaviours of consumers, retailers, and their suppliers. The early models estimating the effects of global ACT subsidies are based on presumptive treatment of malaria, and will need to account for the potential for low cost diagnostic testing, and the influence of counterfeit drugs, which may substantially change the assumptions of the models used.

It is also important that policy-makers explore new approaches for broadening participation in the formulation of policy and in disseminating new policies widely, as current approaches are not reaching their intended audiences. Those most in need of knowing about and following through on policies on the treatment of malaria are community members and the PMVs who provide their drugs.

Knowledge gaps

This was a scoping study aimed at developing a rapid understanding of the current situation in Nigeria. Its findings have identified a number of gaps in our knowledge. There were substantial inter-state differences in the characteristics of patent medicine vendors and in the structure of the medicines market. These findings were based on studies in four wards in each state and a larger scale study is required to gain a more systematic understanding of these regional differences.

The study has documented the different sources of drugs in the three states, but much more information is needed on institutional arrangements within which patent medicine vendors obtain their supplies. This includes the organisation of open markets and the kinds of arrangements between wholesalers and retailers, the role of middlemen and drug retailers, and the activities of wholesaling companies. A better understanding of the incentives and disincentives for PMVs and their suppliers would help to design more relevant interventions. At the least, such interventions would include ways to disseminate knowledge of drug use to PMVs and to reduce the risk of sub-standard drugs reaching PMV shops.

We need more information on the organisation and performance of patent medicine vendors associations. To what extent do they act in the interests of members and are believed to do so? Do members believe that the fines they impose are fair? What is the role of LGA and state-level associations in ensuring that local branches are accountable to their members? To what extent do community members trust them to also act in the public interest and what can be

done to make them accountable? What kind of relationship do these associations have with government health officials and drug regulatory agencies?

We need to understand the relative roles of different agencies at federal, state and LGA levels in the enforcement of regulations concerning the quality of drugs and the performance of PMV shops. This includes front-line enforcement and monitoring the performance of the enforcement agencies.

We need to know more about how health workers and community members understand guidelines for treating malaria. Where do they get information and how do they understand the changes in guidelines? To what extent do they understand issues of drug resistance and changing efficacy of drugs? Will the change in guidelines affect their trust in future guidelines?

Finally, we need systematic evidence of successful Nigerian and international experiences in working with informal drug sellers to improve their performance in addressing health problems of the poor.

Stakeholder meeting

The underlying aim of this study is to support the design of measures to improve access to effective treatment of malaria. These measures will have to be undertaken by a partnership of different stakeholders. The next step is to inform these stakeholders of the findings and explore with them options for change. These stakeholders will include federal and state ministries of health, drug regulatory agencies, patent medicine vendor associations, appropriate NGOs and other social entrepreneurs with a potential interest in innovative approaches for addressing health problems.

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