Antimalarial Drugs Inventory among Urban and Rural Patent Medicine Vendors

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Abstract
Nigeria changed its malaria treatment drug (AMD) policy in 2005 from use of chloroquine (CQ) and sulphadoxine-pyrimethamine (SP) to more effective Artemisinin-based combination therapy (ACT). SP is exclusively reserved for malaria in pregnancy prevention. Sixty percent of Nigerians patronize Patent Medicine Vendors (PMVs). This study assessed AMDs stocking and dispensing practices of urban and rural based PMVs. This is a cross-sectional survey of 120 PMVs in ten LGAs of Akwa Ibom State, Nigeria. The LGAs were divided into five urban and five rural. 12 PMVs were selected from each LGA. A one page questionnaire was used to elicit information on brand-names of AMDs, drug-active-ingredients, cost, and popularity amongst clients. Data was analyzed and results presented in simple frequencies, mean, and confidence intervals (CI). 1,150 AMDs were found under 86 brand-names. Mean in urban shops was 22.6 [SD±20.5] compared to rural 20.1 [SD±16.9]. ACT was more common in urban (71.1% at 95% CI: 0.579-0.822); SP (36.4% at 95% CI: 0.109-0.692); CQ (33.3% at 95% CI: 0.075-0.701); and rural ACT (28.8% at 95% CI: 0.178-0.421); SP (63.6% at 95% CI: 0.308-0.891); CQ (66.7%. at 95% CI: 0.299-0.925). Drug popularity in both areas, clients preferred ACT (74.0%, CI: 0.639-0.832); CQ (12.7%, CI: 0.066-0.217), SP (8.6%, CI: 0.033-0.161); and MADs (4.8%, 0.013-0.115). The cost of drugs ranged < N100 per dose for SP and CQ to ACTs > N301. Twelve years after the change, non-recommended drugs are still prescribed. Promoting training, cost reduction and availability of appropriate and efficacious AMDs may boost current malaria control efforts.

Keywords: Antimalarial drugs, patent medicine vendors, urban and rural, stocking and dispensing.

Introduction
Malaria is a major public health concern in Nigeria. Annually half of the population suffers one episode of malaria while the prevalence rate of malaria amongst children under-five years of age (24 million) was put at 27% (MIS, 2015); and may suffer malaria attacks 2 to 4 times each year (FMOH, 2009). One study in Abeokuta the South-west of Nigeria found a very high malaria prevalence rate of 62.4 % among women attending traditional birth home (Idowu OA et al). Pregnant women and children under-five years of age are the groups mostly at the risks of malaria deaths. In 2015, global malaria deaths was reported at 429,000 (WMR, 2016), with about 92% occurring in Sub-Saharan African. 303,000 of these deaths or 70% occurred among children under-five years of age (WMR, 2016). Nigeria and Democratic Republic of Congo accounted for more than 36% of the global malaria deaths in 2015 (WMR, 2016). Achieving the Sustainable Development Goals of reducing child and maternal deaths by 2030 in Nigeria will require addressing properly illnesses and deaths caused by Malaria.

Current efforts to address malaria illnesses and deaths in Nigeria include updating antimalarial drugs (AMDs) policy by adopting Artemether-lumefrantine (AL) and artemunate–amodiaquine (AA) as the first and second line drugs of choice for treatment of uncomplicated malaria while exclusively reserving sulphadoxine-pyremethamine (SP) for preventing malaria during pregnancy. Similarly, treatment
guideline was updated in 2014, followed by the essential medicines list (EML) 6th edition, 2016 and standard treatment guidelines (2nd edition, 2016). The EML prescribed the list of products to be stocked and sold by patent medicine vendors. Antimalarial medicines under the list include Artesunate + Amodiaquine oral liquid, which also has tablets unit form. Artemether + Lumefantrine and sulfadoxine-pyrimethamine tablets were also recommended.

Furthermore, Nigeria is promoting home management of malaria using ACTs and Rapid diagnostic test kits in line with the World Health Organization’s (WHO) recommendation (WHO, 2015) to ensure prompt and appropriate access to management of malaria (Ajayi, 2016). Available evidence shows that childhood treatment of malaria first line of action in the rural and urban Nigeria doubled through the activities of community health workers (Ajayi et al, 2016). It has be observed that about 15%-82% of Sub-Saharan African care-givers will first visit patent medicine vendors for the treatment of their sick child (Akuse R et al, 2010). Drugs used in home management of malaria are substantially bought from the Patent Medicine Vendors (PMVs) (Ajayi et al., 2008).

PMVs are the registered and unregistered shop owners, itinerant or merchants that sell AMDs, other types of drugs and treatment of illnesses (Akuse et al, 2010). They are found in rural and urban communities in Nigeria and are more accessible to the community people and largely remain untrained. However, there have been recent interventions to train PMVs on malaria prevention and control (Brieger WR et al, 2001; Greer G, 2004). Training has focused on improving the quality of services they provide, and increase the prescription of appropriate and correct doses of anti-malarial drugs. Available records showed that there are 1,224 identified Patent and proprietary medicine vendors (PCN, 2007) compared to 506 primary and secondary health care centers and one tertiary hospital in Akwa Ibom State (SMOH, 2009).

The PMVs dominate the unregulated and informal sector of the Nigerian antimalarial drug market and play significant role in malaria control effort in Nigeria. Public health facilities are more likely to hold only 40% of the recommended frontline choice of drugs for the treatment of malaria compared to 60% by the PMVs (ACT watch, 2014). The sector is profit driven, and with the ACTs’ cost still remaining very high, there is fear on the availability of this drug of choice for home treatment and management of malaria. 2014 ACT watch showed that they are 177 registered ACT products in Nigeria, however sulfadoxine-pyrimethamine accounts for 83% of overall antimalarial drugs in the Nigerian market compared to the recommended ACT 6%. (ACT watch, 2008).

Therefore, the important question remains, can the PMVs promote access to appropriate antimalarial drugs for the treatment of uncomplicated malaria? This study assessed the determinants of AMDs stocking, and dispensing practices of urban and rural based PMVs with the broad objective to identify AMDs stocked by PMVs and client preferences in selected rural and urban Local Government Areas (LGAs) of Akwa Ibom State in the South Eastern region of Nigeria. The specific objectives of the study include determining the active ingredients of the AMDs sold by the PMVs, costs and the drugs’ availability.

**Study area**

The PMVs were the subject of the study. The State is one of the beneficiaries of the World Bank Assisted Malaria Booster funds, and recently embarked on the training of the PMVs on malaria knowledge and dispensing of appropriate ant malarial drugs. There was a delay in rolling out the full packages of the malaria booster program that include procurement and distribution of anti malarial drugs and as a result, there has been persistent gap in anti malarial drugs supply in most public health facilities in the State. The State was created out of Cross River State in 1987.
It consists of 31 Local Government Areas with current population at 3.9 million people (National Population Commission, 2006). The State is part of the Nigerian Niger delta region, rich in oil and most of the LGAs lie across the coast and are riverine with all year round transmission of malaria. There are influxes of people to the urban LGAs because of the oil and the migration include people from both rural LGAs to the urban as well as from outside the State. Urban LGAs are more attractive because of the growing infrastructures such as road networks, schools, water, electricity, hotels and social lives. The rural LGAs are mostly those lying across the coast, social amenities are very limited and the returnees from the Bakassi community that Nigeria recently ceded to Cameroon are part of the residents of the rural communities. The most predominate occupation of the people include fishing, farming, trading, transportation, hotel business and civil service. Economic activities are still very minimal as there are no major industries yet, and people in the urban LGAs are largely government employees.

Methods

The study was a cross sectional survey of 120 PMVs in ten selected Local Government Areas (LGAs) of Akwa Ibom State, Nigeria. The 31 LGAs were divided into urban and rural. Five LGAs were blindly drawn from each arm and 12 PMVs were purposively selected from each LGA among the registered and unregistered PMV groups. One page questionnaire was used to elicit information on brand-names of AMDs stocked by the PMVs, and determinants of AMDs stocking and dispensing practices that include AMDs’ active-ingredients, cost, availability, popularity amongst clients, recommendation amongst shop-owners and health providers, and LGAs of drug sellers.

Data collection was carried out by five trained data collectors and this lasted for 7 days in the month of November 2016. Each PMV was visited by a data collector and requested to bring out all anti-malarial drugs in the shop after explaining the purpose of the study and obtaining consent. Data collector used the one page guide to collect information from the PMV while the drugs active ingredients, dates of manufacturing and expiration were directly copied from the drugs’ packages.

Data was entered into SPSS 17.0 series, cleansed and computed while results are presented in simple frequencies, percentages, confidence intervals (CI), mean and figures. The standard market determinate measured included brand names, drugs-base (by active-ingrediants), costs, availability, prescription pattern and disaggregation of these by urban and rural outcomes.

Results

Drugs’ brand names

A total of 1,150 different anti-malarial drugs were found in the 120 PMVs shops. These drugs came under distinct 86 brand names, with 713(62.0%) at 95% CI: 0.591-0.648) in the urban LGAs compared to...
the rural 437 (38.0%) at 95% CI: 0.352-0.409). Overall, eighty-nine (74%, at 95% CI: 0.654-0.817) of the PMVs stocked ACTs, followed by 15(12.7%, 95%CI: 0.72-0.198) that stocked SP compared to 10(8.6%, 95%CI: 0.041-0.148) stocked CQ and MAD 6(4.7%, 95%CI: 0.019-0.106) Figure 2.

The overall mean of the different brands of AMs found in all the shops was 21.6(SD±19.2) while mean in urban shops was 22.6(SD±20.5) compared to rural shops 20.1(SD±16.9) being statistical significant with p-value at 0.03.

Drug base and availability

The drug base was classified into five distinct categories such as SP, ACT, CQ, ACT monotherapy and artesunate-sulphadoxine-pyremethamine. Availability test showed that ACT base topped the list with 59(69.0%) at 95% CI: 0.577 – 0.782), followed by SP base 11(13.0%) at 95% CI: 0.066 – 0.217). Others include CQ base 9(10.4%at 95% CI: 0.049-0.187), artesunate monotherapy base 5(6.0%) at 95% CI: 0.019-0.130) and artesunate+ sulphadoxine-pyremethamine base 2(1.6%) at 95% CI: 0.003-0.081).

The percentages of these drugs in the urban shops were ACT 42(71.1%) at 95% CI: 0.579-0.822); SP 7(63.6%) at 95% CI: 0.308-0.891); Chloroquine 6(66.7%) at 95% CI: 0.299-0.925) compared to rural shops with ACT 17(28.8 %) at 95% CI: 0.178-0.421); SP 4(36.4%) at 95% 0.109-0.692); and Chloroquine 3(33.3%) at 95% CI: 0.075-0.701) (see figure-3).

Unit forms and dosage

The drugs are sold in five unit forms such as counting, packet/sachet, syrup, powder and injection. Overall, packet/sachet top the list of unit forms with 965 (83.8%) at 95% CI: 0.817-0.860) followed by syrup 127(11.0%) at 95% CI: 0.093-0.130), counting form 40(3.5%) at 95% CI: 0.025-0.047), powder 14(1.2%) at 95% CI: 0.007-0.020) and injection 5(0.5%) at 95% CI: 0.001-0.010).

In the urban, packet/sachet form were more stocked 613 (63.5%) at 95% CI: 0.604-0.666) than others, followed by syrup 73(57.5%) at 95% CI: 0.484-0.666), powder 750.0%) at 95% CI: 0.230-0.770), and counting 15(37.5%) at 95% CI: 0.227-0.542) while in the rural, counting form 25(62.5%) at 95% CI: 0.458-0.773) was stocked more than other forms; followed by powder 7(50.0%) at 95% CI: 0.230.0770), syrup 54(42.5%, at 95% CI: 0.338-0.516), and packet/sachet 352(36.5%) at 95% CI: 0.334-0.396). Injection was found to be stocked only in the urban communities.

Drug dosage was found to be stocked in three dosage formulations. These formulations include dosage for both adult/children overall was 743 (64.5%) [Urban 469(63.1%; rural 274(36.9%);] formulation of adults alone 244(21.2% [Urban 139(57.0%); rural 105(43.0%)); and formulation for children alone 164(14.2%)(Urban 101(61.6%); rural 63(38.4%]).

PMV’s prescription pattern

Fifty (56.2%, 95%CI: 0.453-0.667) of the PMVs in the rural prescribes SPs to their clients compared to 39(43.8%, 95% CI: 0.333-0.547) in the urban; 8(53.3%, 95% CI: 0.266-0.787) PMVs in the rural prescribe CQ while only 7(46.7%, 95% CI: 0.213-0.734) prescribe CQ in the urban. However, four (67.0%, 95% CI: 0.223-0.957) of the PMVs prescribes ACTs in the urban compared to only 2(33.0%, 95%CI: 0.043-0.777) in the rural communities (figure 4).

Costs

The cost of drugs ranged from N35 to N1, 850. CQ and SP cost the least with price range between N35 to N100 while ACT was found to be costlier above N400. The children formulation costs less than adult at N450 compared to N500.

Discussions

This study investigates the pattern of anti-malarial drug stocking and dispensing among urban and rural based patent medicine vendors. The role of PMVs is very important in the control and prevention efforts towards malaria. PMVs are profit driven, and available evidence has shown that more than 60% of
Nigerians will first consult the PMVs during ill health. However, whether they receive the correct and appropriate treatment remains one of the challenges. It can be seen from the results that though the use of ACTs as recommended by WHO and the national malaria treatment policy has improved since the change in policy in 2005. However, in spite of the policy shift in anti-malarial drugs from CQ and SP as first and second lines drugs of choice to more effective ACTs (AL) and (AA); CQ and SP still command about 26% of the anti-malarial drug market amongst the PMVs especially in the rural areas. With high cost of AL and AA, PMVs continue to stock more of the CQ and SP because of their low cost hence very few of AL and AA are on the shelves in the rural urban communities. Recent efforts by Global Funds to expand access to ACTs through the co-payment mechanism in the private sector including the PMVs has not succeeded in crowding out the use of SP and CQ in the treatment of malaria. The prices of the co-paid ACTs still remains high, and above the recommended price. As a result, the ACTs remain largely unavailable at a cost affordable to the poor and those at the risk of malaria more in the rural compared to the urban population.

This is because, PMVs in both urban and rural communities would not want to stock over time drugs that will not be easily sold due to high cost; as a result CQ and SP are more stocked and prescribed to the clients as similarly reported in another study. The implication of the prescription pattern suggests that clients treating malaria buy more of the low cost drugs to the detriment of the recommended drugs of choice as seen in data from the rural communities. Even though PMVs in the urban are more inclined to prescribe ACTs compared to the rural counter-parts; the effect of the above to a large extent poses serious threat to malaria control intervention efforts and programs.

PMVs are in every nook and corners of urban and rural communities in Akwa Ibom State, and to a large extent constitute very important segment of the private sector drugs market. Evidence has shown that PMVs play a key role in home management of malaria, as most of drugs procured for the treatment of malaria at home are bought from PMVs. This is because, treatment of malaria illnesses starts from the home. Therefore, neglecting PMVs activities in our malaria control efforts will undermine the successes of malaria intervention programs. The result of the study also showed that anti-malaria medicines formulation, unit forms and dosages that are not recommended by the national essential medicines list and treatment policy are still stocked and prescribed by the PMVs. Example, suspension, syrup and powder formulated drugs are not recommended because of its instability in the tropical, these medicines still find their ways to the shelves of the PMVs. These are contrary to the oral liquid and tablets listed in the EML for stocking and dispensing by PMVs. This underscores the poor regulation of the market by the relevant agencies. Also the synergy between the agencies responsible for malaria control and prevention program (national malaria elimination program), and medicines formulary essential medicines lists is not clearly understood. Example, the malaria in pregnancy guideline prescribed exclusive use of sulfadoxine-pyrimethamine for malaria prevention during pregnancy under the platform of antenatal care. But it is surprising that EML listed sulfadoxine-pyrimethamine as one of the anti-malarial medicines to be stocked and dispensed by PMVs. But PMVs do not conduct antenatal care, so why stock SP? Therefore, putting SP in the shelves of the PMVs exposes the medicine to be sold for treatment of malaria. Furthermore, it does appear that the regulatory authorities have not introduced the private sector to the use of the essential medicine list for the procurement and sales of anti-malarial medicines in Nigeria. Such introduction must include orientation on the use of the antimalarial treatment policy and other relevant guidelines in the country. If the war against malaria must be won, there is the need for all hands to be on deck and appropriate and correct anti-malarial medicines to be made available. Also, it is important that policies and guidelines are harmonized so that they speak to one another, and relevant agencies close ranks and work together to the benefit of the centenary.

In conclusion, there is need to reduce the cost of anti-malarial drugs (ACTs) and make them more available in the shelves of the rural and urban PMVs to crowd out the low cheap and inappropriate medicines for the treatment of uncomplicated malaria. Regulatory agencies should ensure that PMVs are introduced to the use of essential medicines list in the selection of medicines to be stocked for sales.
Continuous interactions between the PMVs and regulatory agencies must be established to provide the necessary coordination and collaborative efforts in marketing appropriate and correct anti-malaria drugs to the clients.

PMVs are positioned to play key role in malaria prevention and control efforts, but this is compromised if they continue to stock wrong choice of anti-malarial drugs that they offer to their clients. Repositioning the PMVs to stock and dispense appropriate anti-malarial drugs for the treatment of uncomplicated malaria will increase access to the effective drugs of choice for the treatment of malaria illness. Furthermore, specific roles should be assigned to the PMVs by engaging them through participatory approach and learning programs.

References

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Annexes

Figure 2. Overall percentages of medicines in the PMVs shops in both urban and rural areas

Figure 3. Drug based and availability in urban and rural PMVs shops

Figure 4. PMV prescription pattern