KNOWLEDGE AND PRACTICES OF PATENT MEDICINE VENDORS IN THE USE OF ARTEMISININ-BASED COMBINATION THERAPY IN THE TREATMENT OF MALARIA IN AN URBAN COMMUNITY IN LAGOS

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A minithesis submitted in partial fulfillment of the requirement for the Master's degree in Public Health in the School of Public Health in the Faculty of Community and Health Sciences.

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November, 2008

KEYWORDS

Malaria

Patent medicine vendors

Over-the-counter drugs

Prescription-only medicines

Artemisinin-based combination therapy,

Anti-malaria drug

Anti-malaria treatment policy

Home management of malaria

Nigeria

ACRONYMS

ACT	Artemisinin-based combination therapy
CQ	Chloroquine
HMM	Home management of malaria
MSF	Medicines sans Frontiers
NAFDAC	National Agency for Food and Drugs Administration and Control
OTC	Over-the-counter
PCN	Pharmacist Council of Nigeria
PMV	Patent medicine vendors
POM	Prescription only medicines
RBM	Roll Back Malaria
SP	Sulfadoxine-pyrimethamine
WHO	World Health Organisation

ABSTRACT

Background

Malaria is a health, social and economic burden in Nigeria and consistently ranks amongst the four most common causes of childhood deaths. Treatment of malaria is usually started at home; care is only sought from the health facility when the treatment is ineffective (McCombie, 1996). Patent medicine vendors (PMVs) have been identified as a widely patronized source for drugs used in the home treatment of malaria (Breiger *et al*, 2001; Goodman, *et al*, 2007; Salako *et al*, 2001). Inadequate or poor knowledge and practices in the use of anti-malaria drugs (AMDs) increases morbidity and mortality, undermines therapeutic efficacy, and promotes the emergence and spread of drug-resistant malaria.

Aim

The aim of the study was to describe and quantify the knowledge and self-reported practices of PMVs in the use of antimalarials, particularly artemisinin-based combination therapies (ACTs), in a poor urban community in Lagos state, Nigeria

Methods

The study was a cross-sectional, descriptive study of the knowledge and self-reported practices of patent medicine vendors in the usage of ACTs in an urban community in Lagos. All eligible vendors were interviewed between 18th August and 9th September, 2008. A structured questionnaire was used to collect demographic information, knowledge of malaria, ACT anti-malaria treatment policy and the usage of ACTs. These

self-reported practices were assessed in terms of conformity with the ACT policy. Data was analysed using Epi info.

Results

A total of 105 Patent Medicine Vendors were interviewed (92% response rate). The study showed that they had a high knowledge of the symptoms of uncomplicated malaria; however recognition of severe malaria was poor. Awareness of the ACT Anti-malaria Policy was high, but understanding and application seemed to be weak. Knowledge of what constitutes an ACT was poor, with only 14% correctly identifying two ACTs Additionally, 40% vendors were willing to break or share the pack of ACT during sale, potentially selling an inappropriate dose. The vendors engaged in practices that were contrary to the policy; 55% and 71% were still selling chloroquine and sulfadoxine-pyrimethamine, respectively, for malaria treatment. Medicine vendors who had higher education qualifications were more likely to be aware of the policy (Fisher's exact test 0.0138) and to ask for the specific age of the patient (p-value 0.0096, OR 4.7744). Vendor who had been trained on the policy were less likely to use chloroquine in the treatment of malaria.

Conclusions and Recommendations

Knowledge of the ACT Malaria Policy was high, but reported practices were unsatisfactory. Vendors should to be trained and provided with health education information on the policy to improve knowledge and practices. Stricter regulatory control by the Pharmacists' Council of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC) is required to improve adherence to the

Policy. In addition, community health education and re-orientation, is required to inform mothers/care givers to request ACTs for the treatment of malaria.

DECLARATION

I declare that ***Knowledge and practices of patent medicine vendors in the use of artemisinin based combination therapy in the treatment of malaria in an urban community in Lagos*** is my own work that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Full Name: Rametu Omamegbe Momodu **Date: 20 November, 2008**

Signed:

ACKNOWLEDGEMENTS

My gratitude goes to Hazel Bradley and Dr Brian Van Wyk and my family for their commitment and unwavering support to the successful realization of this project.

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CHAPTER 1: INTRODUCTION

1.1: Background

Malaria is a major cause of illness and death in Nigeria and exerts significant pressure on the economy and the poor. It is responsible for 30% of all childhood deaths, 11% of maternal deaths, 50% of all out-patient attendances (Pediatric Association of Nigeria, PAN, 1994) and 70% of out-patient attendances of children under 5 years of age (Federal Ministry of Health, FMOH, 2001). This data is mainly based on clinical diagnosis of malaria. Recent estimates by the World Health Organisation WHO (2007) report that over 40% of the world's population, especially those living in the poorest countries such as Nigeria are at risk of malaria. Annually, over 500 million people become ill with malaria and most of the cases and deaths are in sub-Saharan Africa. Approximately 85% of malaria cases and 90% of malaria related deaths are recorded in Africa (Bremen, Egan & Keutsch, 2007).

Early, effective case management is one of the cornerstones of malaria control and access to diagnosis and effective anti-malaria treatment has been identified as crucial in reducing morbidity and mortality from malaria (FMOH, 2001;WHO, 2000;). Home management of malaria is popular and widespread; evidence from studies has shown that more than 70% of malaria episodes in rural areas and over 50% in urban areas are home treated (McCombie, 1996). Reports of surveys across Africa have shown that between 15-83% of mothers/caregivers utilize the informal private sectors, such as the patent medicine vendors (PMVs) as sources of drugs for childhood illnesses, including fever and malaria. (Biritwum *et al*, 2000; Ene-Obong *et al*, 2000; Hamel *et al*, 2001; Salako *et al*,

2001;Tsuyouk *et al*, 2001). The National Malaria Situation Analysis conducted in Nigeria in 2001 reported that 60% of mothers/caregivers use patent medicine vendors as the primary source of drugs in the home treatment or self treatment of malaria (FMOH, 2005a).

Patent medicine vendors are traders without formal pharmacy training, licensed to sell non-prescription medicines such as anti-malarial drugs. They have also been reported to be a major source of health information to the communities that they serve (Salami & Breiger, 2005). However, concerns have often been expressed about their knowledge, practices and the quality of care they provide. In 2005, Nigeria changed to artemisinin-based combination therapies (ACTs) for the treatment of malaria, with full implementation in 2006. ACTs were re-classified as over the counter (OTC) drugs and so patent medicine vendors can now legally stock and sell these anti-malarial drugs.

1.2: Problem Statement

Malaria is often inappropriately treated, which impedes control causing significant morbidity and mortality. In Sub-Sahara Africa mothers/care givers of children usually start treatment of malaria based on advice and medicines obtained from patent medicine vendors. Patent medicine vendors are a widely patronized source for home management of fevers and malaria illness especially in children and have also been reported to be a major source of health information to the communities that they serve (Salami & Breiger, 2005). In 2005, Nigeria changed to the artemisinin-based combination therapy (.ACT) for malaria treatment, with full implementation in 2006 when ACTs were re-classified as

OTC drugs. With the new policy, there are a number of concerns regarding the practices of patent medicine vendors, including that they may continue to sell the artemisinin alone or sell the component tablets individually (known as monotherapy) and eventually undermine the artemisinin-based combination therapy efficacy (Goodman, *et al* 2007); that they may not supply the correct dosage and full course of treatment; and they may not store ACTs correctly. Strategies for improving practice require accurate information about current practices and usage patterns of these anti-malarial drugs. This study will explore the knowledge and practices of the patent medicine vendors in the treatment of malaria in relation to the new anti-malaria Treatment Policy.

1.3: Context and setting

The city of Lagos lies in the South Western part of Nigeria on the Atlantic coast in the Gulf of Guinea. It is the fastest growing city in Nigeria and most economic and industrial activities takes place here. As with most large cities in developing countries, while there are districts with considerable wealth, many residents live in slums such as Mushin (Breiger, *et al* 2001). The study will be carried out in Mushin, a densely populated area, inhabited by low income and socio-economically disadvantaged population. According to the 2006 census Lagos has a population of 17,552,942 inhabitants while Mushin has a population of 1,321,517. (Lagos, 2008). The main economic activity is petty trading.

CHAPTER 2: LITERATURE REVIEW

2.1: Malaria Infection and Diagnosis

Malaria is an infectious disease caused by the parasite of the genus *Plasmodium* which is spread through the bite of infected, female anopheles mosquitoes. Malaria presents with a wide range of signs and symptoms such as fever, malaise, fatigue, lassitude, headache, dizziness, anorexia, nausea, vomiting and, in severe cases, anaemia, jaundice, convulsions, and prostration. Clinical diagnosis of malaria is difficult as the clinical features are non-specific and may be confused with many other diseases. Generally, malaria is considered in the differential diagnosis of any fever and asymptomatic parasiteamia in endemic areas, but the discovery of parasites in the blood film confirms clinical suspicion of malaria (Payne *et al* 1988).

More recent diagnostic methods include the use of Rapid Diagnostic Tests (RDTs) which are based on antigen derived from malaria parasites in lysed blood, using immuno chromatographic methods (Singh *et al*, 1997). There are other methods, but they are not currently used for diagnostic purposes. They include molecular biological detection tests such as Polymerase Chain Reaction (PCR) or Transcript Amplification System (TAS), probe Amplification Ring Q-beta replicase and Signal Amplification using enzyme linked probes (Craig *et al*, 1997).

2.2: Burden of Malaria in Nigeria

The WHO (2007) estimates that malaria causes a loss of about 1.3% annual economic growth in countries with intense transmission such as Nigeria. It is responsible for 30% of all childhood deaths, 11% of maternal deaths and 50% of all out-patient attendances (PAN, 1994). It is the most common cause of absenteeism amongst workers and school children, thereby impacting negatively on production and development (Asagba *et al*, 1991). A study by the federal Ministry of Health in collaboration with the WHO reveals that the burden of malaria may be in excess of 14% of Gross Domestic Product and 98% of treatment cost is borne by citizens (FMOH, 2004). Apart from the high morbidity associated with the acute symptoms, the disease is also associated with low birth weight, anaemia, prenatal and maternal mortality (Janssens & Wery, 1987).

2.3: Malaria Treatment and the Problems of Drug Resistance

Chloroquine was introduced to treat malaria in the 1950s; it was fast, effective and cheap. However, widespread and uncontrolled use of chloroquine has contributed to the emergence and spread of resistance to the drug. Sulfadoxine-pyrimethamine (SP) was introduced for use in Asia (Thailand) in the early 1970's and was only introduced in Africa in the early 1990's, but resistance developed to SP in a short time. The development of drug resistance is the ability of the malaria parasite to survive in the presence of the minimum inhibitory concentration of a drug (WHO, 2000). The significant consequences of drug resistance are increased morbidity and mortality, as well as higher drug costs and an increased burden of the disease. A study conducted in

Senegal reported a strong link between the emergence of chloroquine resistance and an increase in malaria mortality between 1984 and 1995 (MSF, 2003).

Anti-malarial drug resistance is increasing worldwide (WHO, 2006). In many African countries, including Nigeria, resistance to chloroquine and SP is very high and has rendered these drugs almost useless in the treatment of malaria. Strains of *P. falciparum* resistant to chloroquine were reported in the mid 1950's in Colombia and Thailand (Bloland, 1999), the early 1970's in Tanzania (Onori, Beales and Gilles, 1982) and high resistance to SP has also been reported in South East Asia and East Africa (Reacher *et al*, 1981). The first case of chloroquine-resistant *P. falciparum* was recorded in Nigeria as early as 1987 (FMOH, 1990). The National Malaria Therapy Surveillance Network conducted *in vivo* studies from 1987 to 1988 on chloroquine and SP, using WHO standard protocols; the results indicated a high resistance of over 25% in the South-East and South-South geographical zones and between 10-25% in the North-Eastern and North-Central zones of the country for both chloroquine and SP (FMOH, 1989).

Study reports seem to indicate that the problem of resistance to chloroquine and SP has been increasing steadily (Ezedinachi, 1996), with resistance levels of 27.3% and 60.5% recorded for SP and chloroquine respectively in parts of the Nigeria during the mid-1990's (Falade, *et al* 1997). Another study was conducted to determine chloroquine sensitivity in the South-South area of Nigeria, in children aged 6 to 60 months, with parasitologically proven *P. falciparum, using* the WHO 14-day protocol for in vivo studies. A 65.2% treatment failure was reported, which is similar to, but slightly higher

than Falade's 1997 results (Anita-Obong, *et al*, 1998). These figures are also higher than what is reported from Medicines San Frontiers projects which recorded 40% resistance for both SP and chloroquine in studies conducted in the Niger Delta region (South-South) of Nigeria (MSF, 2003). Resistance has also been reported to other anti-malarials such as mefloquine, halofantrine and quinine in places such as East Central Africa, South East Asia, Southern Africa, South America and many other parts of Africa, where they are widely used (WHO, 2000).

More recently, in 2002, Drug Therapeutic Efficacy Tests (DTET) were conducted on chloroquine and SP in Nigeria and the results indicated that chloroquine and SP were no longer suitable for national first-line use. The results showed an efficacy of between 3.7% and 50.8% for chloroquine and 14.9% to 64.8% for SP (FMOH, 2005a). WHO guidelines recommend that treatment failure rates should be less than 5%, rates higher that 10% indicates that a change of treatment protocol should be established (WHO, 2000). In areas where there is resistance to monotherapy, such as chloroquine and sufadoxine-pyrimethamine, the World Health organization recommends artemisinin-based combination therapy as first line treatment for all patients with falciparum malaria (WHO, 2006). This justified the need to move from monotherapy to the more effective artemisinin-based combination therapy (ACT). As a result, further efficacy trials were conducted in 2004 by the Federal Minisitry of Health (FMOH) on two artemisinin-based combination therapies, namely, artemether-lumenfantrine and artesunate-amodiaquine, with 100% and 98% Adequate clinical parasitological Response Rate (ACPR) respectively, in the six geographical zones of the country. They were thus suitable for use

in the treatment of uncomplicated malaria (FMOH, 2005a). Nigeria therefore changed its anti-malarial treatment policy to the artemisinin-based combination therapy in 2005, although widespread implementation did not commence until 2006.

2.4: Artemisinin-based combination therapy

In order to prevent the emergence of resistance, malaria will no longer be treated with a single drug, but two or more drugs in combination. This combination approach has already been used successfully in the management of HIV/AIDS, cancer, tuberculosis and leprosy. In the treatment of malaria artemisinins are combined with an antimalarial which is long acting and has a different biochemical target in the parasite.

Artemisinins (Qinghaosu) are the active constituents of the Chinese herb *Artemisia annua* and have been used by the Chinese in the treatment of malaria for over 400 years. The artemisinins, which are highly effective against multi-drug resistant malaria, undergo a reduction reaction to dihydro-artemisinin and also inhibit the development of gametocytes and therefore a potential reduction in the transmission of mutants which are responsible for the development of resistance. Artemisinins have a short half-life and so do not remain in the body for long. They are therefore combined with a blood schizonticidal drug, such as lumenfantrine, amodiaquine or mefloquine. This other antimalarial lasts longer in the body and “mops up” the parasites that may have escaped from the action of the artemisinin. The combination works synergistically to treat malaria and to reduce the emergence of resistance.

Artemisinin-based combination therapy produces rapid clinical and parasitological cures, is well tolerated and reduces gametocyte carriage rate (Bloland, 2001). ACTs have been formulated in a fixed combination where components are co-formulated in the same tablet or capsule, for example artemether-lumenfantrine (Coartem) or the separate components are co-blistered, for example artesunate-amodiaquine (Arsucam, Larimal and Dart). The first-line ACT is Coartem® – artemether/lumenfratrine and second line is artesunate/amodiaquine (FMOH, 2005a). In order to ensure broad access to ACTs, the first line and second line ACTs were switched from being a prescription-only medicines (POM) to over-the-counter (OTC) status in late 2006 by the Medicine Regulation Agency (NAFDAC), so that PMVs can legally stock and sell them. It is important to note also that all other ACTs remain prescription-only medicines and other non ACT antimalarials are POMs. Nigeria is the only country to have switched two ACTs to full OTC status; Ugandan has a partial re-classification, where the first line ACT has OTC status in two of the 86 provinces in the country (ACTwatch, 2008)

2.5: National Anti-malaria Treatment Policy

The National Anti-malaria Treatment Policy was launched in May 2005. The policy presents an overview of the malaria situation, treatment and anti-malarial drugs in Nigeria. In addition to chemoprophylaxis in the control of malaria, the policy also outlines the health promotion activities for the control of malaria. The strategy for implementing the policy is the same as that of the Roll Back Malaria (RBM) initiative. The strategy has four key elements.

(i) Patients with malaria should have access to appropriate and adequate treatment within 24hours of the onset of symptoms.

(ii) Pregnant women during their 1st and 2nd pregnancies should receive effective antimalarial prophylaxis and treatment.

(iii) Insecticide treated bed-nets and other materials are to be available and accessible to vulnerable groups, namely children and pregnant women

(iv) Malaria epidemics should be recognized and containment steps initiated within one week of their onset. (FMOH, 2005a).

The policy emphasizes prompt and effective treatment of malaria, especially in children, within twenty-four hours of onset of illness. According to the policy the first drug of choice for the treatment of uncomplicated malaria is the ACT, artemether-lumenfantrine (Coartem®). When this is not available artesunate-amodiaquine, artesunate-mefloquine or dihydro-artemisinin + piperaquine+trimetoprim may be administered. The national anti-malarial treatment guidelines states explicitly that "Monotherapy with dihydro-artemisinin, other artemisinin derivatives and other antimalarial medicines are not recommended. Treatment must be used in combination with another effective antimalarial drug" (FMOH, 2005b).

Artemisinin-based combination therapies (ACTs) have been found to be safe and well tolerated in children and are recommended in the treatment of uncomplicated malaria. There are different dosage regimens for the different ACTs. For example artemether-lumenfantrine (Coartem) has four different dosage regimen for different weight/age

categories; 6-14kg (6mths-3years), 15-24kg (4-8years), 25-34kg (9-14years), >35kg (>14years). In the case of dihydroartemisinin-piperaquine, it's even more complicated because the available brands come in with 8 or 10 tablets in a pack. This obviously presents a problem to dispense the correct dose or give the correct dosage instructions for the different age group. The forgoing underscores the concerns that these varying dosage regimens for the different ages may contribute to the problem of inappropriate prescribing or inaccurate dosages, causing treatment failures and drug resistance.

Severe malaria is a medical emergency and the policy therefore recommends parenteral treatment (intramuscular or intravenous infusion), with quinine as the first drug of choice in the treatment of severe cases of malaria; parenteral artemisinin derivatives may also be used as alternatives. However an ACT must be administered as soon as the patient can tolerate oral medication to complete the antimalarial course. In all malaria cases whether uncomplicated or severe, the full course of treatment should be administered (FMOH, 2005a).

The policy is silent on the status of chloroquine, the first line antimalarial drug before the introduction of artemisinin-based combination therapy; however, in implementing the policy the National Agency for Food and Drugs Administration and Control (NAFDAC) stopped the registration of chloroquine and only permits renewal of old licenses. The Agency has also changed the status of chloroquine to a prescription-only medicine (POM), as an outright ban caused a huge outcry, and it is now reserved for other purposes such as in the treatment of amoebiasis.

2.6: Intermittent Preventive Treatment

The prevention of malaria in pregnancy is of great importance, as malaria is a major cause of maternal morbidity and adverse birth outcomes. In areas with high malaria transmission rates, the WHO currently recommends intermittent preventive treatment (IPT), which consists in the administration of a single curative dose of an efficacious antimalarial drug at least twice during pregnancy. This is administered under supervision during antenatal care visits (Briand, *et al,* 2007). Sulfadoxine-Pyrimethamine (SP) has proven to be effective and is currently used for intermittent preventive treatment during pregnancy in Nigeria. In view of the foregoing, SP is no longer recommended for the treatment of uncomplicated malaria in Nigeria, in order to safeguard the therapeutic lifespan (FMOH, 2005b). In areas of multi-drug resistance the WHO recommends ACT and are considered safe in the 2nd and 3rd trimester of pregnancy, though the study by McGready *et al* indicates that a higher close may be necessary because of observed low drug levels (McGready, *et al,* 2007).

2.7: Home Management of Malaria

In order to address the growing problem of malaria, Roll Back Malaria (RBM) a global partnership was founded in 1998 by the United Nations. The overall goal of RBM is to cut African malaria deaths by 50% by 2010, and the specific targets are as follows:

- to ensure that 80% of those suffering from malaria have prompt access to correct, affordable and appropriate treatment.

- to ensure that at least 80% of those affected by malaria benefit from suitable protective measures, such as insecticide treated nets and
- to ensure that 100% of all pregnant women at risk for malaria receive chemoprophylaxis (WHO, 2005a).

One of the major strategies to achieve the RBM goals is prompt access to effective antimalarial treatment; this means treatment should be available as close to the home as possible so that it is given within 24 hours of the onset of symptoms. Home management of malaria has been shown to be effective in ensuring prompt access to appropriate treatment in Africa, especially in the remote areas (WHO, 2004). A number of studies have provided evidence that home management reduces the progression of malaria to the severe form by more than 50%, and under-five overall mortality by 40% (Kidane & Morrow, 2000, Sirima , 2003).

A number of constraints have been identified in meeting the first RBM target including poverty, distance of home from health facilities, hours of health service operations, cost consideration, drug stock outs and the unfriendly nature of health workers (Jowett & Miller, 2000; McCombie, 1996; Williams & Jones, 2004). These factors have encouraged mothers/caregivers to source drugs from the informal or private sector, with sometimes inappropriate or poor quality drugs, contributing to drug resistance, which could in this era of ACT eventually undermine the therapeutic life of these drugs.

2.8: Medicine Sellers and Pharmacists

Medicine sellers first started to engage in business in Nigeria in about 1889, when European medical officers began training natives in the coastal cities where they carried out their business. The colonial government in Nigeria did not make any concrete effort to train professionals to handle medicines until 1927, when a medical Board of Examiners was formed and the School of Pharmacy at Yaba, Lagos, was formally set up to train dispensers. The first set of pharmacists graduated from the University in the late 1960's. This means that non-pharmacists had been handling drugs in Nigeria for over 50 years before the first set of pharmacists graduated (PCN, 2003). This long-standing existence of medicine sellers in Nigeria underscores their role in medicine supply and highlights their relevance and importance in this study.

2.9: Patent Medicine Vendors

Commercial retailers of drugs in the informal private sector are known by a variety of names including medicine sellers, drug sellers, chemical sellers and patent medicine vendors (PMVs). They operate in general shops, market stalls and as itinerant hawkers (Goodman *et al*, 2007). This study will focus on patent medicine vendors; these are non-pharmacists who are licensed by the Pharmacist Council of Nigeria to stock and sell simple medicinal remedies. The pharmacy law of Nigeria stipulates that PMVs should sell only pre-packaged patent medicines, without splitting the pack (Egboh, 2004). Patent medicines are over the counter drugs (OTC) or non-prescription medicines commonly used as household medicaments. They are oral or external preparations in unit pack sizes

used only for a brief medical intervention. These outlets are not permitted to stock prescription-only medicines (POM), only over-the-counter (OTC) products which include cough syrups, pain killers and some anti-malarials. (PCN, 2003).

PMVs are required to be licensed by the state Pharmacist Council, who issues the Patent and Proprietary Medicine Vendor's license (PPMVL). The more established and experienced patent medicine vendors (PMV) usually have one or two shop assistants to assist with sales at the shop. The basic requirement by law to be licensed as a patent medicine vendor is the ability to read and write in English, a minimum of primary school education and good character. Most PMVs do not have a technical or professional background in pharmacy or medicine, however, the Pharmacist Council usually conducts orientation training for new patent medicine vendors. This training serves to educate the vendor on his role in the healthcare delivery system, and the ethics and guidelines governing the selling of patent medicines in Nigeria. Many PMVs have attended several one or two-day seminars organized by stakeholders such as the National Agency for Food and Drug Administration and Control (NAFDAC), National Drug Law Enforcement Agency and non-governmental organizations and drug manufacturing companies. Evidence exists that there is a strong willingness among PMVs to attend training and they are even willing to pay for course (PATH, 2006, unpublished data).

In addition to the Pharmacist Council of Nigeria (PCN) licensure, medicine vendors often register as members of a district, state or national trade association. Although these trade associations have no legal status, they serve as a platform for prestige, social control and

as a pressure group in dealing with the legal authorities (Breiger, *et al*, 2004). In Nigeria the national trade association for PMVs is known as the Nigerian National Association of Patent & Propriety Medicine Dealers (NAPMED) and has regional, state and local area offices. The unlicensed vendors form a sizeable portion of vendors in any state, there are no official figures in this regard. There are complaints from the licensed vendors that the unlicensed vendors are the ones responsible for the unwholesome practices observed in the trade, such as selling prohibited products, breaking a pack to sell or engaging in other practices contrary to the tenets of the patent medicine vendor regulations.(PATH, 2006 unpublished).

2.10: Regulation of Patent Medicine Vendors

The Pharmacist Council of Nigeria (PCN) is the regulatory authority in charge of pharmacy practice and patent medicine vendor operations. The PCN is responsible for registration, licensing and monitoring of patent medicine vendors. Unfortunately, the oversight activities of monitoring are currently weak due to a six year legal battle between the PCN and the patent medicine vendors.

In 1990, the local government councils were authorized to issue the patent medicine licenses by the then Minister of Health. This, however led to a lot of abuse as the local government officials, who were political office holders without medical or scientific training, used the privilege to serve their own purposes by issuing the licenses without adhering to the guidelines issued by the Pharmacist Council of Nigeria. In 1992 the authority to issue licenses was reverted to the PCN, but this was challenged with a court

injunction which stopped the issuing of licenses completely, and only after a long battle in court did the licensing authority finally revert to the PCN in April 2003. This administrative unrest resulted in a bottleneck in the issuing of licenses and was a major hindrance to regulatory activities which is now slowly being addressed (PCN, 2004).

The National Agency for Food, Drug Administration and Control (NAFDAC) is the agency tasked with the mandate to control the sale, export, import, distribution, manufacture and use of medicines in Nigeria. Their activities include visits to shops where drugs are sold, including patent medicine shops. These inspection visits are conducted to ensure that only products duly registered with NAFDAC are being sold as stipulated by law. However, so far regulation has been poor and visits are irregular (NAFDAC, 2004). This has resulted in vendors stocking illegal products such as prescription only products unregistered by the Agency or selling fake and expired drugs. This problem of irregular visits by regulatory authority is not peculiar to Nigeria as literature evidence indicates. (Goodman, *et al*, 2007).

2.11: Patent Medicine Vendors Practices

The practices of patent medicine vendors are of concern as they are a widely patronized source of drugs for the home management of fever/malarial illnesses, and anti-malarials rank high among drugs sold by medicine vendors in Nigeria (Iweze, 1987). Study reports of home treatment have indicated that drugs bought from vendors and used in the home management of malaria are often inappropriate and in the wrong dosages (Goodman, *et al*, 2007). In the case of childhood malaria this represents a major problem since many

deaths occur within 48 hours of the onset of illness if not treated effectively (Greenwood, *et al*, 1987).

A review of studies of medicine sellers' practices across Africa has shown that they have frequently abused the privilege conferred on them by sale of expired drugs, and other suspect practices. They often stock prescription only medicines (POM) such as antibiotics, antihypertensive and tranquillisers (Fussin,1988; Oshiname & Breiger, 1992). They handle drugs inappropriately storing them in conditions of moisture, light and excessive heat which could damage their potency (Battersby, *et al*, 2003). It has also been documented that the drugs sold may be inappropriate for the complaint, such as selling aspirin to treat childhood malaria (Abiola, *et al*, 1983; Nshakira, *et al*, 2002) and the practice polypharmacy where additional unnecessary drugs such as antibiotics, aspirin and multi-vitamins are dispensed (Okoro & Jones, 1995).

The quality of the drugs presented for sale has also been questioned. There has been evidence of dispensing drugs of substandard quality as a result of poor manufacture and storage (Basco, 2004). In Nigeria, like in many countries around the world especially the developing countries, the problem of counterfeit and fake drugs is huge. However there is evidence that suggests improvements, this is attributed to the frontal attack launched by the medicine regulatory Agency (NAFDAC). In 2001, the counterfeit and fake drugs in the system were estimated to be between 41% and 70%, In 2004, the level was estimated at 35% and 15% to 30% (Science in Africa, 2007). Studies conducted in sub-Saharan

Africa Anti-malarial drugs collected from medicine sellers in urban and rural areas were found to have insufficient active, no active, or the wrong active ingredients. The packaging, labeling and dosing information of the products were also found to be inadequate and in conflict with national treatment guidelines (Goodman, *et al*, 2007).

Some of these practices have been linked to the expectation and demand of the consumer as it has been reported that in most situations, the medicine vendor simply sells what the customer requests for fear of losing business (Akuse, *et al,* 2004; Breiger *et al,* 2004). It has also been argued unconvincingly that selling an inappropriate dose may be as a result of the inability of the customer to buy the complete dose (Iweze, 1987). There are reports which suggest that a lack of knowledge of the appropriate dose may be responsible for selling wrong or inappropriate dosages. For example, in a study by Oshiname & Breiger (1992), it was reported that only 2% of the vendors knew the correct dose of chloroquine for a 3-year old child. Frequently, neither the medicine vendor nor the consumer knows the correct dosage or length of treatment (Gomes, Wayling & Pang, 1998).

The sources of drugs sold by medicine vendors have been widely documented. Study reports indicate that they obtain their drugs from large retailers, wholesalers, wholesale pharmacies, and from mobile distributors, if the vendor is located in remote and hard to reach rural areas (Adiukwu, 1996; Goodman *et al,* 2007). The main source of medical information is sales representative from pharmaceutical companies and pharmacies, as government activities usually target the formal health facilities (Goodman, 2004; Ongore & Nyabola, 1996).

A number of concerns have been raised with regard to medicine vendor practices and the introduction of artemisinin-based combination therapy. These include the high price and susceptibility to degradation by sunlight and moisture of these drugs. Improper storage in a tropical country such as Nigeria is of concern, as they may become ineffective due to degradation, if not stored away from sunlight, heat or moisture. Another major concern is the availability in the market of oral artesunate monotherapy, which though effective and cheaper than ACTs is not recommended in the policy, because it is monotherapy and continued use will lead to the rapid emergence of resistance to the ACTs.

Moreover, artesunate has been on sale and commonly used in malaria treatment before the introduction of the ACTs. Cost considerations have been cited as a motivation for the continued use of artesunate and other monotherapy anti-malarials. Artesunate costs on the average N393 (US $ 3.14) whereas ACTs cost about N504 ($ 4.03) for a treatment course in the private sector. This is considerably more expensive than the older antimalarials on the market such as chloroquine and sulfadoxine-pyrimethamine (SP) monotherapy which cost about N83 (US$ 0.66) and N91 (US$ 0.73) respectively (Oladepo, *et al*, 2007).

Presently some ACTs do not come as fixed dose but as two separate components tablet co-blistered. There are concerns that PMVs, due to a lack of knowledge or other reasons, may break the pack into its components tablets and sell individual components, which may lead to the rapid emergence of resistance and increase the malaria burden.

2.12: Patent Medicine Vendor Interventions

Extensive literature exists documenting the utilization, existing role, strengths and shortcomings of medicine vendors, and the recommendations for legal or educational interventions (Jimmy, Achelonu & Orji, 2000; Okeke *et al*, 2006; Oshiname & Breiger, 1992). However, intervention studies are scarce and the explanation given for this is that in many countries interventions targeting unqualified drug sellers, such as patent medicine vendors meet with a certain amount of resistance from both professional bodies and regulatory organizations. In addition, patient demands, vendors focus on profit making, herbal and alternative therapies, and the documented difficulty of achieving rational prescribing in the commercial private sector has contributed to this dearth of interventions (WHO, 1998).

A review of medicine vendor interventions in sub-Saharan Africa reported that they were implemented in widely varying settings; rural, urban and peri-urban (Goodman *et al*; Greer *et al*, 2004; 2007). The number of vendors in the different interventions ranged from less than 10 to 500, with a median of 50. The major method of collecting information was using structured questionnaires administered to sales staff, sometimes supplemented by in-depth interviews, undercover care-seekers, exit interviews, direct observation and household surveys. Studies documented were mainly research trials or donor sponsored projects. The review indicated that there were two main categories of interventions involving the vendors; in some cases the vendors were the main focus of the intervention, such as where vendors in a rural community in Nigeria were trained

(Oshiname & Breiger, 1992). In other cases the vendors were part of a larger community health intervention as in the Healthy Happy Homes initiative in Ghana (He Ha Ho, 2003).

The main types of interventions recorded were: capacity building to improve knowledge and communication skills; creating an enabling environment through policy, demand generation using the media; and drugs quality assurance through franchising, monitoring and supervision. There appeared to be no distinct pattern in terms of the type of intervention and results obtained and it has been argued that a suitable model of intervention has not been found and that interventions are usually case specific based on prevailing conditions and desired results. (Greer, *et al*, 2004).

A number of interventions reported training on correct drug use, choice and dosages as a common element, through workshops and sometimes supplemented with in-shop or peer education training (Kaona & Tuba, 2003; Ross-Degnan, *et al*, 1996). In general, the interventions reported improvements in vendor performance or caregivers being dispensed an age appropriate dose of a recommended drug. It was also shown that medicine vendors who received training were also more likely to stock approved anti-malarials, such as color-coded, dose and age-specific prepackaged anti-malaria drugs. Nevertheless, it has also been suggested that assessing the success of the intervention should not stop at just improvement in knowledge or evidence of giving the correct dose, but should be determined in terms of overall improvement of a reduction in child or maternal mortality and other health indicators (Oshiname & Breiger, 1992).

The foregoing provides an overview of information regarding documented practices and knowledge of vendors in the sale of drugs. The next chapter will give information on the aim and objectives of this study.

CHAPTER 3: AIM AND OBJECTIVES

3.1: Aim

The aim of the study was to describe the knowledge and self-reported practices of patent medicine vendors (PMVs) in the use of antimalarials, particularly Artemisinin-based Combination Therapy, in the treatment of malaria.

3.2: Objectives

The objectives of the study were;

(1) To determine the proportion of patent medicine vendors (PMVs) with the correct knowledge of the signs and symptoms of malaria.

(2) To determine the knowledge of patent medicine vendors (PMVs) in the use of ACTs.

(3) To describe the self-reported practices of patent medicine vendors (PMVs) in the use of antimalarials especially ACTs in the treatment of malaria.

CHAPTER 4: METHODOLOGY

4.1: Study Design

A cross-sectional, descriptive study design was chosen because it has been shown to be objective, credible and of scientific rigor to quantify and describe knowledge and practices (Blanche and Durrheim, 2006).

4.2: Study Population and Sample

The study population was all licensed patent medicine vendors in Mushin, Lagos. Unlicensed premises were excluded, because, they are not recognized by the government. The list of registered premises was obtained from the Pharmacy Council of Nigeria. Fifty-seven shops were identified and 52 of them participated in the study. In each shop, the owner of the shop and one shop assistant were recruited for interviews. The shop assistants were included in the sample because in reality they attend to the clients. If there was more than one shop assistant on duty, then the assistant to be interviewed was determined by flipping a coin.

4.3: Data Collection

A structured questionnaire with closed and open ended questions was used to collect the data. Information collected included demographic data on the vendors, their knowledge of malaria, the ACT policy, ACTs, and self-reported practices regarding the use of ACTs. Before data collection started, the researcher met with the chairperson of the National

Association of Patent Medicine Dealers (NAPMED), Mushin Branch, to seek support and approval to carry out the study. The participant information sheet (Appendix 2) and informed consent form (Appendix 3) were presented and assurances given by the researcher of the confidentiality of the information and written approval was granted. Data collection commenced after the written approval was received.

The interviews were conducted in English, as all participants can speak English which is the major language of business in Lagos. After explaining the reason for the study, consent was sought and the informed consent form presented to them for their signature. The interview was conducted after signing the informed consent form. As regards the question regarding the appropriateness of ACTs during pregnancy, it was assumed that once the PMV was aware that a patient was pregnant, the patient was considered to be either in the second or third trimester of pregnancy. A copy of the questionnaire is attached in Appendix 1.

Four intern pharmacists were recruited and trained by the researcher to administer the questionnaire to patent medicine vendors and they carried out the data collection. The questionnaire was pre-tested on seven patent medicine vendors at the Lawanson area of Lagos, which is similar to the study site in terms of socio-economic status and socio-economic activities of the population. Some adjustments were made to the questionnaire for clarity, such as the serial number was changed to be continuous throughout the different sections of the data collection tool, instead of starting a new serial number in

each section. Responses of the interviews were recorded in duplicate, to check data quality.

4.4: Data Management and Analysis

In order to ensure that there was no missing data, the data collectors checked the questionnaires for completeness before leaving the site. In addition, the questionnaires were cross checked by the researcher and then entered into Excel and subsequently exported to Epi Info (3.2) by a data clerk. There were two teams of two persons per team. In each team, both persons recorded the responses; this means there was double entry of data to ensure accuracy.

Descriptive statistics were used to compute mainly; frequencies, proportions and means (or medians where distribution is not normal) for all important variables in the data set. The demographic variables were cross-tabulated with other variables such as training, educational qualification and length of employment as a medicine vendor and other knowledge and practice variables, to see if there were associations. These variables were chosen because some knowledge, attitude and practice (KAP) studies have reported associations between demographic variables, educational qualification and other practice and knowledge variables. These associations were tested using the chi-squared test, with p-values of < 0.05 considered statistically significant and when the value of the variable was less than 5 the Fischer's exact test was applied.

4.5: Validity and Reliability

Measurement bias was minimized by first of all using a pre-tested questionnaire. The questionnaire was designed to be simple, short and appropriately formatted to reduce errors of data collection and entry into the database. Furthermore, the data collectors were adequately trained and the tool piloted so that requisite skills were acquired before implementing the survey. Since no gold standard or other means of validation of findings exist, it was recognized that the study may be subject to information bias because since these practices are self-reported, the respondents may report what they feel they should be doing not what they do in reality. Selection bias was ruled out by having an inclusive sample. Five eligible vendors chose not to participate, this was not expected to create selection bias, given that it was an inclusive sample, and this was not likely to have a great effect on the findings of the study.

4.6: Generalisability

It will not be possible to generalize the results of this study to the whole of Lagos State as only one community was used. The study results may be more relevant in settings similar to Mushin; urban area, with low socio-economic population. . It is also anticipated that the study results will have relevance more broadly, specifically in generating hypotheses for further testing.

4.7: Limitations

A limitation of this study was that unlicensed medicine vendors were excluded. This is a limitation because unlicensed vendors may have different practices to those who are licensed and thus the study only reports on knowledge and self-reported practices of one group of PMVs.

A further limitation was the use of self-report measures, which has been documented to produce information bias. This study aimed to provide insight to inform further investigations and interventions, and, as is the case with most cross-sectional studies, the associations in this study cannot be assumed to be causal, as establishing temporality is problematic in this type of study design.

4.8: Ethical Considerations

The proposal was approved by the Ethics Committee of the University of the Western Cape**.** The point of entry to the medicine vendors was through the chairperson of the Mushin Medicine Dealers Association (MMDA) and written consent approval was obtained prior to commencement of the survey. Participants were given the participant information sheet and the informed consent form (Appendix 2 and 3).

It was further explained that participation was voluntary; no harmful procedures were involved in the study and they were free to withdraw from the process at any stage of the project, even after initial consent is given. They were also assured of the confidentiality of the information they provided as the results will be presented in an aggregated form

and cannot be traced to any individual person or premises. Information from this study will be made available to the MMDA and the RBM case management sub-committee.

CHAPTER 5: RESULTS AND DISCUSSION

5.1: RESULTS

This section presents the results of knowledge and self-reported practices of patent medicine vendors in a poor urban community in Lagos in the use of antimalarials, especially ACTs, in the treatment of malaria.

5.1.1: Characteristics of participants

A total of 105 vendors were interviewed out of a sample size of 114; indicating a 92% response rate. The study sample consisted of 82 (78%) males and females 23 (22%). The ages ranged from 15 to 54 years with a mean (SD) of 31.5 (10.40) years. More than half of the participants were between the ages of 21 and 30 years. Most respondents were educated; over two-thirds had secondary school education while only four did not have any formal education. Experience as a medicine vendor varied widely; about 38% have worked 3 years or less, whilst about a quarter have worked for over 10 years (Table 1).

Table 1: Demographic characteristics of patent medicine vendors in Mushin (N=105)

Characteristic	Frequency	Percentage (%)	Mean ± SD
Sex			
Female	23	22	
Male	82	78	
Age (years)			31.50± 10.40
15-20	11	10	
21-30	59	56	
31-40	18	17	
41-50	7	7	
51 and above	10	10	
Education			
No formal education	4	4	
Primary School	33	31	
Secondary School	62	59	
Tertiary	6	6	
Experience as a PMV			8.09 ± 8.69
≤ 3 years	40	38	
4 –10 years	40	38	
Above 10 years	25	24	

5.1.2: Training

The study results indicated that 75% of the vendors have received training as a patent medicine vendor. This orientation training is facilitated by the Pharmacist Council of Nigeria (PCN), 44% of respondents have had training in malaria and malaria related topics in the last three years. However, only 21% have had training in the ACT policy since its inception in 2005.

5.1.3: Knowledge of signs and symptoms of uncomplicated and severe malaria

Hotness of body/high temperature, headache and loss of appetite were the most frequently reported signs and symptoms of malaria reported by 94%, 86% and 75% of the medicine vendors, respectively. This was followed closely by joint pains, dark colored urine and vomiting reported by 79%, 78% and 61% respectively (Table 2).

Table 2: Signs and symptoms of malaria reported by patent medicine vendors in Mushin (N=105)

Signs and symptoms of malaria	Frequency (n)	Percentage (%)
Hotness of body/high temperature	99	94
Dark colored urine	78	74
Joint pains	79	75
Headaches	90	86
Loss of appetite	82	78

Vomiting	61	58
Weakness/dizziness	46	44
Cold/rigors	28	27

Knowledge of symptoms of severe malaria was poor. Whilst the vendors mentioned symptoms of uncomplicated malaria such as high temperature (fever), headaches and joint pains and only 11% mentioned convulsions, which is the most critical clinical symptom of severe malaria for immediate referral to a health facility. However, reported knowledge of conditions for referral was high as 88% and 74% mentioned that patients would be referred if there is no improvement after completing the malaria treatment and severe malaria, respectively.

5.1.4: Knowledge ACT Anti-malaria Policy and ACTs

Awareness of the national anti-malaria ACT policy was high, 96% (101) mentioned that they had heard about it. Over 80% of the respondents mentioned that they heard about the policy from a representative of the drug manufacturers or distributors, while 15% and 4% obtained the information from the Mushin Medicine Dealers Association (MMDA) and government sources, respectively (Figure 1).

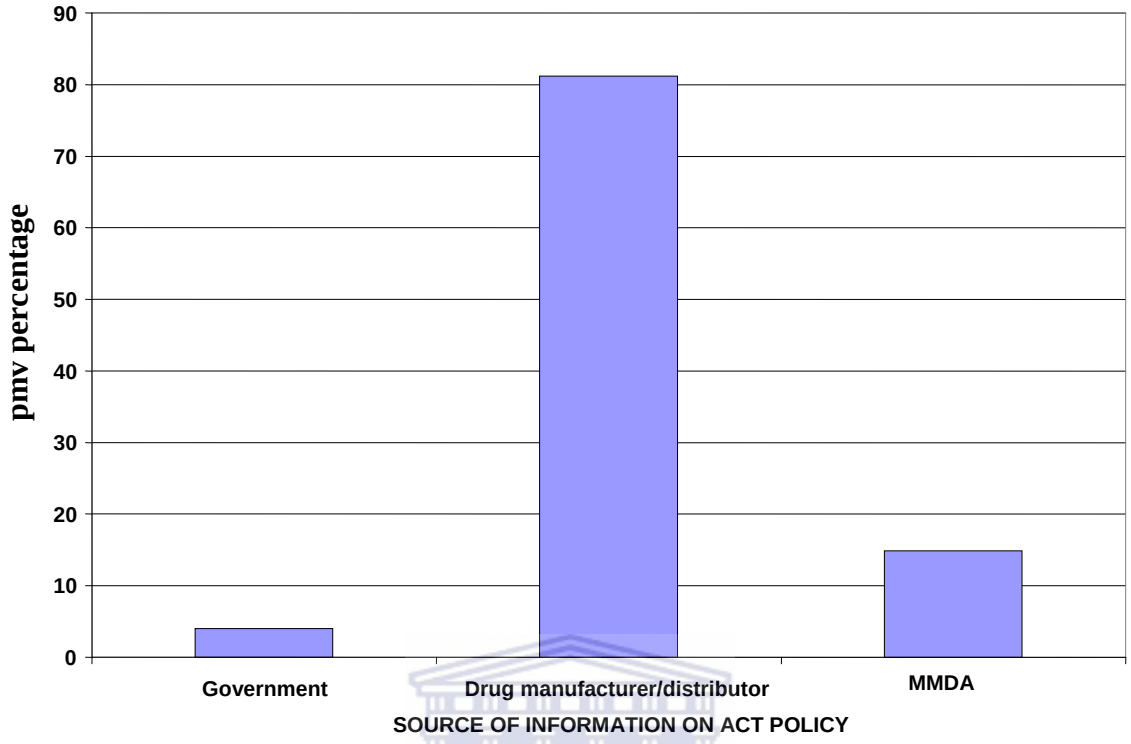

Figure 1: Source of information on the ACT policy by patent medicine vendors in Mushin, Lagos (N=101)

The vendors in the study demonstrated adequate understanding of the reason for the policy change; 62% answered correctly that the reason is that ACTs are more potent than chloroquine in malaria treatment. Knowledge of the recommended use of sulfadoxine-pyrimethamine (SP) according to the policy was average: 56% (57) answered correctly that it is for intermittent preventive treatment (IPT) of malaria in pregnant women, while 41% erroneously considered SP as second line drugs to chloroquine.

A large number of respondents, over 80%, believed that chloroquine is still in useful in the treatment of malaria, while 57% and 19% considered ACTs safe in pregnant women and breastfeeding mothers, respectively.

Respondents were asked to give their opinions on the effectiveness of ACTs compared to chloroquine and fansidar (sufadoxine-pyrimethamine). These were first line and second line antimalarials in the previous malaria policy; 29% and 51% correctly answered that ACTs are more effective than chloroquine and fansider respectively (Table 3).

Table 3: Patent medicine vendors' perceptions of the effectiveness of ACTs compared with chloroquine (CQ) & fansider (SP) (N = 101).

Variable	Frequency (n)	Percentage %
ACTs are more effective than chloroquine	29	29
ACTs have same effectiveness as chloroquine	70	70
ACTs are less effective than chloroquine.	2	2
ACTs are more effective than fansider	51	51
ACTs have same effectiveness as fansider	48	48
ACTs are less effective than fansider	2	2

Table 4: Knowledge of what constitutes an artemisinin-based combination therapy (ACT) anti-malarial by medicine vendors in Mushin (N=101).

Variable	Rating	Frequency	Percent
Mentioned two ACTs correctly	good	14	13.9
Mentioned one ACT correctly	fair	40	39.6
Unable to mention any ACT	poor	15	14.9
No response		32	31.7

Respondents were graded according to the responses provided when asked to mention two artemisinin-based combination therapy anti-malarials. Being able to mention two ACTs correctly was rated as good; fair, if one is mentioned correctly; and poor for no correct answer. All PMVs who mentioned two ACTs correctly also mentioned the first line ACT artemether-Lumenfantrine (Coartem) as one of the ACTs. Interestingly 14% wrongly considered artesunte as an ACT.

5.1.5: Self-reported Practices: Stock Control and Usage of ACTs.

The study results showed that 35% of the medicine vendors had started stocking ACTs from 2005. Acceptance of this anti-malarial seemed to be high as well as over 60% of the vendors have been stocking ACTs since 2007. The main sources of supply mentioned are distributors and manufacturers. They also demonstrated a good knowledge of the storage conditions for ACTs as 90% reported that sunlight affects these drugs and 85% stored them away from sunlight.

Despite this seemingly high acceptance of ACTs, in practice 71% (72) and 55% (56) of the vendors currently sell chloroquine and sulfadoxine-pyrimethamine, respectively, to treat malaria. (Table 5).

Table 5: Self-reported practices of the patent medicine vendors in the usage, stock and sale of ACTs (N=101)

Variable	Frequency (n)	Percentage %
Year started Selling ACTs:		
2005	35	35
2006	32	32
2007	30	30
2008	4	4
Source of ACT Stock:		
Other outlet/pharmacy shops	3	3
Manufacturers	32	32

Distributors	66	65
Can share or break the pack of ACT to sell	41	41
Asks for age of user	70	69
Explains drug dosage	41	41
Provided dosage information Correct Incorrect	 20 21	 49 51

Moreover, when told to rank the anti-malarial most frequently recommended, to their customers in the two months prior to the study, chloroquine, ACTs, and others (mainly artesunate monotherapy) were ranked as first choice antimalarial, by 58% , 17% and 8% respectively, oral artesunate monotherapy was reported by 7%. (Figure 2)

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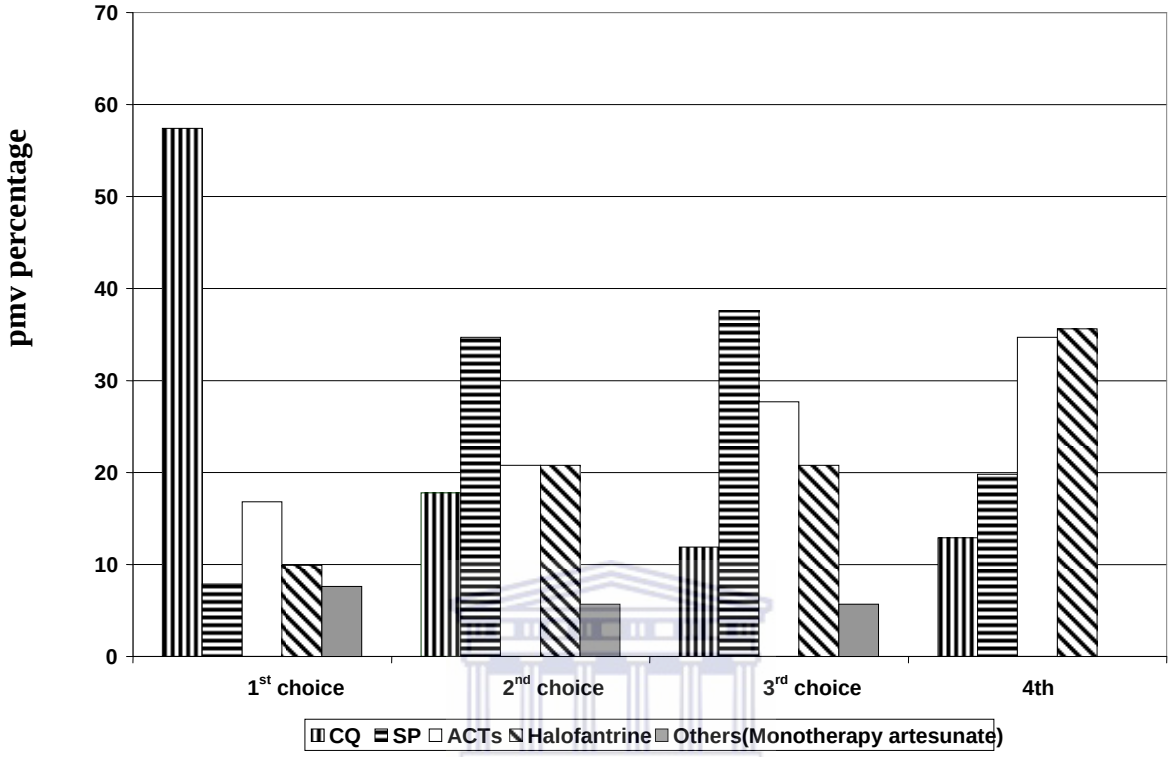

Figure 2: Most frequently recommended anti-malarial by patent medicine vendors in Mushin two months prior to study (N=101).

When asked to rank factors determining what anti-malaria drug was sold in the past 2 months "what the customer requests" was ranked as the most important factor by 37% of respondents. This indicated that the vendor tended to sell what the customer wants regardless of whether it was appropriate (Figure 3).

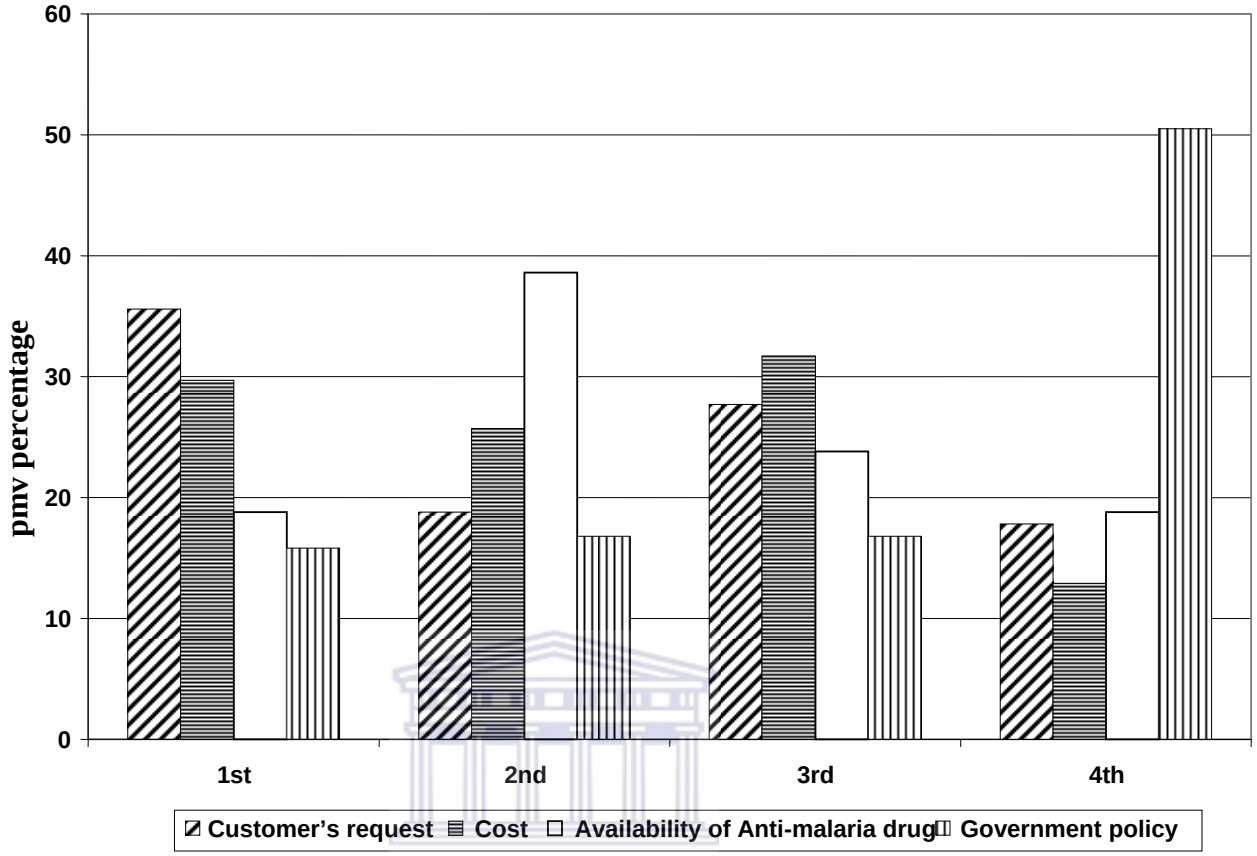

Figure 3: Most important factors determining anti-malarial sold to customers (N=101).

Other practice results showed that 40% would share or break the ACT pack to sell to customers and 70% would ask for the age of the user before selling. However, only 41% would explain the dose, out of which only about 50% gave the correct dosage of Coartem (aretemether-lumenfantrine), the first line ACT anti-malarial.

Tables 6-9: Results of 2 by 2 analysis using different variables. The p-values in bold, are statistically significant suggesting an association between the variables.

Awareness of the ACT policy by the PMVs was very high (96%) but those with secondary/tertiary education were more likely to be aware of the policy and to have had training on the policy than those with primary or no formal education (with statistically significant p-values (Fischers' exact test) of 0.0138 and 0.005 respectively. A greater percentage of those with secondary/tertiary education said that ACTs were unsuitable for use in pregnancy, however, they were less likely to ask the specific age of the user. (Table 6).

Table 6: Comparison of medicine vendor educational qualification with knowledge of the ACT policy and self-reported practices in the use of ACTs.

VARIABLE	**EDUCATIONAL QUALIFICATION**		**DF**	**P-value**	**OR**	**95% CI**
	No formal/ Primary	**Secondary/ Tertiary**				
Awareness of Policy			1	**0.0138***	-	
Yes	33 (89%)	68 (100%)				
No	4 (11%)	0(0%)				
Knowledge of ACT suitability in pregnancy						
Suitable	25 (76%)	33 (49%)	1	**0.017****	3.3144	1.3111 to 8.3784
Not suitable	8 (24%)	35 (51%)				
Knowledge of ACT suitability in breastfeeding women						
Suitable	6 (18%)	14 (21%)	0.9853	1.000	0.2963 to 2.4793	
Not suitable	27 (82%)	54 (79%)				
Reason for change in policy						
Additional drug to CQ	14 (42%)	24 (35%)	0.6349	0.517	0.5769 to 3.1633	
ACTs more potent	19 52%)	44 (65%)				

Training on Policy					
Trained	2 (6%)	21 (31%)	**0.005***	0.005	0.0316 to 0.6600
Not trained	31 (94%)	47 (69%)			
Ask for specific age of user					
Yes	29 (88%)	41 (60%)	**0.005***	0.005	1.5076 to 15.1201
No	4 (12%)	27 (40%)			
CQ still used in malaria treatment					
Yes	31 (94%)	53 (78%)	**0.05***	0.05	0.9399 to 20.4740
No	2 (6%)	15 (22%)			
Can share or break ACT pack to sell					
Yes	9 (27%)	32 (47%)	0.0923	0.083	0.1712 to 1.0398
No	24 (73%)	36 (53%)			

***Fishers' exact test**
**** Chi squared test**

Those vendors who had been trained in patent medicine regulations and practices by the Pharmacist Council of Nigeria were more likely to know the reason for the policy change than those who were not trained - 69% of those trained gave the correct reason compared to 43% who are untrained ($p<0.05$). Those who had attended PMV training were also more likely to ask for the specific age of the patient (84%) than those who were not trained (58%). However, more of those who had attended PMV training reported that CQ is still used for malaria treatment (90%) compared to those not trained (63%). A surprising finding was that those who had attended PMV training were less likely (16%) to have received training on the ACT policy than those who had not received training (46%) (Table 7).

Table 7: Comparison of medicine vendor training with knowledge of ACT Policy, and self-reported practices in the use of ACTs (N=101)

Variable	PMV- training		DF	P-value	OR	95% CI
	Yes	**No**				
Awareness of policy						
Yes	77 (76%)	2 (50%)				
No	24 (24%)	2 (50%)	1	0.255*	0.3117	0.0416 to 2.3329
Reason for change in policy						
Additional drug to CQ	24 (31%)	14 (58%)	1	**0.031****	0.3235	0.1258 to 0.8313
ACTs more potent	53 (69%)	10 (43%)				
Training on policy						
Yes	12 (16%)	11 (46%)	1	**0.006****	0.2251	0.0818 to 0.6198
No	63 (84%)	13 (54%)				
	Yes	**No**				
Asks for age of user						
Yes	59 (84%)	18 (58%)	1	**0.009****	3.8737	1.4819 to 10.1259
No	11 (16%)	13 (42%)				
CQ still used in treatment of malaria						
Yes	69 (90%)	15 (63%)	1	**0.005****	5.1750	1.7157 to 15.6089
No	8 (10%)	9 (38%)				
Can share or break ACT pack to sell						
Yes	27 (35%)	14 (58%)	1	0.0737	0.3857	0.1511 to 0.9843
No	50 (65%)	10 (42%)				

***Fishers' exact test**
**** chi square**

Training on the ACT policy did not seem to improve the PMVs understanding of the reason why the ACT policy was introduced or have a positive impact on some of the self-reported practices in the use of ACTs (Table 8). Less of those trained (57%) in the ACT policy gave the correct reason for the change compared to those who had not received training on the policy (64%) Training on the ACT policy was found to be associated with self-reported practices in the use of ACT such as sharing or breaking the pack of ACT to sell - surprisingly more of those trained on the policy reported that they could share the ACT pack (78%) compared to those not trained (29%). It was also found that less (22%) of those who attended the ACT training asked the age of the user, than those who did not attend the training (83%). One area in which attendance at the ACT training did have a positive impact was in the discontinuance of the use of chloroquine in treating malaria.

Table 8: Comparison of training on ACT policy with understanding of ACT Policy and practices in the use of ACTs (N=101)

Variable	TRAINING ON ACT POLICY		DF	P-value	OR	95% CI
	YES	**NO**				
Reason policy was introduced						
Additional drug in CQ	10 (43%)	28 (36%)	1	0.6784	1.3736	0.5337 to 3.5353
ACTs more potent	13 (57%)	50 (64%)				
Can share ACT pack						
Yes	18 (78%)	23 (29%)	1	**0.0001****	8.6087	2.8544 to 25.9632
No	5 (22%)	55 (21%)				
Ask for age of user						
Yes	5 (22%)	65 (83%)	1	**0.0001***	0.0556	0.0175 to

				*		0.1765
No	18 (78%)	13 (17%)				
CQ still used in malaria treatment						
Yes	9 (39%)	75 (96%)	1	**0.0001***	0.0257	0.0062 to 0.1070
No	14 (61%)	3 (4%)				

***Fishers' exact test**
**** chi square**

Table 9: Comparison of sex of patent medicine vendor training as a PMV and training on ACT policy

Variable	SEX		DF	P-value	OR	95% CI
	FEMALE	MALE				
Training on ACT policy (N=101)						
Yes	6 (26%)	17 (22%)	1	0.8820	1.2664	0.4323 to 3.7099
No	17 (74%)	61 (78)				
PMV training (N=105)						
Yes	18 (78%)	61 (74%)	1	0.9150	1.2393	0.4093 to 3.7531
No	5 (22%)	21 (26%)				

Gender did not seem to be a factor as to whether a PMV received training as a PMV or on the ACT policy, with 26% of females reporting that they had received ACT training compared with 22% of males.

5.2: DISCUSSION

This study sought to describe and quantify the knowledge and practices of patent medicine vendors, in an urban area of Lagos, in the use of ACTs and to assess these against the National Artemisinin-based combination therapy Anti-malaria Treatment Policy (FMOH, 2005a). A large percentage of medicines used in home management of malaria in Nigeria are obtained from patent medicine vendors. Prompt and appropriate home management of malaria is one of the cornerstones of malaria control.

5.2.1: Knowledge of symptoms of uncomplicated and severe malaria.

Malaria is endemic in Nigeria and a common condition amongst the populace. It is therefore expected that the medicine vendors would have adequate experience recognizing the symptoms. The results of this study showed that the knowledge of the symptoms of malaria was very high. This is congruent with results of other studies which indicate that knowledge of the symptoms of malaria is high in endemic areas (Aikens, Pickering & Greenweed, 1994). However, only 11% mentioned convulsions which are the most important signs to recognize severe malaria. A critical condition for referral to a treatment facility or clinic is severe malaria or when or there is a lack of improvement (FMOH, 2005). Surprisingly, 74% of PMVs correctly reported that they would refer severe malaria to a treatment facility; however, given the poor recognition of identifying severe malaria, it is doubtful that adequate referral is occurring in this practice setting. This issue needs to be addressed as high mortality due to severe malaria is likely especially amongst children and pregnant women.

The medicine vendors in this community would benefit from training and educational interventions geared towards the improvement of the recognition of signs of severe malaria (Oshiname & Breiger, 1992).

5.2.2: National ACT anti-malaria treatment policy

Knowledge of existence of the ACT Anti-malaria Treatment Policy was high. There are, however, indications that understanding and application is weak with respect to choice of anti-malarial and appropriate use in specific groups such as pregnant women and children. The study showed that PMVs were not clear about what an ACT is, with only 14% correctly naming two ACTs. At the same time 14% erroneously thought that artesunate, one component of the artemisinin based combination therapy, was an ACT. Responses to questions on the effectiveness of ACTs in comparison to CQ and SP monotherapy provided somewhat confused answers. All this seemed to indicate that PMVs do not have a good understanding of the reasons for the new policy and thus it is not surprising that their practices in the choice of anti-malarial drugs deviate from the policy guidelines. This is worrying because supply of the wrong medicines will increase sickness and fatalities due to malaria and also the rapid emergence of drug resistance.

Over two thirds of PMVs indicated that they obtained information on the policy from representatives of drug manufacturers and only 4% got the information from government sources. A number of studies have provided evidence that information from medical representatives of drug companies is usually distorted, which in this case could mean

providing inadequate or incorrect information as to what constitutes an ACT (Bardeley, Becel, Hoen, 1998). The Federal Ministry of Health (FMOH) is responsible for formulating and ensuring compliance to this policy. The report of the policy implementation indicates that various methods were used, to disseminate information on the change from chloroquine to ACT. These channels included seminars workshops, advocacy visits to communities, decision makers and relevant profession groups including patent medicine vendors. However the level of knowledge of PMVs from this study sample seems to indicate that the government strategies and programmes to disseminate information and implement the policy were inadequate and unsuccessful. This may also be a reflection of the documented constraints and complexities that have been identified in changing and implementing a drug policy change (Zurovac, *et al*, 2005; Amin, *et al*, 2007). Some of these constraints include the availability of the former drug of choice in the market (chloroquine in the case of Nigeria). This can be attributed to a lack of political will power and anecdotal report of continued effectiveness and the adverse drug reactions associated with some of the ACTs especially artesunate amodiaquine.

5.2.3: Anti-malaria treatment Practices

Practices are of great significance especially in the case of childhood malaria as inappropriate or ineffective drugs or the use of wrong dosages can lead to death within 48hours of onset of illness (Greenwood, *et al*, 1997). Although chloroquine and SP are no longer recommended for use in malaria treatment in Nigeria, the study found that 55% and 71% of the medicine vendors are still using CQ and SP, respectively, In fact, in the

two months prior to the study over fifty percent of the medicine vendors ranked chloroquine as the most frequently supplied anti-malarial, with only 16% reporting ACTs as the most frequently supplied.

Furthermore it was observed that the most important factors in determining the choice of anti-malarial supplied by the vendors in this community was “what the customer requests for”. This was followed by cost; availability of anti-malarial; and fourthly by government policy. This is congruent with findings of other studies in which patient and caregivers requests were of high importance (Ongore & Nyabola, 1996; Oshiname & Breiger, 1992; Adome, 1996). This would seem to suggest that in order to improve home management of malaria, and to realize the impact of the ACT policy, there is a need for community level re-orientation on drug use and policy information dissemination to mothers/caregivers. This may be challenging as it would require an understanding of the social, cultural and other factors that influence and determine drug choice and use (Djimide *et al,* 1998). Interestingly however, research results have indicated that mothers/caregivers would take the advice of vendors if they perceive them as adequately trained by a credible health authority (Marsh *et al*, 1999; Marsh *et al*, 2004). This type of intervention can therefore be explored in this setting to improve community drug use.

The second most important factor determining the choice of anti-malarial medication was “cost”. High ACT prices have been identified as a major barrier to usage in the private sector (Gilpin, 2008). ACTs cost N504 (US$4.03) for a treatment dose, which is considerably more expensive than the other anti-malarials such as chloroquine which

costs about N83 (US $ 0.66) and Sulfadoxine Pyrimethamine which costs about N91 (US 0.73) (Oladepo *et al,* 2007). This means the ACTs cannot be afforded by the poor, the socio-economic strata that is frequently sick with malaria (Barat *et al*, 2004, WHO/SEARO, 2002).

To address this issue of affordability, several initiatives are been put in place especially in the public sector, such as the Global fund for AIDs, Tuberculosis and malaria (GFATM). The Global fund has done a lot to ensure adequate supply of ACTs to the public/formal sector. Such programmes are currently not available in the private and informal sector hence the significance and relevance of the, Affordable Medicines Facility - malaria initiative (AM-Fm) by the Roll Back Malaria Coalition. The goal of this initiative is to reduce consumer prices to an affordable level, through a financing mechanism so that ACTs are available at about the same price as chloroquine. It is expected that with the successful implementation of this program, ACTs will be available through the formal and informal drug supply chain including medicine vendors, so ACTs can reach the poorest of the poor at an affordable price (Gilpin, 2008).

The practice of selling oral artesuante monotherapy by these vendors further underscore the difficulty and complexities in the successful implementation of a new drug policy when the transition involves a familiar drug which is available, effective and inexpensive such as artesunate in this case (Williams, *et al*, 2004; Zurovac, *et al,* 2005). The observed practices in this setting is also consistent with that of other studies which have documented practices of medicine vendor practices which are different from the national

treatment guidelines (Battersby, *et al*, 2003; Djimide *et al*, 1998). However, there is evidence from a number of countries that training medicine sellers resulted in improved adherence to policy guidelines (Marsh *et al*, 2004, Greer *et al,* 2004).

5.2.4: Regulation of Patent Medicine Vendors

This study also revealed other illegal practices by PMVs, such as the stocking and sale of chloroquine and sulfadoxine-pyrimethamine monotherapy for the treatment of malaria. CQ and SP have both been re-categorized as prescription only medicines for use in the treatment of amoebiasis, and intermittent preventive treatment (IPT) of malaria in pregnant women, respectively. So PMVs are not allowed to stock or sell these medicines anymore. This practice of stocking prescription only medicines (POM) has also been widely documented by other studies in similar settings (Oshiname & Breiger, 1992; Fassin, 1998). The weak regulation of PMVs may be partly responsible for the observed practices. In recent times, regulatory activities by the Pharmacists' Council of Nigeria (PCN) and NAFDAC have been weak and ineffective due to administrative bottlenecks. This has created an environment for practices that mitigate against the success of the policy, if allowed to go unhindered. The findings of this study point to the need of increased regulatory control of PMVs by both the PCN and NAFDAC.

The study results also indicates that the ACT policy training may not have achieved the desired goal to enlighten PMVs on the policy and use of ACTs . This is in view of the fact that more of those trained on the policy report that ACTs can be shared and are less likely to ask for the age of the user. This is interesting and may require further

exploration because it may be an indication that the training was either inadequate or a refresher course is urgently required. Vendors with secondary or tertiary education were more likely to be trained. This may seem to suggest a perception that training organizers prefer to train vendors with a higher educational qualification. Currently the educational requirement to qualify for a patent and proprietary medicine vendors' license (PPMVL) is not explicit, only the ability to read and write is required and an unverifiable proof of "good character". This study also shows that 4% of respondents had no formal education and by convention primary school education has been found adequate. These results seem to suggest that the PCN should reconsider the educational qualification stipulations for granting a PPMVL.

Patent medicine vendors fill a very critical gap in the health delivery system and in the treatment of malaria and febrile illnesses (Salami & Breiger, 2005).Whilst it has been argued that widespread use of anti-malarials in the hands of non-medical personnel could lead to inappropriate use and the rapid emergence of resistance; evidence exists that if mothers/caregivers, community volunteers, shopkeepers, school teachers and drugs vendors are trained, they can use anti-malarials appropriately. It is the lack of training or information that leads to inappropriate use (WHO, 2004).

Studies regarding the practices and relevance of PMVs have often recommended a role expansion. Some members of the healthcare profession have however argued against this claiming it would erode the functions and position of the pharmacist. This is unlikely to be the case as the there are over 200,000 patent medicine vendors in Nigeria and only

about 12,000 pharmacists and most practice in the urban areas. The communities in the rural areas depend solely on these medicine vendors for their health needs and health information, since the public health facilities cannot be accessed by them for reasons including; distance, cost, stock outs restricted operating times and the unfriendly nature of hospital staff. (Snow, *et al* 1992; Williams & Jones, 2004).

This study identified a number of deficiencies in the current knowledge and practices of PMVs regarding the ACT anti-malarial policy. The Pharmacist Council of Nigeria (PCN), NAFDAC and the Federal Ministry of Health (FMOH) who have over-sight functions, in terms of policy formulation, implementation and regulating the activities of the PMVs should take the lead in training, information dissemination and regulation to ensure optimal implementation of the national ACT anti-malarial treatment policy.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1: Conclusions

This study found that PMVs with correct knowledge of the symptoms of malaria was high, but knowledge of the signs of severe malaria was inadequate.

The medicine vendors in this study had a high awareness of the ACT anti-malarial treatment policy but exhibited an inadequate understanding and application of the policy guidelines in their self-reported practices.

Medicine vendors were engaged in practices which were counter-productive to the success of the policy, and malaria control in general, such as the continued use of chloroquine monotherapy, oral artesunate monotherapy and SP in the treatment of malaria; giving incorrect dosing information; and breaking or sharing the ACT pack to sell which could lead to sub-optimal doses and treatment failures. These indicate an urgent need for educational interventions and behaviour change communication (BCC) for PMVs and caregivers in the community.

Finally, the policy implementers NAFDAC and PCN need to scale up monitoring, supervisory and capacity building activities of the medicine vendors to ensure optimal implementation of the ACT anti-malarial policy guidelines.

6.2: Recommendations

The results of the research study identified a number of key areas that need to be addressed in order to ensure optimal management of malaria in this setting.

- There is an urgent need for educational interventions to improve knowledge and ensure practices are in line with ACT anti-malaria policy guidelines.

- There should be a re-orientation and community-based health education programme to improve the knowledge of mothers/caregivers about the policy, so that they can make informed choices when choosing anti-malarials and improve the home management of malaria.

- The PCN and NAFDAC should improve regulatory control of PMVs to ensure adherence to the ACT policy.

- NAFDAC should encourage the gradual phasing out of co-blistered formulations of ACTs and permit the sale of only fixed dose combination to prevent monotherapy and wrong dosage through breaking or sharing the ACT pack. In addition, there should be a scale up of continuous campaign against oral artesunate monotherapy and other monotherapies including chloroquine, SP and the other anti-malarials to prevent the development of resistance to ACTs.

- The Roll Back Malaria partnership (RBM) and the Federal Ministry of Health should speed up the implementation of Affordable Medicines Facility –malaria (AM-FM) initiative to provide safe, efficacious and affordable ACTs.

- Future studies in this regard, should assess and the knowledge and practices of licensed and unlicensed PMVs and other health care professionals, for example doctors and pharmacists.

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APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

DATA COLLECTION TOOL

Thesis Title: Knowledge and practices of patent medicine vendors (PMVs) on the use of Artemisinin combination therapies (ACTs) in an urban community Lagos.

Name of Interviewer:…….. Date:…….. Questionnaire No: ……

A. **DEMOGRAPHIC INFORMATION:**

(1) Sex : (1) Male ☐ (2) Female ☐

(2) Age ☐

(3) What is your highest level of education?

(i). Tertiary. ☐ (ii). Senior Secondary School ☐

(iii). Primary School ☐ (iv). No formal Education. ☐

(4) How long have you worked as a PMV? ☐

(5A) Have you had any training at all as a patent medicine vendor? Yes ☐ No ☐

(5B)If yes give details

Name of the course attended	When (date)	How long (total number of hours or days)	List all topics covered	Name of Training Provider	Who organized the training?

(5C)Have you attended any training on Malaria in the past 3 years? Yes ☐ No ☐

5D)If yes give detail;

Name of the course attended	When (date)	How long (total number of hours or days)	List all topics covered	Name of Training Provider	Who organized the training?

B. **Knowledge of Signs and Symptoms of Malaria:**

(6). what do you think are the major symptoms of malaria? (tick the correct ones)

	Yes	No
Hotness of the body/high temperature……	1	2
Dark coloured Urine……..	1	2
Joint pains……	1	2
Headache……..1		2
Loss of appetite…….1		2
Vomiting……...1		2
Weakness/Dizziness……	1	2
Cold/rigors	1	2
Others (Specify) [ ]……..1		
Others (Specify) [ ]…….…… ..1		
Don't know [ ]…….……1		

(7). How do you know when someone has severe malaria (pls tick all that is correct)

	Yes	No
Hotness of the body/high temperature.....1		2
Dark coloured Urine……...1		2
Joint pains……...1		2
Headache……....1		2
Loss of appetite…….. 1		2
Vomiting……1		2
Weakness/Dizziness…….....1		2

Convulsions…….1 2

Anaemia.....……...…1 2

Others (specify) [ ]……..1

(8) In what condition do you think a child with malaria should be referred to the clinic? (multiple codes allowed, do not read out)

	Yes	No
No improvement after completing malaria treatment.....1		2
Severe malaria.....1		2
Others , specify**.....1**		

C. **Knowledge Of The Artemisinin based combination therapy (ACT)**

(9) Are you aware of the new government Artemisinin based combination therapy (ACT)

policy in the treatment of malaria? Yes. ☐ No. ☐

(10) If yes, where did you get the information? (tick main source)_

(i) Government sources ☐

(ii) Drug manufacturers/distributors ☐

(ii) PMV association ☐

(iv) Others (specify) ☐

(11) Why do you think this new policy was introduced?

(i)An additional drug to chloroquine in malaria ttreatment ☐

(ii) ACTs are more potent and better to treat malaria ☐

(iii) I don't know ☐

(12) Have you had any training on the ACT policy?

Yes ☐ No ☐

(13) Can you name two ACT antimalarial drugs?

1……..2……

(14) When did you start selling ACTs to your customers? (tick one box)

(i) 2005 ☐ ii) 2006 ☐ (ii) 2007 ☐ (iv) 2008 ☐

(15) Are ACTs suitable for use by:

Pregnant women Yes ☐ No ☐ don't know ☐

Breast feeding mothers Yes ☐ No ☐ don't know ☐

(16) What is the recommended use of sulfadoxine/pyrimethamine now (for example Fansidar, tick one only)?

(i) IPT ☐

(ii) Second line to chloroquine ☐

(iii)Don't know ☐

(iv) Others (specify) …… ☐

(17) Is chloroquine still used in the treatment of malaria?

Yes ☐ No ☐ don't know ☐

(18) How do you rate the effectiveness of ACTs compared to other antimalarials such as chloroquine or fansidar (tick one box).

(A) chloroquine

(i) ACTs are more effective than chloroquine ☐

(ii) ACTs have the same effectiveness as chloroquine ☐

(iii) ACTs are less effective than chloroquine ☐

(iv) Don't know ☐

(B) Fansidar

(i) ACTs are more effective than fansidar ☐

(ii) ACTs have the same effectiveness as fansidar ☐

(iii) ACTs are less effective than fansidar ☐

(iv) Don't know ☐

D. **Current Practices In The Use Of ACT In Treatment Of Malaria**

Use of ACTs:

(19) Do you currently sell chloroquine and fansidar to treat malaria?

chloroquine Yes ☐ No ☐

fansidar Yes ☐ No ☐

(20) In the past 2 months, which antimalaria drug have you most frequently recommended? (rank 1 -4 with one as the most recommended)

(i) CQ ☐ (ii) SP ☐ (iii)ACTs ☐ (iv)Halofantrine ☐

(v) others (specify)

(21) What determines which antimalaria drugs you sell to your customers? (rank these reasons 1-4, 1 being the most important)

(i) What they request for (ii) Cost (iii) Availability of the antimalaria drug . (iv) Govt policy (v) others (specify)…….

(22) If a customer wishes to buy any ACT, can you share the pack or break the pack for sale to the customer: yes ☐ No ☐

(23) Do you usually ask for the specific age of the user before selling ACT?

Yes ☐ No ☐

(24) Do you explain the drug dosage to the customers? Yes ☐ No ☐

(25)If yes, pls give an example of dosage for coartem:

……..

ACTs Stock Control:

(26) What is your main source of ACTs anti-malaria drugs? (Main source only)

(i) Source from other outlets/pharmacy shops

(ii) Manufacturer

(iii) Distributors

(iv) Others..…. (.specify)

(27) Where do you store your ACT anti-malaria drugs? (tick all that apply)

	Yes	No
Cool area on the shelf…….....	1	2
Away from sunlight..... … ...….1		2
A well ventilated area …….....…….. .1		2
In a enclosed glass shelf.....1		2
Others (Specify) [ ]…….... 1		

(28) Do you think sunlight has any effect on ACT anti-malaria drugs?

Yes. ☐ No . ☐

APPENDIX 2: PARTICIPANT INFORMATION SHEET

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School of Public Health

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Tel: +27 21-959 2809, Fax: 27 21-9592872

http://www.uwc.ac.za/comhealth/soph

PARTICIPANT INFORMATION SHEET

Project Title: Knowledge and practices of Patent Medicine Vendors (PMVs) in the use of Artemisinin based combination therapy (ACT) in an urban community in Lagos.

What is this study about?

This is a research project being conducted by Rametu Momodu, a MPH student at the University of the Western Cape, South Africa. We are inviting you to participate in this research project because you are a patent medicine vendor in this community. The purpose of this research project is to determine your knowledge of ACTs and their usage in the treatment of malaria.

What will I be asked to do if I agree to participate?

You will be asked to provide some information about your background such as your, level of education, length of employment or practice as a patent medicine vendor, your knowledge of malaria, ACTs and your practice when attending to customers who come to purchase medicine for fever/malaria.

Would my participation in this study be kept confidential?

The survey is anonymous and will not contain information that may personally identify you. The result of the survey will be presented in an aggregated form which will not be traceable to any respondent.

What are the risks of this research?

There are no risks associated with participating in this research project.

What are the benefits of this research?

The benefits to you include possible improvement in your knowledge and practice in the use of ACTs in malaria treatment and the care received by your customers. The results of this survey and recommendations for improvement will be presented to policy makers in the Federal Ministry of Health and the RollBack malaria committee.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time without any reason. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits.

Is any assistance available if I am negatively affected by participating in this study?

Since this study is not invasive, I do not anticipate any adverse effects of this study on you.

What if I have questions?

This research is being conducted by Rametu Momodu, School of Public Health, at the University of the Western Cape. If you have any questions about the research study itself, please contact Rametu Momodu at: 71 Adisa Bashua Close, Surulere ,Lagos Nigeria, +2348033159778, rametu3@yahoo.com .Should you have any questions regarding this study

and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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APPENDIX 3: INFORMED CONSENT FORM

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INFORMED CONSENT FORM

Title of Research Project: Assessment of the Knowledge and Practices of Patent Medicine vendors in the use of Artemisinin based combination therapy in an urban community in Lagos.

I believe I have been properly informed and that I understand the nature and goals of the study. I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name……..

Participant's signature…….

Date……

Should you have any questions regarding this study or wish to report any problems you have experienced related to the study, please contact the study coordinator:

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