Journal of Scientific and Innovative Research 2013; 2 (3): 512-517
Available online at: www.jsirjournal.com

Research Article

ISSN 2320-4818
JSIR 2013; 2(3): 512-517

Received: 28-06-2013
Accepted: 10-08-2013

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Provider Training on the use of AMFm ACTs in Private Drug Outlets in Ghana: a case study on the impact of malaria services in urban areas

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Abstract

Malaria cases are normally treated at the community level by accessing anti-malarial drugs from licensed chemical sellers (LCSs) and their services of these LCSs are crucial to malaria treatment especially in urban areas. But the introduction of the AMFm ACTs and training of LCSs on malaria case management requires the need to assess the impact of their [LCSs] knowledge on malaria diagnosis and prescription of appropriate anti-malarial drugs and their outcomes on health services in general. This study was a descriptive desk review to gather facts from the literature. Information were obtained from health records, the Ghana Ministry of Health (MOH), Ghana Health Service (GHS), Ghana Statistical Service, (GSS) a wide array of literature from International Journals and from the website. All these were analyzed and described. Ethical approval was obtained from the Ethical Review Board of the Ghana Health Service through the School Of Public Health, University of Ghana. Approval was obtained from the Municipal Director of Health Services. It was observed that the providers prescribed ACTs for the treatment of uncomplicated malaria, although some monotherapies, [Sulfadoxine-Pyrimethamine (SP)], are still being used to treat clinically suspected malaria. However none of the providers prescribed chloroquine for their clients/patients. The training of providers improved knowledge of the beneficiary licensed chemical sellers, in the diagnosis and management of malaria. There is a steady increase in the use of ACTs, despite the fact that some monotherapies are still available on the Ghanaian pharmaceutical market. Awareness of the AMFm ACTs was high among the community with television being the commonest source of information.

Keywords: Trained licensed chemical sellers, AMFm ACTs, Kumasi metropolis, Malaria.

Introduction

Malaria is a global public health disease endemic in 109 countries. It is an infectious life-threatening disease caused by the protozoal parasite Plasmodium, transmitted among humans through the bite of an infected female Anopheles mosquito. Until recently, malaria in humans was known to be caused by four species of Plasmodium: *P. falciparum, P. malariae, P. ovale and P. vivax.* Of these, *P. falciparum* is the most common and most dangerous. However a fifth one, plasmodium knowlesi, which hitherto causes malaria in monkeys, has been discovered to cause malaria in humans around the forest areas of South-East Asia.[1]

The development of drug resistance to monotherapies such as Chloroquine has posed

major challenges in the control of malaria globally. In Ghana research has revealed that treatment failure using chloroquine ranged from 6% to 25%; but parasite clearance rates are low, and in certain areas less than 50%. In the light of this, Ghana switched to the use of Artemisinin-based Combination Therapies (ACTs) in 2005 for the treatment of uncomplicated Plasmodium falciparum malaria, as per WHO recommendations.[2] Recent clinical trials conducted in children under five years in confirmed uncomplicated malaria, revealed that by the third day of treatment with Artesunate-Amodiaquine, 99.8% of them had their parasites cleared; with considerable increase in haemoglobin levels by the 28 days.[3]

Despite their proven efficacy, ACTs are not widely used because they are more expensive than the less-effective anti-malarial drugs. To bridge this gap, the Affordable Medicine Facility-malaria (AMFm) has been introduced to give universal coverage to ACTs.[4] The AMFm is a malaria treatment financing mechanism hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria. It aims to increase universal accessibility and affordability to quality-assured artemisinin-based combination therapies for malaria in endemic countries through subsidies to public health facilities and private drug outlets. The subsidy is expected to translate into low price of ACTs for the final consumer at the end of the distribution chain.

A survey conducted on the knowledge, attitude and practices (KAP) of licensed chemical sellers in the Ashanti Region of Ghana (Health Partners, Ghana) revealed that only 38% of respondents knew that Artesunate–Amodiaquine was the first line anti-malarial drug for the treatment of uncomplicated Plasmodium falciparum malaria; and just 35.3% of them educated patients/clients on their medications.[5] Based on the findings of the KAP study, a series of training for licensed chemical sellers on malaria case management was organized by Mobilize Against Malaria (MAM) and its partners [Family Health International and Ghana Society for Marketing Foundation] since November 2008.

In an effort to confront this malaria burden, several approaches were adopted in the country including provider training on the use of AMFm ACTs in private drug outlets. This study [desk review] seeks to find out the impact of malaria services in the urban areas in Ghana with the view to informing policy decisions among stakeholders.

Statement of the Problem

The Plasmodium falciparum which causes the most severe form of malaria is resistant to monotherapies like chloroquine, and currently ACTs are the only effective first line anti-malarial drugs. However, ACTs are much more expensive than the ineffective monotherapies; therefore to delay the parasites resistance to ACTs, it is only prudent that these ACTs are made easily available, accessible and affordable, as well as ensuring their appropriate use by patients in endemic countries. According to Nkrumah-Mills[6] about 80% of patients do home treatment as the first step by either using herbal concoctions or buying over the counter (OTC) anti-malarial drugs. Nonetheless, most licensed chemical sellers from whom majority of patients/clients buy these over the counter anti-malarial drugs have no structured training on malaria case management.[6]

The large deployment of AMFm ACTs was also followed with training of dispensers and owners of the private drug outlets on how to promote and educate clients/patients on the use and adherence to the quality assured artemisinin-based drug with the aim of delaying resistance and improving treatment outcome. This study therefore sought to assess the effect of this training on activities of the licensed chemical sellers on the AMFm ACTs in the urban areas.

Methodology

This is a descriptive desk review study to gather facts from the literature. Information were obtained from health records the Ghana Ministry of Health (MOH), Ghana Health Service (GHS), Ghana Statistical Service, (GSS) a wide array of literature from International Journals and from the website. All these were analyzed and described.

Ethical Review

Ethical approval was obtained from the Ethical Review Board of the Ghana Health Service through the School Of Public Health, University of Ghana. Approval was obtained from the Municipal Director of Health Services.

Malaria prevention by vector control

The two most effective interventions for malaria vector control are the use of long lasting insecticide treated-nets (LLINs) and indoor residual spraying (IRS), which work by minimizing direct contact of the mosquito with humans and shortening the lifespan of female mosquitoes, thereby reducing bites and parasite transmission. At the end of 2010, an estimated 289 million ITNs were distributed in

sub-Saharan Africa. This figure was expected to cover about 76% of the 765 million persons at risk of malaria. It was also estimated that 42% of households in Africa owned at least one ITN by mid-2010, with 35% of children sleeping under ITNs. This, however, is woefully inadequate to meet the World Health Assembly's target of 80%.[1]

Again, WHO used the quantity of distributed bed for its estimates; nonetheless, Malaria Indictor Surveys collected data on the proportion of households owning a net or sleeping under a net, because distribution does not necessarily correlate with usage.[7]

Griffin et. al. simulated a model to reduce malaria in Africa. This simulation model used six African countries with varying malaria transmission patterns, which suggests that a combination of current malaria control interventions could significantly reduce the malaria prevalence on the continent.[7] The interventions are the use of ACTs as first-line treatment for uncomplicated Plasmodium falciparum malaria, use of long-lasting insecticide-treated nets (LLINs), indoor residual spraying (IRS) and mass screening and treatment (MSAT). According to this model, relatively low malaria transmission areas like Kjenjojo Kasiina in Uganda, sustained universal usage of LLINs and IRS together with changing to an effective ACT as first-line therapy could reduce malaria prevalence to below 1%, which is pre-elimination threshold level. These results correlate with recent observations made in a very low transmission setting in Western Kenya and Zanzibar.[7]

In moderate transmission settings like Nkoteng (Cameroon) and Kinkole (DR Congo) to achieve this, in addition to the above measures, there should be twice-yearly IRS and MSAT. However, in high transmission places like Matimbwa in Tanzania, and the Kassena-Nankana District in Ghana, all these interventions can only reduce parasite prevalence; but to attain a pre-elimination threshold, novel techniques like vaccination should be considered.

A study conducted in two hyperendemic areas in North-East Tanzania from 1998 to 2009, where there were very limited interventions, also revealed a decrease in the Anopheline populations. The study consisted of collecting mosquitoes weekly in 50 households with CDC light traps. During this period there was significant reduction in the number of mosquitoes collected, with only 14 mosquitoes caught in 2009, using 2368 traps.[8]

In 2005 Ghana changed its first line anti-malarial drug from chloroquine, which had a treatment failure rate between 6% and 25%. A study of anti-malarial drug quality in six malaria endemic African countries, including Ghana, revealed that there was an overall 35% substandard monotherapy drugs on the African market; some of which had neither manufacture date nor expiry date. Most of these were manufactured or purported to have been manufactured in Africa and Asia (Bate et. al., 2008).[9] Furthermore, several studies had yielded similar results. This therefore generated the need to switch to ACTs to ensure effective case management and rational use of drug in order to delay development of resistance.[10-12] Piola et. al., also demonstrated that the efficacy of ACTs does not depend on whether they are administered under supervision or not, but rather there should be good patient education on how the drug should be taken.[13]

Efficacy of ACTs

A study in some district hospitals in Senegal on the efficacy and tolerability of combination therapies showed 100% adequate clinical and parasitological response by day 14 for Artesunate-Amodiaquine, Artesunate-Mefloquine and Amodiaquine-Sulfadoxine-Pyremetamine, whilst for Artemether-Lumefantrine it was 99.3%. However, on day 28, there was complete parasite clearance in peripheral blood and resolution of clinical signs and symptoms.[14]

Attitude and practices of private drug sellers

The importance of chemical sellers in healthcare delivery in our communities, more especially in the rural areas in the developing world, cannot be over emphasized. Literature review reveals that in sub-Saharan Africa, between 15% and 83% of clients first contact the chemical shops for first aid of malaria/febrile conditions, and later go to the health facilities if there is no improvement in their condition.[14-18] This therefore calls for the need to ensure that their knowledge and skills in fever/malaria case management are sharpened to enable them deliver quality services to their clients/patients. Nonetheless, chemical sellers facilitate access to anti-malarial medicines, so as to provide treatment within 24 hours of onset of fever/malaria symptoms.

A training of some private drug sellers in malaria case management in rural Tanzania, was conducted and a survey was carried out using 'mystery patients'; that is, persons who pretended to have pre-defined malaria symptoms revealed that, generally, those working in drug

stores mostly (93%) with medical or health-related background had better knowledge in managing uncomplicated malaria than those in general shops (2%).[17] Contrary to the notion that private entities are profit-oriented, most general shopkeepers preferred referring a child with uncomplicated malaria to a health facility to giving a wrong treatment.

However, in some instances, chemical sellers would stock fake, substandard or expired medicines, sometimes including antibiotics which they are not licensed to sell. Most often the store owners or those licensed to dispense are not in the stores and they leave it to unqualified attendants[15] and do not usually keep records of their sales.[5]

Another concern is that chemical sellers merely sell the medicines to their customers like any ordinary commodity on the open market without educating them on the possible side effects, and how these should be managed should they occur.[5] They sometimes 'customize' the prescription to meet the affordability of the customer, in which case they dispense inappropriate drug or dosage.[15]

Processes involved in Malaria confirmation

Microscopy

Microscopy is gold standard for laboratory confirmation of malaria. A drop of the patient's blood is collected by finger prick, or from a larger venous blood specimen. It is then spread on a frosted glass slide (blood smear) bearing a patient identification, dipped in a reagent that stains the malaria parasites (Giemsa stain), and examined under a microscope at a 1000-fold magnification. Malaria parasites are recognizable by their physical features and by the appearance of the red blood cells that they have infected.

Advantages

Microscopy is an established, relatively simple technique that is familiar to most Laboratory Technicians (http://www.parn.org).

Disadvantages

In many developing countries, microscopy is not reliable because the human capacity are insufficiently trained and supervised and are overworked, the microscopes and reagents are of poor quality, and often the supply of electricity is unreliable. Conversely in non-endemic countries, laboratory technicians are often unfamiliar with malaria and may miss the parasites (http://www.parn.org).

Rapid Diagnosis Tests

About 5µl of blood drawn using a loop provided with the device and interpretation of each reading done by trained health officer/nurse;

• Antigen and control line visible in their windows indicates positive results.

• Only the control band visible and control band not visible indicates negative results.

Advantages

High quality malaria microscopy is not always immediately available in every clinical setting where patients might seek medical attention. Although this practice is discouraged, many healthcare settings either save blood samples for malaria microscopy until a qualified person is available to perform the test, or send the blood samples to commercial or reference laboratories. These practices have resulted in long delays in diagnosis. The laboratories associated with these healthcare settings may now use an RDT to more rapidly determine if their patients are infected with malaria (http://www.parn.org).

Disadvantages

The use of the RDT does not eliminate the need for malaria microscopy. The RDT may not be able to detect some infections with lower numbers of malaria parasites circulating in the patient's bloodstream. Also, there is insufficient data available to determine the ability of this test to detect the 2 less common species of malaria, P. ovale and P. malariae. Therefore all negative RDT's must be followed by microscopy to confirm the result and all positive RDTs should also be followed by microscopy. The currently approved RDT detects 2 different malaria antigens; one is specific for *P. falciparum* and the other is found in all 4 human species of malaria. Thus, microscopy is needed to determine the species of malaria that was detected by the RDT. In addition, microscopy is needed to quantify the proportion of red blood cells that are infected, which is an important prognostic indicator (http://www.parn.org).

Malaria treatment

The gold standard for treatment of uncomplicated Plasmodium falciparum malaria is to confirm the diagnosis parasitologically through either microscopy or rapid diagnostic tests (RDTs). Despite a global increase in the parasitological test from 67% in 2005 to 73% in 2009,

there are still cases that are treated based on clinical presentation, especially in Africa where only 20% of suspected cases are confirmed.[1] This is the case in private chemical shops where patients/clients make first contact to seek treatment for uncomplicated malaria in situations where laboratory facilities for malaria rapid diagnostic testing are unavailable.

In areas where malaria density is low (a quarter of febrile cases are RDT positive for malaria) it is cost saving, especially when ACTs are expensive.[19] This is because there might be other causes of acute fever other than malaria. So, confirming clinically suspected malaria is crucial to prescribe anti-malarial drugs for only clients/patients who need them. On the other hand, in malaria high density areas the use of RDTs brings additional cost since most people would actually test positive.[19]

The study showed that none of the licensed chemical sellers (trained or untrained) used RDTs to confirm clinically suspected malaria before treatment. This means that they diagnosed clinical malaria and could over prescribe anti-malarial drugs. This notion has been noted in the World Malaria Report that in Africa less than 20% of suspected uncomplicated malaria cases are confirmed; most clients/patients first go to the chemical shops where there are no facilities for confirmation.$_1$ However, a survey in two districts in southern Mozambique revealed that using RDTs to make definitive diagnosis of malaria (except in children under five years old) is the standard.[19] This is further supported by studies in Tanzania and Dar es Salaam, which demonstrated that after the introduction of policy to confirm malaria with RDTs before treatment, the prescription of anti-malaria drugs reduced whilst that of antibiotics escalated.[19]

The only criteria for diagnosis of malaria by Licensed Chemical Sellers are "clinical manifestations". The fact that Ghana is a malaria endemic country requires the use of RDTs for parasitological confirmation of malaria before treatment.

There is a steady shift from the use of anti-malarial monotherapies to artemisinin-based combination therapies; some licensed chemical sellers still prescribe Sulfadoxine-Pyrimethamine (SP) to treat presumptively uncomplicated malaria.

The awareness of the AMFm ACTs among licensed chemical sellers in the study area is high.

It is clear from this study that there is a difference between the trained and untrained licensed chemical sellers in terms of diagnosis of uncomplicated malaria ($x2=28.753$; $p>0.0001$) and complicated malaria ($x2=9.436$; $p=0.002$). The training had impact on malaria diagnosis and treatment.

Recommendations

To the National Malaria Control Programme (NMCP):

Support should be provided to licensed chemical sellers and those, who treat malaria presumptively, with RDTs for parasitological confirmation before treatment. This will ensure that prescription of ACTs is targeted at those who really need them. It will reduce the over prescription and abuse of anti-malarial drugs that can lead to resistance.

Public education should be intensified to raise public awareness to empower the general public to demand for the AMFm ACTs; and to reduce the monotherapies on the market.

To Mobilize against Malaria (MAM) and its partners:

Because training had positive effect on the way licensed chemical sellers in the study area diagnosed malaria, education and training should be extended to those not trained. Furthermore, those trained earlier need refresher training to update their knowledge regularly through refresher training.

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