



## Assessing the Diagnosis of Uncomplicated Malaria after Introduction of Malaria Rapid Diagnostic Tests

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### Authors' contributions

This work was carried out in collaboration between all authors. Authors AR, BPA and GAK designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors KOB and MAK managed the analyses of the study. Authors AR, BPA, and GAK managed the literature searches. All authors read and approved the final manuscript.

Original Research Article

Received 23<sup>rd</sup> December 2013

Accepted 19<sup>th</sup> February 2014

Published 19<sup>th</sup> March 2014

### ABSTRACT

**Background:** Morbidity and mortality resulting from malaria remains a serious obstacle for social and economic development. Accurate diagnosis and prompt treatment are therefore essential components of case management strategy. The aim of this study therefore was to examine the diagnostic procedure of uncomplicated malaria, and patients' understanding and satisfaction of treatment in Community Health Care Facilities, three years after the deployment of Malaria Rapid Diagnostic Tests in Ghana.

**Methodology:** A prospective and data collation was done randomly, by means of cluster

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and stratified multistage survey at three government hospitals and three private pharmacies in Kumasi, Ghana, between July and September, 2013. Patients treated for uncomplicated malaria, while leaving the health facility, upon consent, were selected and requested to answer questionnaires which served as a source of data to address the objective of the study. Bivariate statistics from the SPSS v 19 was employed to predict the relationships between health institutions and mode of diagnosis, patients' understanding and satisfaction of services.

**Results:** Fifty-three (53) out of 65 patients responded. The study indicated presumptive diagnosis [44 (83.0%)] to be predominantly used over test-based diagnosis [9 (17.0%)]. The mean age of patients was  $34.44 \pm 14.8$  years (Range 17-66). Out of 52 patients who provided information on educational level, those with tertiary education were 24 (46.2%), secondary were 9 (17.3%), primary were 14 (26.9%) and no formal education were 14 (26.9%). Male patients were 25 (47.2%) and female 28 (52.8%). All 53 patients were given Artemisinin-based Combination Therapy at the various health facilities. Of 35 patients at hospitals/clinics, 15 (42.9%) rated "very good value" to explain their understanding and satisfaction of services provided, and of 18 patients from private pharmacies, 10 (55.6%) rated as "very good value". Patients with tertiary education [14/25 (56.0%)] showed better understanding and satisfaction of services than those with no formal education [1/25 (4.0%)]. Not a single use of Malaria Rapid Diagnostic Tests for diagnosis was recorded.

**Conclusion:** Diagnosis of malaria at the periphery of health systems is still mainly presumptive three years after deployment of the Malaria Rapid Diagnostic Test. Patients' good rating on the diagnosis of uncomplicated malaria at private pharmacies, should be an advantage to introducing the Malaria Rapid Diagnostic Tests by healthcare practitioners.

*Keywords: Malaria rapid diagnostic tests; presumptive diagnosis; diagnostic method, uncomplicated malaria, community health care facilities, Ghana.*

## 1. INTRODUCTION

National Malaria Control Programme (NMCP), an agency under the Ministry of Health, (MOH), Ghana, regulates policies as regards to the strategies and management of malaria. In 2009, the NMCP reviewed policy and introduced Malaria Rapid Diagnostic Test (MRDT) to replace presumptive approach to diagnosing malaria in all age groups, particularly at the periphery of health systems. A presumptive diagnosis (which is usually done in a resource-constrained setting) is a presumed judgment giving reasonable ground for the belief that a patient has a likely condition. It is normally given before more tests are done, and a confirmatory diagnosis is made that confirms the presence of a condition. Presumptive diagnosis is a common method used to diagnose malaria in many parts of Africa; including Ghana [1-3]. Although presumptive diagnosis of malaria is less expensive [3], the overlapping of symptoms with other tropical diseases impairs its specificity and can promote overprescription of antimalarial drugs [4-6]. Accurate diagnosis and prompt treatment are the essential components of the NMCPs case management strategy, but both face considerable problems in Ghana [7]. The global impact of malaria has spurred interest in developing diagnostic strategies that will be effective not only in resource-limited areas, where malaria has a substantial burden on society, but also in developed countries, where expertise in malaria diagnosis is often lacking [8]. Accurate diagnosis of malaria is necessary to prevent morbidity and mortality while avoiding unnecessary use of antimalarial agents [9]. Currently fewer than 14% of all malaria diagnoses in Ghanaian health facilities are based on test-

based examination, and the quality of these diagnoses is unknown [10]. This study, an integral part of a main research (which is ongoing), was designed as a pilot to assess the diagnoses of uncomplicated malaria three years after the introduction of MRDTs as a new technology, and to assess the patients' understanding and satisfaction of services provided. The study was carried out in three prominent Hospitals and three Private Pharmacies in Kumasi, the Capital of the Ashanti Region of Ghana.

## **2. MATERIALS AND METHODS**

### **2.1 Study Design**

The study was prospective and data collation was done randomly, by means of cluster and stratified multistage survey for a period of 3 months at the study sites.

### **2.2 Study Site**

The study was carried out in six study sites and assumed to be representation of practice in Kumasi, as each of the sites indicated over 50% of their out-patients who patronized those facilities were diagnosed of uncomplicated malaria. They are; Kwame Nkrumah University of Science and Technology (KNUST) Students' Clinic in Kumasi, under Asokwa sub-metro; and an out-patient quasi-governmental set-up. The medical practitioners operate on rotational basis and this system made the practitioners to be available during the period of study. The clinic only attends to University students (approximately 25,000).

The second was Paradyse Clinic, which is privately owned and situated at Ejisu, a peri-urban area of Ejisu-Juaben district of Kumasi, with catchment area traversing beyond Ejisu community to the surrounding villages. It has permanent residence medical practitioners. Thus, making the facility a highly patronized one in the district with average monthly attendance of 2700 patients of which 35% were malaria cases. The third was a regional Hospital, Manhyia, which is government-owned, situated in the heart of Kumasi under Kumasi Metropolitan Assembly, KMA, serving mostly the surrounding communities, with daily average attendance of 2300 patients, of which 30-40% being malaria cases.

The three Pharmacies were: Kama Health Services, (a distinguished registered retail and wholesale pharmacy) situated at the commercial area of KNUST – Kumasi, with a registered clinical pharmacist and dispensing technician providing pharmaceutical and other related health services, to the University community and surrounding environs. Bandy Chemist, a registered retail and wholesale pharmacy, with registered pharmacists and technicians located at Adum, the commercial centre of Kumasi, and serving mostly the business community within the metropolis. Paso Health Services, located at Roman Hill - Kumasi, though, within Kumasi metropolis, where it provides pharmaceutical services. The facility had a resident registered pharmacist and Medicine Counter Assistant (MCA).

### **2.3 Study Sample/Sampling Technique**

A minimum of 20 uncomplicated malaria cases from hospitals/clinics were sampled by calculation to estimate the primary outcome (diagnostic procedure) with a precision of +/- 13%, assuming that the variability (intra-cluster correlation, ICC) in treatment between facilities is 0.3. For private pharmacies, the minimum of 14 patients, allowed the primary outcome to be calculated with a precision of +/-6.6% assuming the same degree of variation

[11]. Sixty-five (65) patient exit forms (PEF), as a questionnaire, was distributed to the institutions, 53 (81.54%) were retrieved with no tangible reasons for attrition.

To answer the study objectives including reasons (signs and symptoms) for attending health institution, mode of diagnosis, drug therapy, patient's understanding and satisfaction of service, and demographics of patients, patients exiting the health institution was consulted and upon consent was requested to provide information based on the PEF; which was designed to answer the study objective:

1. Patients who were diagnosed at the study sites with suspected uncomplicated malaria and prescribed an antimalarial drug, upon consent, personally or through a guardian, while exiting the facility, qualified for inclusion. Those who rejected the offer were excluded.
2. The patients who expressed appreciation to services at the facility were considered having 'very good value' and those who thought the services rendered to them were not appreciative enough were described 'very poor value'.

## **2.4 Ethical Considerations**

The proposal for the study was reviewed and approved by the Department of Clinical and Social Pharmacy, Faculty of Pharmacy and Pharmaceutical Sciences, College of Health Sciences, KNUST. Consent of the health institutions and the patients were verbally sought and approval obtained. The confidentiality of the patients' information was adequately protected by using code numbers and data extracted through the PEF were archived and locked.

## **2.5 Data Analysis**

Data were entered and analyzed using SPSS Version 19 ([www.ibm.com/software/analytics/spss/](http://www.ibm.com/software/analytics/spss/)). Bivariate statistics was used to identify associations between preselected explanatory variables: health institutions and mode of diagnosis, patients' understanding and satisfaction of MRDTs; and the demographics of patients, drug therapy and reasons (signs/symptoms) were also analyzed. P value  $\leq 0.05$  was considered significant.

## **3. RESULTS**

### **3.1 Demographic Characteristics of Patients**

In the study involving 53 patients, 25 (47.2%) were males and 28 (52.8%) were females. Mean $\pm$ SD of the patients age was 34.44 $\pm$ 14.8 years (Range 17-66). Out of the 52 patients who provided information on educational level, those with tertiary education were 24 (46.2%), secondary were 9 (17.3%), primary were 14 (26.9%) and no formal education were 14 (26.9%); one patient did not provide information on educational level

### **3.2 Mode of Diagnosis**

Of the 53 study subjects, 26(59.1%) and 18 (40.9) were diagnosed presumptively at hospitals/clinics and private pharmacies respectively; while 9 (100%) through test-based confirmation at only hospitals/clinics. The 35 patients who sought medical attention at

Hospitals/Clinics which had laboratories, 26 (74.3%) were diagnosed with presumptive diagnosis (PD) while 9 (25.7%) patients were by microscopy. At the Private Pharmacies, (PPs), of the 18 (100%) who sought medical attention, all were diagnosed by PD.

### 3.3 Drug Therapy

All the 53 patients who sought medical attention at the various hospitals and pharmacies with clinical signs/symptoms suggestive of malaria were given Artemisinin-based Combination Therapy (ACT).

### 3.4 Symptoms of Malaria Presented

Of the various symptoms/signs presented, headache on its own, stands out with frequency 7(13.2%), followed by headache, febrile and joint pains 5(9.4%), headache and chills, 4(7.5%), headache, joint pains, cough, febrile 3(5.7%). These associated signs and symptoms headache (he), fever (fe), chills (ch), cough (co), joint pains (jo), vomiting (vo) and others (ot) are non-specific and overlaps in many other clinical conditions. Details are as shown in Table 1.

**Table 1. Signs and symptoms presented by patients with malaria**

Signs/symptoms	Frequency (%)	Signs/symptoms	Frequency (%)
fe	2 (3.8)	he, co	3 (5.7)
fe, he, ch	2 (3.8)	he, co, vo	1 (1.9)
fe, he, co	2 (3.8)	he, jo	4 (7.6)
fe, he, jo	5 (9.4)	he, jo, ch	4 (7.6)
fe, he, ot	1 (1.9)	he, jo, co	3 (5.7)
fe, jo	1 (1.9)	he, jo, ot	2 (3.8)
fe, jo, co	1 (1.9)	he, ot	1 (1.9)
fe, jo, ot	2 (3.8)	he, vo	2 (3.8)
he	7 (13.2)	jo	1 (1.9)
he, ch	4 (7.6)	jo, co, ot	1 (1.9)
he, ch, co	1 (1.9)	jo, ot	1 (1.9)
he, ch, vo	1 (1.9)	ot	1 (1.9)
he, ch	4 (7.6)		

### 3.5 Patients Rating for Understanding and Satisfaction of Service

By clustering, 25 (47.2%) of the 53 patients sampled gave 'Very Good Value' (VGV), rating for the health institutions in response to good understanding and satisfaction of services provided, while 6 (11.3%) rated the institutions with 'Very Poor Value' (VPV). Applying stratification, 15 (42.9%) of 35 patients those who sought medical attention at hospitals/clinics, rated their understanding and satisfaction of services as VGV, and 4 (11.4%) rated VPV. For the 18 patients who attended private pharmacies 10 (55.6%) gave a rating of VGV while 2 (11.1%) gave VPV (Tables 2 and 3). Bivariate statistical analysis (Table 4), showed that patients with tertiary education had the highest level [14/25 (56.0%)] of understanding and satisfaction of good service, than those with 'no formal education [1/25 (4.0%)].

**Table 2. Rating of health institutions in response to good understanding of services**

			Institution		Total	
			Hospitals and clinics	Private pharmacies		
Understanding	AV	Count	8	1	9	
		% within understanding	88.9%	11.1%	100.0%	
		% within institution	22.9%	5.6%	17.0%	
			% of Total	15.1%	1.9%	17.0%
	FGV	Count	7	4	11	
		% within understanding	63.6%	36.4%	100.0%	
		% within institution	20.0%	22.2%	20.8%	
			% of Total	13.2%	7.5%	20.8%
	SPV	Count	1	1	2	
		% within understanding	50.0%	50.0%	100.0%	
		% within institution	2.9%	5.6%	3.8%	
			% of Total	1.9%	1.9%	3.8%
	VGV	Count	15	10	25	
		% within understanding	60.0%	40.0%	100.0%	
		% within institution	42.9%	55.6%	47.2%	
		% of Total	28.3%	18.9%	47.2%	
VPV	Count	4	2	6		
	% within understanding	66.7%	33.3%	100.0%		
	% within institution	11.4%	11.1%	11.3%		
		% of Total	7.5%	3.8%	11.3%	
Total		Count	35	18	53	
		% within understanding	66.0%	34.0%	100.0%	
		% within institution	100.0%	100.0%	100.0%	
		% of Total	66.0%	34.0%	100.0%	

VPV: Very Poor Value; VGV: Very Good Value; SPV: Somehow Poor Value; FGV: Fairly Good Value; AV: Average Value.

Pearson Chi-Square Test (Value: 2.76; df: 4). Asymp. Significance (2-sided): 0.599, Monte Carlo Significance (2-sided): 0.624, 99% confidence interval (lower boundary: 0.612, Upper boundary: 0.637 Likelihood Ratio (Value: 3.162; df: 4). Asymp. Significance (2-sided): 0.531, Monte Carlo Significance (2-sided): 0.630, 99% confidence interval (lower boundary: 0.618, Upper boundary: 0.642).

Fischer's Exact Test (value: 3.103). Monte Carlo Significance (2-sided): 0.554, 99% confidence interval (lower boundary: 0.541, Upper boundary: 0.567).

**Table 3. Patients rating of satisfaction of services**

		Institution		Total	
		Hospitals and clinics	Private pharmacies		
Satisfaction	Count	3	0	3	
	% within satisfaction	100.0%	0.0%	100.0%	
	% within institution	8.6%	0.0%	5.7%	
	% of Total	5.7%	0.0%	5.7%	
	NSD	Count	1	0	1
		% within satisfaction	100.0%	0.0%	100.0%
		% within institution	2.9%	0.0%	1.9%
	% of Total	1.9%	0.0%	1.9%	
	SS	Count	8	2	10
		% within satisfaction	80.0%	20.0%	100.0%
		% within institution	22.9%	11.1%	18.9%
	% of Total	15.1%	3.8%	18.9%	
VD	Count	1	1	2	
	% within satisfaction	50.0%	50.0%	100.0%	
	% within institution	2.9%	5.6%	3.8%	
% of Total	1.9%	1.9%	3.8%		
VS	Count	22	15	37	
	% within satisfaction	59.5%	40.5%	100.0%	
	% within institution	62.9%	83.3%	69.8%	
% of Total	41.5%	28.3%	69.8%		
Total	Count	35	18	53	
	% within satisfaction	66.0%	34.0%	100.0%	
	% within institution	100.0%	100.0%	100.0%	
	% of Total	66.0%	34.0%	100.0%	

*NSD: Neither satisfied nor dissatisfied, SS: Somehow satisfied, VD: Very dissatisfied, VS: Very satisfied.*

*Pearson Chi-Square Test (Value: 3.8; df: 4). Asymp. Significance (2-sided): 0.424, Monte Carlo Significance (2-sided): 0.5, 99% confidence interval (lower boundary: 0.488, Upper boundary: 0.513 Likelihood Ratio (Value: 5.182; df: 4). Asymp. Significance (2-sided): 0.269, Monte Carlo Significance (2-sided): 0.431, 99% confidence interval (lower boundary: 0.418, Upper boundary: 0.444).*

*Fischer's Exact Test (value: 3.572). Monte Carlo Significance (2-sided): 0.468, 99% confidence interval (lower boundary: 0.455, Upper boundary: 0.481).*

**Table 4. Patients understanding of therapy against educational level**

			Educational Level				Total
			No formal education	Primary education	Secondary education	Tertiary education	
Understanding	AV	Count	0	3	1	5	9
		% within understanding	0.0%	33.3%	11.1%	55.6%	100.0%
		% within education	0.0%	21.4%	11.1%	20.8%	17.3%
	FGV	Count	1	2	3	5	11
		% within understanding	9.1%	18.2%	27.3%	45.5%	100.0%
		% within education	20.0%	14.3%	33.3%	20.8%	21.2%
	SPV	Count	0	1	1	0	2
		% within understanding	0.0%	50.0%	50.0%	0.0%	100.0%
		% within education	0.0%	7.1%	11.1%	0.0%	3.8%
	VGV	Count	1	6	4	14	25
		% within understanding	4.0%	24.0%	16.0%	56.0%	100.0%
		% within education	20.0%	42.9%	44.4%	58.3%	48.1%
	VPV	Count	3	2	0	0	5
		% within understanding	60.0%	40.0%	0.0%	0.0%	100.0%
		% within education	60.0%	14.3%	0.0%	0.0%	9.6%
Total	Count		5	14	9	24	52
	% within understanding		9.6%	26.9%	17.3%	46.2%	100.0%
	% within education		100.0%	100.0%	100.0%	100.0%	100.0%

VPV: Very Poor Value; VGV: Very Good Value; SPV: Somehow Poor Value; FGV: Fairly Good Value; AV: Average Value.  
 Pearson Chi-Square Test (Value: 23.309; df: 12). Asymp. Significance (2-sided): 0.026  
 Likelihood Ratio (Value: 20.724; df: 12). Asymp. Significance (2-sided): 0.55



## **4. DISCUSSION**

### **4.1 Demographic Characteristics of Patients**

The mean age of  $34.44 \pm 14.8$  years represents a productive age. It has been established in a report that malaria has adverse impact on macro economy of endemic countries, particularly relating to productivity; as the direct and indirect costs of illness and worker productivity impede economic growth [12]. So, there is the need for prompt and proper diagnosis and management of malaria to reverse the impact of malaria on Ghana's economy. In fact, malaria has been a major cause of poverty and low productivity accounting for about 32.5 percent of all OPD attendances and 48.8% of under five years hospital admissions in the country [13]. The patients were predominantly adults largely because of the WHO recommendation of test prior treatment on patients above 5 years of age.

### **4.2 Mode of Diagnosis**

Three (3) years after the introduction of MRDTs as a policy in Ghana, none of the study sites were found to adhere to the new policy. There is the need to scale-up education on the policy. Even where microscopy facilities were available, the practitioners were not actually making good use of them, rather using PD; which confirmed, that is still the practice. This is contrary to the NMCP/WHO new policy of parasite-based confirmation prior treatment. Presumptive diagnosis of malaria, based on symptoms alone, is known to be inaccurate [14,15], and diagnosis based on detection of parasites has clear advantages; and in this study only 9/53 (17.0%) were based on detection of parasite. This is a confirmation that in Africa, clear evidence of over diagnosis of malaria and misprescription of malaria treatment to patients who are negative for parasites is a widespread problem. As a consequence, serious non-malarial infections are treated as malaria [16,17], drugs are wasted, and the cost effectiveness of the diagnostic tests is reduced [18,19].

### **4.3 Drug Therapy**

The fact that all patients who sought medical attention at the various hospitals and pharmacies were given ACT were given ACTs indicates that ACTs were used as first-line medications in the treatment of uncomplicated malaria in line with the recommendations of NMCP/WHO, which was introduced in 2004. A similar National Health Facility survey, in mid-2008, recorded 91% of public facilities as using ACTs in their outpatient dispensaries [10]. The 100% success rate over 91% in 2008 could have been due public awareness and/or trainings created by the NMCP of the Ghana Health Service.

However, in that study only 63% of healthcare providers knew the correct Artesunate/Amodiaquine (AS/AQ) dose for a 20 kg patient. In this study, the emphasis was not on the appropriateness of the dosage regimen, rather on type of antimalarial therapy to patients. The drug therapy as seen in this study suggests a wholesale prescription of ACTs regardless of the recommendation of confirmation of malaria parasites prior treatment. This practice has the tendency to promote drug resistance, encourage influx of substandard ACTs because of available patronage, waste of resources and on national level affect the drug-related budget.

#### **4.4 Symptoms of Malaria Presented**

Symptoms/signs noted in this study are not exclusives of malaria conditions only; hence, further diagnostic steps are required for confirmation such as microscopy and/or MRDTs. The risks related to this conclusion on the symptoms and signs captured as indication of malaria disease conditions (shown in table above) has potential of inaccurate diagnosis and with a consequence of missing other clinical condition which could progress to severe symptoms and death rapidly.

#### **4.5 Patients understanding and satisfaction of service**

Malaria is an important disease condition in sub-Saharan Africa and efforts for prompt medical interventions are cardinal in proper management. In this study, results indicated that less than 50% rated with good understanding and satisfaction of services provided to them. This finding is suggesting the need to improve our services and counseling technique to our patients for better understanding and satisfaction of services.

From the findings, patients who sought medical attention at the private pharmacies had better understanding and satisfaction of services than those at the hospitals/clinics. This could be confirmation of a survey that indicated approximately 60% of Ghanaians seek their initial treatment for malaria outside of public health facilities [20] despite being private for-profit facilities. Thus, incorporating a new policy intervention such as MRDTs in such facilities (private pharmacies) against this background of understanding and satisfaction by patients as seen in the study, coupled with adequate and appropriate preparations, would be accepted and patronized by patients/clients.

In this study, the level of education was a factor in understanding and satisfaction of services provided. The understanding of treatment regimen within educated folks was observed to be higher probably because of medium of communication and the confidence to ask questions. Thus, adequate and appropriate counseling using a local dialect/language understandable to patients should be encouraged to maximize therapeutic benefits.

### **5. CONCLUSION**

Diagnosis of malaria at the periphery of health systems is still mainly presumptive in all age groups three years after deployment of the MRDTs. Patients' good rating on understanding and satisfaction of services at private pharmacies should be an advantage to introducing the MRDTs by healthcare practitioners.

### **CONSENT**

Consent of the health institutions and the patients were verbally sought and approval obtained. The confidentiality of the patients' information was adequately protected by using code numbers and data extracted through the PEF were archived and locked.

### **ETHICAL APPROVAL**

The proposal for the study was reviewed and approved by the Department of Clinical and Social Pharmacy, Faculty of Pharmacy and Pharmaceutical Sciences, College of Health Sciences, KNUST.

## ACKNOWLEDGEMENTS

We thank all the participants in this study for their support; and special appreciation to Christian Opoku Gyamfi, Eunice Segbefia, Charlotte Fordjour (all of Kama Health Services), Hikma Yahya and Jemila Mohammed Yaminu (a nurse at Komfo Anokye Teaching Hospital, Kumasi) for their unflinching patience and endurance. Finally, special thanks to the Department of Clinical and Social Pharmacy, FPPS, KNUST, Ghana, for facilitating the study.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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