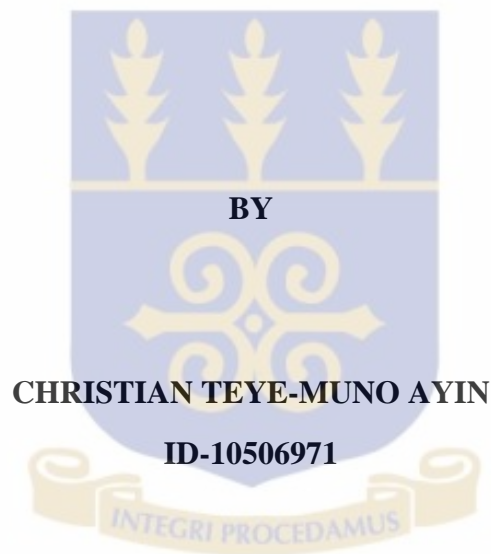


**SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF GHANA, LEGON**

**AVAILABILITY AND USE OF MALARIA RAPID DIAGNOSTIC TEST IN HEALTH
FACILITIES IN GOMOA WEST DISTRICT, GHANA**



**THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON
IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE AWARD OF MASTER
OF PUBLIC HEALTH DEGREE**

JULY, 2015

DECLARATION

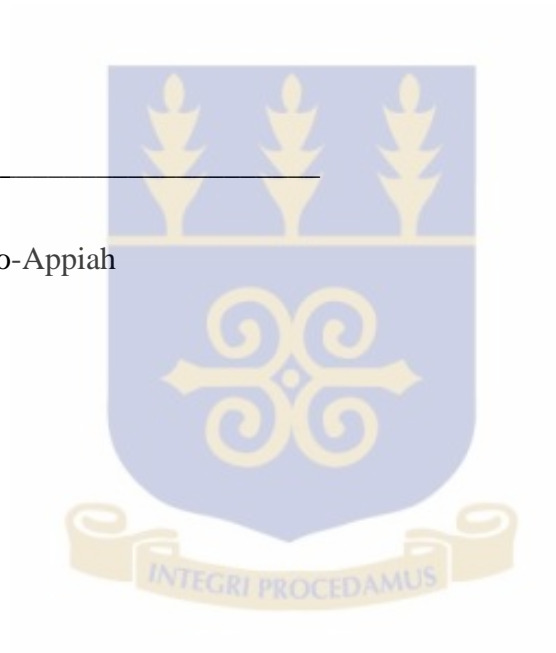
I hereby declare that apart from specific references which have duly been acknowledged, this research proposal is my own work put together.

Christian Teye-Muno Ayin

(Student)

Dr. Anthony Danso-Appiah

(Supervisor)



DEDICATION

Dedicated to my family and friends



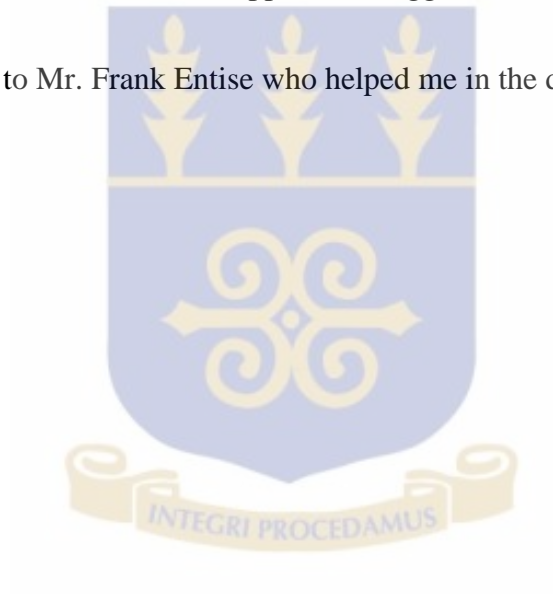
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ABSTRACT

Introduction: Malaria is a major cause of ill-health and death particularly among pregnant women and children under 5 years. Every year about 300 to 500 million cases of malaria and 1 to 3 million deaths are reported globally of which 90% occurs in sub-Saharan Africa. Prompt and accurate diagnosis is key in managing malaria. Drawbacks regarding microscopy use have made the introduction of malaria RDT key in the strategy for scaling up malaria control.

Objectives: The objective of the study was to assess availability and use of malaria RDT in health facilities in the Gomoa West district and investigate adherence patterns of clinicians to the incorporation of malaria RDT results in their case management.

Method: A cross sectional study was carried out in selected health facilities to review stock tally cards for malaria RDT, and to assess malaria RDT availability over one year period. A pretested data extraction sheet was used to extract data on the proportions of suspected malaria cases tested with malaria RDTs. A structured questionnaire was also administered to prescribers to collect data on adherence to RDT use and incorporation of RDT results in their case management. Data were analyzed and chi square test was used to assess associations. Fisher's exact test was used when a cell has a population less than 5. Detailed analysis was done with logistic regression model to assess strength of associations.

Results: The least malaria RDT availability of 87.7% was recorded in 3 health facilities. Three health facilities recorded 100% availability. Overall, 256(73.6%) out of 348

suspected malaria cases were tested with malaria RDT. No significant associations were found between malaria RDT testing and age (below 5 years and 5 years and above), temperature and caseload per day. However there was a significant association between facility type and malaria RDT testing (p value <0.001). Out of 137 positive malaria RDT results, 132(96.3%) received antimalarial in accordance with national case management guidelines. 68 (37.1%) out of 119 negative results did not receive antimalarial while 51(42.9%) received antimalarial against case management guidelines. There was a significant association between malaria RDT results and the prescribing of antimalarial (p value <0.001).

Conclusion: Both malaria RDT availability and RDT testing rates were optimal in all the health facilities with testing rates slightly better in CHPS and health centers than the district hospital. The new malaria case management guideline which encourages universal testing before treatment was being adhered to by clinicians. However, given that the proportion of patients receiving presumptive treatment is high (26.4%) and some negative malaria RDT cases still receive treatment, there is the need for intensified effort if success in adherence to case management guidelines is to be achieved.

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LIST OF ABBREVIATIONS

ACT - Artemisinin-based Combination Therapy

ANX - Auxiliary Nurse Midwives

ASHA - Accredited Social Health Activists

CHPS - Community-based Health Planning Services

GHS - Ghana Health Service

IMCI - Integrated Management of Childhood Illness

IRS - In-door Residual Spraying

ITN - Insecticide Treated-bed Net

MOH - Ministry of Health

NMCP - National Malaria Control Programme

OPD - Out Patient Department

PCR - Polymerase Chain Reaction

PMI - Presidential Malaria Initiative

RDT - Rapid Diagnostic Test

STG - Standard Treatment Guideline

WHO - World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

1.1.1 Epidemiology and transmission of the disease

Malaria is a major cause of ill-health and death, particularly among pregnant women and children under 5 years. Every year about 300 to 500 million cases of malaria and 1 to 3 million deaths are reported globally of which 90% occurs in sub-Saharan Africa.

Malaria is an infectious disease and the parasite (plasmodium parasite) that causes malaria is transmitted through the bite of an infected female anopheles mosquito. The four plasmodium species that infects malaria in humans are *P.falciparum*, *P. malariae*, *P. ovale* and *P.vivax*. Increasingly, human infections with monkey parasite *P.knowlesi* have been reported from the forest regions of South-East Asia.

The nature of malaria clinical disease depends largely on the background level of the acquired protective immunity, a factor which is the outcome of the pattern and intensity of malaria transmission in the area of residence.

Where the transmission of malaria is 'stable' meaning where the populations are continuously exposed to fairly constant, high rate malarial inoculations (entomological inoculation rate (EIR) >10 per year), partial immunity to the clinical disease and to its severe manifestation is acquired early in childhood. Such situations prevail in much of sub-Saharan Africa and parts of Oceania.

In areas of unstable malaria transmission, which prevails in much of Asia and Latin America, and the remaining parts of the world where malaria is endemic, the rates of inoculation fluctuate greatly over seasons and years. Entomological inoculation rates are usually < 5 per year and often < 1 per year. This retards the acquisition of immunity and results in people of all ages, adults and children alike, suffering acute clinical malaria, with a high risk of progression to severe malaria if untreated. Epidemics may occur in areas of unstable malaria when inoculation rates increase rapidly due to a sudden increase in mosquito vector densities. Epidemics manifest as a very high incidence of malaria in all age groups and can overwhelm health services. Severe malaria is common if prompt effective treatment is not made widely available. Non-immune travellers to a malaria endemic area are at a high risk of acquiring malaria, unless protective measures are taken, and of the disease progressing to fatal severe malaria if infections are not treated promptly and effectively.

1.1.2 Presentation of the diagnosis (signs and symptoms)

The first symptoms of malaria are usually nonspecific. These symptoms include headaches, fatigue, abdominal pain, muscle and joint aches, usually followed by fever, chills, perspiration anorexia, vomiting and worsening malaise. Due to the non-specific nature of the symptoms, malaria is usually over-diagnosed on the basis of the reported symptoms alone usually in endemic areas.

At the early stage of the disease with no clear signs of vital organ damage, patients who are put on an effective anti-malarial treatment are able to recover fully and rapidly.

However, if ineffective treatment is given or treatment is delayed, the parasite burden increases and a severe form of malaria may ensue. Severe malaria usually manifests with one or more of the following: coma, metabolic acidosis, severe anaemia, hypoglycaemia, acute renal failure or pulmonary oedema.

Severe malaria has a high case fatality rate of 10% to 20% among patients who receive treatment whilst the outcomes of untreated patients is mostly fatal (WHO Guidelines for Treatment of Malaria 2010).

1.1.3 Diagnosis of the disease

The diagnosis of malaria is based on the clinical suspicion and on the detection of parasites in the blood. High sensitivity of diagnosis in malaria endemic areas is particularly important since this will reduce the unnecessary treatment with antimalarial and also improve the diagnosis of other febrile conditions.

Diagnosis based on clinical signs and symptoms has very low sensitivity and results in over-treatment.

The two methods in routine use for parasitological diagnosis are light microscopy and rapid diagnostic tests (RDTs). The latter detect parasite-specific antigens or enzymes and some have a certain ability to differentiate species.

Polymerase chain reaction (PCR) is also available for diagnosis and it's highly sensitive but its cost and complexity limits its use.

The benefit of parasitological diagnosis depends entirely on health-care providers adhering to the results in managing the patient.

1.1.4 Management of disease

In the management of malaria the main goals of treatment are to avoid the progression of uncomplicated malaria to severe malaria, limit the duration of the disease and to minimize the development of drug resistance parasites.

The artemisinin based combination therapy (ACT) is the recommended treatment of uncomplicated malaria by the WHO. These are combinations in which one of the components is an artemisinin derivative which could be artesunate, artemether or dihydroartemisinin. Specific combinations for treatment of uncomplicated malaria approved by the WHO include artesunate plus amodiaquine, artesunate plus mefloquine, artesunate plus sulphadoxine - pyrimethamine, artemether plus lumefantrine and dihydroartemisinin plus piperaquine. Quinine and artemether is usually the drug of choice for the management of severe malaria.

Artesunate injection has also been recently introduced for the management of severe malaria.

1.1.5 Malaria situation in Ghana

The commonest parasites responsible for malaria in Ghana is *Plasmodium falciparum* which accounts for 80-90% of cases. Other species are *Plasmodium ovale* and *Plasmodium malariae* which account for 0.15% and 20-30% of cases, respectively.

In Ghana, 38.9% of all out-patient visit and 38.8% of all hospital admissions in 2012 were due to malaria (Guidelines for case management of malaria in Ghana, 2014).

The World Health Organization (WHO) recently estimated total malaria attributable child death to be 14000 per year in Ghana (WHO World Malaria Report 2008).

Malaria is hyper- endemic in all parts of the country with population of about 25 million all at risk of malaria in Ghana. Transmission occurs all year round with slight variations between the rainy season from April to July and dry season from December to March According to Pond (2013). Transmission rates tend to be less intense in large urban centers than in small rural communities.

Over the past few years there have been several interventions and strategies for malaria control including the use of insecticide treated bed nets (ITNs), in-door residual spraying (IRS) and early diagnosis and effective management of malaria in healthcare institutions.

Prompt and accurate diagnosis is key in managing malaria (WHO Guidelines for Treatment of Malaria 2010). Microscopy has been used over the years for malaria diagnosis in most healthcare facilities in Ghana. Despite its advantages of being able to quantify parasite load (intensity of infection) in blood and detection of parasite species types, it requires a well-trained and skilled staff. Also it requires an energy source to power the microscope.

However, in most rural settings in sub-Saharan Africa including Ghana, peripheral health facilities where most of the cases are reported lack both material and human resource.

With these drawbacks regarding microscopy use, malaria rapid diagnostic test (RDT) is seen as key in malaria diagnosis and management. This is because RDTs are simple to use, do not require electricity source and highly trained laboratory personnel.

The National Malaria Control Program (NMCP) in 2009 started promoting universal policy of malaria diagnosis with the focus of scaling up malaria RDTs to the lower level facilities. In 2014, the strategy from the NMCP, with funding from the Presidential Malaria Initiative (PMI), was to deploy malaria RDT at all levels of health facilities where microscopy is not operationally feasible. The strategy included training for health workers at the district level on malaria case management, also diagnosis with in-depth practical demonstrations on malaria RDT use.

In the Gomoa West District, training was organized from the 30th July to 1st August 2014. Participants were staff drawn from the district hospital, health centers and the Community based Health Planning Services (CHPS compounds). Health workers are therefore expected to implement the knowledge acquired from this training to improve malaria test based diagnosis in their facilities. However, it is largely unknown whether malaria RDTs are available and being used in peripheral health facilities and the extent to which clinicians adhere to recommended malaria RDTs test results to guide their management especially when the test is negative.

1.2 Statement of the problem

Malaria is a major cause of ill-health and death in Ghana, particularly pregnant women and children under five years. Historically malaria diagnosis has been done more presumptively by using clinical symptoms of patients rather than laboratory confirmed diagnosis. However diagnosis is being shifted from clinical to parasitological confirmation as basis for treatment (Guideline For Malaria Case Mangement 2014). This is in line with the World Health Organization(WHO) policy guideline which recommends clinicians to confirm clinical suspicions of malaria with a parasitological diagnosis (WHO Guidelines for Treatment of Malaria 2010). In late 2009 to date, the National Malaria Control Program has been promoting the use of malaria RDT in health facilities in the country. Ideally, these test kits should be available in facilities where it is needed throughout the year to promote parasitological testing for malaria.

Despite these efforts, there has been reported cases of malaria RDT stock outs in health facilities across the country.(President's Malaria Initiative , Ghana Malaria Operational Plan 2014).In some instances, despite availability of RDTs in health facilities, the PMI End -Use Verification Report for Ghana, 2013 found high percentage (65%) of malaria cases were treated presumptively (without testing) for Greater Accra, Central and Western Regions (PMI End Use verification Report for Ghana,2013). Reluctance of clinicians to adhere to test results, especially when the test is negative has also been identified as a bottleneck with malaria RDT use.

In the Gomoa West district the percentage of health facilities that had stock out for malaria RDTs for more than 7 days was 65% whiles percentage testing rate of all suspected malaria

cases was 50.5% in 2013. In 2012 and 2011, the testing rates for suspected malaria cases was 54.7% and 25.0% whilst health facilities with malaria RDT stock out for more than 7 days was 52% and 67%, respectively (Gomoa West District Health Report 2014). The Ministry of Health (MOH) has set the testing rate for 2015 target at 70%. Despite the steady increase in testing rate, malaria RDT stock out in health facilities and the unwillingness of clinicians to adhere to test guidelines remains a big problem. Following scale up of malaria RDTs nationwide in 2014, it is important to assess availability and use of malaria RDTs in testing for suspected cases of malaria.

1.3 Conceptual framework

A conceptual framework is an interconnected set of ideas (theories) about how a particular phenomenon functions or is related to its parts. The framework serves as the basis for understanding the causal or correlational patterns of interconnections across events, ideas, observations, concepts, knowledge, interpretations and other components of experience (Svinicki, 2010).

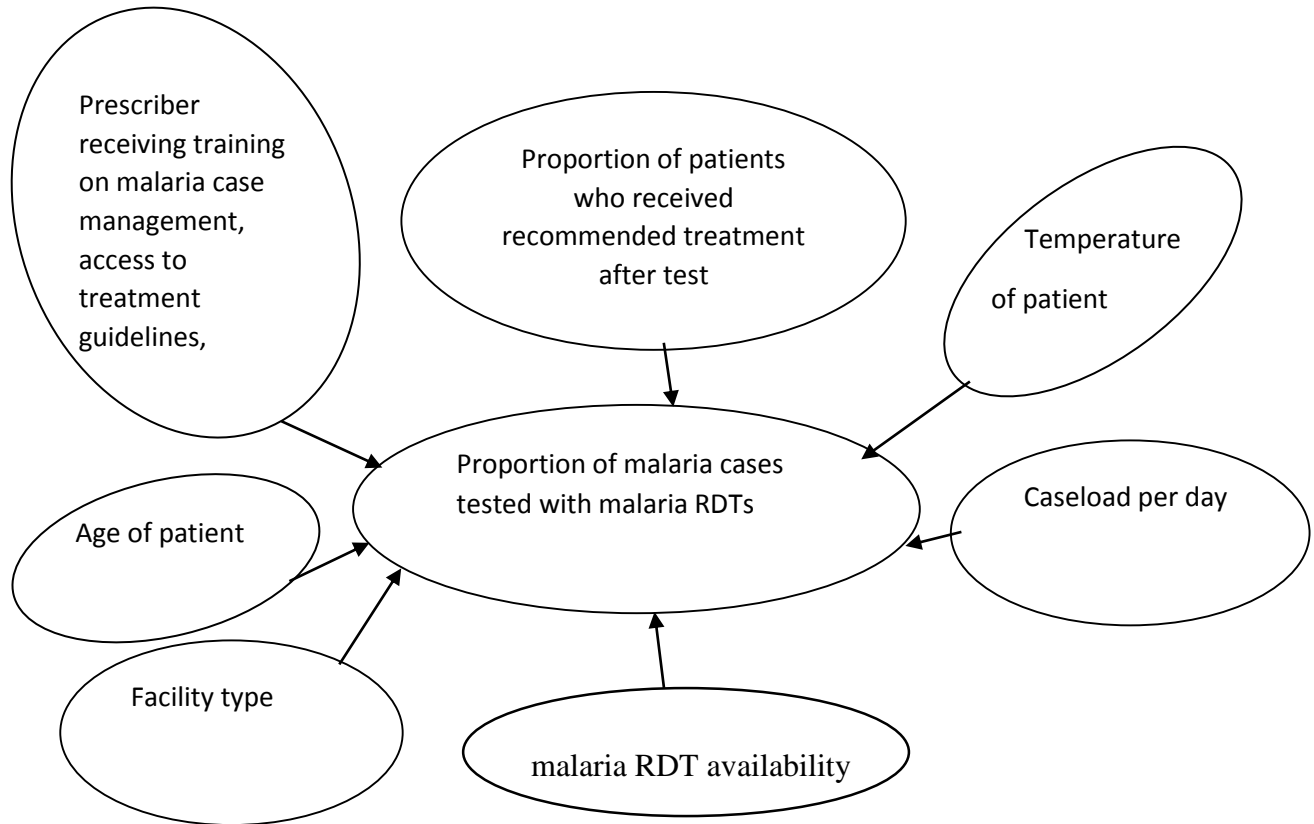


Figure 1: Conceptual framework for factors influencing the use of malaria RDTs.

According to the 2014 guidelines for the management of malaria in Ghana, a history of fever or a body temperature of 37.5°C should predict testing for malaria ((MOH, 2014).

Malaria RDT availability could influence prescribers decision to request for testing or not. There is likelihood that when RDT is not available, patients will not be tested before treatment. The caseload of presumptive malaria diagnosis in a day has also been linked with the proportions that are tested for that day ((Zurovac, D., Githinji S., Memusi D., Kigen S., Machini B., Muturi , A., Otieno, G., Snow, R., Nyandigisi, 2014). Age has also been shown to be linked with whether patients get tested or not. Previous malaria policy

guidelines recommended that children below 5 years should receive treatment without prior testing. On the contrary, the current policy guideline encourages people of all ages to be tested before treatment. Prescribers' training on current malaria treatment guidelines, availability and access to standard treatment guidelines (STGs) could influence request for testing with an RDT. Patient's treatment after the RDT could follow the result of the test as recommended by national guidelines or not.

1.4 Justification for the study

Traditionally, malaria has been diagnosed by microscopic examination of blood films. Despite widespread use, microscopy is not suited for settings without the necessary infrastructure. Polymerase chain reaction (PCR) is much more sensitive but not widely used because of its cost and complexity. Therefore, the introduction of rapid diagnostic test (RDT) which is easy-to-use and can be delivered at point-of-care, shows promise in the management of malaria. Guidelines recommend RDT use in peripheral health facilities with limited human and material resource (Strategic Plan For Malaria Control In Ghana 2008-2015). However, there is paucity of data on factors that could influence prescriber adherence and use of RDT in such settings. Therefore, this study will be conducted to assess availability and use of malaria RDT in health facilities in the Gomoa West District. Undoubtedly, the findings of the study will contribute to improving knowledge and fill gaps in evidence in the management of malaria.

Also, Ghana has scaled up malaria RDTs in 2014 as a strategy to improve parasitological testing before treatment. This will ensure that all higher and lower level health facilities, public or private health facilities, licensed chemical sellers, pharmacies and households all

have access to malaria RDTs. However, it is largely unknown how successful the national scale up programme has been. The study will provide much needed data to aid policy on malaria RDT availability and use in Ghanaian health facilities. Specifically, the study conclusions will benefit health managers in district health facilities by informing them on how well facilities are doing with regard to compliance with malaria policy guidelines.

1.5 Objectives

1.6 Main objective

To assess availability and use of malaria RDT in health facilities in the Gomoa West district.

1.7 Specific objectives

1. To assess availability of malaria RDT in health facilities in the Gomoa West district.
2. To assess factors that influence point-of-care use of malaria RDTs in selected health facilities in the Gomoa district.
3. To assess adherence of clinicians to malaria RDT results in their case management.

CHAPTER TWO

2.0 LITERATURE REVIEW

Malaria is a major cause of illness and death especially in sub-Saharan Africa. Even though there have been a lot of interventions put in place to control malaria, there still remains more work to be done. This chapter presents a review of relevant literature in regard to the subject under study.

2.1 Malaria RDT Availability

Prompt and accurate diagnosis is key in managing malaria. Universal malaria diagnosis with microscopy or malaria RDTs is recommended for all patients suspected of having malaria by the World Health Organization (WHO, 2010). Due to difficulties with microscopy which has already been outlined above, the use of malaria RDTs has shown a lot of promise since it is easy to use and can be used in all health settings. Stock-outs of RDTs has been a challenge in the effective management of malaria. In a study by Hussein et al. (2013) to assess the public health system readiness to treat malaria, the findings showed a high proportion (80%) of auxiliary nurse midwives (ANX) and 77% of accredited social health activists (ASHAs) had the necessary level of knowledge to use malaria RDT for diagnosing the disease. However the relatively high knowledge of malaria diagnosis was undermined by poor availability of malaria RDTs.

In a study to reduce stock outs of Live Saving Malaria Commodities using mobile phone texting showed RDT stock-out trends over the 26 weeks declined from 43% in the first week to 20% by 26 weeks Githinji et al.,(2013). A careful analysis revealed that stock-outs declined rapidly after the start of the project to as low as 7% in week seven then

increased gradually to 32% in week 23 before dropping again to 20% in week 26. Of 103 RDT stock-out alerts signaled by the system, 73% were resolved by district managers through peripheral redistribution, 13% through the routine supply and 15% remained unresolved. Peripheral redistribution was the dominant response action to RDT stock-out signals in all study districts (district range 56–100%). There was no resupply of RDTs in four of the five study districts, hence an increase in stock-outs was observed in the second part of the project. The study concluded with the recommendations that there will be the need for high reporting rates of reasonably accurate, real time facility stock data that will be used by district managers to undertake corrective actions and reduce stock outs of antimalarial commodities including RDTs. Long malaria RDT stock out days greatly reduces the chances of patients that will be tested, especially in lower and peripheral health centers where microscopy may not be available. According to Ginthinji et al. (2013), health facility reporting of RDT availability is useful in providing information for district managers to step in and redistribute RDT to facilities where stock out may have occurred. Good supply chain management is critical in preventing stock outs and preserving the quality of RDTs through safe transport and storage (Malaria RDT Implementation Guide, 2013). This must, however, be centrally planned and integrated into the supply management of the wider health system. Malaria programme managers, clinic workers, medical stores and transport personnel should be involved in supply chain planning.

According to the Medical Technology Service Provider (MTSP) country progress indicator target, which is used by the WHO in monitoring medical products, vaccines and technologies, average availability target in public and private health facilities should be

80%.(WHO, Medical Products,Vaccines and Technologies 2008).Availability is said to be inadequate if it falls below this target.

2.2 Acceptability of Malaria RDT as A Diagnostic Tool

The benefits of using malaria RDT as a diagnostic tool for malaria have well been documented(WHO World Malaria Report,Geneva 2010).

In a survey that utilized both quantitative and qualitative techniques in 6 districts in the Brong Ahafo Region, 98% of care-givers interviewed preferred malaria RDT test based diagnosis to presumptive treatment Baiden et al., (2012). In another qualitative study, 6 focus group discussions were conducted in the Dangme west district of the Greater Accra Region.Malaria RDT was reported to be highly accepted among patients who also saw RDTs as a means of communicating their illness to the clinician (Ansah, Reynolds, Akanpibiam, Whitty, & Chandler, 2013).

In a qualitative study by Chandler et al., (2011) in Uganda on the introduction of malaria rapid diagnostic tests at registered drug shops, it was found that tests were particularly appealing as a means of confirming an expected malaria diagnosis.However,malaria tests were distrusted when they clashed with the patient's or provider's expectation for a negative result. When asked what would happen if the RDT result was negative, most drug store workers responded that they will refer the client to a health facility. In the same study some patients viewed malaria RDT testing as a business especially in private clinics where doctor's requests were viewed as way of extorting money.

Patient and care-givers acceptability of RDTs does not automatically guarantee utilization. Other factors may be responsible for acceptance of new technologies. These factors include organizational features like how well the new technology is integrated with existing technologies, workflow, top management commitment to the new technology. Also mentioned are individual factors like perceptions on negative effects on users, resistance to change, lack of control and readiness for change as well as some other factors mentioned by Karsh et.,al (2006). Therefore, endorsing a new technology in itself does not always guarantee end user utilization as mentioned by Asimwe et al., (2012) in the study “Early experiences on the feasibility, acceptability, and use of malaria rapid diagnostic tests at peripheral health centers in Uganda-insights into some barriers and facilitators”.

Lack of control over the determination of clinical management decision due to the RDT results being an objective indicator of malaria was also emphasized by Ansah et al., (2013).In that study it was reported that RDT results remained elusive, patients did not identify mechanisms by which the test should determine clinical management decisions and the clinicians retain the locus of knowledge and power for clinical decisions.

Despite a high acceptability among patients and care-givers and the fact that clinicians still have control over clinical decisions after the test, there are still reports of low malaria RDT utilization in health facilities. In the Presidential Malaria Initiative (PMI) end- use verification Report, March 2013 there was a report of 65% clinical diagnosis of malaria (diagnosis without laboratory testing) in the Greater Accra, Western and Central Regions despite malaria RDTs being available over the period.

2.3 Factors Influencing Malaria RDT Use

Several factors that predict the use of malaria RDT use have been reported in some studies. Scaling up malaria RDT to increase its availability in health facilities has the potential of increasing proportions of patients who get tested. According to Zurovic et al.(2014) in a cross-sectional health facility survey, RDT scale up led to improvement of testing from 23.9% to 57.9% .In the same study, the use of RDTs improved proportions of children being tested from 20.5% to 55.2%.

In a study by Nyandigisi et al. (2011) malaria case management following a change of policy to universal parasitological diagnosis and targeted Artemisinin-Based Combination Therapy (ACT) in Kenya, some factors influencing malaria testing among febrile patients were assessed. From the study, 38.8% of children below 5 years were tested while 59.6% of children above 5 years got tested This difference was found to be significant (p-value=0.031). Also on the caseload per day on the survey day, the study reported that 60.9% of patients got tested when the caseload was less than or equal to 25 patients per day. However for more than 25 cases per day, the study reported 41.5% of patients were tested. On whether the health worker has received any training on new malaria case management policy, it was reported that health workers who received training contributed to 49.3% of the testing while those who did not receive training contributed 49.5% of malaria testing. Health workers who had access to malaria treatment guidelines contributed 34.5% to testing while those without access to the guidelines contributed 50.0% to testing.

In a study in Tanzania to assess how malaria RDTs guide clinical decision making in rural dispensaries, it was reported that out of the 9,292 children below 5 years of age diagnosed

with malaria, 9,109 (98.0%) were treated presumptively for malaria without performing an RDT despite RDTs being available (Masanja, McMorrow, Kahigwa, Kachur, & McElroy, 2010).

Age has been an important variable in influencing clinicians decision on requesting for malaria testing because until recently, most African countries used the Integrated Management of Childhood Illness (IMCI) guidelines for malaria which allowed children below 5 years in a malaria endemic region to be treated for malaria presumptively. However the current WHO guideline encourages children below 5 years to be tested before treatment. In countries where malaria RDTs has been introduced, most of the studies show a slow response among clinicians to this change.

In the study by Nyandigisi et al. (2011), temperature was assumed to be a constant predictor factor for requesting a malaria RDT test.

However in an observational study by Masanja et al. (2010) they reported that 88.3% of patients who were tested with RDTs had reported fever or history of fever. Despite a high percentage of patients who reported with fever got tested, this study shows that the presence of fever does not automatically guarantee malaria RDT testing. The use of history of fever or temperatures above 37.5⁰c as a predictor factor for requesting malaria laboratory testing is clearly spelt out in the ' Guidelines for case Management of Malaria in Ghana 2014 and therefore would be a useful variable to test.

Facility ownership or type as a factor for influencing malaria RDT use was also studied by Nyandigisi et al. (2011).In the study,79.6% of cases were tested in faith based or Non-

governmental facilities while 45.6% of cases got tested in government facilities. This difference was found to be significant with a p value of 0.002.

2.4 Adherence to Malaria RDT results

The reluctance of clinicians to adhere to test results has also been a major challenge in the implementation of malaria RDT scale up (President's Malaria Initiative Ghana Malaria Operational Plan 2014).

In an observational prospective study in Zambia to assess malaria RDTs for malaria and health workers adherence to results in some selected health centers, it was reported that 68.6% of children who tested negative received coartem which is an antimalarial. 19.4% of children also received drugs before receiving laboratory results (Manyando, Njunju, Chileshe, Siziya, & Shiff, 2014).

A study in Malawi to assess the field performance and adherence to test results of malaria RDTs among febrile patients above 5 years of age reported that 58% of patients with negative RDT results were treated for malaria despite prior training of clinicians on RDT use guidelines (Chinkhumba et al., 2010).

A trial in rural health centers in Ghana reported that 45.5% of patients who tested negative with RDTs were still prescribed antimalarial (Chandler et al., 2010).

In a study in Zambia to assess the early experiences on the feasibility, acceptability of malaria RDTs, a total of 52 of 57 health workers (92%) reported a belief that a positive malaria RDT result was true, although only 41 of 57 (64%) believed that treatment with

antimalarial was justified for every positive malaria RDT case. Of the same health workers, only 49% believed that a negative malaria RDT result was truly negative Asiimwe *et al.*, (2012).

In a study by Chinkhumba et al., (2010) in Malawi on comparative field performance and adherence to test results of four malaria rapid diagnostic tests among patients more than five years of age, it was reported that health workers rarely withheld treatment with a negative malaria RDT results. 58% of negative malaria RDT results were treated with antimalarial in the study.

A study by Yeung, Patouillard, Allen and Socheat (2011) in Cambodia on socially marketed rapid diagnostic tests and ACT in the private sector: ten years' experience in Cambodia revealed that one likely contributory factor for providers to use RDTs or trust their results is about the lack of clarity about what to do when the result is negative. Although referral to the public health provider was advised, in reality this rarely took place. The study concluded that there was the need for simple algorithms, which guide the management of treatment in 'RDT negative' patients and better evidence of aetiology of non-malarial febrile illness on which to base such algorithms.

In a study by d'Acremont et al. (2010) in Tanzania on withholding antimalarial in children who have had a negative malaria RDT, it was reported that 60% of children had negative malaria RDT. 97% of these children were cured on the seventh day when treated for other causes of febrile conditions upon further investigations. All children who had negative RDT initial results had negative results again when they were tested.

One key factor that has been linked to the treating of negative malaria RDT patients with antimalarial has been the capacity of health workers to investigate for other causes of fever testing negative to malaria RDT. This has been highlighted by Asimwe et al. (2012) as well as some other studies. In trying to address the problem of adherence, the capacity of clinicians to investigate other causes of illness could be studied.

In a study by Manyando et al., (2014) in Zambia on Rapid Diagnostic tests for malaria and health workers adherence to test results in health facilities, it was reported that 465(19.4%) out of 2,393 children were prescribed antimalarial drug before receiving laboratory results. Of the children who received anti-malarial prescription before receiving laboratory results, 84.0% were later found to be RDT result negative; 77.8% had no fever; 54.0% received Coartem while 36.1% received sulphadoxine-pyrimethamine, 5.4% quinine and 4.5% did not receive any anti-malarial drug.

The development of malaria RDTs has been a major step in the attempts to diagnose malaria.

CHAPTER THREE

3.0 METHODS

3.1 Study Design

A cross sectional study involving review of data on malaria RDT availability and use was carried out in 6 health facilities in the Gomoa West district. One year stock records of malaria RDT from January to December 2014 was reviewed to gather information on availability. Medical records of provisional malaria diagnosis of patients visiting a health facility between October and December 2014 was also reviewed. Factors such as age, temperature, results of malaria RDT test and antimalarial drug prescribed were extracted using a pre-tested data abstraction form. A structured questionnaire was used to interview prescribers in the selected health facilities on issues such as access to standard treatment guideline, training on malaria case management and whether they will prescribe antimalarial to a patient who tests negative for malaria.

3.2 Study Location

The study was conducted at health facilities in the Gomoa West district in the Central Region.

The district capital is Apam and it is almost equidistant from Cape Coast and Accra.

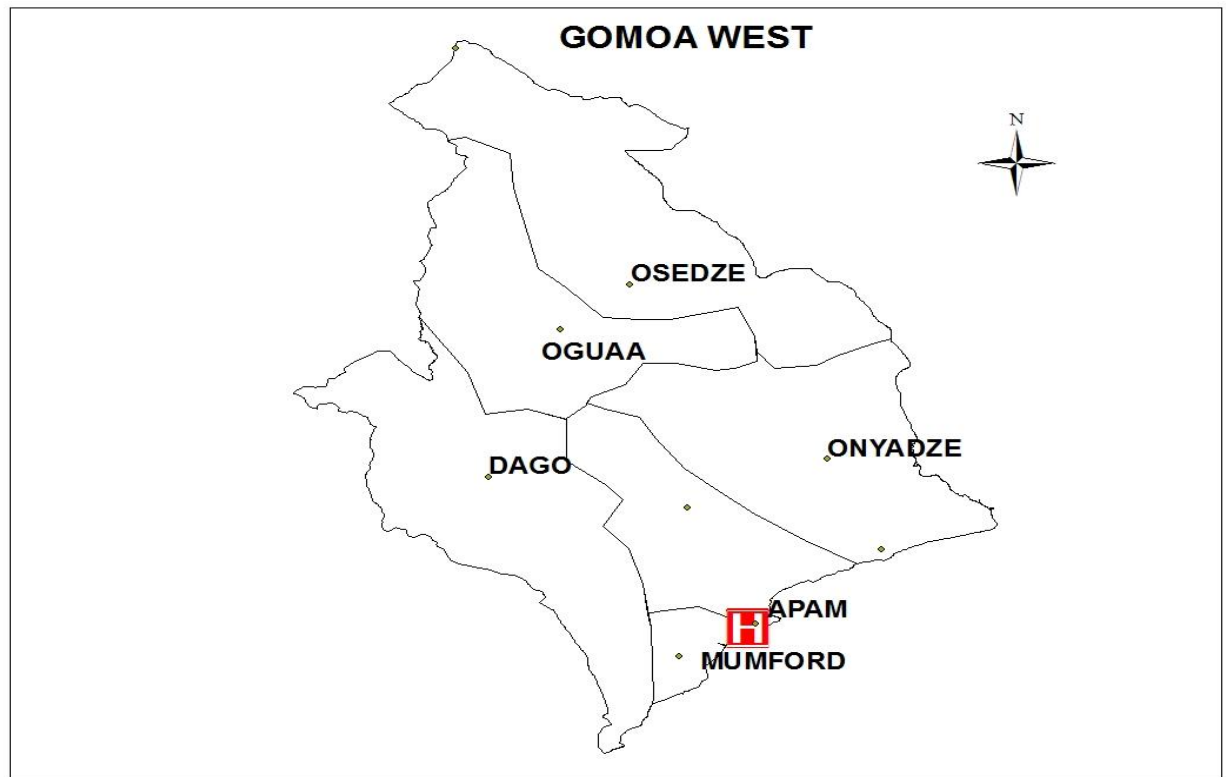
The major occupation is fishing although a sizeable number of the population engage in farming.

Economically, it is one of the most deprived districts in the Central Region .It is divided into 6 health sub-districts namely Oguaa, Osedze, Onyadze, Dago, Mumford and Apam.

There is 1 district hospital, 5 Health Centers, 18 CHPS zones, 1 Nutrition and Health Center

and 1 private Maternity Home. Malaria and diarrhea are the commonest diseases reported to the health facilities.

Figure 2: Map of Gomoa West District Showing Sub-districts



3.3 Variables

The main dependent variable was the proportion of malaria cases tested with malaria RDTs.

The independent variables were malaria RDT availability, age of patient, temperature above 37.5⁰c, case load per day, access to standard treatment guideline, prescriber training on malaria case management and facility type.

Table 1 Definition of variables and scale of measurement

Variables	Operational Definition	Type of variable	Scale of measurement
Proportion of malaria cases tested with malaria RDTs	Fraction of suspected malaria cases from the consulting room registers who are sent to the laboratory to perform the RDT	Main Dependent	-Yes -No
Proportion of patients who received recommended treatment after test	Positive RDT-Receive antimalarial drug Negative RDT-do not receive antimalarial drug	Independent	-Yes -No
Availability of malaria RDTs	Number of days RDT is available at the study site over number of days of review period expressed as a percentage .	Independent	Continuous
Age	This is the age in years of the suspected malaria case.	Independent	Above 5 years, below 5 years
Sex	This will be defined as male or female	Independent	-male -female
Treatment guideline	Access or availability of prescriber to the Ghana standard treatment guidelines	Independent	-Yes -No

Variables	Operational Definition	Type of variable	Scale of measurement
Prescriber training	Prescriber received training on malaria case management	Independent	-Yes -No
Temperature	Temperature of patient recorded using thermometer and documented in consulting room register or folder	Independent	-above or equal to 37.5 ⁰ c -below 37.5 ⁰ c
Caseload per day	The total number of outpatient attendance for the day.	Independent	-less than or equal to 50 cases per day -greater than 50 cases per day.
Facility type	Level of care of health facility	Independent	-CHPS plus health center -District hospital

Table 1: Definition of variables and their scale of measurement

3.4 Study Population

The study population was made up of prescribers in health facilities in the Gomoa West district where malaria RDTs were used.

3.5 Sample Size

In assessing the point of care use of malaria RDT, 1 district hospital, 2 health centers and 3 CHPS compounds were chosen. These facilities had a combined total average outpatient attendance for 3 months to be 3600. The average proportion of malaria cases being tested according to the district health report was 35%. Both these figures were obtained from the Gomoa West District Health Information Management System (DHIMS). At a 5% margin of error and a 95% confidence interval the sample size of 314 was generated from the piface sample size calculator Lenth (2011) using the confidence interval for one proportion analysis. The sample size was increased by 10% to make up for incomplete data set with the resultant being 345.

3.6 Sampling methods

With regards to malaria RDT availability, data was captured from all the government facilities in the district. On the point of care use of malaria RDT, 1 district hospital, 2 health centers and 3 CHPS compounds were selected. Study settings were chosen based on prior knowledge of high patient numbers in those facilities and also the capacity of data collectors available. The only district hospital included in the study was the Apam Catholic hospital which operates with all the features of a government hospital. The 2 health centers involved in the study were the Oguaa and Osedze Health centers. The three CHPS

compounds involved in the study were Mumford, Eshiem and Gomoa Tarkwa CHPS compounds. In determining the sample size for each facility, a 3 month average outpatient attendance for each facility was used. From the records of the District Health Directorate of Gomoa West, the average three-month outpatient attendance for the 6 health facilities selected were as follows:

- Apam Catholic hospital-2400
- Oguaa Health center-300
- Osedze Health center-300
- Mumford CHPS compound-210
- Gomoa Eshiem CHPS compound-240
- Gomoa Tarkwa CHPS compound-150

The total 3-month attendance for all these facilities was 3600.

The attendance for each health facility was divided by the total (of all the facilities above; 3600) and the result for each facility was multiplied by the total sample size 345. After computation, each facility sample size was as follows:

- Apam Catholic hospital-230
- Oguaa Health center-29
- Osedze Health center-29
- Mumford CHPS compound-20
- Gomoa Eshiem CHPS compound-23
- Gomoa Tarkwa CHPS compound-14

Selection of cases

All provisional malaria diagnosis from the consulting room registers between October to December 2014 were counted and assigned with numbers. These numbers were written on a piece of paper, folded and placed in a bowl. Numbers were picked randomly from the bowl without replacement till the required sample size was gotten. This method of case selection was repeated in all the facilities to choose the cases for the study.

3.7 Data Collection Method and Tools**Record Review**

A data abstraction sheet was used to collect all the relevant medical records from the consulting room registers of the suspected malaria cases that were selected. The data captured from the consulting room register included age of patient, date of attendance, identification number (ID), temperature of patient, RDT request status, results of RDT test and the antimalarial prescribed.

The corresponding OPD attendance for the selected case was also recorded. The laboratory RDT register was used to cross check the information from the consulting rooms. A separate data capturing tool was used to abstract daily availability of malaria RDT from the stock tally cards.

Prescriber Interview

Twenty three prescribers in the health facilities were interviewed. A convenient time for interview was sought within the data collection period. Informed consent was obtained and structured questionnaires were administered. Questions asked focused on whether they had received training on malaria case management, access to standard treatment guidelines in their consulting rooms and their opinion on adherence to RDT results in case management.

3.8 Quality Control

To ensure reliability of the data, research assistants were trained to help in the collection of data. Data abstraction forms and questionnaires were critically examined at the end of each day. Data handled by the research assistants were cross checked for consistency and completeness by verifying from the source records. Research assistants also double checked data gathered by the principal investigator.

3.9 Data Processing and Analysis

The completed questionnaires were cross-checked by the principal investigator. Data was coded and cleaned using Microsoft excel software. To ensure that data entered into the computer was accurate, the research assistants and the principal investigator independently cross checked each entry. Data was imported into Stata Version 12 for analysis. The availability of malaria RDTs at the various health facilities was expressed as percentages and displayed using tables. The independent variables influencing the proportions of malaria cases tested with RDTs and the proportions of patients who receive the

recommended treatment after testing, were also displayed using tables. Proportion of malaria cases tested with RDTs was expressed as a percentage of the total. All the provisional diagnosis of malaria (suspected cases) served as the denominator.

In comparing the various proportions, a chi-square test of association between the independent variables and the proportion of malaria cases tested was carried out. A Fishers exact test was used instead of a chi square test for cells with population below 5.

Variables which proved to show some association with the dependent variables were entered into a logistic regression model to assess the strength of associations between the independent and dependent variables to get unadjusted odds ratios.

3.10 Ethical considerations

Ethical clearance for the study was provided by the Ethical Review Committee of Ghana Health Service (GHS). Privacy and confidentiality was maintained throughout the study. Records abstracted from consulting room registers and RDT log books were kept in a locked cabinet. Access was limited to the principal investigator, research assistants and supervisors of the study. No identifying information such as name of patient was captured from the records. A written consent was obtained from the District Health Directorate of Gomoa West. Permission was sought to extract data from information systems. An informed consent was sought from the prescribers who were interviewed and confidentiality was assured regarding the information collected. Privacy was ensured during the interview. During the consenting process, participants were made aware that information they provide will contribute to the improvement of malaria case diagnosis in

the district. Participants were also made aware that they were free to withdraw from the study at any point if they felt uncomfortable and that there were no known risks associated with the study.

The contact information of the principal investigator and the administrator of the ethical review committee were made available to participants to seek further clarification where needed.

Data collected was used solely for research purpose.

There was no conflict of interest and the study was funded entirely by the Principal Investigator.

3.11 Pretest of data collection tools

Pretesting was done at the Winneba Health Center which serves communities with similar characteristics as those treated in the Gomoa West district. This helped to evaluate the time needed to complete each questionnaire, fill each data abstraction form, to ascertain the accuracy of questions, conduct dummy analysis and also evaluate the training received by the research assistants. Winneba Health Center is not in the Gomoa West district and so was not included in the main study.

CHAPTER 4

4.0 RESULTS

4.1 Sample Description

During the period of the study, all 25 health facilities in the Gomoa West district were assessed for malaria RDT availability between January to December 2014. These facilities were made up of 1 district hospital, 6 health centers and 18 CHPS compounds.

In assessing the use of malaria RDT, 1 district hospital, 2 health centers and 3 CHPS compounds were surveyed. 23 prescribers made up of physicians, physician assistants, nurses and midwives were interviewed on malaria RDT use. Malaria RDT use assessment covered the period October to December 2014.

Of the 348 suspected malaria cases studied, 116(33.3%) were children below 5 years while 232(66.7%) were 5 years and above.

4.2 Malaria RDT Availability

Malaria RDT availability was assessed for a full year (365 days). The highest availability over the period was 100% and this was recorded in Gomoa Wassa, Kumasi and Mankoadze CHPS . The least availability of 87.7% was recorded in 3 health facilities namely Gomoa Brofo, Gomoa Sampa and Gomoa Fomena CHPS compounds, having 320 days

availability. The median availability over the period was 95.0%. No health facility had malaria RDT availability below 80% (Table 2).

The main reason for days of malaria RDT unavailability was due to stock-out of the commodity at the district health directorate store.

Table 2**Malaria RDT availability**

Facility Type	No. of days RDT available	Availability (%)*
Hospital		
Apam Catholic Hospital	347	95.07%
Health Centres		
Oguaa Health Centre	357	97.81%
Apam RCH	356	97.53%
Dago Health Centre	351	96.16%
Osedze Health Centre	351	96.16%
Mumford Health Centre	350	95.89%
Noguchi Health Centre	326	89.32%
CHPS Compounds		
Gomoa Kumasi CHPS	365	100%
Mankoadze CHPS	365	100%
Wassa CHPS	365	100%
Tarkwa CHPS	360	98.63%
Abrekum CHPS	357	97.81%
Mprumem CHPS	357	97.81%
Kokofu CHPS	357	97.81%
Mumford CHPS	355	97.26%
Nkoransa CHPS	349	96.62%
Assin CHPS	347	95.07%
Gomoa Eshiem CHPS	343	93.97%
Ngyresi CHPS	342	93.70%
Gomoa Obiri CHPS	342	93.70%
Abonko CHPS	340	93.15%
Kyiren CHPS	323	88.50%
Gomoa Brofo CHPS	320	87.67%
Gomoa Sampa CHPS	320	87.67%
Fomena CHPS	320	87.67%

*Number of days RDT available over the total number of days in a year x 100

Malaria RDT stock out was varied across different facilities and also occurred at different periods. Ten (40%) of the 25 health facilities in the district recorded stock out of malaria RDT for more than 7 days.

Table 3

Facilities with malaria RDT stock out for more than 7 days and the period it occurred	
Facility	Period
Gomoa Brofo CHPS	January
Gomoa Kyeren CHPS	February
Gomoa Sampa CHPS	March
Gomoa Ngyresie CHPS	May
Gomoa Obiri CHPS	May
Noguchi Health Centre	June
Gomoa Fomena CHPS	June
Gomoa Abrekum CHPS	July
Apam Catholic Hospital	September
Gomoa Abonko CHPS	December
Gomoa Abrekum CHPS	December
Noguchi Health Centre	December

4.3 Factors influencing Point of Care Use of malaria RDT

Ninety one (78.4%) of children below 5 years were tested using malaria RDT while 165 (71.1%) of patients 5 years and above got tested. This difference was not found to be significant (p value=0.14). Overall, 256 (73.6%) of all suspected malaria cases were tested using RDTs.

The minimum temperature recorded from patients was 36.3⁰C while the maximum was 40.2⁰C. Of the 348 temperature readings recorded, 185(53.2%) were 37.5⁰ c and below and 163(46.8%) were above 37.5⁰ C. One hundred and thirty four (72.4%) of temperature 37.5⁰c and below got tested while 122(74.8%) of temperature above 37.5⁰ c were tested. No significant relationship was found between temperature and testing with malaria RDT (p value=0.61).

On the caseload per day, analysis was restricted to only the district hospital. The minimum caseload per day per day was 11 while the maximum was 216. The median caseload per day per 3 months period was 49.7. Out of 231 suspected malaria cases studied, 96(41.6%) had a corresponding caseload per day of 50 and below. One hundred and thirty five (58.4%) had a corresponding caseload per day above 50. Sixty four (66.7%) of cases were tested when the caseload per day was less than or equal to 50 while 78(57.8%) were tested when the caseload per day was above 50 patients. This difference was found not to be significant (p value=0.17).

Out of the 117 suspected malaria cases studied in CHPS and health centers, 114(97.4%) were tested with malaria RDT. One hundred and forty two (61.5%) out of the 231 suspected malaria cases studied in the district hospital were tested with malaria RDT.

There was a significant association between facility type and malaria RDT request (OR=0.04; 95% CI=0.013-0.14) (Table 3).

Table 4 Factors influencing prescriber point of care request for malaria RDT

Variable	RDT request (%)		OR (95% C.I.)	P - value
	Yes	No		
Age				
Below 5 years (n=116)	91 (78.4%)	25 (21.6%)		0.114
5 years and older (n=232)	165 (71.1%)	67 (28.9%)		
Temperature				
37.5 and below(n=185)	134 (72.4%)	51 (27.6%)		0.61
Above 37.5 (n=163)	122 (74.8%)	41 (25.2%)		
Caseload per day				
Less than or equal to 50 patient(n=96)	64 (66.7%)	32 (33.3%)		0.17
Above 50 patient(n=135)	78 (57.8%)	57 (42.2%)		
Facility Type				
CHPS + Health Center (n=117)	114 (97.3%)	3 (2.7%)	0.04 (0.013-0.14)	<0.001
District Hospital (n=231)	142 (61.5%)	89 (38.5%)	1.0 (Ref.)	

4.4 Adherence to malaria RDT results in Case Management

With respect to adherence of clinicians to malaria RDT results in case management, out of 119 negative malaria RDT results, 68(57.1%) did not receive an antimalarial. However, 51(42.9%) received antimalarial even though they tested negative. Out of 137 positive malaria RDT results, 5(3.7%) did not receive an antimalarial while 132(96.3%) of the 137 positive malaria RDT received antimalarial. There was a significant association between results of malaria RDT and the prescribing of an antimalarial (OR=35.2; 95% CI=13.42-92.30) (Table 4).

Table 5

Adherence to malaria RDT results

Result of Test	Antimalarial Prescribed		OR (95% C.I)	P- value
	Yes (%)	No (%)		
Negative RDT	51 (42.9%)	68 (57.1%)	1.0(Ref.)	
Positive RDT	132 (96.3%)	5 (3.7%)	35.20(13.42-92.30)	<0.001

The two main antimalarial prescribed for patients were artesunate amodiaquine and artemether lumefantrine. Ninety-Two (26.4%) out of the 348 suspected malaria cases were treated presumptively with antimalarial without testing.

4.5 Prescriber Interview

Of the 23 prescribers interviewed, all had received training on malaria case management and also all facilities had access to standard treatment guidelines. All prescribers answered that they will prescribe antimalarial for positive malaria RDT results. None of them was of the view of prescribing antimalarial for a negative malaria RDT (Table 5).

Table 6 Prescriber interview (N = 23)

Interviews	% Conforming
Access to STG	
Yes (n=23)	100%
No (n=0)	0
Training on Case Management	
Yes (n=23)	100%
No (n=0)	0
Prescribing anti-malaria for Positive RDT	
Yes (n=23)	100%
No (n=0)	0
Prescribing anti-malaria for Negative RDT	
Yes (n=0)	0
No (n=23)	100%

CHAPTER 5

5.0 DISCUSSION

From the results of the study, malaria RDT availability was adequate in all the facilities. The type of facility was found to be associated with using malaria RDT. The study also revealed that clinicians were adhering to malaria case management guidelines, indicated by an association between malaria RDT results and the prescribing of an antimalarial.

5.1 Malaria RDT Availability

Malaria RDT is key in the diagnosis of malaria especially in peripheral health facilities. Using the Medical Technology Service Provider (MTSP) indicator which stipulates average availability of medical products and technologies in health facilities at 80%, the study showed that all 25 facilities in the district had average availability above the standard. The result from this study is in sharp contrast to the result from the study by Hussain et al. (2013) in Odisha state of India which showed poor malaria RDT availability. The implications of this finding is interesting as it demonstrates some promise of the malaria RDT scale up intervention implementation program in 2014.

Malaria RDT availability data compiled during the study revealed that stock out periods were varied across different facilities. This information is vital as district managers can use the availability reports to undertake peripheral redistribution of the commodity to mitigate stock outs in affected health facilities, whilst putting long-term strategies in place for procurement from the Regional Medical Store (RMS) as has successfully being used elsewhere (Githinji et al., 2013). All facilities in the district attributed stock out of RDTs

to unavailability at the District Health Directorate store which supplies these peripheral health facilities.

5.2 Factors that influence point of care use of malaria RDT

On factors that influence the point of care use of malaria RDT, the study showed that there was no significant difference in preference for choosing which case to test with malaria RDT based on age. This finding contradicts the study by Nyandigisi et al.,(2011) where there was a significant difference in testing between age below 5 years and those 5 years and above. This finding reveals a good response by clinicians to the new malaria case management guideline which encourages testing among children below 5 years (MOH, 2014).

The proportion of patients with temperature below 37.5°C who got tested did not differ much from those 37.5°C and above who also got tested. This shows that temperature alone is not an appropriate indicator for suspected cases to be tested. This goes to support the findings of Rowe et al. (2009) which reveals that apart from temperature above 37.5°C , patients showing at least 3 other classical signs and symptoms of malaria warrant testing.

The study by Nyandigisi et al.,(2011) found a significant association between caseload per day and testing, with patients being twice more likely to be tested with a lower caseload. This study however did not show a significant difference in the proportions of cases tested when the caseload per day was less than or equal to 50 or above 50 revealing that caseload per day did not influence clinicians decision to test suspected cases. This finding could

indicate that clinicians do not ignore testing during heavy clinic days in order to reduce their workload.

On facility type as a predictor for testing, the study revealed that CHPS and health center facilities tested a greater proportion of suspected cases than the district hospital. This difference was also found to be significant. In the study by Nyandigisi et al., (2011) which looked at facility ownership as a predictor for testing, it was explained that higher testing rates in a facility could be due to more established cost recovery schemes in such a facility. However in this study, malaria RDT testing was known to be free and therefore the higher testing rate among the CHPS and Health center facilities cannot be easily explained by cost recovery schemes. It could however be attributed to the level of provider education where less qualified providers available in the CHPS and health centers are more likely to rely heavily on testings to make up for lack of clinical expertise than qualified doctors available in the district hospital.

Overall testing rate of suspected cases was 73.6%, slightly higher than the Ministry of Health target of 70% by 2015 which is highly commendable. This high testing rate could be attributed to the scale up of malaria RDT as also highlighted by Zurovac et al.,(2014). Testing is very critical to minimizing over-treatment and missing of other potentially serious diseases with their resultant consequences

5.3 Adherence of clinicians to malaria RDT results in case management

The study also show good adherence to malaria treatment policy with a significant association between the results of malaria RDT and prescription of antimalarial. A large proportion of positive malaria RDT received first line antimalarial according to the malaria policy guidelines. However a proportion of negative malaria RDT results (42.9%) received antimalarial contrary to the malaria policy guideline and also contrary to the responses from prescribers interviewed in this study when all indicated that they did not prescribe antimalarial for negative malaria RDT results. The studies by Manyando et al., (2014) and Chandler et al., (2010) both revealed similar observations. Asimwe et al., (2012) partly attributed the treatment of negative malaria RDT with antimalarial to the lack of capacity of health workers to adequately investigate causes of fever due to other diseases. The study by Rowe et al., (2009) also attributed treatment of negative malaria RDT results with antimalarial to the apparent mistrust of negative test results by clinicians.

Ninety two (26.4%) of all suspected cases surveyed were treated presumptively with antimalarial despite malaria RDTs being available. This finding is similar to the study by Masanja et al., (2010) as well as the PMI end use verification report for Ghana where the issue of presumptive treatment was also identified.

Limitations of the study

- An important limitation of this study was that by collecting self-reported data from health workers in the form of prescriber interviews, they may report what is desirable rather than what is practiced.

However, this has been catered for by triangulation of data using different approaches and data sources.

- There was limited data collected from patients who were not tested for malaria using RDT. Therefore we do not know if the patients who were treated presumptively for malaria had signs of severe disease or other reasons for presumptive treatment.

CHAPTER 6

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Both malaria RDT availability and RDT testing rates were optimal in all the health facilities studied in the Gomoa West District with testing rates slightly better in the CHPS and health centers than the district hospital. The new malaria case management guideline which encourages universal testing before treatment and RDT results -informed prescribing of antimalarial is being adhered to by clinicians. However a proportion of patients receiving presumptive treatment (29.4%) as well as treatment of some negative malaria RDT cases has serious implications on malaria control and calls for new research to explore these further.

6.2 Recommendations

Based on the findings of the study the following recommendations are being made for consideration:

Implication for clinical practice and policy

1. District health managers should use the monthly malaria RDT availability data to implement peripheral redistribution strategies to tackle facility stock outs.
2. Intense monitoring during supervisory visits by district health managers to improve the testing rates and adherence to test results.

Implication for research

3. Further studies are needed to ascertain reasons for treating negative malaria RDT patients with antimalarial.
4. Further studies to include more facilities are needed to get a full picture of malaria RDT use.

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APPENDICES

APPENDIX 1- CONSENT FORM

CONSENT FORM FOR THE DISTRICT HEALTH DIRECTORATE, GOMOA

WEST

Research Topic: Availability and use of malaria RDT in The Gomoa West District

Introduction: I am a student from the University of Ghana, School of Public Health. My assistants and I are carrying out a study on the availability and use of malaria RDT in the Gomoa West district.

We would be grateful if you could kindly read this consent or let someone read it to you so that you can decide taking part in the study or not.

STUDY PROCEDURE, ADVANTAGES AND DISCOMFORTS

This study will involve a total of 345 cases of provisional malaria diagnosis between October to December 2014 in health facilities in the Gomoa West district. Verbal consent will be sought from the health facilities involved in the study. Data on malaria RDTs and its use in diagnosis will be captured and prescribers will also be interviewed. During data collection period, the facility is free to decline to provide data they feel they are not comfortable in putting out. The facility also has the right to reschedule the data collection to the time of the day which they feel will not interfere with their work. The prescriber interview will be brief and at a convenient time for the prescriber and will be based on prescribers use of malaria RDTs. Though by taking part in this study, you would not have any immediate and direct benefits; your responses will provide useful information for the improvement of malaria case diagnosis. The information will also be used for academic

purposes. In accepting to take part in this study the discomforts that you may have are mainly your time taken to answer the questions.

CONFIDENTIALITY

Participation in this study is voluntary. Though we would be very happy if you take part, we are assuring you that neither the facility, prescriber nor the study will be affected or suffer if any decide not to take part in this study. All the information will be kept confidential and the data will be stored in a locked cabinet. Access will be limited to only the researcher and research supervisor. Your name, identity are not needed for the study. However, the information you would provide is going to be identified by a special code number and would be treated strictly as confidential. We assure you that your name shall not appear or be mentioned in any report that might come out from this study. This study has been reviewed and approved by Ghana Health Service Ethical Review Committee (GHS-ERC) and the University of Ghana Legon's Institutional Review Board (IRB) which is committees whose tasks are to make sure that research participants are protected from harm and their rights respected.

For further clarification, you can contact the ERC-GHS administrator, Miss Hannah Frimpong on 0243235225 or 0507041223 or the principal investigator on 0244694995.

PARTICIPANT'S CONSENT FORM

I have read the foregoing information/ the foregoing information has been read to me or translated to me and I have fully understood it.

I consent voluntarily to participate in this study.

(Name and signature of a witness should be provided in a case where the participant cannot speak or read English)

Name of participant: _____

Signature/thumbprint: _____

Name of witness: _____

Signature/thumbprint of witness: _____

Signature of Principal Investigator: _____

Date: _____

APPENDIX 2- DATA COLLECTION TOOLS
FORM A: Malaria RDT Availability Capturing Tool

Facility ID:

Month:

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
RBT																															

NB: Tick (√) if RDT is available, Nil if it is unavailable

REASONS FOR STOCK OUT

- 1.
- 2.
- 3.

FORM C: PRESCRIBERS QUESTIONNAIRE**ID No:**

1. Have you received training on malaria case management?
 - a) Yes
 - b) No
2. Do you have access to the Ghana standard Treatment Guidelines?
 - a) Yes
 - b) No
3. Will you prescribe an antimalarial to a patient who tests positive to a malaria RDT test?
 - a) Yes
 - b) No
4. Will you prescribe an antimalarial to a patient who tests negative to a malaria RDT test?
 - a) Yes
 - b) No

APPENDIX 3-GHANA HEALTH SERVICE ETHICAL REVIEW APPROVAL

GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE

*In case of reply the
number and date of this
Letter should be quoted.*



*My Ref. :GHS-ERC: 3
Your Ref. No.*

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: Hannah.Frimpong@ghsmail.org

30th March, 2015

Ayin Christian Teye-Muno
School of Public Health
University of Ghana
Legon, Accra

ETHICAL APPROVAL - ID NO: GHS-ERC: 105/02/15

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol titled:

“Availability and Use of Malaria Rapid Diagnostic Test in Health Facilities in Gomoa West District, Ghana”

This approval requires that you inform the Ethical Review Committee (ERC) when the study begins and provide Mid-term reports of the study to the Ethical Review Committee (ERC) for continuous review. The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Please note that any modification without ERC approval is rendered invalid.

You are also required to report all serious adverse events related to this study to the ERC within seven days verbally and fourteen days in writing.

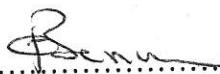
You are requested to submit a final report on the study to assure the ERC that the project was implemented as per approved protocol. You are also to inform the ERC and your sponsor before any publication of the research findings.

Please note that this approval is given for a period of 12 months, beginning March 30th 2015 to March 29th 2016.

However, you are required to request for renewal of your study if it lasts for more than 12 months.

Please always quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....



DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra