Evaluating Medicine Retailer Knowledge and Practice in the Diagnosis and Treatment of Malaria in Western Kenya: An Opportunity for Improved Malaria Case Management

by

Andria Erin Rusk

Department of Global Health
Duke University

Date:____________________

Approved:

___________________________
Wendy O’Meara, Supervisor

___________________________
Jen’nan Read

___________________________
William Pan

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Department of Global Health in the Graduate School of Duke University

2011
ABSTRACT

Evaluating Medicine Retailer Knowledge and Practice in the Diagnosis and Treatment of Malaria in Western Kenya: An Opportunity for Improved Malaria Case Management

by

Andria Erin Rusk

Department of Global Health
Duke University

Date:_______________________
Approved:

___________________________
Wendy O’Meara, Supervisor

___________________________
Jen’nan Read

___________________________
William Pan

An abstract of a thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Department of Global Health in the Graduate School of Duke University

2011
Abstract

Malaria remains one of the world’s most significant global health challenges. Claiming nearly a million lives each year in Africa alone, this continent bears an especially large part of the malaria disease burden, and with 85% of those deaths among children under the age of 5, better management of malaria cases is critical to the healthy future of the nearly 3.3 billion people at risk of malaria infection1.

Improving malaria control is critical to reducing the mortality and morbidity caused by the disease. Key steps to achieving this reduction are early diagnosis, accurate and appropriate treatment, and increased access to these services. In western Kenya, as in much of East Africa, this means improving malaria case management in the informal health sector, specifically in medicine retail locations.

Understanding medicine retailer knowledge and behaviors related to malaria diagnosis and treatment is an important part of improving those practices and thereby the control of malaria in these areas. Two studies were recently conducted that focused on these goals. The first, a quantitative study, examined antimalarial recommendation and dispensing practices and antimalarial knowledge among retailers in the Bungoma East district of western Kenya. The second is a qualitative study investigating retailer diagnostic practices, and their perceptions and concerns regarding alternative diagnostic practices, and their perceptions and concerns regarding alternative diagnostic

1 World Health Organization Roll Back Malaria Program, Key Facts: http://www.rbm.who.int/keyfacts.html
methods, specifically the use of rapid diagnostic tests for malaria, and how their use might influence medicine retailer behavior.

The quantitative survey found that, while more than half of the participants could identify the correct first-line antimalarial medication, less than half of those would recommend it to children. Customer demand, retailer training, education, and drug stocking and dispensing behaviors were all identified as factors influencing the relationship between knowing the correct antimalarial therapy and recommending it. Many opportunities were discovered to improve appropriate use of antimalarials in this setting. Ensuring that all medicine retailers have at least a basic health training and level of education would improve antimalarial drug knowledge. Educating the community on current antimalarial therapies could help alter the pressure of customer demand to align with appropriate treatment.

The qualitative study found that retailers rely heavily on clinical diagnosis to detect malaria in sick customers, even though they are aware of the limitations of such methods, particularly given the symptomatic similarity of several other diseases. Rapid diagnostic tests for malaria were seen as a viable and profitable solution to achieve a more accurate diagnosis. Medicine retailers felt the tests could bring new customers to their businesses, increase sales, and result in increased patient and provider confidence in the accuracy of the diagnosis, which may increase usage and adherence.
However, there were concerns regarding cost, patient acceptance, and issues that may arise with regulatory boards concerning unregistered retail locations in the area. Overall, medicine retailers felt that most of these issues could be overcome if the regulatory bodies were involved in implementation, if their communities were educated on the importance of testing for malaria before treatment, and if they received training on the use, interpretation, and application of the tests.

Both studies identified opportunities for improvement of the management of malaria through interventions focused on retail drug locations. Training, education, and community and leadership involvement were recognized as key components to the success of future implementation efforts. By increasing access to definitive malaria diagnosis, improving the appropriate use of antimalarial therapies, and increasing access to both of these services, incidences of malaria could be better managed, treated, controlled, and eradicated.
Dedication

This book is dedicated to all the mothers all over the world who have a right to appropriate care for their children, and to all the health workers toiling diligently to ensure that they do.
# Contents

Abstract........................................................................................................................................ iv

List of Tables .................................................................................................................................. xii

List of Figures ................................................................................................................................. xiii

Acknowledgements ......................................................................................................................... xiv

1. Introduction ................................................................................................................................. 1
   1.1 The global burden of malaria .............................................................................................. 1
   1.1.2 That borne by Africa ........................................................................................................ 3
   1.1.3 The state of malaria in Kenya ........................................................................................... 4
   1.2 Presumptive diagnosis, overprescription, and drug resistance ........................................... 4
   1.3 The role of medicine retailers in the treatment of malaria .................................................... 6
   1.4 Thesis organization ............................................................................................................... 8

   2.1 Abstract ............................................................................................................................... 10
   2.2 Background .......................................................................................................................... 11
   2.3 Methods ............................................................................................................................... 13
   2.3.1 Study area and sample .................................................................................................... 13
   2.3.2 Data Collection ............................................................................................................... 15
   2.3.3 Consent .......................................................................................................................... 15
   2.3.4 Data entry and analysis .................................................................................................. 16
   2.3.4 Ethics ............................................................................................................................... 16
4.1 Recommendations ........................................................................................................78

4.2 Next Steps ......................................................................................................................79

Appendix A .........................................................................................................................81

Appendix B .........................................................................................................................83

Appendix C .........................................................................................................................88

Appendix D .........................................................................................................................95

References .........................................................................................................................103
List of Tables

Table 1: Background information on the surveyed population, retail location level variables, Western Province, Kenya 2010.......................................................... 18

Table 2: Background information on the surveyed population, individual level variables, Western Province, Kenya 2010.......................................................... 19

Table 3: Association of medicine retailer characteristics with correct knowledge of firstline antimalarial therapy................................................................. 21

Table 4: Association of medicine retailer knowledge and behavior with correct knowledge of firstline antimalarial therapy .................................................. 25

Table 5: Participant characteristics by focus group discussion ........................................ 52
List of Figures

Figure 1: Map of study area including numbered boundaries of each focus group discussion ....................................................................................................................................................... 49
Acknowledgements

Thank you to my thesis committee and those that reviewed this manuscript in part or in full: Wendy O’Meara, Jen’nan Read, Randall Kramer, William Pan, Catherine Goodman, and Andrew Obala. I was honored by the opportunity to work with an unbelievably dedicated team while in Kenya who went out of their way to support this effort; especially Beatrice Koech, Vioet Naanyu, Christopher Siminyu, Emily Mukwanja, and Jane Nyongesa. I also wish to thank Mike Merson, Lysa MacKeen, Sarah Martin, Brian Pence, Daniel Westreich, Manoj Mohanan, and the faculty and staff of the Duke Global Health Institute for their encouragement and support. I also send a deep and heartfelt thank you to my family for their love and support along this journey. Thank you Taylor, you are my confidence and my strength.
1. Introduction

1.1 The global burden of malaria

Malaria is a life-threatening disease caused by Plasmodium parasites that are transmitted to humans through the bite of an infected mosquito. Infection is caused by four species of the Plasmodium genus: *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*, while *P. falciparum* causes the most serious cases of malaria and is the most widespread [1].

An estimated 0.5 to 2.5 million deaths result from these infections [2] from 109 countries, representing a total at-risk population of over three billion – approximately half the global population [3]. Of those countries at risk for malaria, 35 account for 98% of the global malaria deaths, 30 in sub-Saharan Africa and 5 in Asia.

Malaria morbidity also represents a significant part of the global health burden of malaria. Although an accurate count of the annual number of clinical malaria cases is hindered by poor surveillance, inconsistent recording and reporting methods, and little to no parasitological diagnosis, estimates range from 247 to 515 million cases [1, 4] worldwide per year. It has even been argued that, considering average episodes per year in endemic areas and average rates of parasitemia among the exposed, well over two billion febrile episodes resembling malaria can be expected annually, with the majority of these parasitemic [5].
Malaria morbidity is responsible for 2.2% of the global disease burden in terms of disability-adjusted life years (DALYs), according to the 2004 World Health Organization (WHO) estimates [6]. This equates to over 35 million years of life lost to morbidity attributed to malaria infection [3].

Malaria can also contribute to the development of a host of other syndromes, further increasing the impact on mortality and morbidity. Consequences of *Plasmodium* infection, particularly with *P. falciparum* in cases of severe malaria, include severe anemia, hypoglycemia, neurological disorders, transient immune suppression, increased risk of HIV mortality, cerebral malaria, adverse events from malaria drugs, and death [5]. In addition to these direct effects, other indirect contributions to morbidity are ascribed to malaria infection: increases in maternal anemia, low birth weight, intrauterine growth retardation, immune suppression, bone marrow suppression, and nutritional deficiencies [5].

Co-infection contributes significantly to the impact malaria has on morbidity and mortality. In patients infected with human immunodeficiency virus, febrile malaria episodes increase HIV viral load and the probability of HIV transmission from HIV and malaria co-infected patients [7]. Co-infected pregnant women are at high risk of anemia, placental infection and low weight births [8]. In areas endemic for both malaria and tuberculosis, the partial immune suppression associated with *Plasmodium* infection may increase the risk of co-infection with tuberculosis [9]. The risk of co-infection may be
higher in rural areas where the burden of both diseases is high and the increased risk of tuberculosis is higher due to over-crowding of public health facilities, which increases the risk of exposure to nosocomial infection in admitted patients.

1.1.2 That borne by Africa

Of the estimated annual deaths from malaria, over 90% of these are borne by Africa alone [2]. Nearly 31 million of the over 35 million DALYs attributed to malaria, are suffered in Africa [6] making malaria the fourth-highest contributor to disease burden on the continent.

The economic burden resulting from malaria is considerable. Malaria-related costs in the region total USD 12 billion annually, equating to an average loss of 1.3% of gross domestic product (GDP) growth per year across countries on the African continent [3]. This financial burden impacts families as well. The average household expenditure on malaria is roughly 10% of their yearly spend [3].

Exacerbating the healthcare costs that directly impact local and national economies are indirect costs resulting from the malaria burden. Lost productivity due to illness and time in patient care, lost education for students, teachers, and facilitators, costs related to long-term physical disability, and even increased family size due to increased fertility compensation for high child mortality all contribute to the economic impact of malaria [10].
1.1.3 The state of malaria in Kenya

The burden of malaria is particularly high in Kenya. Nineteen percent of all deaths in Kenya during the year 2006 were attributable to malaria [12], and 20% of all deaths in children under five [11]. Between 30-50% of all outpatient attendance and 20% of all health facility admissions are due to malaria [11]. The morbidity associated with malaria has a significant impact on the country, which ranks fifth in the world in annual malaria incidence [3].

The economic burden contributed to the prevention, treatment, and management of malaria in Kenya is great. Over USD 61 million was spent on malaria control in 2008 [12], not including the costs to health systems and human resources, which are considerable. Kenya loses an estimated 170 million working days due to malaria infection annually [11].

1.2 Presumptive diagnosis, overprescription, and drug resistance

The poor specificity of a clinical diagnosis for malaria [19], due to signs and symptoms that can be caused by other diseases [20], leads to significant overdiagnosis of febrile illness as malaria and an overprescription of antimalarials [21]. Overprescription is exacerbated by presumptive treatment practices that assume most febrile illnesses are caused by malaria.

Overdiagnosis, overprescription of costly antimalarials, increased burden on health facilities, and loss of time and productivity from school or employment that result
from misdiagnosis of untreated disease all contribute to the economic burden of malaria. In Sudan, the estimated cost of diagnosis and treatment of malaria was USD 100 million in 2000, but the cost of actual malaria cases and needed treatment was estimated to be closer to USD 14 million [14].

In a review of studies looking at the misdiagnosis of malaria in Africa, it was found that an average of 67% of patients clinically diagnosed with malaria have illnesses attributable to other causes [16]. A study in Ghana showed that, in a typical rural health facility that does not have diagnostic capability, 90.1% of patients with negative research slides received a clinical diagnosis of malaria and were wrongly treated with antimalarials [22].

The practice of presumptive diagnosis of malaria often leads to treatment of non-malaria fevers with antimalarials, thus increasing the risk of spreading drug resistance to antimalarial medications [15, 16, 17, 17]. Drug resistance is further exacerbated by the misuse of antimalarials. Overprescription, as well as incomplete dosing, exposes the parasite to the drug without eradicating it, thereby increasing the risk of developing resistance.

In 1998, Kenya changed its frontline antimalarial policy from chloroquine to sulfadoxine-pyrimethamine (SP), and by 2003, resistance to this drug was already noted. In just four years, from 1998 to 2001, treatment failure was reported throughout Kenya. In Kisumu, failure rates were noted between 11 and 42%, and between 3 and 27% in
Bondo, both near our study area and both considered significant failures in treatment [23]. This development of resistance to SP led the Kenyan Ministry of Health to change the firstline antimalarial policy to artemisinin-based combination therapies (ACTs) in 2006. With this new treatment recommendation in place, delaying drug resistance development to ACTs became even more of a priority.

In resource-constrained settings such as western Kenya, where the burden of malaria is high and the need for accurate diagnosis and appropriate treatment is critical, it is important to maximize efforts by focusing interventions on areas where it is most needed, and that are positioned to have the greatest benefit for the smallest cost.

1.3 The role of medicine retailers in the treatment of malaria

Many studies in sub-Saharan Africa have shown that most families first seek treatment for mild febrile illnesses in the retail sector rather than through formal health services. Particularly in populations with inadequate health services, self-medicating with drugs purchased at retail locations is a common practice [26, 27, 28, 29]. Retail drug businesses are well positioned to receive interventions focused on improving malaria case management because of this treatment-seeking behavior [24, 25].

There are many possible explanations for the preference of seeking treatment from retail drug outlets over public health facilities. In Kenya, where public health facilities are few and far between, there are fewer patients using public health services the further they are from that facility [30]. Retail drug locations are often more
convenient and closer to home [31, 32]. A study conducted in coastal Kenya [33] found that 32% of homes were within 2 kilometers of a public health facility, while 87% of homes were within one kilometer of a retail outlet. In the Bungoma East district of western Kenya, the average distance from a residence to a public health facility is 2.03 kilometers, but the average distance to a retail location is 1.06 kilometers [34]. This savings in time and transportation costs contributes to retail drug outlets often being less expensive than health facilities [35]. Customers of retail drug outlets can also avoid paying the consultation and user fees often found in the formal health sector, and if they are not able to afford to pay for all of the needed treatment, customers can often purchase on credit at a retail drug outlet – a service not offered at most health facilities [45].

Retail outlets are often open longer than public health facilities. In the Bungoma East district of western Kenya, 54% of outlets surveyed were open at least 2 hours longer than public health facilities, while 43% of outlets were open 4 hours longer or more. Additionally, 85% of drug retail outlets were open on Saturdays, while few public health facilities are, and 42% of outlets were open on Sundays, while no public health facilities keep hours on Sundays [34].

Frequent drug stock outages at public health facilities is another reason customers may choose to visit local drug outlets, where they have access to a more consistent supply of medications [36]. Customers may also choose to seek care at a retail
drug outlet over a public health facility because of perceptions held of facility staff. Patients have expressed their dislike for health worker’s rudeness and perceived aggressive behavior [25].

1.4 Thesis organization

This thesis combines two related pieces of work focused on improving malaria case management through the informal health sector, specifically retail medicine outlets, in the Bungoma East district of western Kenya. To combine these two streams of work, this thesis is divided into three following sections. Section two is a quantitative study that sought to identify the determinants of provider behavior as it relates to diagnostic and treatment practices for malaria. This section is a modification of a manuscript that was written together with colleagues from Moi and Duke Universities, including Wendy O’Meara, Andrew Obala, and Diana Menya.

The third section is a qualitative study that investigated those determinants from the perspective of medicine retailers, and evaluated how the introduction of a new diagnostic tool might affect their diagnostic and treatment behavior. This section was also modified from a shorter manuscript that was co-written with Wendy O’Meara, Andrew Obala, and Catherine Goodman, with the support of members of the Webuye DSS team Chris Simiyu and Emily Mukwanja, and colleagues from Moi University Violet Naanyu, Beatrice Koech, and Imran Manji.
Section four combines the conclusions from these two streams of work, and summarizes the recommendations to improve malaria case management in the region, including proposed next steps for achieving those recommendations.
2. Malaria diagnostic and treatment practices of medicine retailers in western Kenya: An evaluation of determinants

2.1 Abstract

Background

Malaria is a major cause of morbidity and mortality in Kenya, where it is the fifth leading cause of disease in both children and adults. Effectively managing malaria is dependent upon appropriate treatment. Since most treatment for malaria is sought in retail drug locations, understanding medicine retailer knowledge and behavior in treating malaria and dispensing antimalarials is crucial. In this study, we examine retailers’ knowledge of antimalarials and their dispensing behaviors.

Methods

We conducted a survey of all retail drug outlets that sell antimalarial medications and reside within or are accessible to those living within the Webuye Health and Demographic Surveillance Site in the Bungoma East district of western Kenya.

Results

Most of the medicine retailers surveyed (65%) were able to identify artemether-lumeflathrine (AL) as the Kenyan Ministry of Health recommended firstline antimalarial therapy. Retailers who identified the correct treatment were more likely to recommend that treatment to adult and pediatric customers. However, the proportion of medicine
retailers who recommend accurately are disappointingly low. Only 48% would recommend AL to adults, and 37% would recommend it to children. We discovered that customer demand has an influence on retailer behavior. We also found that retailer training, education, and gender are potential determinants to antimalarial drug knowledge. Medicine retailer behavior, including patient referral practice and dispensing patterns are also correlated with knowing the correct firstline antimalarial medication and recommending it to customers. The Kenyan Ministry of Health guidelines were also found to influence retailer drug stocking and dispensing behaviors.

**Conclusion**

Most medicine retailers could identify the recommended firstline treatment for malaria, but the percentage that couldn’t is still too high. Furthermore, knowing the correct medication does not always ensure it is recommended or dispensed to customers. Retailer training and education are both areas that could be improved. Considering the influence customer demand has on retailer behavior, future interventions focusing on community education may have even more of an impact on the appropriate use of antimalarials.

**2.2 Background**

Malaria is a major cause of morbidity and mortality, with infection by *Plasmodium falciparum* responsible for approximately 515 million clinical infections worldwide [4]. An estimated 0.5 to 2.5 million deaths result from these infections, with
over 90% of these borne by Africa alone [2]. In Kenya, it is the fifth leading cause of death in both children and adults [37].

In response to the development of drug resistance to sulfadoxine-pyrimethamine (SP), the Kenyan Ministry of Health changed its first-line antimalarial policy to artemisinin-based combination therapies (ACTs) in 2006. With this new treatment recommendation in place, it became vital that development of drug resistance to this new therapy was delayed as long as possible, and that antimalarial drug providers adhered to the new recommendation, discontinued the use and prescription of ineffective treatments, and that access to ACTs was broadened to reach as many infected individuals as possible.

In order to ensure access, efforts were invested in interventions targeting retail drug locations, since most treatment for malaria is sought outside the formal health sector [24, 25]. In August of 2010, Kenya was one of six countries to launch Affordable Medicines Facility-malaria (AMFm), a global subsidy program aimed at reducing the price of and improving access to ACT therapies. This initiative focused on making ACTs more attractive to medicine retailers and consumers in order to encourage their use over other ineffective drugs.

One goal of AMFm is to increase availability of the Ministry of Health recommended firstline antimalarial treatment while decreasing the use of SP and other antimalarials for which there is known drug resistance. However, drug retailers have
been found to continue prescribing outdated antimalarials even with knowledge of current recommended drugs. In two previous studies, one conducted in rural Tanzania and the other in Kenya, drug retailers who knew the recommended firstline treatment for malaria were found to continue dispensing and selling ineffective medications [40, 41].

We therefore conducted a study in the fall of 2010 to survey all medicine retailers, including drug shops and private clinics, in the Webuye Health and Demographic Surveillance Site (WHDSS) in the Bungoma East district of western Kenya. We focused on evaluating medicine retailer knowledge of antimalarials, specifically the firstline recommended antimalarial medication, as well as dispensing and treatment practices. We also aimed to discover if medicine retailers were aware of the change in Ministry of Health guidelines regarding firstline antimalarial recommendations, and if this knowledge had an impact on dispensing practices. The location of a retail business, in an urban or rural setting, as well as the type of retail business, as a shop or a clinic, were also examined to better understand the determinants of medicine retailer knowledge and behavior.

2.3 Methods

2.3.1 Study area and sample

The study was conducted in the Webuye Health and Demographic Surveillance Survey (WHDSS) site in the Bungoma East district of Kenya’s Western Province. Kenya
has a population of 39.8 million people according to the 2009 census, 78% of whom live in rural areas [42]. The Bungoma East district is located approximately 380 kilometers west of Nairobi, the capital of Kenya. The WHDSS is home to approximately 70,000 residents. The primary economy is subsistence farming, with roughly 1,500 residents employed by a local sugar-processing factory, and others growing sugar cane to sell to the factory. The malaria burden in the WHDSS is particularly high, despite the varied transmission rates of the Western Province [43]. A longitudinal study conducted in 1998 in western Kenya found *Plasmodium falciparum* parasites in 55.4% of asymptomatic children in the wet season and 44% of children in the dry season [44].

The healthcare services within the WHDSS are provided by both the formal and the informal health sector. The formal sector is made up of four government-owned health facilities: one district hospital, one health center, and two medicine dispensaries. In addition to these, there are also faith-based hospitals that offer healthcare services. The informal health sector is made up of many retail businesses, including pharmacies, drug outlets, traditional healers, and herbalists.

The study population included all pharmacies, outlets, and private clinics within and accessible to those living in the WHDSS, up to and within 5 kilometers of the WHDSS borders [45]. These locations were identified by a team of 10 fieldworkers each assigned a specific region to cover on motorbike. Fieldworkers started in the market centre and identified each outlet, taking down the name and GPS coordinates of each. At
each outlet, fieldworkers asked outlet staff if there were any additional outlets in the area. Fieldworkers continued visiting outlets and inquiring after additional outlets until no new outlets were identified. Inclusion criteria were comprised of locations selling antimalarials, including private clinics, retail shops, chemists, pharmacists, and agrovets. Exclusion criteria included public health facilities, general shops that sold mostly consumables and only a few medications, and refusal to participate in the survey.

2.3.2 Data Collection

A survey tool was used to collect data on medicine retailer knowledge of the Ministry of Health recommended firstline antimalarial drug treatment, self-reported actions regarding diagnosis, recommendation, and dispensing practices, and responses to scenarios involving customer interactions. The scenarios included mothers inquiring after medication for a sick child, with specific symptoms, or requesting specific medication. Basic demographic data on medicine retailers were also included. The survey included components from two previous questionnaires used in retail outlet studies [46, 47]. Fieldworkers were trained on the survey tool, which was piloted outside the study area. The fieldworkers visited each location that had originally been identified in the canvassing activity during the study period.

2.3.3 Consent

All study participants provided verbal consent before participating in the survey.
2.3.4 Data entry and analysis

Fieldworkers administered paper questionnaires to retail staff. All collected data was double entered into a Microsoft Access database and confirmed, with discrepancies clarified by consulting the original survey forms. Data was exported to and analyzed using Stata v11.

Analysis examined unadjusted odds ratios comparing demographic and education variables related to malaria knowledge variables and outcomes with appropriate recommendation and dispensing practices using univariate logistic regression. We considered p values of less than 0.05 to be statistically significant. We used multivariate regression analysis when looking at the relationship between recommending appropriate treatment in children and referral behavior, correcting for antimalarial drug knowledge. This was the only comparison for which there were adequate observations in each group to make meaningful comparisons. In this case, both unadjusted and adjusted odds ratios are reported.

2.3.4 Ethics

Ethical approval for the research was granted from ethical review boards at Moi University Institutional Research and Ethics Committee in Eldoret, Kenya and the Duke University Institutional Review Board in Durham, North Carolina. Additional approval was also sought from the Webuye HDSS site authorities, community chiefs, assistant chiefs, and village elders from the study area.
2.4 Results

2.4.1 The study community

There were 117 individuals from 97 different outlets that participated in the survey. Of them, two individuals were excluded from analysis on the basis that they did not dispense medications and could not comment on antimalarial dispensing practices. Nearly all the outlets included in the survey were in a rural setting (95%), and were classified as shops (89%) rather than clinics (Table 1). Rural locations were defined as those outside of Webuye Town, and clinics were defined as those that self-identified as clinics by business name.
Table 1: Background information on the surveyed population, retail location level variables, Western Province, Kenya 2010

<table>
<thead>
<tr>
<th>Variables</th>
<th>N = 115</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of retail outlet</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shop</td>
<td>n = 102</td>
<td>89%</td>
</tr>
<tr>
<td>Clinic</td>
<td>n = 13</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Location of retail outlet</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>n = 6</td>
<td>5%</td>
</tr>
<tr>
<td>Rural</td>
<td>n = 109</td>
<td>95%</td>
</tr>
<tr>
<td><strong>Operating hours</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 8 hours per day</td>
<td>n = 3</td>
<td>3%</td>
</tr>
<tr>
<td>8 - 10 hours per day</td>
<td>n = 71</td>
<td>62%</td>
</tr>
<tr>
<td>&gt; 10 hours per day</td>
<td>n = 40</td>
<td>35%</td>
</tr>
<tr>
<td>Open on Saturday</td>
<td>n = 94</td>
<td>82%</td>
</tr>
<tr>
<td>Open on Sunday</td>
<td>n = 52</td>
<td>45%</td>
</tr>
<tr>
<td><strong>Number of staff -- Mean (min - max)</strong></td>
<td>1.62 (0 - 6)</td>
<td></td>
</tr>
<tr>
<td><strong>Number who dispense -- Mean (min - max)</strong></td>
<td>1.33 (0 - 3)</td>
<td></td>
</tr>
</tbody>
</table>

2.4.2 Characteristics of medicine retailers

Of the 115 respondents included in the analysis (Table 2), 71% were female, and 83% were under the age 40, with the largest proportion of respondents (n=52) between the ages of 30 and 40. The majority of retailers surveyed had reached an education level
above secondary school (67%), with fewer having just completed secondary school (30%), and the smallest proportion having finished only primary school (2%).

Table 2: Background information on the surveyed population, individual level variables, Western Province, Kenya 2010

<table>
<thead>
<tr>
<th>Variables</th>
<th>N = 115</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 15-20</td>
<td>n = 1</td>
<td>1%</td>
</tr>
<tr>
<td>Age 20-30</td>
<td>n = 43</td>
<td>37%</td>
</tr>
<tr>
<td>Age 30-40</td>
<td>n = 52</td>
<td>45%</td>
</tr>
<tr>
<td>Age 40-50</td>
<td>n = 9</td>
<td>8%</td>
</tr>
<tr>
<td>Age 50-60</td>
<td>n = 6</td>
<td>5%</td>
</tr>
<tr>
<td>Age 60+</td>
<td>n = 2</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Female Ratio</strong></td>
<td></td>
<td>71%</td>
</tr>
<tr>
<td><strong>Health Qualification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>n = 25</td>
<td>22%</td>
</tr>
<tr>
<td>Pharmacy Technologist</td>
<td>n = 10</td>
<td>9%</td>
</tr>
<tr>
<td>Pharmacy Assistant</td>
<td>n = 10</td>
<td>9%</td>
</tr>
<tr>
<td>Clinical Officer</td>
<td>n = 1</td>
<td>1%</td>
</tr>
<tr>
<td>Nurse</td>
<td>n = 38</td>
<td>33%</td>
</tr>
<tr>
<td>Nurse Assistant</td>
<td>n = 9</td>
<td>8%</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>n = 1</td>
<td>1%</td>
</tr>
<tr>
<td>Others</td>
<td>n = 6</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed primary</td>
<td>n = 2</td>
<td>2%</td>
</tr>
<tr>
<td>Completed secondary</td>
<td>n = 35</td>
<td>30%</td>
</tr>
<tr>
<td>Above secondary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>education</td>
<td>n = 77</td>
<td>67%</td>
</tr>
</tbody>
</table>
Over 82% of respondents had received health-related training, with most of these having been trained in pharmacy (40%) or in nursing/midwifery including one clinical officer (42%) with 18% of the surveyed population having no relevant health training. These results are incongruous with the self-reported education levels, since 82% of those surveyed reported a health training in either pharmacy or nursing/midwifery, but only 67% had received an education above secondary school.

### 2.4.3 Antimalarial drug knowledge

Most of the population surveyed could identify the current MOH recommended antimalarial medication to treat uncomplicated malaria (65%), but the odds of knowing the recommended treatment are higher amongst participants with health training (OR = 3.26, 95% CI 1.23 – 8.63; 0.017). Seventy-one percent of those with health training knew the correct antimalarial medication, but less than half the retailers without any formal health training could identify the recommended firstline antimalarial (Table 3).

The field in which a medicine retailer is trained, such as pharmacy or nursing, is also correlated with knowing the right antimalarial. Pharmacy-trained retailers are 3 times more likely to identify artemisinin-based combination therapies as the recommended firstline antimalarial treatment when compared to retailers without training (OR = 3.28, 95% CI 1.12 – 9.65; 0.031). Those trained in nursing were also more
likely to know the current firstline antimalarial than those without training (OR = 3.24, 95% CI 1.12 – 9.39; 0.031).

Table 3: Association of medicine retailer characteristics with correct knowledge of firstline antimalarial therapy

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
<th>Unadjusted odds ratio and (95% confidence interval; P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under 30</td>
<td>34</td>
<td>77%</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Between 30 and 40</td>
<td>27</td>
<td>52%</td>
<td>0.32 (0.13 - 0.77; 0.012)*</td>
</tr>
<tr>
<td>Over 40</td>
<td>14</td>
<td>82%</td>
<td>1.37 (0.33 - 5.75; 0.665)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>54</td>
<td>66%</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Male</td>
<td>21</td>
<td>66%</td>
<td>0.99 (0.42 - 2.34; 0.982)</td>
</tr>
<tr>
<td><strong>Health qualification type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untrained</td>
<td>9</td>
<td>43%</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>32</td>
<td>71%</td>
<td>3.28 (1.12 - 9.65; 0.031)*</td>
</tr>
<tr>
<td>Nurse/Midwife</td>
<td>34</td>
<td>71%</td>
<td>3.24 (1.12 - 9.39; 0.031)*</td>
</tr>
<tr>
<td><strong>Health qualification level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Untrained</td>
<td>9</td>
<td>43%</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Assistant level</td>
<td>22</td>
<td>76%</td>
<td>4.14 (1.25 - 14.09; 0.021)*</td>
</tr>
<tr>
<td>Professional level</td>
<td>44</td>
<td>69%</td>
<td>2.93 (1.07 - 8.08; 0.037)*</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed primary</td>
<td>1</td>
<td>50%</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Completed Secondary</td>
<td>22</td>
<td>63%</td>
<td>1.69 (0.10 - 29.41; 0.718)</td>
</tr>
<tr>
<td>Some or completed above secondary</td>
<td>52</td>
<td>68%</td>
<td>2.08 (0.12 - 34.64; 0.610)</td>
</tr>
</tbody>
</table>

*denotes statistical significance  
n = proportion with correct antimalarial drug knowledge

The level of health training, whether a retailer was trained at an assistant level, such as a nursing assistant or laboratory assistant, rather than a professional, such as a
pharmacist, clinical officer, or nurse, was also a significant predictor of identifying the correct firstline antimalarial. Unexpectedly, assistants had a higher proportion of staff who knew the right antimalarial medication, at 76% (n=22), compared to professionals such as nurses, pharmacists, and clinical officers, at 69% (n=44), even though they were less likely to have attended a workshop on malaria treatment than professionals (OR = 0.27, 95% CI 0.097 – 0.751; 0.012).

Level of education was related to antimalarial drug knowledge, which increases with each level of education attained. One out of the two participants with a primary education could correctly identify AL as the firstline MOH recommended antimalarial. Sixty-three percent of those with a secondary education identified AL, and 68% of those above a secondary education identified accurately. Given the small sample size of those participants with only a primary education (n=2), these comparisons did not reach statistical significance.

### 2.4.4 Antimalarial dispensing practices

In the survey, each respondent was asked an open-ended question to identify which antimalarial medication they would recommend to adult and pediatric clients. In both cases, knowing the MOH recommended antimalarial medication was found to be a strong predictor of recommending and dispensing the correct medication (Table 4).

Health-related qualification was a significant predictor of dispensing the correct antimalarial treatment. Pharmacy-trained retailers had the highest proportion of those
who recommended the correct treatment to adults when compared to untrained retailers (OR = 4.50, 95% CI 1.263 – 16.036; 0.020). However, training in nursing/midwifery was not a statistically significant predictor of identifying appropriate treatment in adults (OR = 2.30, 95% CI 0.67 – 7.86; 0.184). Those trained in nursing or midwifery were, however, more likely to recommend AL to a child under 5 (44%) than those trained in pharmacy (38%) and those without training (24%) though these comparisons did not reach statistical significance.

The level of health training was also associated with recommending the correct firstline antimalarial drug, particularly in adults. Those with a professional level of training were more than 3 times more likely to recommend the correct treatment to adults when compared to the untrained (OR = 3.89, 95% CI 1.16 – 13.03; 0.027). Although assistants had a higher proportion of those who recommended AL for adults than the untrained (45% versus 24%) they had a lower proportion when compared to professionals (45% compared to 58%) although neither of these comparisons reached statistical significance. Those with an assistant level of training were more likely to recommend AL to children than those with a professional level of health training, at 48% compared to 38%, but these figures did not reach statistical significance.

Knowing the correct firstline antimalarial was not associated with having attended a workshop on malaria or antimalarial drugs (Table 4), regardless of whether the workshop was held before or after the change to AL in 2006. The same is true for
medicine retailers having received information on antimalarial drugs from the Ministry of Health.

### 2.4.5 Retailer actions and behaviors

Study participants were asked to respond to a scenario in which a mother requests Fansidar tablets, an outdated antimalarial medication containing sulfadoxine and pyrimethamine, for a sick child. How a participant would react in this situation was recorded as an open-ended response. It was found that retailers who refer sick children to a laboratory or hospital, or those who ask for signs or symptoms from the guardian as their first reactions to this scenario, are 2.5 times more likely to recommend the correct antimalarial for children under 5 when compared to those retailers who reported they would just treat (OR = 2.45, 95% CI 1.04 – 5.80; 0.041) (Table 4). Even when controlling for the effects of antimalarial drug knowledge, referral practice remains correlated with recommending appropriate treatment for children (Adjusted OR = 2.50, 95% CI 1.04 – 6.02; 0.041).

Although referral behavior was associated with knowing the correct firstline antimalarial medication, there was still a high percentage of retailers who had this knowledge and would dispense Fansidar to a mother who requests it. Of those who would give Fansidar in this scenario, 58% of them knew that it was not the MOH recommended firstline treatment.
Table 4: Association of medicine retailer knowledge and behavior with correct knowledge of first line antimalarial therapy

<table>
<thead>
<tr>
<th>Malaria and Antimalarial training</th>
<th>n</th>
<th>%</th>
<th>Unadjusted odds ratio and (95% confidence interval; P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended malaria workshop</td>
<td>30</td>
<td>65%</td>
<td>0.94 (0.42 - 2.07; 0.873)</td>
</tr>
<tr>
<td>Attended malaria workshop after 2006</td>
<td>21</td>
<td>62%</td>
<td>1.00 (0.99 - 1.01; 0.799)</td>
</tr>
<tr>
<td>Received drug information from MOH</td>
<td>65</td>
<td>69%</td>
<td>0.96 (0.85 - 1.08; 0.483)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dispensing Practices</th>
<th>n</th>
<th>%</th>
<th>Unadjusted odds ratio and (95% confidence interval; P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct treatment of under 5</td>
<td>32</td>
<td>74%</td>
<td>2.41 (1.01 - 5.76; 0.048)*</td>
</tr>
<tr>
<td>Correct treatment of adults</td>
<td>42</td>
<td>76%</td>
<td>3.55 (1.49 - 8.47; 0.004)*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pediatric Case Management</th>
<th>n</th>
<th>%</th>
<th>Unadjusted odds ratio and (95% confidence interval; P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer pediatric patients rather than treat</td>
<td>21</td>
<td>49%</td>
<td>2.45 (1.04 - 5.79; 0.041)*</td>
</tr>
<tr>
<td>Withhold Fansidar rather than dispense</td>
<td>4</td>
<td>21%</td>
<td>3.59 (1.08 - 11.90; 0.036)*</td>
</tr>
</tbody>
</table>

* denotes statistical significance
n = proportion with correct antimalarial drug knowledge

Retailer motivations behind choosing which antimalarials to stock and which to dispense were also correlated with recommending the first line antimalarial to children. Participants were asked an open-ended question regarding how they decide on what malaria medications to carry in their outlets. This motivation was found to be a significant predictor of recommending the correct treatment for malaria in children, when comparing the two most frequent responses: those who said they stock according to the antimalarials recommended by the Ministry of Health (n=24) and those who stock
according to what their customers demand (n=74). Participants who stock according to MOH guidelines were 6 times more likely to identify the correct antimalarial treatment in children under 5 than those who stock according to customer demand (OR = 6.00, 95% CI 1.90 – 18.99; 0.002). However, the motivations behind drug stocking were not found to be related to recommending the correct treatment in adults.

Participants were also asked an open-ended question regarding how they choose which medication to dispense to a customer. Those who would dispense according to MOH guidelines (n=11) were 7 times more likely to recommend correctly to children than those who dispense according to customer demands (n=41) (OR = 7.00, 95% CI 1.24 – 39.49; 0.027). Dispensing practice was not found to be correlated with whether they recommend correctly for adults.

To understand if customer pressure could explain this gap between antimalarial knowledge and dispensing practices, we conducted additional analysis on the relationship between medicine retailers and their customers. However, we found that 98% of all retailers surveyed said they provide advice outside the customers’ demands, 95% suggest specific medicines to their customers, and 89% said their customers would take this advice and purchase the medication they recommend. Very few retailers were found to act solely on customer demand, it was therefore difficult to isolate the effect of customer demand on knowledge or dispensing practices.
2.4.6 Access to quality care

Since a discrepancy was seen between the level of health-related training and frontline antimalarial treatment knowledge, we conducted additional analysis to identify the distribution of training, and thereby access to quality care, amongst retail outlet locations.

This analysis yielded that 100% of the untrained retailers worked in rural locations, and that only one untrained retailer worked in a clinic rather than a shop. Those with training in nursing or midwifery, who had the highest odds of recommending the correct frontline antimalarial to children under 5, are less likely to work in shops than clinics whereas pharmacy-trained retailers were more likely to work in shops (OR 0.18, 95% CI 0.04 – 0.86; 0.032).

Access to diagnostic capabilities is also divided along outlet lines. A larger proportion of clinics offer microscopy testing (MST) for malaria than shops, with 6 out of 13 clinics offering MST, and only 2 shops. One clinic had rapid diagnostic testing for malaria (MRDT) available at one time but not on the day of the survey, while none of the shops had ever offered MRDTs. Access to antimalarials also varied between shops and clinics, with 47% of shops having had a time when they had run out of all their antimalarials, but only 23% of clinics had ever experienced a complete stock outage.

Medicine dispensing practices vary between shops and clinics. A higher proportion of shop workers (70%) than clinic workers (62%) would cut blister packs of
medications to sell to customers, but this proportion was not enough to reach statistical significance. In situations when a customer with malaria specifically requests Fansidar, a sulfadoxine and pyrimethamine treatment for malaria that has been withdrawn by the MOH for malaria treatment, 63% of those working in shops would withhold Fansidar, while 19% would dispense it to their customer. Of those working in a clinic, 92% would withhold Fansidar in favor of further examining the patient, or referring to a laboratory or health facility, and none would dispense Fansidar to their customer.

2.4.7 Gender dichotomy

Gender is a significant predictor of several differences in medicine retailer training and treatment practice. Male retailers are nearly three times more likely than female retailers to have no related health training (OR = 3.77, 95% CI 1.41 – 10.10; 0.008). Men are also less likely to be trained in nursing or midwifery than women, a type of training associated with the highest proportion of accurate antimalarial knowledge (OR = 0.22, 95% CI 0.08 – 0.59; 0.003).

Men are less likely than women to refer sick children or ask for additional medical history (OR = 0.38, 95% CI 0.15 – 0.99; P = 0.048) but are not more likely to dispense Fansidar to mothers who demand it for their sick child. Men are just as likely to know the correct antimalarial medication (OR = 0.99, 95% CI 0.42 – 2.34; P = 0.982). However, fewer men (25%) than women (43%) would recommend that medication to children, but more men (53%) than women (46%) would recommend that medication to
adults. Though these percentages are disparate, they did not reach statistical significance.

2.5 Discussion

Retail drug outlets are a significant part of the effort to manage malaria. Self-medicating with drugs purchased at retail businesses is common practice [26-29, 33, 34], and medicine retailers have an important role in the diagnosis and treatment of their customers [48]. It is important to understand the determinants of medicine retailer dispensing and treatment practices if malaria care is to be improved.

This study explored drug retailer characteristics, level of training, level of education, and antimalarial drug knowledge and dispensing practices in rural western Kenya. We examined determinants of provider knowledge, its relationship to treatment and dispensing practices, rural and urban variations and gender dynamics as it relates to these determinants.

In concurrence with previous studies on medicine retailer antimalarial drug knowledge [25, 40], our study found that most retailers were aware of the current recommended treatment for malaria. We found that 65% of participants in our study population could correctly identify the Kenyan Ministry of Health recommended firstline antimalarial. We also found that participants who correctly identified the current treatment for malaria recommended by the MOH were more likely to recommend that treatment to both adult and pediatric clients. This suggests that the
change in the recommended antimalarial treatment from SP to AL made in 2006 by the MOH has had an impact on retailer antimalarial knowledge as well as dispensing practices.

Our study also found that a medicine retailer’s training is a significant determinant of their reported antimalarial drug knowledge. Having a health-related qualification was a significant predictor of identifying the correct first-line treatment for malaria when compared to having no qualification, or qualification in a field unrelated to health, indicating that it is not professional training alone that improves antimalarial drug knowledge, but pertinent and relevant training.

We also found that the type of health training, be that in the field of pharmacy or of nursing, was not a determinant of identifying the correct antimalarial medication. However, pharmacy-trained retailers were more likely to recommend the correct treatment in adults, and nursing or midwifery-trained retailers were more likely to recommend the correct treatment in children. This could be a result of the curriculum behind these types of trainings, or the previous work experience common to each field. Both pharmacy and nursing/midwifery-trained retailers were significantly more likely to have appropriate knowledge and dispensing practices than the untrained, further underscoring the need for medicine retailers to have at least a basic training in a health-related field.
The level of health training was also found to be a significant predictor of accurate antimalarial drug knowledge, but in an unexpected way. Surprisingly, a higher proportion of those with an assistant-level training identified AL as the first-line antimalarial than those with a professional level of training. This could be because assistants, able to complete their training in less time, may have completed their training since the change to AL in 2006, and that professionals may have completed their training before 2006, consequently dispensing in accordance with outdated guidelines.

In our study population we found a high proportion of medicine retailers who reported having an education at or below secondary school; 33%. This finding is in alignment with evidence from previous studies that also found education levels to vary across retailers [49, 50]. Considering that anti-malarial drug knowledge increased with each level of education, retailer education is significant to antimalarial drug knowledge. However, where these studies found the proportion of trained participants to be between 7 and 31%, we found that over 80% of our study participants reported having health-related training.

We did find an inconsistency between participants’ self-reported health training and education levels, since 82% of the study population reported having health training in pharmacy or nursing/midwifery, but only 67% of the population reported an education level above secondary school. These results could be explained by either the participants misunderstanding the health training survey question, or that they self-
identify with a certain health title that comes from holding that occupation rather than from having formal training. However, since both health training and education level were associated with antimalarial drug knowledge, this incongruence does not invalidate the relationships.

A similar dichotomy was discovered in a recent qualitative investigation that studied a similar population in the same area [48]. It was the opinion of the local research team that medicine retailers, particularly in the rural areas, are referred to by the local community as “pharmacists” or “nurses” because these are the roles they fill in the community, even if that individual does not hold official health qualification in that field. It was conjectured that these retailers would likely self-identify in accordance with these roles.

Even though training and education are important factors in knowing the correct firstline antimalarial treatment, and this knowledge increases the likelihood of a retailer dispensing medication appropriately, we found that only 48% of participants would recommend AL to adults, and only 37% would recommend it to children. This finding is in keeping with evidence reported in previous studies that found retailer practice to be below the level needed for appropriate malaria control [18, 25, 48, 49] and that retailers often dispense inappropriately despite having accurate treatment knowledge. This suggests that there are determinants to retailer behavior, as it specifically relates to dispensing practices, which are stronger than the influence of retailer knowledge.
Thirty-five percent of participants said that they would dispense malaria medicine according to what customers demanded, the most frequently cited reason for choosing which medication to dispense. This finding is consistent with that of Okeke and colleagues in their study on treatment practices of drug vendors in southeast Nigeria [28]. They found that 61.5% of those surveyed would dispense medications according to what customers demanded. They also discovered a connection between antimalarial drug knowledge and dispensing practices, in that participants in their study would dispense antimalarial drugs according to what their customer requested, or could afford, even if this action was contrary to what they knew to be appropriate treatment for malaria.

We also found dispensing practices to be related to antimalarial knowledge. Retailers who reported stocking and dispensing drugs based on Ministry of Health guidelines are more likely to identify the correct malaria treatment than retailers who dispense according to the demands of their customers. This is also true for stocking practices. Retailers who stock their drugs according to MOH guidelines are more likely to know the current recommended antimalarial than retailers who stock according to customer demand. This is further evidence that Ministry of Health guidelines have an impact on medicine retailer treatment and dispensing practices, but even though knowing the MOH guidelines influences stocking and dispensing practices, still too few retailers adhere to these recommendations.
Medicine retailer treatment and dispensing practices are also a vital part of appropriate management of malaria. Knowing the right antimalarial medication is an important first step, but adhering to that knowledge influences patient outcomes directly.

In examining treatment practices, we found that participants who refer sick children are more likely to recommend the correct antimalarial medications to children than those who would treat the child and not refer. When controlling for identifying the MOH recommended antimalarial, retailers who refer are still more likely to also recommend proper treatment in children under 5. This was the only comparison for which we conducted multivariate regression analysis because these were the only variables with a large enough sample size in each group.

Working in a clinic rather than a shop was also found to be related to referral practice in children. This could be because clinics have a higher proportion of retailers trained in nursing than shops, who have been shown to be more likely to recommend the correct antimalarial to children, and more likely to refer sick children to a health facility than those trained in pharmacy.

A strong gender divide was also revealed in this study, indicating that male and female retailers are consistently dissimilar in whether they have health training and the type of health training they have, and that these factors may influence the additional differences in patient treatment practices. We found that the men surveyed in our study
were nearly 4 times more likely than women to be untrained, are less likely to be trained in nursing, and less likely to appropriately recommend treatment in children.

2.6 Conclusions and recommendations

Malaria remains a major challenge to the health and well-being of the people of Kenya, and is still the nation’s fifth leading cause of death of both children and adults [37]. The appropriate use of antimalarials and the fast and accurate treatment of malaria cases are both critical to malaria control [38] and the improvement of Kenya’s quality of life.

Retail drug outlets are often the first point of care sought by patients, particularly for children with febrile episodes [29]. Drugs purchased at retail outlets are often used to self-treat [26-29, 33, 34] and drug retailers have been found to have a role in the diagnosis of their customers as well as the selection of medications purchased [48].

The relationship retailers have with their customers positions them well to increase the rate of appropriate treatment for malaria and improve malaria case management. It is then of utmost importance to target training and education interventions in retail drug outlets, and to inform such interventions with the evidence found in medicine retailer behavior and practice studies.

Our findings are confirmation to most previous studies. Most retailers are aware of the recommended firstline treatment for malaria, but the percentages that are not aware is far too high, and reported adherence to that knowledge is far too low. While it
is encouraging to see evidence that Ministry of Health guidelines for appropriate antimalarials are well known amongst retailers, it is important to recognize that significant improvements to retailer knowledge and behavior need to be realized before malaria control can be improved in this area.

Well-designed interventions should focus on the large population of untrained retailers, as their outcomes in terms of knowledge and dispensing practices are lowest. It is important for medicine retailers to have health-related training, that their training is current, and that they be given specific information regarding the appropriate treatment of malaria in children. Interventions should also have educational components focused on patient management, including referral practice for patients under 5.

There is an opportunity for future interventions to leverage the influence customer demand has on retailer behavior by focusing education efforts on patient communities. Specifically targeting mothers and young women may additionally improve outcomes for children, and help increase awareness of AL as the firstline treatment for malaria in both children and adults.

### 2.6.1 Limitations

The sample size from the study was too small to conduct multivariate regression analysis on all but one comparison. We were therefore not able to explore the specific relationships between additional variables of interest while controlling for potential confounders.
All data were self-reported actions, not directly observed behaviors, and are therefore subject to reporting bias. The study was also conducted over one geographic area, which may impact generalizability of study findings, a potential concern for the education and health qualification disparity.
3. The perceptions of challenges and benefits to implementing rapid diagnostic tests for malaria among medicine retailers in western Kenya

3.1 Abstract

Background

Presumptive diagnosis of malaria has led to evidence of overdiagnosis, misuse of antimalarials, and the development of drug resistance. Such developments could be improved with the regular use of malaria testing. However, access to microscopic testing for malaria is limited due to cost, trained staff shortages, and inadequate quality control and supervisory systems. Rapid diagnostic tests for malaria (MRDTs) are comparatively easy to use, less expensive, and often have a higher sensitivity and specificity in detecting and confirming parasitemia. Care-seeking behavior in Kenya positions retail medicine outlets as an ideal place to provide and administer MRDTs. However, little is known about the challenges to implementing MRDTs in this environment. It is necessary to know more about how MRDTs may be perceived and used by medicine retailers in order to effectively design an implementation of MRDTs in this community.

Methods

We conducted a qualitative study with six focus group discussions involving medicine retailers in the Bungoma East district of western Kenya, an area of variable malaria transmission, during July 2011.

Results
MRDTs were perceived by retailers to be a beneficial diagnostic tool that they anticipated would be both useful and profitable. Participants felt MRDTs would improve the accuracy of malaria diagnoses and resulting treatment, as well as save time and money, bring additional business, and increase the overall access of malaria diagnostics to their customers. Retailers did have concerns that MRDTs may be too expensive for customers, and there was evidence that patients’ demands for antimalarials may affect a retailer’s ability to adhere to test results. Retailers also had concerns regarding regulatory agencies allowing them to administer tests in their outlets, and how the referral process may be impacted in cases of severe malaria. Issues of patient acceptance of an alternative diagnosis to malaria were also raised.

**Conclusion**

Medicine retailers support implementing MRDTs in drug outlets in this area. However, certain challenges face implementation efforts, and should be addressed in advance.

**3.2 Background**

Malaria is a major cause of morbidity and mortality, with infection by *Plasmodium falciparum* responsible for approximately 515 million clinical infections worldwide [4]. An estimated 0.5 to 2.5 million deaths result from these infections, with over 90% of these borne by Africa alone [2]. In Kenya, it is the fifth leading cause of death in both children and adults [37]. While significant strides have been made toward controlling malaria, antimalarial drug resistance has been considered a major factor in
the resurgence of malaria, and one of the greatest obstacles for effective malaria control [38].

Drug resistance development is exacerbated by the misuse of antimalarials. The poor specificity of a clinical diagnosis for malaria [19], due to symptoms and signs that can be caused by other diseases [20], combined with presumptive treatment practices, leads to significant overdiagnosis of febrile illness as malaria, and overprescription of antimalarials [21].

When the Kenyan Ministry of Health changed its firstline antimalarial policy to artemisinin-based combination therapies (ACTs) in 2006, delaying drug resistance became even more of a priority. The key to preventing drug resistance is the appropriate use of antimalarial medications through accurate diagnosis. In 2010, the WHO published the second edition of the Guidelines for the Treatment of Malaria [52] in which it states,

“In all settings, clinical suspicion of malaria should be confirmed with a parasitological diagnosis. However, in settings where parasitological diagnosis is not possible, the decision to provide antimalarial treatment must be based on the prior probability of the illness being malaria. Other possible causes of fever and need for alternative treatment must always be carefully considered.”

Considering alternative causes of fever is an important part of managing fever, and diagnostic testing is crucial to confirm or rule out malaria.

Improving access to accurate parasitological diagnosis is a critical concern for malarial control. Access to microscopy, considered the gold standard for malaria diagnosis [16], is limited because it requires trained laboratory staff, costly equipment, a
constant supply of reagents, and quality control and supervisory systems [15, 50]. For these reasons, retail drug outlets are even less likely than district hospitals or other public health facilities to offer microscopic testing services.

Compared to microscopic testing, MRDTs are relatively easy to use. They do not require any specialized equipment other than the MRDT kit itself, and the tests are relatively inexpensive, priced at between 50 and 81 Ksh ($0.70-$1.00) [54]. In a recent review of rapid diagnostic testing for malaria, Clinton Murray and colleagues determined that using “a quality manufactured MRDT selected based on the malaria epidemiology and clinical situation will improve malaria diagnosis” [55].

An implementation project of rapid diagnostic tests for malaria in five districts in Uganda had a positive impact on reducing overprescription of antimalarials [53]. Kyabayinze and colleagues found that, after the implementation of MRDTs, 90% of patients suspected of malaria were tested with an MRDT. Test result adherence was noted as a challenge to appropriate treatment practices, as 35% of patients with a negative test result were prescribed antimalarials, although this figure did decline over the six-month follow-up period to 29%. Despite this finding, the implementation of MRDTs, based on a ‘pre-and post’ evaluation, showed a 39% point reduction in the prescription of antimalarials in all health facilities combined, while maintaining appropriate treatment for those with positive test results-99% of whom received antimalarial prescription.
This finding of maintaining appropriate treatment for confirmed malaria cases following the implementation of MRDTs was reflected in an implementation evaluation in the Mkuranga district of Tanzania [15]. In this study, 99.1% of patients with a positive MRDT result were prescribed antimalarials. This important indication confirms that the implementation of rapid diagnostic tests presents little risk of reducing access to appropriate treatment. Williams and colleagues also found significant reductions in the overprescription of antimalarials, from 29.5% to 3.9% over eight weeks in children under five, and from 71.9% to 24.7% in patients at or over five. This reduction is considerable in children under five, a population at significant risk of harm from delayed appropriate treatment, overdose, and under referral, all potential outcomes from antimalarial overprescription and incorrect diagnosis.

Studies have also examined the safety of withholding antimalarial treatment in children who present with fever, but have a negative rapid diagnostic test for malaria. D’Acremont and colleagues [57], as well as Njama-Myea and colleagues [58], found no complications or deaths resulting from withholding antimalarials from febrile children with negative test results in their study. On the contrary, they found that withholding malaria drugs reduced the risk of unnecessary adverse events associated with antimalarial therapy, and allowed the clinicians to investigate and treat the true causes of fever, which included upper respiratory tract infection and pneumonia. These
findings support adherence to MRDT test results, even in children living in highly endemic settings.

However, while these studies demonstrate success of using MRDTs in the public health sector, most treatment for malaria is sought in the informal sector, at retail drug outlets [24, 25], especially in populations with inadequate health services, and in cases of seeking treatment for uncomplicated febrile episodes. In Webuye, Kenya, 24% of mothers purchased drugs at retail outlets to treat children suspected of being sick with malaria [34]. C. S. Molyneux and colleagues found that medicines purchased at retail drug outlets were the first or only treatment for 69% of childhood fevers in coastal Kenya [33].

There are many reasons why families may prefer to visit retail drug outlets over public health facilities. Outlets are often closer to home [31, 32], resulting in savings in time and transportation costs [35]. Outlets are open longer [34], have a more consistent supply of medications [36] and customers may be more inclined to interact with outlet staff, who are often members of their community, rather than public health facility employees, who are perceived to be rude and aggressive [25].

This pattern of seeking care for malaria at retail medicine outlets creates a barrier to accessing diagnostic testing under typical circumstances. With limited capacity for microscopic testing at these outlets, introducing rapid diagnostic tests for malaria (MRDTs) in this sector presents an opportunity to increase access to diagnostic services.
and improve management of fever, as well as reduce overprescription of antimalarials and delay the development of drug resistance.

However, there are potential challenges to implementing MRDTs in retail drug outlets that need to be evaluated. Rural outlets are often understaffed, and are already straining to respond to customer demand [15]. Adding a rapid diagnostic test to their patient evaluation process could put an unmanageable burden on the existing manpower. There are also customer expectations to consider, particularly in an area where presumptive diagnosis of malaria followed by dispensing of antimalarials is common practice. There are concerns as to whether medicine retailers or customers would adhere to the results of the test. Understanding the perceptions held by retailers as to the profitability of stocking and selling rapid diagnostic tests, their views on customer acceptance and adherence, and the feasibility of administering these tests in their outlets is critical to evaluating the potential impact of implementing MRDTs in this environment.

Previous studies have examined the acceptance of the use of rapid diagnostic tests for malaria in retail drug outlets in Uganda and Tanzania, and have identified several benefits and challenges to implementation. One study conducted in the Mukono district of Uganda found that respondents anticipated MRDTs could improve confidence in treatment, increase confidence and business for drug outlets, encourage referral, and reduce the amount of drug wastage and resulting cost to clients, as well as
the likelihood of inappropriate treatment, and the amount of transport and ancillary costs incurred by patients requiring laboratory tests [56].

However, this study also uncovered perceptions that selling MRDTs at drug outlets could increase the cost of a visit requiring purchase of a test as well as the needed drugs, and that sellers might prescribe antimalarials even with a negative test result. There was also concern regarding the administration of the MRDT by a medicine retailer: that the retailer may test clients for HIV, that poor hygiene practices could spread infections, or that retailers were unqualified to diagnose and treat effectively.

The implementation of MRDTs in the public health sector has been demonstrated to improve community health through reducing overprescription of antimalarials, avoiding unnecessary exposure to adverse drug reactions, opening the possibilities for alternative diagnoses in cases with negative test results, increasing access to diagnostic testing, and encouraging referral of severe cases. Also evidenced is the importance of MRDT acceptance, on behalf of the patient and the provider, and there is evidence to support the safety of this practice. With retail drug outlets positioned as the most frequent first point of care, it is critical to understand the perceived challenges and opportunities of implementing rapid diagnostic tests for malaria held by drug retailers in this area.
We therefore conducted a study in the summer of 2011 conducting focus group discussions with retailers in this area to gain an understanding of their perspectives of the benefits and challenges to using and selling rapid diagnostic tests for malaria.

3.3 Methods
3.3.1 Study area and sample

The study was conducted in the Webuye Health and Demographic Surveillance Survey (WHDSS) site within the Bungoma East district of the Western Province of Kenya. Kenya has a population of 39.8 million people according to the 2009 census, 78% of whom live in rural areas [42]. The Bungoma East district is located approximately 380 kilometers west of Nairobi, the capital of Kenya. The Demographic Surveillance Area (DSA) is home to approximately 70,000 residents. The primary economy is subsistence farming, with about 1,500 residents employed by a local sugar-processing factory, and others growing sugar cane to sell to the factory. The malaria burden in the WHDSS is particularly high, despite the varied transmission rates of the Western Province [43]. Based on a WHDSS survey conducted in September of 2009, 70% of 1000 randomly sampled children were infected with malaria as determined by microscopic testing [34].

The healthcare services within the Webuye HDSS are provided by both the formal and the informal health sector. The formal sector is made up of four government-owned health facilities: one district hospital, one health center, and two medicine dispensaries. In addition to these, there are also faith-based hospitals that offer
healthcare services. The informal health sector includes many pharmacies, private clinics, drug outlets, traditional healers, and herbalists.

The study population included all medicine retailers working in a drug shop, chemist shop, clinic, or pharmacy that sells antimalarials and is located within or is accessible to those living in the WHDSS area. Inclusion criteria were comprised of retailers who actively sell antimalarials to customers and who agreed to participate in the study. Exclusion criteria included public health facility workers, retailers in outlets that did not dispense antimalarials, and refusal to participate in the study. Ninety-one outlets were identified through canvassing the study area, with written and verbal invitations delivered to each location in operation at the time of selection (see Appendix A for a copy of the written invitation).

3.3.2 Data collection

The focus group discussions were conducted in July 2011 in the Bungoma East district by a female social scientist well trained in focus group discussion moderation and fluent in both Kiswahili and English. The discussions began with a brief questionnaire focused on participant education and health qualification level, previous experience with malaria diagnosis and treatment, and knowledge of specific diagnostic methods (see Appendix B for a copy of the questionnaire). Following this, the discussion explored experiences with malaria diagnosis and treatment, retailer relationships with customers, a demonstration of a rapid diagnostic test for malaria, and perceptions of the
test, its feasibility, profitability, and potential role in the diagnostic and treatment process. Specific questions were asked regarding treatment patterns in retail drug outlets, and how the introduction of MRDTs might influence these patterns.

The focus group discussion guide and questionnaire were pretested in Eldoret, Kenya, revised and translated into Kiswahili. Revisions were made following the pilot to increase clarity, relevance, and efficacy. The focus group discussion moderator was trained on the implementation of this specific discussion guide as well as on the study protocol and objectives (see Appendix C for a copy of the discussion guide).

Each focus group discussion was held in a public space collocated with the outlets invited to that discussion. The resulting discussions took place in Lugulu (n=1), Misikhu (n=1), Webuye Town (n=2), Bukembe (n=1), and Milo (n=1) for a total of 6 discussions and 61 participants, with a median group size of 10 (see Figure 1).

The discussion included an introduction, consent script, and questionnaire, followed by a demonstration of a rapid diagnostic test for malaria. The MRDT selected was the ICT malaria Pf cassette by ICT Diagnostics, which meets the recommended selection criteria for malaria rapid diagnostic tests as published by the World Health Organization [59]. A laboratory technician employed by the Webuye District Hospital performed the demonstration.
3.3.3 Consent

All study participants were informed of the objectives of the study in the written invitation as well as prior to participation in the discussion. Verbal consent was obtained from all participants in the study. Verbal consent was also obtained from all participants to voice-recordings of the discussion, and manual notation of discussion subject matter, non-verbal behavior, and environmental content. Study participants received light refreshments at the close of the discussion, as well as modest compensation for their travel expenses.
3.3.4 Data entry and analysis

Focus group discussions were recorded with digital audio recorders, and translated into English by the research team. Hand-written notes captured during the discussions were also translated into English. Both sources were entered and coded using QSR NVivo 9 software. Initial codes were developed based on findings from previous studies. After these data were examined, subsequent codes were developed from themes that emerged during data review. Data were coded into these themes, and then analyzed for similarity, frequency, strength, and relationship. These themes were vetted with the research team, project collaborators, and local members of the Webuye DSS team to gain more insight into the significance of the emerged themes. A second analysis was then conducted, incorporating these additional findings, and drawing new comparisons between the more relevant themes.

3.3.5 Ethics

Ethical approval for the research was granted from ethical review boards at Moi University in Eldoret, Kenya and Duke University in Durham, North Carolina. Additional approval was also sought from the Webuye DSS site authorities prior to commencement of the study.

3.4 Results

Our reported results are presented in three parts. The first of these, subsections 3.4.1-3.4.3, outlines the characteristics and behaviors of medicine retailers, including
population demographics, malaria disease and diagnostic knowledge, and malaria diagnosis and treatment practices. The second section includes subsections 3.4.4 and 3.4.5 describing retailer perceptions of rapid diagnostic tests presenting first the benefits and then the challenges.

The final section, including subsections 3.4.6 through 3.4.9, presents findings of particular interest. Medicine retailers’ perspectives on acceptance and adherence to test results, as well as their recommendations for an MRDT implementation are included in this section. We also report findings of an urban/rural dichotomy in the data that is related to retailer perceptions, as well as the influence of competition on retailer perceptions and behaviors. For additional supporting quotations, please see Appendix D.

3.4.1 Population Characteristics

More than half the study population was female (59%) and most were between the ages of 21 and 40 (66%). Most participants were trained in pharmacy (44%) or nursing/midwifery (44%) with only one participant without any formal health training. Most participants had reported receiving some education above secondary school (41%) or had completed secondary school (39%). However, the level of education received did not always align with health training. One clinical officer is stated to have received only a primary school education, and 5 out of 11 pharmacists and 8 out of 17 nurse/midwives
did not have any education above secondary school. Participant characteristics by focus group are covered in Table 5.

**Table 5: Participant characteristics by focus group discussion**

<table>
<thead>
<tr>
<th></th>
<th>FGD 1</th>
<th>FGD 2</th>
<th>FGD 3</th>
<th>FGD 4</th>
<th>FGD 5</th>
<th>FGD 6</th>
<th>TOTAL</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Participants</strong></td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>5</td>
<td>16</td>
<td>17</td>
<td>61</td>
<td>100</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>36</td>
<td>59</td>
</tr>
<tr>
<td><strong>Men</strong></td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>5</td>
<td>25</td>
<td>41</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under 20</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21-30</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>8</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>31-40</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>5</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>41-50</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Over 50</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Pharmacy Tech</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Pharmacy Asst</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nurse/Midwife</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>6</td>
<td>17</td>
<td>28</td>
</tr>
<tr>
<td>Clinical Officer</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Untrained</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Missing</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>14</td>
<td>23</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed Primary</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Some Secondary</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Completed Secondary</td>
<td>6</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>25</td>
<td>41</td>
</tr>
<tr>
<td>Above Secondary</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>11</td>
<td>5</td>
<td>24</td>
<td>39</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>11</td>
</tr>
</tbody>
</table>

**3.4.2 Malaria disease and diagnostic knowledge**

Before the start of each focus group discussion, each participant completed a brief questionnaire. The survey tool covered antimalarial drug dispensing and malaria diagnosis and testing knowledge, and basic demographic information. Clinical observation was found to be the most well known form of malaria diagnosis, with 75% of medicine retailers familiar with clinical or symptomatic diagnosis. Rapid diagnostic tests were the least; only 15% of retailers had heard of MRDTs before the study. Clinical
diagnosis was also the most frequently performed diagnostic method, with 71% of retailers having performed this method previously.

Available training is a possible driver behind the widespread use of clinical diagnosis. If retailers received any training in malarial diagnostic methods, 85% of them received this training in clinical diagnosis. Twenty-four percent received training in microscopic testing, with only 6% having received training in rapid diagnostic tests. Despite inconsistent levels of training and familiarity with diagnostic tools, nearly all study participants were able to identify the most common symptoms of malaria as fever, headache, and vomiting, as well as convulsions in severe cases, jaundice, and splenomegaly.

However, most participants also listed other symptoms of “malaria” that are unlikely to be caused by Plasmodium infection, indicating a possible expansion of the term to include other ailments. These symptoms included chest pain, congestion, sore throat, pain in the joints or spinal chord, dizziness, and anorexia. Further evidence of the possible expansion of the term “malaria” is seen in the discussion regarding knowledge of malaria transmission.

“Malaria can be caused by so many things. Even a cut can cause malaria.” (Participant in FGD 6, at Milo)

Retailers stated that their customers could also identify malaria symptomatically, but that presumptive diagnosis was a more common practice among patients.
“When somebody feels unwell or has complaints while still at home, she/he normally rushes to a conclusion that I have malaria.” (Participant in FGD 2, at Misikhu)

Retailers relayed an understanding that malaria could be identified through diagnostic testing, but they did not believe that tests would always detect a malaria infection. There was expressed belief that the presence of fever was necessary to get a positive result for malaria infection, and that certain stages of plasmodium development would not be detected by a test.

“I think we have states before the plasmodium passes the liver, it will not show/appear in terms of testing…” (Participant in FGD 2, at Misikhu)

3.4.3 Current diagnostic and treatment practices

The role of retailers in diagnosis and treatment is varied, and was often dependent on the client, the illness, and the circumstance. There were three most common categories of customers: those that arrive at outlets with a prescription after having been to a public health facility, those that come directly to the outlets relying on retailers to diagnose and treat them, and those that come directly to the outlets, but already have a clear idea of what they think is wrong with them, and request specific treatment.

Some participants expressed a feeling of duty to accurately diagnose and treat a client, and to intervene if a client is seeking the wrong treatment or their self-diagnosis is not consistent with the retailer’s diagnosis.
“For that case, it is very simple, you give the right information. You tell them, apart from malaria, we can have other disease that are related to or resemble malaria. That is when you can send someone to the nearest dispensary. If in that case someone is tested and has typhoid or brucella, the customer will come back and say, sister you did good. I had this disease and not malaria. In that case you give the right drug.” (Participant in FGD 5, at Bukembe)

A medicine retailer’s ability to intervene and influence a patient’s understanding of their diagnosis and requested treatment is limited by patient cooperation. Some customers may insist that their self-diagnosis is correct, while other clients may send a proxy to the retail drug outlet to relay their diagnosis and request specific drugs.

“…in the rural set up, a sick person may decide to send a relative to the drug shop to buy a given drug she/he has been using. It becomes a challenge because the person who has been sent will insist on being given that drug.” (Participant in FGD 6, at Milo)

Retailers retain some influence over final treatment decision, even for clients who visit a drug outlet with a prescription. Retailers said they may change the prescription if they interpreted the patient’s symptoms to require a different medication.

“My case is to dispense as prescribed by the doctor, or give another alternative based on how someone is feeling.” (Participant in FGD 6, at Milo)

Patients may also choose to not follow a doctor’s prescription, particularly if that medication is too costly.
This conflict between retailer recommendation and customer expectation is compounded by an understanding that clinical diagnosis is not always reliable. When a retailer doubts a diagnosis, either their own or a patient’s self-diagnosis, they manage this uncertainty one of three ways: they treat according to the patient’s requests, they refer the patient for testing, or they administer a prophylactic drug.

The use of prophylactics for malaria was common among retailers as a way to give the patient what they want (when demanding an antimalarial). Retailers believed that prophylactics would have fewer side effects than an antimalarial and so could be used to pacify a patient, or to prevent malaria in a case where a patient is unsure of a malaria diagnosis.

“…we have prophylaxis drugs. Not specifically that you are treating malaria, so you may give a simpler drug which is not as serious as the drugs given to a real patient.” (Participant in FGD 1, at Lugulu)

“So if you are doubting, there are no bigger signs of malaria, may be early in the lab it is not showing up, you give prophylaxis. It will treat and prevent.” (Participant in FGD 1, at Lugulu)

There is some indication that prophylaxis is also used to retain a drug sale when retailers and patients do not agree on the diagnosis.
“There are those who just insist and since I need money, I just give out the medication. If they insist, they want. You tell him that he doesn’t have malaria, but give out the drugs.”

(Participant in FGD 4, at Webuye Town)

Retailers also indicated that they could use referral as a way to resolve a diagnostic dispute, or to garner a firm diagnosis before issuing treatment. However, there was resistance to referring customers expressed by the retailers, and through their perceptions of their customer’s wishes, due to the poor opinion of public health facilities. Retailers shared several reasons for their resistance to referring clients to a public health facility: long queues, additional fees, and inappropriate treatments.

Retailers saw the long queues at public facilities as a waste of their clients’ time, and that clients would prefer to come to a retail drug outlet rather than public health facilities because of the long wait times. They also felt that visiting a public health facility would incur additional fees, making the visit more expensive than it would be if a patient went to an outlet. Retailers said that their customers do not necessarily think that the service at a public health facility is worth the higher price because patients can get the same medications from a drug outlet, and because the care given at public facilities is not always appropriate.

“Maybe if you advise somebody to go for testing at the district hospital, they say if I go to the district hospital, they write the same same drugs, so why should I go to the hospital? That is why they come back to us.” (Participant in FGD 4, at Webuye Town)
“…most of our hospitals, you will find that the diagnostic tests don’t show any malarial parasites, but on the prescription you find that they have already prescribed antimalarials.”

(Participant in FGD 2, at Misikhu)

Retailers also said that customers would often refuse to be referred, citing these complaints, putting retailers in the delicate position of either treating without a prescription, or sending the patient away.

### 3.4.4 Perceived benefits of selling MRDTs in retail drug outlets

Though most medicine retailers were not familiar with rapid diagnostic tests for malaria, after the demonstration, many of them felt it would be a beneficial product.

“If it can be easily available, it can prevent this issue of giving patients drugs without knowing the exact disease because somebody can come to the shop explaining those symptoms related to malaria, but if you have the kit, you can test the patient and confirm there instantly.”

(Participant in FGD 4, at Webuye Town)

Several specific benefits to implementing rapid diagnostic tests in retail outlets were identified by retailers, from furthering retailer expertise to reducing malaria incidence in the area, however four major benefits emerged in the analysis: MRDTs may attract more business to drug outlets, MRDTs may save time and money for both customers and retailers, they may increase access to malaria diagnostics and thereby appropriate treatment, and they may increase customer and retailer confidence in diagnosis and treatment.
3.4.4.1 MRDTs may bring business to outlets

Retailers anticipated that selling MRDTs in their outlets would help them retain customers that they would have previously referred to hospitals or laboratories for testing. They felt they could even bring in new customers by offering diagnostic services, and that this could improve an outlet’s reputation making them more attractive than their competitors.

“I think you will also be getting direct patients, not those who come with prescriptions. You actually create your own patients. After testing, now you have your clients. Like me, I will not be referring. Sometimes you send a client for testing and she/he goes away. So it’s a benefit.”

(Participant in FGD 5, at Bukembe)

3.4.4.2 MRDTs may save time and money

Retailers felt that selling rapid diagnostic tests in drug outlets would prevent customers from needing to travel to public health facilities for testing, saving them the time and cost of travel. They would also be able to save time by avoiding the long queues at the public health facilities, and the additional costs associated with hospital visits.

Retailers perceived that using rapid tests for malaria would save them money as well, since it is cheaper for them than microscopy, in terms of equipment price and staff training. Only 7% of medicine retailers had ever performed microscopic testing (MST), in their outlets. Performing microscopic testing can be challenging for retail drug outlets
due to the cost of equipment, training personnel, and necessary experience to read slides accurately [26].

Conducting MST is also a laborious and time-consuming process. The simplicity and ease of use of MRDTs was seen as a benefit by participants, specifically over microscopic testing, which may lead to an increase in use of diagnostic testing by retailers. The rapid tests also deliver a definitive diagnosis quickly, allowing retailers to serve more customers in less time.

“I think it is a very nice one because now you don’t need to go for a microscope and it’s cheaper. The microscope, the machine is very expensive, but for this one, if you buy at Ksh.50, you can afford Kshs.500 per week and test those clients. Also, everybody can test provided the instructions are followed well.” (Participant in FGD 5, at Bukembe)

3.4.4.3 MRDTs may increase access to malaria diagnostics and appropriate treatment

Retailers saw MRDTs as a way to increase access to malaria diagnostics. Since their outlets are open more often than public health facilities, and outlets service rural areas not accessible to public facilities, offering MRDTs in retail locations would increase access to diagnostics to these communities. They also saw offering testing in their outlets to be more convenient and less costly for their customers, also increasing access since this may encourage more customers to take advantage of testing services.
Retailers felt that increasing the use of malaria diagnostics would also increase the appropriateness of treatment. This was significant to retailers, because they felt it was important to treat patients accurately.

“When you test, it can help you to give the right drugs to the patient.” (Participant in FGD 1, at Lugulu)

“What matters most is the test, to know exactly what you are treating. That’s the most important thing.” (Participant in FGD 1, at Lugulu)

3.4.4 MRDTs may increase confidence in diagnosis and treatment

Retailers felt that having access to definitive diagnosis could increase a customer’s confidence in the accuracy of that diagnosis, and in the treatment they receive. They may be more likely to accept the treatment recommended by the retailer, or to purchase alternative medications in cases with a negative test result. Retailers also felt that customers may have more confidence in MRDTs than in laboratory tests, since they can see the results themselves, rather than relying on a lab technician to interpret the results for them.

“I think the patient will be comfortable because she/he will just look at the results. Maybe in the lab, the person may not be able to see the results.” (Participant in FGD 3, at Webuye Town)

Retailers also appreciated avoiding uncertainty in their diagnoses and the resulting “guesswork” in dispensing treatment.
“I think there will be no more guess work. I will be doing something I am sure of and dispensing the right drug.” (Participant in FGD 5, at Bukembe)

3.4.5 Perceived challenges of selling MRDTs in retail drug outlets

Medicine retailers recognized several challenges to implementing and selling MRDTs in their outlets. Of the concerns mentioned, four challenges were mentioned most frequently and with the most emphasis. They include the costs of MRDTs, customer fears associated with diagnostic testing, the risk of customer self-treatment with the tests, and regulatory problems that providing diagnostic services might cause for retail drug outlets.

3.4.5.1 The cost of MRDTs may dissuade customers

Retailers perceived that customers may not be able to afford the additional cost of a test, or may refuse altogether, choosing to only buy the medication. There were also concerns that some customers would believe retailers were selling tests only to make more money, and that the cost is being manipulated by retailers to increase profits. It was felt that these issues could be overcome if customers are educated on the use of MRDTs, and the importance of diagnostic testing.

“Some customers will think we want to squeeze out some money from them. Some will even say, my money was meant for buying drugs not testing. This is especially so among those who don’t know. So, a lot of talking and convincing is needed. If good health is given, they will understand.” (Participant in FGD 5, at Bukembe)
3.4.5.2 Customers may fear MRDTs

Some medicine retailers held the perception that some of their customers may be afraid of getting tested, associating the finger prick necessary for an MRDT with a needle injection. Others felt that their customers may associate the malaria test with an HIV test. Retailers also said that if they started testing with MRDTs, their customers might think the government is secretly testing for HIV.

“There might be a challenge somewhere, in local areas, we have some people who fear these HIV/AIDS tests, so they might think that now the government is involved in testing malaria but in a real sense they are testing HIV/AIDS.” (Participant in FGD 6, at Milo)

3.4.5.3 MRDTs may lead to self-treatment and reduce business in retail drug outlets

Several retailers expressed strong opinions against selling rapid tests directly to customers to perform themselves at home. One of these concerns was that customers may test at home and not use the tests correctly, but would self-medicate according to the results. There were fears that this could lead to misdiagnosis or under-diagnosis, and mismanagement of undetected diseases.

“RDTs should not be sold to customers because we will have self-medication. Someone could be suffering from something else, and someone may end thinking she/he has been bewitched and maybe it could be another illness so, strictly, RDTs should not be sold to customers.”

(Participant in FGD 3, at Webuye Town)
Since MRDTs do not indicate the severity of malaria infection, as correctly interpreted MST results can, retailers were worried that severe cases of malaria may go unnoticed and patients, especially children, may be harmed.

“Like for me, I think it should not be used in children because they are very delicate. Maybe the child has severe malaria and the RDT doesn’t show the severity. So we shall lose our babies.” (Participant in FGD 3 at Webuye Town)

There were also concerns that self-testing may cause outlets to lose business.

“…some customers are very funny. They may just come and buy and go, because it has some manual inside, so they will start testing at home. It can be a routine and they can be their own doctors at home. They can make our customers disappear.” (Participant in FGD 2, at Misikhu)

3.4.5.4 MRDTs may create regulatory problems for retail drug outlets

The Kenya Pharmacy and Poisons Board requires that all retail drug outlets must be registered with the board, that the operator of the outlet be licensed by the board, and that all pharmacy-only medicines must be dispensed under the supervision of a certified pharmacist or pharmaceutical technologist [33]. Medicine retailers expressed concerns that the regulatory bodies overseeing pharmacies and chemists would not allow them to carry out testing in their outlets.

There were also concerns that carrying MRDTs would bring the attention of the regulatory board, especially on those locations that are unregistered, and may even
require outlets to hire more staff, bringing additional cost to the owner if they wish to conduct testing.

“In my case, if I carry out such a diagnostic test, I must have a lab technician, and in fact, I am supposed to register the premises. Because if I am found by the P.H.O. [public health officer], they can really harass me.” (Participant in FGD 2, at Misikhu)

Some retailers, particularly those that are near public health facilities, felt these facilities may prevent the outlets from performing malaria testing.

“Personally, my shop is located near a dispensary which has got no laboratory. If they get to know that I am now performing RDTs for malaria, they will even threaten to close my shop.” (Participant in FGD 6, at Milo)

3.4.6 Acceptance and adherence

Retailers perceived challenges regarding customer acceptance of and adherence to test results, especially in cases with a negative test result. They felt that customers who expected a positive result but tested negative for malaria would likely demand antimalarials anyway. This was seen as a particular problem with clients, often mothers with sick children, refusing an alternative diagnosis and even assuming witchcraft was causing the illness.

“The mother won’t accept the results…some will think of supernatural things…like bones, that is witchcraft. How can the child be sick and there’s no malaria?” (Participant in FGD 1, at Lugulu)
Participants also anticipated customer resistance in cases with positive test results when the patient does not believe they have malaria.

“in a chemist, some patients are very rude. They will tell you ‘I don’t have malaria’ irrespective of the test. ‘How do you give me antimalarials?’” (Participant in FGD 3, at Webuye)

Customer resistance to adhering to a test result may put pressure on retailers, making it difficult for them to adhere to results as well in terms of dispensing appropriate medication. However, they did not see the loss of a drug sale as a motive to not adhere to test results. Some would dispense antimalarials anyway, and yet others put a higher priority on treating their customers well than making a sale, showing that there are motivations outside of profit that influence medicine retailer behavior.

“To me actually, even if it is business, it is good you heal somebody than getting money for its sake. So to me, I don’t see any problems the drugs more, so I better treat the patients, not just get money from somebody.” (Participant in FGD 1, at Lugulu)

There remained concerns regarding adhering to test results if a retailer feels the test was inaccurate. There were cases cited in which retailers believed a test would not detect malaria, and that in those cases, retailers would not dispense according to test results.

“Sometimes they test for malaria but it may not show up, but they could be having malaria.” (Participant in FGD 3, at Webuye Town)
3.4.7 Medicine retailer perceptions of implementation feasibility

Retailers anticipated several preparations that could be undertaken to improve the feasibility of a MRDT implementation in their community. They felt educating their customers about the need for testing and building awareness regarding MRDTs would help them be more successful in selling and administering the tests. They also felt a need to have regulatory approval before selling or administering MRDTs.

Nearly all participants voiced strong opinions regarding the need to set consistent pricing for rapid diagnostic tests across retail outlets. There were concerns that, if pricing was not regulated, outlets may try to undersell each other.

“you know, people are funny, they will compare prices of testing with my neighbors, so my price should tally with my neighbors’ price, to maintain my customers.” (Participant in FGD 2, at Misikhu)

Even though all participants agreed that a consistent price should be enforced, very few could agree on what that price should be. Recommended prices ranged from as little as 40 Ksh to as much as 200 Ksh, with evidence that urban area retailers felt their market could absorb a higher cost, while rural area retailers felt anything over the price of an antimalarial would not be tolerated.

“You know, for me, I am in the urban centre, people have money, so for me I would charge Ksh 100.” (Participant in FGD 2, at Misikhu)
“…there are some who can be able [to afford an RDT and still have money to buy drugs] and some cannot because this is a rural area, where people don’t have money sometimes.”

(Participant in FGD 1, at Lugulu)

3.4.8 The urban/rural dichotomy

This urban/rural dichotomy was found to be a factor in the perceptions of the local economy, as well as perceptions of public health facilities, differences in the customer/retailer relationship, as well as levels of education among urban compared to rural retailers.

The dynamic between retailers and their customers appears to differ along urban and rural boundaries. In rural areas, customers are said to seek out treatment from drug retailers outside of business hours, coming to their homes, even at night. Customers of rural outlets are also able to receive medication with the promise to pay later – an agreement mentioned several times by rural retailers but not at all by urban retailers.

Rural retailers also seemed to be aware of a difference in education or awareness between customers from rural areas versus urban areas. Retailers perceive urban customers to be more educated, while rural clients are more likely to turn to witchcraft as an alternative diagnosis, are fearful of needles and diagnostic tests, and would benefit from community health education efforts especially as it relates to preventing and managing malaria.
“At least people around the village, those who come from the interior parts, will be updated…They will be enlightened.” (Participant in FGD 2, at Misikhu)

This variability in education also extends to the medicine retailers themselves.

Ten percent of all rural participants had below a secondary education, while none of the urban participants had below a secondary education. A similar gap is seen in health-related training. Six percent of all rural participants had a pharmacy technologist training, and 17.6% had a pharmacy assistant training. While among urban participants, 20% had a pharmacy technologist training, and 20% had a pharmacy assistant training.

The urban versus rural location also influences the role a retailer has in the outlet. Urban retailers are more likely than rural retailers to be outlet owners, at 10% compared to 7%. Urban retailers are also more likely to recommend medications to patients, rather than just dispense them, at 20% compared to 14%.

However, these perceptions of public health facilities may be related to an outlet’s location, in an urban rather than rural setting. When examining the word frequency of public health facility related terms, we found that the participants in the two urban focus group discussions held in Webuye Town had a higher percentage of their discussion pertaining to hospitals and referral practice than the discussions held in rural settings.

For example, in all four rural focus groups, the word “hospital” was mentioned 32 times, or 0.23% of all dialogue. The word “refer” was mentioned 35 times, or 0.26% of
all dialogue. However, in the urban groups, the word “hospital” was mentioned 33 times, or 0.53% of all dialogue, and “refer” was mentioned 19 times, or 0.31% of all dialogue.

The fact that the word “hospital” was brought up with such a higher frequency, more than twice as often, in the urban focus groups than the rural focus groups, shows an increase in awareness of the hospital by urban participants, and an increase in relevance of the hospital to the discussion at hand as perceived by those participants. This is most likely because the district hospital of Webuye is located in Webuye Town, where these medicine retailers work and where the focus group discussions were held. But this also reveals that proximity to a public health facility may alter the perceptions and awareness of nearby retailers.

3.4.9 The influence of competition

While the location of an outlet may influence retailer behavior and the retailer/consumer relationship, the concentration of outlets in a particular area also has an influence on how retailers manage their clients. The competition that results from having a large number of drug outlets in a concentrated area, such as urban centers or marketplaces, is perceived by retailers to influence how they aim to attract and retain clients. Retailers also perceived that the density of outlets affects how their customers seek care at outlets. Customers were said to avoid outlets that gave expired drugs, or drugs that didn’t heal their ailment.
“...the patient expects to be healed immediately, so he will run to another shop and buy a different drug, claiming that I took some drugs but I am not seeing an improvement.”

(Participant in FGD 2, at Misikhu)

The influence retail outlet competition has on customer behavior also effects retailers’ treatment and dispensing practices. In a conversation about patients who mistakenly self-diagnose with malaria, a participant said they would not withhold antimalarials from that clients because they will most likely visit another outlet to get what they want.

“You will not have helped in that way, because he will go to the next shop.” (Participant in FGD 5, at Bukembe)

3.5 Discussion

Our results show that presumptive diagnosis based on clinically observed signs and symptoms was common practice among medicine retailers and their customers, but that retailers are aware of the limitations of clinical diagnosis and the propensity for inaccuracy and misdiagnosis. Participants expressed belief that rapid diagnostic tests for malaria would resolve much of this uncertainty, and could enable them to diagnose and treat with more accuracy and confidence. However, several pressures were identified that could prevent or interfere with their appropriate use of the tests.

Customer demands were identified as a strong force that influences retailer behavior and could affect the success of a MRDT implementation in this area,
particularly in terms of retailer adherence to a negative test result. The cost of MRDTs is also a concern, since retailers felt their customers would not be willing to spend money in addition to the cost of drugs, even though this was not seen as a reason for drug retailers to disregard test results. Retailers believed appropriate pricing of kits could mitigate some of the resistance customers might have to purchase tests, but determining the right price presents a considerable challenge. Their recommendation to involve the Kenyan Ministry of Health, local health authorities and public health facilities in the setting of MRDT pricing could be a possible solution to this concern.

Educating the community is a necessary step in preparing for MRDT implementation. Particularly in mothers with young children, participants felt that sensitizing their customers to MRDTs, and sharing more information about the nature of malaria transmission, symptoms, and treatment could encourage them to get testing before purchasing medication, and make them more receptive to a negative test result. Withholding antimalarials in children with fever was found to not increase the risk of complication or death, but rather reduce the incidence of adverse reactions to antimalarials, and was found to be a safe practice even in children under five [15, 55, 57].

It was also apparent that concerns might arise out of fear of HIV testing. Informing the community about the difference between testing for HIV and malaria could support consumer acceptance of testing. This information, along with MRDT
demonstrations, diagnostic testing campaigns, and out-reach programs may assist in the efforts to prepare this community for a successful implementation.

Additionally, training should be provided to medicine retailers in the appropriate use of MRDTs and the incorporation of this diagnostic tool in the overall management of fever cases. Retailers should be aware of how to identify severe cases symptomatically, and the referral process to be reiterated to ensure severe cases are not put at risk with the introduction of MRDTs.

Perceptions of public health facilities, as held by retailers and demonstrated by their perceptions of customer behavior, is currently a barrier to seeking diagnostic testing for malaria, and supports the implementation of MRDTs in drug outlets. Retailers are in a delicate position of being trained and regulated to only dispense antimalarials according to prescriptions, but face customers who refuse to go to public health facilities due to time lost in transport, additional costs incurred, long queues, or substandard care. The present reality of competition among drug outlets in this area places additional pressure on retailers to meet customer demands. Supportive supervision has been recommended to ensure the delivery of quality care in drug outlets [53]. Improvements to the service found in public health facilities in this area, and a more defined distribution of services and responsibilities between the formal and informal health sectors could also improve access to diagnostics and appropriate treatment.
Our findings also reveal a tense relationship between drug retailers and the regulatory agencies overseeing pharmacies and chemists. It is clear to retailers that they should register their outlets with the Pharmacy and Poisons Board, but for most it is cost prohibitive. In order to expand the coverage of attempts at outlet regulation, a process should be established for lower-income retailers to become registered. A realistic look at the appropriate avenues for delivery of healthcare in this area could also improve access to needed services.

3.6 Conclusion

Our results show that introducing MRDTs in drug outlets in the Bungoma East district is highly accepted by medicine retailers. MRDTs were perceived to save time and money for both retailers and customers, to bring additional business to outlets and improve their reputation, to increase confidence in diagnostic outcomes and resulting treatment recommendations, and to increase access to malaria diagnostics.

Implementing MRDTs should be a priority in this area. This action is supported by recent studies that found 67% of patients clinically diagnosed with malaria had illnesses attributable to other diseases [16]. This overdiagnosis of malaria leaves many illnesses untreated, and increases the risk of the development of drug resistance to ACTs, what is now the last line of defense against malaria. Introducing MRDTs is also supported by several studies that found rapid tests for malaria to be highly sensitive and
specific for malaria [57] and do not put children at greater risk for complication or death by withholding antimalarials in cases with a negative test [15, 58, 59].

Incorporating the feedback gathered in this present study, the perceptions and opinions of medicine retailers in the Bungoma East district of Kenya on the benefits and challenges to implementing MRDTs in drug outlets, should be considered in the development of future implementation plans. Focus group discussions involving customers, mothers, and members of this community regarding their perceptions of MRDTs would be helpful in completing our understanding of the diagnostic and treatment-seeking environment.

Support from local community leaders, chiefs, and elders, as well as that from public health facilities and regulatory agencies will assist in developing a solid foundation for the implementation of MRDTs. Documenting the community’s experiences with MRDTs pre- and post-implementation will help measure the wider impact of providing testing in drug outlets, and how this provision relates to or may impact the greater healthcare and delivery system, the supplier/consumer relationship, treatment-seeking behavior, and the relationship between the informal and formal healthcare sectors.

3.6.1 Limitations

One of the limitations of qualitative research in the form of focus group discussions is the inability to measure strength of an outcome across various types of
respondents, or to compare findings at an individual level. However, it was not an
objective for this study to quantify the effect of the discussion topics on the participant
responses. Including participation from across the entire geographical area of the district
in which the study was conducted allowed us to achieve as much representation in the
study population as was possible. This study did divide study participants into urban
and rural focus groups, allowing us to include comparison between these groups, while
coding responses across all groups allowed us to crosscheck for consistency and identify
outliers.
4. Conclusion

We set out to better understand medicine retailer knowledge and behavior as it pertains to the detection and treatment of malaria, and to use this understanding to identify relevant, evidence-based interventions that will improve the accuracy and availability of malaria diagnosis and increase the appropriate use of antimalarials. We found that retailers are open to receiving training to better serve their customers and to expanding their services to include diagnostic testing to increase their customer’s confidence in a more definitive diagnosis, to expand their business, and improve their business’ reputation. This willingness, combined with a demonstrated need, opens the door for future implementations to have a significant impact on malaria control in the area.

We discovered that most medicine retailers are able to identify the appropriate treatment for uncomplicated malaria in both children and adults, but that this proportion is still far below what is needed to adequately treat malaria. We also found that there are several factors that determine whether this knowledge influences dispensing behaviors. A retailer’s professional training, level of education, and gender are all associated with knowing the correct firstline antimalarial, and a retailer’s referral practice, drug stocking practice and the demands of their customers are also correlated with which antimalarial is dispensed to a patient. Significant improvements need to be
made in both of these areas if malaria case management is to be improved, drug resistance delayed, and the hope of malaria eradication is to be realized.

In discussions regarding a retailer’s perceptions of using rapid diagnostic tests for malaria, we discovered that retailers rely heavily on clinical symptoms and customer demand in determining a malaria diagnosis. Diagnostic tests were recognized as a more conclusive method of identifying malaria, and retailers believed the tests could be sold profitably to customers. Retailers also felt that offering testing would distinguish their businesses, making them more competitive in a concentrated market. When probed on the appropriate application of test results, there were concerns regarding patient acceptance of results that are in contradiction with their self-diagnosis. However, retailers expressed that they had a role in the diagnostic and treatment process and could influence a customer’s treatment decision.

Selling convenient and affordable testing for malaria in retail drug outlets would increase access to diagnostics, benefiting both drug retailers and outlet patrons, but both communities need to be trained and educated on the importance of diagnostics, the application and limitations of rapid tests, and how results should be interpreted and applied for an implementation to be as successful as possible.

4.1 Recommendations

There is an urgent need to increase awareness of the change in policy to ACTs as the firstline antimalarial therapy, and to ensure retailers are educated on its use and
dosage. Considering the weighty influence customers have on the behavior of drug retailers, in both determining diagnosis and treatment options for malaria, community members should also be involved in education campaigns. Special attention needs to be given to identifying and referring severe cases of malaria, particularly in children, to prevent delay of treatment.

The participation of local public health facilities and regulatory authorities will facilitate the distribution of these messages and could increase diagnosis-seeking behavior and use of appropriate antimalarial medicines. The approval and involvement of community leaders, elders, chiefs, public health officers, and key opinion leaders will also support adherence to the policy change, and encourage community receptivity.

4.2 Next Steps

To increase awareness and application of appropriate antimalarial medications, training workshops for medicine retailers should be developed without delay. Parallel educational campaigns for the local community will work symbiotically with retailer training to leverage customer influence on retailer behavior toward appropriate antimalarial use. Given that mothers are a specific community that are important to early detection and prompt treatment of malaria, education of this group will be especially important.

Focus group discussions involving outlet customers and their perceptions of using rapid diagnostic tests for malaria will further our understanding of the possible
challenges and benefits to implementing rapid diagnostic tests in this area. Support from regulatory agencies and the public health sector will be crucial to a successful implementation. Challenges to implementation should be identified and mitigated, followed by data collection of malaria diagnosis in shops and clinics, treatments used, and outcomes, in order to develop a baseline against which rapid test implementation efforts can be compared and evaluated. It is the recommendation of this paper to proceed with the implementation of rapid diagnostic tests for malaria in the retail sector.
Appendix A

Dear Sir or Madam,

I am here on behalf of the Webuye DSS and Moi University. We have organized focus group discussions with retail drug shop workers to discuss your perspectives on rapid diagnostic tests for malaria.

Information from the discussion will be used to better understand diagnostic opportunities and inform future implementations of rapid diagnostic tests.

Your thoughts and opinions are very important to us, and are critical to understanding possible ways to improve home-based management of care for malaria.

The focus group discussion will take about 90 minutes. Participants will receive 300Ksh compensation for transportation expenses. We will also be serving sodas and snacks.
The focus group discussion will take place at ______________________________
on ________________________________ date, at ________________________________ time.

If you agree to participate, please bring this invitation with you.

I will contact you again later in the week to answer any questions you may have about the study and to confirm your participation. Thank you.

Kind regards,

The Webuye DSS and Moi University
Appendix B

Instructions:

An important goal of this study is to understand malaria diagnostic capability in Webuye District. Please answer each question honestly and to the best of your ability, your responses are important. Please answer the questions on both pages. If you have any questions, please ask for assistance.

1. Does the shop you work in dispense antimalarial medicines?
   - Yes
   - No
   - Don’t Know
   - Refuse to State

2. Do you perform malarial testing in your shop?
   - Yes
   - No
   - Don’t Know
   - Refuse to State
3. Are you familiar with ways to diagnose malaria? (mark all that apply)
   - Microscopic Test
   - Rapid Diagnostic Test
   - Clinical Diagnosis (symptomatic)
   - Other (please specify) _________________________________
   - Refuse to State

4. Have you performed any of these tests previously? (mark all that apply)
   - Microscopic Test
   - Rapid Diagnostic Test
   - Clinical Diagnosis (symptomatic)
   - Other (please specify) _________________________________
   - Refuse to State

5. Have you ever received training or attended workshops on how to diagnose malaria?
   - Yes
   - No
   - Don’t Know
   - Refuse to State
6. If so, in what methods were you trained? (mark all that apply)

   - Microscopic Test
   - Rapid Diagnostic Test
   - Clinical Diagnosis (symptomatic)
   - Other (please specify) ________________________________
   - Don’t Know
   - Refuse to State

7. What is your role in the drug shop? (mark all that apply)

   - Own the shop
   - Recommend medications
   - Dispense medications
   - Work in the shop but do not dispense medications
   - Other (please specify) ________________________________
   - Refuse to State

8. What is your education level?

   - None
   - Some primary
86

9. What is your level of health-related qualification?
   
   - Completed primary
   - Some secondary
   - Completed secondary
   - Some or completed above secondary
   - Refuse to State

10. What is your age? ________________

   - Refuse to State

11. Gender
- Male
- Female
Appendix C

Good afternoon.

My name is Beatrice. I am a research associate at Moi University in Eldoret. You are being asked to participate in a focus group discussion about rapid diagnostic tests for malaria. Before you agree to participate, I want to be sure you understand the goals of the project, and that your participation is completely confidential and voluntary. Today’s discussion is part of a project that is looking at ways to diagnose malaria. The goal of the focus groups is to get your perspectives on using rapid diagnostic tests. This information will be used to evaluate whether using rapid diagnostic tests for malaria is an appropriate tool or not. Do you understand the goals of the project?

It is also important that you know that your participation in today’s discussion is completely confidential. We will not be recording your name, the name of the shop you work in, or where your shop is located. We hope you will answer openly and honestly, and we will maintain the confidentiality of your responses, but we do not want you to feel obligated to share private or sensitive information you would not want others to hear. You are free to participate or decline to participate, and if you do participate, you are free to answer or decline
to answer any of the questions. You are also free to stop participation and leave the focus group at any time. Do you understand that your responses are confidential? Do you understand that your participation in today’s discussion is voluntary?

We would also like to audiotape the discussion. This will help me listen to you without having to write down everything you are saying. Your names will not be used in my report of this group, and no one outside of the project team will hear this tape. Is it okay with you if we use audiotape?

Your participation in today’s discussion will last for about one and a half hours. This will include a short questionnaire we would like for you to complete before we begin the discussion. We will also be conducting a demonstration of a rapid diagnostic test during the discussion.

We also have compensation for you to cover your travel expenses to come here today. We will be distributing the compensation at the end of the discussion.

Do you have any questions? [please wait for questions] If you find you have questions at a later time, please feel free to contact the research team. Contact information is available on a different sheet that you will be able to keep and take home with you.
Do you agree to participate? [wait for responses] Does anyone here not agree to participate? If you would rather not participate, you are free to go.

I will be moderating today’s discussion. I want you to know that I have nothing to sell you, I am only interested in hearing your thoughts and opinions. I will start by asking you some questions. Please feel free to share any thoughts you have on the subject. There are no specific answers that I am looking for, and there are no wrong answers. It is your opinions that are important.

If you have an opinion that is different from what is being said, please share it. Please feel free to answer truthfully. During the discussion, if you don’t understand what I am asking or if you have any questions for me, please let me know.

We will now being with the questionnaire. Please respond as accurately as you can. When you have finished, please pass the papers to me. [wait no more than 10 minutes]

Let’s get started. First I would like to ask you some questions about your experiences working in the drug shops:

**Topic #1: Introductory questions**

- About how many people do you see in your shop each day?
• How many come in with malaria?

• How do you know they have malaria?
  o Do you diagnose them?
  o Do they tell you they have malaria?

• Do shopkeepers ever perform diagnostic tests? If yes, for what diseases could a shopkeeper offer testing?

• Who decides which medication the customer buys? How do they decide?

• What symptoms would indicate that the customer has malaria?

• Are there any other illnesses that also have those symptoms?

• What is known about giving someone an antimalarial who does not have malaria? Are there any risks to doing this?

• Have any of you heard about rapid diagnostic tests before today?

• If yes, what is your opinion of them? What have you heard about them?

[Perform malaria RDT demonstration]

**Topic #2:** What is your impression of this product?

• Useful

• Sellable
• Profitable
• Customer’s opinion
• Would a customer be willing to pay for this product
• How much would they spend on it
• Would they have enough money to buy drugs also
• Would a negative test lose them a drug sale
• what about a customer who demands antimalarials even with a negative test, would the shop lose business?
• Is having access to diagnostic tests necessary
• What are the alternatives to having a test
• Are these alternatives effective

**Topic #3:** Would you be comfortable performing this test?

Yes – What makes it comfortable?

No – What makes you uncomfortable?

• Are there any issues to performing a finger prick in your shop?
• Would you need additional training to administer the test?

**Topic #4:** I would like to go through some scenarios to understand how mothers might react to having access to a diagnostic test in a drug shop.
• Let’s say that a mother comes into a shop with a child who is sick with fever and malaise, and a shopworker gave the child the rapid diagnostic test. What would the mother do if the test was negative?

• Then what would the shopworker do?

• If the test was negative, is it possible to explore alternative diagnosis?

• If the test was negative, would other non-antimalarial medications be recommended to the mother?

• Would the mother accept the recommendation that her child does not have malaria?

• Would the mother purchase a non-antimalarial medication in that case?

• Let’s say that an adult man comes into a shop and he says he has malaria, and asks for antimalarial medicine, but the shopworker does not think he has malaria. What would a shopworker do? If he gives him medication, what medication would he give? If he asks for a test to confirm malaria, where would he tell the customer to get the test?
**Topic #5:** Are there any challenges to using or selling RDTs?

- What changes could be made that would help shopworkers sell and administer RDTs successfully

**Topic #6:** Are there any benefits to using or selling RDTs?

- Would it improve the reputation of a drug seller
- Could it help them get more business

Before we end, does anyone have any other comments about what we have discussed today?

Does anyone have any questions?

We are now going to pass out the compensation for your travel costs. [pass out receipts and compensation envelopes] The envelopes each contain 200 Ksh.

Please sign the receipt as you take the envelope. [be sure each participant has 1 envelope and has signed the receipt sheet]

Thank you so much for participating in our discussion today. As I mentioned at the beginning, this focus group is part of a project looking at using rapid diagnostic tests for malaria. We will be writing a report on the results of these discussions. If you would like a copy of the report, or if you would like any further information about this research project, please let me know.
Appendix D

3.4.2 Malaria disease and diagnostic knowledge

“when they complain of stomach upsets, fever, vomiting, headache, so automatically and you look at the eyes, you know that that person is suffering from malaria.” (Participant in FGD 2, at Misikhu).

“Most of the patients just come and say they have malaria because they know the symptoms of malaria.” (Participant in FGD 3, at Webuye Town)

“If the mother is breastfeeding and becomes unfaithful the child becomes sick…it’s true. You just give antimalarial. That is malaria.” (Participant in FGD 6, at Milo)

“You know, with severe malaria, there must be fever, and with fever, the micro-organisms will be seen in the blood. Without fever, you can’t see.” (Participant in FGD 1, at Lugulu)

3.4.3 Current diagnostic and treatment practices

“Proper treatment can only proceed after we know what the problem is. One way of knowing what the problem is, is by conducting the test.” (Participant in FGD 4, at Webuye Town)

“…there are some customers who come with prescriptions from the hospital. In that case you just dispense the drugs indicated in the prescription.” (Participant in FGD 6, at Milo)
“It will depend on history, signs and symptoms, to determine which drug to give. Is it a must to give anti-malarial? Or you need to give another drug. If you are not sure, just refer for the test.” (Participant in FGD 1, at Lugulu).

“…in this place, a mother may just come and explain how she is feeling. In this place, mothers and even people generally believe someone working in the drug shop has an idea of how someone can be treated. They also expect a lot of assistance from us.” (Participant in FGD 6, at Milo)

“…there are some people who know how malaria starts in them, it presents with certain signs and symptoms. So if that person is sure, and maybe he knows the drug he uses, you just give.” (Participant in FGD 2, at Misikhu)

“If you try to convince them…they will refuse because they say, every time I have malaria, I usually feel this way.” (Participant in FGD 4, at Webuye Town)

“If someone insists, the only way you can handle that one is to refer the client for a test; for a BS (blood smear). That is the only way she/he can prove that she/he has malaria.” (Participant in FGD 2, at Misikhu)

“…some people can queue in the labs and someone can even collapse while in the queue.” (Participant in FGD 4, at Webuye Town)

“Some think that, when they come to queue, it is a waste of time. And then congestion in the hospital. In that case, they prefer to come to drug shops, thus save time.” (Participant in FGD 4, at Webuye Town)
“…if they come to the district hospital, they normally buy the books, pay the consultation fee, but in the shop, I will not charge them that.” (Participant in FGD 3, at Webuye Town)

“…many, at times, you refer them to the hospital, and they claim they don’t have the time and the money.” (Participant in FGD 4, at Webuye Town)

“There are some patients who tell you that when I was sick previously, I used a particular drug. In that case, we consider what the customer says, especially if she/he reacts to a given drug. You will give a drug that the customer doesn’t react to.” (Participant in FGD 6, at Milo)

“For those who come with prescription, diagnosis or lab results, we just give drugs. The second category is those who come claiming they have malaria, we ask for signs and symptoms. The person who decides the medication is me, as the shop worker.” (Participant in FGD 4, at Webuye Town)

“At times, the doctor can prescribe the drug and the patient may not afford. So you know, normally we give those are a bit cheaper and affordable for the patient.” (Participant in FGD 3, at Webuye Town)

3.4.4 Perceived benefits of MRDTs in drug shops

3.4.4.1 MRDTs may bring business to shops

“Sometimes we get patients who go for tests first. If they go for tests, they don’t come back to you! So if you have the test in the shop and the patient comes to you, he’ll be tested and it is profitable.” (Participant in FGD 1, at Lugulu)
“It will improve the reputation of our shops because customers will be saying nowadays testing is done in the shops.” (Participant in FGD 5, at Bukembe)

“And also, you know, maybe your shop or chemists will be referred to. Because clients or people will maybe know you and then refer most of the people to your chemists.” (Participant in FGD 1, at Lugulu)

3.4.4.2 MRDTs may save time and money

“It is not strenuous, as compared to the microscope.” “If I am overwhelmed, I may not diagnose all of them. You know a microscope is very tiresome.” (Participants in FGD 2, at Misikhu)

“You can also carry the RDT to go and diagnose the patient while at home.” (Participant in FGD 1, at Lugulu)

“I think it is a very nice one because now you don’t need to go for a microscope and its cheaper. The microscope, the machine is very expensive, but for this one, if you buy at Ksh.50, you can afford Kshs.500 per week and test those clients. Also, everybody can test provided the instructions are followed well.” (Participant in FGD 5, at Bukembe)

“The time it takes, one can carry out the test and at the same time attend to clients or ask more questions about signs and symptoms from the patient.” (Participant in FGD 4, at Webuye Town)

“The process is simple and easy to use. It’s quick and time saving.” (Participant in FGD 1, at Lugulu)
3.4.4.3 MRDTs may increase access to malaria diagnostics and appropriate treatment

“I think, if a patient has malaria, there will be accuracy on the drugs to give than going with signs and symptoms.” (Participant in FGD 4, at Webuye Town)

3.4.4.4 MRDTs may increase confidence in diagnosis and treatment

“I think they will have a positive opinion because they will have a higher confidence now. They will feel that, now there’s a test, we are sure. It will boost their confidence.” (Participant in FGD 1, at Lugulu)

3.4.5 Perceived challenges of selling MRDTs in drug shops

3.4.5.1 The cost of MRDTs may dissuade customers

“The customers may find that the cost of testing and buying drugs is high. Just let me take the drugs as I have been doing.” (Participant in FGD 5, at Bukembe)

3.4.5.2 Customers may fear MRDTs

“They will refuse. You know, somebody can tell you, since I was born I have never been injected...Somebody can even prefer to die than to be tested.” (Participant in FGD 4, at Webuye Town)

“The method being used is almost the same as that of testing HIV, and the majority of people fear knowing their status. They don’t want and especially the youths.” (Participant in FGD 1, at Lugulu)

3.4.5.3 MRDTs may lead to self-treatment and reduce business in shops
“RDTs should not be sold to the customers, they may not have good/correct results especially if they don’t follow the instructions. So, I think testing should be done in shops.”

(Participant in FGD 3, at Webuye Town)

“Because sometimes you find the lab tests written ++, +++ and they are told to admit. Now how can I tell that considering that the other method normally shows?” (Participant in FGD 3, at Webuye Town)

3.4.5.4 MRDTs may create regulatory problems for shops

“You know, we have not been doing this before. It means we may need a room and a license to be effective. What will we do if the people from the board come and find us performing RDTs.” (Participant in FGD 5, at Bukembe)

3.4.6 Acceptance and Adherence

“[with a negative test result] the mother will also doubt the RDT kit. Because a mother always knows that fever means malaria.” (Participant in FGD 5, at Bukembe)

“Here, with the different cultures, we have somebody can even say it is the ‘bones’ witchcraft, because she/he is not responding. So if the mother has a child who is not responding to drugs, she will just walk around looking for the traditional healers. The child can even die in the process. It is very dangerous.” (Participant in FGD 5, at Bukembe)

“We will test there while they are watching, within fifteen minutes they have the results and we dispense the right drugs and they will be satisfied with what we are doing.” (Participant in FGD 2, at Misikhu)
“You know everyone has their symptoms of malaria. Some will start with sore throat and fever. If such a person comes and ask for antimalarials, they know themselves better, and so I will with the drugs.” (Participant in FGD 2, at Misikhu)

“It won’t make me lose business because I will give the pain killers. So it won’t.” (Participant in FGD 3, at Webuye Town)

“So whenever I see the negative result, I have no problem because my work is to dispense, so I will dispense if the result is positive. So there is no need to dispense when there is a negative result.” (Participant in FGD 2, at Misikhu)

### 3.4.7 Shop worker perceptions of implementation feasibility

“Simply sensitize the community. It’s just enough on the radio, the media, and the Government involvement.” (Participant in FGD 1, at Lugulu)

“Having charts or posters in our shops showing how RDTs are administered can help a lot...like the case of AL, the government got involved and the public became aware. The same can be done on RDTs, through the media.” (Participant in FGD 5, at Bukembe)

“In my view, I think it is important to register with the pharmacy and poison board to avoid issues...The poison and pharmacy board should be made aware that RDTs are being administered in shops.” (Participant in FGD 2, at Misikhu)

“if it is more than Ksh. 50, I will prefer to come and see the doctor at the district hospital.” (Participant in FGD 3, at Webuye Town)
“I think this way, if it is too cheap, most people may not trust you. People will doubt you, so it is better a higher figure.” (Participant in FGD 1, at Lugulu)

3.4.8 The urban/rural dichotomy

“Maybe on one side, it depends on the place. Most of our patients come during late hours.” (Participant in FGD 4, at Webuye Town)

“There are those who even wake us up at night.” (Participant in FGD 2, at Misikhu)

“There are others who will just request to be tested and be given drugs then pay later.” (Participant in FGD 6, at Milo)

“There are some customers who can come and say that please help me, I will bring the money later.” (Participant in FGD 5, at Bukembe)

3.4.9 The influence of competition

“…we work for money and reputation of our shops…the reputation of the business is important. We normally get customers based on the service we offer. Someone will say that I went to a particular shop, I was given drugs, and I’m now well. Someone on the other hand can say that I have been going to a particular shop and I don’t know what is wrong with their drugs, maybe they have expired. I don’t respond to them.” (Participant in FGD 6, at Milo)
References


18. Goodman, Catherine et al, 2007, “Medicine sellers and malaria treatment in sub-Saharan Africa: How can their practice be improved?” American Journal of Tropical Medicine and Hygiene 77(6); 203-218


22. Ansah, E. et al, 2010 “Rapid testing for malaria in settings where microscopy is available and peripheral clinics where only presumptive treatment is available: a randomised controlled trial in Ghana” British Medical Journal, 340:c930


30. Noor, A.M. et al, 2003, “Defining equity in physical access to clinical services using geographical information systems as part of malaria planning and monitoring in Kenya.” *Tropical Medicine and International Health* 8:917-926


32. van der Geest, S. 1987, “Self-care and the informal sale of drugs in south Cameroon” *Social Science Medicine* 25: 293–305


41. Abuya, T. et al, 2009, “Impact of ministry of health interventions on private medicine retailer knowledge and practices on anti-malarial treatment in Kenya” American Journal of Tropical Medicine and Hygiene, 80(6); 905-913
44. Shililu, J.I. et al, 1998, “Seasonal density, sporozoite rates and entomological inoculation rates of Anopheles gambiae and Anopheles funestus in a high-altitude sugarcane growing zone in western Kenya” Tropical Medicine and International Health 3(9); 706-710


50. Oshiname, Frederick et al, 1992, “Primary care training for patent medicine vendors in rural Nigeria” Social Science Medicine 35(12); 1477-1484


57. d’Acremont, V. et al 2010, “Withholding antimalarials in febrile children who have a negative test result for a rapid diagnostic test” Clinical Infectious Diseases, 51(5): 506-511