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The Accuracy and Perception of Test-Based Management of Malaria at Private Licensed Chemical Shops in the Middle Belt of Ghana

Anthony Kwarteng,[1] Keziah L. Malm,[2] Lawrence Gyabaa Febir,[1] Theresa Tawiah,[1] George Adjei,[1] Solomon Nyame,[1] Francis Agbokey,[1] Mieks Twumasi,[1] Seeba Amenga-Etego,[1] Daniel Amaning Danquah,[2] Constance Bart-Plange,[3] Seth Owusu-Agyei,[4] and Kwaku Poku Asante[1]*

[1]*Kintampo Health Research Center, Ghana Health Service, Kintampo, Ghana;* [2]*The National Malaria Control Program, Ghana Health Service, Accra, Ghana;* [3]*The Pharmacy Council of Ghana, Ministry of Health, Accra, Ghana;* [4]*Institute of Health Research, University of Health and Allied Sciences, Ho, Ghana*

Abstract. The sale of artemisinin-based combination therapy (ACT) by private licensed chemical shops (LCS) without testing is contrary to current policy recommendations. This study assessed the accuracy and perception of test-based management of malaria using malaria rapid diagnostic test (mRDT) kits at private LCS in two predominantly rural areas in the middle part of Ghana. Clients presenting at LCS with fever or other signs and symptoms suspected to be malaria in the absence of signs of severe malaria were tested with mRDT by trained attendants and treated based on the national malaria treatment guidelines. Using structured questionnaires, exit interviews were conducted within 48 hours and a follow-up interview on day 7 (±3 days). Focus group discussions and in-depth interviews were also conducted to assess stakeholders' perception on the use of mRDT at LCS. About 79.0% ($N = 1,797$) of clients reported with a fever. Sixty-six percent (947/1,426) of febrile clients had a positive mRDT result. Eighty-six percent (815/947) of clients with uncomplicated malaria were treated with the recommended ACT. About 97.8% (790/808) of clients with uncomplicated malaria treated with ACT were reported to be well by day 7. However, referral for those with negative mRDT results was very low (4.1%, 27/662). A high proportion of clients with a positive mRDT result received the recommended malaria treatment. Test-based management of malaria by LCS attendants was found to be feasible and acceptable by the community members and other stakeholders. Successful implementation will however require effective referral, supervision and quality control systems.

INTRODUCTION

Innovative malaria case-management strategies are urgently needed in sub-Saharan Africa (SSA) if the global targets of reducing the malaria incidence and mortality by at least 90% in 2030 are to be achieved.[1] This is because access to health services in SSA, the region with the heaviest disease burden is inadequate and people travel long distances to seek formal health-care services.[2,3] As a result, private auxiliary pharmaceutical outlets popularly known as licensed chemical shops (LCS) fill this void by supplying by retail only, over-the-counter medicines (Class C), including antimalarials in the community.[4]

Licensed chemical shops are found in almost every town or village in Ghana and are the first point of call when most community members are unwell probably because of their ease of access to services at relatively lower cost.[5,6] They, therefore, play a complementary role in the formal health system by bringing health-care services to the doorsteps of people in deprived communities.[7]

The Pharmacy Council of Ghana (PCG) oversees the registration, accreditation, and operations of LCS.[4] Application for a license is open to only adult Ghanaian citizens with a minimum high school education. Before issuing a license, the premises of an applicant are first inspected to assess ease of access by customers and it is also ensured that facilities are available for optimal storage of medicines. The approval for a license is given when the minimum requirements are met and is subject to renewal every year. Licensure is restrictive in nature as the licensee can only operate from the approved location specified on the license. Notwithstanding these guidelines and regulations, infringements on the use of unauthorized personnel and substandard premises have been reported.[8,9] In addition, poor prescribing practices such as sales of prescription-only medications and polypharmacy are common in the community.

The recommended treatments for uncomplicated malaria are artemisinin-based combination therapy (ACT), namely, artesunate–amodiaquine, artemether–lumefantrine, and dihydroartemisinin–piperaquine.[10] The treatment of suspected malaria through the sale of ACT at LCS without any confirmation of diagnosis is contrary to the World Health Organization's policy recommendations to test and treat all suspected cases of malaria regardless of age and malaria transmission levels.[11,12] The clinical and economic benefits in averting inappropriate use of ACT have been evident in settings where this policy is in practice.[13–15] Currently, malaria rapid diagnostic test (mRDT) kits are provided free of charge to most health facilities by the National Malaria Control Program (NMCP) under a Global Fund program. At health facilities registered as service providers under the National Health Insurance Scheme (NHIS), the cost of mRDT is covered for NHIS subscribers.[16] However, at private health facilities that do not provide services on behalf of the insurance authority, the cost of mRDT may be subsidized or paid for at market price depending on the availability of mRDT supplies from the NMCP.

It has been posited that empowering LCS to confirm the presence of malaria with mRDT, especially in highly endemic malaria regions, will improve access to ACT under rational drug use and align practice with the current malaria management protocols.[7,17]

Test-based management of malaria (TbMM) using mRDT by trained non-health professionals has been found to be feasible

* Address correspondence to Kwaku Poku Asante, Kintampo Health Research Center, Ghana Health Service, P. O. Box 200, Kintampo, Ghana. E-mail: kwakupoku.asante@kintampo-hrc.org

in Uganda, Senegal, and other African countries and recommended for other high–malaria transmission areas of which Ghana is included.[18–20] The use of mRDT by non-health professional is most appropriate, given their ease of use with minimal training and logistical requirements.[21,22]

In this study, we assessed the proportion of clients suspected of uncomplicated malaria and tested with mRDT who received the recommended ACT at LCS in two predominantly rural areas in the middle part of Ghana. In addition, the perceptions of community members and stakeholders on the use of mRDT at LCS for managing malaria were explored.

MATERIALS AND METHODS

Study site and design. The study was carried out in the Kintampo North Municipality and Kintampo South districts which lie within the forest savannah transitional ecological zone in the Brong Ahafo region of Ghana. Both districts cover an area of 7,162 km^2 with a resident population of approximately 140,000.[23] Farming is the main economic activity with increasing level of petty trading. Malaria transmission is high (269 infective bites per person per year) throughout the year, with the highest intensity between May and October.[24] The incidence of malaria among children less than 5 years of age in 2003 was about seven malaria episodes per child per year, but recent evidence suggests much lower incidence.[25] The study area had 26 community-based health-planning services, 12 health centers/clinics, and two district/municipal hospitals which serve as patient referral centers. In addition, there are three pharmacy shops and 68 LCS.

The study design was mixed methods using a cross-sectional survey, in-depth interviews (IDIs), and focus group discussions (FGDs). The study was carried out between March and October 2013.

Selection of LCS. All LCS in the study area were invited to participate in the study. However, a shop was included in the study if they met the following eligibility criteria: 1) the shop was in good standing with the Pharmacy Council (who oversees the work of LCS), demonstrated by a valid current certification; 2) the shop attendant has basic literacy and numeracy skills; and 3) the attendant operated from a recognized shop open at least once a week. In all, shop attendants from 42 LCS participated in the study.

Training and provision of logistics for LCS. A 1-week training workshop was organized for all licensed chemical shop attendants (LCSA) from LCS that met the study eligibility criteria. The training was facilitated by the district health management team using the PC training manuals and the 2009 Ghana NMCP malaria treatment guidelines.[26] The training package included malaria symptom recognition, identification of general danger signs, and how to collect finger-pricked blood samples for mRDT using sterile techniques. The treatment of malaria based on proper interpretation of mRDT results was explained. The LCSA were further advised to withhold ACT treatment from a client if the mRDT is negative and any of the signs and symptoms of severe malaria were absent. Such persons were to be given palliative treatment where necessary and counselled to return for referral if their conditions persist or deteriorate in the next 24 hours. The need to refer immediately pregnant women, children less than 6 months, and those presenting with any danger signs to the nearest health facility and the processes to follow were explained. In addition, the essence of good record keeping was explained.

Study-specific inputs namely CareStart® mRDT kits (Access Bio, Inc., Somerset, NJ), gloves, and safe disposal bins were supplied by NMCP and distributed free of charge to participating LCS. Logbooks for recording patient information and treatment protocols were also supplied to each of the shops. Licensed chemical shops were however required to procure ACT through their normal procurement channels. The NMCP malaria district focal persons in the districts subsequently undertook bimonthly supervisory visits to the LCS to ensure adherence to aseptic practices and offered support on proper bookkeeping.

Training of the study team. A 2-week training workshop was organized for the study team who undertook the data collection. Data collectors had a minimum of a high school certificate and at least 3 years of research experience which is equivalent to Ghana Health Service (GHS) trainee technical officer. The team was trained on the study objectives, data collection procedures, and general field techniques. The team also received training on how to administer the study questionnaire and correct techniques for assessing the validity of mRDT results.

The training involved practical sessions and a pilot of the study tools and procedures. Feedback on the suitability of study questionnaires was discussed and necessary corrective measures were addressed before the study commenced.

Sample size estimation. Accuracy of TbMM was defined as the proportion of clients presenting at the LCS with fever or other malaria-suspected signs and symptoms in the absence of signs of severe malaria who were tested with mRDT and on the basis of a test result treated in line with the national malaria treatment guidelines. In a recent study, the accuracy of TbMM among health personnel was found to be 66.7%.[27] Assuming a power of 85% at the 95% confidence level and a 20% clustering effect, a sample size of 1,680 clients presenting at the LCS suspected of malaria was required. Accounting for a 5% nonresponse rate, a minimum of 1,764 clients was estimated to determine the accuracy of TbMM by LCSA.

Quantitative surveys. Any client presenting with fever or other malaria signs and symptoms in the absence of signs of severe malaria was invited to participate in the study. Detailed study information, including the objectives, design, and procedures, for malaria testing and data collection were provided. Clients or their caregivers were given the opportunity to ask questions or mention any issue of concerns relating to the study. All questions and clarifications were addressed before a written consent was obtained. Two copies of the consent forms were signed and a copy given to the study participant or the caregiver. About 0.5 μL of finger-pricked blood was obtained from each consented participant for mRDT by the LCSA. The personal details of the clients, including household and telephone contact numbers, mRDT results, and treatment given, were recorded in a logbook. The mRDT results were independently confirmed by a trained laboratory technician within an hour after reading. Trained field staff obtained the contact details of clients and followed them at their homes for exit interviews within 48 hours of consultation. The choice of clients' home was to provide a convenient place for an interview without any influence from the LCSA. A second home visit was made on day 7 (±3 days) to ascertain patients' treatment outcome. Using a structured questionnaire, information on clients' demographics, presenting symptoms,

and LCSA diagnoses and treatment were collected. Last, an inventory of antimalarials, supporting medications, and other logistics (functional weighing scales, thermometers, and materials for administering drugs) was conducted at the LCS.

Qualitative method. Each interview was performed by two trained research officers with a basic degree in the social sciences and a minimum 3 years of experience conducting qualitative interviews.

Focus group discussion. Six FGDs were conducted separately: three among clients/caregivers who had recently sought care at LCS involved in the study and three among caregivers of children aged less than 5 years (< 5) who never accessed services at any LCS since the inception of the study. Communities were purposively selected based on their homogeneities and geographical locations. Respondents for those who used the LCS were randomly selected from the lists of entries made in the logbooks. These selections of discussants were restricted to the purposively selected communities in which LCS were located. Caregivers of children aged < 5 years who never accessed services at any LCS in the course of the study were randomly selected from the database of the Kintampo Health and Demographic Surveillance System.[23] Each FGD comprised 6–12 participants and lasted for about an hour. The FGDs explored the perceptions of TbMM by the LCSA using mRDT, affordability of malaria treatment, quality of care, and other related issues.

In-depth interview. Fourteen IDIs were conducted among key stakeholders. These include district health authorities, health service providers, district health insurance managers, community opinion leaders, and LCSA (Table 1). Licensed chemical shop attendants were interviewed on their treatment practices, experiences, and challenges encountered in the management of clients using mRDTs. The perceptions of these stakeholders on LCSA ability to undertake TbMM in the community were also assessed.

Data management and analysis. Administered survey questionnaires were manually checked for completeness and consistency. Double data entry and validation were carried out using Microsoft Access (Microsoft Corp 2013, Redmond, WA). The quantitative analysis was carried out in STATA, version 12 (StataCorp, College Station, TX). Information on LCS, including demographics of LCSA, was summarized into percentages. Clients were categorized into age groups and data summarized as frequencies and proportions with corresponding 95% confidence interval adjusted for clustering per LCS.

Qualitative interviews were conducted in the local dialect among community respondents and in English language among health stakeholders. They were digitally recorded and transcribed verbatim. Those in the local dialect were back-translated to the English language within 24–72 hours after each interview session. The audio recordings were independently vetted to ensure they matched with the transcripts. Themes identified a priori from the study objectives were as follows: use and acceptability of TbMM using mRDT, referral of danger signs to health facilities, cost, and potential challenges of TbMM using mRDT. Using NVivo version 8 (QSR International, Australia), two independent researchers coded the transcripts. To ensure inter-coder agreement, 10% of the transcripts were coded independently. This was followed by debriefing sessions to discuss and agree on common themes. Inter-coder agreement was more than 90%. Emerging themes were also derived from the data. Anonymized quotes that best described these themes were included to support the quantitative findings.

Ethical consideration. Approvals were obtained from the Kintampo Health Research Center (KHRC) Scientific Review Committee and KHRC Institutional Ethics Committee, as well as the Ghana Health Service Ethical Review Committee. An informed written consent was obtained by a field staff from all adult patients or caregivers of children less than 18 years old. In addition, adolescents aged 12 to –17 years gave their written assent. Unaccompanied minors were excluded from the study. All study forms and digital data are kept under lock and key, with restricted access.

RESULTS

Description of the study population. Forty-two of the 65 LCS that met the selection criteria were included in the study. Altogether, 1,973 suspected malaria cases were tested with mRDTs at the LCS. Eventually, matched datasets of exit interviews and validated mRDT results of 1,797 clients were analyzed. Seventy-six clients who could not be identified at their addresses for the exit interviews were excluded. Furthermore, 25 poorly labelled mRDT cassettes and 75 mRDT results found to be inconclusive on independent verification by trained laboratory technicians were also excluded (Figure 1).

Background characteristics of LCSA and clients. The mean age of LCSA was 44 years (standard deviation [SD]:

TABLE 1
Summary of respondents in the in-depth interviews

Category	Role/description	Number of interviews
Health stakeholders (n = 5)		
District health management team	Implementers of community health programs at the district level	1
Hospital management team	Clinical management of malaria	1
Laboratory technologists	Laboratory diagnosis at the district hospital.	1
National Health Insurance Authority, district management	Stakeholder in health financing	2
Community members (n = 3)		
Opinion leaders	Key informant in the community	3
LCSA in the study (n = 6)		
LCSA	Located in rural communities	3
LCSA	Located in urban communities	3
Total		14

LCSA = licensed chemical shop attendant.

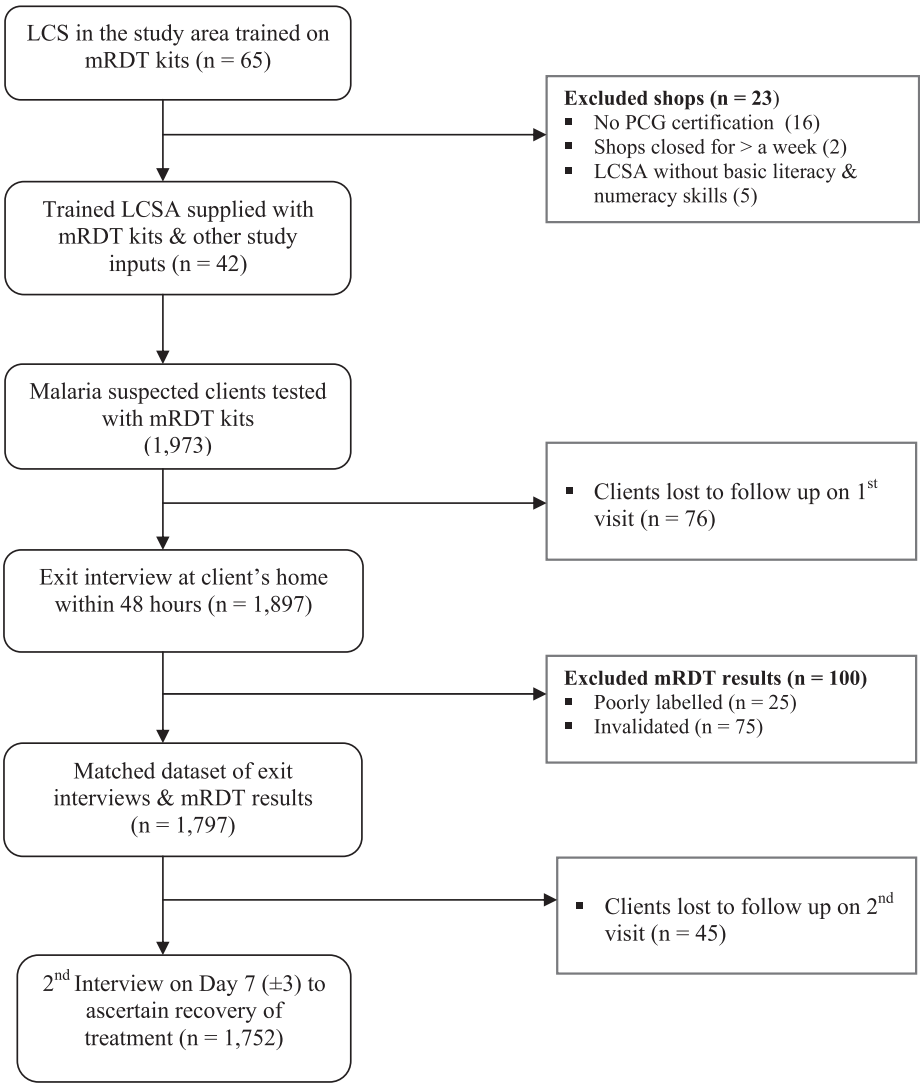

FIGURE 1. Description of the sample population and study procedure among clients visiting licensed chemical shops. LCS = licensed chemical shops; LCSA = licensed chemical shop attendant; mRDT = malaria rapid diagnostic test; PCG = Pharmacy Council of Ghana.

11.5). Majority (90.5%) of the shop attendants were males (Table 2). Sixty-nine percent of shop attendants had at least a high school education (Table 2).

About 20.3% of clients presenting at LCS were children aged < 5 years (Table 2). Fifty-seven percent of the clients were males (Table 2). The reported use of insecticide treated nets the night before the exit survey was 53.8% (Table 2). The mean walking/travel time of clients visiting the LCS from their homes was 14 (SD: 17.3) minutes.

The age range of focus group discussants in the qualitative interview was between 21 and 75 years; those between the ages of 31 and 40 years were in the majority (Table 3). Females were slightly more than males. Farming was the main occupation of the majority of discussants (Table 3). The respondents in the IDIs were mainly men (85.7%).

Presentations of complaints and use of antimalarials before visiting LCS. The commonest presenting complaint was fever (79.4%) (Table 4). The reported use of antimalarials before the LCS visit for the current illness was low (2.8%, 52/1,797). These were leftover medications from previous treatments or from close relatives and friends. About two-thirds of antimalarials used were ACTs (65.4%, 34/52), monotherapies (13.5%, 7/52), and quinine (1.9%, 1/52); however, 19.2% (10/52) of clients did not know the type of antimalarial used.

Licensed chemical shop attendants assessment of clients' vitals and danger signs. The assessment of age and fever was frequently performed among all age groups (Figure 2). Weight was infrequently (< 5%) measured among all the age groups before drug administration. Clients were rarely assessed for danger signs such as breathing or feeding difficulty.

Accuracy of TbMM at LCS. A history of fever was reported in 79.4% (1,426/1,797) of all clients, higher among children aged < 5 years than in older clients (97.8% versus 74.7%; $P < 0.001$) (Figure 3). Those with fever who had positive mRDT results were 66.5% (Figure 3). This was significantly higher among children aged < 5 years than in older clients (82.6% versus 61.1%, $P < 0.001$). A positive malaria test was observed among 35.8% (133/371) of clients who presented without signs or symptoms of fever.

TABLE 2
Background characteristics of licensed chemical shop attendants and their clients

Background characteristics	Frequency (*n*)	Percent (%)
Licensed chemical seller (*N* = 42)		
Male	39	90.5
At least high school education (O'L/SSS/SHS)	29	69.0
Clients (*N* = 1,797)		
Children < 5 year	365	20.3
Male	1,024	57.0
Holders of valid NHIS card	994	55.3
Slept under ITN the previous night	966	53.8
Household heads with minimum high school education	317	17.6

ITN = insecticide treated net; NHIS = National Health Insurance Scheme; O'L = ordinary level; SHS = senior high school; SSS = senior secondary school.

The accuracy of uncomplicated malaria (fever and mRDT positive results) treatment with ACT among all clients was 86.1% (816/948); children aged < 5 years were 83.4% (246/295) and older participants, 87.3% (570/653) (Figure 3).

Artemisinin-based combination therapies were withheld in a high proportion of clients who were suspected to have malaria but had a negative malaria test; this was 69.4% among clients who presented with fever and 82.4% in those without fever (Figure 3).

Outcome of treatment at LCS. The majority of clients (97.4%, 1,639/1,682) who were either treated or counselled reported being well on the follow-up visit. High recovery rates were also reported among clients with uncomplicated malaria (fever plus mRDT positive results) given an ACT of 97.8% (790/808). This was similar in children aged < 5 years (97.9%; 553/565) and the older age group (97.5%; 237/243).

Referral of clients. Clients with a negative mRDT test in the absence of any danger signs who were prescribed no medications but counselled to return for referral should their conditions worsened were only few (7.5%; 54/716). Referral to the nearest health facility for clients with a negative mRDT result was low (4.1%, 27/662). Of those referred, 81.5% (22/27) adhered to the referral advice, but only seven (25.9%) did so within 24 hours.

Perception on referral-related issues. The common conditions that community members described as needing referral to the health facilities were severe conditions such as jaundice, hypertension, and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS).

TABLE 3
Background characteristics of focus group discussants

Characteristics	*n* (%) Used LCS	Did not use LCS	All discussants
Gender			
Male	17 (50.0)	10 (35.7)	27 (43.5)
Female	17 (50.0)	18 (64.3)	35 (56.5)
Age (years)			
Range	21–75	23–65	21–75
Mean	37.8	35.8	36.9
Occupation			
Farming	18 (52.9)	24 (85.7)	42 (67.7)
Trader	8 (23.5)	1 (3.6)	9 (14.5)
Student	3 (12.5)	1 (3.6)	4 (6.5)
Unemployed	3 (12.5)	0	3 (4.8)
Others	2 (5.9)	2 (7.2)	4 (6.5)

LCS = licensed chemical shops.

TABLE 4
Proportion of presenting symptoms/complaints among different age groups at the first visit to licensed chemical shops

	Age groups (years)				All ages	
	< 5	5–10	11–19	20+	*N*	%
Numbers (*n*)	365	267	225	940	1,797	100.0
Symptoms	%	%	%	%	%	%
Fever	97.8	98.5	83.6	65.7	1,426	79.4
Headache*	–	53.6	76.4	72.8	999	69.8
Weakness	16.4	29.2	41.8	55.5	754	42.0
Chills*	–	36.7	40.9	37.6	543	37.9
Shivering	16.2	24.3	10.2	11.9	259	14.4
Vomiting	52.9	52.1	23.6	12.9	506	28.2
Diarrhea	39.2	16.9	12.9	7.7	289	16.1
Cough	34.3	23.2	13.3	13.7	346	19.3
Nausea*	–	7.1	19.6	14.8	202	14.1
Abdominal pains*	–	31.8	32.4	20.2	348	24.3

* Not assessed among children aged < 5 years.

"Jaundice is what worries me so if I go to the LCS and the operator asks me to go the facility I have to go because when I buy medicine at home to treat the sickness it doesn't help me. . . ." (IDI, opinion leader from rural Community B).

However, some health staff expressed concerns that LCS are likely to delay referrals to sell their drugs. This concern is expressed in the following quote:

"I think they are generating income so if you tell them to refer those negative malaria cases to the health facilities, it means that they are increasing the income rate at the facility. They will prefer to treat the patients at their end rather than refer. . . ." (IDI, laboratory technologist at District Hospital).

However, an LCSA attributed his low referral practices to clients' refusal to honor referral advice. According to him, clients under the guise of obtaining first aid often failed to report to the facility for further management.

"When a person has high body temperature, there is no need keeping such a person at the drug store but sometimes, the relatives put pressure on you to give some initial drugs which may not be effective." (IDI, LCSA 4 from the rural community).

In spite of the challenges of the low referral and referral completion rates, a senior district health officer opined that an optimized referral system was feasible if the capacity of LCS is strengthened through effective education. Following is a demonstrative quote:

"If we have regular contacts with them [LCS] and we keep on stressing that if you do the test and the result is negative the condition may be due to several serious conditions so refer quickly, they will but that will depend on the proximity from their facility." (IDI, district health management member).

Willingness to undergo rapid diagnostic testing for malaria. Most community members indicated LCS as their first convenient point of call for the treatment of many ailments in the

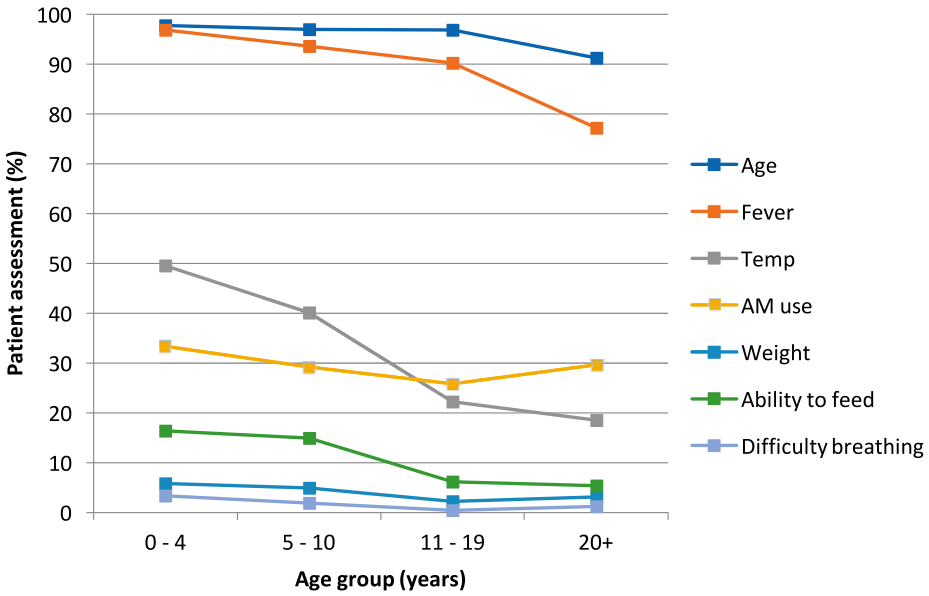

FIGURE 2. An assessment of vital and danger signs among clients at licensed chemical shops. This figure appears in color at www.ajtmh.org.

community and that they only proceed to a health facility if they do not get well after receiving the initial treatment.

"We first go to the drug store to buy the drugs but when we see that there is no improvement then we go to the hospital to seek for further treatment." (Discussant 8, FGD with users of LCS at Community E).

A community member who had not accessed services at any of the participating LCS indicated her willingness to visit the drug store if they have the capacity to conduct laboratory investigations.

"If they have the malaria test at the drug store, then we can visit there for the test because it may happen that the clinic does not even have the drugs so we still have to come back to the drug store to buy the malaria drug." (Discussant 1, FGD with nonusers of LCS at Community A).

Generally, respondents welcome TbMM using mRDT at LCS. This was reported to be especially good for those who do not have the means to visit the health facilities.

"If the test (mRDT) is brought to the LCS, it will be very good especially for those of us in the village who cannot afford to always visit the clinic or the hospital due to transportation problems." (Discussant 3, FGD with users of LCS at Community B).

However, many caregivers of children aged less than 5 years said they visit the health center when their child has fever and proceed to the hospital if the condition persists.

"As for me if I will visit the health centre and if the illness persist I proceed to hospital any time my child has a fever." (Discussant 1, FGD with nonusers of LCS at Community A).

Rapid diagnostic testing as a means of improving malaria diagnosis at LCS. Respondents also expressed the need for testing (with mRDT) at the LCS as effective means of improving malaria diagnosis before an ACT is prescribed. The use of mRDT was perceived to boost the business of LCS.

"I think it is good they take blood sample [for a test] to be able to know whether the sickness is malaria or not, if the test is done, you can be sure if it is malaria or not and the right medicine will be given to you for treatment." (IDI, opinion leader from the urban community).

"Most patients like the mRDT test because they have realized that it is the best way to diagnose malaria ... we, the drug sellers want customers so if we get to use mRDTs, it will pull customers for us. . . ." (IDI, LCSA 1 from the urban community).

"I think it is a good thing for all of us because the rate at we give out the malaria drugs will reduce. If you test and it is not malaria you will not give the malaria drugs to them [clients]. So it will be a very good thing." (IDI, LCSA 4 from the rural community).

There were, however, concerns whether the knowledge of LCSA on the mechanisms under which mRDT works is adequate, a situation that could results in misdiagnoses. This is illustrated in the following quote:

"You see if they [LCSA] do not have knowledge on the principle by which RDT works, they might misdiagnose. . . . . a person suffering from other diseases but had treatment for a recent malaria infection could still test positive. If the operator doesn't know all these, he might give malaria drugs again but the patient may have other serious conditions." (IDI, laboratory technologist at District Hospital).

Another concern was whether LCSA will adopt aseptic measures when drawing blood for a test, a practice that could

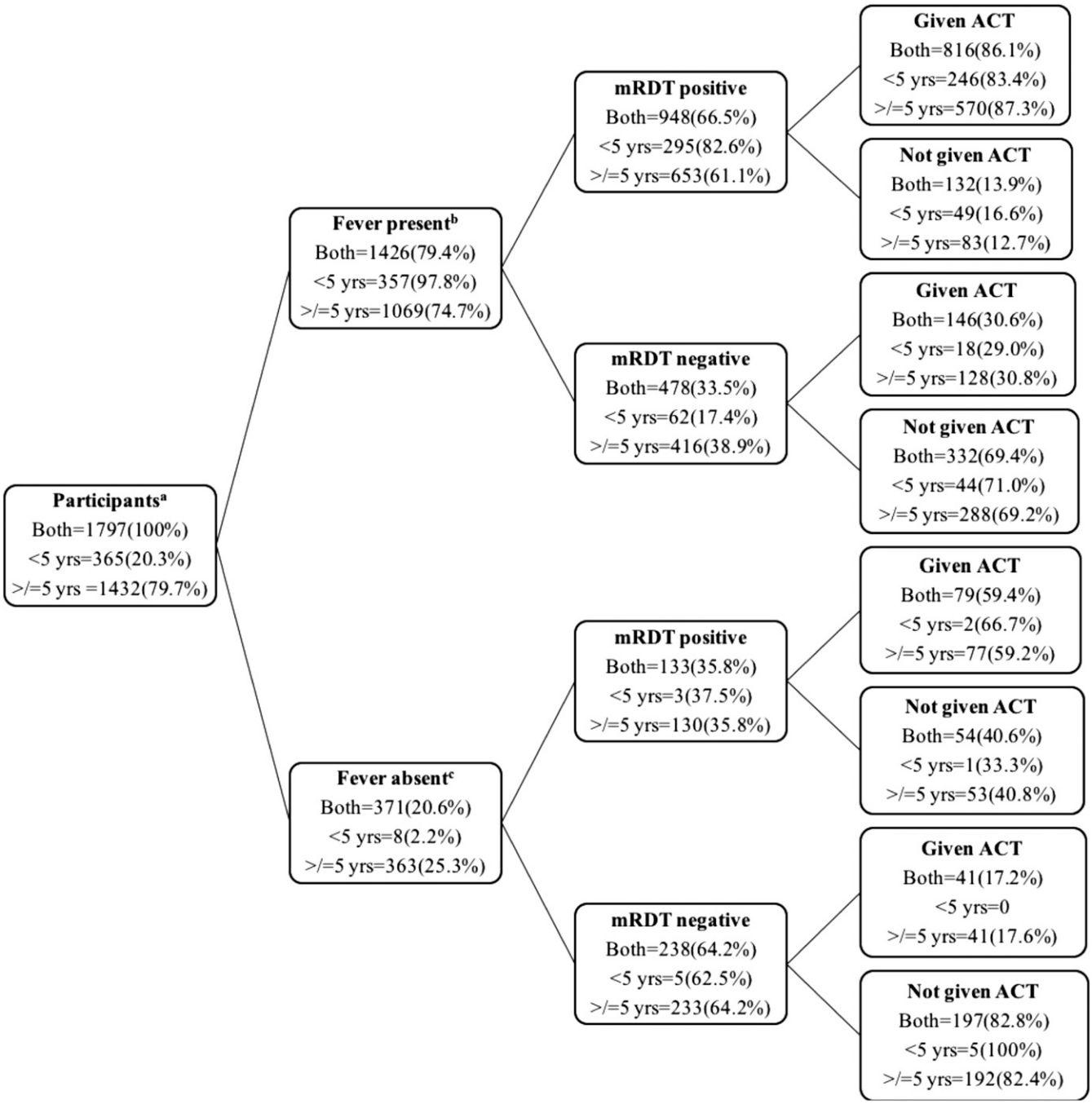

FIGURE 3. Prescription of artemisinin-based combination therapy (ACT) by licensed chemical shop attendants based on the interpretation of malaria rapid diagnostic test (mRDT) results among clients suspected with malaria. [a]Clients suspected with malaria; [b]clients suspected with malaria based on a presentation of fever; [c]clients suspected with malaria based on a presentation of other symptoms other than fever.

expose shop attendants and other clients to infections such as HIV and hepatitis. These are illustrated in the following quotations:

"I think essentially it boils down to they [LCSA] being able to employ aseptic techniques. Once you do any form of puncture and body fluids are involved, the disposal of these sharp objects if not done properly may be a problem. They are at risk themselves getting infected with any of the virus, i.e. hepatitis and HIV and could infect other patients. Furthermore, many clinicians are vaccinated against these viral infections but we might not be able to say so for the LCSA." (IDI, hospital management member).

However, a community member who had visited an LCS confirmed that aseptic techniques were employed when a blood sample was taken for the malaria test.

"He put on gloves and used some medicine to clean my fingertips before pricking me for the blood sample." (IDI, opinion leader from rural Community A).

Perceptions on cost of mRDT and LCS accreditation as NHIS service providers. The cost of mRDT was seen as a potential barrier to TbMM at LCS. Many expressed the desire for the mRDT to be provided free of charge as pertains at the health facilities or subsidized by government. This is because customers will have to pay not only for the mRDT but also for the medication that will be provided. This view is represented in the following quotes:

"In fact, paying for both the test and drugs will even drive us away from the drug stores to the hospital since when one is insured he go to the hospital for free." (Discussant 5, FGD with users of LCS at Community F).

"The only problem will be the money that you will have to collect from the person, all the sick persons will like to test but the only problem will be the money to pay for the test and buy medications after the test." (IDI, LCSA 6 from the rural community).

Others, mainly subscribers of the NHIS would rather visit the health facility if LCS will charge for the malaria test.

"I have made my mind that I will use my money for insurance so if the LCS will charge for malaria test, then I will rather visit the clinic instead." (Discussant 6, FGD with nonusers of LCS at Community D).

Licensed chemical shop attendants were willing to be accredited as service providers for the NHIS. They were, however, challenged by operational issues such as accreditation requirements, perception of inadequate staffing, and delays in NHIS reimbursement. These challenges had been experienced by LCS operators.

"I am ready for accreditation any time because we want to help in promoting health care and also it helps to get more customers. Some of the patients don't have enough money so if you have the accreditation they will use the insurance to buy drugs from our end." (IDI, LCSA 1 from the urban community).

"Most of them do not want to register as a company so that is the main problem. Some [LCS] do not have the requisite staff, you go there and the one operating the shop has not even completed senior high school to be able to read prescriptions. Proper record keeping is also a problem." (IDI, NHIS district management member).

Perception on supply of mRDTs and antimalarials. The uninterrupted supply and potential stock-out of mRDT and antimalarials were concerns expressed by LCSA in both the rural and urban communities.

"One other challenge might be the continuous supply of the RDT. If there is no shortage and we get continuous supply, selling them will not be a problem." (IDI, LCSA 5 from the rural community).

"We don't actually get supply daily and more frequently because some suppliers come even after one month of supply so we always have to wait between these periods. Assuming that I am supplied one box of malaria drugs today and it get finished today, I still have to wait for the next supply period to be able to re-stock and that is the challenge." (IDI, LCSA 3 from the urban community).

Functional thermometers were available at most shops (Table 5). The availability of weight measuring scales was fairly low for both infants and adults. Every shop had at least an ACT in stock during the study period (Table 5). More than 85.0% of the shops had guides (posters, leaflets, etc.) for antimalarial treatment available (Table 5). Water and cups were available in most shops (66.7%) to immediately start drug administration (Table 5).

DISCUSSION

The accuracy and perception of TbMM using mRDT at LCS were assessed in this study. The majority (86.1%) of clients with uncomplicated malaria received the recommended ACT in accordance with the 2014 Ghana National Malaria Treatment Guidelines. Contrary to the perception that LCSA are likely to ignore negative mRDT results and inadvertently prescribe antimalarials in the pursuit of their business interest, ACT was withheld in a high proportion of clients who had a negative malaria test. For example, 69.4% of febrile clients with a negative malaria test and 82.4% of clients with other symptoms initially suspected to be malaria were prescribed no antimalarials. Test-based management of malaria at LCS was widely accepted as effective means of improving malaria diagnosis and treatment albeit few implementation challenges. Our findings add to the growing evidence in many resource-constraint countries, including Uganda,[18] Ethiopia,[19] Senegal,[20,28] Sudan,[29] Zambia,[30] and Cambodia,[31] that the deployment of TbMM using mRDT by non-health professionals has proven to be an innovative strategy in improving the specificity of malaria diagnosis and treatment.

Despite the high level of appropriate treatment for uncomplicated malaria, overtreatment (ACT prescription in the absence of malaria parasitemia) was relatively high among clients presenting with fever (30.6%) and those with other symptoms (17.2%) initially suspected to be malaria. Such poor prescribing practices are similar to findings from studies even among health professionals.[32,33] Notwithstanding significant progress over the last decade in malaria case management, inappropriate treatment remains a challenge for health systems of many malaria-endemic countries. The risk of untreated malaria manifesting into severe malaria, particularly for children, could be potentially fatal.[34,35] Overexposure to ACT, on the other hand, leads to build up in the overall drug

TABLE 5

The availability of ACT and other logistics at licensed chemical shops at the start of the study

Characteristics	Frequency	Percent (%)
Had a functioning thermometer	29	69.0
Had a functioning infant weighing scale	6	14.3
Had a functioning adult weighing scale	8	19.0
Dosing cups and portable water available	28	66.7
Malaria treatment algorithms/guidelines/ flowchart	36	85.7
Had at least an ACT in stock	42	100.0
Had artesunate–amodiaquine	30	71.4
Had artemether–lumefantrine	29	69.0
Had dihydroartemisinin–piperaquine	12	28.6

ACT = artemisinin-based combination therapy. $N = 42$.

pressure, facilitating the development of resistant strains of the malaria parasite and rendering ACT inactive.[36] Improving access to antimalarials through the use of mRDT by trained LCSA in the community poses a lesser threat to fostering resistance to ACT than the current practice of presumptive malaria treatment.[37,38] The identification of artemisinin resistance in five countries in the Greater Mekong subregion must be a clarion call for malaria program managers to pursue far-reaching interventions that mitigate against the development of antimalarial resistance and prolong the therapeutic life span of ACT.[39,40]

Another important observation in our study was that LCSA rarely referred clients with negative malaria test (4.1%) and only few referrals (25.9%) were honored within 24 hours. Such poor referral practices are major concerns that need to be addressed. Factors identified as potential barriers to referral include cost of transport, long waiting time at higher facilities, severity of ailments, and perceived lack of competence at the referred facility to properly manage cases.[41,42] These factors may have contributed to the low client referral completion albeit indirectly. The suspicion of malaria as the focus of clinical investigation and the subsequent negative test for malaria are likely to be perceived by community members as the absence of any severe condition for which further management at health facility may not be required.[33] The clients' persistent failure to honor referral advice after receiving first aid treatment may perhaps account for the poor attitude of LCSA to refer, as observed in a study in Sierra Leone.[43] This may have lent credence to the widely held perception mostly by health workers that LCSA will rather pursue their business interest at the expense of quality care for their clients. Similar findings have been observed in a Ugandan study, where the reluctance of accredited drug dispensers to refer clients due to previous experience of not complying with referral advice after receiving first aid treatment was similarly misconstrued.[18] Regular capacity-building programs for LCSA with the active support of health workers will improve the conduct of LCSA professionally and address these health worker mistrust.

The availability of simple functioning instruments (i.e. thermometers and weighing scales) and the ability of LCSA to accurately use them are important for proper management of malaria. For example, most shops lack weighing scales and could, therefore, not measure clients' weight to calculate correct doses required for treatment. Although dose estimations based on weight are more reliable, the use of age band indicators in the drug inserts or national treatment guidelines as references for determining doses is an acceptable practical alternative for less qualified LCSA that could avert errors in calculating doses based on body weights.[44,45]

Our data suggest that the combined cost of mRDT and ACT is a potential barrier to many people especially the rural folks. The government must ensure continuous provision of subsidy on mRDT to make the cost of malaria treatment affordable to rural dwellers. Furthermore, steps should be taken to make LCS attractive points of care by accrediting them as service providers under the NHIS. These initiatives are likely to address the high indirect cost of malaria such as cost of travel; and improve access to TbMM particularly for rural dwellers.[6] In addition, innovative financing mechanism should be explored. For instance, Hansen et al. proposed the sale of mRDT and ACT as a single commodity, where a customer who purchased mRDT will be offered a course of ACT free or at a discounted price if the malaria test is positive.[46] Further research to assess its feasibility and cost-effectiveness in our local context are needed.

The ubiquity and convenience of access to LCS coupled with inadequate health workforce have created the need for alternate ways of addressing the health-care needs of people living in communities underserved by the formal health system. Licensed chemical shops can fill this void by taking up easy-to-perform tasks traditionally reserved for skilled health personnel to increase access to and uptake of health services.[18–20] In Ghana, the sale of depot medroxyprogesterone acetate, a prescription-only injectable contraceptive to women of reproductive age, and referral to qualified health providers by LCS have been shown to be successful in increasing access to safe family planning services.[47] Identifying the level of training needed to adequately equip LCS to provide the required quality of care is key. Changes to existing health legislations to allow and regulate LCS to delivering on their new mandate are also needed.[48]

In light of our findings, a nationwide deployment of TbMM at LCS requires the following efforts to ensure successful implementation. First and foremost, LCSA need to be properly trained to reorient their behavior to safe and acceptable standards of practice. For example, LCSA must be able to take a good history to identify danger signs and refer clients for early and proper management at the health facilities. Second, the PC needs to intensify efforts with the district malaria focal persons to provide regular supportive supervision for strict adherence to the licensed chemical sellers' code of practice. This will require the implementation of effective measures to ensure that newly licensed shops are adequately trained on the use and interpretation of mRDT results to achieve the high level of accuracy observed in this study. Third, effective community sensitization on improved LCS capability should be aggressively pursued to engender community trust and confidence in the operations of LCS and thereby promote demand for malaria testing.[49] Last, the availability and supply of essential commodities, such as mRDT, ACT, gloves, and other inputs, need to be sustained. The health system challenge of perennial shortages of mRDT and other commodities needs to be fixed.[50–52] Government- or donor-supported interventions aimed at addressing similar challenges often involve free supply of such commodities. Such interventions are difficult to sustain in the midst of competing health needs and are stopped when funds are depleted.[53] The private sector can be incentivized through the provision of tax exemptions to support the importation and marketing of mRDT kits.[54]

In conclusion, the use of mRDT by LCSA is largely accurate and acceptable to community members. However, potential challenges associated with large-scale deployment need to be addressed. These include continuous training and supervision by the PCG in partnership with the local health authorities to strengthen the capacity of LCS and address the perceived weak regulatory oversight. Community sensitizations aimed at addressing the poor referral practices must also be pursued. In addition, quality control systems derived from effective monitoring and evaluation regime must be put in place.

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Authors' addresses: Anthony Kwarteng, Lawrence Gyabaa Febir, Theresa Tawiah, George Adjei, Solomon Nyame, Francis Agbokey, Mieks Twumasi, Seeba Amenga-Etego, and Kwaku Poku Asante, Kintampo Health Research Center (KHRC), Ghana Health Service, Kintampo, Ghana, E-mails: anthony.kwarteng@kintampo-hrc.org, lawrence.febir@kintampo-hrc.org, theresa.tawiah@kintampo-hrc.org, george.adjei@kintampo-hrc.org, solomon.nyame@kintampo-hrc.org, francis.agbokey@kintampo-hrc.org, mieks.twumasi@kintampo-hrc.org, seeba.ae@kintampo-hrc.org, and kwakupoku.asante@kintampo-hrc.org. Keziah L. Malm and Constance Bart-Plange, The National Malaria Control Program, Ghana Health Service, Accra, Ghana, E-mails: keziah.malm@ghsmail.org and constance.bartplange@ghsmail.org. Daniel Amaning Danquah, The Pharmacy Council of Ghana, Ministry of Health, Accra, Ghana, E-mail: dandanquah45@gmail.com. Seth Owusu-Agyei, Institute of Health Research, University of Health and Allied Sciences, Ho, Ghana, E-mail: sowusuagyei@uhas.edu.gh.

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