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Knowledge and Adherence to the National Guidelines for Malaria Diagnosis in Pregnancy among Health-Care Providers and Drug-Outlet Dispensers in Rural Western Kenya

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Abstract. Prompt diagnosis and effective treatment of acute malaria in pregnancy (MiP) is important for the mother and fetus; data on health-care provider adherence to diagnostic guidelines in pregnancy are limited. From September to November 2013, a cross-sectional survey was conducted in 51 health facilities and 39 drug outlets in Western Kenya. Provider knowledge of national diagnostic guidelines for uncomplicated MiP were assessed using standardized questionnaires. The use of parasitologic testing was assessed in health facilities via exit interviews with febrile women of childbearing age and in drug outlets via simulated-client scenarios, posing as pregnant women or their spouses. Overall, 93% of providers tested for malaria or accurately described signs and symptoms consistent with clinical malaria. Malaria was parasitologically confirmed in 77% of all patients presenting with febrile illness at health facilities and 5% of simulated clients at drug outlets. Parasitological testing was available in 80% of health facilities; 92% of patients evaluated at these facilities were tested. Only 23% of drug outlets had malaria rapid diagnostic tests (RDTs); at these outlets, RDTs were offered in 17% of client simulations. No differences were observed in testing rates by pregnancy trimester. The study highlights gaps among health providers in diagnostic knowledge and practice related to MiP, and the lack of malaria diagnostic capacity, particularly in drug outlets. The most important factor associated with malaria testing of pregnant women was the availability of diagnostics at the point of service. Interventions that increase the availability of malaria diagnostic services might improve malaria case management in pregnant women.

INTRODUCTION

Since 2010, Kenya Ministry of Health (MoH) malaria diagnostic guidelines have recommended universal parasitological testing, via microscopy or malaria rapid diagnostic test (RDT), of febrile patients across all demographic groups, including pregnant women.[1,2] Antimalarial treatment on the basis of clinical malaria signs and symptoms should only be considered in situations where a parasitological diagnosis is not available, particularly in vulnerable populations such as pregnant women.[2]

Malaria in pregnancy (MiP) can have devastating consequences for the woman and fetus, including maternal anemia, fetal loss, intrauterine growth retardation, premature delivery, and low birth weight (LBW) with increased risk for neonatal death.[3] The Kenya MoH recommends that pregnant women receive prompt and effective diagnosis and treatment of malaria with a safe drug to prevent adverse consequences. Treatment with non-recommended drugs, whether antimalarials, antibiotics, or other drugs, can have adverse consequences for the woman. With the added risk to the fetus, it is particularly important to avoid unnecessary drug exposures during pregnancy.[4,5]

Kenya introduced malaria RDTs for malaria diagnosis in 2006 in low-transmission areas and nationally in late 2012. The 2010 Kenya National Malaria Strategic Plan goal was to have universal availability of malaria diagnostic capacity, defined as having either functional microscopy or RDTs, by 2013.[1,6] By mid-2013, 90% of health facilities nationally had the capacity to provide a malaria parasitological diagnosis and 70% had RDTs.[7] Although malaria testing rates among febrile patients increased by 34% from a baseline of 24% in 2010, only 58% of patients with suspected malaria were tested at health facilities with diagnostic capacity.[7]

Provider reliance on clinical diagnosis, rather than parasitological diagnosis, with poor adherence to treatment policy has been consistently observed throughout malaria-endemic countries.[8] Malaria diagnosis in pregnant women also has been suboptimal, particularly in the first trimester.[8] With women of childbearing age (WOCBA) representing about 25% of the total population and pregnant women representing approximately 4% of the population in many malaria-endemic countries, including Kenya, understanding provider diagnostic behavior toward women of reproductive age and pregnant women is important to optimizing case management and minimizing potential harmful drug exposures. In Kenya, studies have estimated that 17–83% of persons with fever are treated first with medicine purchased from private-sector drug outlets (registered pharmacies, drug shops/chemists, or general shops) rather than in health facilities.[9–11] Therefore, a cross-sectional study was conducted to assess health-care provider and drug-outlet dispenser behaviors and knowledge of malaria diagnostic guidelines for pregnant women in a malaria-endemic region of western Kenya in 2013.

METHODS

Study site & sampling. The study was conducted from September to November 2013 in rural Siaya County in western Kenya, where malaria transmission is perennial and holoendemic. The study area included the Kenya Medical Research Institute (KEMRI) and U.S. Centers for Disease Control and Prevention (CDC) Research and Public Health Collaboration's Health and Demographic Surveillance System (HDSS). The

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KEMRI-CDC HDSS platform has been detailed previously.[12] At the time the study was conducted, approximately 20% of pregnant women were parasitemic by polymerase chain reaction at first antenatal clinic visit[13] and 9% of women delivering in Siaya District Hospital had microscopically confirmed placental malaria.[14]

Adherence to the Kenya national malaria diagnostic guidelines was observed by 1) exit interviews with women aged 18–49 years, including pregnant women, being treated for febrile illness at all participating health facilities within the study area and 2) use of a simulated-client approach within randomly sampled drug outlets.[1,15,16] Knowledge of diagnostic guidelines and self-reported diagnosing behavior for MiP was assessed by structured questionnaires administered to health-care providers and drug dispensers. The assessments were conducted after completion of the provider- and dispenser-practice component to avoid influencing actual practice. The data were collected as part of a broader study to assess overall provider knowledge and adherence to MiP case management guidelines. Detailed methods have been published elsewhere.[17]

Health facility selection. All public and private health facilities, including hospitals, health centers, or dispensaries, in the KEMRI-CDC HDSS study area and within a 5-km radius surrounding the HDSS were assessed for eligibility. Facilities were eligible if they provided outpatient care to WOCBA and the facility supervisor consented to participate. Facilities with other ongoing malaria studies were excluded.

Drug outlets selection. During September to October, 2013, a census was conducted of all drug outlets, including registered pharmacies, unregistered (i.e., informal) drug shops/chemists, and general shops, selling antimalarial drugs within the HDSS border; detailed methods have been published elsewhere.[18] Malaria RDT availability was 10% in surveyed drug outlets; 84% of drug outlets had never stocked RDTs.[18] Of 181 identified drug outlets, 27 home-based shops were excluded because a simulated-client approach was not feasible in this setting, and 152 consented for future participation in the knowledge and practice assessment. Among the 152 consenting drug outlets, 39 were selected for participation by simple random sampling; the sample size allowed estimation of the proportion of providers with adequate knowledge with 14% precision at 80% power, assuming that 45% of providers had adequate knowledge and prescribing practices.[19]

Data collection. *Exit interviews in health facilities.* Patients were assessed for eligibility after completing a provider consultation in either the outpatient department or antenatal care clinic and receiving all prescribed tests and medications. Exit interviews were conducted with consenting patients after a standard format. Pregnancy status was based on patients' self-report and is defined as: 1) WOCBA who could potentially be pregnant; 2) women in first trimester (up to and including 14 weeks); and 3) women in the second or third trimester of pregnancy (15 weeks and beyond); gestational age and trimester were calculated from date of self-reported last menstrual period. In cases where an antimalarial contraindicated for pregnancy had been prescribed, the incorrect medication was replaced with the recommended treatment by the study clinician. Health providers were not made aware of these changes until after completion of the study.

Simulated clients in drug outlets. The simulated-client or mystery-client approach was used to assess diagnostic practice.[15,16] Trained female study staff presented as either WOCBA or in early pregnancy and male staff presented as the husband of a WOCBA or woman in the third trimester of pregnancy; all three scenarios (WOCBA, early pregnancy, and late pregnancy) were simulated at each outlet. A single dispenser-client simulation had the potential to include both nonpregnant and pregnant scenarios. Study staff members were not to disclose pregnancy status unless asked by the dispenser. If dispensers failed to assess pregnancy status, the simulated clients disclosed pregnancy status after receiving medication(s). The pregnancy scenario was then assessed based on any changes in practice made after pregnancy status disclosure.

Provider surveys in health facilities & drug outlets. Immediately after the completion of exit interviews and 1 week after client simulations, a structured questionnaire was administered to providers and dispensers to assess knowledge and diagnostic practice. One to two providers per health facility (dependent on number of staff treating WOCBA and pregnant women) and one dispenser per drug outlet was interviewed; provider and dispenser selection was based on whether the provider treated WOCBA and availability at time of interview.

Definitions. After the 2010 Kenya National Malaria Treatment Guidelines[1] and 2010 World Health Organization Malaria Treatment Guidelines,[2] correct practice was defined as the use of parasitological testing (either microscopy or malaria RDT), or when testing was unavailable, accurate description of symptoms consistent with clinical malaria (i.e., fever, chills, headache, vomiting, body aches, and general malaise). Adequate knowledge was defined as both an accurate description of malaria signs and symptoms and the requirement for parasitological testing for malaria diagnosis. Criteria for having performed a diagnostic assessment were if the dispenser offered a malaria RDT, asked if a malaria RDT or microscopy had been previously performed, or asked about clinical malaria symptoms.

Data management & analysis. The provider survey data were collected by personal digital assistant, and simulated-client and exit interview data were collected on scannable forms. All analysis was performed with SAS 9.3 (SAS Institute, Cary, NC). Statistical significance of categorical variables was assessed by χ^2 or Fisher exact tests with a significance level of $P \leq 0.05$. The proportion of providers who were adequately assessed for malaria was calculated, accounting for clustering by facility. Logistic regression models to identify significant ($P \leq 0.05$) predictors of malaria diagnostic knowledge were developed at the individual-provider level, accounting for clustering by facility. Intra-cluster correlation at the facility level was accounted for in all analysis.

Ethics. The study was approved by the ethical and institutional review boards of KEMRI (KEMRI/RES/7/3/1), Liverpool School of Tropical Medicine (#13.18), and Emory University. Centers for Disease Control and Prevention's involvement was deemed non-engaged by the Human Research Protection Office. Written informed consent was obtained from all providers and patients before interviews; verbal informed consent regarding future participation in a MiP study to assess diagnosis and treatment was obtained from the dispenser during the drug-outlet census.

RESULTS

After excluding nine health facilities because of ongoing studies, 52 facilities were eligible for the study; supervisors in 51 facilities (four hospitals, 19 health centers, and 28 dispensaries) consented to participate (Table 1).[18]

Malaria in pregnancy diagnostic knowledge. A total of 112 providers and dispensers across 86 point-of-care facilities were surveyed; 75 (67%) in health facilities and 37 (33%) in drug outlets. Of respondents, 44% were nursing staff, 16% were clinical officers or physicians, 18% were pharmacists (inclusive of degree, diploma, and certificate holders), and 13% were shopkeepers; overall, 52% were female.

Most (90%) providers reported suspecting malaria in patients presenting with fever; other clinical symptoms cited included headache (84%), vomiting (82%), body ache (67%), and chills (65%). Health-facility providers had significantly greater knowledge of clinical malaria symptoms compared with drug-outlet dispensers. Eighty-four percent of health-facility providers reported using parasitological testing (81% of providers reported using RDT and 70% reported using microscopy); 25% of those who did not use diagnostics reported always treating clinically versus regularly, sometimes, or never. In drug outlets where malaria diagnostics were not widely available, 30% reported always treating based on clinical symptoms, and 19% reported never treating based on clinical presentation alone. Among the 12 dispensers who reported using parasitological testing, 50% reported using microscopy and 75% reported using RDTs. Across all providers and dispensers surveyed, 93% exhibited correct malaria diagnosis knowledge, reporting that they used parasitological testing (microscopy or RDT) or, when testing/test results were unavailable, were able to describe signs and symptoms consistent with clinical malaria diagnosis (Table 2).

Malaria diagnosis in health facilities. A total of 209 eligible patients were interviewed across 51 health facilities: 111 (53%) nonpregnant women, 22 (11%) women in first trimester, and 77 (37%) women in second and third trimesters (Table 1).

TABLE 1
Characteristics by health facilities and drug outlets

	Health facilities		Drug outlets	
Characteristics	*N* = 51	%	*N* = 39	%
Facility managing authority				
Government	44	86.3	0	0.0
Mission	2	3.9	0	0.0
Private	5	9.8	39	100.0
Facility type				
Hospital	4	7.8	–	–
Health center	19	37.3	–	–
Dispensary	28	54.9	–	–
Total health facilities	51	100.0	–	–
Registered pharmacy	–	–	9	23.1
Informal drug shop	–	–	13	33.3
General shop	–	–	17	43.6
Total drug outlets	–	–	39	100.0
	Patient interviews		Simulated clients	
Patient encounter method	*N* = 209	%	*N* = 147	%
Pregnancy status				
Nonpregnant	111	53.1	72	49.3
First trimester	22	10.5	37	25.3
Second or third trimester	76	36.4	38	26.0

Of the 209 women, 160 (77%) were tested for malaria using either RDT or microscopy. Eighty percent of health facilities had confirmed malaria testing capacity; 160 (92%) patients were tested at these facilities. Hospitals and health centers had significantly higher testing rates than dispensaries (89% and 90% versus 64%, $P = 0.02$) (Table 3). Providers who had attended a malaria diagnostic training in the last 5 years were only one-fifth as likely to test for malaria (adjusted odds ratio = 0.2, 95% confidence interval 0.04–1.0, $P = 0.05$) (Table 4) as those who had not attended a training in the last 5 years. There was no difference in testing rates across pregnancy status (73% in first trimester, 79% in second/third trimester, and 76% in nonpregnant, $P = 0.79$), number of malaria symptoms at presentation (77% with zero to one symptoms versus 75% for two or more symptoms, $P = 0.66$) or for public versus private facilities (75% versus 91%, $P = 0.11$).

Nearly 60% (28/49) of women who were not tested were seen in facilities that did not have malaria diagnostic capacity. Therefore, 90% of women were properly assessed for malaria according to facility diagnostic capacity (Table 3). Of the 151 patients (94%) who tested positive for malaria, 98% received an antimalarial; no reason was provided for not prescribing an antimalarial to the remaining malaria-positive patients, although all facilities had antimalarials available on the day of the survey.[17] The three (100%) patients who tested negative for malaria were incorrectly prescribed an antimalarial. There was no difference in antibiotic prescribing for patients who were tested for malaria compared with those who were clinically diagnosed. Before antimalarial prescription, 61% of providers asked patients if they had received previous treatment of the current malaria episode and only 16% asked about allergies to medications.

Malaria diagnosis in drug outlets. A total of 77 simulated client dispenser encounters were completed at 39 drug outlets (Table 1). In 5% of all interactions (2 [22%] registered pharmacy interactions, 1 [8%] informal drug outlet, and 1 [6%] general shop interaction), dispensers either offered an RDT or asked if one had previously been performed; there was no difference between simulations when the woman was the simulated client or when a male relative was the simulated client. Nine (23%) drug outlets had RDTs available (5 [56%] of registered pharmacies, 4 [31%] of informal drug outlets, and no general shops); at these facilities, RDTs were offered or inquired upon in the case of a relative in 17% of simulations. Thirty-three percent of dispensers asked about any symptoms; 16% inquired about specific malaria symptoms. In 34% of all simulations, dispensers either asked about malaria symptoms or requested a prescription for an antimalarial before dispensing. A higher proportion of dispensers asked about malaria symptoms when interacting with female clients seeking treatment of themselves compared with male clients seeking treatment on behalf of a spouse (Table 5). Neither facility type nor recent MiP training were associated with diagnostic practice among drug outlets (Supplemental Table 1).

Of 27 clients who were not sold an antimalarial despite presenting with malaria symptoms in the simulations, 17 (63%) were referred to a health facility. Eight (30%) did not receive an antimalarial because of a stock out; other reasons included refusal to dispense an antimalarial without a prescription, diagnostic test, or clinical evaluation. Before dispensing, only 16% of dispensers asked the simulated client if any previous treatment had been given for the current illness and only 5% asked about potential medication allergies.

TABLE 2
Provider malaria diagnostic knowledge between health facility and drug outlet providers

	Overall			Health facilities			Drug outlets			
	N = 112	%	95% CI	*N* = 75	%	95% CI	*N* = 37	%	95% CI	*P* value
Recognition of clinical symptoms										
Fever	100	89.3	(83.5, 95.0)	70	93.3	(87.8, 98.9)	30	81.1	(68.2, 94.0)	P = 0.04
Chills	65	58.0	(47.9, 68.2)	55	73.3	(61.6, 85.1)	10	27.0	(12.4, 41.6)	P < 0.001
Headache	84	75.0	(66.4, 83.6)	64	85.3	(76.4, 94.3)	20	54.1	(37.7, 70.4)	P < 0.001
Vomiting	82	73.2	(64.4, 82.0)	64	85.3	(76.7, 93.9)	18	48.6	(32.2, 65.1)	P < 0.001
Body ache	66	58.9	(49.0, 68.9)	51	68.0	(55.8, 80.2)	15	40.5	(24.4, 56.7)	P = 0.01
Frequency of treatment based on clinical suspicion										
Always	19	17.0	(10.1, 23.9)	8	10.7	(4.0, 17.3)	11	29.7	(14.7, 44.8)	0.037
Regularly	13	11.6	(5.1, 18.1)	7	9.3	(1.8, 16.9)	6	16.2	(4.1, 28.3)	
Sometimes	56	50.0	(39.6, 60.4)	43	57.3	(44.3, 70.3)	13	35.1	(19.4, 50.8)	
Never	24	21.4	(12.6, 30.2)	17	22.7	(11.2, 34.1)	7	18.9	(6.0, 31.8)	
Use parasitological testing	75	67.0	(56.6, 77.3)	63	84.0	(73.1, 94.9)	12	32.4	(17.0, 47.8)	< 0.001
Microscopy	50	44.6	(32.9, 56.4)	44	58.7	(43.4, 73.9)	6	16.2	(4.1, 28.3)	< 0.001
RDT	60	53.6	(42.4, 64.7)	51	68.0	(54.8, 81.2)	9	24.3	(10.2, 38.4)	< 0.001
Correct malaria diagnosis knowledge*	104	92.9	(88.0, 97.7)	73	97.3	(93.7, 100.0)	31	83.8	(71.7, 95.9)	P = 0.01

CI = confidence interval; RDT = rapid diagnostic test.
* Correct malaria diagnosis is defined as the utilization of microscopy or RDT, or clinical diagnosis when diagnostic testing is unavailable.

Antimalarial dosage and timing directions were given to 87% of simulated clients.

DISCUSSION

Overall, provider and dispenser knowledge of clinical malaria signs and symptoms was very high across health facilities and drug outlets. However, health facilities and drug outlets differed significantly when it came to both observed and self-reported malaria parasitological testing. In health facilities overall, just over three-quarters of women with symptoms were tested for malaria, but in facilities with diagnostic capacity, 92% were tested. In drug outlets overall, only 5% of simulated clients were offered or asked about malaria testing results. In the few drug outlets with malaria RDTs, less than one-fifth of simulated clients were offered testing. No differences in parasitological testing rates by pregnancy status were observed in either health facilities or drug outlets. The findings suggest that the single largest factor contributing to malaria testing was access to diagnostics at the point of service.

Sixty percent more pregnant women were tested for malaria at facilities in western Kenya compared with the national estimates of parasitological testing among the general population in 2013 (92% versus 58%).[7] Pregnant women were tested more despite lower availability of diagnostics (80%) in surveyed facilities in Siaya County compared with 90% nationally.[7] These findings are consistent with a previous study at a provincial hospital in Garissa, northeastern Kenya, which cited high adherence to parasitological diagnosis among pregnant patients and similar to 2013 diagnostic capacity and testing rates in neighboring Tanzania (80% and 63%, respectively).[20,21] The high parasitological testing for malaria among pregnant women is encouraging; pregnant women might be more likely to be prioritized for testing, particularly in the HDSS area of Siaya County, which

TABLE 3
Malaria diagnostics practice in health facilities as observed through exit interviews stratified by facility type

	Overall			Hospital			Health center			Dispensary			
	N	%	95% CI	*N*	%	95% CI	*N*	%	95% CI	*N*	%	95% CI	*P* value
Tested for malaria	209	–	–	18	–	–	83	–	–	108	–	–	–
Yes	160	76.6	(64.9, 88.3)	16	88.9	(68.2, 100.0)	75	90.4	(77.9, 100.0)	69	63.9	(46.0, 81.8)	0.02
No	48	23.0	(8.0, 38.0)	2	11.1	(0.0, 31.8)	8	9.6	(0.0, 25.2)	38	35.2	(10.7, 59.7)	
Don't know	1	0.5	(0.0, 1.4)	0	0.0	–	0	0.0	–	1	0.9	(0.0, 2.7)	–
Malaria test results	160	–	–	16	–	–	75	–	–	69	–	–	–
Positive	151	94.4	(90.4, 98.3)	14	87.5	(68.3, 100.0)	70	93.3	(87.3, 99.4)	67	97.1	(93.6, 100.0)	–
Negative	3	1.9	(0.0, 4.5)	2	12.5	(0.0, 31.7)	1	1.3	(0.0, 3.6)	0	0.0		–
Don't know	6	3.8	(0.7, 6.8)	0	0.0	–	4	5.3	(0.0, 10.8)	2	2.9	(0.0, 6.4)	–
Test location	160	–	–	16	–	–	75	–	–	69	–	–	–
Outpatient clinic	28	17.5	(5.6, 59.4)	0	0.0	–	3	4.0	(0.0, 10.3)	25	36.2	(13.3, 59.2)	–
Laboratory	131	81.9	(69.6, 94.1)	16	100.0	–	72	96.0	(89.7, 100.0)	43	62.3	(38.8, 85.9)	–
Pharmacy	1	0.6	(0.0, 1.9)	0	0.0	–	0	0.0	–	1	1.4	(0.0, 4.4)	–
No diagnostic test	49	23.3	–	2	11.1	–	18	21.7	–	57	52.3	–	–
Correct clinical diagnosis*	28	57.1	(37.2, 77.1)	0	0.0	–	4	50.0	(3.3, 96.7)	24	61.5	(40.1, 82.6)	0.45
Incorrect diagnosis†	21	42.9	(22.9, 62.8)	2	100.0	–	4	50.0	(3.3, 96.7)	15	38.5	(17.0, 59.9)	–
Correct malaria diagnosis	188	90.0	(85.2, 94.7)	16	88.9	(68.2, 100.0)	79	95.2	(90.4, 99.9)	93	86.1	(79.2, 93.0)	0.20

CI = confidence interval.
* Correct clinical diagnosis indicates women presenting with fever, multiple symptoms, and/or were pregnant with symptom(s) at facilities without diagnostic capacity.
† Incorrect diagnosis indicates patients treated for malaria without diagnostic testing at facilities where it was available or without clinical presentation if at a facility with no diagnostic capacity.

TABLE 4
Predictors of malaria parasitological testing in health facilities with confirmed diagnostic capacity

Predictor	*N*	%	Crude OR	95% CI	*P* value	Adjusted OR	95% CI	*P* value
Facility type	151	–	–	–	–	–	–	–
Health center or hospital	80	53.0	4.3	(0.8, 21.6)	0.08	3.0	(0.6, 15.5)	0.19
Dispensary (reference)	71	47.0	–	–	–	–	–	–
Malaria symptoms at patient presentation								
0–1	104	68.9	3.0	(1.0, 8.7)	0.05	3.0	(1.0, 9.7)	0.06
2 or more (reference)	47	31.1	–	–	–	–	–	–
Providers completed malaria diagnostic training in prior 5 years								
Yes	55	36.4	0.2	(0.03, 0.8)	0.02	0.2	(0.04, 1.0)	0.05
None (reference)	96	63.6	–	–	–	–	–	–

CI = confidence interval; OR = odds ratio.

has been the site of numerous malaria interventions historically and likely resulted in increased awareness among health-care providers.[12] The increased diagnostic capacity at health facilities due to the national RDT implementation, which started in late 2012, has certainly contributed to the high testing rates observed. From 2010 to 2013, malaria microscopy capacity at the health-facility level was unchanged at 51%, whereas malaria RDT capacity increased from 8% to 70% nationally.[7]

In Kenya, only registered health facilities are officially allowed to provide diagnostic testing, including malaria RDTs. Private-sector drug outlets, including registered pharmacies that are licensed to sell medications, are not licensed to provide point-of-service diagnostic testing.[18] Thus, diagnostic capacity in drug outlets was very low at the time of the study with less than one-quarter of drug outlets stocking malaria RDTs.[18] Only one-quarter of surveyed drug outlets were registered pharmacies; most of the drug outlets in rural communities are unlicensed informal drug outlets and general shops. Despite not being licensed to sell medications, there is evidence that these informal drug outlets increased availability and affordability for quality-assured artemisinin-combination therapy in rural communities.[22] Furthermore, evidence from private-sector malaria RDT pilots across malaria-endemic countries, including Kenya, has demonstrated that the use of RDTs in drug shops can improve appropriate case management and is comparable to use in health facilities, particularly when coupled with the implementation of quality assurance systems and point-of-use guidance tools.[23] In addition, the private-sector market in Kenya can sustain unsubsidized quality-assured RDTs. Consumer and provider marketing of RDTs in Kenya doubled the monthly sales, suggesting that awareness of mRDTs can build and sustain demand.[23] These results are driving crucial changes in national policies and regulations to allow point-of-service diagnostic testing at registered pharmacies to improve malaria case management practices.[23–26] Increased and sustained advocacy for updated policy surrounding licensing for quality-assured mRDTs in drug outlets, which are often the first point of care, is a necessary first step to increase diagnostic testing rates.

No significant associations between pregnancy status and parasitological testing were observed in either health facilities or drug outlets, which is incongruous with recent meta-analysis findings.[8] Parasitological testing by pregnancy status was consistent across all facilities with diagnostic availability. Improving patient and customer access to malaria diagnostic testing through increased availability of malaria RDTs at health facilities and private-sector drug outlets is crucial to meeting national strategy targets for case management. Interestingly, neither malaria diagnostics nor MiP trainings were associated with increased testing in this study. Studies in Tanzania and Uganda have introduced behavior change interventions to support the use of malaria RDTs, including the use of feedback and motivational text messages, small group workshops, and ensuring availability of treatment algorithms and medications for non-malaria febrile illnesses.[27,28] In addition, evidence from neighboring countries suggests that educational initiatives around the importance of malaria testing for both providers and the general public should be expanded.[26] Intensive communication campaigns via television and radio mass media were an effective means to improve private-sector provider awareness and knowledge of malaria case management,

TABLE 5
Malaria assessment practice in drug outlets observed via simulated clients stratified by pregnancy status

	Overall			WOCBA or first trimester			Relative: second or third trimesters			
	N	%	95% CI	*N*	%	95% CI	*N*	%	95% CI	*P* value
Symptoms	77	–	–	38	–	–	39	–	–	–
Any inquiry	25	32.5	(21.6, 43.3)	15	39.5	(23.2, 55.7)	10	25.6	(11.3, 40.0)	0.20
Specific	12	15.6	(7.1, 24.1)	4	10.5	(0.3, 20.7)	8	20.5	(7.3, 33.8)	0.23
Fever	7	9.1	(1.7, 16.5)	6	15.8	(3.7, 27.9)	1	2.6	(0.0, 7.8)	0.02
Chills	3	3.9	(0.0, 8.3)	3	7.9	(0.0, 16.9)	0	0.0	–	–
Headache	10	13.0	(5.7, 20.2)	8	21.1	(7.5, 34.6)	2	5.1	(0.0, 12.4)	0.05
Nausea	6	7.8	(0.7, 14.9)	4	10.5	(0.3, 20.7)	2	5.1	(0.0, 12.4)	0.30
Pain	3	3.9	(0.0, 8.3)	2	5.3	(0.0, 12.7)	1	2.6	(0.0, 7.8)	0.55
Prescription	4	5.2	(0.0, 11.5)	1	2.6	(0.0, 8.0)	3	7.7	(0.0, 16.4)	0.17
Diagnostic test or test inquiry	4	5.2	(0.0, 11.5)	2	5.3	(0.0, 12.7)	2	5.1	(0.0, 12.4)	0.35
Any malaria diagnostic inquiry	26	33.8	(22.4, 45.2)	16	42.1	(25.7, 58.5)	10	25.6	(11.3, 40.0)	0.12

CI = confidence interval; WOCBA = women of childbearing age.

particularly in areas comparable to western Kenya.[29] Quality assurance systems that integrate routine reporting systems such as district health information software 2 and Foundation for Innovative New Diagnostics' troubleshooting guide for mRDTs[30] offer an opportunity to monitor and improve provider performance.[23]

All patients, including pregnant women, should receive malaria parasitological testing to ensure appropriate treatment and prevent complications. Although no differences in malaria testing were observed by pregnancy status, testing for malaria is particularly crucial for women in the first trimester of pregnancy. In health facilities, almost three-quarters of women in the first trimester of pregnancy were tested compared with only 5% of clients simulating a first-trimester pregnancy either by being asked for diagnostic test results or offered a diagnostic test in drug outlets. In the absence of diagnostic testing, pregnant women are at risk of being incorrectly diagnosed with malaria and not appropriately treated for other causes of febrile illness. In addition, incorrect diagnoses result in unnecessary treatment with an antimalarial, which has the potential to cause adverse events in the woman and threatens the efficacy of antimalarial drugs in the population. The only recommended treatment of uncomplicated malaria in first-trimester pregnant women is quinine. Artemisinin-combination therapies are presently not recommended during the first trimester of pregnancy because of limited available data on human exposures and the potential for teratogenicity.[31]

Limitations and challenges. Correct diagnostic practice in patients evaluated in health facilities might have been overestimated; for 20% of health facilities, diagnostic capacity at the facility was not confirmed. These facilities were either health centers or dispensaries, which were assumed to not have malaria diagnostic capacity based on historical knowledge of them never having had microscopy or RDTs. Therefore, a clinical diagnosis of malaria in these facilities was considered correct. In addition, the type of parasitological test, microscopy or RDT, was not collected nor were they subjected to quality assurance to confirm a malaria diagnosis. Therefore, patients could have been misclassified. Because overdiagnosis is common for clinically- and microscopically diagnosed malaria in Kenya, the study likely overestimated correct diagnosis.[32,33] Recall bias was minimized by conducting exit interviews directly after patient–clinician interaction. Rapid diagnostic test availability at the time of the study may have been negatively affected by the loss of 4.2 million RDTs in a central warehouse fire in early 2013, which resulted in widespread stock-outs and delayed integration of RDTs into the malaria community case management strategy.[34] Last, the small number of drug outlets with malaria RDTs prevented stratification by facility type, limiting a more robust analysis.

CONCLUSION

Both provider and dispenser knowledge of clinical malaria signs and symptoms was very high across health facilities and drug outlets in Siaya County, western Kenya. Over three-quarters of health facilities had malaria diagnostic capacity and almost all pregnant women with suspected malaria had parasitological testing before treatment. However, less than one-quarter of drug outlets, where many people in rural communities first seek care in Kenya, had malaria RDTs. Limited malaria RDT availability at drug outlets is likely reflective of both a lack of regulatory guidance for point-of-service diagnostic testing and limited customer demand. Moreover, only one-third of dispensers asked about malaria symptoms or requested a prescription before dispensing antimalarials to pregnant women. The most important factor associated with malaria testing of pregnant women was the availability of diagnostic capacity at the point of service. The study demonstrated the need to increase the availability of malaria diagnostic services, particularly among drug outlets. To increase malaria diagnostic testing at the drug-outlet level, regulatory action and implementation of pilot projects should be a priority. A clear diagnostic testing policy for the private sector is a crucial first step toward facilitating successful strategies that create awareness and demand for malaria testing before treatment in rural communities, including evidence-based educational initiatives and behavior change interventions in Kenya.

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