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STUDY REPORT

The Use of Malaria Rapid Diagnostic Tests in Private and Public Health Facilities in Shinyanga, Simiyu and Geita Regions of Tanzania



JUNE 2015

This study report was prepared by University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and was authored by Eliphace Mkumbo, Naiman Msangi, Michael Bajile, Christine Skladany (MSH consultant) and Mwita Wambura, an external consultant. The work described was conducted under the USAID Diagnosis and Management of Febrile Illness (Tibu Homa) Program which is managed by URC under Cooperative Agreement No. 621-A-00-11-00011-00 and is made possible by the generous support of the American people through USAID.

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DISCLAIMER

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Acronyms

ACT	Artemisinin-based Combination Therapy
AMREF	Africa Medical and Research Foundation
CM	Case Management
DMOs	District Medical Officers
HCW	Health Care Worker
KAP	Knowledge, Attitude and Practices
MoHSW	Ministry of Health and Social Welfare, Government of Tanzania
mRDT	Malaria Rapid Diagnostic Test
MSD	Medical Stores Department
MSH	Management Sciences for Health
MTCs	Medicines and Therapeutic Committees
PQITs	Pediatric Quality Improvement Teams
RMOs	Regional Medical Officers
R&R	Reporting and Requisition
SCM	Supply Chain Management
SOP	Standard Operating Procedures
SS	Supportive Supervision
SS&M	Supportive Supervision and Mentorship
TDHS	Tanzania Demographic Health Survey
USAID	United States Agency for International Development
URC	University Research Co., LLC

EXECUTIVE SUMMARY

Background: Tanzania is among the six countries with the highest malaria morbidity and mortality ¹rate in the world, especially in children under the age of five (5). The USAID-funded Tibu Homa (Treat Fever) project in the Lake Zone of Tanzania has the overall goal of reducing morbidity and mortality in children under five due to severe febrile illness. The main objective is to treat all children Under-five within 24 hours of onset of fever, using malaria Rapid Diagnostic Test (mRDT) followed by treatment as appropriate, for example, artemisinin combined therapy (ACT) should mRDT result be positive. However, project supervisors have noted a tendency among some health care workers to ignore the results of mRDT tests and treat children empirically with anti-malarials. This study was designed to: 1) Identify the extent of this practice; 2) Develop a profile of Health Care Workers (HCW) who routinely ignore mRDT results and the reasons why they follow this practice; and 3) Identify interventions to improve the quality of malaria diagnosis and treatment.

Methodology: The project staff developed survey tools for hospitals, health centers and dispensary staff assessment to measure knowledge and attitudes towards mRDTs, the correct use of the mRDT, and patient assessment. A cross-sectional sample of 51 facilities in three Lake Zone Regions (Shinyanga, Geita, and Simiyu) was conducted. The sample included four (4) hospitals, 12 health centers and 35 dispensaries, and a total of 184 observed evaluations and treatments for febrile illness in children under-five were included in the analysis.

Results: The results showed that overall, only 64% of HCWs completed all steps necessary for an accurate mRDT. Use of the mRDT in febrile illness varied by Region: 67% in Simiyu, 87% in Geita, and 96% in Shinyanga. Treatment for malaria even with a negative mRDT was low; 12% in private facilities and 7.8% in public facilities, but the differences are not statistically significant. The study showed a high acceptance rate for using mRDTs for diagnosis of malaria, ranging from 87% to 100% in the regions studied. Advantages of using the mRDT cited by the study participants were (in decreasing order): 1) Shorter time for results (76.5%); 2) More accurate diagnosis (63%); 3) Ease of use (58%); 4) Targets treatment (44%); 5) No electricity required (28%); 6) Patient satisfaction (18%). Disadvantages cited by participants include (in decreasing order): 1) Negative results in patients with high fevers (28.4%); 2) Does not quantify the parasite (21.6%); 3) Inaccurate results (18.5%); 4); and, Lack of confidence in results by parents (1.7%).

Conclusion: Overall, the results show a high degree of acceptance and use of the mRDT in evaluating fever in children Under-five, and only a relatively small percentage of treating HCWs ignore negative results and treat for malaria presumptively (7.8%-12%). However, a quarter of providers don't trust the results in a child with a high fever. The study assessed the HCWs competency to perform mRDT procedures using the mRDT checklist previously developed. Almost 98% of HCWs assembled the mRDT kit correctly, but only 64% of the HCWs performed all 15 steps correctly. The most common error was failure to write the patient

¹ The most recently published Tanzania Demographic and Health Survey (TDHS 2010) revealed that the national under five mortality rate had declined from 112 per 1000 live births in 2003/04¹ to 81 per 1000 live births in 2010¹. However, in the Lake Zone region of Tanzania, it remains high with an estimated under five mortality rate of 109 per 1000 live births in 2010¹. The high under five mortality rate in the Lake Zone is closely linked to lack of successful child survival interventions, including inadequate malaria control efforts in the region.

name and ID number on the cassette, raising the possibility of erroneous recording of results in the chart

Recommendations: A combination of continued in-service training, clear and simple bench-site job aids, supportive supervision and mentoring visits will contribute to correct end-user's performance. Supportive supervision visits need to focus on the correct use of the mRDT and to increase confidence in using the results to guide treatment. These steps need to be combined with public education on the value of an mRDT, and wide dissemination that only 30% of fevers are now caused by malaria, the majority are caused by other diseases. HCWs should be advocates for mRDT—a role they have yet to step in to in order to counteract parental pressure to prescribe ACTs when they are not required.

1. INTRODUCTION

The Tibu Homa project (funded by USAID), in collaboration with the Ministry of Health and Social Welfare (MoHSW) and other partners are implementing a collaborative project in the Lake Zone regions to address febrile illness among children under the age of five years. The most recently published Tanzania Demographic and Health Survey (TDHS 2010) revealed that the national under five mortality rate had declined from 112 per 1000 live births in 2003/04² to 81 per 1000 live births in 2010³. However, in the Lake Zone regions of Tanzania, it remains high with an estimated under five mortality rate of 109 per 1000 live births in 2010⁴. The high under five mortality rate in the Lake Zone is closely linked to lack of successful child survival interventions, including inadequate malaria control efforts in the region.

The Tibu Homa project aims to improve the diagnosis and management of severe febrile illness in children under-five years of age, focusing on improving case management at the facility level (both public and private). The project is jointly implemented by University Research Corporation (URC), Management Sciences for Health (MSH), and African Medical and Research Foundation (AMREF). MSH contributes to improving case management at the facility level by ensuring availability of medicines and other diagnostics, including malaria rapid diagnostic tests (mRDTs) and training of health care workers (HCWs) in accurate diagnosis and treatment of febrile illness.

In Tanzania, as in most sub-Saharan Africa settings, malaria is the first reported cause of attendance to the health facilities. The National Bureau of Statistics estimates that a total of 16 million cases and 100,000 deaths (mainly children) in Tanzania are due to malaria each year⁵. The majority of these deaths could have been avoided if there were prompt diagnosis and proper case management of malaria and other febrile illnesses within 24 hours, which inevitably depends on correct diagnosis of malaria using mRDTs or microscopy. However, due to the high cost and poor quality of microscopy, the project stresses the use of mRDTs over microscopy.

The Tanzanian Ministry of Health and Social Welfare (MoHSW) is implementing a strategy to roll out mRDTs at all levels of health care, in both public and private facilities. However, after roll-out almost 50% of febrile patients still did not receive a diagnostic test, and almost 50% of patients testing positive did not receive ACTs, according to a study conducted in Mwanza, Mbeya, and Mtwara⁶ in 2013 in the Lake Zone project areas.

Tibu Homa has implemented a number of key interventions at the facility level, including a) training Pediatric Quality Improvement Teams (PQITs) on Supply Chain Management (SCM),

² Tanzania Commission for AIDS (TACAIDS), National Bureau of Statistics (NBS), and ORC Macro. 2005. *Tanzania HIV/AIDS Indicator Survey 2003-04*. Calverton, Maryland, USA: TACAIDS, NBS, and ORC Macro

³ Tanzania National Bureau of Statistics and ICF Macro. 2011. *2010 Tanzania Demographic and Health Survey: Key Findings*. Calverton, Maryland, USA: NBS and ICF Macro.

⁴ Tanzania National Bureau of Statistics and ICF Macro. 2011. *2010 Tanzania Demographic and Health Survey: Key Findings*. Calverton, Maryland, USA: NBS and ICF Macro.

⁵ Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC), National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), and ICF International 2013. *Tanzania HIV/AIDS and Malaria Indicator Survey 2011-12*. Dar es Salaam, Tanzania: TACAIDS, ZAC, NBS, OCGS, and ICF International.

⁶Bruxvoort K, Kalolella A, Nchimbi H, Festo C, Taylor M, Thomson R, Cairns M, Thwing J, Kleinschmidt I, Goodman C, Kachur SP: Getting antimalarials on target: impact of national roll-out of malaria rapid diagnostic tests on health facility treatment in three regions of Tanzania. *Trop Med Int Health* 2013 Oct; 18(10):1269-82. doi: 10.1111/tmi.12168. Epub 2013 Aug 13

b) monthly joint Supportive Supervision visits c) logistic mentorship to providers in facilities through revitalization of Medicines and Therapeutic Committees (MTCs) and d) follow up on the functionality and performance of the MTCs. The Tibu Homa Annual Report 2013-2014 demonstrates the improvement in the availability of tracer medicines, mRDTs and ACTs over the course of the reporting year⁷. However, during Supportive Supervision and Mentorship visits, the Tibu Homa project staff has observed that some Health Care Workers do not use the results of mRDTs and may prescribe antimalarials even with a negative mRDT result. Therefore, this study was developed to determine the extent of this practice, develop a profile of HCWs who do not use the mRDT results, and develop interventions to improve the use of mRDTs for accurate treatment of malaria.

The objectives of the study are three-fold:

1. To determine whether malaria RDTs are correctly used to test children under five years of age presenting with fever at a health facility;
2. To assess the attitude of private and public facility health care workers on the use of mRDT and acceptability of mRDT results;
3. To identify interventions to improve the quality of malaria testing and treatment.

This report is set out in four chapters. Following this chapter, Chapter 2 presents the methods used to collect and analyze data while Chapter 3 describes the findings of the study. Chapter 4 consolidates the material and highlights conclusions and recommendations.

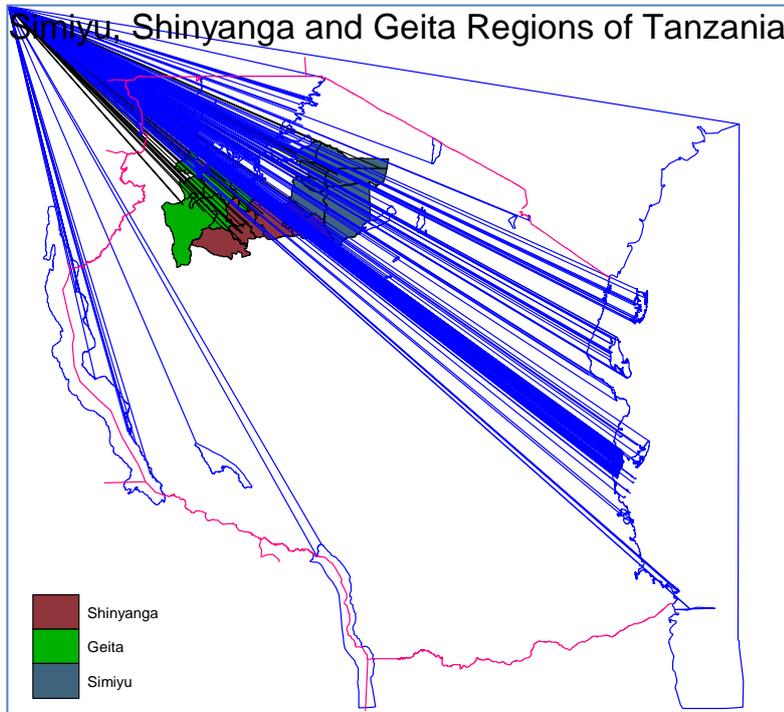
⁷Tibu Homa Project. Significant improvement in the availability of ACTs - 11% (Jan.2012) - 80 % (June 2014) in public facilities and – 32%-89% in private facilities.

2. METHODOLOGY

2.1 Study Design

A cross-sectional survey was conducted in the Lake Zone regions⁸; Shinyanga, Simiyu, and Geita (Figure 1). The project has scaled down most of its activities in the start-up regions of Mwanza, Kagera and Mara due to the imminent closure of the project.

Figure 1. Location of Study Regions in Tanzania



2.2 Selection of Health Facilities

Purposeful sampling was used for selecting study health facilities, while random sampling was used to select health care workers⁹treating children with fever; and, laboratory personnel¹⁰ at the selected facilities. Prior to study facility selection, a list of all Tibu Homa supported facilities was developed and stratified by three key criteria:

- Ownership (public vs. private)
- Type of facility (hospital, health center and dispensary)
- Study regions (Shinyanga, Simiyu, and Geita)

Out of 151 project-supported facilities (Table 1), a purposeful sampling was done to select 51 health facilities to be included in the survey. Of the 51 facilities, 17 facilities (6 private, 11 public) were selected in Geita region, 17 facilities (6private, 11public) selected in Shinyanga and 17 facilities (8 private, 9 public) selected in Simiyu region. A total of 4hospitals, 12 health centres and 35 dispensaries were selected in the three study regions.

⁸Mwanza, Kagera, Mara, Shinyanga, Simiyu, and Geita

⁹ Health Care Workers included the following: Clinicians, nurses and nursing assistants.

¹⁰Laboratory personnel included the following: laboratory technicians, laboratory technologists, and laboratory attendants.

Table 1: Number of Health Facilities in 3 project regions (Geita, Shinyanga and Simiyu)

Region	Public			Private			Total
	Hospitals	Health Centers	Dispensaries	Hospitals	Health Centers	Dispensaries	
Geita	1	6	19	0	2	13	41
Shinyanga	1	6	41	2	1	3	54
Simiyu	2	6	46	0	1	1	56
Total	4	18	106	2	4	17	151

Considering type and level of facilities, public facilities outnumber corresponding private facilities by a ratio of 2 or more. Given the smaller number of private facilities and the desire to probe in this area, a larger proportion of private facilities (82.6%) were selected into the study compared to public facilities (25%).

Within the selected facility, a random sampling was used to select two key professional cadres: health care workers treating children with fever; and, laboratory personnel who performed malaria diagnostic testing at Tibu Homa supported public and private facilities. Up to four health providers were interviewed in hospital and health centers, given the higher number of staff, while two health providers were interviewed at the dispensary level. Two types of professional cadres were targeted: the first cadre included clinicians, nurses, nurse assistants; and the second cadre included laboratory technicians, laboratory technologists, and laboratory assistants (Table 2).

Table 2: Overview of methodology related to study questions

Objectives	Methodology	Eligibility Criteria	Sampling	Assumptions	Sample Size
1. Are mRDTs correctly being used to test children under-five years of age presenting with fever?	<p>Use checklist to observe testing of malaria using mRDT for children presenting with febrile illness. A minimum of 3 to 5 children per health care facility will be observed. The aim is to assess whether mRDT are correctly being used to test children under-five years of age presenting with fever.</p> <p>Questionnaire administered to Health Care Workers and laboratory personnel attending children under-five presenting with febrile illness. The aim to assess whether HCWs use mRDT correctly during management of febrile illness.</p>	<ul style="list-style-type: none"> • Aged less than 5 years who is at the facility with fever complaint • Care taker has given an oral informed consent • Healthcare workers (clinicians, nurses) and laboratory personnel managing children under-five years • Provided a written informed consent 	<p>Between 3 and 5 under five children observed. Cases selected randomly.</p> <p>Random selection by cadre: - Up to 3 HCWs in Hospital & Health Centers -Up to 2 HCWs for Dispensaries.</p>	<p>The number of observations will depend on the number of children with febrile illness on the day.</p> <p>The no. of HCWs at the selected health facilities is unknown and varies with level and type of ownership.</p>	<p>Between 153 and 255</p> <p>118 HCWs</p>
2. To assess the extent to which mRDT results are used to guide febrile illness treatment.	<p>Medical Record Review: Patient registers of 10 under-five children with fever who sought treatment at the target facilities during a fourteen-day (14) period (prior to the team's visit) will be reviewed to assess whether children were tested with mRDT, results of mRDT and what treatment was offered.</p>	<ul style="list-style-type: none"> • Aged less than 5 years who presented at a facility with fever complaint in the last 14 days 	<p>10 records reviewed randomly</p>		<p>510</p>
3. Assess the attitude of private and public facility health care workers on use of mRDT and acceptability of mRDT results.	<p>Questionnaire administered to HCW and laboratory personnel attending children under-five presenting with febrile illness. The aim is to assess the attitude of HCWs on the use of mRDT and acceptability of mRDT results.</p>	<ul style="list-style-type: none"> • Healthcare workers (clinicians, nurses) and laboratory personnel managing children under-five years • Provided a written informed consent 	<p>Random selection by cadre: - Up to 3 HCWs in Hospital and Health Centers -Up to 2 HCWs for Dispensaries.</p>	<p>The no. of HCWs at the selected health facilities is unknown and varies with level and type of ownership.</p>	<p>118 HCWs</p>

2.3 Data Collection

Data were collected using the questionnaire shown in Annex I. Three tools were used to collect data: 1) Knowledge, Attitude and Practices (KAP) questionnaire administered by trained research assistants to selected HCWs. 2) Check list for mRDT observation visits 3) Patient Care Assessment form.

The KAP questionnaire was used to assess private and public health care workers on the use of mRDT and acceptability of mRDT results. This tool contained questions on HCWs roles in utilizing mRDT, mRDT training, advantages and disadvantages of using mRDT. Other questions were HCWs confidence with mRDT results, whether HCWs prescribe antimalarials to under-fives with negative mRDT results, level of trust of parents /guardians in mRDT results and whether parents/guardians demand antimalarials even when their children have a negative mRDT result and HCWs knowledge questions about mRDT.

A check list for observation visits (unannounced spot checks) by trained enumerators on how mRDT is used in the facility based on Standard Operating Procedures and guidelines currently in use by MoHSW. The observation checklist contained questions on laboratory guides and standard operating procedures, availability of equipment, supplies and consumables and observations on mRDT preparation and utilization.

Patient Care Assessment form collected information on health care workers' practices in prescribing and dispensing medicines for management of febrile illness in children under-five years of age. Data collectors reviewed the OPD charts for 10 randomly selected children who were seen and treated for fever at the selected facilities in the past two weeks. Key data collected for these children included age, sex, whether mRDT was used, final diagnosis, and medications that were prescribed. No names or other identifying information was collected from patient charts.

The assessment required interviewer's knowledge and experience in medicine, laboratory and nursing of malaria case management to collect valid and reliable data, and required interviewer's familiarity with the organization of the local health system.

Data collectors were recruited and trained on the contents of the data collection forms and interview techniques. . After training, three teams with four members in each team were set up; the field data collection exercise took 12 days. At the end of each interview, supervisors reviewed the completed questionnaire to assess quality and reduce errors.

Data collectors visited each of the selected facilities, interviewed the appropriate health personnel, and conducted unannounced observation visits and reviewed patient files /registers for a period of fourteen days prior to the visit.

2.4 Sample Size

For this study, investigators aimed to accurately determine the proportion of children under five years with febrile illnesses who were correctly tested with mRDT. This proportion was expected

to be 50% (considering maximum variation). Allowing 4% error (i.e. 45-55%) and with the total population of under-five in the 3 regions estimated at 900 000¹¹, a sample size of 384 children with febrile illness was sufficient to determine the proportion of children under five with febrile illnesses who were correctly tested with mRDT at the 95% confidence level. To obtain a representative sample from the study facilities, respondents were sampled from hospitals, health centers and dispensaries.

2.5 Data Management

All questionnaires were entered by two independent data entry clerks in EpiData and comparison done to check for consistency. Data cleaning involved range and consistency checks. The data were cleaned and analyzed using the STATA data analysis software (STATA Corp 2011).

2.6 Data Analysis

Data were presented separately by district and chi-square tests were used to compare the similarity of the study districts with respect to age, sex and correctly testing children under-five with febrile illness. The chi-square statistic with its P values is reported where appropriate.

2.7 Ethics

Approval of this protocol was sought from the Lake Zone IRB. Permission from Regional Medical Officers (RMOs) and District Medical Officers (DMOs) and Medical Officers/Clinicians in-charge of selected facilities were also sought. Explanation to parents/care takers about the study was given and informed consent for use of information obtained in the study was sought. Verbal informed consent was obtained from each care taker by the research assistant who made it clear that participation was voluntary. Parents/care takers were informed that refusal to allow use of child's information would in no way affect the services offered to the child at the facility. Finally, private information obtained from caretakers, facility workers, and facilities in general was kept confidentially.

¹¹ National Bureau of Statistics (NBS), *National census survey 2012*. Dar es Salaam, Tanzania

3. RESULTS

3.1 Description of the Health Facilities Visited

Table 3 presents the health facilities visited by type of facility and ownership. Twenty (20) private facilities (1 hospital, 2 health centers and 17 dispensaries) and thirty-one (31) public facilities (3 hospitals, 10 health centers and 18 dispensaries) were included in the study.

Table 3: Selected Facilities by Ownership and Level of Facility

	Geita Region		Shinyanga region		Simiyu Region		Overall	
	Private	Public	Private	Public	Private	Public	Private	Public
Hospital	0	1	1	1	0	1	1	3
Health Centre	0	4	1	3	1	3	2	10
Dispensary	6	6	4	7	7	5	17	18

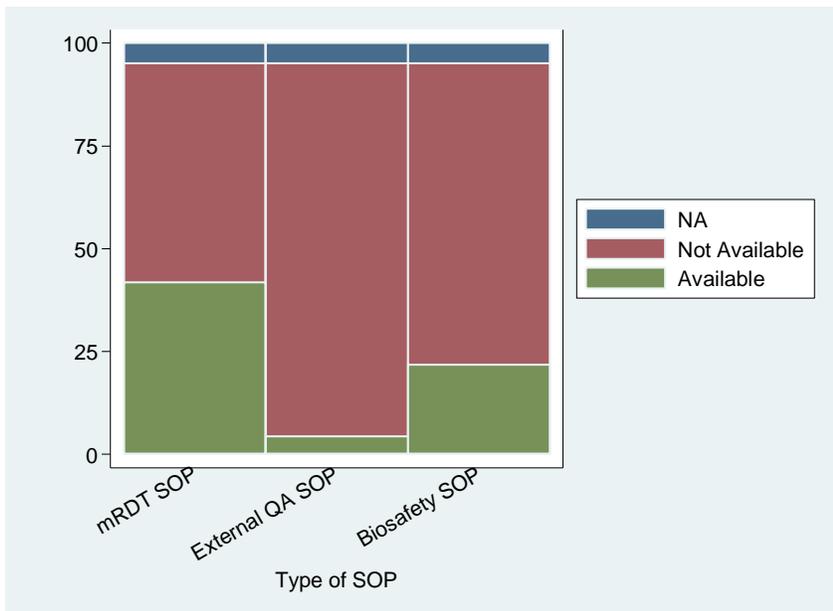
3.2 Malaria RDT Observation Checklist

An observation checklist was used to observe preparation and testing using malaria RDTs. All observations were done by trained study staff using real patients, not volunteers. The study staff observed the entire process, including finger-pricking, to ensure that blood safety practices are being followed. A standard checklist was used for all observations.

A total of 184 observations (64 Simiyu, 65 Geita and 55 Shinyanga) were done in 51 health facilities. Of these, 165 under-fives were tested for malaria by Malaria RDT while 19 were tested for malaria by microscope. Generally, 35/165 (21.2%) had a positive mRDT result. This proportion was high in Geita region (32.1%), moderate in Shinyanga region (20.4%) and low in Simiyu region (10.9%), perhaps reflecting regional differences in malaria incidence.

Of the 51 facilities visited, 8 facilities (3 facilities in Simiyu, 3 in Geita and 2 in Shinyanga) were using microscope while 43 (14 Simiyu, 14 Geita and 15 Shinyanga) were using malaria RDT for testing malaria infection. Figure 2 present the proportion of HCWs with mRDT Standard Operating Procedures (SOP), external quality SOP and bio-safety SOP.

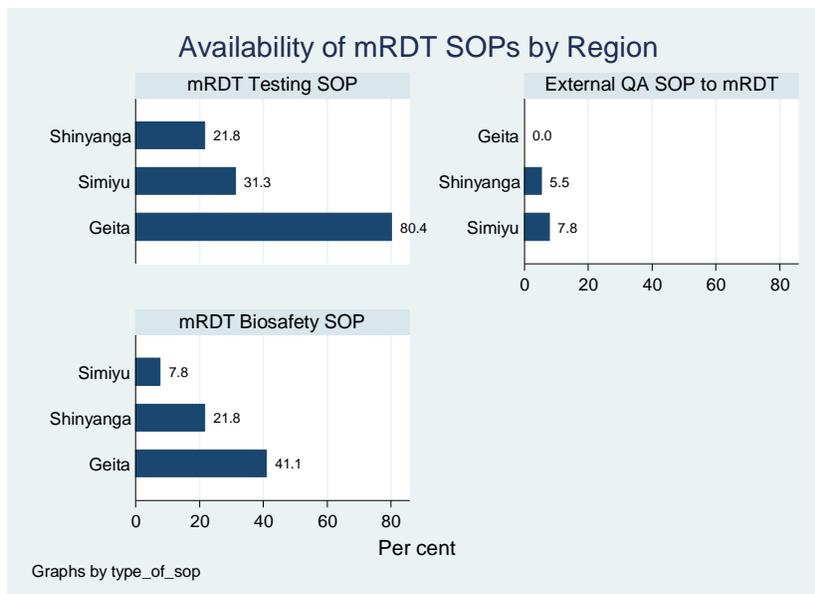
Figure 2: Availability of Malaria RDT SOPs



Only 4.4% of the HCWs had external quality assurance for microscopy (Figure 2). Almost 42% of the HCWs had a SOP on how to perform malaria RDT tests while 21.7% had bio-safety SOP.

Figure 3 presents the availability of malaria RDT SOPs by region. A SOP on RDT performance (mRDT SOP) were more available in the facilities visited while bio-safety SOP was less common in the facilities visited. External quality control SOP was unavailable in most of the facilities visited (Figure 3).

Figure 3: Availability of Malaria RDT SOPs by Region



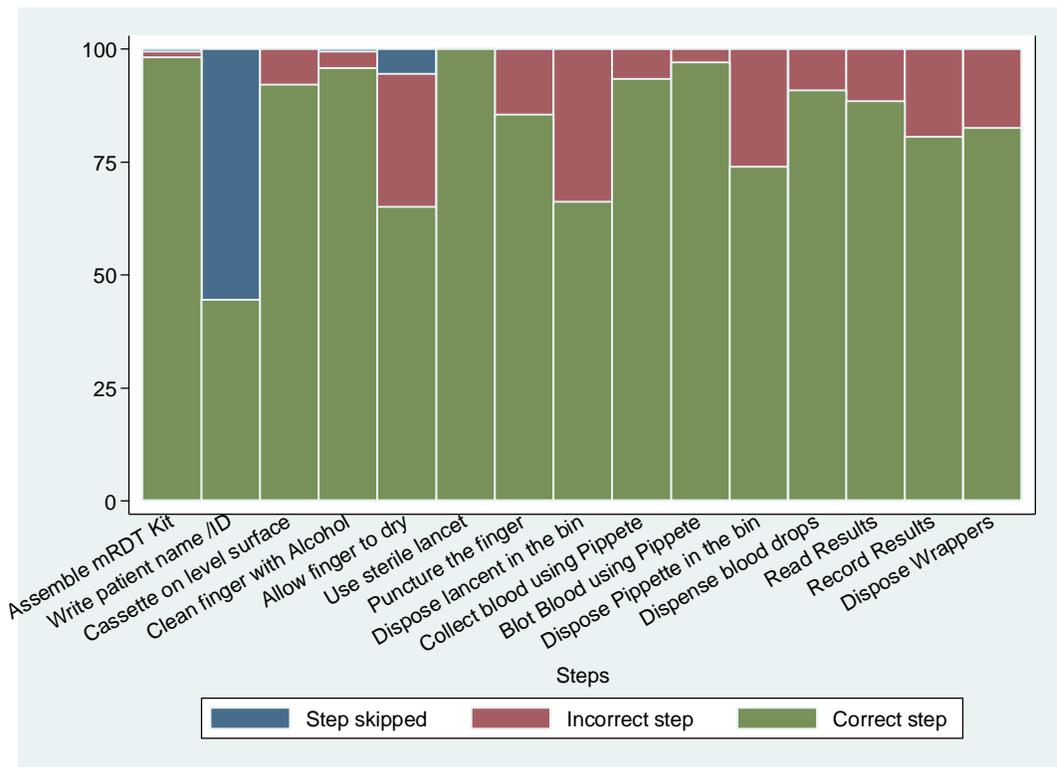
3.2.1 Observation of RDT Preparation and Use

Researchers evaluated the health workers performance in mRDT preparation and mRDT use according to the Ministry of Health and Social Welfare guidelines. Most HCWs performed the mRDT steps correctly (Figure 3).

The HCW collected accurate blood volume in 93.3% of the tests and blotted sufficient amount of blood to the tests in 97% of the tests. The study staff also observed that only the correct buffer solution (buffer supplied with the kit) was used during testing. This is because using the wrong buffer solution could produce false positive or false negative results. We also assessed that blood and buffer solution were put in the correct wells. This is important because only the buffer solution moves towards the test and control lines. Interchanging blood and buffer solution will produce negative or invalid results.

The first step observed was to assemble a new test packet, swab, buffer, pipette, lancet and gloves. Almost 98.2% of HCWs performed this step correctly. However, slightly less than half (44.2%) completed the 2nd step which was writing the patient name /ID on the cassette. Only 64.9% of HCWs allowed the finger to dry after cleaning the finger with alcohol. Overall, 64% of the HCWs performed all 15 steps correctly (Figure 4).

Figure 4: Competency of HCWs in Performing mRDT Tests



3.3 Malaria Patient Care and Medicine Use

In this study, 461 children under-five years of age (250 males, 211 females) with febrile illness in the last 14 days were identified in the outpatient register. A similar number of children were registered in each region.

3.3.1 Influence of mRDT results on febrile illness treatment

Of those screened with mRDT, 181 under-fives had a negative mRDT results while 116 had a positive mRDT results. Of those with negative mRDT results, 17 (9.4%) were prescribed anti-malarials (Table 4).

Table 4: Medication provided to Under Fives with Negative MRDT Test Results

Factors	Other medication	Anti-malarials	χ^2 (P value)
Study Regions			
Simiyu	74/86 (86.0%)	12/86 (14.0%)	4.2 (0.12)
Geita	42/45 (93.3%)	3/45 (6.7%)	
Shinyanga	48/50 (96.0%)	2/50 (4.0%)	
Level of Facility			
Hospitals	14/14 (100.0%)	0/14 (-)	2.6 (0.28)
Health Centre	43/46 (93.5%)	3/46 (6.5%)	
Dispensary	107/121 (88.4%)	14/121 (11.6%)	
Prescriber Type			
Assistant Clinical Officer	52/55 (94.6%)	3/55 (5.5%)	3.7 (0.45)
Assistant Medical Officer /Medical Officer	10/11 (90.9%)	1/11 (9.1%)	
Clinical Officer	76/84 (90.5%)	8/84 (9.5%)	
Nurse	23/28 (82.1%)	5/28 (17.9%)	
Others	3/3 (100.0%)	0/3 (-)	

Almost 12% and 8% of the under-fives reviewed in the privately and publicly owned facilities, respectively, had received antimalarials even though the mRDT results showed that the patient had no malaria. These differences by type of facility were not statistically significant. Of those with positive mRDT results (n=116), 109(94.0%) were prescribed anti-malarials.

3.4 Malaria RDT Use

A total of 162 HCWs were interviewed to assess the KAP of private and public facility health care workers on use of mRDT and acceptability of mRDT results. All HCWs (100%) in Simiyu and Shinyanga regions and 87% in Geita region reported using mRDT to confirm malaria. Generally, only 33.3% of the HCWs either prescribing or performing mRDT tests had received training on mRDT diagnosis. Advantages of using the mRDT cited by the study participants were (in decreasing order): 1) Shorter time for results (76.5%); 2) More accurate diagnosis (63%); 3) Ease of use (58%); 4) Targets treatment (44%); 5) No electricity required (28%); 6) Patient satisfaction (18%). Disadvantages cited by participants include (in decreasing order): 1) Negative results in patients with high fevers (28.4%); 2) Does not quantify the parasite (21.6%); 3) Inaccurate results (18.5%); 4) Lack of confidence in results by parents (1.7%).

3.5 Malaria RDT Acceptability

Overall (90.0%) of the HCWs reported that they have confidence with mRDT results with some divergences noted among regions (Figure 10). The remaining ten (10%) percent reported they had no confidence with mRDT results because mRDT would give negative test results while the same sample would test positive on microscopy; or mRDT negative patients would recover if given antimalarials. This proportion was high at the dispensary level (12.1%) compared to hospitals (5.9%) and health centers (6.5%) and high at private (23.8%) and FBO owned facilities (13.2%) compared to public (5.8%).

Almost 17% of the HCWs reported prescribing antimalarials to mRDT negative patients. The reasons given for prescribing antimalarials to mRDT negative patients were: a) the child had all symptoms of malaria; b) HCWs do not trust mRDTs; and c) children recovered after taking antimalarials. This proportion of HCWs was high at the hospital level (44.4%) and health centers (25.0%) compared to dispensaries (10.5%).

Approximately, 77% of the HCWs reported that parents/guardians trust mRDT results. The remaining 23.5% do not trust mRDT results because if a child has fever, parents expect the child to have malaria. Other reasons were as already mentioned above i.e. a) parents do not understand causes of fever; b) they lack understanding about mRDTs. The proportion of parents/guardians who trust mRDT results was higher in hospitals (82.4%) and health centers (87.0%) than in dispensaries (70.7%). About 76.5% of the HCWs in the public facilities, 82.6% in the facilities owned by FBO and 52.5% of those owned by the private sector reported that parents/guardians trust mRDT results.

Almost 48% of the HCWs reported that parents/guardians demand antimalarials even when mRDT results are negative. They gave same reason as already mentioned (i.e. the children with fever have all symptoms of malaria; parents do not trust mRDT results and do not understand causes of fever). The proportion of parents/guardians who trust mRDT results was higher in hospitals (47.1%) and health centers (34.8%) than in dispensaries (53.5%).

4. DISCUSSION

This study was conducted to assess the use of mRDTs in both public and private facilities, and the extent to which the results are used (or ignored) to support appropriate treatment. Quantitative and qualitative methods were used to collect data for three complimentary areas: a) whether mRDT is correctly being used to test children under-five years of age presenting with fever and guides treatment; b) Knowledge, Attitudes and Practices of HCWs on the use and acceptability of mRDT results; and c) what interventions will improve the quality of malaria diagnosis and treatment?

4.1 Correct Use of mRDT to test Children

The MoHSW malaria guidelines require a confirmed diagnostic test for malaria prior to treatment. In this study, 67% of under-fives with febrile illness in Simiyu region, 87% in Geita region and 96% in Shinyanga region were tested for malaria using mRDT or microscope. The apparent simplicity of malaria RDTs makes them attractive for diagnosis at all levels of health care systems, particularly in remote areas where health workers have limited supervision, on the job mentorship and classroom trainings. Standard Operating Procedures (SOP) were unavailable in most facilities (58%); only 4.4% of the HCWs had external quality assurance for microscopy, 42% had an SOP on how to perform malaria RDTs and 21.7% had bio-safety SOP. Consequently, only 64% of the HCWs performed all 15 steps correctly. Performing all steps correctly and reading mRDT results accurately are pivotal in the management of malaria to avoid withholding anti-malarial treatment in mRDT test-positive patients¹²⁻¹³.

The most critical steps either skipped or done incorrectly were writing patients' name/ID number on the cassette, bio-safety issues and waiting for the correct time to read negative results. Placing unidentified cassettes on top of the patient register could easily lead to mix-up of cassettes and, therefore, withhold antimalarial treatment to patients in need or providing antimalarials to mRDT negative patients. Bio-safety issues included improper disposal of lancets, pipettes and failure to allow the finger to dry before pricking. Regarding improper disposal of sharps, the sharps containers were always available but not within reach, therefore lancet and other sharps were not disposed immediately after the patient was tested. In Simiyu and Geita regions, most of the HCWs did not wait for the specified time before reading negative results. This may lead HCWs to miss the weak test lines that appear late in the reading, when the blood staining has cleared.

4.2 Extent that mRDT Guides Malaria Management

Of those screened by mRDT, 181 under-fives had negative mRDT results while 116 had positive mRDT results. Of those with negative mRDT results, 17 (9.4%) were prescribed anti-malarials. This proportion was non-significantly different in privately owned facilities (12.3%) compared to 7.8% in public owned facilities. Likewise, only 94% of all mRDT positive patients received

¹²Bisoffi, Z., et al., *Accuracy of a rapid diagnostic test on the diagnosis of malaria infection and of malaria-attributable fever during low and high transmission season in Burkina Faso*. Malar J, 2010. **9**: p. 192.

¹³ Morankar, S., et al., *Validity and reliability of RDT for diagnosis of malaria among febrile children in Jimma Town: southwest Ethiopia*. Ethiop Med J, 2011. **49**(2): p. 131-8.

antimalarials. Due to the small numbers in the sub-group analysis, this section should be interpreted with caution.

This study has shown that even where mRDTs are available and used, some HCWs do not manage malaria cases based on mRDT results. A similar conclusion was reached in a study conducted in Zambia with microscopy for malaria diagnosis. In this study, about 20 to 54% of patients with negative blood slides were prescribed antimalarials¹⁴. Despite the availability of mRDT and microscopy results, some HCWs treat presumptively based on their experience. Lower level facilities were more likely to give antimalarials to negative mRDT patients while hospitals were more likely to withhold antimalarials to positive mRDT patients.

While the percentage is not high, HCWs resist using mRDT results for treatment due to multiple reasons, first, the inconsistent evidence about their accuracy. Second, in the absence of mRDT, some of the HCWs managed patients presumptively and they find it difficult to change their patient diagnostic habit. Third, parents and guardians expect to receive antimalarials when their children have fever, therefore, to maintain customer satisfaction, some of the HCWs may be enticed to give antimalarials to mRDT negative patients. Public education about the benefits of test based malaria management will help HCWs to use mRDT test results in the management of their patients, as will training of HCWs in effective mRDT procedures and use in diagnosis.

4.3 Knowledge, Attitude and Practices of HCWs on the Use and Acceptability of mRDT results

There is high use and acceptability of mRDT results in the study regions. All HCWs in Shinyanga and Simiyu regions and 87% of HCWs in Geita region reported using mRDT for parasitological confirmation of Malaria. Major advantages of malaria RDT reported were: a) ease of use, b) shorter time is required to produce results, c) does not require electricity, d) helps to target treatment, e) confirms malaria, d) accurate and specific and e) gives patient satisfaction. Disadvantages of using malaria RDT were a) false negative/inaccurate results, b) lack of trust by patients, c) test remains positive after treatment, d) test does not quantify parasite, e) negative results in patients with high fever, f) invalid results.

Overall (90%) of the HCWs reported to have confidence in mRDT results. The remaining ten percent (10%) reported that they had no confidence with mRDT results because mRDT would give negative test results while the same sample would test positive on microscopy. Similarly, almost 17% of the HCWs reported to have prescribed antimalarials to mRDT negative patients. Conversely, almost 24% of the HCWs reported that parents/guardians do not trust mRDT results therefore, some parents/guardians demand antimalarials even when mRDT results are negative.

¹⁴Lawrence Barat, James Chipipa, Margarette Kolczak, and Thomas Sukway, "Does the Availability of Blood Slide Microscopy for Malaria at Health Centers Improve the Management of Persons with Fever in Zambia?" *American Journal of Tropical Medicine and Hygiene* 60 (1999): 1024–1030.

Management of malaria using mRDT involves conflicting decisions because:

- 1) Malaria RDTs may miss suboptimal infections but it is adequate for detecting clinically relevant malaria infections. Mortality risk of misdiagnosis with mRDTs (from a false-negative result) exceeds the costs and risks of overtreatment (from a false-positive result) that can occur in clinical diagnosis.
- 2) Patients demand antimalarials irrespective of mRDT results.

5. Conclusion

A high proportion of under-five children with fever were tested for malaria parasites using mRDT or microscope. Similarly, HCWs were more likely to prescribe antimalarials to mRDT positive patients.

Findings show that:

- Only 67% of under-fives with febrile illness in Simiyu region, 87% in Geita region and 96% in Shinyanga region were tested for malaria using mRDT or microscope.
- Only 64% of the HCWs performed all 15 steps of mRDT testing correctly. Performing all steps correctly and reading mRDT results accurately are pivotal in the management of malaria and ensures that the bio-safety standards are observed.
- This study has shown that even where mRDTs are available and used, a minority of HCWs do not manage malaria cases based on mRDT results. Lower level facilities were more likely to give antimalarials to negative mRDT patients while hospitals were more likely to withhold antimalarials to positive mRDT patients. However, this finding is affected by low numbers and should therefore be interpreted with caution.
- There is high use and acceptability of mRDT results in the study regions. However, mRDTs are subject to limitations related to design and storage as well as end-user performance, many of which can easily be prevented or remediated. Misdiagnosing fevers may have several consequences. First, an incorrect fever diagnosis leaves the patient vulnerable to worsening of the underlying true cause of fever. Second, unnecessary anti-malarial treatment of non-malarial fevers with the generally recommended ACTs is expensive and could potentially spur evolution and spread of resistance towards these compounds. Third, overuse of antibiotics could facilitate the selection of antibiotic resistance.
- Almost 24% of the HCWs reported that parents/guardians do not trust mRDT results therefore, some parents/guardians demand antimalarials even when mRDT results are negative.

6. Recommendations:

- A combination of continued on-job training, clear and simple bench-site job aids, supervision and mentoring visits done will contribute to correct end-user's performance. Detailed febrile illness case review done weekly to assess management of under five children would also improve the management of febrile illness cases and acceptability of mRDT results.
- Public education on the value of an mRDT, and wide dissemination of the information that, currently only 30% of fevers are caused by malaria, the majority are caused by other diseases. HCWs should be advocates for mRDT—a role they have yet to step in to in order to counter act parental pressure to prescribe ACTs when they are not required.
- We recommend that a quality assurance plan should be put in place to monitor mRDT quality. A method for validating mRDT results should be decided upon and then be integrated into the HCWs training to ensure that RDTs retain adequate performance to detect clinically-relevant malaria infections. This strategy will increase the confidence of HCWs and help to reassure users and clinicians that the test results are reliable.

ANNEXES

ANNEX 1: Health Care Workers consent form in Swahili

MRADI WATIBU HOMA

FOMU YA RIDHAA KWA WAFANYAKAZI WA VITUO VYA HUDUMA YA AFYA

Madhumuni ya Utafiti

Mradi wa Tibu Homa (unaofadhiliwa na Shirika la Misaada la Marekani - USAID) kwa kushirikiana na Wizara ya Afya na Ustawi wa Jamii (MoHSW) na wadau wengine, wanatekeleza mradi katika mikoa ya Kanda ya Ziwa kushughulikia magonjwa yanayosababisha homa kwa watoto wenye umri chini ya miaka 5. Madhumuni ya mradi huu ni kuboresha upimaji na matibabu ya magonjwa yanayosababisha homa kwa watoto wenye umri chini ya miaka mitano. Mradi huu unafuatilia kwa makini ubora wa matibabu yanayotolewa kwenye vituo vya afya (vya binafasi na vya serikali).

Taarifa Juu ya Utafiti

Ikiwa utakubali kushiriki kwenye utafiti huu, utaombwa uweke sahihi kwenye fomu hii ya ridhaa. Mfanyakazi wa utafiti atakuuliza maswali kutoka kwenye dodoso na kuandika majibu utakayompa na pia atakuuliza iwapo umewahi kushiriki kutoa huduma kwa kutumia mRDT na ulishirikije. Maswali utakayoulizwa yatahusu mafunzo yoyote uliyowahi kupata ya mRDT na changamoto unazokumbana nazo kwenye matumizi ya kipimo hiki. Mahojiano haya yatafanyika mara moja tu kwa kipindi chote cha utafiti na yatachukua muda wa kama dakika 25. Kwa madhumuni ya utafiti huu, tunatarajia kufanya mahojiano na watoa huduma ya afya wapatao 118. Maswali yote uliyonayo kuhusu utafiti huu yatajibiwa mpaka utakaporidhika. Unaweza kuuliza maswali yako sasa au baadae au wakati wa mahojiano.

Tahadhari

Baadhi ya maswali yetu yatahusu masuala nyeti juu ya matumizi ya mRDT; lakini una hiari ya kujibu au kutojibu swali lolote ambalo hutapenda.

Faida

Hakuna faida ya moja kwa moja kwako kwa kushiriki kwenye utafiti huu, lakini majibu /mawazo yako yatasaida kuleta matokeo ya utafiti huu, ambayo yatausaidia mradi wa Tibu Homa kuboresha namna ya kuvisaidia vituo vya huduma ya afya, vinavyopata msaada kutoka Tibu Homa, ili viweze kutoa huduma bora zaidi kwa wananchi.

Gharama

Hautatakiwa kulipa gharama yoyote ili kushiriki kwenye utafiti huu, isipokuwa ni kutoa muda wako tu, kushiriki kwenye utafiti huu.

Usiri

Kama utaridhia kushiriki kwenye utafiti huu, usaili huu utafanyika kwenye sehemu yenye usiri ambapo hamna mtu ataye sikiliza mahojiano yetu. Na taarifa hizi zitahifadhiwa kwa usiri mkubwa. Vitambulishi ama viasharia vyovyote vya majina ya washiriki havitatumika kwenye ripoti zozote za utafiti huu au kwenye machapisho ya utafiti huu katika majarida ya kisayansi. Ni watafiti

waandamizi tu ndio watakaona takwimu hizo na kamwe hawataweza kuzihusisha na majibu yako.

Malipo

Hautatakiwa kulipwa chochoteili kushiriki kwenye utafiti huu.

Uhuru wa kukataa kushiriki au kujitoa kwenye utafiti

Unahiari ya kukubali au kukataa kushirikikwenye utafiti huu bila kutoa sababu yeyote. Pia unahiari ya kusitisha kuendelea na usaili wakati wowote bila kutoa maelezo. Na kukataa kwako kushiriki kwenye usaili huu hakutaathiri kazi yako au upataji wa huduma za afya kwenye kituo chochote cha huduma ya afya, kama ulivyokua unapata hapo awali.

Maswali ya ziada na Mawasiliano

Msaili atakujibu maswali yote utakayokua nayo mpaka uridhike. Lakini kama utapenda kupata taarifa zaidi au kama una maoni/maswali zaidi baada ya timu ya watafiti kuondoka kwenye eneo la utafiti, tafadhali wasiliana na:

- Mwita Wambura, Mtafiti Mwandamizi, Utafiti wa Matumizi ya mRDT - Tibu Homa, SLP 1462, Mwanza, Tanzania. Simu: 0787 697430 / 0762 283912 **AMA** Eliphace C. Mkumbo, Mradi wa Tibu Homa, SLP 1403, Mwanza, Tanzania. Simu: +255-28-2981015;
- Pia unaweza kutembelea ofisi za TibuHoma mwenyewe kwa taarifa zaidi. Ofisi zipo barabara ya Isamilo, jengo la Ekacliff, ghorofa ya kwanza, ofisi ziko wazi kuanzia saa 2asubuhi mpaka saa 10 jioni, Jumatatu mpaka Ijumaa.

Je. Una swali au maoni yoyote?

Ridhaa yako

Nimesoma maelezo ya fomu hii ya ridhaa na nimeyaelewa. Nimeongea na mfanyakazi wa utafiti huu kuhusu fomu hii. Nimepata muda wa kuuliza maswali na nimeridhika kwa majibu niliyopewa. Ninakubali kwa hiari yangu, kushiriki kwenye utafiti huu.

Jina la mshiriki:

Sahihi: Tarehe:/...../.....

Jina la msaili:

Sahihi: Tarehe:...../...../.....

ANNEX 2: Health Care Workers consent form in English

TIBU HOMA PROJECT

Health Workers participants consent form

Research purpose:

The Tibu Homa project (funded by USAID), in collaboration with the Ministry of Health and Social Welfare (MOHSW) and other partners are implementing a collaborative project in the Lake Zone regions to address febrile illness among children under the age of five years. The project aims to improve the diagnosis and management of severe febrile illness in children under-five years of age, focusing on improving case management at the facility level (both public and private).

Information on research:

If you choose to be in this study we will ask you to sign this consent form. An interviewer will then ask you some questions from a questionnaire and the answers will be recorded. There will be questions on whether and how you have been involved in providing services using malaria rapid diagnostic test (mRDT) at the clinic. We will also ask about any training received on mRDT and challenges you have faced in using this test. The interview will happen only once during this study and take approximately 25 minutes. For the purpose of this study we are expecting to interview about 118 health workers. We will try to answer all the questions you may have about this study to your satisfaction. You can ask your questions at any time you like.

Risks:

Some of the questions on the use of mRDT in the questionnaire may be sensitive, but you are free to decline to answer any questions you do not wish to answer at any time.

Benefits:

There is no direct benefit to you from taking part in this study, but the results of this study will help the Tibu Homa Project how best to support facilities benefiting from the Project.

Costs: There are no extra costs to you for taking part in this study, except for giving up the time to participate in the interview.

Confidentiality:

If you decide to answer questions, the interview will be conducted in a private setting where no one else can hear your answers to the questions. Your information will be kept as confidential as possible. No individual identities will be used in any reports or publications resulting from this study. Only senior researchers may see your information, but will be unable to link that information to you.

Compensation:

You will not be paid any money for participating in this study.

Voluntary participation:

It is your choice to be in this study and you can choose not to participate in this study without giving a reason. You are also free to stop the interview at any time without giving an explanation. If you decide not to take part in this study, it will not affect your job and will not affect the care you receive in the clinics and health centers you have been attending.

For additional information:

The interviewers will answer any questions that you may have to your satisfaction. Any further questions or concerns after the research team has left your community can be addressed as follows:

- Mwitwa Wambura, Lead Investigator, Tibu Homa’s mRDT Use Study, Box 1462, Mwanza, Tanzania; Tel 0787 697430 / 0762 283912 OR Eliphace C. Mkumbo, Tibu Homa Project, P. O. Box 1403, Mwanza, Tanzania. Phone: +255-28-2981015
- Visit the Tibu Homa offices in person. The office is located along Isamilo Road, Ekacliff Building, 1st floor and is open between 8:00am and 4:00pm, Monday through Friday

Do you have any Questions or Opinions?

Your Consent:

I have read this consent form. I have talked about what it says with the project staff. I had a chance to ask questions and my questions were answered satisfactorily. I agree to be in this study.

Name of participant: _____

Signature: _____ Date: ____/____/____

Name of person taking consent: _____

Signature: _____ Date: ____/____/____

ANNEX 3: Care taker's verbal consent form Swahili

MRADI WA TIBU HOMA

FOMU YA RIDHAA KWA WANAUGUZA MGONJWA

Jina langu ni [***taja mina lado***]; Matokeo kwenye mradi wa Tibu Homa. Mradi wa Tibu Homa kwa kushirikiana na Wizara ya Afya na Ustawi wa Jamii (MoHSW) na wadau wengine wanatekeleza mradi katika mikoa ya Kanda ya Ziwa kushughulikia magonjwa yanayoleta homa kwa watoto wenye umri chini ya miaka 5. Madhumuni ya mradi huu ni kuboresha upimaji na matibabu ya magonjwa yanayoleta homa kwa watoto chini ya miaka mitano. Mradi unatilia mkazo matibabu yanayotolewa kwenye vituo vya afya (vya binafsi na vile vya umma).

Leo, tunaangalia ubora wa huduma wanayopata watoto chini ya miaka 5. Hivyo, ninaomba ruhusa yako ili nikae kwenye chumba cha matibabu wakati wa kutibiwa mtoto wako. Dhumuni ni kuchunguza na kushauri iwapo maboresho kwenye huduma za matibabu kwa watoto wadogo yanahitajika.

Ushiriki wako ni wa hiari. Ikiwa hupendi kushiriki (yaani kama hupendi nikae kwenye chumba cha matibabu wakati wa kutibiwa mtoto wako), tafadhali naomba unijulishe na nitaondoka. Chochote kile tutakachokiona, kitatunzwa kwa usiri mkubwa. Jina la mtoto wako halita andikwa kwenye karatasi yeyote ile ya utafiti. Hakuna athari yeyote kwa wewe kuniruhusu kusikiliza matibabu ya mwanao (yaani kwa wewe kushiriki kwenye utafiti). Ikiwa ungependa kupata nakala ya barua hii kwa kumbukumbu yako, tafadhli nijulishe ili nikupe.

Kama una swali lolote kuhusu utafiti, tafadhali wasiliana na Mwita Wambura, Mtafiti Mwandamizi, Utafiti wa Matumizi ya mRDT - Tibu Homa, SLP 1462, Mwanza, Tanzania. Simu: 0787 697430 / 0762 283912 **AMA** Eliphace C. Mkumbo, Mradi wa Tibu Homa, SLP 1403, Mwanza, Tanzania. Simu: +255-28-2981015;

ANNEX 4: Care taker's verbal consent form English

TIBU HOMA PROJECT

Care Takers' Verbal Consent Form

My name is [***mention your name***]; I am from Tibu Homa Project. The Tibu Homa project in collaboration with the Ministry of Health and Social Welfare (MOHSW) and other partners are implementing a collaborative project in the Lake Zone regions to address febrile illness among children under the age of five years. The project aims to improve the diagnosis and management of severe febrile illness in children under-five years of age, focusing on improving case management at the facility level (both public and private).

Today, we are observing care provided to children under five years of age. I therefore, request your permission for me to sit in the consultation room during the management process of your child. The aim is to observe and advice if improvement in care is required.

Your participation is voluntary. If you do not wish to participate (i.e. if you don't want me to stay in the room during consultation process), kindly inform me and I will leave. Anything we observe and document will be kept confidential. The name of your child will not appear anywhere in our documents. There are no risks associated with this activity.

If you would like a copy of this letter for your records, please let me know and I will give it to you. If you have any questions regarding the research, contact Mwita Wambura, Lead Investigator, Tibu Homa's mRDT Use Study, Box 1462, Mwanza, Tanzania; Tel 0787 697430 / 0762 283912 **OR** Eliphace C. Mkumbo, Tibu Homa Project, P. O. Box 1403, Mwanza, Tanzania. Phone: +255-28-2981015

ANNEX 5: Patient Care and Medicine Use

MEDICAL RECORDS REVIEW FORM

INSTRUCTIONS

Where to go: Selected Public and Private Health facilities

Who to Ask: Medical Records Officer, Health Facility in charge, Laboratory personnel

What to do: Identify a random sample of 10 children under five years of age, with febrile illness from the outpatient register over the past 14 days; and then go to the registry and pull out the medical/patient record cards of each of the 10 selected individuals at the facility, over the past 14 days. If patient records are not available, use the prescriber's outpatient register.

Instructions on how to fill out this data form

Date: Write the date the data is collected at the facility

Name of Facility: Write the name of the health facility from which the data is being collected

Name of District: Write the name of the district the data is being collected

Name of Data Collector: Write the name of the person who is collecting the data

Column 1: Number of participants recruited in the study

Column 2: Write the age of the child in number of months

Column 3: Write the gender of the child, either Female or Male

Column 4: Specify, if the child was confirmed or Not confirmed with Malaria by a laboratory test, enter either **Y** for **Yes**, or **N** for **No, respectively**. .

Column 5: If the answer on column 4 = Yes, then specify if the method of confirmation was by mRDT test

Column 6: Write the results of mRDT test, if malaria was confirmed with mRDT test, by entering either **P** for **positive**, or **N** for **Negative** results

Column 7: Enter the date the child visited the clinic (if multiple visits, collect data for the first visit within the 14 day review period)

Column 8: Write the prescriber's cadre: clinical officer, nurse, other specify

Column 9: Write the name of the medicine and strength that was prescribed for the child

Column 10: Write the number of tablets/mls (dosage) of the medicine prescribed

MEDICAL RECORDS REVIEW FORM

Date: ___ / ___ / ___

Name of District: _____

Name of Facility: _____ Name of Data Collector: _____

No.	Age (months)	Sex (M/F)	Lab Confirmed (mRDT/ Microscopy) Malaria (Y/N)	mRDT (Y/N)	mRDT Results (P/N)	Date of Visit	Prescriber's cadre	Medicine Name and Strength	No. of Units (Dose)
Col 1	Col 2	Col 3	Col 4	Col 5	Col 6	Col 7	Col 8	Col 9	Col 10
1									
2									
3									
4									

No.	Age (months)	Sex (M/F)	Lab Confirmed (mRDT/ Microscopy) Malaria (Y/N)	mRDT (Y/N)	mRDT Results (P/N)	Date of the Test	Prescriber's cadre	Medicine Name and Strength	No. of Units (Dose)
Col 1	Col 2	Col 3	Col 4	Col 5	Col 6	Col 7	Col 8	Col 9	Col 10
5									
6									
7									
8									
9									
10									

ANNEX 6: Malaria RDT Observation Checklist

SECTION A: Health Facility General Information

1	District	
2	Name of health facility	
3	Level of health facility	1=Hospital; 2=Health Centre; 3=Dispensary;
4	Type of Ownership	1=Government; 2=Private;
5	Date of visit	
6	Name of Data Collector	

SECTION B: Laboratory Guides and Standard Operating Procedures

Type of Reference	Topic	1=Available 2= Not Available	Location	Comments
Standard operating Procedures (SOPs)	Use of Malaria Rapid Diagnostic Tests (mRDTs)			
	External quality assurance for microscopy			
	Biosafety			
Reference books on mRDT	Please list titles			
Have the reference materials been updated within the last 12 months? 1=Yes; 2=No; 8=NA;				

SECTION C: Laboratory Equipment, Supplies and Consumables

(NOTE: This information has to be obtained from the storekeeper or Facility In charge)

Check the ledger book for stock outs of essential supplies lasting ≥7 days in a row during the last 3 months and fill in the table below.

Item	Stock outlasting ≥7 days in a row? 1=yes 0=No	Comments	Item	Stock outlasting ≥7 days in a row? 1=yes 0=No	Comments
Buffer Solution			RDT brand1		
Lancets			RDT brand2		
Pipette			Cotton wool		
Timers available 1=Yes; 2=No;			Alcohol swab		

SECTION D: General Observations

1. Did HCW follow the job aid while performing the test? determine	1=Yes; 2=No; 3=cannot		
2. Mark any critical errors HCW performed			
a) Used lancet or pipette on more than one patient	1=Yes; 2=No;		
b) Did not prescribe antimalarials for a positive mRDT result	1=Yes; 2=No;		
c) Prescribed antimalarials for a negative mRDT result	1=Yes; 2=No;		

SECTION E: Observation of mRDT Preparation and Use

1. Patient IDNO			
2. Was this patient febrile?		1=Yes; 2=No;	
3. <i>For each step below, write 1 if the HCW performed the step correctly, 2 if the HCW performed the step incorrectly, 3 if the HCW skipped the step, 4 if the observer missed the step</i>			
a. Assemble new test packet, swab, buffer, pipette and lancet			
b. Write patient's name or ID on cassette			
c. Place cassette on a level surface			
d. Clean finger with antiseptic/alcohol			
e. Allow finger to dry before pricking it			
f. Use a sterile lancet for a finger prick			
g. Puncture the side of the ball of the finger			
h. Dispose of the lancet in sharps bin immediately after pricking finger			
i. Collect blood with the pipette making sure to fill close to the first cross line			
j. Using the pipette, blot blood onto the pad in the correct well			
k. Dispose of the pipette in sharps container immediately			
l. Dispense correct number of drops of clearing buffer into the correct well			
m. Wait correct time before reading negative results			
n. Read test results correctly			
o. Record results in the lab register			
p. Dispose of wrappers and alcohol swab safely			
q. Was the RDT expired		1=Yes; 2=No	
r. How do you know?			
i. Looked at the expiry date on the packet		1=Yes; 2=No; 9=DK;	
ii. Looked the expiry date from the box		1=Yes; 2=No; 9=DK;	
iii. Others (explain)			
s. Patient's results		1=Positive; 2=Negative; 3=Invalid;	

Positive results may be read before the specified reading time if control line has also appeared. Results should not be read after the maximum specified time minutes.

ANNEX 6: Health Care Workers Questionnaire Swahili

Wafanyakazi wa vituo vya huduma ya afya wahojiwe kwa kutumia dodoso hili

Interviewer's code/___/___/

Date: |_|_|. |_|_|. |_|_|_|_|

IDNO: |_|_|. |_|_|. |_|_|. |_|_|_|. |_|_|_|

Tafadhali soma kipengele hiki kwa sauti:

Tunafanya utafiti wa kuangalia uzoefu na uelewa wa wataalamu wa afya juu ya matumizi ya kipimo cha malaria cha mRDT katika wilaya hii. Tungependa kujifunza kutokana na uzoefu wako (kama unao) na kupata maoni yako juu ya matumizi ya kipimo cha mRDT katika kituo hiki cha huduma ya afya. Hatutumia jina lako wala kukutaja popote katika kuripoti majibu ya utafiti huu. Tafadhari jibu maswali haya kwa uaminifu kwa namna inavyowezekana. Uko huru kukataa kujibu swali lolote, lakini tungefurahi na kupata faida kubwa iwapo utatupa majibu kwa uaminifu katika maswali yote utakayoyajibu.

Taarifa za Ujumla

1. Mkoa: _____ Wilaya: _____

2. Jina la kituo cha huduma ya afya: _____

3. Aina ya kituo cha huduma ya afya _____ |___|
1=Hospitali; 2. Kituo cha Afya; 3=Zahanati; 4=Nyingine (Taja) _____

4. Umiliki wa kituo cha huduma ya afya _____ |___|
1=Serikali; 2=Asasi za kidini; 3=Asasi zisizo za kiserikali; 4=Binafsi; 5=Nyingine (Taja) _____

5. Jinsia ya mtoa taarifa _____ 1=Mwanaume; 2=Mwanamke _____ |___|

Taarifa juu ya mtumishi wa kituo cha huduma ya afya

6. Wewe ni mtumishi wa kada gani?

1=Daktari; 2= Daktari msaidizi; 3=Tabibu; 4= Tabibu Msaidizi; 5=Mmuuguzi; 6=Mtaalamu wa maabara; 7=Mhudumu wa Afya

8=Nyingine (Taja)

_____ |___|

7. Umefanya kazi hii kwa muda gani? |__|__| miaka |__|__| miezi
8. Umefanya kazi katika kituo hiki cha huduma ya afya kwa muda gani? |__|__| miaka |__|__| miezi
9. Je, kituo chako kinatumia kipimo cha mRDT katika kuhakiki maambukizi ya malaria
1=Ndiyo; 2=Hapana; |__|
10. Majukumu yako katika matumizi ya kipimo cha mRDT ni yapi?
- a. Matibabu 1=Ndiyo; 2=Hapana; |__|
- b. Kufanya upimaji wa mRDT 1=Ndiyo; 2=Hapana; |__|
- c. Mengine: (Taja): _____
11. Katika miaka 2 iliyopita, umewahi kupata mafunzo yeyote kati ya haya yafuatayo?
- a. Matibabu ya ugonjwa wa Malaria 1=Ndiyo; 2=Hapana |__|
- b. Matibabu ya homa 1=Ndiyo; 2=Hapana; |__|
- c. Upimaji malaria kwa kipimo cha mRDT 1=Ndiyo; 2=Hapana; |__|
- d. Upimaji malaria kwa darabuni 1=Ndiyo; 2=Hapana; |__|
- e. Mengine: (Taja): _____
12. Ni nini faida ya kutumia kipimo cha mRDT kwa ajili ya upimaji wa malaria kwa watoto wenye homa walio na umri chini ya miaka mitano?
- a. Ni rahisi kutumia 1=Ndiyo; 2=Hapana; |__|
- b. Huchukua muda mfupi kutoa majibu |__| 1=Ndiyo; 2=Hapana;
- c. Hakihitaji umeme 1=Ndiyo; 2=Hapana; |__|
- d. Husaidia utoaji wa dawa 1=Ndiyo; 2=Hapana; |__|
- e. Hutoa uhakika wa uwepo ama kutokuwepo kwa malaria 1=Ndiyo; 2=Hapana; |__|
- f. Ni ya uhakika na haina mashaka 1=Ndiyo; 2=Hapana; |__|
- g. Humridhisha mgonjwa 1=Ndiyo; 2=Hapana; |__|
- h. Nyingine: (Taja): _____
13. Ni nini hasara ya kutumia kipimo cha mRDT kwa ajili ya upimaji wa malaria kwa watoto wenye homa walio na umri chini ya miaka mitano?
- a. Hutoa majibu yasiyo sahihi/potofu 1=Ndiyo; 2=Hapana; |__|
- b. Kutokuaminiwa na wagonjwa 1=Ndiyo; 2=Hapana; |__|
- c. Kipimo hubaki kikionesha malaria hata baada ya matibabu 1=Ndiyo; 2=Hapana; |__|
- d. Kipimo hakiwezi kutoa hesabu ya vimelea vya malaria 1=Ndiyo; 2=Hapana; |__|
- e. Majibu hasi hata kwa wagonjwa wenye homa kali/dalili za malaria 1=Ndiyo; 2=Hapana; |__|

f. Majibu yasioonyesha kama mgonjwa ana malaria au la 1=Ndiyo; 2=Hapana; |_____|

g. Nyingine: (Taja): _____

14. Je, wewe binafsi, una uhakika na majibu ya kipimo cha malaria cha mRDT? 1=Ndiyo; 2=Hapana; |_____|

15. *Kama jibu la swali na. 14 ni hapana, uliza; Kwanini hauna uhakika na majibu ya kipimo cha mRDT? (kama jibu la swali na. 14 ni Ndiyo, jaza 8=HAIHUSIKI)*

16. *Uliza iwapo Q10 a=1; Je, kuna wakati huwa unaandika dawa za malaria kwa watoto chini ya miaka mitano hata majibu ya mRDT yanapokuwa hasi (negative mRDT results)?* 1=Ndiyo; 2=Hapana; 8=Haihusiki; 9=Sijui; |_____|

17. *Kama jibu la swali na. 16 ni ndiyo, uliza; Kwanini huwa wakati mwingine unaamua kumuandikia dawa za malaria mtoto wa chini ya miaka mitano hata pale majibu ya kipimo cha mRDT yanapokuwa hasi (Negative mRDT results)? (kama jibu la swali na. 16 ni HAPANA, jaza 8=HAIHUSIKI)*

18. Je, wazazi/walezi wa watoto chini ya miaka mitano wenye homa wanayaamini majibu ya kipimo cha malaria cha mRDT 1=Ndiyo; 2=Hapana;9=Sijui |_____|

19. *Kama jibu la swali na. 18 ni Hapana, uliza; Unadhani ni kwanini wazazi/walezi wa watoto chini ya miaka mitano wenye homa hawayaamini majibu ya kipimo cha malaria cha mRDT (kama jibu la swali na. 18 ni Ndiyo, jaza 8=HAIHUSIKI)*

20. Je, kuna wakati wazazi/walezi wa wagonjwa huomba kupewa dawa za malaria hata pale ambapo majibu ya kipimo cha mRDT ni hasi (negative mRDT results)? 1=Ndiyo; 2=Hapana;8=Haihusiki; 9=Sijui |_____|

21. **Kama jibu la swali na. 20 ni ndiyo, uliza; Unadhani ni kwanini wakati mwingine wazazi/walezi huomba kupewa dawa za malaria hata pale ambapo majibu ya kipimo cha mRDT ni hasi (negative)? (Kama jibu la swali namba 20 ni Hapana; andika 8=HAIHUSIKI)**

22. **Je, mfumo wa taarifa za huduma ya afya (MTUHA) una idadi yote ya wagonjwa wenye homa waliotibiwa kwa dalili pekee katika kituo hiki katika kipindi cha mwezi mmoja uliopita?**

1=Ndiyo; 2=Hapana; 9=Sijui | ___|

23. **Tafadhali niambie kama unakubaliana au hukubaliani na sentensi zifuatazo:**

- a. MRDT inaweza kutoa idadi ya vimelea vya malaria katika damu 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- b. MRDT inatoa majibu chanya pale tu panapokua na vimelea vingi sana katika damu
1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- c. MRDT siyo bora kuliko uwezo wa kitabibu katika kugundua malaria 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- d. MRDT ni ngumu kutumia 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- e. MRDT huongeza uwingi wa kazi 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- f. Majibu ya MRDT huongeza uhakika katika utambuzi wa malaria 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- g. MRDT inawezesha ushirikishaji bora zaidi wa wagonjwa katika kutoa maamuzi
1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- h. MRDT husaidia kuokoa matumizi ya dawa za kwanza za malaria 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- i. MRDT huongeza weledi/ustadi kwa wahudumu wa afya 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|
- j. MRDT inaongeza uhakika katika sekta ya afya 1=Ndiyo; 2=Hapana; 9=Sijui; | ___|

ANNEX 7: Health Care Workers Questionnaire English

All health facility workers are to be interviewed using this form.

Interviewer's code |__|__|

Date: |__|__|. |__|__|. |__|__|

IDNO: |__|. |__|. |__|. |__|__|. |__|__|

Please read out this narrative loudly:

We are carrying out an assessment of the experience and knowledge that health professionals have on mRDT use in this district. We would like to learn from your experiences (if any) and obtain your opinions about the use of mRDT at this health facility. Please, answer the questions as truthfully as possible. We will not use your names or refer to you personally, when reporting the results of this assessment. You are free to refuse to answer any questions, but we would appreciate and benefit much if you give us truthful answers to all the questions you do answer.

General Information

1. **Region:** _____ **District:** _____

2. **Name of the health facility:** _____

3. **What type of health facility is it?** |__|__|
1=Hospital; 2=Health Centre; 3=Dispensary; 4=Other (Specify) _____

4. **Type of ownership of the health facility** |__|__|
1=Government; 2=FBO; 3=NGOs; 4=Private; 5=Other (Specify) _____

5. **Gender of the informant/respondent:** 1=Male; 2=Female; |__|__|

Information about the Health facility Worker

6. **What is your designation?** |__|__|
1=Medical Officer; 2=Assistant Medical Officer 3=Clinical Officer; 4=Assistant Clinical Officer; 5=Nurse; 6=Lab personnel
7=Medical Attendant; 8= Other (specify) _____

7. **How long have you been practicing?** |__|__| years |__|__| months

8. **How long have you been working at this facility?** |__|__| years |__|__| months

9. Does your facility use mRDTs to confirm malaria infection? 1=Yes; 2=No |____|

10. What has been your role(s) in the utilisation of mRDT?

a. Prescriber 1=Yes; 2=No; |____|

b. Performing the test in the lab 1=Yes; 2=No; |____|

c. Other: (*specify*): _____

11. In the last 2 years, have you received any of the following training?

a. Malaria case management 1=Yes; 2=No; |____|

b. Febrile illness management 1=Yes; 2=No; |____|

c. mRDT diagnosis 1=Yes; 2=No; |____|

d. Microscopy diagnosis 1=Yes; 2=No; |____|

e. Other: (*specify*): _____

12. What are the advantages of using mRDT to test for malaria in under-five with febrile illnesses?

a. Ease of use 1=Yes; 2=No; |____|

b. Takes shorter time to produce results 1=Yes; 2=No; |____|

c. Does not require electricity 1=Yes; 2=No; |____|

d. Helps to target treatment 1=Yes; 2=No; |____|

e. Confirms or rules out malaria 1=Yes; 2=No; |____|

f. Accurate and specific 1=Yes; 2=No; |____|

g. Patient satisfaction 1=Yes; 2=No; |____|

h. Other: (*specify*): _____

13. What are the disadvantages of using mRDT to test for malaria in under-five with febrile illnesses?

a. False negative/inaccurate results 1=Yes; 2=No; |____|

b. Lack of trust by patients 1=Yes; 2=No; |____|

c. Test remains positive after treatment 1=Yes; 2=No; |____|

d. Test does not quantify parasite 1=Yes; 2=No; |____|

e. Negative results in patients with severe fever/ symptoms 1=Yes; 2=No; |____|

f. Invalid results 1=Yes; 2=No; |____|

g. Other: (*specify*): _____

14. Do you personally have confidence with mRDT results 1=Yes; 2=No; |____|

15. ***If No in Q14 above ask; Why don't you have confidence with mRDT results? (if Q14=Yes, enter NA)***

16. **Do you sometimes prescribe anti-malaria drugs to under-fives with negative mRDT results**

1=Yes; 2=No;

17. ***If Yes in Q16 above, ask; Why do you sometimes decide to prescribe anti-malaria drugs to under-fives with negative mRDT results? (if Q16=No; enter NA)***

18. **Do parents/guardians of children under five with febrile illness trust mRDT results?**

1=Yes; 2=No; 9=DK

19. ***If No in Q18 above, ask; Why do think care givers of under five children with febrile illness do not trust mRDT results? (if Q20=Yes; enter NA)***

20. **Do the patients' parents/guardians sometimes demand anti-malarial drugs even when mRDT results are negative?**

1=Yes; 2=No; 9=DK

21. **If Yes in Q20 above, ask; why do you think patients/guardians demand anti-malaria drugs even when mRDT results are negative? (if Q20=No; enter NA)**

22. **Does the HMIS have data on the total number of febrile cases presumptively treated as malaria in this health facility in the last 1 month?** 1=Yes; 2=No; 9=DK

23. **Please state whether you agree or disagree with the following statements:**

- | | |
|--|---|
| a. MRDT can be used to quantify malaria parasitemia | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| b. MRDT becomes positive only on very high levels of parasitemia | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| c. MRDT is not better than clinical acumen in malaria diagnosis | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| d. MRDT kit is difficult to use | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| e. MRDT increases workload | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| f. MRDT results improves confidence in the diagnosis | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| g. MRDT enables better engagement of patients in decision making | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| h. MRDT helps to save stock of first-line anti-malarial medicine | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| i. MRDT increases HCWs sense of professionalism | 1=Yes; 2=No; 9=DK; <input type="text"/> |
| j. MRDT improves confidence in the health system | 1=Yes; 2=No; 9=DK; <input type="text"/> |

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