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Field Evaluation of Diagnostic Performance and Factors Affecting Malaria Rapid Diagnostic Test in Seme, Kisumu County, Kenya

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Abstract:

Quality diagnosis is important for effective management and control of malaria. The study assessed the factors affecting the performance of malaria rapid diagnostic test kits (mRDTs) in Seme Sub County, Kisumu. The study targeted three health facilities which were purposively sampled and convenience sampling was used to select the health care workers interviewed. The RDTs were randomly sampled. Descriptive statistics were summarized using tables and charts. The study revealed that RDTs storage, stock outs, staffs training, quality assurance, lack of bench job aids and standard operating procedures are factors affecting the performance of mRDTs. In conclusion, several factors affects the performance of mRDTs. The study recommends environmental monitoring of mRDTs during transportation, storage and testing process. The study also recommends regularly training of the health care workers on mRDTs and biannual proficiency testing for all mRDTs end users.

Keywords: Diagnostic performance, evaluation, rapid diagnostic tests, quality control, proficiency testing

1. Background

Malaria is a parasitic infection caused by protozoan of the genus *Plasmodium* and transmitted by female *Anopheles* mosquitoes (Bassey *et al.*, 2017). It is the highest contributor to morbidity and mortality in developing countries, in Kenya, there are an estimated 3.5 million new clinical cases and 10,700 deaths each year, and those living in western Kenya especially have high risk of malaria (Kishoyian *et al.*, 2021). Accurate, reliable and timely diagnosis of malaria infection is important for effective malaria case management, surveillance and public health concern. The diagnostic methods used to diagnose malaria include microscopy, rapid diagnostic test and molecular techniques. Microscopic examination remains the 'gold standard' for laboratory confirmation (Mathison *et al.*, 2017). However, different types of RDTs kits have been developed for the diagnosis of malaria infection in both malaria non-endemic and endemic regions due to challenges of availability of skilled, Laboratory personnel and logistics to microscopy in several endemic countries, as part of malaria management and control program (Maltha *et al.*, 2013).

Since 2010, World Health Organization (WHO) recommended that malaria case management be based on parasite diagnosis in all cases (Cunningham *et al.*, 2019). The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained. The number of RDTs available and the scale of their use have increased rapidly over the last decade. Kisumu County has adopted the same strategy in the entire region, however Seme Sub county has the highest utilization rate of RDTs of about 76% (Kenya health information system 2020-KHIS), hence the need to determine the factors affecting the performance of rapid diagnostic test kits in Seme and to determine the parasite density detection limit of the available RDTs.

Like other biological tests, malaria RDT is prone to deterioration through exposure to heat and humidity, and through manufacturing faults. Field evaluation of the factors affecting the performance of RDTs has a major role in determining the suitability for of the RDTs available. The apparent accuracy of any RDTs in detecting malaria parasites will

depend on various factors, including: the concentration of the target antigen, the mechanics of antigen and antibody flow along the nitrocellulose strip, the physical condition of the RDT, the competency of the end users, availability of the reference materials, the quality of test preparation and interpretation, and the accuracy of the reference standard (Mehlotra *et al.*, 2019). The study assessed the factors affecting the performance of malaria rapid diagnostic test kits in Seme Sub County, Kisumu County.

2. Materials and Methods

2.1. StudyArea

The study was conducted in Seme Sub County, situated approximately 36 km West of Kisumu city, along Kisumu Bondo highway, (Lat 0.103661/long 34.518190). Kombewa County hospital is the central hub. The study facilities included Miranga, which is 9.4km from the central hub, Ratta 16.4km, and Manyuada Sub County hospital 10km. Seme Sub County has a total population of 98,805 with an area of 190.20km² and 25 health facilities. The study facilities had different catchment population as indicated in the brackets, Miranga (9,864), Manyuada (14,059), and Ratta (10,011) (KHIS Aggregate 2019). Kisumu West, part of Kisumu central Sub Counties and Rarieda Sub County in Siaya County, borders Seme. The Hospitals serve the majority of the malaria-infected patients. Malaria still remains among the top ten diseases causing morbidity and mortality within the region.

The hospitals are along the lake region hence the high incidence rate of malaria infection. There are frequent power outbreak and no backup systems in place in most of the hospitals. Road infrastructure is good, though problematic during rainy seasons. Economic activities within the area are majorly fishing because of the lake, beaches, and surrounding Islands, and small-scale farming is taking place. However, the majority are also engaged in small-scale businesses to earn a living at the locally available market centers. Seme Sub County has only 24% microscopy diagnostic sites and a large percentage of malaria tests are being done using mRDTs (KHIS Moh 643 summary report).

On the other hand, malaria is among the top ten causes of death by age group. The adult prevalence is at 28% (Jenkins *et al.*, 2015). According to KHIS Aggregate data for quarter one 2019, indicates that malaria prevalence is at 56.8%. Evaluating the diagnostic performance and assessing the factors affecting the performance of malaria rapid diagnostic test is vital to ensure an accurate diagnosis is in place (fig 1).

Figure 1: Map Showing the Study Site in the Western Kenya. Seme Sub County, Kisumu County (Miranga, ManyuadaAnd RattaHealth Centers)(SifunaEt Al., 2014)

2.2. StudyDesign

Cross-sectional observational study design was used; questionnaire was administered to the health care workers to assess the factors that affects the performance of rapid diagnostic tests. Observation checklist was also used to determine the factors that affect the performance of RDTs. The facilities and health care workers were purposively sampled. Quantitative limit of Parasite cut off points detected by different RDTs was determined using microscopy as a reference method.

2.3. Study Population

The study population were health care providers, who included nursing officers, clinicians, medical laboratory officers and community health volunteers. The distribution of the study population was as illustrated in Figure 2. The study included all the health providers who accepted to take part in the study and perform rapid diagnostic testing in their routine work in malaria case management. However those who decline to participate and those not performing malaria rapid diagnostic test in their routine work were excluded from the study.

Figure 2: Health Care Providers

2.4. Ethical Statement

Ethical approval was obtained from institutional Ethical review committee of MasindeMuliro University of science and technology (MMUST). The study permit from National Commission for Science, Technology and innovation (NACOSTI) and permission obtained from the sub county health management team. Written informed consent was obtained from the participants. The participants had freedom of choice to join the study and leave at will without coercion

2.5. Data Analysis

Primary data was documented in the questionnaires forms and keyed in a password-protected Microsoft Office Excel 2010. The researcher checked for data completeness and consistency. The data officer resolved all queries after data entry. Analysis of data was done using STATA software version 15. The data analyst did descriptive data analysis and frequencies to analyse data on factors affecting the performance of mRDTs, proportions and percentages were used for data presentation.

3. Results

3.1. TestDevice-Related Factors

In all the three sampled health facilities (Ratta, Miranga, and Manyuada), 47.37% (18/38) of the health care providers reported that RDTs were stored well. That is, the storage facilities are fairly ventilated with thermometer and monitoring chart updated. Out of 38 health care providers, 8(21.05%) did not achieve the recommended storage standards for RDTs since the room temperature was not observed. There was no proper ventilation, and there was a lack of thermometer in these facilities. The results further show that 12(31.58%) had an excellent storage area for RDTs. 16(42.11%) of the health care providers checked the expiry date of mRDTs before use, however only 7(18.42%) were able to monitor mRDTs expiry date regularly. Stock monitoring was reasonably achieved in all the sampled health facilities. A few of the interviewed health care providers 15(39.47%) reported that malaria commodities' availability was somewhat achieved (Fig 3).

Figure 3: The Achievement of Test Device-Related Factors
Handling of the Rapid Diagnostic Test Kits

The results show that 10/22(45.45%) of community health volunteers (CHVs) training on malaria case management was not achieved, 10(45.45%) reported that training of staff on malaria RDTs were reasonably achieved, and 2(9.09%) said that training was excellent. The health facilities did not achieve training of staff in malaria RDTs as indicated

by the results, 4(66.67%), 3(50.00%) and 2(50.00%) of clinicians, medical laboratory officers, and nurses respectively. Concerning checking of the expiry date of mRDTs, 10/22(45.45%), 3/6(50.00%), 3/6(75.00%) of CHVs, clinicians, and nurses reported having achieved checking the expiry date of mRDTs before use as fairly. However, 4/6(66.67%) of the medical laboratory officers reported that checking of expiry date was excellently achieved. Putting on of new gloves when making a malaria diagnosis was excellently achieved by all the health care workers.

Out of 6 clinicians who participated in the study, 4(66.67%) excellently achieved cleaning of the puncture sites with alcohol and allowed the site to air dry. At the same time, 2(33.33%) reported that cleaning of puncture was fairly achieved. Collecting of adequate amount of blood was fairly achieved by 16(72.73%) of CHVs and 2(50.00%) of nurses, and 3(50.00%) of clinicians and medical laboratory officers 5(83.33%). The majority of medical laboratory officers 4(80.00%) dispensed blood samples in a correct well of RDTs excellently.

The result further shows that 17(77.27%) of CHVs fairly achieved applying the appropriate amount of buffer, and 4(18.18%) of CHVs excellently achieved application of the appropriate amount of buffer in RDTs well. Most of the medical laboratory officers achieved the use of the correct amount of buffer, and a half (50.00%) of clinicians and nurses reported that the application of the appropriate amount of buffer was excellently achieved (Table 1).

Factors	Health Care Provider Cadre				n (%)
	CHV	Clinician	Lab officers	Nurse	
	n (%)	n (%)	n (%)	n (%)	
Staff trained in malaria RDTs.					
Not achieved	10(45.45)	4(66.67)	3(50.00)	2(50.00)	19(50.00)
Fairly achieved	10(45.45)	1(16.67)	1(16.67)	2(50.00)	14(36.84)
Excellent	2(9.09)	1(16.67)	2(33.33)	0(0.00)	5(13.16)
The expiry date of RDTs checked					
Not achieved	10(45.45)	2(33.33)	2(33.33)	1(25.00)	15(39.47)
Fairly achieved	10(45.45)	3(50.00)	0(0.00)	3(75.00)	16(42.11)
Excellent	2(9.09)	1(16.67)	4(66.67)	0(0.00)	7(18.42)
New gloves worn					
Not achieved	7(31.82)	0(0.00)	1(16.67)	2(50.00)	10(26.32)
Fairly achieved	9(40.91)	2(33.33)	1(16.67)	2(50.00)	14(36.84)
Excellent	6(27.27)	4(66.67)	4(66.67)	0(0.00)	14(36.84)
Puncture cleaned with alcohol					
Not achieved	7(31.82)	0(0.00)	1(16.67)	2(50.00)	10(26.32)
Fairly achieved	10(45.45)	2(33.33)	0(0.00)	0(0.00)	12(31.58)
Excellent	5(22.73)	4(66.67)	5(83.33)	2(50.00)	16(42.11)
The adequate volume of blood collected					
Not achieved	1(4.55)	0(0.00)	1(16.67)	1(25.00)	3(7.89)
Fairly achieved	16(72.73)	3(50.00)	0(0.00)	2(50.00)	21(55.26)
Excellent	5(22.73)	3(50.00)	5(83.33)	1(25.00)	14(36.84)
Blood dispensed incorrect well of RDTs					
Not achieved	5(23.81)	0(0.00)	1(20.00)	2(50.00)	8(22.22)
Fairly achieved	9(42.86)	3(50.00)	0(0.00)	0(0.00)	12(33.33)
Excellent	7(33.33)	3(50.00)	4(80.00)	2(50.00)	16(44.44)
An appropriate amount of buffer applied					
Not achieved	1(4.55)	0(0.00)	1(16.67)	0(0.00)	2(5.26)
Fairly achieved	17(77.27)	3(50.00)	0(0.00)	2(50.00)	22(57.89)
Excellent	4(18.18)	3(50.00)	5(83.33)	2(50.00)	14(36.84)

Table 1: Handling of Rapid Diagnostic Test

3.2. Adherence to Standard Operating Procedures (Sops)

Out of 38 health care workers interviewed, 27(71.05%) were able to read test results correctly, and 8(21.05%) were not able to read test results correctly (Table 2). Table 2 also shows that 18(47.37%) healthcare workers reported that the recording of test results was excellent. However, 12(31.58%) did not achieve recording test results correctly in the health facilities. In terms of blood volume collected, 21(55.26%) of the health care workers reported that collecting adequate blood volume for malaria diagnosis was fairly achieved, 14(36.84%) reported that collecting adequate blood volume was excellently achieved, and 3(7.89%) did not achieve adequate blood collection in their health facilities. When diagnosing malaria, 16(44.44%) of the health care workers said that dispensing blood in the correct well of RDTs was excellently achieved. The results further reveal that the application of buffer in the appropriate well of RDT was fairly achieved by 22(57.89%) of the healthcare providers. Also, 14(36.84%) health workers said that applying appropriate buffer in well of RDT was excellently achieved (Table 2).

Factors	Not achieved n (%)	Fairly achieved n (%)	Excellent n(%)
Storage	8(21.05)	18(47.37)	12(31.58)
Stock out of malaria	14(36.84)	15(39.47)	9(23.68)
Expiry date	15(39.47)	16(42.11)	7(18.42)
Staff trained	19(50.00)	14(36.84)	5(13.16)
mRDTs SOPs available	11(28.95)	17(44.74)	10(26.32)
mRDTs sops and bench used	24(63.16)	7(18.42)	7(18.42)
Labeling of cassette	8(21.05)	26(68.42)	4(10.53)
Gloves worn	9(23.68)	14(36.84)	15(39.47)
New gloves worn	10(26.32)	14(36.84)	14(36.84)
puncture site cleaned	10(26.32)	12(31.58)	16(42.11)
Adequate blood volume collected	3(7.89)	21(55.26)	14(36.84)
Blood dispensed incorrect well of RDT	8(22.22)	12(33.33)	16(44.44)
Buffer applied to correct well of RDT	8(21.05)	14(36.84)	16(42.11)
Appropriate buffer applied	2(5.26)	22(57.89)	14(36.84)
Control line visible	9(23.68)	5(13.16)	24(63.16)
Reads test result correctly	8(21.05)	3(7.89)	27(71.05)
Records result correctly	12(31.58)	8(21.05)	18(47.37)

Table 2: Adherence to Standard Operating Procedures (Sops)

Figure 4: Factors Influencing the Performance of Rdts

4. Discussions

4.1. Factors Affecting the Performance of Malaria Rapid Diagnostic Tests

It is widely established that the key factor in improving diagnosis of malaria is availability of mRDTs in health facilities. This study found that rapid diagnostic kits were available in 39.4% of the health facilities this was higher than a study done in Enugu state where 31% of health facilities had mRDTs and lower than a study done in Ogun state that reported mRDTs was available in 50.7% of the health facilities (Boyce *et al.*, 2017). This however, is less than the WHO average availability which is said to be inadequate if it falls below 76%. Stock out of testing commodities can be due to erratic supplies from Kenya medical supplies urgency (KEMSA), improper documentation and erratic reporting of quantity used and probably due to inadequate information needed during forecasting and quantification period. Planning to have adequate stock, especially over the peak transmission period, is vital to preventing stock-outs. Liaison with the Sub County medical laboratory officer is crucial to ensure a steady stream of stock replacement.

The manufacturer's recommendations for storage of mRDTs are 2°C to 30°C (Diagnostic package insert). The study revealed that effective storage was at 31.58%, which means that temperature monitoring and storage conditions were not effectively monitored. Poor storage is basically due to the different level of health care that RDTs are used. The primary level is not able to offer the expected storage conditions for the RDTs and this can only be achieved in level 2 health care facilities. Like other biological tests that rely on antibody-antigen interactions, current malaria RDTs deteriorate more quickly on exposure to moisture (humidity) and extreme temperature. Poor storage might interfere with the integrity of the test kits leading to the poor performance of the mRDTs. In the study sample, only 12 participants reported having excellent storage conditions for mRDTs test kits. Increases in temperatures above 30°C can affect the overall performance of mRDTs. Therefore it becomes important that room temperatures are maintained below 30°C, and temperature monitoring is taking place regularly in mRDTs storage room of all the health facilities and community field testing. Those

rooms that exceed temperatures of 30°C should be cooled with air conditioning or similar cooling equipment, this being dependent on financial resources available to local health authorities in the study Sub County, this agrees with the study done by Moody (Obeagu *et al.*, 2018).

There was huge uncertainty in the quality control and accuracy of mRDTs by end-users and malaria management staff. The study revealed that health care workers did not use known positive control wells for external quality control, and the test kit verification was not being done. The health facilities depend on the inbuilt internal quality control. This is because there were no known positive control wells available and the health care workers have not been trained on lot to lot verification process hence the knowledge gap. It is important to consider the use of positive control wells and temperature monitoring to assure the quality of the rdt and to build the confidence of the users on mRDT (Bell *et al.*, 2017). Discrepancies between microscopy results and end-user findings on mRDTs are a concern. The discrepancies point to two challenges, either the test kits were not working, or the end-user was not using the kits correctly, as reported by Rennie and Moonasar (Boyce, 2017). The discrepancies can be attributed to lack of SOPs. Bench job aids and WHO guidelines. Adherence to the standard operating procedures was at 26.36% and the expected performance target should be greater than 100 %. To improve on this indicator it is important the reference materials be made available to all users at all level.

Another factor influencing mRDTs utilization and performance found in this study was training. This is similar to previous studies that showed that training of health care workers on mRDTs improves health care workers performance with increased likelihood of adherence to malaria treatment guidelines (Opoku, 2018). External training was not being conducted for the end-users regularly as expected. On job training was not based on the standard operating procedures using standardized materials and methods. There is also uncertainty on the quality of existing on job training for mRDTs because even the supervisors had not been refreshed. Various studies have documented significant variation between end users in both preparation and interpretation (Boyce *et al.*, 2017; Harvey *et al.*, 2017; Mathison *et al.*, 2017). A standardized training guide for on job training may need to be considered (Kosack *et al.*, 2017). Although package inserts are useful, it would be easier for end-users to have bench job aids so that the test procedures can be easily visible and interpretation of results easily read, especially during busy periods and late in the night. Preparation and interpretation can also be affected by manual ease of interpretation, visual perceptiveness and available lighting. To perform the tests in a realistic test environment the training and previous experience of the end users is necessary. The key challenges for malaria mRDTs in the health facilities are frequent stock outs, the accuracy of the kit, the proficiency of the end-user, and quality control to ensure that the kits are working well to monitor the diagnostic performance. This concurs with a study done in Zamfara State on predictors of malaria rapid diagnostic tests utilization among the health care workers (Usman *et al.*, 2018).

5. Conclusion

The uncertainty about the skills of use of mRDTs from both the health facilities users and the community health volunteers is a cause for concern.

The value of the mRDTs for diagnosis of malaria at the primary healthcare level was understood by all the categories of respondents: end-users, clinicians, nurses' community volunteers, and laboratory staff.

The storage of malaria rapid test kits was not entirely satisfactory; temperature monitoring will need to be conducted to bring this component to more acceptable standards.

Factors affecting the performance of RDTs in Seme Sub County included unsatisfactory storage, inadequate training for health care workers, and failure to adhere to the standard operating procedures. There were also lack of WHO laboratory guidelines, bench job aids and standard operating procedures and there was no evidence of external quality assurance in place.

6. Recommendation

Temperature monitoring of the storage areas for mRDTs, training of staff, standard operating procedures, and verification exercise is recommended for the effective performance of mRDTs.

Biannually, proficiency testing organized by malaria control unit for malaria rapid diagnostic test end user at all health care levels should be considered to evaluate the skills of the end-users of mRDTs scientifically.

7. Author Summary

Our study was informed by the observation that malaria Rapid Diagnostic Test kits (mRDTs) have become widely used but predominantly in primary health care and level two hospitals. Their use in Seme Sub County is at 76% where only six microscopy sites were present at the time of the study out of the twenty five health facilities. The study assessed the factors affecting the performance of mRDTs in Seme Sub County. The study revealed that there were several factors affecting the performance of mRDTs which included stock availability, storage, end user training, availability of the standard operating procedures and external quality assurance mechanism

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8.1. Conflict of Interest

The authors have no any conflict of interest.

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