

The Place of External Quality Assurance (EQA) on Malaria Diagnosis in Malaria Control: A case study of Primary Health Care services in Cross River State

Iniabasi Nglass

PhD., Texila American University, Nigeria

*Corresponding Author: eeniabasi@yahoo.com

Abstract

*Malaria remains the leading cause of morbidity and mortality, causing more than one million deaths worldwide each year, and over 90% of them occur in Africa. Nigeria has the highest malaria burden in the world and more than 60% outpatient visits in Nigeria is due to malaria. According to World Malaria report of 2018, 19% of global malaria death occur in Nigeria. This can be attributed partly to poor patient management due to poor diagnosis; therefore, prompt and reliable laboratory diagnosis is recognized as an important component of effective malaria case management and control. It is therefore necessary to establish **External quality assurance (EQA) on malaria diagnosis**, which will seek to achieve reliable and **accurate malaria diagnosis** which leads to improved patient care and rationale drug use. EQA provides objective evidence of laboratory competence for customers, accrediting bodies and regulatory agencies, and serves as a unique source of information that is not obtainable in other ways. It involves the assessment of factors that influence the **quality of malaria diagnosis**. This study looked at **Malaria Diagnosis** in 40 primary health centers in Cross River State of Nigeria within 2013-2015, comparing the reports of each year, there was a progressive improvement in the processes of diagnosis, reliable results were produced, record keeping improved, storage, work space improved and skills of personnel from inception of 2013 till 2015. DHIS report for same period when compared showed significant reduction in confirmed uncomplicated malaria. Therefore, **external quality assurance on diagnosis has positive impact malaria control**.*

Keywords: External quality assurance (EQA) on malaria diagnosis; malaria diagnosis; malaria control.

Introduction

Malaria has remained a major public health problem in Nigeria; children under the age of five and pregnant women are still the most affected. More than 60% outpatient visits in Nigeria is due to malaria. The disease has impacted negatively on the economy with about 132 billion Naira lost to the disease as cost of treatment and loss in man-hours.

The Nigerian Malaria Strategy Plan, Specific objective 2 seeks to Increase diagnostic testing of suspected malaria cases to 100% by 2020. To achieve malaria control, a network of accurate, reliable and timely malaria diagnosis, since unreliable malaria diagnosis will definitely result in poor malaria case management is required. For this reason, a quality assurance system of malaria diagnosis, a key component of WHO Roll Back Malaria (RBM) strategy, is essential for early

diagnosis of malaria. Parasitological diagnosis of malaria is performed by microscopic methods at comprehensive health centers and hospitals and malaria Rapid Diagnostic test (mRDTs) at the Primary Health Care level. Although tremendous progress has been recorded by the National Malaria Control programme supported by some implementing partners, in rolling out mRDT and capacity building of health care providers at all levels, there remain critical gaps and challenges in malaria diagnosis. These challenges could be attributed to lack or non-existence of a quality assurance system for malaria diagnostics (microscopy and mRDTs).

One of the key strategies to control malaria is effective case management, Unfortunately, this has received a major setback in the past years because of the high level of resistance to the first- and second-line antimalarial medicines; Chloroquine and Sulphadoxine-pyrimethamine.

Until recently, in areas of high malaria transmission such as Nigeria, malaria treatment has been based mainly on clinical diagnosis which was presumptive, because malaria was considered one of the commonest causes of fever. (National Guideline 2015).

The Nigerian National Strategy Plan for malaria control is based on a network of accurate, reliable and timely malaria diagnosis, since unreliable malaria diagnosis will definitely result in poor malaria case management. For this reason, a quality assurance system of malaria diagnosis was introduced, a key component of WHO Roll Back Malaria (RBM) strategy, is essential for early diagnosis of malaria. Parasitological diagnosis of malaria is performed by microscopic methods at comprehensive health centers and hospitals and malaria Rapid Diagnostic test (mRDTs) at the Primary Health Care level.

Methodology

An unstructured approach of research was adopted. The Primary source of data was collected directly from the reports of External Quality Assurance (EQA) carried out to forty primary health facilities in Cross River State over a period of 3 years (2013-2015). The secondary data source was from related publication research topic in other regions, textbooks, internet, journals and magazines. Then data from Nigeria District Health Information System (DHIS), on disease trend, diagnosis and case management comparing fever cases tested positive against fever cases treated.

Research design and sampling technique

- Observational sampling.
- Review of EQA reports
- Review of DHIS data on diagnosis and case management.

Data collection

- Observation and review of other related data from 40 Primary Health Care (PHC) facilities.
- Review of EQA reports conducted in these health facilities from 2013 till 2015.
- Analyses of data from DHIS from these health facilities from 2013 - 2015 fever cases treated for this period.

Data Analysis

- Descriptive statistics using average, frequency table, observational view and presented in tables and graphs.

Results and discussion

Quality assurance (QA) of malaria diagnosis is essential for early and accurate diagnosis of malaria. It involves the assessment of factors that influence the quality of malaria diagnosis such as the quality of infrastructure, personnel and work tools.

- The results of the study showed that from the first EQA exercise (2013), only 31PHCs were involved and actual implementation of the mRDT ranged from 35.7% to 88.1%. Only 2PHCs were the best implementers while the one PHC had only 35.7% implementation rate of mRDT. The effective range of observance of QA/QC ranged between 0-70% with about 12 centers not observing it (0%). General assessment of the 1st EQA showed: Poor results of mRDT at the PHC levels and Poor observance of QA/QC at the PHC level as regards malaria diagnosis by rapid test. Table 1 has a breakdown of the assessment criteria.
- Overall result on the 2014 EQA conducted on mRDT was made to 45 PHCs, Table 2 shows the breakdown. Nine indicators used to assess the quality of malaria RDT conducted in the state were: Documentation, Lab space, Lab safety practices, Lab safety supplies, storage, stock management, mRDT training, Testing, and QA/QC. All mRDTs available in the different facilities were assessed. The actual implementation of the mRDT ranged from 50% to 100. Only 61.1% of the Carestart mRDT tested at 18 health centers gave positive results at parasite count of 200 and 2000 parasite/ul of blood. Only 15.4% of the SD Bioline mRDTs tested at 13 centers gave positive results at both parasite levels used. However, at 2000parasites/ul, both Carestart and SD Bioline gave positive result. A significant improvement over the first EQA in 2013. Several PHC had a 100% use of mRDT. The effective range of observance of

QA/QC ranged between 0-80% with about 10 centers not observing it (0%). And there was improvement in documentation by PHCs when compared to 2013.

- In 2015, a total of 35 primary health facilities (PHCs) were assessed for malaria diagnosis. Some of the indicators used to assess the quality of malaria RDT conducted in the state were: Documentation, Laboratory space, Laboratory safety practices, Laboratory safety supplies, storage, stock management, mRDT training, Testing, QA/QC etc. All mRDTs available in the different facilities

were assessed during the visit to the facilities, Table 3 below shows the result. A comparison was also done to see if there was an improvement in the present EQA compare to the previous EQA in the primary health centers. This was carried out by evaluating five of the PHCs that were visited in the last EQA and the present EQA. The result of the analysis showed that we had improvement in some of the parameters used. This is captured in Figures 1-5 below: Previous-2014 & Present -2015.

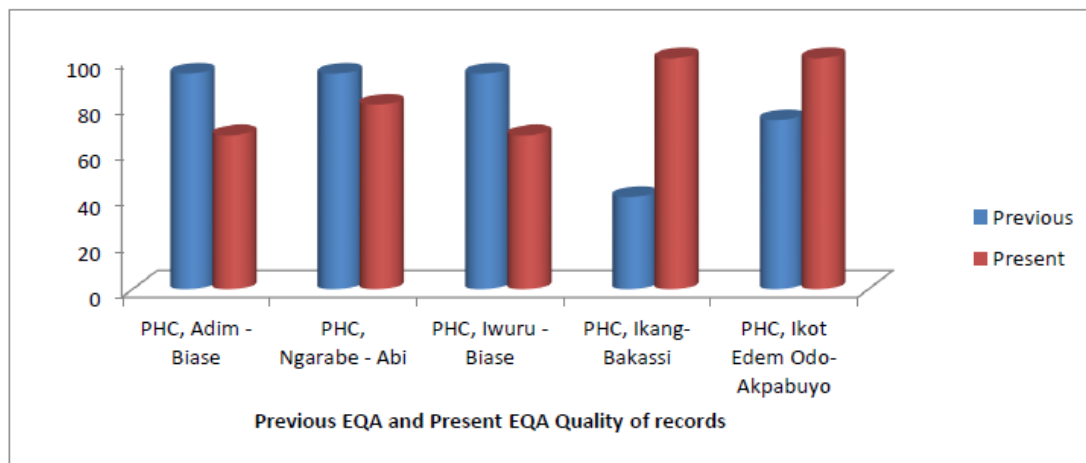


Figure 1. Comparison between the previous and present quality of records in PHC

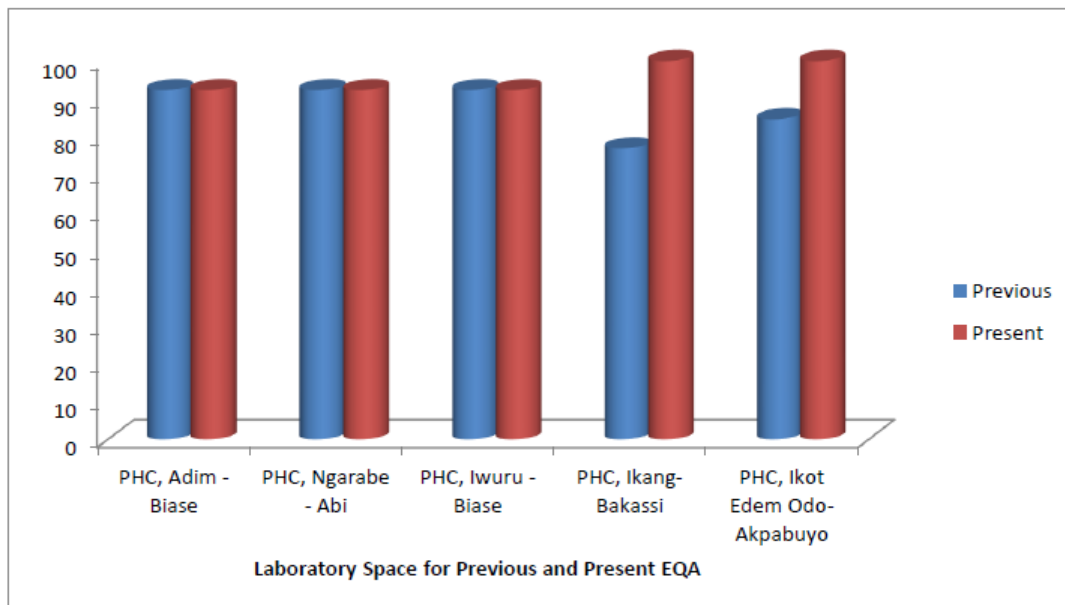


Figure 2. Comparison between the previous and present laboratory space in PHC

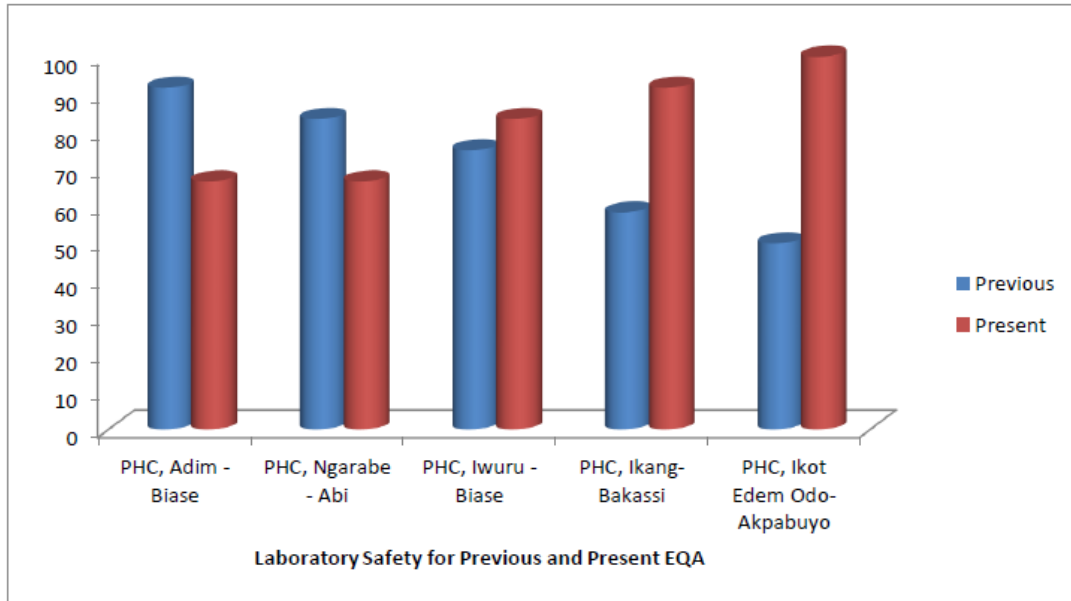


Figure 3. Comparison between the previous and present laboratory safety in PHC

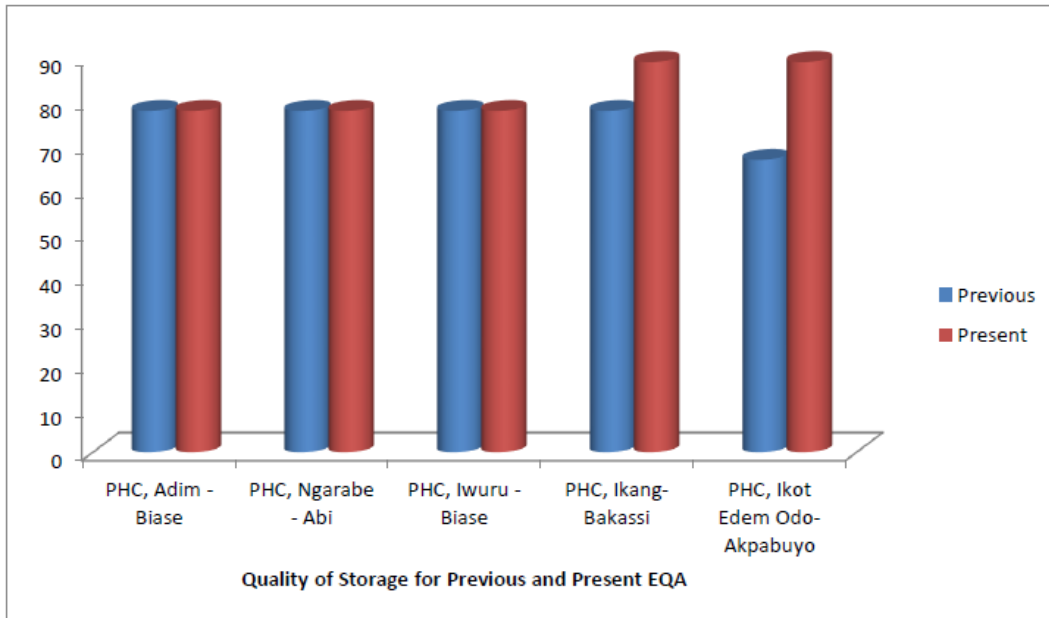


Figure 4. Comparison between the previous and present quality of storage in PHC

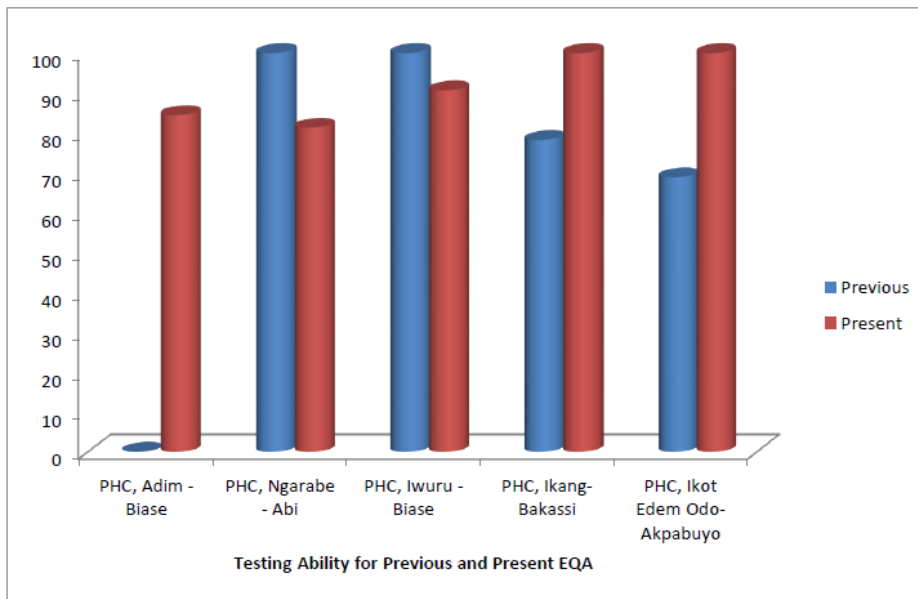


Figure 5. Comparison between the previous and present testing ability in PHC DHIS Data for the period under review

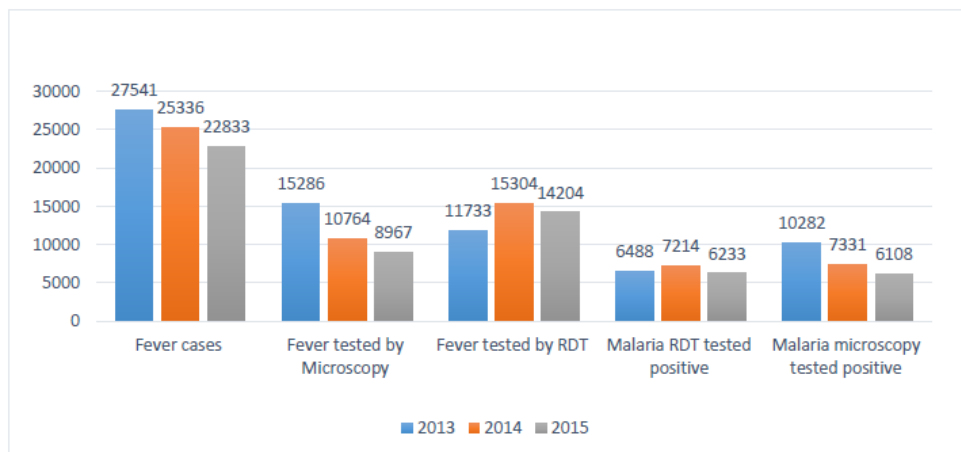


Figure 6. Data from DHIS for 2013 to 2015 showing downward trend in malaria cases

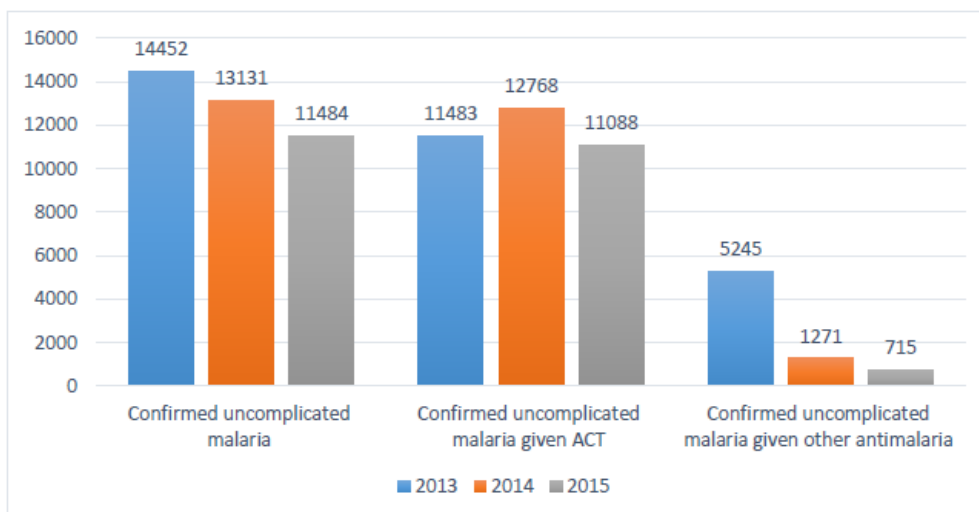


Figure 7. DHIS data showing confirmed uncomplicated malaria trend and treatment

Figures 6 and 7 shows a downward trend in confirmed cases of malaria when comparing 2013 to 2015. This can also be attributed to improved skills in malaria diagnosis, which led to reduced number of confirmed, rational drug use and improved patient management. Just as the mentoring exercise was being carried-out to laboratory personnel, other members of the healthcare team were equally coached and supervised, their capacity was also built on malaria prevention, diagnosis and case management. With all the interventions, they were able and equipped to look out for other causes of fever and treat accordingly.

Discussion

The mRDT and malaria microscopy EQA program was seen to be strengthening the implementation of parasite-based policy on malaria diagnosis. There was a remarkable impact of the EQA program on malaria diagnosis in the state since inception.

- There was an improvement over the last two years EQA.
- The skills of the trained macroscopics at the centers, although not very good had significant improvement, this can be attributed to mentoring and on-the-job coaching gave during the EQA and training. This can be seen from the high agreement rate of the results.
- Availability of high-quality microscopes was still a limiting factor for accurate malaria diagnosis.
- Lack of adherence to the malaria diagnostic protocol
- Poor observance of QA/QC at the PHC level as regards malaria diagnosis by rapid test
- Continuing qualitative reporting of results of malaria microscopy needs to be emphasized
- Improved documentation from both PHCs.

Data capturing, safety procedures, storage and detection agreement as well as specificity and sensitivity, was shown to have improved over time from inception of EQA in 2013 to 2015. The continuity of this program will help to track the correct malaria prevalence and over diagnosis in the country. It will also help improve patient care and proper management of malaria fever.

Conclusion

Nigeria with the high malaria burden needs an institutionalization of EQA to improve rational drugs use, skills of malaria macroscopics and patient management. A continuum of interventions can have a direct impact on capacity, diagnosis, patient management and rational drugs use as well as improved documentation as Data from DHIS showed an improvement in diagnosis and patient management with the right drugs. The skills and capacity of the laboratory macroscopics in the proper diagnosis of malaria was improved by EQA. There was improvement and better understanding of the need for documentation, which helped in decision making and policy development. Continuous improvement in skills, proper diagnosis will ultimately lead to proper patient management and rational drug use. Private health facilities and Private laboratories should be considered for EQA because a good number of the population seek healthcare in the places.

Tables

Table 1. Percentage Performance for Primary Health Centers in using RDT

S/N	Facilities	Documentation	Lab space	Lab safety practices	Lab safety supply	Storage	Stock Management	mRDT Training	Testing	QC/QA
1	p H C Mbarakom	38	0	23	50	100	31	67	63	50
2	P H C SANKWALA EAST 2	81	90	77	83	67	85	33	94	10
3	P H C UGEP	25	0	0	0	67	54	100	78	0
4	MODEL PHC ABOCHECHE	75	57	77	83	67	92	0	100	20
5	P H C EFRAYA	38	90	69	83	67	85	67	91	0
6	P H C AGBOKIM	25	49	69	83	67	31	33	88	20
7	P H C MKPANI	31	90	54	0	67	92	67	78	0
8	P H C UGAGA	50	81	69	67	67	100	100	100	0
9	P H C OKUNDI	84	98	62	100	67	77	100	94	0
10	P H C BANSARA	97	90	69	100	67	92	33	100	70
11	P H C HENSHAW TOWN	69	81	77	83	33	46	100	100	50
12	NYSC/ COMMUNITY BASED H C	66	41	69	83	33	38	33	94	50
13	P H C IKOT EDEM ODO	69	98	77	67	67	62	100	97	70
14	P H C AKWA IKOT EFFANGA	69	57	62	83	33	31	100	94	60
15	P H C OBUBRA CENTRAL	50	8	62	83	67	54	33	91	60
16	P H C EDIBA	31	57	69	67	67	46	0	81	0
17	p H C AKPET 1	0	90	77	100	67	85	100	94	70
18	p H C OKUKU	72	98	77	83	67	162	67	94	70
19	p H C EKORI	28	98	62	33	67	77	0	81	0
20	p H C BATRIKO	63	73	77	83	67	69	67	91	20
21	P H C APIAPIUM	59	90	54	83	67	77	33	88	0
22	P H C AKORSHI	63	90	69	83	67	85	100	94	30
23	MATERNAL & CHILD HEALTH OB	75	41	69	83	67	100	67	94	60

24	PHCEKPRI IKANG	69	81	54	83	33	31	100	100	50
25	P HC IKOT OKPARA	19	0	0	67	67	69	100	81	0
26	P HC IGOLI OGOJA	88	81	69	100	100	100	100	100	70
27	P HC IBOM ABI LGA	75	24	92	100	67	69	100	97	60
28	P HC OKUNI	31	98	92	100	67	69	100	100	70
29	P HC IKOT OMIN	38	16	62	83	0	31	33	81	0
30	P HC AKPARABONG	56	57	69	83	67	85	100	88	40
31	P HC ODUKPANI QUA	47	90	69	100	67	54	33	88	0

Table 2. Percentage Performance for Primary Health Centers in using RDT

Percentage Performance for Primary Health Centers in using RDT										
S/N	Primary Health Facilities	Documentation	Laboratory Space	Laboratory Safety	Storage	Stock Management	MRDT Training	Testing	QA/QC	
1	Betakwel PHC, Obudu	44	8	50	67	77	33	78	0	
2	epoule ebo PHC, Ebo	41	38	67	89	92	33	81	0	
3	NSADOP, Boki	38	92	75	78	100	33	81	0	
4	PHC, Nyanya- Bekwana	72	77	75	78	46	33	97	70	
5	Maternal & Child Health Clinic, Obudu	31	69	67	56	38	67	91	0	
6	PHC, Sankwala-Obanleku	28	69	75	78	46	100	94	0	
7	BUSI III, Obanleku	31	69	50	89	85	33	84	0	
8	OLACHOR, PHC - Yala	75	92	75	78	85	33	88	80	
9	Ekumtak PHC, Ogoja	28	15	58	78	46	33	75	0	
10	PHC, Ikang-Bakassi	41	77	58	78	62	100	78	50	
11	Health Centre Abakpa	44	69	58	67	38	0	50	60	
12	PHC, Ifiang Nsung- Bakassi	38	85	58	33	62	33	69	70	
13	PHC, Ikot-Nakanda	3	77	50	78	31	0	53	10	
14	PHC, Idundun-Akpabuyo	38	92	75	67	8	0	66	60	
15	PHC, Ikot Edem Odo-Akpabuyo	38	85	50	67	85	0	69	50	

16	PHC, MMA-EFA Akamkpa Urban	0	77	42	11	0	100	6	0
17	PHC, Odukpani, QUA Town	59	69	50	78	46	0	63	30
18	Okoyong Usang Abasi, HC - Odukpani	47	100	50	44	54	0	50	40
19	PHC, Ikot Ansa - Calabar Municipality	41	100	58	78	69	0	69	40
20	St. Joseph Ikot Ene - Akpabuyo	66	100	100	100	92	33	100	90
21	Lutheran Hosp. Yala	97	92	92	89	92	67	100	80
22	PHC, Ukpe - Ogoja	63	85	83	89	85	33	94	80
23	Wonye Health Centre - Yala	94	69	83	89	77	33	91	80
24	PHC, Ibil - Ogoja	94	85	92	67	100	67	100	80
25	PHC, Kawagani - Boki	97	85	75	56	46	33	100	80
26	MPHC Ukulia - Obudu	97	77	92	89	92	100	100	80
27	PHC, Utuhu - Obaniliku	97	92	92	78	100	67	100	80
28	PHC, Gakem - Bekwara	97	100	92	89	100	67	100	10
29	PHC, Amantigha	56	92	92	89	77	0	63	30
30	PHC, Etomi	56	100	92	89	54	33	100	70
31	PHC, Abia - Etung	63	100	92	89	31	0	0	80
32	PHC, Agbokim	63	0	100	78	69	100	84	60
33	PHC, Ikom Ward - Ikom	38	77	58	22	15	33	0	40
34	PHC, Adijinkpor - Ikom	53	54	83	89	31	67	84	30
35	Edor PHC - Ikom	53	100	75	78	85	0	69	0
36	Model PHC, Ababene-Obubra	56	85	75	89	46	33	100	50
37	PHC, Ofodua - Obubra	53	100	92	78	62	33	100	60
38	PHC, Onyadama - Obubra	63	92	58	67	38	33	100	50
39	PHC, Ngarabe - Abi	66	92	83	78	46	33	100	50

40	Esa Memorial Joint Hosp. Itigidi	91	100	100	67	62	33	100	60
41	Health Post Ketabebe - Yakur	63	8	83	78	46	33	100	60
42	PHC, Iwuru - Biase	63	92	75	78	38	33	100	50
43	PHC, Adim - Biase	63	92	92	78	38	33	0	60
44	PHC, Agwagung - Biase	63	100	75	78	46	100	94	60
45	PHC, Assiga - Yakurr	0	0	0	0	0	0	0	0

Table 3. Results of RDT QA Done in EQA for Malaria Diagnosis in Calabar

S/N	Facilities	Name of RDT	Dilutions	Result	Remarks
1	NYSC Clinic PHC, Calabar South	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
2	PHC, Ederly, Ward 7, Calabar South	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
3	PHC, Aka I Esuk, Calabar South	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
4	PHC, Unyangha	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
5	PHC, Anwi	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
6	Dr Lawrence Henshaw	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	

7	PHC, Adiabo Okunukang	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
8	PHC Mfanosuung	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
9	PHC Edem Odo	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
10	PHC, Agoi Ekpo	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
11	PHC Benedeghe	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
12	PHC, Ochon	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
13	Ashikpe PHC	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
14	Nwang PHC	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
15	PHC Wula	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	

16	PHC Utanga	CareStart	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
17	Uganga PHC	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
18	Lutheran Hosp. Yabe	CareStart	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
19	General Hosp. Akampka	SD Bioline	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
20	St. Joseph Ikot Ene	SD Bioline	2000	Pos	Passed
			200	Pos	
			Neg	Neg	
21	PHC Ngarebe, Ekureku II	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
22	PHC, Idomi	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
23	Holy Family Catholic Ikom	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
24	Comprehensive HC Ikom	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	

25	Model PHC, Okuni	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
26	PHC Idomi	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
27	PHC Adim	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
28	PHC Iwuru	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
29	Ukpe PHC	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
30	Model PHC, Ukwutia	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
31	PHC Abo Abam	SD Bioline	2000	Pos	Failed
			200	Neg	
			Neg	Neg	
32	PHC Ediba	Orchid Paracheck	2000	Neg	Failed
			200	Neg	
			Neg	Neg	
33	Health Centre Assiga, Old Town	No Kits	2000	Neg	No Kits
			200	Neg	
			Neg	Neg	

34	PHC, Asiga	No Kits	2000	Pos	No Kits
			200	Pos	
			Neg	Neg	
35	PHC Obutong	No Kits	2000	Neg	No Kits
			200	Neg	
			Neg	Neg	
36	PHC Ikang	No Kits	2000	Neg	No Kits

References

- [1]. Clinical and Laboratory Standards Institute (CLSI). Using Proficiency Testing to improve the clinical laboratory; Approved Guideline-Second Edition. CLSI document GP27-A2. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.
- [2]. Global Malaria situation, with special reference to Africa. NMCP Managers Meeting Dakar, Senegal, 22 – 26 October, 2018.
- [3]. Global Technical Strategy for Malaria 2016-2030.
- [4]. Guidelines for the treatment of malaria. Third edition. WHO April 2015.
- [5]. Hoeltge GA, Duckworth JK. Review of proficiency testing performance of laboratory accredited by the College of American Pathologists. *Arch Pathol Lab Med* 1987; 111:1011-4.
- [6]. Jenny RW, Jackson KY. Proficiency test performance as a predictor of accuracy of routine patient testing for theophylline. *Clin Chem* 1993; 39:76-81.
- [7]. Malaria Action Program for States (MAPS) External Quality Assurance (EQA) Report. April, 2014.
- [8]. National Health Act, 2010 (Act No 61 of 2010, sections 55 and 56).
- [9]. South Africa Draft Malaria Elimination Strategy, 2010 -2018.
- [10]. Uldall A. Origin of EQA programmes and multidisciplinary cooperation between EQA programme organizers within laboratory medicine. *EQA News* 1997; 8:1-27.
- [11]. Westgard JO. Managing quality vs. measuring uncertainty in the medical laboratory. *Clin Chem Lab Med* 2010;48: 31-40.
- [12]. Westgard JO. Internal quality control: planning and implementation strategies: *Ann Clin Biochem* 2003; 40:593-611.
- [13]. WHO Malaria Elimination Manual; Global Malaria Programme, 2009.
- [14]. World Health organization (2016). Guidelines for the treatment of malaria (3rd edition). WHO, Geneva.
- [15]. World Health Organization (2017). Malaria report 2017. WHO, Geneva.
- [16]. World Health Organization (2018). Malaria report 2018. WHO, Geneva.
- [17]. WHO. Global technical strategy for malaria 2016–2030. Geneva: World Health Organization (WHO); 2015 (http://www.who.int/malaria/areas/global_technical_strategy/en, accessed 19 November, 2018).