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Baseline health facility assessment of quality assurance for malaria diagnosis in existing government hospital laboratories in Sokoto State, Nigeria

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Abstract:

Background: Quality laboratory services are needed to direct reasonable malaria case management through malaria microscopy and rapid diagnostic test. This study assessed the existing diagnostic capacities including laboratory structures and systems, human resource, skills and competences, using the standardized WHO/NMEP EQA assessment tool.
Methodology: Data were collected by an assessment team using a standardized assessment instrument/checklist drawn from WHO/NMEP assessment tool and analyzed with Open Data Kit (ODK) and Open-source suite of tools on Android mobile devices from September 3-11, 2020. The use of ODK allowed data to be collated offline where internet services were poor or unavailable and uploaded thereafter.
Results: Of the 24 laboratory facilities assessed, diagnostic services on malaria are routinely done with combined malaria rapid diagnostic test (mRDT) and microscopy at 17 (65.0%) laboratories, microscopy only at 7 (27.0%) laboratories, while only mRDT was performed in 1 (3.8%) laboratory due to lack of functional microscopes, supplies, or trained personnel in microscopy. In the 24 facilities providing laboratory services, 16 (63.0 %) had one of the staff received basic malaria microscopy and mRDT training in the year prior to the assessment, and 23 (96.0%) of the laboratories had at least one functional electric binocular microscope. None of the laboratory had a good structured quality assurance/quality control procedure or standard operating procedures for either microscopy or mRDT.
Conclusion: There were gaps in laboratory services due to lack of well-established quality control framework and ineffective communication system, which could have substantial impacts on the quality and accessibility of malaria diagnosis. These issues can be addressed by improving laboratory services.

Keywords*:* malaria; quality assurance; hospital laboratory; secondary health facilities; capacity

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Évaluation de base par les établissements de santé de l'assurance qualité pour le diagnostic du paludisme dans les laboratoires hospitaliers gouvernementaux existants dans l'État de Sokoto, au Nigéria

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Résumé

Contexte: Des services de laboratoire de qualité sont nécessaires pour diriger une prise en charge raisonnable des cas de paludisme grâce à la microscopie du paludisme et au test de diagnostic rapide. Cette étude a évalué les capacités de diagnostic existantes, y compris les structures et les systèmes de laboratoire, les ressources humaines, les aptitudes et les compétences, à l'aide de l'outil d'évaluation EQA standardisé de l'OMS/NMEP.
Méthodologie: Les données ont été collectées par une équipe d'évaluation à l'aide d'un instrument d'évaluation/liste de contrôle standardisée tirée de l'outil d'évaluation de l'OMS/NMEP et analysées avec Open Data Kit (ODK) et une suite d'outils open source sur les appareils mobiles Android du 3 au 11 septembre 2020 L'utilisation d'ODK a permis de rassembler les données hors ligne lorsque les services Internet étaient médiocres ou indisponibles et de les télécharger par la suite.
Résultats: Sur les 24 établissements de laboratoire évalués, les services de diagnostic du paludisme sont systématiquement effectués avec un test de diagnostic rapide du paludisme combiné (mRDT) et une microscopie dans 17 laboratoires (65,0%), la microscopie uniquement dans 7 laboratoires (27,0%), tandis que seul le mRDT a été effectué. dans 1 (3,8%) laboratoire en raison du manque de microscopes fonctionnels, de fournitures ou de personnel qualifié en microscopie. Dans les 24 établissements fournissant des services de laboratoire, 16 (63,0 %) avaient un membre du personnel ayant reçu une formation de base en microscopie du paludisme et mRDT au cours de l'année précédant l'évaluation, et 23 (96,0%) des laboratoires avaient au moins un microscope binoculaire électrique fonctionnel. Aucun des laboratoires ne disposait d'une bonne procédure structurée d'assurance qualité/contrôle qualité ou de modes opératoires normalisés pour la microscopie ou le mRDT.
Conclusion: Il y avait des lacunes dans les services de laboratoire en raison de l'absence d'un cadre de contrôle de la qualité bien établi et d'un système de communication inefficace, ce qui pourrait avoir des impacts substantiels sur la qualité et l'accessibilité du diagnostic du paludisme. Ces problèmes peuvent être résolus en améliorant les services de laboratoire.

Mots clés: paludisme; assurance qualité; laboratoire hospitalier; établissements de santé secondaires; capacité

Introduction:

The 2020 World Malaria Report estimates that 229 million cases of malaria occurred worldwide with approximately 409,000 deaths (1). The most vulnerable malaria-affected group were children under the age of 5 years who accounted for 67% (272,000) of all deaths from malaria worldwide. Nigeria alone accounts for 27% of the world malaria cases (1). Over 97% of the projected 5.4 million people in Sokoto State are at risk of malaria infection every year caused by *Plasmodium falciparum*. The main determinants of malaria epidemiology in the State are rainfall, environmental factors, and human status, and with a childhood mortality of over 19 per 100,000 population, the disease still ranks as the highest cause of deaths amongst children and places a huge burden on the economy in terms of man-hours lost in business and schools (2).

In Sokoto State, Nigeria, most secondary health facilities are primarily concentrated in urban and semi-urban areas, whereas primary health care (PHC) centers are situated in rural areas and are usually staffed by at least one community health officer, nurse, laboratory technicians, pharmacists or midwife. Rural area are settlements with fewer than 2,500 residents while urban areas comprise larger places and densely populated areas around them, with semi-urban in between rural and urban, but not wholly characteristic of rural areas. Most patients with complicated malaria are evaluated and treated at secondary or tertiary health facilities. The secondary health facilities have laboratory services that examine blood films under the microscope, whereas the PHCs rely on malaria rapid diagnostic tests (mRDTs).

High-quality laboratory services for the diagnosis of malaria are not widely available in Sokoto State, especially at the community level, where access to accurate malaria diagnosis and appropriate treatment are inadequate. Both the WHO policy on malaria diagnostics and the National Guidelines for Diagnosis and Treatment of malaria recommends the use of microscopy and quality-assured mRDTs for parasitological diagnosis of malaria. However, microscopy should be deplored at tertiary and secondary health facilities while mRDTs at the PHC facilities, and supported by quality assurance (QA) program, since microscopy remains the "gold standard" for parasitological diagnosis of malaria. Although molecular techniques such as polymerase chain reaction (PCR) and loop-mediated isothermal amplification (LAMP) assays have higher sensitivity and specificity, they are mostly research tools, and are not used for routine diagnosis due to high cost and technical complexity.

The mainstay of an efficient, effective, and accurate diagnosis of malaria revolves around putting in place QA program. In Sokoto State, there had been few research publications on malaria (3,4) but there is probably no published QA information concerning the study area across the tiers of health care system. The introduction of QA system is therefore an opportunity to review and strengthen the entire available

malaria diagnostic system for provision of a quality assured malaria parasite-based diagnosis in the State which are crucial in reducing misdiagnosis, over-diagnosis, quality-assured care, and reduce drug resistance and wastages due to wrong prescription of antimalarial.

The national guidelines for diagnosis and treatment of malaria recommends that all persons suspected for fever cases be tested with mRDT at PHC levels or microscopy at secondary and tertiary health facilities before treatment. The parasitological diagnosis should be quality assured (5). It is important to confirm the existence of the malaria parasite, as clinical diagnosis is often inaccurate, resulting in antimalarial drug waste and possibly contributing to drug resistance. Therefore, setting up an effective and functional QA system for both microscopy and mRDT is considered indispensable to ensuring accuracy and reliability of the diagnostic test result for effective malaria treatment. This is complemented by trained, competent and motivated staff, and supported by effective supervision to achieve reliable, accurate and timely malaria diagnosis.

To achieve this objective, the National Malaria Elimination Program (NMEP) has prioritized the development, design, and implementation of malaria diagnostic QA system in Nigeria. A comprehensive baseline study was conducted in Sokoto State to assess the existing malaria diagnostic capacities with the use of microscopy, including laboratory structures, human resource, skills and competences, waste disposal, equipment, commodity and reagents, availability of water, and storage facility, in order to ensure the accuracy and reliability of the diagnostic test result for effective malaria case management.

Materials and method:

Study setting, design and data collection tool

A profiling assessment on malaria diagnostic capacity was carried out in 24 out of 25 laboratories of public secondary health facilities across the 23 Local Government Areas (LGAs), covering the three Senatorial Districts of Sokoto State, Nigeria (Fig 1). This study used a purposive sampling technique to ensure total quality coverage of health facilities across the State, but the 25th heath facility could not be assessed due to security issues in the LGA at the time of the study. The study was adapted from the WHO Malaria Microscopy Quality Assurance Manual, Version 2, 2016 (6), and the Federal Ministry of Health National Malaria Elimination Program on Malaria Diagnostic External Quality Assurance Operational Guidelines 2018 tools (5).

Ethical approval

The study was approved by the Ethical Committee of Sokoto State Ministry of Health, and informed consent was obtained from the head of every medical facility assessed.

Data collection

A two-day training was conducted for the assessment team using the adapted tools from WHO and FMOH (5,6). The tool is health facility malaria microscopy QA checklist that; (i) describes health facility and laboratory, hours of operations, biosafety across the health facility; (ii) a logistic system required to ensure adequate, continuous supply of good-quality reagents, and essential equipment maintained in working order for microscopy services; (iii) human resources comprising competent and motivated staff, supported by effective training and supervision; (iv) laboratory infrastructures, standard operating procedures (SOPs) or bench aids; and (v) equipment and QA of malaria diagnosis.

Using an Android mobile device, Open Data Kit (ODK) platform deployed for data collection involves the following steps; form building, validation/testing, training, data collection, collation (aggregate and briefcase), and data analysis. The original assessment questionnaire was a 13-page assessment interviewer-administered tool in various subsections. However, this was expanded to incorporate introduction page, global positioning system (GPS) capturing of facility coordinates; facility information; information on facility characteristic, catchment popu lation, kilometer radius, followed by response questions.

Data analysis

Field data were collected into an open-source Google data which was transcribed into Microsoft Excel 16 version dataset and analysed using Stata 12 (StataCorp, College Station, TX, USA).

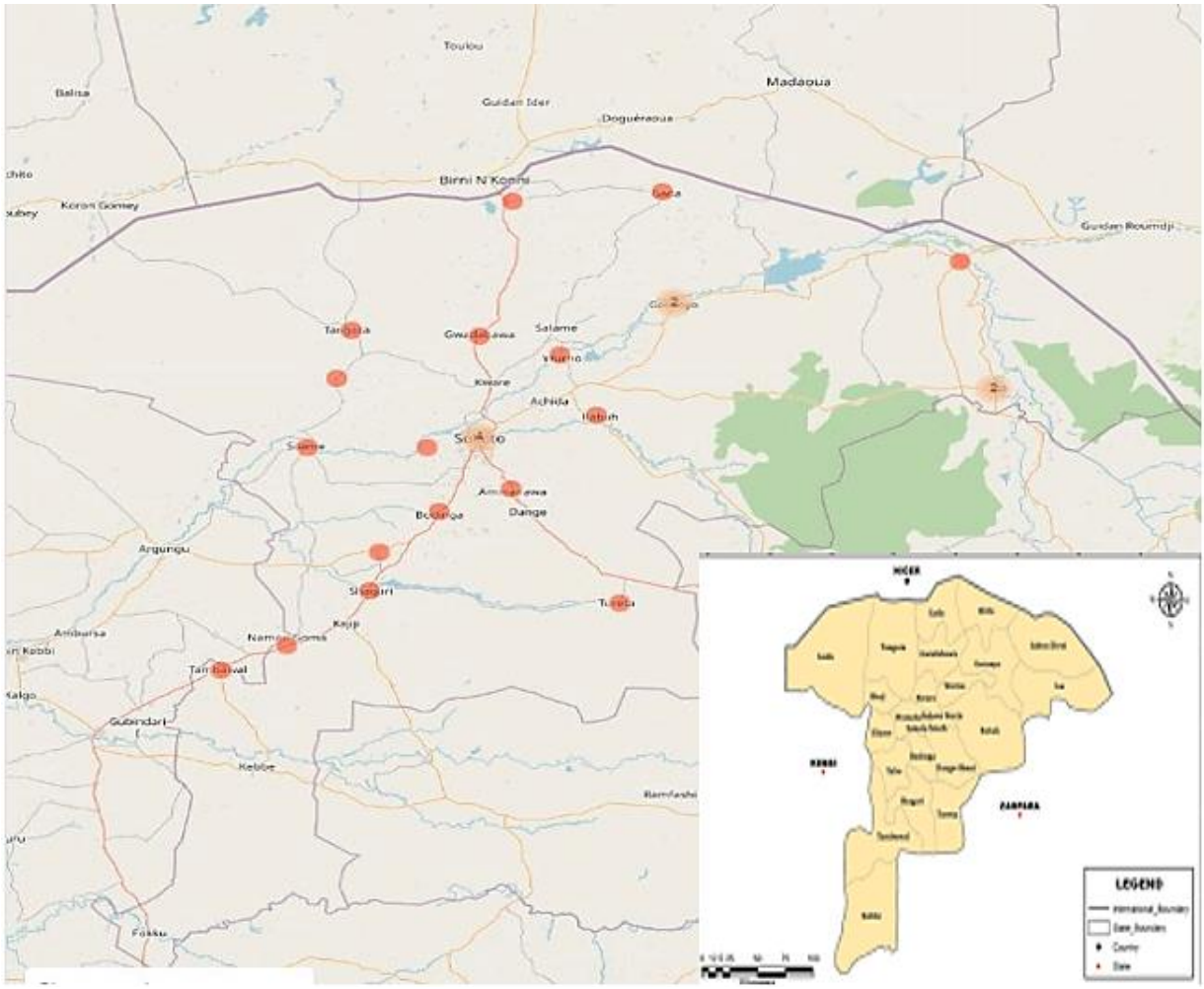

Fig 1: Location and distribution of health facilities surveyed in Sokoto State, Nigeria

Results:

The location of the facilities determines availability of basic amenities required for effective functioning of a laboratory. Majority of the health facilities (80%) were typically in semi-urban settings often without electricity while 20% are in urban centers. There was marked variability in the laboratory diagnostic capacities among the facilities assessed.

Regarding competency, 16 (63.0%) laboratories had one scientist who had received basic malaria microscopy training, but with none of the scientists passing the National certification (equivalent to WHO certification) in microscopy and mRDT training in the year prior to the assessment. Twenty-three (96.0%) of the facilities had at least one functional electric binocular microscope. The facilities had variable levels of equipment, materials, and biosafety procedures necessary for laboratory diagnosis of malaria. None of the assessed laboratory facility had a good formal quality assurance/quality control protocols for either microscopy or mRDTs.

Characteristics of health facilities assessed

The median catchment population was 350,000 people (range of 154,709 - 1,255,709) with a geographical kilometer in radius mean standard deviation of 65±47 km (the standard deviation calculation of distances between points, which are defined by geographical coordinates in terms of latitude and longitude to Sokoto, the State capital).

The hours of operation were 24 hours per day in 22 (92.0%) of the assessed facilities and 8am-4pm per day for 7 days a week in 2 (8.3%) facilities. Electricity was available in all (100%) the facilities through; generator (89%), solar (42%), and inverter (26%), while (38%) was from the national electricity grid.

Of the 24 assessed health facility laboratories, 10 (42.0%) do have electricity interruptions interfering with the ability to perform malaria microscopy. Only 6 (23.0%) health facilities had ready access to running piped water, with borehole/well water in 22 (85.0%). Most laboratories have leaking roofs (Fig. 2), and only 6 (25.0%) facility laboratories had floor tiles while there were no floor tiles in 19 (75.0%) laboratory facilities.

Human resources and training

From the assessed laboratory facilities, poor personnel distribution and general management was observed. As a result, some facilities are over staffed while other are understaffed with no malaria EQA National certified malaria microscopist (Fig. 3). There were many unqualified personnel (17.0% of the total laboratory personnel, n=80) in the assessed health facilities performing malaria microscopy.

Fig 2: Laboratory without benches and with dilapidated equipment and leaking roof in selected health facilities, Sokoto State, Nigeria

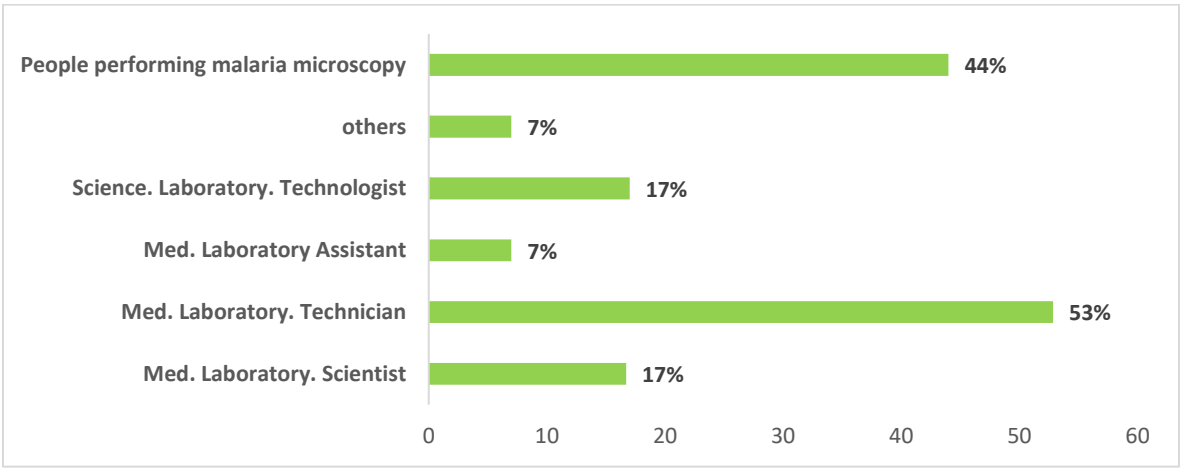

Fig 3: Distribution of Medical Laboratory Scientists, Medical Laboratory Technicians, Medical Laboratory Assistants and other technical staff in assessed heath facilities, Sokoto State, Nigeria

Biosafety and laboratory operations

Majority (92.0%, n=24) of the laboratory staff use hand gloves and protective coats when in the laboratory facilities. Hand-washing facilities were available for staff where malaria diagnosis was performed in 21 (81.0%) facilities. The use of different disinfectants and anti septics was observed. Over 70% (n=17) of the laboratories do not segregate waste appropriately, with only 7 (27.0%) using colored-coded buckets waste bins for storing both contaminated sharp and contaminated non-sharp wastes (e. g. used plastic wares, gloves and swabs) (Fig 4a).

Immediate disposal of contaminated sharp wastes was encouraging as obtained in 85% of the health facilities. However, the final method of waste disposal for contaminated sharps, non-sharps, blood, and blood products was mainly open field burning (88.0%) with only 23.0% and 12.0% using incinerator and pit burial respectively (Fig 4b).

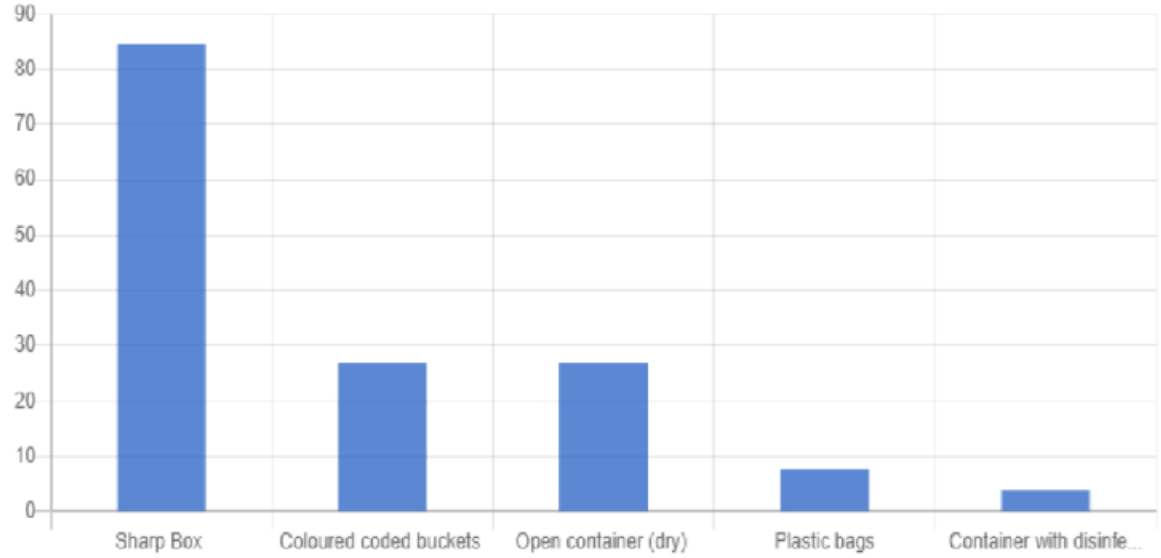

Fig 4a: Methods used for sharp collection in assessed heath facilities, Sokoto State, Nigeria

Fig 4b: Disposal systems at assessed health facilities showing pit disposal system and waste storage at one of the assessed laboratories

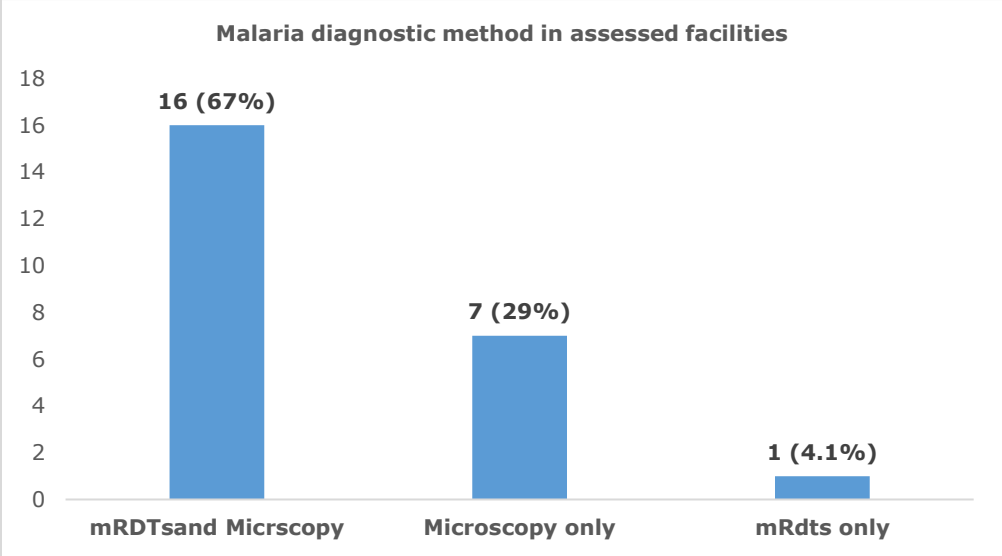

Fig 5: Malaria diagnostic services routinely available at health facilities, Sokot State, Nigeria

Malaria diagnosis

Of the 24 health facility laboratories reportedly performing malaria diagnostic services routinely, combined mRDTs and microscopy was performed in 16 (67.0%), microscopy only in 7 (29%), and mRDTs only in 1 (4.1%). Reasons for non-availability of microscopic diagnosis includes lack of functional microscopes, supplies, or lack of personnel trained in microscopy (Fig. 5). Malaria RDTs were reportedly used in place of microscopy during busy laboratory working conditions when additional microscopy workload would cause excessive delays in clinical management of patients, and when laboratory staff were not available.

Among the facility laboratories assessed, 15 (62.0%) employed only thick blood films routinely for malaria diagnosis, while 9 (38.0%) employed both thick and thin blood films, with 1 (3.8%) facility laboratory employing only thin film for malaria diagnosis. Also, 20 (83.0%) facility laboratories used Giemsa stain for malaria blood films, while 2 (8.0%) used both Giemsa and field stain and 2 (8.0%) used only field stain.

Major malaria laboratory equipment

Availability and functionality of equipment was equally assessed. Twenty-three (96%) of the assessed facility laboratories had at least one WHO recommended electric binocular microscope and 1 (4.1%) had one daylight binocular microscope using the phone touch light as the light source (Fig. 6a) because there was no spare bulb to replace the burnt microscope bulb. Among the facility laboratories with binocular microscopes, only 2 (8.3%) reported having spare microscope bulbs, but we observed slide staining and drying racks in all (100%) facilities.

There were no benches in 3 (12%) laboratories, as a result, microscopes were kept on chairs or ordinary tables (Fig. 6b), and malaria staining done in the toilet (Fig. 6c), and outside the laboratory (Fig.6d). There was no water distillation system in 16 (67.0%) assessed facility laboratories, while 8 (33.0%) have one in place.

Fig 6 showing; (a) a technician examining a slide using touch light of a mobile phone as source of light to the microscope; (b) microscope kept on a chair, (c) toilet used as staining basin due to lack of a staining rack, and (d) staining for malaria parasites done outside the laboratory

Fig 7: A store without cabinets, leaking ceiling of a store, and consumables/supplies on the floor of a store in one of the selected health facilities, Sokoto State, Nigeria

Consumables, storage, and equipment maintenance

Of the assessed facility laboratories, 23 (95.0%) reported getting their supplies of Giemsa stain from local suppliers while 1 (4.2%) reported getting its supplies from Sokoto State Drug Revolving Fund. Reportedly, the assessment indicated shortage problems with supply of lancets, immersion oil, lens tissue, lead or grease pencils, alcohol, and bleach in all the facilities. It was also observed that staff were not trained on equipment maintenance in all the assessed facilities. Also, there was no good storage facility for supplies and commodities in all the laboratories and where there were storage facilities, there were no cabinets for storing reagents or mRDTs (Fig. 7).

Quality Assurance (QA) practices

In terms of QA practices, findings from the assessment show that 19 (79.0%) facility laboratories did not perform equipment calibration and maintenance as per standard instruction. Almost all (88.0%) of the laboratories also indicated that there were supplies and reagents interruption and where supplies and reagents are available, there were poor quality staining outputs. Likewise, internal quality control (IQC) was not conducted regularly.

QA protocol in place for malaria microscopy was not available in 22 (92.0%) assessed laboratories while 2 (8.3%) had QA protocol in place. There was no microscopy or mRDT training or QA training provided to the assessed facility laboratories in the past 12 months. In 4 (17.0%) laboratories, no SOP was available, while 22 (83.0%) had SOPs in place. In addition, 5 (21.0%) did not have bench aids for malaria procedures, while 19 (79.0%) had bench aids in place.

Discussion:

Many countries across the sub-Saharan Africa are scaling up malaria prevention and control measures such as mass distribution of long-lasting insecticide-treated nets, indoor residual spraying of households, and provision of early diagnosis and treatment in response to the Global Malaria Action Plan (GMAP) (Roll Back Malaria Alliance RBMA, 2008) and increased global commitment to malaria prevention and control programs. Presumptive malaria care should be avoided, according to the WHO and GMAP, all suspected malaria cases in all age groups should be verified by laboratory diagnosis (6).

Knowing that laboratory services play important role in the diagnosis of infectious diseases such as malaria, most of the laboratories in most heath facilities assessed had dilapidated laboratory infrastructures. We discovered high workload in some facilities, shortage of resources, poor management supports, poor staff motivation, lack of training, high number of faulty equipment and failure, shortage of supplies and reagents were the main factors impacting the laboratory QA practices. Some of the laboratory professionals do not practice IQC activities and do use SOPs. Poor personnel distribution and general management issues were observed, and as a result, some facilities are over staffed while others are understaffed.

There was also poor quality malaria diagnosis coupled with lack of mentorship, training and retraining for the scientists and technicians/assistants; poor quality and insufficient number of light microscopes at all levels of healthcare, high prevalence of sub-standard reagents for malaria microscopy, logistic problems and high costs of maintaining adequate supplies and equipment; inadequate provision of malaria diagnostic equipment and commodities; insufficient number of trained malaria microscopists and lack of effective QA system. There were variety of issues, including inconsistent and erratic electricity supply, security issues, and lack of storage systems for laboratory supplies. Clearly, some of the needs and gaps identified such as supply of gloves and laboratory coats should be

easily addressed than others such as access to water and electricity, adequately trained and motivated staff, and proper waste disposal management, which may require having more substantial policy and financial support.

While our baseline assessment indicated that laboratory diagnosis of malaria, either by microscopy or mRDTs, was available in all (100%) the facilities assessed, the assessment also revealed major deficiencies in laboratory service functions such as laboratory infrastructures, equipment, materials, and human resources, which could have effect on the quality and accessibility of malaria diagnosis. The data provided in the study could be useful in preparation, budgeting, and developing strategies to increase malaria laboratory capability. Even at the community level, dependable techniques exist to enable accurate malaria diagnosis (7), and distinct stages of the healthcare delivery system may have different diagnostic needs (8). It is also clear that improving malaria diagnosis is critical to improving a country's laboratory services as a whole (9,10).

Effective and reliable laboratory malaria diagnosis is a major challenge across all our secondary facilities in Sokoto State and our assessment revealed that laboratory diagnosis of malaria, either by microscopy or mRDTs, was available in most of the facilities assessed. However, it also revealed significant gaps in the laboratory service functions, such as laboratory infrastructure, equipment, poor human resource management, poor resources provision, poor management commitment, lack of supplies and faulty equipment, ineffective communication system and lack of well-established quality management system (QMS).

To address these gaps, there is urgent need for proper planning, provision of required materials, equipment, and recruitment of qualified manpower and capacity building of the existing staff as findings from this assessment should be used to design and implement activities to strengthen laboratory capacity for malaria diagnosis in Sokoto State. To ensure that all laboratories have reagents and materials, facilities with non-functional microscopes have to be fitted with microscopes to ensure that blood slide examination is not interrupted, Medical laboratory workers from these facilities need to be re-trained in malaria diagnosis including basic malaria microscopy, RDTs, laboratory protection, and QA and QC by strengthening laboratory services through urgent planning, provision of required materials, equipment, and recruitment of qualified manpower and capacity building of the existing staff and need for adequate funding and the implementation of a QA system.

Conflict of interest:

Authors declare no conflict of interest

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