CAPACITY OF PUBLIC LABORATORIES IN DIAGNOSING SELECTED PRIORITY AND EPIDEMIC PRONE DISEASES IN OYO STATE, SOUTHWEST NIGERIA

By

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DECLARATION

I, Oluwayomi Temitope BANKOLE, of the University of Ibadan, Ibadan, Oyo-State, Nigeria, hereby declare that this dissertation entitled: "**Capacity of Public Laboratories in Diagnosing Selected Priority and Epidemic Prone Diseases in Oyo State, Southwest Nigeria**" has been written by me and that it is a record of my own research work. It has not been presented in any form for another degree or diploma in any other institution. All questions and sources of information have been duly acknowledged in the reference section.

Signature.....

Date 09-09-2015

CERTIFICATION

This is to certify that, this dissertation entitled: "**Capacity of Public Laboratories in Diagnosing Selected Priority and Epidemic Prone Diseases in Oyo State, Southwest Nigeria**" by Oluwayomi Temitope BANKOLE was carried out under our supervision and has been approved for submission to the Department of Epidemiology and Medical Statistics in partial fulfilment of the requirements for award of the degree of Masters of Public Health in Field Epidemiology of the University of Ibadan.

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DEDICATION

This work is dedicated to my mum – Mrs Alice Omonike Dada in acknowledgement of the grace and mercy of God upon her life and also to me.

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ABSTRACT

Laboratory diagnosis remains a critical component of global communicable disease detection, prevention and control but it is often neglected in Nigeria due to inadequate infrastructure. Although reference laboratories are being established for confirmation of outbreaks of some specific communicable diseases, capacity of laboratories at peripheral hospitals require strengthening so as to meet demands of local health authorities. However, capacities of such hospitals and possible gaps in their functioning are not well documented. Thus, this study was carried out to assess the capacity of hospital-based laboratories to diagnose selected priority and epidemic-prone diseases in Oyo State, Nigeria.

A descriptive cross-sectional study was carried out in 17 hospital-based microbiology laboratories in Oyo State. All the functional laboratories in the state were surveyed. A WHO Laboratory Assessment Tool (WHO/LAT) was modified and used to interview one laboratory scientist per facility. The tool was used to collect information on socio-demographics of the participants, laboratory testing capacity, availability of laboratory infrastructures and utilities, laboratory staff supervision practice, number of laboratory personnel and involvement in disease surveillance. Laboratory capacity was assessed on a 100 point scale in which scores were rated low (≤49%), fair (50-79%) and good (≥80%). Data were analysed using descriptive statistics and t-test at p= 0.05.

Age and length of service of participants were 42.0 ± 5.1 years and 11.9 ± 8.8 years respectively. Laboratory testing capacity for measles and meningitis was 'low' in all the 17 laboratories but all had 'good capacity' to carry out tests for malaria. More than half (11) of the laboratories had 'low capacity' to test for tuberculosis and 6 had 'fair capacity'. Most (14) laboratories had 'low capacity' to carry out HIV/AIDS tests while 3 had 'fair capacity'. Sixteen of the laboratories had 'low capacity' to test for cholera and one had 'fair capacity'. Seven of the laboratories had poor infrastructure, two had laboratory staff supervision problems and seven had laboratory personnel problems such as insufficient laboratory

scientists and technicians. Twelve laboratories had 'fair capacity' in disease surveillance programmes while five of the facilities had 'low capacity'. There was no association between the extra level of training received by laboratory scientists and testing capacity for the selected diseases. The reasons why the laboratories could not carry out WHO standard tests for the selected diseases as reported were inadequate instruments/equipment (17), non-availability of reagents (16) and clinicians' failure to request for tests (13).

Laboratory capacity to carry out tests for most of the selected diseases (malaria, measles, meningitis, cholera, tuberculosis and HIV/AIDS) was very low in Oyo State hospitals. Equipping the laboratories with modern instruments, reagents and the recruitment of more laboratory scientists and technicians are recommended to enable them attain full capacity to provide diagnostic services relating to the selected diseases.

Keywords: Hospital-based laboratory, Notifiable diseases, Epidemic-prone diseases, Laboratory scientists.

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CHAPTER ONE

INTRODUCTION

1.1 Background

Medical laboratory services are an essential, yet an often neglected component of health systems in developing countries. So also, public health laboratories are a critical component of global communicable disease detection, prevention, and control. Many therapeutic decisions rely heavily on data from health laboratories and, at the time of disease outbreaks or other public health events, laboratories are at the very heart of the public health investigation and response mechanisms. Therefore, prevention and management of infectious diseases require accurate laboratory diagnostic information. Accurate and rapid diagnostic tests are required to diagnose illness, identify causative factors, monitor the effectiveness of treatment, and perform surveillance for key diseases. Thus, reliable, timely and actionable laboratory test results are often a prerequisite to the delivery of high-quality patient care and are at the centre of efficient treatment of patients (Trevor et al., 2010). Today's world cannot afford unreliable or inaccurate laboratory results, wasting precious time, precious samples, and too often, precious lives.

The value of laboratory testing in patient care cannot be over-emphasized. Laboratory results are required for making a large proportion of medical decisions. In developed countries, an estimated 60% to 80% of patient management decisions are based on laboratory data (Trevor et al., 2010). This is because laboratory investigations are often more sensitive and specific than clinical decision criteria alone (Phillips et al., 2008). Diagnostics and clinical patient management have an interdependent relationship; laboratory data provide justification for clinical decision making, while clinical signs or the clinical management protocol often prompt laboratory testing.

For example, during the management of Human Immunodeficiency Virus (HIV) infection, poor performance of tests at any stage of the care and treatment continuum (such as

diagnosis, disease staging, treatment initiation, the monitoring of drug efficacy and toxic effects) can reduce the effectiveness of treatment and deny appropriate care to patients in need by impeding the path of patients along the continuum (Trevor et al., 2010). Without a reliable diagnosis, patients will not receive most HIV-related services for treatment or prevention. Without an accurate cluster of differentiation 4 (CD4) cell count, many patients cannot have their disease correctly staged, which could prevent them from accessing lifesaving antiretroviral drugs before the onset of serious illness. Once a patient is receiving therapy, ongoing CD4 count, clinical chemistry, hematology, and, in some settings, viral load tests provide clinicians with necessary information on the safety and efficacy of the drugs. If these tests are not available or are inaccurate, treatment outcomes for patients are likely to be poorer, with higher mortality and more frequent illness (Dart Trial Team, 2010). Therefore, reliable laboratory testing is needed and of high importance.

Admittedly, laboratory testing is an essential component of improved health care for patients in resource-limited settings (Nkengasong, 2009). However, access to and provision of reliable laboratory testing remains limited in many resource-limited countries (Burgess, Wasserman & Dahl, 2006). While cost and infrastructure development are notable challenges to providing laboratory testing services, policy-makers have to weigh the benefits of diagnostics against the opportunity to invest in other areas of the health care system. Historically, laboratories in developing countries have been under-resourced and marked by poor performance. This has fostered distrust in laboratory data among clinicians and helped to reinforce cycles of underinvestment in laboratory systems (Trevor et al., 2010).

Despite strong commitment from the international community to fight major infectious diseases, weak laboratory infrastructure remains a huge rate-limiting step. Some major challenges facing laboratory systems in resource-poor settings include dilapidated infrastructure, lack of human capacity, laboratory policies strategic plans, limited synergies between clinical and research laboratories, poor communications, inadequate or obsolete

equipment, lack of reagents, low morale, lack of educators and training programs, de-emphasis of laboratory testing, insufficient monitoring of test quality, decentralization of laboratory facilities and lack of government standards for laboratory testing (Stuart et al., 2010). These challenges also disproportionately affect laboratory services in sub-Saharan Africa. Most investigators have also identified inadequate laboratory capacity as the most common barrier to laboratory test use (Kehinde et al., 2005). Together, these factors compromise the quality of test results and impact patient management. These factors also suggest reasons why diagnosis of infectious diseases without laboratory confirmation occurs routinely in sub-Saharan Africa, which often leads to delayed diagnosis, misdiagnosis, ineffective and inappropriate treatment with subsequent increased morbidity and mortality (English, 2004; Amexo et al., 2004).

Owing to long-term under-investment and poor funding in laboratory networks, there is considerable unmet need for reliable diagnostics services in many developing countries. Even though, the fight against the HIV/AIDS (Acquired Immune Deficiency Syndrome) pandemics and other epidemic prone diseases in resource-limited countries, particularly in sub-Saharan Africa, has benefited from the recent global funding surge, primarily from the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund for AIDS, Tuberculosis and Malaria, UNITAID(unit-aid), the World Bank and other donors. It is time for the government of every nation to take responsibility of this 'fight' and stop relying on funds from external donors.

When Disease Surveillance and Notification (DSN) was introduced in Nigeria in 1988 following a fatal yellow fever outbreak, the role of laboratory confirmation of cases during epidemics was however poorly defined (Christie & Chris,2009). Later in 1998, WHO introduced the Integrated Disease Surveillance and Response (IDSR). During this period, laboratory involvement in disease epidemic was established. One of the major objectives of IDSR establishment is to improve laboratory capacity in identification of pathogens.

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However, since its establishment, laboratory services have been under-utilised due to poor laboratory capacity to diagnose priority and epidemic prone diseases. Meanwhile, the roll-out of a high-quality treatment, care, and prevention program depends on effective and reliable laboratory diagnosis.

In Nigeria, lack of knowledge of laboratory safety procedure, poor facility and equipment provision have been identified as weaknesses in the area of laboratory services (Kehinde et al., 2005). In addition, where capacity in terms of human resources was available for diagnostic techniques, facilities and equipment were lacking (Chris, 2010). Because Nigeria lacks an overall vision of the critical role of laboratory in health care delivery, investments in laboratories such as dedicated budgets for laboratories are absent or inadequate at best, resulting in rundown services and unreliable laboratory results (Abimiku, 2009). Consequently, the current laboratory capacities and status are insufficient to meet the need of confirming clinical diagnosis. Therefore, Nigeria urgently requires support in the provision of laboratory facilities to reduce threats posed by epidemic prone diseases and increase the likelihood that diagnosis of any disease outbreak is reliable and accurate so that public health action will be efficient and appropriate (Chris, 2010). If the reagents and chemicals used are not potent, laboratory scientists are not properly trained, no reasonable level of power supply and non-availability of right equipment, a good laboratory result cannot be achieved or obtained.

Each national government establishes what health events must be reported by health care providers in that country. Some countries require as few as 35 conditions to be reported; others require as many as 130 conditions. Nigeria presently has 42 priority diseases which are notifiable (Federal Ministry of Health (FMoH) and National Health Management Information System (NHMIS), 2014). Twelve of these are epidemic-prone while six are targeted for elimination and eradication. Others are diseases of public health importance. This study shall focus on laboratory capacity to diagnose **malaria, cholera, measles, meningitis,**

tuberculosis and HIV. Capacity in this study means potential strengths and weaknesses surrounding testing of clinical specimens and this was determined in the domain of building/utility services, laboratory personnel, staff supervision, logistics of consumables and reagents, laboratory tests capable of performing, organisation and management and laboratory involvement in public health activities such as surveillance.

1.2 Problem Statement

Diagnoses based on clinical signs and symptoms without laboratory tests can be non-specific, unreliable, and associated with increased morbidity and mortality. Laboratory errors on the other hand can lead to significant variance in the accuracy of the reported result, potentially leading, in some cases, to incorrect diagnosis, inappropriate treatment, or withholding of lifesaving therapy (Trevor et al., 2010). The magnitude of laboratory errors in resource-limited settings is underreported. It is likely that error rates are greater than in resource-rich settings, but studies to evaluate these are needed.

In the United States, it is estimated that 6% to 12% of laboratory errors or misdiagnosis put patients at risk of inappropriate care and potentially of adverse events (Trevor et al., 2010). The World Health Organization (WHO) estimates that fewer than 10% of malaria cases in Africa are properly diagnosed which suggests that over 90% of malaria cases are misdiagnosed. In Kumasi, Ghana, 40% of patients who had been given a WHO-defined clinical diagnosis of malaria were confirmed to actually have bacterial sepsis (Evans, 2004). Clearly, the absence of laboratory support contributes to misdiagnosis or over-diagnosis that leads to a failure to treat or a delay in treatment of life-threatening infections and potentially increases mortality (Amexo et al., 2004).

In Kenya, a country statistics showed that 4 in 10 laboratory results are erroneous. This means that only about 60% of patients in Kenya get accurate laboratory diagnosis of their diseases (Pamela, 2012). One study found evidence of tuberculosis infection in only 52% of 229 patients with suspected tuberculosis in Botswana (Lockman et al., 2003). This

means that over a 40% has been misdiagnosed. In many cases in sub-Saharan Africa, misdiagnosis commonly occurs and diagnosis based on clinical symptoms is the rule rather than the exception. This leads to inappropriate treatment, increased morbidity, and unnecessary loss of life. Most cases of laboratory misdiagnosis could be attributed to poor laboratory capacity (Pamela, 2011).

In Nigeria, first of all, it is worth appreciating what the Federal government has done through the President's Emergency Plan for AIDS Relief (PEPFAR) programme for medical laboratories. PEPFAR programme has brought some significant improvement in diagnosis of HIV/AIDS for instance by constructing and equipping HIV testing laboratories. Another project under the administration of former President Olusegun Obasanjo tried to rehabilitate some tertiary health institutions and then the laboratories got a little part of the funding and some new equipment were procured for some laboratories in teaching hospitals. However, this is not enough but it is something to work with in the absence of a well equipped laboratory.

In Nigeria, many misdiagnoses happen because physicians and patients frequently lack access to a reliable and high-quality clinical laboratory (Pamela, 2011). The growing problem of misdiagnosis occasioned by poor state of laboratories in Nigeria and inability of health professionals to carry out accurate diagnosis before treatment has become a public health concern. This has not only caused a lot of medical errors but had led to the deaths of so many Nigerians (Pamela, 2012). For instance, a case was reported for a victim who was wrongly diagnosed and treated for malaria and typhoid. Clinical indications and further diagnosis in another hospital showed that this victim actually had heart-related disease (which had already damaged her organs) and not malaria and typhoid (Chioma, 2011) but it was too late to discover this and so the victim died. This suggests that a false positive result may have been obtained from the laboratory where the samples were tested. Unfortunately, the number of deaths due to laboratory misdiagnosis is underreported and not well documented. It is then

suggested that laboratory misdiagnoses are usually or probably covered up but may prompt public outcry if it wrecks havoc, like in the case mentioned above.

Wrong laboratory diagnosis can potentially facilitate epidemics and consequently raise the case fatality rate of diseases. Inability of most laboratory scientists to diagnose properly due to obsolete or lack of equipment, poor training and poor regulatory measures has been implicated in the poor state of laboratory results in the country (Chioma, 2011).

Without any intervention to improve the capacity of laboratories and upgrade them to standard, misdiagnosis and associated mortality will continue to increase.

1.3 Justification

Although reference laboratories are being established for confirmation of outbreaks of some specific communicable disease, capacity of laboratories at peripheral hospitals require strengthening so as to meet demand of local health authorities. However, capacities of such hospitals and possible gaps in their functioning are not well documented and researchers have not explored much or direct searchlight to the state of laboratories in this state. Hence, this study was carried out to address such research gaps and challenges.

There are forty two diseases earmarked for notification in Nigeria and it is not feasible to study the availability of laboratory diagnosis for all. Therefore, this study focused on **malaria, cholera, measles, meningitis, tuberculosis and HIV/AIDS**. Any suspected case of these diseases must be laboratory-confirmed and/or epidemiologically linked to a laboratory-confirmed case. Therefore, laboratory diagnosis remains a significant part of their case classification. According to National Health Management Information System, secondary healthcare facilities are charged with the responsibility of providing efficient laboratory diagnostic services and management of referrals from primary healthcare centers. Hence, public secondary level hospitals (secondary healthcare centers) have been selected for this study.

It has been widely reported (Chioma, 2011) that the state of laboratories in Nigeria remains worrisome and the incidence of misdiagnosis has been seen in almost all health conditions especially in infectious diseases such as those selected for this study. This report however, is not excluding Oyo State because it is an important state in Nigeria with significant health facilities and activities. Asides, there have been several outbreaks of diseases in the state with the recent one being cholera outbreak in year 2013. The burden of severe malaria is higher in persons above 5 years in outpatient clinics of public health facilities in Oyo state, with yearly progressive increase in cases and case-fatality rate (CFR) (Olugbade et al., 2014). According to figures from WHO and the United States Embassy in Nigeria, Oyo State ranked third on the list of states with highest prevalence rate of tuberculosis (Oyo state increased by 46.5% from 2008 to 2010).

While this development is not comforting, studying laboratory capacity in diagnosing these diseases will assist in providing evidence-based information to plan intervention to stem their prevalence. Public hospital–based laboratories were focused on in this study because the national government is leading the fight against infectious diseases and responsible to improve public laboratory services. Apart from this, private laboratories in this part of the world are not really involved in laboratory based surveillance which can also improve detection of diseases. Besides, there is no or very little in the literature that assessed the state of public laboratories in the diagnosis of priority diseases in Oyo State.

The findings from this research project will be disseminated in debriefing with medical practitioners at their association's meeting, Ministry of Health, Integrated Disease Surveillance and Response (IDSR), educators and policy makers. This should subsequently enable policy makers and health care providers to understand that accurate diagnosis is essential to the prevention and treatment of disease. It will provide stakeholders with a comprehensive view of all aspects of the laboratory services and supply chain; a snapshot of testing capabilities and commodity availability at laboratories throughout the system; and

input for work planning. This will also trigger proper action and strategic efforts to build and improve laboratory capacity in the area of instrumentation, provision of test reagents and laboratory based disease surveillance.

1.4 Research Questions

1. What are the states of laboratory capacity in diagnosing malaria, cholera, measles, meningitis, tuberculosis and HIV?

2. What are the factors influencing effective functioning of the laboratories in diagnosing the selected diseases?

1.5 Objectives of the study:

Main Objective

The aim of this study was to assess the capacity of public laboratories in diagnosing selected priority and epidemic prone diseases.

Specific Objectives

1. To assess the state of laboratory capacity in diagnosing malaria, cholera, measles, meningitis, tuberculosis and HIV.
2. To determine the factors influencing effective functioning of the laboratories in diagnosing the selected diseases.

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview of Capacity of Public Health Laboratories in the United States

The Association of Public Health Laboratories (APHL) and the University Of Michigan Center Of Excellence in Public Health Workforce Studies (CEPHS) partnered to develop a national laboratory workforce assessment to gauge capacity in all United States (U S) public health laboratories. In the study, 106 public health laboratories across the country were assessed. The results of the multilevel study showed that national laboratory infrastructure is below optimal capacity in many areas. From their results, the education and training of laboratorians need to be strengthened. Fifty percent of the laboratory scientists who participated in the study had low or no competence (in terms of education and training) in clinical, medical, pathogenic bacteriology. In addition to that, 54% of the laboratorian respondents reported no competence in emergency preparedness-which is very important in epidemics (United States. University of Michigan Centre of Excellence in Public Health Workforce Studies and Association of Public Health Laboratories, 2011).

Furthermore, fewer than 25% of the laboratories reported no, minimal or partial capacity to perform activities in molecular biology (8%), bacteriology (9%), laboratory safety and security (9%), emergency preparedness and response (11%), laboratory administration and operation (14%), serology/immunology (14%) and virology (24%). Also, slightly over half (54%) of the laboratories were reported to have substantial to full capacity in carrying out parasitological test. Concerning instrumentation and equipment in their laboratory, 51% of the laboratories rated the quality of their equipment in terms of availability and functionality as 'fair'. (United States. University of Michigan Centre of Excellence in Public Health Workforce Studies and Association of Public Health Laboratories, 2011).

The study recommended that local, state and federal agencies responsible for insuring adequate laboratory capacity should engage in ongoing discussions to develop methodologies

for addressing structural deficiencies in the laboratory network to detect incidences of infectious diseases.

However, the study by APHL and CEPHS only concentrated on all public health laboratories in the US but did not include hospital–based laboratories. This study could not have given a 'true picture' of laboratory capacity in the US because some other important laboratories were left out. At the same time, advancement in technology in the US must have also contributed to the possibility of APHL and CEPHS to carry out the study because public health laboratories are not many and standard in poor-resource settings like Nigeria. This gap however, has to be addressed by another study by concentrating on hospital-based laboratories.

2.2 Overview of Capacity Assessment of Laboratory in Africa and Asia

Cathy et al. (2006) published a journal titled Laboratory Medicine in Africa: A Barrier to Effective Health Care. In the study, they reported that misdiagnosis commonly occurs in Nigeria especially in infectious diseases. They conclusively attributed this problem to poor state of laboratory capacity in terms of lack of laboratory consumables, basic essential equipment, limited numbers of skilled personnel, lack of educators and training programs, inadequate logistical support and no governmental standards for laboratory testing (Cathy et al., 2006).

The study by Cathy et al. (2006) generalised infectious diseases but failed to specify the diseases in which misdiagnosis occurs as a result of poor state of laboratory capacity – a gap which has been addressed by this current study. Cathy et al (2006) did not specify the type of laboratory in which the study has been carried out unlike the study by APHL and CEPHS in which public health laboratories were focused and this current study focused on hospital-based laboratories.

Furthermore, Stuart (2010) conducted a study titled: Strengthening Laboratory Systems in Resource-Limited Settings. In this qualitative case study, laboratory systems in

three countries (Ethiopia, Kenya and Thailand) were assessed on the state of the laboratory services. From their results, laboratory capacity has drop in national and reference laboratories, district hospitals and health centres. In addition, this 'drop-down' was attributed to lack of equipment and supplies, staffing issues, inadequate leadership, complicated bureaucracies, 'brain drain', lack of coordination and poor oversight (Stuart et al., 2010).

In Kenya, Cowman, 2015 conducted a study on cholera prevention and control in Kenya. In the study, key challenges to laboratory detection of cholera cases were attributed to limited laboratory capacity to diagnose cholera. It was then suggested that there is urgent need to intensify efforts to strengthen laboratory capacity and disease surveillance. In Papua New Guinea, a similar study by Greenhill, 2012 revealed that there were diagnostic challenges and logistical factors that impacted on low capacity of laboratories to perform test especially during the first reported outbreak of cholera. Consequently, the study recommended that regional hospital-based laboratories in Papua New Guinea should be equipped with culture facilities in order to increase capacity in bacterial culture.

In a wide laboratory survey conducted by Mekong Basin Disease Surveillance across 6 countries (Cambodia, China, Laos, Myanmar, Thailand and Vietnam) in 2013, which involved 7 core diseases including malaria, cholera and tuberculosis, capacity of laboratories at national, provincial and cross border level was determined in areas such as laboratory equipment, quality control, laboratory human resource, technical training, surveillance and response. In Cambodia, 3 laboratories were assessed. At national level, the laboratories had sufficient capacity to test for the diseases. At provincial and cross border level, the capacity was lagged for the diseases' (except for malaria) diagnosis due to no sufficient supply, human resource, personal protection equipment and very low rate of biosafety training to laboratory staff. The report of the assessment suggested solution such as provision of basic laboratory apparatus (standard glassware, basic equipment and reagents) and Personal Protective

Equipments (PPE) to cross border and provincial levels, training of biosafety and basic laboratory operation.

In Guangxi and Yunnan (China), the assessment was carried out in 7 laboratories also across the provincial and cross border sites on 7 and 3 core diseases diagnosis (malaria, cholera and typhoid) respectively. At both levels, they all had sufficient capacity to diagnose the diseases with sufficient human resource and personnel. The findings from the assessment suggested provision of research support on the use of rapid test and molecular epidemiology. In Laos, the assessment was conducted in 9 laboratories across the 3 levels (national, provincial and cross border level). At national level, the laboratories were capable of testing 6 of 7 core diseases including malaria and cholera but excluding Enterovirus (EV) 71.

In Myanmar's laboratories' capacity assessment, 8 human diseases laboratory from national, provincial and cross border levels were covered. In the assessment, malaria, cholera and tuberculosis were included among the diseases. At the national level, the laboratories had good capacity to test 6 of the diseases except EV71. Outcome of the assessment at provincial and cross border level was however, not reported. On the contrary, there was no biosafety program at the national level and safety/infection controls were not included in Standard Operating Procedures (SOPs).

The same type of assessment was also done in Thailand across the 3 levels but in 6 laboratories. At the national level, the laboratories had strong capacity to diagnose all the 7 core diseases including malaria and cholera especially in the area of laboratory supply and equipments to the extent that the whole national level laboratories passed International Standardisation Organisation (ISO) 15189 and the laboratories could be said to comply with standard. At the provincial and cross border level, the laboratory supplies and equipment was relatively insufficient and there was biosafety practices also had a gap especially at the cross border laboratories. Following the assessment, solutions such as provision of basic lab

equipment, PPE and laboratory technician training were suggested to improve capacity at the cross border and provincial levels.

Finally, at Vietnam, the assessment was done and it covered 7 laboratories across just two levels (national and provincial). At the national level, the laboratories were capable of testing all the diseases. On the other hand, the provincial level laboratories could also diagnose most of the diseases but reagent and basic equipment were insufficient. Moreover, quality assurance and quality control were not being carried out at the provincial level. In addition to provision of basic lab equipment and PPE to provincial laboratories, comprehensive quality assurance and quality control program were suggested to be developed at the national level.

In 2002, the HIV/AIDS Network of the WHO African Region conducted an assessment of existing laboratory capacities in Africa with a view to identifying competences and gaps in HIV/AIDS and care programmes in the WHO/AFRO Region. In the assessment, national, regional and district level HIV reference laboratory were focused. The report of the assessment showed that Enzyme Linked Immunosorbent Assay (ELISA) testing method was limited to laboratories at central level and was little used at district level. Simple Rapid assays were more available at district level. Erratic supply of reagents continued to be a major challenge. All the countries experienced interruptions with supply of reagents, Response from countries in the WHO/AFRO region where the assessment was conducted show a general lack of adequate numbers of trained personnel and paucity of technical skills. All these factors were reported to significantly impair the capacity of the laboratories to carry out quality testing or diagnosis of the HIV/AIDS.

The WHO/AFRO region assessment recommended that countries plan and budget for the regular and timely procurement of reagents. Furthermore, countries should establish a clearly defined National HIV reference laboratory with adequate personnel and resources to support the country in HIV test kit validating and managing the National Quality Assurance

Programme. This assessment focused on HIV/AIDS only leaving other infectious diseases of public health importance which is a gap that must be addressed by another study or assessment.

2.3 Overview of Capacity of Laboratory in Nigeria

Another assessment of laboratories in Nigeria was done by the Medical Laboratory Science Council of Nigeria (MLSCN). They assessed over two thousand medical laboratories. From their result, over a thousand were found not worthy of operation due to lack of operational requirement such as consumable, equipment, reagents, infrastructures, qualified personnel among others (Chioma, 2010). The differences in the outcomes of studies carried out by APHL/CEPHS and MLSCN must have been due to differences in their resource settings. While APHL/CEPHS focused their laboratory assessment on public health laboratories, MLSCN concentrated theirs on medical laboratories. However, none of the two studies was infectious-disease specific in their assessment.

CHAPTER THREE

METHODOLOGY

3.1 Study Area

Oyo State, located in the South-West geopolitical zone of Nigeria was carved out of the former Western State in 1976. Oyo State consists of 33 Local Government Areas. The State covers a total of 27,249 square kilometres of land mass and it is bounded in the south by Ogun State, in the north by Kwara State, in the west it is partly bounded by Ogun State and partly by the Republic of Benin, while in the East by Osun State. Oyo State has an equatorial climate with dry and wet seasons and relatively high humidity. Oyo State which is homogenous has a population of about 4.5million and covers approximately an area of 28,454 square kilometres. The state is predominantly inhabited by the Yoruba ethnic group who are primarily agrarian but have a predilection for living in high density urban centers. The indigenes mainly comprise the Oyos, the Oke-Oguns, the Ibadans and the Ibarapas. (Source: The Official website of the Government of Oyo State).

One of the landmarks in Oyo state is the first university in Nigeria population known as U.I (University of Ibadan). Other noteworthy institutions in the city include the University College Hospital; the first teaching hospital in Nigeria, the internationally acclaimed International Institute of Tropical Agriculture (IITA) and the Cocoa House, the first skyscraper built in Africa (Source: The Official website of the Government of Oyo State). There are about 33 public hospital laboratories in the state (Oyo State Hospital Management Board, 2015). These laboratories are usually manned by laboratory scientists who have been trained in either School of Health Technology or School of Medical Laboratory Science. The laboratory scientists are charged with the responsibility of carrying out laboratory diagnostic testing of clinical specimens.

3.2 Study Design

The study used a cross-sectional design which comprises a quantitative survey of laboratory using laboratory scientists as facility representative. And the use of observational checklist to inventory of equipments and supplies to generate necessary descriptive information about the functional capacity of the laboratories and other factors that could be associated with the effective functioning.

3.3 Study Population

The study population was public hospital-based laboratory facilities in Oyo State. The laboratory scientists represented the appropriate contact in the facilities. There are 29 functional hospital-based laboratories in the state (Verbal/Documented Information from Oyo State Hospital Management Board).

3.3.1 Inclusion Criteria for Facilities and Respondents

1. The head of the laboratory unit in each health facility.
2. Technical staff carrying out microbiological testing of clinical specimen was also included in the interview.
3. For facilities, only public laboratories in hospitals (secondary healthcare) were assessed.

3.3.2 Exclusion Criteria for Respondents

1. Laboratory assistants and others not performing tests were excluded from the interview.

3.4 Sample Size and Sampling

A total population survey of 17 consenting hospital-based laboratories was conducted owing to the finite size of the population of secondary healthcare centres with functional laboratories in Oyo state. At each facility, one laboratory scientist conducting microbiological testing of clinical specimens was interviewed (most of the laboratories had only one laboratory scientist). Where laboratory scientists were more than one, the head or the most senior was purposely chosen to represent the facility.

3.5 Data Collection

This study adapted the WHO laboratory assessment tool (World Health Organisation, 2012). This is a standardised tool that rapidly assesses the functional laboratory capacity for diagnosis of priority diseases. This tool was modified appropriately to suit the objectives of this study and was self –administered. The questionnaire (Appendix 2) covered information on variables such as socio-demographic, building facilities and utility services, laboratory personnel, staff supervision, consumables and reagents, tests performance, organisation and management, safety/infection control and public health functions. Altogether, there were 9 sections or domains in the questionnaire. Apart from the 9 socio-demographic questions, 64 out of the total 75 questions in the questionnaire and observation checklist were qualitative categorical variables with maximum of three/four outcomes (such as 'Yes, No and Not applicable/Sometimes/Partially', 'Good, Fair and Poor' and 'Never, Sometimes, Regularly and Not applicable'). The remaining questions were quantitative variables.

Observation checklist (Appendix 3) was used for the facility assessment which includes laboratory infrastructure, availability and functional status of laboratory equipment, laboratory supplies, test SOPs (standard and operating procedures), registers and safety manuals. During data collection at the facility, the data collection team was split into two groups: one observed and recorded information on the laboratory infrastructure, availability and status of laboratory equipment and storage conditions for laboratory supplies; the other interviewed laboratory staff to collect information on personnel, testing services, and inventory management. The tool was pretested in two public hospital-based laboratories in Ekiti State, South-western Nigeria.

3.6 Data Analysis

Epi-Info version 3.5.1 and SPSS version 18 were used for data entry and analysis, respectively. Descriptive statistics (mean, median, mode, variance and standard deviation) were used to summarise the data. Test of association between categorical variables (capacity

of equipments, consumables/reagents and testing capacity for the selected diseases) was carried out using Chi Square and Independent T-test was used to test differences in mean for independent groups (educational group and testing scores for the selected diseases). The level of significance was set at 5%.

Most of the responses to the questions were qualitative, so the overall capacity was measured qualitatively in three outcomes (that is low capacity, fair capacity and good capacity). For **section II to IX,** each qualitative response was given a score. 'Yes/Regularly/Good' responses were scored as 1 point=100%, 'No/Never/Bad' responses were scored as 0 point=0% and 'Fair/Medium/ Partial/Sometimes' responses were scored as 0.5 point=50% while 'Not applicable' responses or any unanswered question were excluded from analysis. Recoding of some of these responses was done for some questions for example 'Never' was scored 1 point=100% in some questions when it is the appropriate response. The average point score for each section was then calculated. Particularly for **section VI**, each testing capacity point score for a disease was calculated from average point score for tests specific for such disease. And average point score for each test was also calculated from other variables determining the testing performance. For example in same **section VI**, thick/thin blood film microscopy for malaria test average point score was calculated from variables determining the test performance. These variables are staff competence to perform test, availability/adequacy/up-to-date of SOP, availability of appropriate and maintained equipment, adequacy/in-date of reagents, quality control and external quality assessment. These variables also determined the average point score of other tests for other diseases in same **section VI.**

3.7 Scale/Indicator for Measuring Laboratory Capacity in Section II - IX

The scale indicator for average point score was as follows:

Below 50% -- low capacity

Between 50-80% -- fair capacity

Above 80% -- good capacity (World Health Organisation, 2012)

The dependent variable was the state of laboratory capacity test the selected diseases and the independent variables were the highest education attained by the laboratory scientists, availability of a medical supervisor and level of training status of the laboratory scientists. Tables and graphs were used to present results.

3.8 Ethical Considerations

Ethical approval (Appendix 4) for this study was obtained from Ethics Committee of the Oyo State Ministry of Health. An informed consent was also obtained from participants and confidentiality of information provided was maintained by storing them in a restricted folder on the Personal Computer. The hard copies of the completed questionnaire were kept in a safe place. The names of the interviewees and hospital/laboratory were coded and the codes were kept under lock and key. This ensured the participants were protected as a result of their participation in this study. A pen was given to the participants as a form of appreciation.

CHAPTER FOUR

RESULTS

4.1 Characteristics of Respondents

Of the 17 laboratory scientists who participated in the study, 58.8% were males while 41.2% were females. The mean age of participants was 42.0 ± 5.1years and range of 34-51 years. All the participants belonged to the Yoruba ethnic group. The married respondents constituted almost all (94.1%) the entire participants while 5.9% were widowed. Many of the respondents (70.6%) belonged to the Christian religion while 29.4% were Muslims. The level of educational status showed that 52.9% of the respondents were educated up to the postgraduate level while 47.1% stopped education at 1st degree level or its equivalent (Medical Laboratory Science degree) (**Table 1**). Many of the respondents had additional professional certification (76.5%) while 23.5% had no extra study certification from professional body. The mean duration of service of respondents in their respective facility was 11.9 ± 8.8 years.

Table 1. Socio-demographic status of the respondents (N=17)

VARIABLES	n	%
Age		
30-39	6	35.3
40-49	10	58.8
50-59	1	5.9
Sex		
Male	10	58.8
Female	7	41.2
Ethnicity		
Yoruba	17	100
Marital Status		
Married	16	94.1
Widowed	1	5.9
Religion		
Christianity	12	70.6
Islamic	5	29.4
Highest Education Status		
Tertiary(1stDegree/Medical Lab Science)	8	47.1
Postgraduates	9	52.9

4.2 Availability of Building Facilities and Utility Services in the Laboratories

Out of the 17 hospital-based laboratories assessed, 64.7% could carry out bacteriological tests, virological test (23.5%), mycobacteriological test (64.7%), parasitological (94.1%) and only one facility (5.9%) could carry out cell culture. About a quarter (23.5%) of the laboratories had good in-built laboratory structure, 64.7% had fair and 11.8% had poor in-built structure. Almost all (88.2%) the laboratories had alternative power source. Of all the laboratories, 41.2% had their laboratory structure well ventilated and 58.8% had fair ventilation provision. Concerning availability of communication gadgets, 23.5% of the laboratories had telephone (Intercom), computer (11.8%) and mobile telephone (47.1%). Only two (11.8%) laboratories had uninterrupted power source for electricity sensitive equipments. Tap water was running in 64.7% of the laboratories and 94.1% had clean working areas (**Table 2**).

Table 2. Frequency distribution of variables used in domain of building facilities and utility services (N=17).

VARIABLES	n	%
***Tests Performed**		
Bacteriology	11	64.7
Virology	4	23.5
Mycobacteriology	11	64.7
Parasitology	16	94.1
Cell culture	1	5.9
In Built structure		
Good	4	23.5
Fair	11	64.7
Poor	2	11.8
Alternative Power Source		
Yes	15	88.2
Ventilation Provision		
Good	7	41.2
Fair	10	58.8
***Availability of Communication Gadget**		
Intercom	4	23.5
Computer	2	11.8
Mobile telephone	8	47.1
Availability of UPS		
Yes	2	11.8
Water Tap Running		
Yes	11	64.7
Clean Working Areas		
Yes	16	94.1

*multiple response variable

4.3 Availability of Laboratory Personnel and Training Received by Staff

In the domain of laboratory personnel for all the laboratories assessed, 70.6% of them had medical supervisor, 47.1% had at least one laboratory scientist carrying out laboratory test, 47.1% had at least a laboratory assistant, 52.9% had clerical staff available in the laboratory. Only 64.7% of the staff received training in the past year. Out of those who received training in the past year, 41.2% had the training conducted in their national laboratory, 41.2% on-site and 5.9% was international. Concerning provision of educative programs, 64.7% of the laboratories were providing continued training and workshop for their personnel. Also, 64.7% of the laboratories had a professional programme available to staff and all the staff (100%) had appropriate qualification or competency to perform laboratory work (**Table 3**).

Table 3. Frequency distribution of variables used in laboratory personnel domain (N=17).

VARIABLES	n	%
***Availability of Personnel**		
Medical supervisor	12	70.6
At least a Lab. scientist	8	47.1
Laboratory assistant	8	47.1
Clerical staff	9	52.9
Training in past year		
Yes	11	64.7
***Training site/location**		
National Laboratory	7	41.2
On-site	7	41.2
International	1	5.9
Provision of continued education to staff		
Yes	11	64.7
Availability of professional programme for staff		
Yes	11	64.7
Appropriate qualification of staff	17	100
Yes		

* multiple response variable

4.4 Supervision of Test and Persons Involved

When samples first arrived in the laboratory, 58.8% of the laboratories reported that the tests to perform on them were strictly what the clinicians have requested, technician (29.4%), supervisor (17.6%) and laboratory scientists (17.6%). If further testing was indicated, 58.8% of the laboratories reported that medical supervisors decide what to do, laboratory scientist (17.6%). Almost all (88.2%) the laboratories review test results before reporting and 70.6% reported that such reviews were usually done by medical supervisors, laboratory scientist (11.8%) and another laboratory scientist (35.3%) (**Table 4**).

Table 4. Frequency distribution of variables used in domain of laboratory staff supervision for performing tests (N=17).

VARIABLES	n	%
***Personnel deciding test to perform**		
Requesting clinician	10	58.8
The technician	5	29.4
Supervisor/Med. microbiologist	3	17.6
Laboratory scientist	3	17.6
***Personnel deciding further testing**		
Laboratory scientist	3	17.6
Supervisor/Med. microbiologist	10	58.8
Review of test before reporting		
Yes	15	88.2
***Personnel Reviewing result of test**		
Laboratory scientist	2	11.8
Supervisor/Med. Microbiologist	12	70.6
Another Lab scientist	6	35.3

* multiple response variable

4.5 Logistics and Use of Consumables and Reagents

Out of the 17 laboratories assessed, 70.6% obtain their consumables and reagents from commercial supply, another laboratory (17.6%) and in-house (70.6%). About a third (35.3%) of the laboratories use distilled and deionised water for media preparation, distilled water (76.5%), deionised water (23. 5%) and tap water (11.8%). Sometimes, 70.6% of the laboratories experience problems like delay in consumables and reagents delivery while 29.4% regularly experience such problems. All the laboratories inspect and attach appropriate label to reagents upon delivery and 41.2% of the laboratories store them in good condition. Expired reagents were sometimes used by 11.8% of the laboratories and 88.2% had never used expired reagents for test. Sometimes, 5.9% of all laboratories reuse disposable supplies, 5.9% regularly do and 88.2% had never reused disposable supplies. There were expired reagents in 23.5% of the laboratories and 94.1% carry out quality control on the expired reagents (**Table 5**).

Table 5. Frequency distribution of variables used in domain of consumables and reagents (N=17).

VARIABLES	n	%
***Source of reagents**		
Commercial supply	12	70.6
Another laboratory	3	17.6
Some in-house	12	70.6
***Water used for media preparation**		
Deionised	4	23.5
Distilled	13	76.5
Distilled and Deionised	6	35.3
Tap water	2	11.8
Delay in reagent delivery		
Sometimes	12	70.6
Regularly	5	29.4
Inspection of reagents upon delivery		
Yes	17	100
Labelling of reagents		
Yes	17	100
Storage of reagents		
Good	7	41.2
Fair	10	58.8
Availability of expired reagents		
Yes	4	23.5
Reuse of disposable supplies		
Never	15	88.2
Sometimes	1	5.9
Regularly	1	5.9
Use of expired reagents		
Never	15	88.2
Sometimes	2	11.8
Quality control on expired reagents		
Yes	16	94.1

* multiple response variable

4.6 Managerial Activities of the Laboratories

In organisation and management of the laboratories, all the laboratories organise staff meeting periodically, participate in hospital board meeting and organise special meeting when a particular problem occurs. Concerning availability of services, 41.2% render twenty-four hour services all through the week, 82.4% offer emergency services, 70.6% inform clients of available services by verbal means and 64.7% used door posts (**Table 6**).

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Table 6. Frequency distribution of variables used in domain of organisation and management (N=17).

VARIABLES	n	%
Organisation of periodic staff meetings		
Yes	17	100
Availability of uninterrupted services		
Yes	7	41.2
Availability of emergency services		
Yes	14	82.4
***Means of informing clients**		
Verbal	12	70.6
Door posts	11	64.7
Participation in hospital board meeting		
Yes	17	100
Organisation of meeting during a particular problem		
Yes	17	100

* multiple response variable

4.7 Safety and Infection Control Practices in the Laboratories

In safety/infection domain, 76.5% of the laboratories receive training in laboratory safety, 17.6% use autoclave for their solid waste disposal, 76.5% burn in incinerator and 23.5% bury the waste without pre-treatment. Also, 88.2% of the laboratories dispose liquid waste without treating, 17.6% use autoclave and 70.6% use chemical disinfection. There is a safety officer in 52.9% of the laboratories and 35.3% offer immunisation to their staff. All the laboratories had gloves and lab coats, sharp containers (88.2%), safety glasses (17.6%) and operational disposal equipments (47.1%) available as protective clothing/equipment. In addition, 76.5% of the laboratories have a safety manual/safety SOP and 41.2% had good general cleanliness (**Table 7**).

Table 7. Frequency distribution of variables used in domain of safety/infection control (N=17).

VARIABLES	n	%
Training received in laboratory safety		
Yes	13	76.5
***Methods of solid waste disposal**		
Autoclaving	3	17.6
Incineration	13	76.5
Burial without pre-treatment	4	23.5
***Methods of liquid waste disposal**		
No treatment	15	88.2
Autoclaving	3	17.6
Chemical disinfection	12	70.6
Availability of a safety officer		
Yes	9	52.9
Immunisation to staff		
Yes	6	35.3
***Availability of protective clothing/equipment**		
Gloves	17	100
Lab coats	17	100
Safety glasses	3	17.6
Sharp containers	8	88.2
Operational disposal equipments	8	47.1
Availability of safety manual/safety SOP		
Yes	13	76.5
General cleanliness and organisation		
Good	7	41.2
Fair	10	58.8

* multiple response variable

4.8 Involvement of the Laboratories in Public Health Programmes

In the domain of public health functions or involvement of the laboratories in surveillance activities, 94.1% of the laboratories knew designated reference laboratories and are aware the laboratory has responsibility in preparedness and public health emergencies while 88.2% were part of surveillance network for epidemic-prone diseases. During outbreaks, 47.1% of the laboratories receive specimens or test requests from public health authorities during field investigation and response to emergencies, 70.6% refer isolates to reference laboratories and 76.5% keep registers of persons with notifiable diseases. Furthermore, 70.5% of the laboratories send data to public health (PH) authorities on periodic basis, 41.2% had duplicates of such data and 17.6% had hard copy of notifiable diseases. Only one of the laboratories provides information to epidemiologist on antimicrobial susceptibility pattern (AST) and had guidelines for laboratory investigation of public health events. Only 17.6% however, had emergency sampling kits available (**Table 8**).

Table 8. Frequency distribution of variables used in public health function domain (N=17).

VARIABLES	n	%
Knowledge of reference laboratories		
Yes	16	94.1
Involvement of laboratory in surveillance network		
Yes	15	88.2
Awareness of responsibility in preparedness and public health emergencies		
Yes	16	94.1
Reception of specimen from PH authorities during outbreaks		
Yes	8	47.1
Reference of specimen to referral laboratory		
Yes	12	70.6
Keeping of registers of person with notifiable disease		
Yes	13	76.5
Sending of data to PH authorities on periodic basis		
Yes	12	70.5
Provision of information to epidemiologist on AST patterns		
Yes	1	5.9
Availability of hard copy of notifiable diseases		
Yes	3	17.6
Availability of guidelines for lab investigation of PH events		
Yes	1	5.9
Availability of emergency laboratory sampling kits		
Yes	3	17.6
Availability of duplicate of aggregated data sent to PH authorities		
Yes	7	41.2
Availability of record book for previous test carried out and type of disease for which test was required		
Yes	13	76.5

4.9 Availability of Functional Equipments in the Laboratories

None of the laboratories had CO_2 tank, liquid nitrogen storage, ELISA washer, safety cabinet-level 1, safety cabinet-level 3 and electron microscope but all had staining facilities and slide rack. Only one of the laboratories had warm air incubator, CO_2 incubator, pH meter, water distillation system and safety cabinet-level 2. So also, 11.8% of the laboratories had ELISA plate reader and inverted microscope, 35.3% had freezers and autoclave, 23.5% had pH paper and glassware for media preparation, 41.2% had magnifying lens and fluorescent microscope, water-bath (17.6%), refrigerator (82.4%), weighing balance (47.1%), centrifuge machine (94.1%) and hot air oven (29.4%) (**Table 9**).

Table 9: Frequency distribution of functional equipments in the laboratories (N=17)

*Equipments	n	%
ELISA plate reader	2	11.8
Waterbath	3	17.6
Warm air incubator	1	5.9
CO_2 incubator	1	5.9
CO_2 tank	0	0
Liquid nitrogen storage	0	0
ELISA washer	0	0
Safety cabinet-level I	0	0
Safety cabinet-level 2	1	5.9
Safety cabinet-level 3	0	0
Refrigerator	14	82.4
Freezers	6	35.3
Microscope (oil-immersion)	17	100
Magnifying lens	7	41.2
Scale or weighing balance	8	47.1
Staining facilities and slide rack	17	100
Glassware for media preparation	4	23.5
pH paper	4	23.5
pH meter	1	5.9
Water distillation system	1	5.9
Centrifuge machine	16	94.1
Autoclave(manual/electrical)	6	35.3
Hot air oven	5	29.4
Inverted microscope	2	11.8
Fluorescent microscope	7	41.2
Electron microscope	0	0

* multiple response variable

4.10 Laboratory Tests that can be Performed for each Disease

For meningitis, one of the laboratories could carry out blood culture, identification tests and culture/antimicrobial susceptibility tests on cerebrospinal fluid (CSF). None of the laboratories could perform latex agglutination assay and A-M susceptibility on CSF and blood specimen. However, 17.6% of the laboratories could carry out cell count and Gram stain assays on CSF. As regards cholera, 52.9% of the laboratories could perform wet microscopy, culture using alkaline peptone (1) and none could perform serotyping and culture- TCBS on faecal samples. All the laboratories could carry out thick and thin film microscopy on blood samples for malaria test (**Table 10**).

For measles, none of the laboratories could perform viral isolation on throat/conjunctival swab and serological tests apart from IgM by EIA (5.9%). For both sputum and CSF specimens for tuberculosis tests, none of the laboratories could carry out culture and A-M susceptibility testing. However, 52.9% could perform Ziel-Neelseen, Rhodamine/Auramine staining (47.1%) on sputum and CSF. For HIV, 41.2% of the laboratories could perform IgG by EIA using serum, viral load using blood samples (17.6%) and viral isolation using blood samples (5.9%) (**Table 10**).

Table 10: Frequency distribution of laboratories based on assay they perform on clinical specimens for selected diseases (N=17)

DISEASE	SPECIMEN TYPE	ASSAY PERFORMED	n	%
Meningitis	CSF	Cell count	3	17.6
		Latex agglutination	0	0
		Gram stain	3	17.6
		Culture	1	5.9
		Identification tests	1	5.9
		A-M susceptibility	0	0
	Blood	Culture and A-M susceptibility	1	5.9
Cholera	Faeces	Wet microscopy	9	52.9
		Culture-TCBS	0	0
		Culture Alk. Peptone	1	5.9
		Serotyping	0	0
Measles	Serum	IgM by EIA	1	5.9
		Other serological test	0	0
	Throat swab, conjuctival swab	Virus Isolation	0	0
Malaria	Blood	Thick/thin microscopy	17	100
Tuberculosis	Sputum, CSF	Z-N staining	9	52.9
		Rhodamine/Auramine staining	8	47.1
		Culture	0	0
		A-M susceptibility	0	0
HIV	Serum	IgG by EIA	7	41.2
	Blood	Viral load	3	17.6
		Viral Isolation	1	5.9

4.11 Composite Score of Capacity of Laboratories by the Domain of Laboratory Capacity

Generally, from the results for all facilities (n=17), the mean(SD) capacity score for the domain organisation/management was 0.80(0.14), laboratory supervision 0.75(0.18), consumables/reagent 0.71(0.07), safety/infection control 0.69(0.13), laboratory personnel 0.58(0.19), laboratory facility/utility services 0.51(0.12), public health functions 0.54(0.19) and for equipments domain was 0.29(0.12) (**Table 11**).

Table 11. Capacity point score (mean and standard deviation) of each laboratory by domain of laboratory capacity (N=17)

Domain/ Section / Laboratories	Laboratory facilities and utility service	Laboratory personnel	Laboratory supervision	Logistics of Consumables/reagents	Organisation and Management	Safety/Infection Control	Equipments	Public Health Function
	Mean(SD)							
Facility 1	0.46(0.50)	0.73(0.47)	0.90(0.32)	0.69(0.44)	0.71(0.49)	0.62(0.49)	0.27(0.45)	0.62(0.51)
Facility 2	0.79(0.38)	0.82(0.40)	0.70(0.48)	0.69(0.48)	0.86(0.38)	0.79(0.40)	0.53(0.50)	0.54(0.52)
Facility 3	0.68(0.46)	0.45(0.47)	0.90(0.32)	0.81(0.36)	0.71(0.49)	0.68(0.47)	0.47(0.50)	0.23(0.44)
Facility 4	0.64(0.50)	0.73(0.47)	0.60(0.52)	0.78(0.41)	0.65(0.49)	0.65(0.49)	0.27(0.45)	0.69(0.48)
Facility 5	0.64(0.50)	0.59(0.49)	0.80(0.42)	0.75(0.41)	0.71(0.49)	0.65(0.49)	0.49(0.51)	0.38(0.51)
Facility 6	0.57(0.51)	0.41(0.49)	0.30(0.48)	0.66(0.47)	1.00(0.00)	0.50(0.50)	0.27(0.45)	0.54(0.52)
Facility 7	0.36(0.46)	0.45(0.52)	0.90(0.32)	0.72(0.45)	1.00(0.00)	0.76(0.44)	0.20(0.40)	0.69(0.48)
Facility 8	0.39(0.49)	0.36(0.50)	0.90(0.32)	0.69(0.44)	0.57(0.53)	0.62(0.49)	0.22(0.42)	0.69(0.48)
Facility 9	0.50(0.48)	0.36(0.50)	0.70(0.48)	0.81(0.36)	1.00(0.00)	0.47(0.50)	0.22(0.42)	0.69(0.48)
Facility 10	0.43(0.47)	0.23(0.41)	0.70(0.48)	0.59(0.49)	0.71(0.49)	0.62(0.49)	0.31(0.47)	0.62(0.51)
Facility 11	0.29(0.43)	0.73(0.47)	0.80(0.42)	0.66(0.47)	0.86(0.38)	0.68(0.47)	0.13(0.34)	0.46(0.52)
Facility 12	0.64(0.50)	0.82(0.40)	0.80(0.42)	0.59(0.46)	0.57(0.53)	0.82(0.39)	0.29(0.46)	0.69(0.48)
Facility 13	0.50(0.48)	0.45(0.52)	1.00(0.00)	0.69(0.44)	0.86(0.38)	0.62(0.49)	0.22(0.42)	0.62(0.51)
Facility 14	0.32(0.46)	0.82(0.40)	0.80(0.42)	0.75(0.41)	0.71(0.49)	0.88(0.33)	0.22(0.42)	0.23(0.44)
Facility 15	0.64(0.46)	0.64(0.50)	0.80(0.42)	0.75(0.45)	1.00(0.00)	0.94(0.24)	0.31(0.47)	0.77(0.44)
Facility 16	0.32(0.46)	0.83(0.41)	0.70(0.48)	0.81(0.36)	0.71(0.49)	0.62(0.49)	0.18(0.39)	0.15(0.38)
Facility 17	0.57(0.47)	0.50(0.50)	0.40(0.52)	0.66(0.47)	0.86(0.38)	0.76(0.44)	0.13(0.34)	0.62(0.51)
All facilities	0.51(0.12)	0.58(0.19)	0.75(0.18)	0.71(0.07)	0.80(0.14)	0.69(0.13)	0.29(0.12)	0.54(0.19)

4.12 Capacity of Laboratory for each domain

On the overall, 7(41.2%) had 'low capacity' while 10(58.8%) had 'fair capacity' in building facility/utility services' domain. In the domain of laboratory personnel, 7(41.2%) had 'low capacity', 6(35.3%) had 'fair capacity' and 4(23.5%) had 'good capacity'. More than half 10(58.8%) had 'good capacity', about a third 5(29.4%) had 'fair capacity' and 2(11.8%) had 'poor capacity' in the domain laboratory staff supervision. For consumables/reagents, many 14(82.4%) had 'fair capacity' while only 3(17.6%) had 'good capacity' **(Table 12)**.

Just above half 9(52.9) had 'fair capacity' and 8(47.1%) had 'good capacity' for the domain organisation/management. Only 1(5.9%) had 'low capacity', 13(76.5%) had 'fair capacity' and 3(17.6%) had 'good capacity' for safety/infection control domain. Almost all 16(94.1%) had 'low capacity' and just 1(5.9%) had 'fair capacity' for equipment domain. The public health functions domain had 5(29.4%) of the facilities in 'low capacity' and 12(70.6%) had 'fair capacity' **(Table 12)**.

Table 12: Frequency distribution of laboratories by capacity level of each domain using capacity scale indicator (N=17)

Domain / Capacity level	Laboratory facilities and utility service	Laboratory personnel	Laboratory supervision	Logistics of Consumables/reagents	Organisation and Management	Safety/Infection Control	Equipments	Public Health Function
	n (%)							
Low	7 (41.2)	7 (41.2)	2 (11.8)	0(0)	0(0)	1 (5.9)	16 (94.1)	5 (29.4)
Fair	10 (58.8)	6 (35.3)	5 (29.4)	14 (82.4)	9 (52.9)	13 (76.5)	1 (5.9)	12 (70.6)
Good/high	0(0)	4 (23.5)	10 (58.8)	3 (17.6)	8 (47.1)	3 (17.6)	0(0)	0(0)

4.13 Laboratory Testing Capacity for the Selected Diseases

On the overall, all the facilities (100%) had 'low capacity' to test for meningitis. Almost all (94.1) had 'low capacity' and only 5.9% had 'fair capacity' to test for cholera. The entire facilities (100%) had 'low capacity' and 'good capacity' to test for measles and malaria, respectively. In testing for tuberculosis, more than half (64.7%) had 'low capacity' and 35.3% had 'fair capacity'. Most (82.4%) of the facilities had 'low capacity' and just 17.6% had 'fair capacity' in testing for HIV. All the facilities (100%) had 'low capacity' to test for the six selected diseases (**Figure 1**).

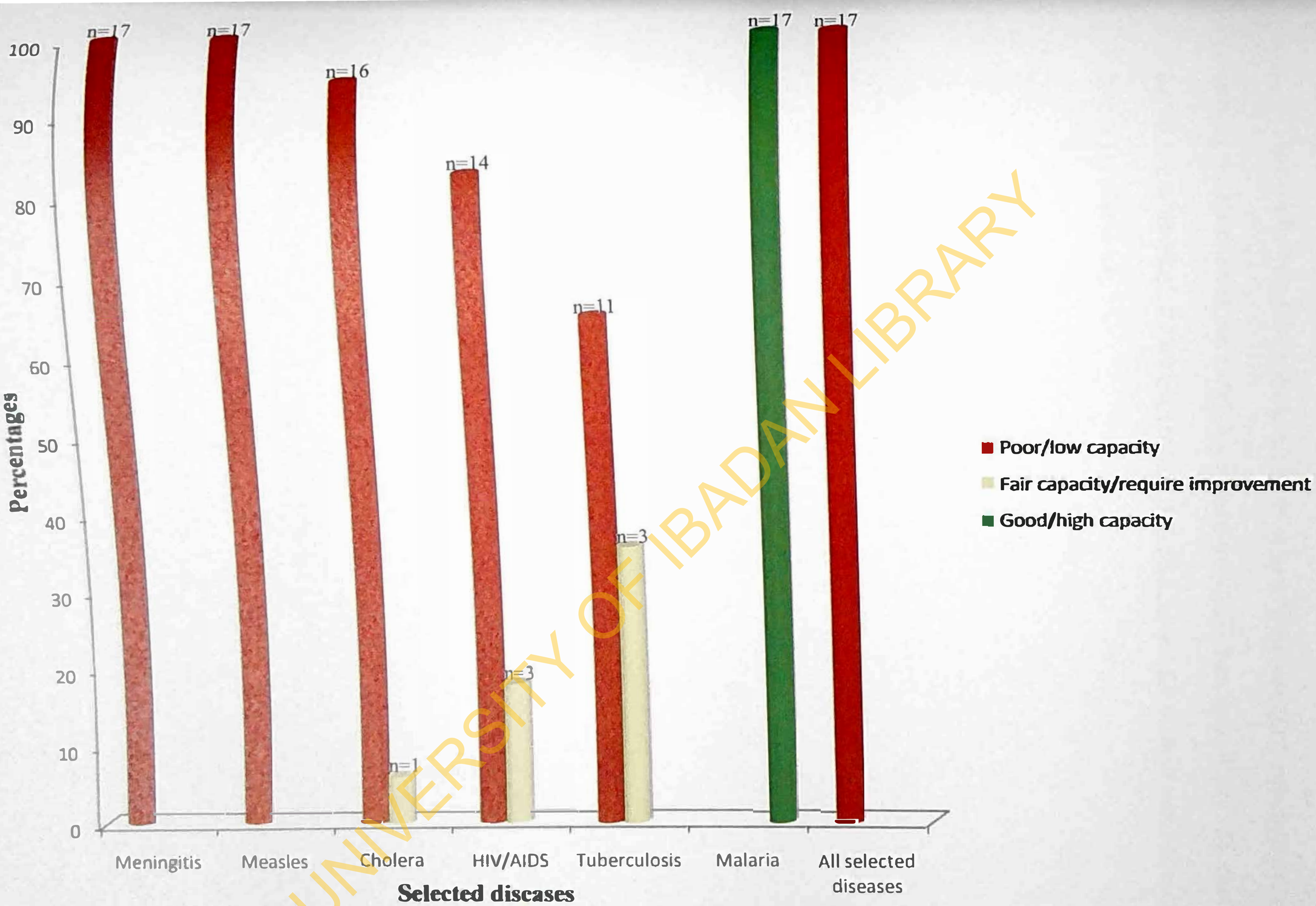

Figure 1: Capacity level of the laboratories for testing of the selected diseases using capacity scale indicator (N=17)

4.14 Score of Capacity of Laboratories in Testing for the Selected Diseases by each Facility

Generally, from the results for all facilities (n=17), the mean(SD) capacity score for carrying out malaria test was 1.00(0.00), measles 0.02(0.08), meningitis 0.08(0.15), cholera 0.15(0.15), tuberculosis 0.25(0.22), HIV/AIDS 0.22(0.26) and for all the selected diseases 0.22(0.11) (**Table 13**).

Table 13: Distribution of statistics (mean scores, standard deviations) obtained for the selected diseases in the area of laboratory testing performance capacity for each facility (N=17)

Selected Diseases / Laboratory	Malaria	Measles	Meningitis	Cholera	Tuberculosis	HIV/AIDS	All Selected diseases
	Mean (SD)						
Facility 1	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.25(0.50)	0.00(0.00)	0.17(0.39)
Facility 2	1.00(0.00)	0.00(0.00)	0.43(0.53)	0.25(0.50)	0.50(0.58)	0.67(0.58)	0.43(0.51)
Facility 3	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.00(0.00)	0.33(0.58)	0.17(0.39)
Facility 4	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.50(0.58)	0.33(0.58)	0.22(0.42)
Facility 5	1.00(0.00)	0.00(0.00)	0.14(0.38)	0.58(0.58)	0.50(0.58)	0.67(0.58)	0.39(0.50)
Facility 6	1.00(0.00)	0.00(0.00)	0.43(0.53)	0.25(0.50)	0.25(0.50)	0.00(0.00)	0.26(0.45)
Facility 7	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.09(0.29)
Facility 8	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.25(0.50)	0.00(0.00)	0.17(0.39)
Facility 9	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.50(0.58)	0.00(0.00)	0.13(0.34)
Facility 10	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.09(0.29)
Facility 11	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.00(0.00)	0.13(0.34)
Facility 12	1.00(0.00)	0.00(0.00)	0.29(0.49)	0.25(0.50)	0.25(0.50)	0.67(0.58)	0.35(0.49)
Facility 13	1.00(0.00)	0.33(0.58)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.13(0.34)
Facility 14	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.04(0.21)
Facility 15	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.00(0.00)	0.50(0.58)	0.33(0.58)	0.22(0.42)
Facility 16	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.50(0.58)	0.33(0.58)	0.26(0.45)
Facility 17	1.00(0.00)	0.00(0.00)	0.00(0.00)	0.25(0.50)	0.00(0.00)	0.33(0.58)	0.17(0.39)
All facilities	1.00(0.00)	0.02(0.08)	0.08(0.15)	0.15(0.15)	0.25(0.22)	0.22(0.26)	0.20(0.11)

4.15 Reasons Reported for Poor Testing Capacity of the Laboratories

All the facilities (100%) attributed reasons for not performing WHO standard tests for **measles, meningitis, cholera, tuberculosis, HIV** to 'no equipment', 11.8% attributed it to 'no technical expertise', 17.6% attributed it to 'staff not trained', 5.9% attributed it to 'equipment not functioning', 94.1% attributed it to 'no reagent', 17.6% attributed it to 'no laboratory guideline', 76.5% attributed it to 'test not requested' from clinicians and 11.8% attributed it to 'cost consideration' (**Table 14**).

Table 14: Frequency distribution of reasons for not performing WHO standard tests for selected diseases (N=17)

*Reasons reported	n	%
No equipment	17	100
No technical expertise	2	11.8
Staff not trained	3	17.6
Equipment not functioning	1	5.9
No reagent	16	94.1
No laboratory guideline	3	17.6
Test not requested	13	76.5
Cost consideration	2	11.8

* multiple response variable

4.16 Bivariate Statistical Analysis

There was no association between the 'extra level of training received by laboratory scientists (categorical)' and the 'testing capacity for the selected diseases (continuous - raw average point score before categorising)' (p-value= 0.242, t-value= -1.219). Because of the finite population surveyed in this study, all other statistical analyses of associations using chi-square were invalid.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Overall Outcome of Laboratory Capacity by Domain

Generally, in this study, the mean score for all facilities was highest in the domains of organisation and management (0.80), laboratory supervision (0.75), logistics of consumables and reagents (0.71), safety/infection domains (0.69) maybe indicating better laboratory capacity in these domains. Meanwhile, the average point score in the laboratory facilities/utility services (0.51) and laboratory personnel (0.58) were at intermediate level. This indicates some specific inadequacies in infrastructures, services provided and training for staff/staff shortages. The average point score for public health functions (0.54) was also average which indicates that the contribution of the laboratories to disease identification and prevention programmes for example surveillance is 'fair'. The average point score was lowest in the equipment domain (0.29) suggesting that equipping the laboratories has suffered serious setback and attention of government.

5.1.2 Differences and similarities from other literature in Africa

In a study conducted by Cathy et al. (2006), problem in laboratory diagnosis and poor state of laboratory capacity to carry out test accurately was attributed to lack of laboratory consumables and basic essential equipments. This is very similar to the findings from this study because the results showed that over 90% of the laboratories assessed could not carry out WHO specific tests for the selected diseases due to 'lack of equipments and reagents'. In the same study by Cathy et al. (2006), further reasons for not carrying out quality and reliable tests were attributed to lack of government standards and limited numbers of skilled personnel. On the contrary, this study found that just 11.8% of the facilities attributed poor capacity to 'no technical expertise'. Also 17.6% of the facilities attributed poor capacity to 'no laboratory standard operating procedure'. This suggests that the laboratories assessed

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were manned by competent and qualified laboratory scientists. Again as documented by Cathy et al. (2006), lack of educators and training programs also contributed to poor state of laboratory capacity but this study found that very few (17.6%) of the facilities complained of staff not trained and most (64.7%) of the facilities reported there were ongoing or continued educational/training programs for staff. These observed differences could be due to recent recruitment (duration of service of some respondents were less than a year) of qualified scientists into the laboratories and frequent organisation of training/seminar by Association of Medical Laboratory Scientists of Nigeria.

5.1.3 Review of findings with related outcome in Nigeria

In a study conducted by Medical Laboratory Science Council of Nigeria (MLSCN) (Chioma, 2010) in which over 2000 medical laboratories were assessed, about 1000 (at least 50%) of the laboratories lacked operational requirement such as essential equipments, reagents, infrastructures and qualified personnel, a result observed to be similar with the finding of this study except that of 'qualified personnel' in which this study found that about half (52.9%) of the facilities had laboratory scientists even with postgraduates education and all facilities reported they had qualified/competent scientists performing laboratory work. This difference might be due to higher sample size used by MLSCN.

Furthermore, Stuart et al. (2010) conducted a study titled: Strengthening Laboratory Systems in Resource – Limited Settings. His results showed that laboratory capacity has dropped in district hospital laboratories and even national and reference laboratories. He attributed this 'drop down' to lack of equipment and supplies, staffing issues, lack of coordination and poor oversight. These results are similar to findings from this study. These similarities could be linked to the fact that both studies were carried out in poor resource settings. However, this study found that laboratory oversight such as staff supervision was poor in only 11.8% of the facilities contrary to finding of Stuart et al. (2006) result.

5.1.4 Comparison with related findings from the United States

Association of Public Health Laboratories (APHL) and the University of Michigan Center Of Excellence in Public Health Workforce Studies (CEPHS) partnered to develop a national laboratory workforce assessment to gauge capacity in all U.S. public health laboratories (University of Michigan Centre of Excellence in Public Health Workforce Studies and Association of Public Health Laboratories, 2011). In the study, just over half (51%) of responding laboratories reported low/poor capacity to provide education and training to their workers. This current study also showed from the laboratory personnel domain that 41.2% of the facilities had low/poor capacity in providing education and training to their workers – a slight similarity observed in both studies. However, a different result was obtained in the equipment and instrumentation domains. In the former study by APHL and CEPHS, 51% of the laboratories rated equipments domain to have fair capacity while this current study reported that almost all (94.1%) the laboratories had low/poor capacity. This observed disparity in equipment domain could be attributed to high and rich technological advancement in the United State where the former study was conducted. The study by APHL and CEPHS also reported that laboratory infrastructure is below optimal capacity (45%) in many areas. Their findings are similar to what was obtained in this study. The capacity of laboratory in terms of infrastructure and/or building facilities in this study was found to be 41.2%.

In the current study, 76.5% of the laboratories reported that WHO standard tests for the selected diseases were not usually requested by the clinicians. This however, did not mean cases of the selected diseases are not being reported at the hospital. Therefore, this observed high percentage in 'tests not requested' could be due to the perception of clinicians that the laboratories were in poor state and so cannot carry out quality and reliable tests. Consequently, the clinicians may have resorted to the use of clinical algorithms to diagnose the selected diseases instead of requesting for laboratory tests. For instance, malaria is

endemic in Nigeria; clinicians may use patient symptoms to prescribe malaria drugs instead of requesting for a malaria parasite test. Though, reliance on clinical diagnosis or use of clinical signs and symptoms is attractive in areas with a high prevalence of disease (World Health Organisation, 2009).

5.1.5 Testing Capacity of Selected Diseases and Associated Factors

This study went further to determine the testing capacity for the selected diseases. No laboratory could carry out WHO standard tests for meningitis due to lack of equipments, reagents and clinicians' failure to request for test. This absolute poor capacity to test for meningitis could also be because the study area was not located in the meningitis belt hence prevalence is low.

In recent times, several outbreaks of cholera have been reported in Oyo State. These outbreaks have had no positive influence on the capacity of the laboratories to carry out WHO cholera tests as 94.1% of the laboratories had poor capacity. In addition to reasons like no reagent and equipment, the poor capacity could be attributed to 'tests not requested' from clinicians because cholera can easily be diagnosed using clinical signs and symptoms e.g. rice water stool. However, WHO specified that case of cholera must be laboratory confirmed or epidemiologically linked to a confirmed case.

All the laboratories were in good standing capacity to test for malaria. The likely reasons for this were not far-fetched. In recent times, there had been concerted effort by National and State Government to wage war against malaria because malaria is endemic in Nigeria with associated mortality and the burden of severe malaria is higher in persons above 5 years in outpatient clinics of public health facilities in Oyo state, with yearly progressive increase in cases and CFR (Olugbade et al., 2014). Good testing capacity for malaria could also be attributed to ease in carrying out malaria parasite test. Practically, malaria parasite test does not require much equipment and technical expertise.

Poor capacity was reported by all the laboratories in testing for measles. Apart from the non-availability of reagents and lack of equipments, measles could also be diagnosed using clinical signs and symptoms. Hence, the low capacity in the laboratories could be caused by the test not being requested. Low prevalence of measles in the state can also contribute to this low capacity.

In Nigeria, the fight against tuberculosis and HIV has been dominated by international donor agencies and non-governmental health organisation. Consequently, this has caused a lot of negligence on the part of government's attention and role in this 'fight'. This reflected in the current study in which 82.4% and 64.7% of the laboratories had low capacity for any test for HIV and tuberculosis, respectively. Reasons were attributed to no reagents and equipments. In Nigeria, tests for HIV are usually or mostly done in HIV counselling and testing centres established by donor agencies. Standard TB tests are accessible to patients living only around the capital cities where standard TB laboratories are available. Hence, people living far away from the state capital cannot access TB tests even though there are hospitals around them but these hospitals lack the capacity to do so as indicated in the result. On the overall, to test for the six selected diseases, all the laboratories had poor capacity.

Occasional training of laboratory scientists can potentially boost the capacity of their respective laboratories to carry out specific tests especially when new methods of test are being discovered. However, there was no association between the 'extra level of training received by laboratory scientists' and the 'testing capacity for the selected diseases'.

Some hospital laboratories declined informed consent; therefore some laboratories could not be assessed. Due to poor record keeping in some of the laboratories, few records of notifiable disease specimens sent to the laboratory could not be retrieved.

5.2 Conclusion

This study has provided a comprehensive assessment of the status of laboratory capacity in the state hospitals and found that laboratory capacity to carry out tests for most of the selected diseases was very low in the study facilities. Particularly, for the selected epidemic-prone diseases (meningitis, measles and cholera), all the laboratories were found incapable of performing all WHO standard laboratory tests for the diseases. Also, most of the laboratories reported that reasons affecting the capacity of the laboratories to carry out tests for the selected diseases were as a result of no equipments, no reagents and test not requested by clinicians.

This study also found laboratory facilities, utility services capacity and general work conditions to be 'fair' in fewer above half of all the laboratories surveyed. In laboratory personnel domain (provision of continuous education, qualifications and staffing), also just over half of the laboratories were found to report fair and good capacity. Concerning the supervision of test performance in the laboratory (laboratory staff supervision domain), most all the laboratories were functioning above the low capacity level. Pertaining to procurement, inventory, storage and use of reagents (consumable and reagents domain), more than three quarters of the laboratories was found have fair capacity.

In organisation and management (internal/external communication structure and service hours), none of the laboratories was operating at low capacity but most of the laboratories were at least functioning fairly. Regarding management of possible risks in the laboratories (safety/infection control), only three-quarters of the laboratory was found to be at fair capacity. Most of the laboratories had low capacity in the availability and functional status of necessary equipments. In surveillance and response, referral and reporting of specimens (public health domain), almost three-quarters of the laboratories reported fair capacity.

5.3 Recommendations

1. More awareness of the importance of laboratory tests should be created and clinicians should be encouraged to embrace use of the laboratory tests while diagnosing some infectious diseases and not limiting diagnosis to clinical algorithms. This will facilitate more case confirmation of infectious diseases since the latter must be laboratory confirmed. However, this does not restrict clinicians during emergency conditions from using case classification to prescribe appropriate therapy.

2. Equipping the laboratories with modern instruments, provisions of test reagents and consumables, improving laboratory infrastructure and recruitments of more laboratory scientists are also recommended to attain full capacity in the laboratories and improve on service delivery in the hospitals.

3. Regular staff supervision and monitoring should be conducted.

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Appendix 1

Information To Respondent In Order To Obtain Voluntary Consent

My name is Bankole, Oluwayomi T. I am a student of Dept. of Epidemiology and Medical Statistics, Faculty of Public Health, University of Ibadan. I am currently carrying out a study titled: **Assessment of capacity of public laboratories in diagnosing selected priority and epidemic prone diseases in Oyo State, South-western Nigeria.** I am carrying out this study because laboratories have not been given much attention in most health facilities.

The study requires your participation which will take about a half hour. You are being invited to take part in this research because we feel that your experience as a laboratory scientist will contribute much to our understanding and knowledge of state of laboratories in Oyo State.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

You will be asked questions on your demographics, building and utility services, equipment, laboratory personnel, supervision, reagents, tests performed, management, public health functions and safety/infection control.

You do not have to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you uncomfortable. However, we do not wish for this to happen.

Information you provide will be taken as confidential and will be protected. In conclusion, your participation will help stakeholders to take action on the improvement of laboratories.

The research has been reviewed and approved by the Ethics Review Committee of Oyo State Ministry of Health.

(This section is mandatory)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any question I have asked has been answered to my satisfaction. I consent voluntarily to be a participant in this study

Signature of Participant _____

Date _____

Witness_____

Appendix 2

QUESTIONNAIRE

TITLE: Assessment of capacity of public laboratories in diagnosing selected priority and epidemic prone diseases in Oyo State, South-western Nigeria.

STUDY NUMBER:.....

SECTION I: Demographics

1. Age at last birthday (in years) .....

2. Sex: Male ( ), Female ( )

3. Ethnicity: Youba ( ), Igbo ( ), Hausa ( ), others ( )

4. Religion: Christianity ( ), Islamic ( ), Traditional ( ), others ( )

5. Marital Status: Married ( ), Single ( ), Widowed ( ), Divorced ( ), Engaged ( )

6. What is your position or cadre in the laboratory .....

7. Have you any professional study certification? Yes ( ), No ( ). Please specify .....

8. Highest educational Status: Post secondary non tertiary e.g School of Health Technology ( ), Tertiary education ( ), Post graduates ( )

9. Duration of your service with the laboratories in months: .....

SECTION II: Building Facilities and Utility Services

10. Does the laboratory perform tests for:

Bacteriology? Yes ( ), No ( ) Virology? Yes ( ), No ( ) Mycobacteriology? Yes ( ), No ( )

Parasitology? Yes ( ), No ( ), Cell culture facility? Yes ( ), No ( )

11. What % of the day do you have the following services available?

Electricity?.....

Running water?.....

Gas?.....

SECTION III: Laboratory personnel

12. Do you have a technical/medical supervisor available in the lab? Yes ( ) No ( )

13. Do you have enough scientist/technologist doing test? Yes ( ) No ( )

14. Do you have a laboratory assistant not doing test? Yes ( ) No ( )

15. Do you have a clerical staff available in the lab? Yes ( ) No ( )

16. Has training been conducted for your laboratory staff in the past year? Yes ( ), No ( )

If Yes, indicate the type of training and the number of staff trained	
Formal training at national lab	Yes ( ), No ( ), Number ( )
Formal training on-site	Yes ( ), No ( ), Number ( )
International training	Yes ( ), No ( ), Number ( )

17. Is continuing education (training, workshop, conference, etc.) provided to staff members?
Yes ( ), No ( ), Sometimes ( )

18. Is there a professional development programme in place for the staff?
Yes ( ), No ( ), Partially ( )

19. Does staff have appropriate qualifications or competences to perform laboratory work?
Yes ( ), No ( ), Partially ( )

SECTION IV: Laboratory Staff Supervision

20. Who usually decides which tests to perform when the samples first arrive in the laboratory?

The requesting clinician	Yes ( ) No ( )
The technician	Yes ( ) No ( )
Microbiologist/supervisor	Yes ( ) No ( )
Laboratory scientist	Yes ( ) No ( )

21. Who makes decisions about further testing if indicated?

Laboratory scientist	Yes ( ) No ( )
Microbiologist/supervisor	Yes ( ) No ( )
Are ALL tests reviewed before results sent for reporting?	Yes ( ) No ( )

22. Who reviews the results of tests (or test runs)?

Only the Laboratory scientist performing the test	Yes ( ) No ( )
Another scientist	Yes ( ) No ( )
A supervisor/medical microbiologist	Yes ( ) No ( )

SECTION V: Consumables and Reagents

23. Do you obtain your reagents from commercial supply? Yes ( ) No ( ); If yes, what % ( )
24. Do you obtain your reagents from another laboratory? Yes ( ) No ( ); If yes, what % ( )
25. Do you prepare some part of your reagents in-house? Yes ( ) No ( ); If yes, what % ( )

26. What type of water is used for preparation of media and reagents?

Deionized	Yes ( ), No ( )
Distilled	Yes ( ), No ( )
Distilled and deionized	Yes ( ), No ( )
Tap water	Yes ( ), No ( )

27. Does the laboratory experience problems with reagent delivery like delays, temperature not adequate, reference error, etc? Never ( ), Sometimes ( ), Regularly ( ), Non applicable ( )

28. Do you inspect consumables and reagents upon receipt? Yes ( ), No ( ), Sometimes ( )

29. Are disposable supplies reused? Never ( ), Sometimes ( ), Regularly ( ), Not applicable ( )

30. Are expired reagents used? Never ( ), Sometimes ( ), Regularly ( ), Not applicable ( )

31. If 'sometimes or regularly', do you perform quality control on the expired reagent?

Yes ( ), No ( )

32. If 'yes', does quality control testing demonstrate that the quality of reagents is still acceptable? Yes ( ), No ( )

SECTION VI: Laboratory Testing Services

33. Indicate which of the following tests are/can be performed at your laboratory.

Disease	Specimen type	Assay Performed	Available		Number/ Month	If 'no' for any assay, Indicate reasons by writing the letters that represent each assay on these options (MULTIPLE RESPONSE)
			Yes	No		
Meningitis	CSF	a. cell count				No technical expertise .....
		b. latex agglutination				Staff not trained.....
		c. Gram stain				No equipment.....
		d. Culture				Equipment not functioning....
		e. Identification tests				No reagent.....
		f. A-M susceptibility				No lab guideline.....
	Blood	g. Blood Culture and tests b, e, f above				Test not requested.....
						Cost considerations.....
Cholera	Faeces	h. Wet microscopy				No technical expertise .....
		i. Culture-TCBS				Staff not trained.....
		j. Culture-Alk.Peptone				No equipment.....
		k. Serotyping				Equipment not functioning....
						No reagent.....
						No lab guideline.....
						Test not requested.....
						Cost considerations.....
Measles	Serum	l. IgM by EIA				No technical expertise .....
		m. Other serological tests				Staff not trained.....

	Throat swab, conjunctival swab	n. Virus Isolation				No equipment..... Equipment not functioning.... No reagent..... No lab guideline..... Test not requested..... Cost considerations.....
Malaria	Blood	o. Thick/thin microscopy				No technical expertise ..... Staff not trained..... No equipment..... Equipment not functioning.... No reagent..... No lab guidelines..... Test not requested..... Cost considerations.....
Tuberculosis	Sputum, CSF	p. Z-N staining				No technical expertise ..... Staff not trained..... No equipment..... Equipment not functioning.... No reagent..... No lab guideline..... Test not requested..... Cost considerations.....
		q. Rhodamine/Auramine Staining				
		r. Culture				
		s. A-M Susceptibility				
HIV	Serum	t. IgG by EIA				No technical expertise ..... Staff not trained..... No equipment..... Equipment not functioning.... No reagent..... No lab guideline..... Test not requested..... Cost considerations.....
	Blood	u. Viral load				
		v. Virus Isolation				

SECTION VII: Organisation and Management

34. Do you organise staff meetings periodically? Yes ( ), No ( )

35. Indicate below the normal hours/days of service of the laboratory.

Number of days per week.....

Hours per day.....

If no 24-hour service, is out-of-hours or emergency service available? Yes ( ), No ( )

36. How does the laboratory inform existing or potential clients about the services it offers?

Verbally only (informal) Yes ( ), No ( )

Posted on door of the laboratory Yes ( ), No ( )

37. Do laboratory representative participate in hospital board meeting as relevant? Yes ( ), No ( )

38. Do you organise meeting when a particular problem occurs? Yes ( ), No ( )

SECTION VIII: Safety/Infection Control

39. Does laboratory staff receive training in laboratory safety? Yes ( ), No ( )

40. Which of the following methods are used for solid waste disposal?

Autoclaving Yes ( ), No ( )

Incineration Yes ( ), No ( )

Burial with no pre-treatment Yes ( ), No ( )

Other (briefly describe): .....

41. What are the methods used for liquid waste disposal?

No treatment Yes ( ), No ( )

Autoclaving Yes ( ), No ( )

Chemical disinfection Yes ( ), No ( )

Other (briefly describe): .....

42. Do you have a safety officer? Yes ( ), No ( )

43. Are staff offered immunisation? Yes ( ), No ( )

44. Are gloves worn for all manipulations of specimens, organisms, and reagents? Yes ( ), No ( )

SECTION IX: Public Health Functions

45. Does the laboratory know the designated reference laboratories? Yes ( ), No ( )

46. Is the laboratory part of surveillance network/s for endemic/epidemic-prone diseases (e.g. HIV, malaria, measles, cholera, meningitis)? Yes ( ), No ( )

47. Do you think or know that the laboratory has defined responsibilities in national preparedness and response to public health emergencies like outbreaks? Yes ( ), No ( )

48. Does the laboratory receive specimens or test requests from public health authorities during field investigation of public health events or outbreaks? Yes ( ), No ( )

49. Does the laboratory refer specimens or isolates to reference laboratories for public health purpose (e.g. routine surveillance, outbreak investigation)? Yes ( ), No ( )

50. Do you keep register of persons with notifiable diseases? Yes ( ), No ( )

51. Do you send aggregated laboratory data on periodic basis to public health authorities?

Yes ( ), No ( )

52. If 'yes', specify other recipients of such data. ----------

53. Do you provide information to epidemiologists about AST patterns? Yes ( ), No ( )

Appendix 3

Observation Checklist

TITLE: Assessment of capacity of public laboratories in diagnosing selected priority and epidemic prone diseases in Oyo State, South-western Nigeria.

OBSERVATION CHECKLIST

BUILDING FACILITIES AND UTILITY SERVICES

1. Check if laboratory building is free-standing or inbuilt to hospital. If free standing, observe.

Laboratory building Good ( ), Fair ( ), Poor ( )

2. Alternative power source (in case of power failure) Yes ( ), No ( )

3. Ventilation provision Good ( ), Fair ( ), Poor ( )

4. Communication and data storage system

Gadgets	Yes	No
Telephone		
Computer(Internet)		
GSM		

5. Uninterrupted Power Supply (UPS) for sensitive equipment Yes ( ), No ( )

6. Running tap water Yes ( ), No ( )

7. Clean work areas and proper maintenance Yes ( ), No ( )

EQUIPMENT

8. Observe the availability, number and/or functional state of the following equipment

Equipment	Yes	No	Number	If 'yes' functional	
				Yes	No
ELISA plate reader					
Waterbath					
Warm air incubator					
CO_2 incubator					
CO_2 tank					
Liquid nitrogen storage					
ELISA washer					
Safety cabinet-level 1					
Safety cabinet-level 2					
Safety cabinet-level 3					
Refrigerator					
Freezers					
Microscope (oil-immersion)					
Magnifying lens					
Scale or weighing balance					

Equipment	Yes	No	Number	If 'yes' functional	
				Yes	No
Bunsen burner/alcohol Lamp					
Petri dishes					
Test tubes and racks					
Staining facilities and slide rack					
Glassware for media preparation					
pH paper					
pH meter					
Water distillation system					
Centrifuge machine					
Autoclave(manual/electrical)					
Hot air oven					
Inverted microscope					
Fluorescent microscope					
Electron microscope					

CONSUMABLES AND REAGENTS

9. Are the reagents in the laboratory appropriately labelled? Yes ( ) No ( )

10. Are there expired/outdated reagent? Yes ( ) No ( )

11. Appropriate storage of reagents Good ( ), Fair ( ), Poor ( )

TESTING

12. Typed or written protocols (SOP) for performing tests Yes ( ), No ( )

SAFETY AND INFECTION CONTROL

13. Safety manual/safety SOP for staff Yes ( ), No ( )

14. General cleanliness and organisation Good ( ), Fair ( ), Poor ( )

15. Protective clothing/equipment
Gloves Yes ( ), No ( ) Lab coats Yes ( ), No ( ) Safety glasses Yes ( ), No ( )

16. Hazardous waste disposal equipment operational Yes ( ), No ( )

17. Sharp containers Yes ( ), No ( )

PUBLIC HEALTH FUNCTIONS

18. Availability of hard copy of list of notifiable diseases Yes ( ), No ( )

19. Guidelines for Lab investigation of public health events Yes ( ), No ( )

20. Stockpiles of emergency Laboratory sampling kits Yes ( ), No ( )

21. Duplicate of Lab aggregated data sent to public health authorities Yes ( ), No ( )

22. Availability of record book to review request sent to the laboratory to determine their role and the type of disease for which laboratory tests are required. Yes ( ), No ( )

MINISTRY OF HEALTH

DEPARTMENT OF PLANNING, RESEARCH & STATISTICS DIVISION

PRIVATE MAIL BAG NO: 5027, OYO STATE OF NIGERIA

Your Ref. No. .....

All communications should be addressed to the Honorable Commissioner quoting

Our Ref. No. AD 13/ 479/569 3rd February, 2014

The Principal Investigator,
Department of Epidemiology and Medical Statistics,
Faculty of Public Health,
College of Medicine,
University of Ibadan,
Ibadan.

Attention: Bankole .O. Temitope

Ethical Approval for the Implementation of your Research Proposal in Oyo State

This acknowledges the receipt of the corrected version of your Research Proposal titled: "Assessment of Capacity of public Laboratories in diagnosing selected priority and epidemic prone diseases in Oyo State, South-Western Nigeria."

2. The committee has noted your compliance with all the ethical concerns raised in the initial review of the proposal. In the light of this, I am pleased to convey to you the approval of committee for the implementation of the Research Proposal in Oyo State, Nigeria.

3. Please note that the committee will monitor closely and follow up the implementation of the research study. However, the Ministry of Health would like to have a copy of the results and conclusions of the findings as this will help in policy making in the health sector.

4. Wishing you all the best.

Sola Akande (Dr)
Director, Planning, Research & Statistics
Secretary, Oyo State, Research Ethical Review Committee