FACTORS AFFECTING QUALITY OF LABORATORY SERVICES AT INFECTIOUS DISEASES HOSPITAL, KANO – NIGERIA

BY

ABDU MIKHAIL ABUBAKAR
MPH-NFELTP/MED/11534/2011-2012

A THESIS SUBMITTED TO POSTGRADUATE SCHOOL,
AHMADU BELLO UNIVERSITY, ZARIA
IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE AWARD OF MASTER OF PUBLIC HEALTH (MPH) FIELD EPIDEMIOLOGY

DEPARTMENT OF COMMUNITY MEDICINE,
FACULTY OF MEDICINE,
AHMADU BELLO UNIVERSITY,
ZARIA

DECEMBER, 2014

DECLARATION

I declare that the work in the dissertation entitled “Factors affecting quality of laboratory services at Infectious Diseases Hospital Kano, Nigeria” was performed by me in the Department of Community Medicine, Ahmadu Bello University Zaria under the supervision of Dr S.A. Ahmed and Prof. M.S. Shehu. The information derived from the literature has been duly acknowledged in the text and a list of references provided. No part of this dissertation was previously presented for another degree or diploma at any university.

_____ _____

Mikhail A. Abubakar Date

CERTIFICATION

I certify that the work for this dissertation entitled “Factors affecting quality of laboratory services at Infectious Diseases Hospital, Kano, Nigeria” by Mikhail A. Abubakar meets the regulations governing the award of the degree of Masters of Public health in Field Epidemiology of Ahmadu Bello University, Zaria and is approved for its contribution to knowledge and literary presentation.

_____ _____

Dr. S.A. Ahmed Date
MBBS, MPH, FMCPath, FICS, IFCAP
Chairman, supervisory committee

_____ _____

Prof. M.S. Shehu Date
MBBS, MWACP, FMCPath, FICS
Member, Supervisory committee

_____ _____

Dr. M.N. Sambo Date
MBChB, FWACP, MIAD
Head of Department,
Department of community medicine,
Ahmadu Bello University, Zaria

_____ _____

Prof. H.A. Zoaka Date
DVM, MSc, PhD
Dean, School of Postgraduate Studies,
Ahmadu Bello University, Zaria

DEDICATION

This work is dedicated to my elderly Mum who has been in my support right from primary school. It is also dedicated to my beloved wives for their moral support and endurance throughout the entire two years of this didactic study.

ACKNOWLEDGMENTS

Thank be to almighty Allah who made this piece of work possible. I would like to acknowledge all those who contributed towards making this work a reality, especially my entire family for their moral support and endurance during the period of this study.

I would like to recognize my able academic supervisor Dr. S. A. Ahmed with whose major contributions this work was made possible. I also wish to acknowledge NFELTP program for the opportunity and support given to me to pursue this course. My thanks go to my entire academic and field supervisors especially Prof M.S. Shehu, Prof A. T. Olayinka, Dr. Gabriel Poggensee, Dr. Patrick Nguku, Dr. Saheed Gidado, and Dr. Kabir Getso. My sincere appreciations go to my research assistants, Sadisu Musa Nabaruma (HOD Laboratory Department, IDH), Sadiq B. Yakubu, Aminu Yusuf, Nasir Bichi and entire staff of ART clinic and laboratory Department of IDH Kano.

I wish to thank Hospitals Management Board Kano State for the two-year study leave granted and all the support given throughout the period of this study.

TABLE OF CONTENTS

Contents

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AAVP	African AIDs Vaccine Program
ABU	Ahmadu Bello University
AFRO	African Region
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase
ART	Antiretroviral Therapy
AST	Aspartate Aminotransferase
CBC	Complete Blood Count
CD4	Cluster of Differentiations
EQA	External Quality Assurance
FCT	Federal Capital Territory
FGDs	Focus Group Discussions
GHAIN	Global HIV/AIDS Initiative Nigeria
GLP	Good Laboratory Practice
HAART	Highly Active Antiretroviral Treatment
HOD	Head of Department
IDH	Infectious Diseases Hospital
IOM	Institute of Medicine
IQC	Internal quality control
LGAs	Local Government Areas
SMoH	State Ministry of Health
OIs	Opportunistic Infections

PEPFAR	President Emergency Program for AIDS Relief
PLWHA	People Living With HIV/AIDS
PHCs	Primary Health Centres
SLIPTA	Stepwise Laboratory (quality) Improvement Towards Accreditation
SOPs	Standard Operating Procedures
TAT	Turnaround Time
WHO	World Health Organization

SUMMARY

Quality laboratory services are essential and integral part of improved health outcome especially for HIV/AIDS patients on ART. We aimed to assess clients' satisfaction with laboratory services as an indicator of quality and factors affecting quality of laboratory services from service providers' perspective.

We conducted a hospital based cross-sectional study from January-April 2014 among adult HIV/AIDS patients attending IDH Kano, Nigeria. An exit and service providers' questionnaires were administered to clients and laboratory service providers respectively. We used SLIPTA laboratory inventory checklist to assess the availability of equipment, reagents, consumables and test profiles for patients on ART.

A total of 212 HIV positive patients attending laboratory for ART monitoring tests at IDH participated in the study. Of these, 65.6% were females. The mean (±SD) age, of the participants was 36.7 ± 10.2 and 36.3% were in the age group (30-39), 58% were married, 10% were single, while 6% and 26% were divorced and widowed respectively. Majority of the clients (70%) were on antiretroviral therapy (ART). The overall level of satisfaction with laboratory services calculated from a single indicator variable was 97.6%. Internal quality control (IQC) is conducted always for chemistry, and CD4 counts as stated by more than 90% of the respondents (records seen) while IQC for haematological indices is done only occasionally due to stock out of control reagents. The equipments used for HIV/AIDS monitoring tests for CD4 count, haematology and chemistry were available and functional but more than 50% were in use for more than 5 years. Repairs and service maintenance are done on site through service contract signed by donor organizations.

In conclusion, the satisfaction level of the clients on laboratory services received was high, which suggested acceptable quality of services offered. Form of visit to HF (follow-up visit), and "waiting time" before clients are attended by service providers, were found to be the factors associated with client satisfaction. Inadequate work force was identified as one of the major factors affecting quality of laboratory services by 80% of service providers, inadequate training of laboratory personnel (72%), lack of EQA and IQC on some tests (45%), interrupted power supply that led to frequent equipment breakdown (86%) and infrastructural inadequacy (space) to accommodate all the equipment, staff, as well as the patients (64%). The clients identified stigma, location of the laboratory distant from the ART clinic and lack of awareness on the

importance of the laboratory tests in the management of the patient as barriers to accessing laboratory services.

Key words: Quality, laboratory, Kano, Nigeria.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Medical laboratory services are essential in the diagnosis and assessment of the health of patients. Their services encompass arrangements for requisition, patient preparation and patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent result validation, interpretation, reporting and advice. [1] For people suffering from HIV/AIDS, these services are critical for initial placement of patients on antiretrovirals (ART) and continuous monitoring of disease progression over a period. In the West African region, laboratory services are the most neglected components within the health systems especially regarding HIV/AIDS treatment and monitoring.[2] Lack of access to necessary quality diagnostic tests in support of HIV/AIDs treatment and monitoring such as CD4 cell counts, viral load, complete blood count (CBC), chemistry tests, has significantly affected the provision of drug therapy for more than two decades from the emergence of HIV/AIDs in the region.[5] This factor alone, served as a catalyst to increased morbidity with increased burden on global public health. [4]

In Nigeria, prior to considerable efforts devoted to strengthening laboratory systems under Global HIV/AIDS Initiative, provision of clinical laboratory services was a major issue. All laboratories in hospitals offering ART services faced major challenges including poor infrastructure, inadequately trained personnel and lack of standardized operating procedures that could potentially compromise quality of services to patients.[4]

In 2004, United State Government under President's Emergency Plan for AIDs Relief (PEPFAR) launched a Global HIV/AIDs Initiative in Nigeria (GHAIN) that yielded significant improvements in

laboratory service delivery by strengthening the existing network of public sector laboratories at primary, secondary, and tertiary health facilities throughout the country.[5] The improved capacity of the upgraded laboratories enabled the provision of HIV services to meet the accelerated rollout of HIV prevention, care and treatment services including TB and other opportunistic infections (OIs). Infrastructure upgrades included structural renovation and repairs to the laboratory buildings; provision of basic amenities to ensure reliable water and power supply, stand-by generators and power inverters; and the provision of equipment necessary for efficient laboratory service delivery to people living with HIV/AIDs (PLWHA), including state-of-art automated equipment and provision of training to selected staff. In all the upgraded laboratories, improvements in work and patient flow and safety were accomplished by creating separate sample collection and patient waiting areas.

The World Health Organization (WHO) defines quality of health care as health care consisting of the proper performance (according to standards) of interventions that are known to be safe, affordable to the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition.[5]

1.2 Problem Statement

The fight against the HIV/AIDS epidemics in resource-limited countries, particularly in sub-Saharan Africa, has benefited from the recent global funding surge, primarily from the US President's Emergency Plan for AIDS Relief; the Global Fund for AIDS, Tuberculosis and Malaria; the World Bank and other donors. The United States spends an estimated $10 billion per year on scaling up HIV/AIDS prevention, care, and treatment programs.[1,2] However, rapid program expansion has accentuated a problem that has long plagued the health system and undermined the program goals—weak laboratory services, dilapidated laboratory infrastructures, and non-functioning laboratory networks.[3,4] Globally strengthening laboratory systems, infrastructure, and personnel is necessary to achieve universal access to care and treatment.[1,3]

In 2004, Nigeria initiated the pilot project Global HIV/AIDS Initiative in Nigeria (GHAIN) under President Emergency Plan for Aids Relief (PEPFAR) to scale-up and strengthen laboratory capacity to monitor treatment for people living with HIV/AIDS (PLWHA). The expectation was that this project would provide a more cost-effective means of producing quality laboratory investigations to assist clinicians in taking appropriate decisions before and after initiation of antiretroviral treatment (ART). The project was piloted in six states: Kano, Edo, Lagos, Anambra, Cross Rivers and Federal Capital Territory (FCT) Abuja. In Kano, two secondary health facilities were selected; Murtala Muhammad Specialist Hospital (MMSH) and Infectious Disease Hospital (IDH).[4]

In 2010, the end of project evaluation revealed that internal quality processes were noted to be poor in all the facilities especially MMSH & IDH and GHAIN has not introduced and institutionalized an internal quality control strategy. The quality of service in terms of documentation & records keeping, turnaround time (TAT) between sample collection and results reporting and patient flow to access laboratory investigations among adult PLWHA declined in 2012 by more than 30% compared with 2006-2010 in the State.[4]

The identified gaps were; despite huge investment by GHAIN/PEPFAR on ART- laboratories, the number of patients expected to access the services and quality of services keeps on declining. Further research is needed to identify the reasons/barriers to decreased patients' turnover and poor internal quality control processes. Information expected to result from the study is clients' opinion based on satisfaction with laboratory services offered, service providers' skills on ART-laboratory procedures and availability of reagents and equipment. This information will help close the identified gaps by introducing and institutionalizing a quality control monitoring

strategy that will improve service quality as well as overcoming the barriers /factors responsible for decreased patients' turnover.

1.3 Rationale of the Study

Health system strengthening is a key area of focus for some of the major programs, including the GHI. For example, in 2009, the US President's Emergency Plan for AIDS Relief (PEPFAR) dedicated 1.0 to 1.4 billion US Dollars to supporting health systems, of which 6% was earmarked for strengthening laboratory systems.[31] The Global Fund to Fight AIDS, Tuberculosis and Malaria has also allocated a similar proportion to strengthening laboratory services.[30] In addition, clinical diagnosis without quality laboratory testing often results in significant misdiagnosis and over diagnosis, leading to inadequate or inappropriate treatment, drug resistance, and increased mortality.[1, 2]

In Nigeria, more than 1.5 million PLWHA require ART services with Kano State contributing about 2.6% out of this figure.[4] This indicates invariably that they need Laboratory services before and after treatment enrolment for proper monitoring. Continuous decrease in internal quality control processes coupled with decreased clients' turnover due to some factors yet to be identified in all ART-laboratories pose a great public health challenge to the State Government and partners in terms of resources and for sustaining quality to accommodate the increasing number of PLWHA requiring Laboratory services.[4]

1.4 Research Questions

1. What is the satisfaction level and factors associated with the quality of laboratory services among adult HIV/AIDs patients attending IDH Kano?

2. What are the barriers impeding access to laboratory services among adults HIV/AIDS patients attending IDH Kano?
3. What are the factors affecting quality of laboratory services from service providers' perspective?

1.5 General and Specific Objectives

1.5.1 General objective

To evaluate the quality of laboratory services among adult HIV/AIDS patients attending infectious diseases hospital (IDH) Kano.

1.5.2 Specific objectives

1. To assess the satisfaction level and factors associated with the quality of laboratory services among adult HIV/AIDs patients attending IDH.
2. To determine the barriers in accessing laboratory services among adults HIV/AIDs patients attending infectious diseases hospital (IDH) Kano State.
3. To identify factors affecting quality of services from service providers' perspective.

CHAPTER TWO

LITERATURE REVIEW

2.1 Historical Perspectives about Concept of Quality

Quality has become an increasingly major part of our lives. People are constantly looking for quality products and services. The existence of this desire for quality has caused firms and organizations throughout the world to consider it as an essential component of any service and production process. Quality is a strategic differentiator tool for sustaining competitive advantage. Improving quality through improving structures and processes leads to a reduction of waste, rework, and delays, lower costs, higher market share, and a positive company image.[6,7] As a result, productivity and profitability improve.[8] Therefore, it is very important to define measure and improve quality of healthcare services.

Quality, because of its subjective nature and intangible characteristics, is difficult to define. Definitions vary depending on whose perspective is taken and within which context it is considered. No single universally accepted definition exists. Quality, therefore, has been defined as 'value'[9] 'excellence,'[10] 'conformance to specifications,'[11] 'conformance to requirements,'[12] 'fitness for use'[16]; 'meeting and/or exceeding customers' expectations'[13], and 'consistently delighting the customer by providing products and services according to the latest functional specifications which meet and exceed the customer's explicit and implicit needs and satisfy producer/provider'.[14]

Healthcare service quality is even more difficult to define and measure than in other sectors. Distinct healthcare industry characteristics such as intangibility, heterogeneity and simultaneity make it difficult to define and measure quality. Healthcare service is an intangible product and

cannot physically be touched, felt, viewed, counted, or measured like manufactured goods. Producing tangible goods allows quantitative measures of quality, since they can be sampled and tested for quality throughout the production process and in later use. However, healthcare service quality depends on service process, customer, and service provider interactions.[15, 16] Some healthcare quality attributes such as timeliness, consistency, and accuracy are hard to measure beyond a subjective assessment by the customer.

It is often difficult to reproduce consistent healthcare services. Healthcare services can differ between producers, customers, places, and daily. This 'heterogeneity' can occur because different professionals (e.g. physicians, nurses, etc.) deliver the service to patients with varying needs. Quality standards are more difficult to establish in service operations. Healthcare professionals provide services differently because factors vary, such as experience, individual abilities, and personalities.[16] Healthcare services are simultaneously produced and consumed and cannot be stored for later consumption. This makes quality control difficult because the customer cannot judge 'quality' prior to purchase and consumption.[17] Unlike manufactured goods, it is less likely to have a final quality check. Therefore, healthcare outcomes cannot be guaranteed.

2.1.1 Definitions of terms pertaining to quality

Quality control: The collection of mechanisms used to determine accuracy, reliability and consistency of assays or tests in a clinical laboratory.

Internal Quality Control (IQC): It includes all methods which are performed every day by the laboratory personnel with the laboratory's materials and equipment. It checks primarily the precision (repeatability or reproducibility) of the method

External Quality Control (EQC): It includes all methods which are performed periodically (i.e. every month, every two months, and twice a year) by the laboratory personnel with the contribution of an external center (referral laboratory, scientific associations, diagnostic industry etc.). It checks primarily the accuracy of the laboratory's analytical methods. However, there are certain EQC schemes that check both the accuracy and the precision.

2.1.2 Quality in healthcare system

Quality healthcare is a subjective, complex, and multi-dimensional concept. Donabedian defined healthcare quality as 'the application of medical science and technology in a manner that maximizes its benefit to health without correspondingly increasing the risk.[18] He distinguishes three components of quality: 1) technical quality, 2) interpersonal quality, and 3) amenities. Technical quality relates to the effectiveness of care in producing achievable health gain. Interpersonal quality refers to the extent of accommodation of patient needs and preferences. Amenities include features such as comfort of physical surroundings and attributes of the organization of service provision.[19]

Øvretveit defines quality care as the 'Provision of care that exceeds patient expectations and achieves the highest possible clinical outcomes with the resources available'.[20] He developed a system for improving the quality of healthcare based on three dimensions of quality: professional, client, and management quality. Professional quality is based on professionals' views of whether professionally assessed consumer needs have been met using correct techniques and procedures. Client quality is whether direct beneficiaries feel they get what they want from the services. Management quality is ensuring that services are delivered in a resource-efficient way.

According to Schuster *et al*., good healthcare quality means, "providing patients with appropriate services in a technically competent manner, with good communication, shared decision making and cultural sensitivity". [21] For Lohr, quality is "the degree to which healthcare services for individuals and population increases the likelihood of desired healthcare outcomes and is consistent with the current professional knowledge". [22]

Mosadeghrad defined quality healthcare as "consistently delighting the patient by providing efficacious, effective and efficient healthcare services according to the latest clinical guidelines and standards, which meet the patients needs and satisfies providers". [15] He identified 182 attributes of quality healthcare and grouped them into five categories: environment, empathy, efficiency, effectiveness and efficacy. Quality healthcare includes characteristics such as availability, accessibility, affordability, acceptability, appropriateness, competency, timeliness, privacy, confidentiality, attentiveness, caring, responsiveness, accountability, accuracy, reliability, comprehensiveness, continuity, equity, amenities, and facilities.[17]

Various healthcare stakeholders' perspectives, desires and priorities must be considered in any effort to define, measure, and improve quality of healthcare. While several empirical studies have been carried out to assess the quality of healthcare organizations,[23, 24] few researches have been conducted to identify factors that affect quality of healthcare services.

Quality of care consist of " ...the degree to which health services for individuals and populations increase the likelihood of desired health outcomes, are consistent with current professional knowledge, and meet the expectations of healthcare users."[25]

Quality in laboratory medicine should be defined as the guarantee that each single step throughout the total testing process is correctly performed, thus assuring valuable medical decision-making and effective patient care.[26]

The concept of quality is elusive and different people interpret/define quality differently. David Garvin, in his book 'managing quality' summarised five principal approaches to defining quality: transcendental view of quality, product-based view, user-based view, manufacturer-based view and value-based view.[27]

The three commonly used definition of quality of care are by Donabedian who defined quality as "That kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of expected gains and losses that attend the process of care".[27]

2.1.3 Conceptual framework

The Donabedian framework[28] for measuring quality of care is based on three-part approach, which includes the structure, process and outcome. These are possible only because good structure increases the likelihood of good process, and good process increases the likelihood of good outcome.

Structure: denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment and money), of human resources (such as the number and qualification of personnel), and of organization structure (such as medical staff organization, methods of peer review, and methods of reimbursement).

Process: this embodies what is done to and for the patient/client (e.g. specimen analysis). Process measures of quality can be made for individual practitioners, groups of practitioners, or for entire systems of care.

Outcome: are the end results of care or the effect of the care process on the health and well-being of patients and populations. The relevant health care outcomes were described as "the five Ds"—death, disease, disability, discomfort, and dissatisfaction. Furthermore, these relevant health care outcomes were positively framed as survival, states of physiologic, physical and emotional health, and satisfaction.

According to the Institute of Medicine (IOM), the Donabedian model categorizes dimensions of quality into:

Structure indicators - for example whether staff are qualified and facilities well equipped; **process indicators** - whether ART-laboratory services are delivered according to established SOPs (protocols)

Outcome indicators – the effectiveness of services offered in improving the quality of lives of patients.

The Donabedian-Maxwell dimensions of quality of care include availability, accessibility, client satisfaction, interpersonal relations, safety and availability of social amenities. Other aspects are efficiency, effectiveness, utilization rate (coverage), and professional (technical) competence of health care providers. [28]

2.2 Quality Systems in Laboratory

Quality systems in any clinical laboratory can be defined as the comprehensive and coordinated efforts to meet quality objectives.[1] For these objectives to be achievable, concerted efforts have to be invested towards quality improvement at different stages within the organization. In sub-Saharan Africa, “laboratory services are one of the most neglected areas of health care provision and are disproportionately affected by the staff shortages, poor communications, inadequate equipment, low morale, and lack of training that impinges on all those involved in delivering

health care."[32] HIV/AIDS, Tuberculosis (TB) and malaria are among the major public health problems of sub-Saharan Africa that require efficient and quality-controlled laboratory services for their management and control to reduce their impact on morbidity and mortality that affect millions of people throughout the region.[33] Medical laboratory services in general, should have the capacity and ability to assist in early and reliable diagnosis and treatment, investigate disease outbreaks and collect reliable surveillance data for disease control and prevention. It has been reported that, "Provision of accurate and reliable laboratory data is crucial if public health problems are to be properly managed, if treatment of individual patients is to be effective, and if national drug purchase is to be cost-effective."[30] Poor laboratory results affect the overall impact of patients' treatment outcome with added economic burden of buying drugs that are not essentially needed. Comprehensive and accurate data collection and analysis are essential to inform good policy making and planning whilst knowledge generation through research is required to solve local and national health problems.[1] Researchers have shown that the underlying reason for the gaps and weaknesses in laboratory services provision is historically based.[1] However, because of a lack of access to reliable diagnostic testing and an acute shortage of trained staff, coupled with under-resourced laboratory infrastructure in developing countries, inconsistent diagnoses frequently lead to inadequate treatment, increased morbidity, and inaccurate determination of the true burden and/or stage of the disease.[3]

2.2.1 Strengthening laboratory network

The lack of laboratory services was highlighted in a survey conducted in 2000 by the WHO-sponsored African AIDS Vaccine Program (AAVP).[5] The survey revealed that, as of 2000, fewer than 10 countries in sub-Saharan Africa had the capability to perform HIV-1 RNA viral load or CD4 lymphocyte count testing. A similar survey performed by the WHO African Regional

Office (AFRO) found out that although many countries were performing HIV serologic testing; only very few laboratories were enrolled in any form of quality control or external quality assessment (EQA) program.[31] The UN Global Report on HIV/AIDS, states that: "most patients in low and medium-income countries will continue to be monitored clinically over the next few years".[29]

In developing countries, CD4 cell count, viral-load and resistance testing are a standard part of clinical management for patients with HIV. These laboratory tests help to guide the decisions of when to start or switch treatment. For example, the decision of when to treat is guided by CD4 cell counts. Treatment is recommended before an individual's CD4 cell count falls below 350, with some guidelines advocating earlier treatment for patients with very high viral loads.[30] Treatment failure is usually recognized by rising viral load measurements, sometimes combined with the detection of drug resistance mutations or declining CD4 cell counts. Although opinions and guidance differ as to what viral-load measurements make before treatment initiation. In general, the goal is to switch treatments before CD4 cells slip significantly and put the patient at risk of clinical progression, and before ongoing viral replication on the failing treatment permits the accumulation of drug resistance mutations, which could impair responses to subsequent regimens. However, in much of the world, access to these tests and laboratory capacity

is severely limited and even the most basic services are often unavailable or unreliable.[31]

In order to support the national HIV programme, Brazil invested heavily in laboratories that could perform all HIV-related testing, including both CD4 counts and viral load testing. By the end of 2002, there were 130 000 people on ARV drugs and by the end of 2004, 305 hospitals, 73-day clinics, and 166 special HIV units had been accredited for HIV care. Quality laboratory management was an important part of Brazil's laboratory support programme as well as External Quality Assessment (EQA) for CD4 count, which was conducted six times per year.[31]

In 2002, Uganda developed an ART policy whose goal was to provide a framework to allow universal access to ART to all those in need that were clinically eligible. Hence, meeting of clinical eligibility required fully functional laboratories to support the ART implementation. The Government made a decision to improve the laboratory infrastructure, equipment, and human resources, supplies and reagent availability. The experience has been that with fully functional quality-assured laboratories, diagnosis and monitoring tests for HIV/AIDS patients on ART are performed and results given to clinicians within 24 hours.[32]

In Nigeria, significant improvements in laboratory service delivery have been made by strengthening the existing network of public sector laboratories at primary, secondary, and tertiary health facilities throughout Nigeria. The improved capacity of the laboratories enabled the provision of HIV services to meet the accelerated roll out of HIV prevention, care and treatment services in the country. The laboratories were strengthened to provide baseline laboratory tests for HIV positive clients, which include clinical chemistry tests (SGOT, SGPT, serum Creatinine, potassium, and blood glucose), hematology (full blood count), CD4 count, hepatitis B surface antigen test and pregnancy tests as needed.[4] GHAIN provided generic standard operating procedures (SOPs), bench top references and job aids to ensure quality service in all the laboratories. Most of the supported laboratories were enrolled into one or more proficiency programs with National Health Laboratories Services (NHLS), South Africa for proficiency testing (PT) program for CD4, hematology, chemistry and HIV serology. Some facilities participated in the Medical Laboratory Science Council of Nigeria's PT program for CD4 count and HIV serology. These enrollments formed part of GHAIN's quality assurance strategy. GHAIN also supported the development of a specimen referral system within its laboratory networks to ensure uninterrupted service delivery even during equipment breakdown and long downtimes.

Although the absence of HIV monitoring tests should not delay the institution of HIV treatment programmes, and ART can be initiated on the basis of clinical staging (as the World Health Organization set out to do when it launched the 3 x 5 Initiative in 2003), a study presented at the International AIDS Society Conference in Rio de Janeiro in 2007 has since shown that the use of clinical

staging alone (treating those with WHO Stage III and IV disease) misses many of the people who would qualify for treatment on the basis of CD4 cell counts. The above results were confirmed by a study presented at Implementers' Meeting, held on 12-15 June 2006 in Durban, South Africa. [3] The meeting found that clinical staging would miss up to half of the patients who would qualify for treatment based on low CD4 cell counts below 200. In response to such findings, the WHO has updated its staging guidelines to encourage more widespread use of CD4 cell counts.

2.2.2 Service quality and customer satisfaction

Various studies that have focused on a link between satisfaction and quality argued for different views in terms of relationship. Some think that quality leads to satisfaction and vice versa [33] while some researchers propose that quality and satisfaction are determined by the same attributes; thus, they tried to relate customer satisfaction to service quality and clearly points out that overall service quality is significantly associated with and contributes to the overall satisfaction of customers. [34] Some believed that customer satisfaction is based on the level of service quality delivered by the service providers [35] while others contends that when perceived service quality is high, then it will lead to increase in customer satisfaction. [34] They argue that service quality leads to customer satisfaction and this agree with Lee *et al.* who acknowledge that customer satisfaction is based upon the level of service quality provided by the service provider.[36] Organizations that consistently satisfy their customers enjoy higher retention levels and greater profitability due to increased customers' loyalty.[36] It is vital to keep consumers satisfied by trying to know their expectations and perceptions of services offered by service

providers. In this way, service quality could be assessed and thereby evaluating customer satisfaction. Service quality and customer satisfaction have been proven from past researches to be positively related.[38] Customer brand loyalty is based on the satisfaction achieved after the purchase of a product or service.[35] According to the customer satisfaction model developed by Oliver, when customers compare their perceptions of actual products/services performance with the expectations, the feelings of satisfaction arise which may lead to repeat purchase.[38] Satisfaction from service quality is usually evaluated in terms of technical quality and functional quality. This happens when customers do not have much information about the technical aspects of a service;[39] under such circumstances, functional quality becomes the major factor from which customers base perceptions of service quality. Service quality may also be defined as customer perception of how well a service meets or exceeds their expectations and can be measured in terms of customer perception, customer expectation, satisfaction and attitude.[39] Studies indicate that the evaluation of service quality leads to customer satisfaction and observed that satisfaction was a customer fulfilment response, an evaluation on both customer emotion and customer response to a service.[38]

2.2.3 Concept of service quality

The word 'service' has many meanings, which lead to some confusion in the way the concept is defined in management literature, where service could mean an industry, a performance, an output or offering or a process. It was further argues that services are mostly described as 'intangible' and their output viewed as an activity rather than a tangible object which is not clear because some service outputs have some substantial tangible components like physical facilities, equipments and personnel.[40]

Initial efforts in defining and measuring service quality emanated largely from the goods sector, research work in the area of service quality was laid down in the mid-eighties by Parasuraman, Zeithaml and Berry.[34] Their contributions on service quality have continued to shape the direction of research in the services sector. The researchers defined service quality as a global judgment, or attitude, relating to the superiority of the service and the difference between consumer perceptions and expectations, which is the outcome interaction and experience with the service.[34]

Service quality can also be described as the result from customer comparisons between their expectations about the service they will use and their perceptions about the service company. That means that if the perceptions would be higher than the expectations then the service will be considered excellent, if the expectations are equal to the perceptions the service is considered good and if the expectations are not met the service will be considered bad.[38] Service quality is an assessment of how well a delivered service conforms to the client's expectations. Service business operators often assess the service quality provided to their customers in order to improve their service, to quickly identify problems, and to better assess client satisfaction.[34,35]

It has been argued that satisfied customers are likely to become loyal customers and that means that they are also likely to spread positive word of mouth, which will lead to growth of market share. Understanding which factors that influence customer satisfaction makes it easier to design and deliver services that corresponds to the market demands.[41] Others, posit that service quality is an extrinsically perceived attribution based on the customer's experience about the service that the customer perceived through the service encounter.[34] According to the Japanese production philosophy, quality implies 'zero defects' in the firm's offerings. This conforms to the work of

Wicks *et al* who argued that quality is conformance to the requirements where no room is given for any defects.[37]

2.2.4 Assessment of client satisfaction

Patient satisfaction is a subjective and complex concept, involving physical, emotional, mental, social, and cultural factors.[42] It is determined by the quality of the provided care and the patient's expectations of that care. Dissatisfaction arises if the patient experiences a discrepancy between expected and provided care.[43,44]

Patient satisfaction reflects provider's ability to successfully deliver care that meets patients' expectations and needs.[45,46] A numbers of factors have been shown to influence patients' satisfaction with health care services including patients' socio-demographic characters, physical health status, patients' personal understanding and expectations from various health care services.[47-49] The general physical appearance of the clinic as well as the general environment of the premises also influences the overall satisfaction of the patient.[50] Length of waiting time before seeing the laboratory service provider has also been shown to influence patient satisfaction.[51] If patients are dissatisfied with the quality of care, they may not adhere to treatment regimen, or they may fail to attend follow-up visits.[52]

For patients suffering from HIV/AIDS in particular, adherence to regimen and strict follow up schedules play a central role in treatment success. Any laboratory should have a written policy focusing on customer's satisfaction, and should periodically measure and evaluate their customer's satisfaction.[53,54]

The satisfaction of customers is measured to identify problems and resolve them. [55, 56] It is also an important and useful quality improvement tool for clinical laboratory, health care

organizations, and business in general. Most clinical laboratories in the United States are required to assess their customers' satisfaction in order to maintain their accreditations. [56] This is not the situation in sub-Saharan Africa, where laboratory accreditation is a new phenomenon yet to be implemented in both private and public health facilities.

It has been noted that, patient satisfaction is the patient's perception of care received compared with the care expected.[57] Therefore, evaluating to what extent patients are satisfied with health services is clinically relevant, as satisfied patients are more likely to comply with treatment, [58] take an active role in their own care,[44] continue using medical care services and stay within a health provider (where there are some choices) and maintain with a specific system. On the other hand, clients who are not satisfied with a service may have worse outcomes than others may because they miss more appointments, live against advice or fail to follow through on treatment plans. In clinical laboratory, monitoring patients' satisfaction is an important and useful tools required for quality improvement as well as to maintain their accreditation.[59,60]

Antiretroviral treatment (ART) monitoring laboratory services have crucial roles in delivery of quality of ART by diagnosing and staging HIV infection.[61] However, comprehensive quality laboratory services are a challenging process; need multiple sources of supports from clients, providers, managers, and other stakeholders. Especially, needs and preferences of clients in clinical laboratory must be addressed in the design and implementation of laboratory quality system. Disregard for patients' feedback may cause persistent disruption of testing because a patient has to return several times for the results and treatment. Thus monitoring patient satisfaction is an important and useful quality improvement indicator and is required by clinical laboratories.[59] The literature indicates that there are only a few reports of patients' satisfaction

from developing countries, as compared to the high volume of publications on patients' satisfaction from developed countries.[62,63]

Satisfaction level is usually rated on 5-points scale of very satisfied, satisfied, neutral, dissatisfied, and very di4ssatisfied. [59] Thus rating of different dimensions of satisfaction and the scores on the dimension added together to yield overall satisfaction rating. Different methods are used in assessing client satisfaction, but most common methods are use of: self-administered questionnaire that may be given as client enter or leave service (exit interview) or at various times in between; face to face interview; telephone interview; and focus groups discussion.

2.2.5 Customer Satisfaction

Satisfaction is a psychological constructs that form the basis upon which evaluation of the quality of a product or service is done. Customer satisfaction is defined as a function of the customer's expectations and perceptions of performance according to the expectancy - disconfirmation paradigm and it is a construct closely related to perceived service quality.[64]

Today, customer focus and satisfaction is a driving force for many companies and organizations. Measuring customer satisfaction provides an indication on how an organization is performing or providing products or services. Customer satisfaction is generally understood as the satisfaction that a customer feels when comparing his/her preliminary expectations with the actual quality of the service or product acquired. In other words, customers are typically concerned with the value and quality of the product or service they receive. In addition, customers generally want the best possible product or service at a low cost. The perception of the best product or service and lowest price can, however, vary significantly by customer segment or industry. In order to obtain an

overall picture of customer perception, a company or organization needs to measure the customer satisfaction level.[65]

Organizations mostly employ external agencies to listen to their customers and provide dedicated feedback to them. These feedbacks needs to be sophisticated and in structured format so that conclusive results could be fetched out. Face to face meetings and complaint or appreciation letter engages immediate issues. The feedback received in this is not uniform as different types of customers are addressed with different domains of questions. This hinders the analysis process to be performed accurately and consistently. Hence the best way is to implement a proper survey which consists of uniformed questionnaire to get customer feedback from well segmented customers. The design of the prepared questionnaire is an important aspect and should enclose all the essential factors of business. The questions asked should encourage customers to respond in an obvious way. These feedback received by the organizations can be treated as one of the best way to measure customer satisfaction.[39] The need for survival and growth in ever increasing competitive markets are main critical factors in the search for providing superior service quality and achieving customer satisfaction. [35]

Customer satisfaction is conceptualized as based on the customer's experience on a particular service encounter, and some think customer satisfaction is cumulative based on the overall evaluation of service experience. [36] These highlight the fact that customer satisfaction is based on experience with service provider and also the outcome of service. According to Wicks *et al,* customer satisfaction is formed through an effective evaluation process, which is done following the purchase experience by the consumer.[37] Sahim *et al*, in an effort to find out whether customers were satisfied with the food services in the military hospital in Turkey realized that specific demographic characteristics were not of significance in determining the satisfaction of

the patients but the appearance and taste of food.[66] Bailey *et al* identified 38 factors that affected the satisfaction of consumers of computers that were customized for computer users some of which were quality of the product, flexibility, reliability, priorities determination, security and expectations.[67]

CHAPTER THREE

METHODS

3.1 Study Area

Infectious Diseases Hospital (IDH) was established in the early 1960s' as an isolation unit for smallpox patients. Subsequently the unit was expanded into a fully-fledged hospital and caters for all epidemic diseases prevalent in the state, such as Measles, Meningitis, Cholera, Pertussis, TB as well as HIV/AIDS. At present, the hospital has 250-bed capacity with three wards (male, female and pediatrics) and a new MDR clinic. It has a laboratory, an X-ray unit and a pharmacy providing 24 hours dispensing services. A Medical Director heads this hospital, which has over 120 staff including four Medical officers, 48 Nurses, 27 PHC staff, 17 Laboratory personnel, 6 X-ray personnel, 5 Medical records, 6 Pharmacists and 44 other workers.

IDH provides comprehensive testing, treatment and care for HIV/AIDS under the support of USAID/PEPFAR implemented by FHI 360. The hospital offers HIV counseling and testing, ART services, treatment of STIs OIs including TB, and palliative care. The FHI 360 project has provided extensive infrastructural upgrade and refurbishing and power supply assistance in the main laboratory. FHI 360 provides support in the training of doctors, nurses, counselors and laboratory scientists, technicians to strengthen the delivery of ART and provides continuous monitoring and mentoring at all points of service. FHI 360 is also responsible for test-kits and drugs procurement, logistics and chain management strengthening.

3.2 Study Design

Mixed methods study comprising descriptive cross–sectional study among the adult HIV/AIDS clients attending ART clinic and accessing laboratory services, including laboratory service

providers and a qualitative study among some HIV positive patients at IDH Kano was conducted.

3.3 Study Population

A. All adult PLWHA 18 years or older, who visited IDH ART clinic for at least three months and referred to ART-Laboratory for monitoring tests, including clinical chemistry (liver and renal function), haematology (Complete Blood Count, CD4 count) and fasting blood sugar (FBS).

B. All laboratory service providers who perform bench work for investigations pertaining to HIV/AIDS clients.

3.3.1. Inclusion criteria

Clients 18 years or older who enrolled into ART program at IDH, and agreed to participate by signing an informed consent form. Service providers who conduct assays in the HIV-Laboratory for at least three months were also included in the study

3.3.2 Exclusion criteria

Clients who are too sick to participate/hospitalized and laboratory service providers who were on leave during the study period or opted out voluntarily.

3.4 Sample Size Determination for HIV/AIDS Clients

The sample size was determined using the formula

$n = Z^2pq/d^2$ [42]

Where

n = minimum sample size desired

$Z_{1-}\alpha_{/2}$ = standard normal deviation at 95% confidence levels = 1.96

P= estimated proportion of variable of interest in the population (proportion of HIV/AIDs clients that were satisfied with ART-laboratory Services = 87.6% p=0.876 [68]

q= complementary probability of estimated proportion of variable of interest in the population (proportion of HIV/AIDs clients that were satisfied with ART-laboratory Services= 1-P = 1-0.876 = 0.124

d= level of precision= 5%=0.05 i.e. we would like the result to be within 5% of the true value

$N= 1.96^2 \times (1-0.876)/0.05^2 = 191$

To compensate for non-response and poorly completed questionnaires, the desired sample size, 'NF' was multiplied by a factor (100/100-R %) to increase the sample size so that the precision of the study shall not be jeopardised; R % is the percentage loss to non-response by participants or poorly filled questionnaire by the interviewer; assumed to be 10%.

To compensate for non-response of 10%, we used (NF x 1/1-R %), were

NF= calculated sample size

R%= Non-response rate

Therefore, N= 191 x 1/1-0.1 = 211.7 ≈ 212

3.4.1 Sampling technique for study participants – systematic random sampling

Sampling interval was generated using a formula K= N/n, where:

K= Sampling interval

N= Total number of registered clients (currently accessing ART clinic and laboratory services) = 981

It was used/adopted as the Sampling frame

n = Calculated sample size = 212

Therefore, K = 5

A client is considered as a sampling unit

Numbers were allocated to each participant within the sampling frame (list of registered clients in the ART clinic).

First participant was selected from the first five clients in the register using simple random sampling through blotting.

Then the rest of the participants were selected as every subsequent fifth client till the desired sample size (212) was obtained.

3.5 Sampling Technique for Laboratory Service Providers

Total population study was conducted on all the laboratory personnel who conducted assays pertaining to HIV/AIDS clients.

3.6 Study Instruments

3.6.1 Laboratory service provider questionnaire

3.6.2 Client exit interview questionnaire

3.6.3 Facility inventory checklist

3.6.4 Focus group discussion guide

3.7 Data Collection Methods

The data for the study was collected using both the quantitative and qualitative methods.

3.7.1 Laboratory service provider questionnaire

Data was collected using semi-structured questionnaires that consist of seven sections:

1. Personnel demographics
2. Tests profile for HIV/AIDS patients on ART
3. Quality assurance
4. Equipment
5. Laboratory commodity management system
6. Human resource development and supervision
7. Challenges

3.7.2 Client exit interview questionnaire

Exit interview was conducted after a client received all laboratory services. Data was collected using exit questionnaire that consist of two sections:

1. Socio-demographic profile of the client
2. Assessing clients' satisfaction with laboratory services provided

3.7.3 Facility inventory checklist

A checklist adopted from SLIPTA that consist of five sections was used**:**

1. Physical infrastructure
2. Laboratory reagents and consumable inventory
3. Equipment and instrument inventory
4. Records keeping
5. Visual aids/Job aids

3.7.4 Focus group discussion guide: To explore information on barriers to accessing laboratory services

FGD was conducted among the clients using focus group guide that consist of four themes:

1. Information on the knowledge, experience and satisfaction with laboratory procedures.

2. Critical experience at the laboratories.
3. Perception on the existing laboratory infrastructure.
4. Clients' perception of factors affecting accessibility of ART-Laboratory investigations

3.7.5 Training of research assistants

A total of four research assistants comprising two males and two females were recruited for administering research questionnaire.

A two-day training sessions of four hours duration each was conducted for the recruited research assistants on the research topic including objectives and the various aspects of the study. They were specifically trained on the general principles and conduct of research, interpersonal communication skills, use of research instruments, and research ethics.

The principal researcher trained the research assistants; conducted direct observations of client-provider interactions and supervised the administration of the pre-tested questionnaire to clients.

For the conduct of the FGDs, four personnel were recruited from the facility (2 moderators and 2 note takers/recorders) and a two-day training session of three hours duration each was held to introduce the facilitators to the research topic, use of facility guide (how to establish rapport with the participants; how to phrase questions carefully using local language; how to use probing techniques for fuller, clearer response; control discussion to balance out participation; minimize group pressure when there is disagreement). A total of two sessions were conducted and each session comprised of 10 female and 10 males respondents who were asked various questions including probes and responses recorded verbatim. Responses were immediately transcribed to obtain full details of the discussions. For each transcript, additional information was obtained from notes taken during the discussions.

3.7.6 Pre-test of instruments

Pre-testing of the data collection instruments was conducted at Muhammad Sir Sanusi Specialist Hospital, which was among the six facilities offering ART services within the Metropolis.

3.8 Data Management

3.8.1 Measurement of variables

Standardized 5-point Likert scales ranging from very satisfied to very dissatisfied (1 to 5 points) were used to measure satisfaction status for all items. Patients' satisfaction was classified into two categories "satisfied" and "dissatisfied" by using the demarcation threshold from formula: [(total highest score-total lowest score)/2] + Total lowest score. (*)

Independent variables such as sex, age, religion, marital status, educational status, means of transport to the facility, form of visit to health facility (follow up or first visit) and waiting time before receiving services among others were used while the dependent variable used was "clients' satisfaction" (as satisfied or not satisfied).

3.8.2 Scoring and grading of responses on provider knowledge

Each correct response of knowledge of laboratory practice was scored 1 mark, while zero (0) awarded for wrong answers and no-response. The laboratory provider's knowledge was graded as either good or poor knowledge. Scores were allotted and knowledge and skills levels adjudged as either good or poor depending on questions asked and the direction of the correct answers.

Parameter	Score	Grading
Knowledge of laboratory service providers	≥4 correct answers	Good
	<4 correct answers	Poor

3.8.3 Statistical analyses

Univariate analysis was conducted to compute frequencies and proportions. Bivariate analysis using Chi square test at 95% confidence interval was conducted to determine the association between some of the client factors and the level of satisfaction with the quality of the laboratory services. A p-value of ≤ 0.05 was considered statistically significant. Tables, proportions and percentages as well as charts were used to summarize data obtained from the study. Epi-Info version 3.5.4 and Microsoft Excel were used for data analysis.

The qualitative data was grouped into themes and sub-themes and analysed using Nvivo software.

The questionnaires (client exit interview), facility inventory checklist were checked manually for completeness and accuracy.

3.9 Ethical Considerations

An ethical approval (written form) from ethic and research committee of Kano State Hospitals Management Board was obtained, while written informed consent of the study participants was obtained by signing or thumb printing on the consent form; and confidentiality was assured and maintained by using identifiers (ID and codes) instead of names and keeping all the records in a password protected personal computer.

3.10 Limitations of the Study

Satisfaction level of clients on laboratory services was calculated from single variable or question.

CHAPTER FOUR

RESULTS

4.1 Baseline Socio-Demographic Data

Table 1: Socio-demographic characteristics of respondents in IDH, 2014 (n=212)

Descriptive variables	No. of clients (N)	Percent (%)
Sex		
Male	73	34.4
Female	139	65.6
Marital status		
Single	21	9.9
Married	123	58.1
Divorced	13	6.1
Widowed	55	25.9
Occupation		
Civil servant	25	11.8
Business	138	65.1
Farmer	1	0.5
House wife	24	11.3
Daily labourer	11	5.2
Retired	3	1.4
Student	10	4.7
Age group		
19-29	43	20.3
30-39	76	35.8
40-49	56	26.4
50-59	33	15.6
60-69	4	1.90
Highest Educational level		
Primary	45	21.2
Secondary	57	26.9
Tertiary	36	17.0
None	74	34.9

Table 1 above shows that a total of 212 HIV positive patients attending ART-laboratory at Infectious Disease Hospital (IDH) participated in the study. Of these, 65.6% were females. The mean age of the participants was 36.7 ± 10.2 SD and 36.3% were in the age group (30-39 years). Based on the marital status 58.6% were married, and 9.9% single, while 6.1% and 22.9% were divorced and widowed respectively. Among the participants, 65.1% are engaged in business while farmers constituted only 0.5%, 34.9% had no formal education and only 17% had tertiary education. Majority of the clients (70%) were on antiretroviral treatment (ART).

4.2. Other Tables Based on the Specific Objectives

Table 2: HIV/AIDS clients' satisfaction with different aspects of ART lab services in IDH, Kano State, 2014

Variables	Very Satisfied (N)	Satisfied (N)	Neutral (N)	Dissatisfied (N)	Very Dissatisfied (N)	Percentage rating (N)
Overall satisfaction on laboratory Services	74(34.9)	133(62.7)	4	1(0.5)	0	97.6
Courtesy & respect of service providers	91(42.9)	114(53.8)	2	5(2.4)	0	96.7
Phlebotomy done	39(18.4)	165(77.8)	3	5(2.4)	0	96.2
Measures taken on privacy	50(23.6)	139(65.6)	17	3(1.4)	0	89.2
Overall cleanliness of phlebotomy area	29(13.7)	171(80.7)	10	2(0.9)	0	94.4
Cleanliness of toilets	23(10.8)	75(35.4)	16	29(13.7)	3(1.4)	46.2
Waiting time before services	23(10.9)	139(65.6)	27	23(10.9)	0	30.9

Table 2 above shows that generally, respondents were satisfied with courtesy and respect of service providers (96.7%), phlebotomy done (96.2%), overall cleanliness of the laboratory (94.4%), measures taken to ensure clients' privacy (89.2%), and waiting time before receiving laboratory services (76.5%). On the other hand, respondents showed low satisfaction rate on waiting time before receiving laboratory services (30.9%) and cleanliness of toilets (46.2%).

The overall level of satisfaction on laboratory services was 97.6% calculated from single indicator variable.

Table 3: Bivariate & logistic regression showing relationship between level of Clients' satisfaction with independent variables (n = 212)

Variables	Satisfied(N)	Not Satisfied(N)	OR (95%CI)	AOR (95%CI)
Visit to HF:				
Follow-up visit	198	3	14.7 (1.5-131.8)	11.7(2.1-98.5)
First visit	9	2		
Waiting time:				
≤30 minutes	139	23	10.7 (4.9-23.8)	8.9 (5.7-32.4)
≥30 minutes	18	32		
Religion:				
Islam	180	5	0.7 (0.08-16.99)	_
Christianity	26	1		
Sex:				
Female	135	4	0.5	_
Male	72	1		
Educ. Status:				
High	35	1	1.0	_
Low	171	5		

OR = Crude Odds ratios

AOR = Adjusted Odds ratios

The table 3 above shows that form of visit (first and follow-up visits) and waiting time before receiving laboratory services were found to be associated with the clients' satisfaction, OR 14.7, CI (1.48-131.79) and OR 10.7, CI (4.9-23.8) respectively, however there is no statistically significant association between sex, religion, educational status, means of transport (used) to health facility and clients' satisfaction. Logistic regression on form of visit to health facility and waiting time before receiving laboratory services when considered together remained significant predictors of clients' satisfaction, AOR 11.7 CI(2.1-98.5) and AOR 8.9 CI(5.7-32.4) respectively.

Table 4: Distribution of laboratory personnel (conducting assays) by their position in IDH, 2014

Title of respondent	No of personnel (n)	Percent (%)
Laboratory Scientists	10	58.9
Laboratory Technicians	3	17.6
Laboratory Assistants	3	17.6
Laboratory Technologist	1	5.9
Total	17	100

Table 4 above shows that there was total of 17 technical laboratory staff in the health facility who offered services on tests profile for HIV/AIDS patients. Majority of the staff (58.9%) were laboratory scientists who ran complex tests using automated and semi-automated machines for HIV/AIDS monitoring tests. However, only 15 (88.2%) staff responded to the administered questionnaire, with dropout rate of 11.8%.

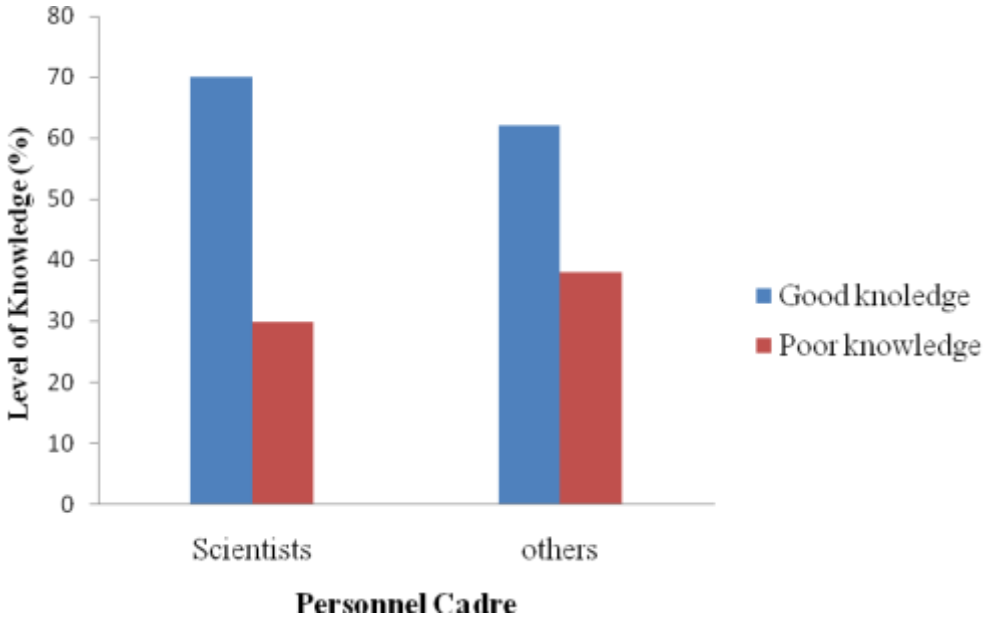
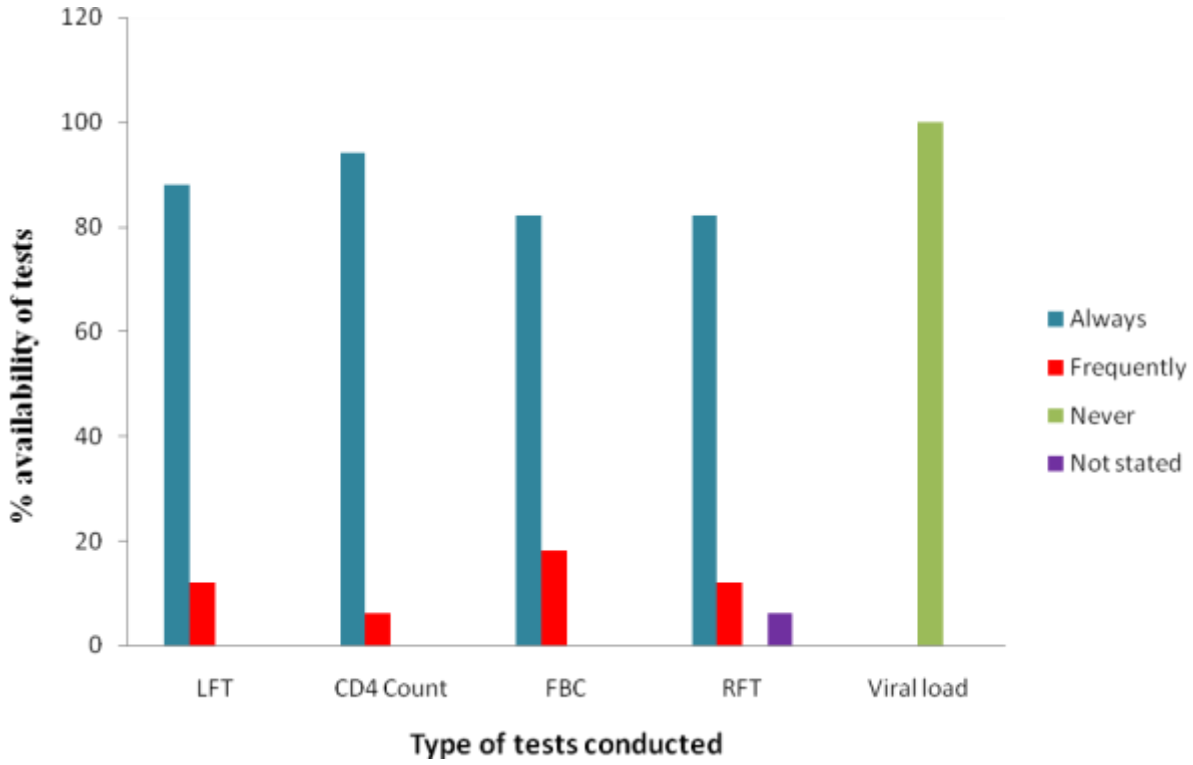


Figure 1: Level of knowledge on laboratory processes and procedures among service providers in IDH, 2014

Figure one above shows that seventy percent (70%) among laboratory scientists and (62%) among other personnel (Laboratory technicians and Assistants) identified correctly ≥4 answers of most important monitoring tests for HIV/AIDS and had adequate knowledge on laboratory processes and procedures.

The findings from our study revealed that internal quality control (IQC) is conducted always as stated by more than 90% of the respondents (records identified) while IQC for complete blood count (CBC) is done not always but sometimes due to stock out of control reagents. The equipment used for HIV/AIDS monitoring tests for CD4 count, haematology and chemistry were available and functional but more than 50% were above 5 years in use. Repairs and maintenance are conducted on site through service contract signed by donor organizations.

The study findings also revealed that EQA was part of the laboratory's quality improvement towards accreditation process and had received external proficiency samples from an external body from South Africa four times in the last twelve months. The proficiency testing was conducted on chemistry panels, CD4 counts and HIV serological testing. The results for the EQA on all the parameters were satisfactory based on documented records.



LFT = Liver Function Test, **FBC** = Full Blood Count, **RFT** = Renal Function Test

Figure 2: Availability of laboratory test profiles for HIV/AIDS patients on ART for the past 12 months at IDH, 2014.

At least 85% of the tests profile for patients on ART was always available within the last 12 months from the period of the study, while FBC, LFT, RFT and CD4 count were available frequently by 20%, 10%, 10% and 5% respectively.

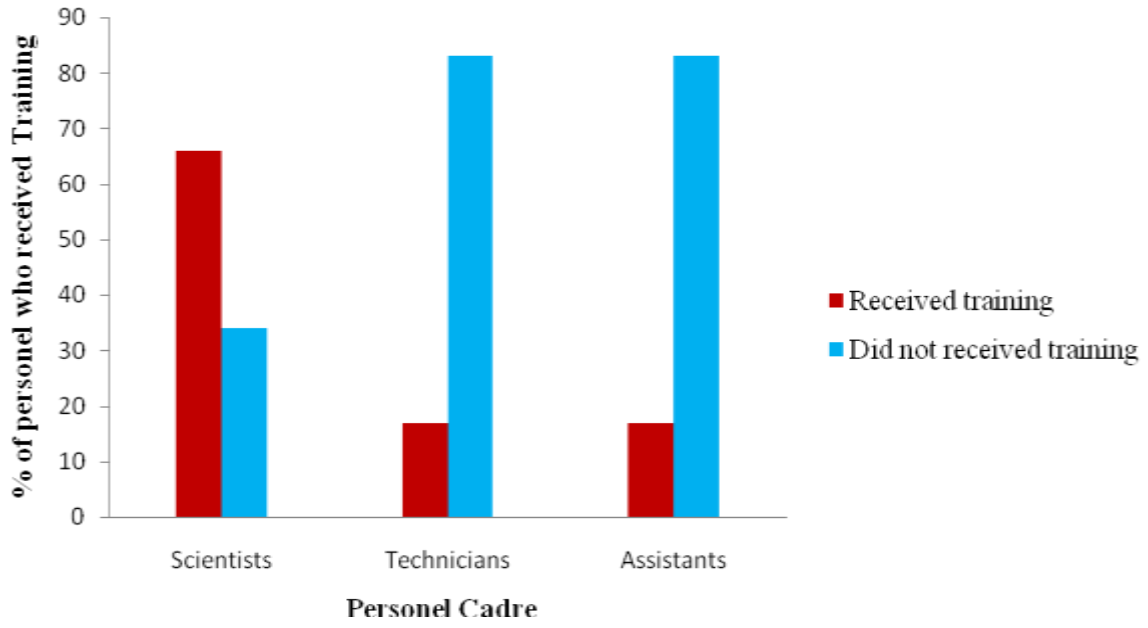


Figure 3: Percentage of laboratory staff who had at least 1 training within the last 12 months at IDH, 2014

Figure three above shows that 66% among laboratory scientists received at least 1 training within the last 12 months while only 18% each among laboratory technicians and assistants received training within the same time period.

Focus group discussions (FGDs) conducted with both males and females adult PLWHA revealed that knowledge on CD4 as the most important test for monitoring HIV/AIDS patients was near universal. Other tests equally important mentioned were renal function tests, liver function tests, hepatitis and malarial test. The respondents unanimously agree that laboratory tests were a good way of monitoring HIV/AIDS progression and were ever concerned when they missed their scheduled laboratory investigations.

"I really felt bad, to the extent I wept one day when I missed my laboratory tests"

Female respondent.

"Laboratory test is good; it gives us courage to continue with the treatment because we are seeing progress"

Male respondent

The study showed that major barriers to accessing laboratory services for HIV/AIDS monitoring tests mentioned were as follows:

1. Stigma was a major challenge to both female and male respondents. The stigma was higher among females, and this is the reason why they missed their scheduled laboratory appointment more often than males. Clients were afraid to be identified as PLWHA among numerous patients attending the laboratory for different services. They also felt being isolated and different from other patients and assumed their condition was the main reason for the isolation.

"*I cover myself from head to toe before going to laboratory because I don't want to be identified by anybody"*

Female respondent

"I sighted my neighbour in the laboratory one day; I quickly left, that is how I missed my laboratory schedule that day"

Male respondent

2. No felt need for laboratory tests by some clients since they can be given drugs (refill) with or without laboratory results. Some male respondents complained that there was no specific schedule time for laboratory test request by the clinicians; they decide when to go for test at their own discretion. Some clients revealed that they avoid laboratory because scheduled hours at the laboratory were not convenient as samples are collected only early in the morning.

"You can imagine somebody spending 12 months without laboratory tests and still collect drugs"

Male respondent

3. Respondents (males and females) unanimously agreed that they should have their own separate laboratory within the ART clinic; the laboratory for patients on ART should be attached to the ART clinic for easy access and confidentiality.

"*We need to have our own separate laboratory and within the ART clinic because we were not happy with the sitting arrangements in the hospitals' main laboratory*"

Female respondent

"*The laboratory is too far from ART clinic and I felt exhausted before reaching the lab; hence the need for separate laboratory within the clinic"*

Male respondent

Clients were unanimously satisfied with the courtesy and respect of the service providers in the laboratory. They mentioned that all staff behaves maturely and treat them with sense of honour, dignity and empathy.

"We are been treated with full respect and dignity by the laboratory staff, I have never come across a day being maltreated or humiliated by any staff."

Male respondent

"They respect us and that was the reason we offer them respect all the times"

Female respondent

CHAPTER FIVE

DISCUSSION

The overall satisfaction level on laboratory services was high, which is suggestive of good quality laboratory services. The overall satisfaction on ART laboratory services in IDH by HIV/AIDS patients was 97.6%; this reported result could be explained in two possible ways; one explanation could be due to introduction of social desirability biases by clients as clients might not be ready to tell their dissatisfaction status freely since interviews were conducted within the hospital setting. However, unless special precautions are taken, clients might be reluctant to reveal their opinions for fear of alienating their service providers as laboratory services are given free of charge.[68] A similar study conducted by Million Belay et al on patients' satisfaction on ART laboratory service in selected Governmental hospitals, Sidamma zone, southern Ethiopia, showed 90.7 % satisfaction level.[69]

Our study showed there is no statistical difference between level of clients' satisfaction and age, sex, marital status, main means of transport to HF and educational status. This was consistent with a similar study conducted by Birna Abdosh 2006, [70] although Birna had found association with main means of transport probably because the ART sites were centralized in cities and the distance between facilities is far. The study also revealed that there was significant association between level of clients' satisfaction and "form of visit to HF" (first or follow-up). Clients who visit the HF for follow-up were 14 times more likely to be satisfied with laboratory services than those that are visiting the HF for the first time. This is in agreement with a similar study conducted in Tanzania by Mfinanga SG *et al* in 2008.[71] Also, "waiting time" before laboratory service providers attended to clients was found to be associated with clients' satisfaction. Those prepared to be attended within 30 minutes from their arrival to the laboratory were 10.7 times

more likely to be satisfied with laboratory services than those prepared to be attended within 60 minutes. Similar study in Ethiopia by Teklemariam *et al* showed consistent findings.[68] Cleanliness of toilets/latrines had the lowest level of clients' satisfaction (46.2%) as many patients were not satisfied with the hygienic conditions of the toilets, and this was consistent with studies conducted by Mindaye et al in Ethiopia.[72]

In comparison with other studies describing patient satisfaction on ART laboratory services, our study showed higher satisfaction level (97.6%) than studies conducted by Teklemariam *et al* (87.6%), Mindaye et al (85.5%) and Million Belay *et al* (90.8%) all in Ethiopia. The underlying justifications for higher clients' satisfaction with laboratory services could be attributed to current efforts by FHI 360 for implementing quality management systems aimed at preparing the laboratory to attain accreditation level based on ISO 15189. In addition, the ART laboratory had external assessors who visited the facility few months prior to the commencement of the study which lead to improved service quality based on identified gaps and corrective actions taken.

The responses from laboratory staff indicated that they had a good level of knowledge and skills to support ART laboratory services on the most frequently requested tests for diagnosis and monitoring tests for HIV/AIDS patients on ART in IDH. The findings suggest that there is a need to strengthen continuous training to conform to quality system requirements towards accreditation. This was consistent with WHO requirement for AFRO region for all laboratories to strengthen laboratory management towards accreditation.[60]

The study findings indicated that the laboratory staff practices in performing internal quality control and test profiles for the management of HIV/AIDS patients on ART was good for all the

tests except CBC, which could not be run always due to stock out of control materials. Weekly quality control charts were available and within range for all the tests.

There was a lack of infrastructural development at the facility especially space in which clean area for records entering was within the testing area. There was no separate area for office use; hence, all activities were conducted within the working area. Laboratory tests for clients on ART were run in parallel with other routine tests, which led to delay in implementing National laboratory policies and regulations with weak laboratory network system. This was consistent with a study conducted by Wertheim and colleagues [73] which showed that major challenges of developing effective laboratory capacity in resource-limited settings, includes lack of infrastructure, failure to create and/or implement national laboratory policies, weak national regulatory and laboratory networks system, weak procurement and supply systems, variable quality of laboratory performance due to lack of standardization and quality standards, lack of equipment maintenance, and the inability to follow manufacturers' recommendations to ensure proper operational capacity of laboratory instruments.[1]

The findings also showed that human resource in terms of laboratory staff number was inadequate and more personnel are required for improved health care services. Major complain by staff was work overload because each staff had his/her own primary work schedules apart from working on tests for PLWHA. Moreover, only few numbers among the staff have had at least one training within a period of twelve months. A similar study indicated that adequate human resource capacity is the backbone of a strong health care system and consumes the majority of resources allocated to health systems. Efforts to improve the quality and managerial capacity of health care workers and to maintain skilled staff, including laboratory professionals, are central to improving health care systems. [2] The study was in consonance with other studies [31]

indicating that there is a major human resource crisis with inadequate numbers of suitably trained and motivated laboratory staff for deployment at each level of health care delivery.[32] This is clearly indicated in our study findings that the number of laboratory staff that offered technical services was inadequate. This has an implication for the ART scale-up plan in terms of laboratory services. There is a need to retrain the laboratory staff on HIV/AIDS management (diagnosis and monitoring tests) and care to support the ART plan. Poorly or insufficiently trained laboratory personnel can be costly to the ART programme because they can contribute to human errors due to inaccurate test results. Beyond training the laboratory staff, there is a need to maintain competency in laboratory techniques. This can be achieved through continuing education or refresher courses.

The study findings on participation in EQA indicated that it was established for HIV serological test, CD4 count and chemistry panels to support the ART services and all records were fully documented. However, EQA for CBC was not available. To support these findings a similar survey, conducted by the WHO African Regional Office (AFRO) [5], found that although many countries were performing HIV serological testing, only very few laboratories were, enrolled in any form of quality control or external quality assessment (EQA) programme. Comparable to results of this study, other studies showed that quality laboratory management and (QA) had been an important part of Brazil's laboratory services support for their ART programme. External Quality Assessment for CD4 count was conducted six times per year to ensure quality-assured performance of laboratories to support their ART programme.[31]

Internal quality control is part of the quality assurance that deals with control of errors during actual performance of the laboratory tests and the verification of test results. Quality Control is carried out on a daily basis for each test during routine laboratory work as indicated by service

providers. The present study findings indicated that internal quality control was performed always for LFT, RFT and CD4 count, frequently for CBC.

FGDs conducted on both males and females adult PLWHA revealed that knowledge on CD4 as the most important test for monitoring HIV/AIDS patients on ART was near universal because is a marker believed to indicate disease progression and health status improvement over time. Other tests equally important mentioned were renal function tests and liver function tests, because some participants believed that the drugs have detrimental effect on these two organs since drugs are metabolized and excreted by them. The respondents were concerned whenever they missed their scheduled laboratory days because taking drugs without laboratory investigations mask disease progression even when it is positive.

Stigma was a major barrier that stands as an obstacle to patients on ART for accessing laboratory services. Many patients prepare to miss their scheduled laboratory hours rather than being identified by people they believed knew their identity. Because of this reason, high proportion of them has inconsistent laboratory tests with reference to their ART start date. While some ignore laboratory investigations because of no felt need since they can have their refill with or without laboratory results. Location of the laboratory away from the ART clinic was another countable barrier to reaching laboratory, as many patients were not comfortable with even the sitting arrangement within the laboratory. They all agreed that having a separate laboratory within the ART clinic would reduce stigma, improve confidentiality and uptake of laboratory services.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

In conclusion, the satisfaction level of the clients on laboratory services received was high, which suggested acceptable quality of services offered. Form of visit to HF (follow-up visit), and "waiting time" before clients are attended by service providers, were found to be the factors associated with client satisfaction. Inadequate work force was identified as one of the major factors affecting quality of laboratory services by 80% of service providers, inadequate training of laboratory personnel (72%), lack of EQA and IQC on some tests (45%), interrupted power supply that led to frequent equipment breakdown (86%) and infrastructural inadequacy (space) to accommodate all the equipment, staff, as well as the patients (64%). The clients identified stigma, location of the laboratory distant from the ART clinic and lack of awareness on the importance of the laboratory tests in the management of the patient as barriers to accessing laboratory services.

6.2 Recommendations

1. The State MoH should provide adequate work force to the laboratory and train each staff at least twice in a year for quality improvement.
2. The facility in collaboration with SMoH should provide adequate space for the laboratory to accommodate ever-increasing demand for laboratory services by HIV/AIDS patients on ART.
3. The Ministry of health should look into the possibility of providing a separate sampling area within the ART clinic to improve service uptake by the clients.

4. Counseling sessions should be organized and conducted monthly by the HOD laboratory at the ART clinic on the importance of laboratory services to patients on ART to improve awareness and service utilization.

REFERENCES

1. Petti CA, Polage CR, Quinn TC *et al*: Laboratory medicine in Africa: a barrier to effective health care. *Clin Infect Dis.* 2006; 42:377–382.

2. Mindaye T, Taye B: Patient's satisfaction with laboratory services at antiretroviral therapy clinics in public hospitals, Addis Ababa, Ethiopia. *BMC Research Notes 2012*, 5:184.

3. Abimiku AG: Building laboratory infrastructure to support scale-up of HIV/AIDS treatment, care, and prevention. *Am J Clin Pathol.* 2009; 131:875-886.

4. End of project evaluation of Global HIV/AIDS Initiative Nigeria; Final Report, January-2011; pp: 68-74.

5. Roemer MI, Montaya-Aguilar C. Quality assessment and assurance in primary health care. Geneva, *World Health Organization, 1998*. Publication number 105: 82.

6. Lagrosen Y, Lagrosen S. The effects of quality management – a survey of Swedish quality professionals. *Intern J of Oper. & Prod Manag.* 2005; 25: 940–52.

7. Rahman SB. A comparative study of TQM practice and organizational performance with and without ISO 9000 certification. *Int J of Qual. & Reliability Manag.* 2001; 18: 35-49.

8. Alexander JA, Weiner BJ, Griffith J. Quality improvement and hospital financial performance. *J of Organisational Behaviour.* 2006; 27: 1003–29.

9. Feigenbaum AV. Quality control: *Principles, practice, and administration 1951*; New York: McGraw-Hill.

10. Peters T, Waterman R. *In search of excellence: lessons from America's best run companies 1982*; New York: Harper and Rowe.

11. Gilmore HL. Product conformance. *Quality Progress* 1974; 7: 16–9.

12. Crosby P. *Quality is free* 1992; New York: McGraw-Hill.

13. Juran J. Quality control handbook 1988; 4th ed. New York: McGraw- Hill.

14. Parasuraman A, Zeithaml VA, Berry LL. A conceptual model of service quality and its implications for future research. *J of Marketing* 1985; 49: 41–50.

15. Mosadeghrad AM. Healthcare service quality: Towards a broad definition. *Int J Health Care Qual Assur.* 2013; 26: 203–19.

16. McLaughlin CP, Kaluzny AD. *Continuous quality improvement in health care* 2006; 3rd Ed. Sudbury, MA: Jones & Bartlett Publishers.

17. Mosadeghrad AM. A conceptual framework for quality of care. *Mat Soc Med.* 2012; 24: 251–61.

18. Mosadeghrad AM. Towards a theory of quality management: an integration of strategic management, quality management and project management. *Int J of Modelling in Oper Manag.* 2012; 2: 89–118.

19. Ladhari R. A review of twenty years of SERVQUAL research. *Int J of Qual and Service Scie.* 2009; 1: 172–98.

20. Øvretveit J. *Does improving quality save money? A review of evidence of which improvements to quality reduce costs to health service providers* 2009; London: The Health Foundation.

21. Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in the United States? *Milbank Q* 1988; 76: 517–64.

22. Lohr K. *Medicare: A Strategy for Quality Assurance 1991; (*I). Washington, DC: National Academy Press.

23. Jun M, Peterson RT, Zsidisin GA. The identification and measurement of quality dimensions in health care: Focus group interview results. *Health Care Manage Rev.* 1998; 23: 81–96.

24. Padma P Rajendran C, Sai LP. A conceptual framework of service quality in healthcare: Perspectives of Indian patients and their attendants. *Benchmarking: An Int J.* 2009; 16: 157–91.

25. Buttell P., Hendler R., Daley J. Quality in healthcare: Concepts and practice. *Westport Praeger. 2008*; P.62-83.

26. Plebani M. The detection and prevention of errors in laboratory medicine. *Ann. Of Clin. Biochem. 2010*; 47: p.101-10.

27. Donabedian A. The quality of care: how can it be assessed? *J of Am Med Assoc. 1988*; 260: p.1743-1748.

28. Donabedian A. Explorations in Quality Assessment and Monitoring: The Definition of Quality and Approaches to its Assessment. *Health Administration Press; 1980*. (1)

29. Mhalu FS. Burden of disease in poor resource countries: meeting the challenge of combating HIV/AIDS, tuberculosis and malaria. *Tanzanian Health Respiratory Bullet. 2005*, (3) p.179-184.

30. Harries AD, Schouten EJ, Libamba E. Scaling up antiretroviral treatment in resource poor settings. *Lancet. 2005*, (367) p.1870-1872.

31. HIV/AIDS Laboratory Capacity. How Far We Have Come and Where We Are Going: An Assessment Report of the Capacity of Laboratories to Support the Scaling-Up towards Universal Access to HIV/AIDS Prevention, Treatment, Care and Support Services in the WHO/AFRO Region. Geneva, Switzerland: WHO; 2003.

32. Bates I, Maitland K. Are laboratory services coming of age in Sub-Saharan Africa? *Clin Infec. Dis J. 2006*, Volume 42, p.383-384.

33. Negi R. Determining customer satisfaction through perceived service quality: A study of Ethiopian mobile users. *Int J of Mobile Market.* 2009*;* (4) 1; p.31-38.

34. Berry LL, Parasuraman A Zeithaml VA. The service-quality puzzle. *Business Horizons. 1988*; September/October, pp. 35-43.

35. Saravanan R, Rao KS. Measurement of service quality from the customer's perspective – An empirical study, *Total Quality Management.* 2007; (18) 4, p.435-449.

36. Cronin J, Taylor SA. Measuring Service Quality: A Re-examination and Extension, *Am J of Market. 1992*, (56) p.55-68.

37. Wicks AM, Roethlein CJ. A Satisfaction-Based Definition of Quality. *J of Business & Econ Studies. 2009;* (15) 1, 82-97**.**

38. Oliver RL. A cognitive model of antecedents and consequences of satisfaction decisions: *J of marketing Research. 1980;* (27), P. 460-469

39. Czepiel AJ, Gilmore R. Exploring the idea of Loyalty in Services. *Am J of Marketing. 1987;* (44) 3, 23-46.

40. Johns N. What is this thing called service? *European Journal of Marketing. 1999*; (33), 9/10, p.958-973.

41. Gibson HA. Towards an understanding of why sport tourists do what they do. *Sport in Society Special Issue, Sport Tourism, Concepts and Theories 2005;* (8) 2, P.198–217

42. Auquier P, Pernoud N, Bruder N, *et al*. Development and validation of a peri-operative satisfaction questionnaire. *Anaesthesiology.* 2005; (102): 1116–23

43. Gentile S, Auquier P, Antoniotti S, *et al*. Satisfaction apre`s prise en charg anesthe´sique: revue des diffe´rents outils existants. *Presse Med.* 1999; (28) 1040–5

44. Fung D, Cohen M. Measuring patient satisfaction with anaesthesia care: a review current methodology. *Anesth Analg.* 1998; (87): 1089–98

45. Sitzia J, Wood N. Patient satisfaction: A review of Issues and concepts. *Social Science and Medicine* 1997; (12) 5: p.1829–1843.

46. Thiedke CC. What do we really know about Patient Satisfaction? *Farm Pract. Manag. 2007*; (1)14:33–36.

47. Muula AS, Chipeta J, Siziya S, *et al*. Human resource requirements for highly active antiretroviral therapy scale-up in Malawi. *BMC Health Serv. Res. 2007*; (7): p.208.

48. Anderson RT, Camacho FT, Balkrishnan R *et al*. Will to wait? : The influence of patient waiting time on satisfaction with primary care. *BMC Health serv. Resear. 2007*; (7) p.31.

49. Tsasis P, Tsoukas C, Deutsch G *et al*. Evaluation of Patient Satisfaction in a Specialized HIV/AIDS Care Unit of a Major Hospital. *AIDS Patient Care and STDs. 2002*; (7) 14: p.347–349.

50. Muhondwa EP, Leshabary MT, Mwangu M *et al*. Patient Satisfaction at the Muhimbili National Hospital in Dar es Salaam Tanzania. *East Afr. J of Pub. Health. 2008*; (2)5: p.67–73.

51. Marquez-Peiro JF, Perez-Peiro C. Evaluation of Patient satisfaction in outpatient pharmacy in Brazil. *Farm Hosp. 2008*; (2)32: p.71–76.

52. Wouters LA, Heunis FG. Patient Satisfaction with Anti retroviral Services at Primary Health Care Facilities in the Free State, South Africa: a two-year study using four waves of cross-sectional data. *BMC Health Serv. Research. 2008*; (8): p.210.

53. Kuisma M, Määttä T, Hakala T *et al*. Customer satisfaction measurement in emergency medical services. *Acad. Emerg. Med. 2003*; 10: p.812–5.

54. Mfinanga S, Kahwa A, Kimaro G *et al*. Patient's dissatisfaction with the public and private laboratory services in conducting HIV related testing in Tanzania. *BMC Health serv. Research. 2008*; (8): p.167.

55. Oja PI, Kouri TT, Pakarinen AJ. From customer satisfaction survey to corrective actions in laboratory services in a university hospital. *Int J. Qual. Health Care. 2006*, (6)18: p.422–428.

56. Jones BA, Bekeris LG, Nakhelh RE *et al*. Physician satisfaction with clinical laboratory services: College of American Pathologist Q-Probes study of 138 institutions. *Arch. Pathol. Lab. Med. 2009*; 133:38–43.

57. Oakbrook Terrace. Joint Commission on accreditation of Health care organizations. *Comprehensive Accreditation Manual for Pathology and clinical Laboratory service. 2005*; (3): p.10.

58. Aiello A, Garman A, Morris BS. Patient satisfaction with nursing care: A multi-level analysis. *J. Quality Management in Health Care. 2000*; 312(3): p.187–191.

59. Marquis MS, Davies AR, Ware JE. Patient satisfaction and change in medical care provider: a longitudinal study. *Med Care 1983*; (21):821–829.

60. Joint Commission on Accreditation of Health care Organizations: Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services. Oakbrook Terrace, Ill: *Joint Commission on Accreditation of Healthcare Organizations. 2005*; P.3-10.

61. Laboratory General Checklist: laboratory accreditation program. Northfeld, Ill: *College of Amer Path. 2005*; GEN.20316.

62. Mfinanga SG, Kahwa A, Kimaro G *et al*. Dissatisfaction with laboratory service in conducting HIV related testing among public and private medical personnel in Tanzania. *BMC Health Res Bull. 2007*; (9): p.110–114.

63. Gadallah M, Zaki B, Rady M *et al*. Patient satisfaction with primary health care services in two districts in lower and upper Egypt. Comparative study. *East Mediterr. Health J. 2003*; (9): p.422–430.

64. Tse, David K, Peter C. *et al*. Models of Consumer Satisfaction: Extension, *Journal of Marketing Research. 1988*, (25) p. 204-212.

65. Czarnecki M. (1998) Managing by Measuring: How to Improve Your Organization's Performance Through effective Benchmarking. New York: *Amacom. 1998*; (271) p.0390-5.

66. Sahin B, Demir C, Celik Y *et al*. Factors affecting satisfaction level with the food services in a military hospital, *Journal of Am medical systems. 2006;* (30) 5.

67. Baileyt, JE. Pearson SW. Pearson development of a tool for measuring and analyzing computer user satisfaction. *Management science*, (25) 5.

68. Teklemariam et al. Clients and clinician satisfaction with laboratory services at selected government hospitals in eastern Ethiopia. *BMC Research Notes. 2013;* (6): p.15.

69. Million B, Seid A, Debela B *et al*. HIV/AIDS Patients' Satisfaction on ART Laboratory Service in Selected Governmental Hospitals, Sidamma Zone, Southern Ethiopia. *Scie. J of Pub. Health. 2013*; (1) 2, p. 85-90.

70. Birna A. The quality of hospital services in eastern Ethiopia: Patient's perspective. *Ethiop. J. Health Dev. 2006*; 20(3).

71. Mfinanga SG, Kahwa A, Kimaro G. *et al*. Patient's dissatisfaction with the public and private laboratory services in conducting HIV related testing in Tanzania. *BMC Health Serv. Res. 2008*; (8) p.121–125.

72. Mindaye T, Taye B. Patient's satisfaction with laboratory services at antiretroviral therapy clinics in public hospitals, Addis Ababa, Ethiopia. *BMC Research Notes 2012*; (5) p.184.

73. Wertheim HF, Puthavathana P, Nghiem NM. et al. Laboratory capacity building in Asia for infectious disease research: Experiences from the South East Asia Infectious Diseases Clinical Research Network (SEAICRN). *PLoS Med*. 2010; (7) p. 116-123.

APPENDICES

Appendix 1- Informed Consent for laboratory service providers

Researcher: Mikhail A. Abubakar

E-mail: mikobchi@yahoo.com

Phone: 08091305827

Introduction

You are kindly invited to participate in a health research being conducted to assess the factors affecting the quality of laboratory investigations among HIV/AIDS patients attending this facility (IDH). You may take your time to make decision about participating in this process after reading the information carefully. Your participation is voluntary and you may withdraw from the study at any time. Refusing to participate in the research will not in any way affect you or your practice. All personal information including interview data you provide will be kept strictly confidential. At the conclusion of this study, we will destroy all electronic and paper records containing your identifying information.

There will be no monetary gain by participating in this study, but information gained may be directly or indirectly beneficial to you and others in the future.

If you decided to participate in this study, please sign and fill in the questionnaire given to you.

If you have any questions or queries regarding this study, please contact the research investigator through direct contact or the phone numbers and e-mails provided on the questionnaire.

Your Participation is highly appreciated.

.....
Signature or thumb print

Appendix 2 - Exit interview questionnaire for HIV/AIDs clients

Exit interview questionnaire for HIV/AIDs clients

Patient ID..... Date.....

My name is _____. We are trying to improve services for clients, and we would like your honest opinion of how well we are doing and what we need to improve—both the good things and the bad things. This interview is private and confidential. You are free not to answer any questions you do not want to, and if you do not want to take part in the interview at all, you do not have to. Your participation is voluntary and you may withdraw from participation any time. But it is advisable to inform the investigator before withdrawing from participation. Your name will not be used and all personal information including interview data you provide will be kept strictly confidential. At the conclusion of this study, we will destroy all electronic and paper records containing your identifying information.

This will take about 20 minutes. Your ideas are important to us—may I ask you a few questions?

Site: ---------- Name of interviewer----------

Section A: Socio-Demographic Profile of the Clients

1. Type of client 1. New Non-ART client [ ] 2. Old ART client [ ]
2. Age (in years) 1. ---------- 2. Don't Know [ ]
3. Sex: 1. Male [ ] 2. Female [ ]
4. Marital status: 1. Single [ ] 2. Married /monogamous [ ] 3. Married/ polygamous [ ] 4. Divorced [ ] 5.Widowed [ ]

5. If polygamous, how many wives 1. Two [ ] 2. Three [ ] 3. Four [ ]

6. Number of living Children: 1. (< 5) [ ] 2. (5-15) [ ] 3. (16-30) [ ] 4. (> 30) [ ]

7. How much are you earning Monthly: 1. (10-40 Thousand Naira) [ ] 2. (41-80 Thousand Naira) [ ] 3. (81-120 Thousand Naira) [ ] 4. (Above 120 Thousand Naira) [ ] 5. Doesn't have any monthly income [ ]

8. Occupation: 1. Civil Servant [ ] 2. Business [ ] 3. Farmer [ ] 4. House Wife [ ] 5. Daily Labourer [ ] 6. Retired [ ] 7. Student [ ]

9. Religion: 1. Islam [ ] 2. Christianity [ ] 3.Others (specify) [ ] ----------

10. Highest educational level: 1. Primary [ ] 2. Secondary [ ] 3.Tertiary [ ] 4. None [ ]

Section B: Assessing clients' satisfaction with the services provided including costs

11. Visit to facility: 1. First visit [ ] 2. Follow-up visit [ ]

12. How long on average, did it take you to arrived at this Laboratory from your home?: 1. Less than 1 hr [ ] 2. 1 to 2 hrs [ ] 3. 3 to 4 hrs [ ] 4. Above 4 hrs [ ]

13. What was the main means of transportation you use to come here today? 1. Walk 2. Bus 3. Taxi [ ] 4. Motorbike [ ] 5. Private car [ ] 6. Keke [ ] NAPEP (Adaidaita Sahu) [ ]

14. Did you feel the scheduled (Laboratory) hours were convenient for you?
    1. Yes [ ] 2. No [ ]

15. How satisfied are you with the courtesy and respect of the laboratory Staff during your visit?: 1. Very Satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

16. How satisfied are you by the Phlebotomy done by the Phlebotomist? 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

17. How satisfied are you with measures taken to assure your privacy during your test?: 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

18. How satisfied are you by the waiting time to get the Laboratory services? 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

19. Do you feel that you stayed too long waiting to see a service provider? 1. Yes [ ] 2. No [ ]

20. In your opinion, how long do you think a client should wait to be attended to by service provider? ----------(minutes)

21. Are services offered freely in this facility? 1. Yes [ ] 2. No [ ]

22. If No, how much do you pay per service for each visit?.....(Naira)

23. If Yes to Q21, were you ever at one time asked to pay money before you receive services? 1. Yes [ ] 2. No [ ]

24. Was there a time in this facility you were referred to another facility or asked to come back some other time because there were no reagents available or machines are faulty within the last six months? 1. Yes [ ] 2. No [ ]

25. If answer to the above question is yes, then how many times do you experience such problem? 1. Only once [ ] 2. Two times [ ]

26. How do you evaluate the overall cleanliness and comfort of the waiting area?: 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

27. How do you rate your overall level of satisfaction regarding the delivery of the laboratory service you received?: 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ]4. Dissatisfied [ ] 5. Very Dissatisfied [ ]

28. Do you know any other hospital that provide ART-Laboratory services?: 1. Yes [ ] 2. No [ ]

29. Do you have the intention to change your ART follow-up site? 1. Yes [ ] 2. No [ ]

30. If the answer to the above question is yes, then why? .....

31. Would you recommend the services of this Laboratory to someone else?

    1. Yes [ ] 2. No [ ]

32. During this visit, did you have any question you wanted to ask your provider?

    1. Yes [ ] 2. No [ ]

33. If yes, did you feel comfortable to ask your question? 1. Yes [ ] 2. No [ ]

Thank you for your time, helps and ideas.

Appendix 3 - Facility inventory checklists

Health facility: physical infrastructure

	1.Yes	**2.No**	**Remarks**
1. Space:			
Reception /waiting area			
Office room			
Counselling room with privacy			
Storage facility room			
2. Washing facility			
3. Toilets facility for clients			
4. Toilets facility for member of staff			
5. Water source:			
6. Light source:			
7. Suitable area for office work			
8. Adequate chairs for service providers			
9. Adequate chairs/benches for clients			
10. Adequate air conditions			

Laboratory reagent and consumables inventory for the last 6 months

Reagents	**Availability** **1.Yes [ ]** **2. No [ ]**	**Stock out** **1. Yes [ ]** **2. No [ ]**	**Period** **(weeks)**
1. GOT			
2. GPT			
3. Creatinine			
4. Potassium			
5. Glucose			
6. CD4			
7. Haematology			
Consumables			
8. Latex hand gloves			
9. Aprons			
10. Goggles			
11. Face mask			
12. Boot			
13. Methylated spirit			
14. Bleach			
15. Hand wash			
16. Vacutainer tubes & needles			
17. Capillary tubes			
18. Cotton wool			
19. Tissue paper			
20. Waste bins			
21. Sharp containers			
22. Biohazard bags			

Equipment and instrument inventory for the last 6 months

	Yes	No	Type	Breakdown	Period (Weeks)
Microscope					
Chemistry machine/s					
Haematology machine/s					
Alternative power source					
CD4 Machine/s					
Centrifuge					
Voltage Stabilizers					
Refrigerators					

Health management information system/record keeping

	1.Yes [ ]	1. No [ ]
FMOH-approved management information system forms:		
▪ Monthly report		
▪ Daily consumption record		
▪ Commodity supply		
▪ Commodity request		
Referral forms		
Cost recovery record form		
Informed consent form		
Client register		
Tally Cards		

Visual Aids/Job Aids

	1.Yes [ ]	**2. No [ ]**
Flip chart for relevant laboratory procedures for 1. CD4 2. Chemistry 3. Haematology		
Standard operating procedures (SOPs) for various tests for 1. CD4 2. GOT 3. GPT 4. Creatinine 5. Potassium 6. Haematology		
Equipment Manuals		
Pamphlets or method booklets		
Posters		
Service provision guidelines/protocols		

Appendix 4 - Questionnaire for Laboratory personnel

Section A: Identification

Questionnaire ID ..... Date of interview .....

State..... LGA..... Name of Facility.....

Qualification of Respondent..... Position.....

Section B: Test profiles for diagnosis and monitoring of HIV/AIDS patients on ART

Q1. What are the five most important monitoring tests requested for patients on ART at this centre?

1.....

2.....

3.....

4. .....

5.....

Q2. Do you have SOP Manual to support the ART program? 1. Yes [ ] 2. No [ ] >>Q4

Q3. If yes, check

Q4. If not, briefly explain why?.....

Q5. Do you perform internal quality control (IQC) on the following tests? (Check records of results and tick in the appropriate box)

Nos	Type of test	Always [1]	Sometime [2]	Never [3]
1	CD4 count			
2	CBC			
3	Liver function tests (ALT, AST)			
4	Kidney function tests (Creatinine, Potassium)			
5	Fasting blood sugar			

If never, go to Q7

Q6. If sometimes, when did you last perform IQC on the above tests?

1. In the last week [ ] 2.In the last month [ ] 3. In the last 3 months [ ]

Q7. Please state the availability of the below listed tests requested for monitoring HIV/AIDs patients on ART (Tick in the appropriate box)

Nos	Test	Always [1]	Frequently [2]	Never [3]
1	CD4 count			
2	CBC			
3	Liver function tests (ALT, AST)			
4	Kidney function tests (Creatinine, Potassium)			
5	Fasting blood sugar			

Section C: Quality Assurance

Q8. Do you take part in external quality assurance (EQA) program? 1. Yes [ ] 2. No [ ] >>Q10

Q9. If yes, which program are you participating? (Briefly explain).....

Q10. Are records of EQA kept? 1. Yes [ ] >> check and attach 2. No [ ]

Q11. If no, why are you not keeping the records? (Briefly explain).....

Section D: Equipment

Q12. For each of the following equipment, indicate if it is available, type/make, functional to-date?

Type of equipment	**Is it available 1. Yes [ ] 2. No [ ]**	**Type/make**	**How old is it..? (Years)**	**Is it functional..? 1. Yes [ ] 2. No [ ]**
CD4 count machine				
Haematology Analyzer				
Chemistry Analyzer				
Centrifuge machine				

Q13. If the above equipment is available, are tests done always? 1. Yes [ ] >>Q15 2. No [ ]

Q14. If no, what are the major reasons for this? (Briefly explain).....

Q15. Do you have a service/maintenance contract plan for your laboratory equipment?

1. Yes [ ] 2. No [ ] >>Q17

Q16. If yes, check the plan.

Q17. If no, why not (Briefly explain).....

Q18. Where do you send your lab. Equipment for repairs? (Briefly explain).....

Q19. How long does it take on average to repair equipment? 1. One week [ ] 2. Two weeks [ ] 3. One month [ ] 4. More than 2 months [ ] 5. Other (Specify).....

Section E: Laboratory commodity management system

Q20. Where do you receive most of your lab. Supply and reagents? 1. From central medical store [ ] 2. Directly from local supplier/agent [ ] 3. Directly from co-operating partners [ ] 4. Other (Specify).....

Q21. How satisfied are you with the present system for procurement of lab. Supplies and equipment? 1. Very satisfied [ ] 2. Satisfied [ ] 3. Neutral [ ] 4. Dissatisfied [ ] 5. Very dissatisfied [ ]

Q22. How often do you run out of the following reagents and supplies for diagnosis and monitoring tests for HIV/AIDS patients on ART? (Tick in the appropriate box)

Reagents & supplies for...	**1.Rarely [ ]**	**2.Weekly [ ]**	**3.monthly [ ]**	**4.Every few months [ ]**	**5. Never [ ]**
CD4 count					
CBC					
Liver function tests (ALT, AST)					
Kidney function tests (Creatinine, Potassium)					
Fasting blood sugar					

Q23. If tests are not available, where did you refer the samples/specimen?.....

Section F: Human resource development and supervision

Q24. Please list ART training programs that you have received in the last one year?

Position held	**Training received**	**Sponsor**	**Duration**

Q25. Please estimate your current and required number of staff for provision of quality lab. Services.

1. Current staff (Number).....
2. Required staff (Number).....

Section G: Challenges

Q26 What are the five main problems on diagnosis and monitoring test for HIV/AIDS patients on ART in your laboratory?

1.....

2.....

3.....

4.....

5.....

Q27. What countermeasures are needed to overcome these challenges? (Briefly explain).....

Q28. Do you have any other comments? 1. Yes [ ] 2. No [ ]

Q29. If yes, what are the comments? (Briefly explain).....

End of interview

Thank you for your time and information

Appendix 5 - Focus Group Discussion Guide

Purpose of Focus Group Discussion: The FGD was used as a tool to discuss and obtain pertinent information on both the clients and service providers' perception on the factors affecting quality of laboratory services in Kano metropolitan health facilities.

Focus Group Themes

1. Information on the knowledge, experience and satisfaction with laboratory procedures

2. Critical experience at the laboratories

3. Perception on the existing laboratory infrastructure

4. Clients' perception of factors affecting accessibility of ART-Laboratory investigations

Focus group Guide for the clients

Section A: Information on knowledge and experience about ART-Laboratory

1. What are the 3 or 4 departments/units you think are most significant in a hospital setting like this one?

a).....

b).....

c).....

d).....

2. Do you think Laboratory is significant for improving your health?

If Yes, why?.....

If No, why not?.....

3. What are the 5 most common Laboratory tests do you know?

a).....

b).....

c).....

d).....

e).....

4. What are the 3 most significant tests for PLWHA?

a).....

b).....

c).....

5. Why do you think these tests are important to you?

.....

.....

6. Are laboratory tests a good way to monitor HIV progression?

If Yes, why?.....

If No, why not?.....

Probe: If yes, are you ever concerned if you miss your scheduled Laboratory investigations during your first or follow-up visit?

If Yes, why?.....

If No, why not?.....

7. Do PLWHA generally willing to go for Laboratory tests? Yes [ ] 2. No [ ]

Probe: If people in the group responded No, ask, "What are the main reasons why people do not go for Laboratory tests?

Section B: Critical experience at the laboratories

8. Generally, how do you perceive the attitudes of Laboratory staff towards patients?

…….....

9. Was there any time you were humiliated during the course of obtaining Laboratory services in this facility?

If Yes, can you share your individual experience?.....

.....

.....

10. What do you dislike most whenever you find yourself in the Laboratory?.....

.....

Section C: Perception on the existing laboratory infrastructure

11. What are your impressions generally about the building structure of the Laboratory?

12. In your own opinion, is the sitting arrangement convenient and comfortable for you?

If Yes, why?.....

If No, why not?.....

Section D: Clients' perception of factors affecting accessibility of ART-Laboratory investigations

13. Have you at any time decided not go for Laboratory tests when you were sent by a doctor?

Probe: If respondents say yes, ask, "What reasons prevented you from going?"

14. What other factors do you think prevent people from accessing Laboratory investigations?

15. Are there ways you think these factors can be overcome?

If yes, then, list.....

Appendix 6 - Other ethical considerations

3.9.1. Informed consent

Participants' consent was sought before participating in the study and was asked to sign an informed consent form.

3.9.2. Risks and discomforts

This is a minimal risk study. You may feel uncomfortable with some questions.

3.9.3. Costs

The interviews were conducted at no cost to all the participants.

3.9.4. Anticipated benefits

There may or may not be direct benefit to you from participating in this study. When the study is completed, it will help the researcher make valuable recommendations to the appropriate authorities that when implemented shall improve the quality of services rendered to you in the various facilities, which in turn is likely to improve the quality of your lives after treatment.

3.9.5. Payments for participation

Participants received an amount to cover transportation costs to interview venue, but no payment for participation in the focus group discussion was made.

3.9.6. Confidentiality

Information obtained in this research study will be published or presented in a public forum, but the names or other identifying information of participants will not be used. Every effort was made to protect participants' identity and all information gathered will be treated with utmost confidentiality. It is saved in a password locked personal computer of the researcher.

3.9.7. Voluntary participation/withdrawal from the study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decisions will affect neither the healthcare service you receive nor your relationship with service providers.

3.9.8. Questions

You are free to ask any questions that you may have about the research or participation. If any question/s comes up during or after the interview, contact Principal Investigator on above address.

Appendix 7 - Copy of Ethical clearance letter

KANO STATE
HOSPITALS MANAGEMENT BOARD
BOARD HEADQUARTERS
P.M.B 3540, Post Office Road, Kano

18/07/1434AH, (28/05/2013)

MIKHA'IL ABDU ABUBAKAR
Department of Phathology,
Ahmadu Bello University Teaching Hospital,
Zaria, Kaduna State.

PROVISIONAL ETHICAL CLEARANCE

Sequel to conduct research title **"EVALUATION OF FACTORS AFFECTING THE QUALITY AND ACCESSIBILITY OF LABORATORY INVESTIGATIONS REQUIRED BY HIV/AIDs PATIENTS ATTENDING MMSH & IDH"** In the light of the above, I am mandated to convey provisional clearance to proceed on your study based on the following conditions.

i. That the consent of all participants must be obtained by filling inform consent form.
ii. That you should liase with the Management of the Facility of you. Focus for appropriate guidance.
iii. That any publication related to the study should be brought to the knowledge of the Ethical Committee for approval.
iv. That a copy of your finding should be submitted for documentation, record and final approval, please.

Best regards,

ZAHRA SULEIMAN
Asst. Sec. I. (Estb).
FOR: EXECUTIVE SECRETARY