CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS OF HIV/AIDS PATIENTS ON ANTIRETROVIRAL THERAPY IN ZAMBIA

by

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DECLARATION

I Grace Cecilia Musonda Kahenya hereby declare that the work on this thesis is original (except where acknowledgement indicate otherwise), that this dissertation hereby submitted to the University of Limpopo, for the degree of Doctor of Public Health and neither the whole work nor any part has been or shall be submitted by me for a degree at this or any other University; that it is my work in design and in execution, and that all material contained here in has been duly acknowledged.

Signed: ----------on the ----------day of ----------year------

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DEDICATION

What a privilege to dedicate this dissertation, in memory of my dear late father, Cosmas Musonda, to my dear mother, Mary Musonda, for their care and love, my husband Tiens and our children, Kiznski, Musonda and Tiens Jnr, for their patience, support and tolerance during my long absence from home during the course work and fieldwork. It is greatly appreciated. We thank God the Almighty for blessing us abundantly.

This study is also dedicated to all the developing countries in Sub-Saharan Africa with a high burden of HIV/AIDS/TB requiring quality laboratory systems services to support the scale up and implementation of ART services.

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ABSTRACT

The aim of the study was to determine the challenges of scaling up and strengthening quality-assured laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on Anti- retroviral Therapy (ART). The objectives of the study were to: review the current national HIV/AIDS/STI/TB policy, Laboratory policy, ART strategic plan and guidelines on the implementation of ART services in Zambia; assess the knowledge, attitudes, and practices (KAP) of medical doctors/clinicians and knowledge and practices of laboratory staff in the diagnosis and monitoring tests for HIV/AIDS patients on ART; assess the quality of laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia compared to WHO standard guidelines; quantify the time taken for CD4 count results to reach the ART centres and determine the difference between the knowledge, attitudes and practices (KAPs) of medical doctors/clinicians in the ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.

The study design was a cross-section descriptive survey of one hundred and thirty-seven (137) ART centres in the public health sector of the nine (9) provinces in Zambia. The study population consisted of six directors and managers from the Ministry of Health at national level, medical doctors/clinicians, laboratory staff, district directors of health, in charge of ART centres, and data-entry clerks in charge of Health Information Management Systems (HIMS) from one hundred and thirty-seven (137) ART centres in the public health sector in Zambia.

The study findings indicated that only 23% of public sector laboratories were offering a full complement package of quality-assured laboratory services to support the ART programme in Zambia. The HIV/AIDS policy, Laboratory policy, Laboratory Standard Operating Procedures (SOPs) and guidelines on ART scale-up implementation plans exist at national level but had not been fully disseminated to all the ART centres. The average number of qualified laboratory staff at district hospitals surveyed was one (1) qualified laboratory personnel which is lower than the WHO recommendation of four (4) staff per district hospital. Most of the laboratories had no CD4 count machines to support ART

services. Unfortunately, CD4 count results took more than a week to reach the ART centres. Laboratories surveyed indicated a lack of equipment maintenance plans and service contracts. External Quality Assessment for diagnosis and monitoring tests for HIV/AIDS patients on ART was not yet well established. The findings also indicated that Medical Doctors/Clinicians working in the ART centres with laboratory services to support ART programme had better prognosis and treatment of patients on ART compared to those working in the ART centres without laboratory services. There was no difference in the knowledge, attitude and practices of Medical Doctors/Clinicians in the diagnosis and monitoring tests for the management of HIV/AIDS patients on ART in ART centres with and without laboratory service to support the ART programme in Zambia.

In conclusion, the Ministry of Health should improve and increase accessibility to fully functional laboratory services to support ART programmes in order to reduce turn-around time for the CD4 count results to reach the ART centres. CD4 count machines should be provided to all the laboratories in ART centres and include service maintenance contracts to support ART services. The policy and decision makers should improve and strengthen the quality of laboratory services by disseminating the National HIV/AIDS policy, Laboratory policy, Laboratory SOPs and guidelines on ART scale-up implementation plan. The recruitment, training and improvement of redistribution of qualified staff should be accelerated to accommodate the current high workload, range of tests performed and an increase in laboratory operations with ART scale-up programme. A standard format of recording and reporting CD4 count results should be put in place (i.e. computerised or manual system). The Ministry of Health should develop guidelines and establish quality assurance systems and affiliate the laboratories to participate in the SADC regional External Quality Assurance for accreditation such as the South African National Accreditation Systems (SANAS), to support the ART programme.

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LIST OF ACRONYMS

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CIDR2	Centre for Infectious Diseases Research in Zambia
EQA	External Quality Assessment
FTE	Full-time equivalent
GDP	Gross Domestic Product
HAART	Highly Active Antiretroviral Treatment
HIMS	Health Information Management System
HIV	Human immunodeficiency virus
IQC	Internal Quality Control
MAP	Multi-country AIDS Project
MDGs	Millennium Development Goals
MERC	Medunsa Ethics Research Committee
MOH	Ministry of Health
NAC	National AIDS Council
PEPFAR	President's Emergency Plan for AIDS Relief
PLHA	People Living with HIV and AIDS
PRB	Population Research Bureau
QA	Quality Assurance
REPC	Research Ethics and Publication Committee
SOPs	Standard Operating Procedures
SPSS	Statistical Package for Social Sciences
STI	Sexually transmitted infections
TAT	Turn-around time
TB	Tuberculosis
TDRC	Tropical Disease Research Centre
UNAIDS	Joint United Nations Programme on AIDS

UNZA	University of Zambia
USAID	United States Agency for International Development
WHO	World Health Organization
ZDHS	Zambia Demographic and Health Survey
ZPCT	Zambia Prevention Care and Treatment

LIST OF OPERATIONAL DEFINITIONS

OPERATIONAL DEFINITIONS (KEY CONCEPTS)

The Challenges (problems) of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART are problems which need to be overcome by identifying and analyzing the root causes. Thereafter solutions have to be provided and implemented that will address the need for increasing the quality of laboratory services in diagnosis and monitoring tests (Full Blood Count, Creatinine, Liver Function Tests and CD4 Count) for HIV/AIDS patients on ART.

Scale up ART: is the process of reaching universal access to Antiretroviral therapy and increasing the number of treatment centres.

The WHO 3 by 5 Initiative: Treat three million people living with HIV/AIDS by 2005. Zambia embraced the Global 3 by 5 targets that aimed to have three million people worldwide on ART by end of the year 2005. The World Health Organisation (WHO) leading the global efforts to achieve this goal, developed a strategy that intended to provide focused support to highly affected countries such as Zambia.

Quality of Laboratory Services: is the degree to which services for individuals and populations increase the likelihood of desired laboratory outcomes and are consistent through the use of new technologies, financial and human resources.

ART Centre: is defined as a health facility with a full complement of laboratory support (CD4, Chemistry and Haematology functions) including issuance of antiretroviral drugs.

Outreach/Mobile ART Centre: is defined as a health facility with partial laboratory support (chemistry and Haematology functions only, CD4 is referred out).

WHO staging for HIV/AIDS for adult patients in resource-limited settings: is when HIV-infected adults and adolescents should start the antiretroviral treatment when the infection has been confirmed and one of the following conditions is present:

- Clinically advanced HIV disease;
- WHO Stage IV HIV disease
- WHO Stage III disease with consideration of using CD4 cell counts of less than and equal to 350/ cubic millimetres
- WHO Stage I or II if HIV disease with CD4 cell count less than 200/cubic millimetres.

CHAPTER I

INTRODUCTION

1.1 Introduction

This chapter outlines the broad field of study on the global pandemic of HIV/AIDS and the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy in Zambia and leads to the focus of the research problem statement.

Laboratory services are a critical component of the delivery of effective quality health care systems. HIV infection in humans may lead to the development of immunological responses that make laboratory support critical in all areas of HIV diagnosis and management. Diagnosis of HIV infection cannot be established by any means other than serological tests. The CD4 lymphocyte count is a prerequisite for the initiation of antiretroviral therapy and for monitoring the treatment outcome.

The laboratory services provide a basis for good clinical diagnosis and patient management but are also an objective means to manage the patient's response to treatment and monitor disease trends. The role of the laboratory services in HIV prevention and intervention strategies is increasingly being recognised especially in the implementation and monitoring of ART in resource-poor countries. The capacity of the laboratory needs to be strengthened to cope with the scaling up of HIV intervention programmes and provide effective support for HIV/AIDS epidemic response.

1.2 Prevalence of HIV/AIDS

The Human Immunodeficiency Syndrome has continued to spread across all continents for the past two decades, killing millions of adults in their prime, disrupting and impoverishing families, turning millions of children into orphans. This has weakened the workforce, thereby threatening the social and economic fabric of communities as well as the political stability of nations. The World Health Report of 2003 puts HIV/AIDS as the leading cause of death in adults aged 15 – 59 years, killing 5 000 men and women in this age group, and almost 1 000 of their children every 24 hours in Sub-Saharan Africa. Currently Sub-Saharan Africa has 25.3 million people living with HIV/AIDS (PLHA). Of these, 16.4 million have died (WHO 2006a). The greatest tragedy is the growing number of orphans, estimated at 13.2 million worldwide in 2006 of which 12.1 million are in Africa. The advent of HIV/AIDS has caused a re-emergence of TB epidemics throughout Southern Africa, with as many as two-thirds of TB patients likely to be HIV positive.

Southern Africa has the highest burden of the worldwide HIV/AIDS pandemic. The emergence of HIV/AIDS in Africa has weakened societies and their economical status, making it even more difficult to ensure food security, education, health and other basic services (WHO 2003).

In 1996 during the Vancouver International AIDS Conference, it was learnt that triple combination therapy with antiretroviral drugs had made a critical breakthrough in the care of HIV-infected individuals. This led to the United Nations' agencies, initially the Joint Programme on HIV and AIDS (UNAIDS), closely followed by the World Health Organisation (WHO) and the World Bank, putting in place mechanisms to increase access to antiretroviral therapy (ART) and related care for those who needed it most particularly in the resource-limited settings. UNAIDS put in place the Medical Access Programme in 1996-1998 in collaboration with some drug companies initially to benefit four countries, namely Uganda, Ivory Coast, Chile and Vietnam. This was followed by

the World Bank, which allowed some countries to use a portion of the Multi-country AIDS Project (MAP) funds to buy ARV drugs. The big push came from the WHO through their 3 by 5 programme which aimed to put three million individuals on ART by the end of 2005. Although the campaign failed to reach the target of three million in sub-Saharan Africa, it was able to increase the number of individuals on ART from approximately 100 000 in 2003 to 810 000 by the end of 2005. According to the article by Harries Et al. (2006), access to ART was further accelerated by the introduction of the United States President's Emergency Plan for AIDS Relief (PEPFAR) Programme. PEPFAR is now benefiting 15 countries most affected by the HIV pandemic, including Zambia and also contributes approximately 50% of its budget to treatment, and the Global Fund for AIDS, TB and Malaria.

The Resolution agreed to and adopted by the United Nations General Assembly, 60/262 87th Plenary Meeting, Lome (2006), is a political declaration on HIV/AIDS, which reads as follows: *"Therefore, we ……commit ourselves to pursuing all necessary efforts to scale up nationally driven, sustainable and comprehensive responses to achieve broad multi-sectoral coverage for prevention, treatment, care and support, with full and active participation of people living with HIV, vulnerable groups, most affected communities, civil society and private sector, towards the goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010."*

Despite the progressive increase in access to ARV drugs in countries with limited resources promoted by the 3 by 5 initiatives, the World Health Organisation (WHO) recognised that the limitations of laboratory capacity in resource-poor settings could be a significant barrier in the way of reaching the planned treatment target. The WHO states in its global HIV Antiretroviral Therapy (ART) guidelines for resource-limited settings, that it will work with the international community and countries to improve the laboratory infrastructure at national and regional levels so as to permit wider availability of HIV

testing, CD4 testing, wider availability of automated haemoglobin and chemistry testing and a national availability of viral-load testing while the capacity of HIV drug-resistance testing should be available at regional level (WHO 2003).

Zambia is one of the Sub-Saharan African countries worst affected by the HIV and AIDS pandemic. Estimates put the prevalence rate at about 16 percent among the 15-49 years age group and about 1 million Zambians are infected with HIV, of which over 200 000 are in need of ART. HIV rates vary considerably among and within provinces, ranging from 8% in Northern Province to 22% in Lusaka Province. There is a higher prevalence in urban areas with 23% HIV infected people, compared with 11% in rural areas (Zambia Central Statistics Office 2002).

Since the first diagnosed case of AIDS in Zambia in 1984, the pandemic is now showing signs of stabilization in urban areas. However, the rates continue to rise in some rural areas. The AIDS epidemic poses serious health, development and security challenges. The Zambian Government has since declared HIV/AIDS as a national disaster and has developed multi-sectoral strategic plans to stem the rapid spread of the epidemic.

1.3 ARV Policy and Implementation

The Zambia National HIV/AIDS/STI/TB Policy which was launched in June 2005 provides the framework for addressing the HIV/AIDS/STI/TB situation in Zambia. It outlines the causes and factors that perpetuate transmissions, including the debilitative effect on the Zambian population. The policy also outlines the response and impact mitigation interventions that are already in place and states the vision, measures institutional and legal frameworks necessary for implementation. The goal of the National HIV/AIDS/STI/TB Strategic Framework for 2006-2010 is to prevent, halt and begin to reverse the spread and impact of HIV and AIDS by 2010 (National HIV/AIDS/STI/TB/Council 2006).

The Ministry of Health has developed an implementation plan for the scale up of HIV care and ART services from 2006-2008 (Ministry of Health 2006). The scale up plan is based on the National HIV/AIDS/STI/TB Strategic Framework for 2006-2010. The former 2004-2005 scale up plan contributed to the comprehensive care and treatment of 51 764 people living with HIV/AIDS by December 2005. The most recent 2006-2008 scale up plan is aimed to increase the comprehensive care and treatment to 130 000 people in need of ART by December 2008. The scale up programme is implemented along nine main intervention strategies namely:

- Creating an enabling legal/policy environment for rapid ART scale up;
- Increasing access to ART services for eligible persons nationwide;
- Developing and implementing strategies to strengthen human resource development and management in order to increase the number and capacity of health workers required to effectively deliver HIV care and ART services, strengthen the health infrastructure, laboratory, pharmacy, and imaging services for accelerating HIV care and ART services;
- Strengthening the community partnership;
- Strengthening the systems for procurement and storage;
- Improving distribution and logistics;
- Strengthening monitoring and evaluation systems including surveillance and operations research;
- Developing and strengthening national quality evaluation and accreditation systems; and
- Strengthening programme management and coordination for the health sector HIV/AIDS prevention care treatment and support at all levels.

Lessons learnt from the evaluation report of the National ARV Programme 2004-2005, were that the ART implementation plan was well disseminated at the central level only

but not at the lower levels and the majority of the lower levels had not seen the HIV/AIDS Policy. The ART services were expanded but there was only a partial implementation of the free ARV policy because of difficulties encountered due to lack of revenue for sustaining the activities. There was a large gap between private and public health institutions in the implementation of ART. Guidelines were lacking at almost all ART sites and there was poor infrastructure for laboratories, imaging and pharmacies. The frequent stock-out of ARV drugs and laboratory reagents was mainly due to poor logistic management systems. The biggest challenge was the shortage of human resources to deliver and support ART services (Ministry of Health 2006).

The management of HIV/AIDS with antiretroviral (ARV) drugs has been practised in the private sector in Zambia since 1996, soon after the discovery and wide use of the drugs in other parts of the world. The application of Antiretroviral Therapy (ART) in the public sector was limited to research purposes only but in 2003 the Zambian Government made a policy decision to make ART free and universally accessible to people in Zambia through the public sector. The programme was implemented in phases, beginning with two pilot centres at the University Teaching Hospital (UTH) Lusaka and Ndola Central Hospital, to be extended to provincial hospitals and eventually to district hospitals (Ministry of Health 2004). By the end of 2005, an estimated 50 000 people living with HIV and AIDS (PLHA) out of an estimated 200 000 persons requiring treatment were on ART. Currently there are 330 ART centres in Zambia (Ministry of Health 2007) ART is also being provided in a number of private clinics and at all the provincial hospitals in the public sector, some district and some urban health centres. The Ministry of Health (2006) estimated the total number of patients on ART in the public sector to be 90 000 by March 2007.

Zambia embraced the Global 3 by 5 targets that aimed to have three million people worldwide on ART by end of the year 2005. The World Health Organisation led the global efforts to achieve this goal and developed a strategy that aimed to provide focused

support to highly affected countries such as Zambia. The target for Zambia was to put 100 000 people on ART by the end of 2005. In order to implement the scaling up of and access to antiretroviral therapy it was necessary to build capacity and strengthen the laboratory diagnosis and monitoring for HIV/AIDS patients on ART. This was to be implemented following WHO guidelines on laboratory services for diagnosis and tests for monitoring HIV/AIDS patients on ART (WHO 2004).

1.4 Laboratory Policy and Strategic Plan

Medical laboratory services are critical in the delivery of health care, yet they are often a neglected component of health systems in resource-poor countries. The laboratory service plays a pivotal role in patient care and management and is a source of reliable information for policy development and health planning. There has, however, been insufficient long-term investment in the strengthening of laboratory systems and services in many resource-poor settings with a high burden of the key diseases, HIV/AIDS, TB and Malaria. Petti Et al. (2006) report that "many resource-poor countries with high prevalence of HIV/AIDS experience severe challenges with planning, organization, management and delivery of accessible, quality-assured laboratory services to support the national scale up of testing and care including monitoring the treatment of ART". Yet many resource-poor countries do not yet have a government-approved national laboratory policy, strategic plan or dedicated budget for laboratories. There is lack of an articulated laboratory leadership and direction for effective laboratory management. In addition, many countries do not yet have a national quality assurance system, hence the quality of the laboratory results is not known, leading to mistrust and underutilisation of the laboratories. There has been little evidence of an overall vision or clear communication of the critical role of the laboratory in health care delivery.

The underlying reason for the gaps and weaknesses in laboratory service provision is historical. For much of the developing world, access to these tests and laboratory capacity is severely limited and even the most basic services are often unavailable or unreliable. According to the United Nation's Global Report on HIV and AIDS (UNAIDS 2006), "over the next few years most of the patients in low- and medium-income countries will continue to be monitored clinically".

In Zambia, the overall goal of health reform is to improve the health status of all Zambians through the vision of "providing Zambians with equity of access to cost effective quality health care as close to the family as possible" (Ministry of Health 2005). The underlying principles of the health reforms are leadership, accountability and partnership.

The "Situation Analysis of Medical Laboratory Services in Zambia" (Ministry of Health and Irish Aid 1996) highlights a number of major constraints in providing quality laboratory services. These include a lack of basic inputs, (i.e. supplies and equipment, poor infrastructure and limited human resources). In order to address these constraints, a National Medical Laboratory Policy was developed in 1997.

One of the objectives of the policy is to improve laboratory diagnostic services in support of the Ministry of Health's goal to achieve equity of access to cost effective quality care as close to the family as possible. The National Medical Laboratory Policy of 1997 was considered a necessary prerequisite to develop coordinated strategies to address the challenges in the context of the health reforms and user expectations (Ministry of Health 1997). The Laboratory Policy is based on appropriate needs assessment and provides evidence-based strategies aimed at improving the quality of laboratory services. As a result of the Laboratory Policy, laboratory services have been given a high profile in all the National Health Strategic Plans that have been developed. The National Laboratory Policy of 1997 is currently under review to include HIV/AIDS-related issues and the

ART scale up. The Ministry of Health ART Scale Up Plan 2006-2008 demands that laboratory services are provided at the same place as the ART services and that provisions to ensure testing are feasible at the earliest possible time at the next higher level. A reliable and dependable network for easy specimen transfer is therefore necessary. Strategies must be developed to ensure equitable access to laboratory services (Ministry of Health 2006).

Zambia has developed Ministry of Health national strategic plan for 2006-2010, the objective of which is "Towards attainment of the Millennium Development Goals (MDGs) and national health priorities." The plan articulates issues on laboratory strategy to support the ART scale up.The Ministry of Health Strategic Plan 2006-2010 vision is equity of access to assure quality cost-effective and affordable health services in Zambia with an overall goal of further improving health services delivery in order to significantly contribute to the attainment of the health MDGs and national health priorities.

Currently the importance of laboratory services in the Ministry of Health has been given a higher profile mainly due to the scaling up of ART which demands certain laboratory tests for monitoring patients' response to ART, because laboratory baseline data and follow-up data is critical for the management of HIV/AIDS patients on ART (Ministry of Health 2005).

The Millennium Development Goals (MDGs) Declaration was signed in 2000. The MDG number six (6) objective is to combat HIV/AIDS by halting and beginning to reverse the spread of HIV/AIDS by the year 2015 and the target set for this goal is to achieve universal access to treatment of HIV/AIDS to all those who need it by 2010 (UN Global Report on HIV/AIDS 2006). To achieve this target requires scaling up and strengthening of the laboratory services to support the ART programme. It is very important that infrastructure, expertise and networking be strengthened in the country and among developing countries.

1.5 Problem Statement

Zambia is one of the high disease-burden countries in Africa with high morbidity and mortality due to HIV/AIDS. The ART intervention programme has become a priority in the management of HIV/AIDS. From 2004 to date Zambia has been rolling out and scaling up the access to antiretroviral treatment in accordance with the WHO guidelines. The Ministry of Health in 2007 reported that there were 246 ART Centres in the public sector across the country, but only 57/246 (23%) had laboratory services that provide full diagnosis and monitoring tests for HIV/AIDS patients on ART. Furthermore the distance between some of the full complement laboratories from the ART centres was not in accordance with WHO guidelines. Consequently, in many situations clinicians had to clinically stage and manage patients according to WHO staging guidelines without any laboratory support or evidence (WHO 2006a). In addition, the antiretroviral treatment was given to patients without performing monitoring tests for response and toxicity to therapy. This poses a risk to some HIV/AIDS patients on ART to develop pathophysiological damage and drug resistance (WHO 2003).

1.6 Research Questions

1.6.1 Are there national HIV/AIDS/STI/TB policy, Laboratory policy, ART strategic plan and guidelines on the implementation of ART services in Zambia?

1.6.2 What are the levels of knowledge, attitude and practice (KAP) of Medical Doctors/Clinicians and knowledge and practice of Laboratory staff of the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?

1.6.3 What is the quality of the laboratory services in performing diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia compared to the World Health Organization (WHO) standard guidelines?

1.6.4 What is the turn-around time (TAT) for CD4 count results to reach ART centres in Zambia?

1.6.5 Is there any difference between the KAPs of Medical Doctors/Clinicians in ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART?

1.6.6 What are the predictive values and discriminative powers of performing diagnosis and monitoring tests for HIV/AIDS patients on ART by using the KAP of Medical Doctors/Clinicians with and without laboratory services to support ART programmes in Zambia?

1.7 Study Aim

The purpose of the study was to determine challenges of scaling up and strengthening laboratory services in the diagnosis and monitoring tests for HIV/AIDS patients in Zambia and recommend solutions.

1.8 Objectives of the Study

The objectives of the study were to

1.8.1 Review the current national HIV/AIDS/STI/TB policy, laboratory policy, ART strategic plan and guidelines on the implementation of ART services in Zambia;

1.8.2 Assess the knowledge, attitudes, and practices (KAP) of medical doctors/clinicians and knowledge and practices of laboratory staff of the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia;

1.8.3 Assess the quality of laboratory services available for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia compared to the WHO standard guidelines;

1.8.4 Determine the turn-around time for CD4 count results reaching the ART centres in Zambia;

1.8.5 Compare the KAP of medical doctors/clinicians in ART centres with and without laboratory services;

1.8.6 Determine the predictive value and discriminative power of performing diagnosis and monitoring tests for HIV/AIDS patients on ART by using KAP of medical doctors/clinicians with and without laboratory services to support the ART programme in Zambia.

1.9 Study Rationale

Bates and Maitland (2006) state that laboratory services are some of the most neglected areas of health care provision and are disproportionately affected by the staff shortages, poor communication, inadequate equipment, low morale and lack of training that impinge on all those involved in delivering health care in poor African countries. The study assesses and determines the laboratory capacity and Knowledge, Attitude and Practices (KAPs) as well as skills of laboratory staff to perform laboratory diagnosis and monitoring tests of HIV/AIDS patients on ART.

Antiretroviral Therapy Treatment (ART) requires the use of laboratory services. Scaling up of the laboratory services requires support by an appropriate quality assurance system. It is acknowledged that the challenges of scaling up laboratory services in Zambia is a progressive way of ensuring that the implementation of the ART programme is well supported by quality-assured laboratory services. The decision about when to start treatment is guided by CD4 cell counts, with some guidelines advocating earlier treatment for patients with very high viral loads. Treatment failure is usually recognised by rising viral-load measurements. This enables clinicians to make a switch in treatment to second-line drugs.

So far, there is limited literature on this problem. The study will therefore contribute additional information on knowledge to public health practice, policy makers, management of health services, implementers, laboratory staff, HIV/AIDS patients, health caregivers/workers (HCW) and researchers on the need for scaling up of quality-assured laboratory services for monitoring HIV/AIDS patients on ART. Planners will be provided with information to help them allocate resources more efficiently to strengthen and build the capacity of the laboratory services in support of scaling up the ART programme.

The results of the study will guide clinicians in making decisions on when to start or change ART. Furthermore, information will be shared with other developing countries especially in Sub-Saharan Africa with a high disease burden of HIV/AIDS/TB in scaling up and strengthening of laboratory services to provide quality monitoring tests for HIV/AIDS patients on ART in accordance with WHO guidelines.

1.10 Conceptual Framework

The conceptual framework of this study was based on the generic WHO guidelines for the year 2003 on the scaling up of ART services in resource-limited settings (WHO 2003). It must be noted that in the Sub-Saharan African countries there are indeed challenges regarding the implementation of ART services in relation to laboratory services support. So far there has not been a study that addresses the challenges on the scaling up of laboratory services to support the ART programme.

The conceptual framework is as illustrated in Figure 1. It tries to depict the relationship between the ART services and the quality-assured laboratory services support. The framework is based upon a combination of two framework models, the WHO (2001) Health System, and the Public Health System (Handler, 2001). The Quality-Assured Laboratory Services framework consists of four components which can be considered to be in relation to each other and are divided into three objectives under the following main headings:

1. the core functions (policy, health management systems, planning and budgeting);
2. the structural capacity inputs required at the facility level (human resources, infrastructure, equipment and organisation of ART services); and
3. the process of performing the diagnosis and monitoring test for HIV/AIDS patients on ART.

Then there are the outcomes, which are increased timely effective diagnosis, increased efficiency of laboratory service, and increased clinicians' confidence in the laboratory services, patient satisfaction, and equity of access to the laboratory services. The impact on patients will be increased timely diagnosis for HIV/AIDS patients on ART, early treatment and monitoring tests, early detection of drug resistance and treatment adherence problems. The priorities of the laboratory services are presented along with the framework. The framework explains the relationship among the various components of

the laboratory services which are essential steps towards providing quality laboratory services.

The framework will be used for analysis of quality-assured laboratory services to determine at which component of the framework the challenges are and to recommend countermeasures or solutions for the scaling up and strengthening of laboratory services for the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.

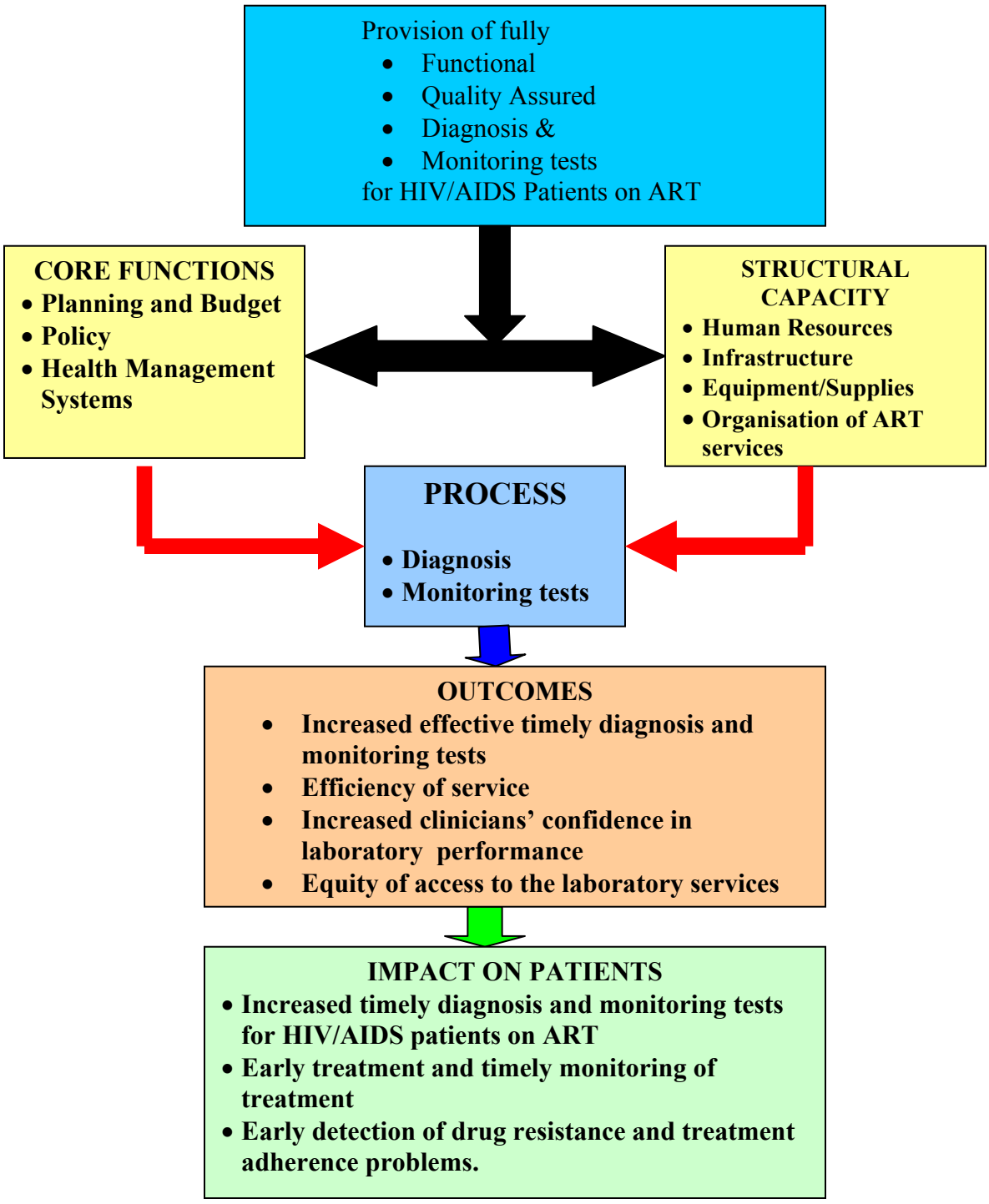

Figure 1: Conceptual framework of fully functional quality-assured laboratory services in ART centres.

Source: WHO (2001) Health System and Public Health System, (Handler, 2001) with modification.

1.11 Conclusion

In conclusion, this chapter laid the foundation for the research study on the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy in Zambia. It introduced the research problem statement, research questions, objectives, and the conceptual framework. The research study was justified on this foundation. The study proceeds with the next chapter on literature review.

CHAPTER II

LITERATURE REVIEW

2.1 Introduction

This chapter aims to build a theoretical foundation upon which to study the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy in Zambia is based. The literature review aims to identify research issues which are worth researching because they are controversial and have not been answered by previous researchers.

A review of the literature pertaining to the challenges of scaling up laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on antiretroviral therapy in Zambia will be discussed under subheadings of the six themes as follows:

1. HIV/AIDS policy;
2. ARV scale up strategies, implementation plan and health management systems;
3. Human resources management;
4. ART scale up interventions;
5. Quality of laboratory systems; and
6. Clinicians' perception and value of the laboratory services for ART monitoring tests.

2.2 HIV/AIDS Policy

HIV/AIDS is a major development crisis that affects all sectors. During the last two decades the HIV/AIDS epidemic has spread relentlessly, affecting people from all walks of life and decimating the most productive segments of the population, particularly

women and men between the ages of 20 and 49 years. The epidemic is a serious threat to the Sub-Saharan countries' social and economic development and has serious and direct implications for their social services and welfare. Given the high prevalence of HIV in the society and in the absence of a cure, the devastating impact of the epidemic is almost incomprehensible. In view of the above, a strong political commitment and Government leadership is necessary to spearhead the fight against the epidemic. In most of the developing countries HIV/AIDS has been declared a national crisis and is now top priority on the development agenda of the Government along with poverty alleviation and improvement of the Social Sector Services (UNAIDS 2006).

As the HIV/AIDS epidemic affects all sectors, its control demands a well-coordinated response. Therefore, it has become necessary for all the countries with an HIV/AIDS epidemic to have a national policy which provides a framework, direction and general principles for the national response interventions for the prevention of the disease, the care and support of those infected and affected by the epidemic, and mitigation of its impact. However, in view of the complex social, ethical, legal, cultural and economic aspects of the HIV/AIDS epidemic, the national policies are subject to review from time to time in order to address emerging issues. The overall goal of these national policies on HIV/AIDS is to provide a framework for leadership and coordination of a national multi-sectoral response to the HIV/AIDS epidemic. As of now almost all the Sub-Saharan African countries hit by the epidemic have national policies in place, for example, Uganda1998 (Coutinho Et al.2004), Tanzania 2001 (Prime Minister's Office 2001), Kenya 2002 (Denje Et al.2004), South Africa 2004 (Ministry of Health 2000) and Zambia 2005 (Ministry of Health 2006).

The main objective of the Zambia National HIV/AIDS/STI/TB Policy of 2005 was to attain a society in which the prevalence and impact of HIV/AIDS/STI/TB were significantly reduced to levels where they become manageable socio-economic and public health problems in which people infected and affected by HIV/AIDS/STI/TB live positively without stigma and discrimination. Policy measures include the following: Prevention and Control, Treatment, Care and Support, and Institutional arrangements.

The policy has been operationalised through the development and implementation of the National HIV/AIDS/STI/TB Strategic Plan, 2006. Sectoral, thematic and institutional action plans on HIV/AIDS/STI/TB form part of the policy operationalisation process. The Ministry of Health is responsible for the implementation of the policy. The various sectoral ministries, non-governmental organisations, community-based organisations and the private sector are required to play their respective roles. The overall monitoring and evaluation of the policy based on implementation is conducted by the Cabinet through the Ministry of Health in conjunction with the National AIDS Council (NAC). In order to meet the demand that requires implementation of policy, the Government of Zambia has scaled up resource mobilisation, both domestic and international, by establishing a National HIV Trust Fund, made annual allocations in the national budget and also raised funds from other sources including bilateral and multilateral cooperating partners and other stakeholders (National HIV/AIDS/STI/TB Council 2005).

2.3 ARV Scale up Strategies, Implementation Plan and Health Management Systems

The use of antiretroviral drug therapy in developing countries has an effect on AIDS-related mortality and morbidity. Studies conducted by Edward and David (2006) have shown that while the ultimate goal of ART is to reduce HIV-related morbidity and mortality, the initial goal is full and durable viral suppression. Full viral suppression allows for maximum reconstitution or maintenance of immune function and minimises the emergence of drug-resistant virus selected by ongoing replication in the presence of antiretroviral drugs. The article published by Waineburg and Friedland (1998), indicates that drug-resistant strains of HIV selected through ongoing replication in the presence of ART can be transmitted to uninfected or drug-naïve patients, leaving them with fewer treatment options.

Despite this hope, control is required as the cost is still too high to implement the full scale range of services necessary for large scale up ofART programmes, especially

laboratory services, in most developing countries. Resource-limited countries have inadequate infrastructure and human resources. The available ART regimens are demanding and require full patient adherence for life. ARV drugs have side effects and may interact negatively with drugs needed to treat opportunistic infections commonly associated with AIDS. In view of the above, Tawtik et al. (2002) published an article on the guidance of the ART Programme in planning and management for resource-limited countries that seek to implement expanded ART and have to decide on treatment protocols, laboratory services, clinical care, counselling and pharmaceutical services.

Antiretrovirals (ARVs) alone are not the answer to the HIV/AIDS pandemic. Linked inextricably to the ultimate success of these drug interventions are logistic systems that ensure the safe and timely procurement and delivery of the drugs and laboratory commodities to the intended destinations, and provision to the people whose lives depend on them. Well functioning countrywide ART programmes require significant investments to build the capacity of a broad range of other technical and managerial fields of expertise from data analysts' procurement strategies to supervisory personnel. The needs of each country to support the ART programmes are different and defined in the national strategies. The strategies usually consist of components to support quality ART services, such as laboratory tests, training of and support for health care workers, infrastructure development, including clinics, counselling rooms, laboratories and distribution and logistic systems, monitoring and reporting systems and various other relevant components of treatment (Economic Commission for Africa CHGS 2004).

The United States President's Emergency Plan for AIDS Relief (2005) has moved rapidly to support national strategies for treatment in partnership with the public and private sector, committing more than US$ 231.9 million for ART or 40.8 percent of the total resources committed to prevention, treatment and care in 15 focus countries. In the first eight months of the Emergency Plan, the United States of America supported ART for 155 000 HIV-infected adults and children in the 15 focus countries, achieving 78% of its target by June 2005. The Emergency Plan is well on track to meet the goal of supporting

two million adults and children in five years (Presentations at HIV/AIDS Implementing meeting of the PEPFAR 2006).

A fundamental means of rapidly expanding services while developing sustainable capacity is to support national strategies to build HIV/AIDS care and treatment networks. Network systems ensure comprehensive reach of high quality services by building capacity to support centres of excellence at referral hospitals, with health professionals trained in all aspects of HIV/AIDS care and excellence, adequate infrastructure and laboratory capacity. These core institutions should link with the regional hospitals and district facilities down to community-level health centres, mobile units and community-based services. These linkages are shown in Figure 2 providing clinical support for laboratory tests, training, logistical and distribution systems, monitoring and reporting systems and other aspects of quality care treatment (WHO 2002).

In most of the developing countries where scale up of ART has been implemented, there has been political commitment by that government by constituting a National AIDS Council for development of policy in those countries. Under certain circumstances, changes in national government policy or legislation are required to bring greater flexibility to health care delivery. In Uganda and Haiti, home health aides perform routine follow-up and patient adherence counseling necessary to achieve a rapid scale up of quality ART (WHO 2003).

There is a global recognition that without strengthened health systems, greater access to antiretroviral therapy (ART) is unlikely to be achieved. Service delivery needs to be oriented from acute to chronic disease care, ensuring uninterrupted supplies of treatment and high levels of adherence over many years. If adequate resources are provided, the constraints to ART can be overcome. But there are a number of questions raised by Harries Et al. (2006) which need to be answered, such as: Is it possible, and what constraints need to be overcome to make ART available to large numbers of people who need it? How will the equity of access principle be maintained in the incremental process of scale up or roll out? Is it feasible to structure the investment in ART so that it does not

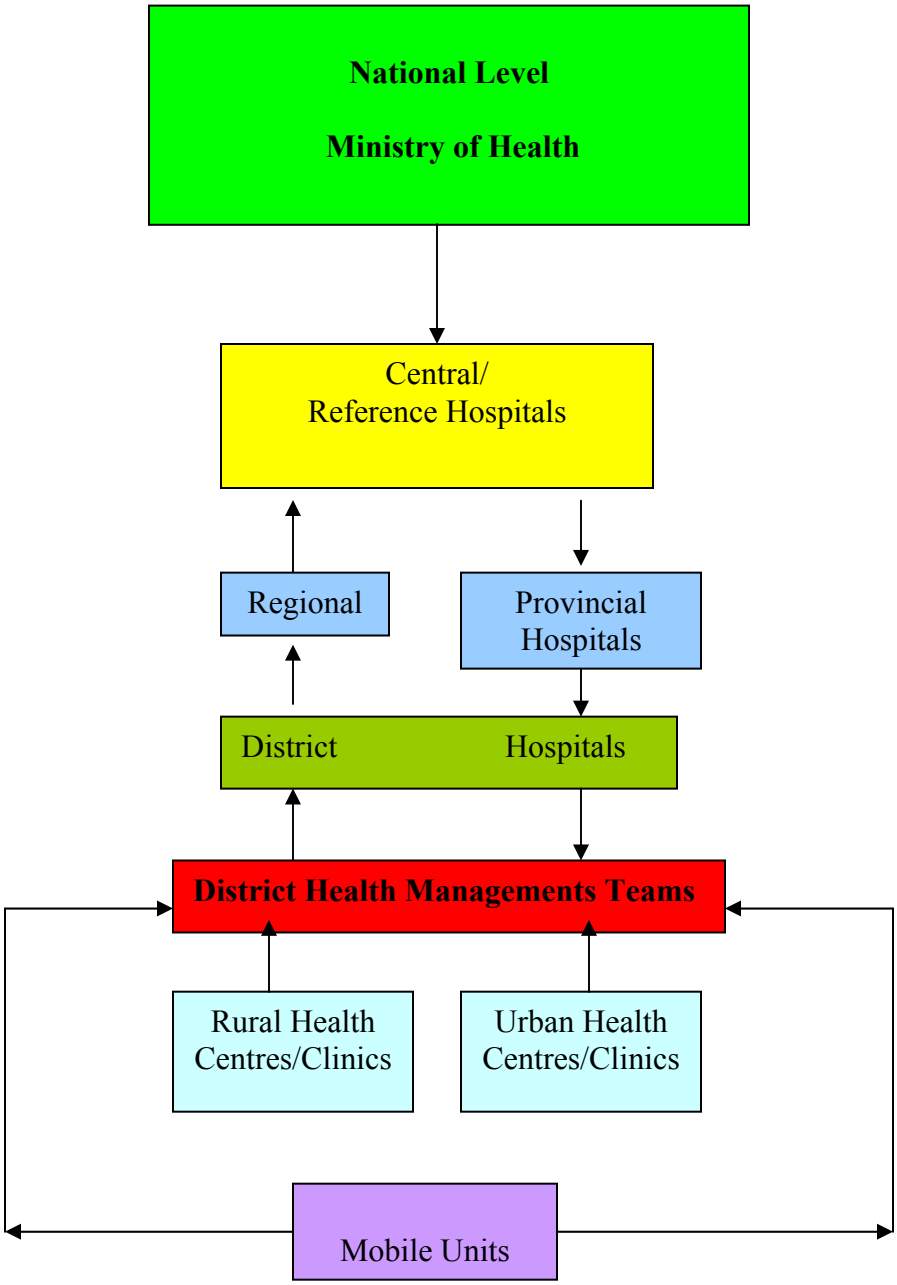

Figure 2: A model of quality ART services with linkages to support the services.
Source: WHO 2002.

divert scarce resources away from other essential activities instead of benefiting the health system for delivery of all health programmes? According to Helens Et al. (2004),

these questions are not only confined to ART scaling up, but a renewed global concern to address the overwhelming disease burdens of Southern Africa.

In Zambia, Mulimbi (2009) recently reported in *The Post* that "People on Anti-Retroviral Therapy (ART) in St. Dorothy area, 85 kilometres from Solwezi General Hospital, have complained that since October 2008 they are taking the drugs without monitoring their CD4 count because of lack of transport to take their blood samples to Solwezi General Hospital for monitoring tests in response to treatment". The people said that "we are just drinking drugs without knowing whether we are responding to treatment or not as you know some of these drugs have side effects. But we have no option other than to just take the drugs as we have no money to be taking our blood samples to Solwezi General Hospital where there is a CD4 count machine"(Mulimbi 2009).

2.4 Human Resource Management

ART scale up requires tens of thousands of health care workers with the experience and training needed to treat many people with a complex medical intervention.

Although scientific data on health care personnel in resource-constrained settings, particularly Sub-Saharan Africa, are extremely difficult to collect, WHO surveys and general reports indicate that human resource capacity is generally extremely weak in such settings and in many places is a critically limiting factor in providing access to ART. According to the evidence provided by Kober and Van Damme (2004), ART scale up could fail on these grounds alone. A USAID article by Liese *Et al. (*2003) states that "many of those countries with the highest number of people living with HIV/AIDS have very few health care providers trained in comprehensive care for the disease." In acknowledgement of the situation, WHO's 3 by 5 (2003) plan calls for the rapid training of ten thousand workers in those countries with the highest number of PLHA to aid with the delivery of ARVs.

The seriousness of the situation is illustrated by Kombe and Smith (2003) who analysed the cost and resource requirements associated with providing ART through the Zambian Public Health Sector. Despite key findings indicating that the provision of highly active antiretroviral therapy (HAART) to all clinically eligible patients will be prohibitively expensive, Kombe and Smith (2003) suggest that human resource capacity may become the most critical rate limiting factor. On the other hand, 10 000 people still represent only about 10 percent of the total number of Zambians currently in need of ART, and many more infected but currently immuno competent Zambians will join these ranks over the next decade. Providing full ARV coverage for the entire clinical population in need, as it now stands (i.e. about 100 000 people, rising to about 330 000 in five years, but also assuming a 20 percent mortality rate), would marginally require an additional 130 full-time equivalent (FTE) nurses and physicians in the first year and 429 by the fifth year, 316 laboratory technicians in the first year and more than 1 000 by the fifth year. Furthermore, these estimates do not even begin to address additional voluntary counselling and testing (VCT) staffing needs. Clearly, the human workforce needs for full coverage are immense.

Recent data related to the overall health-sector human resource crisis in Africa , collected for the United States Agency for International Development (USAID) in 2004 reveals that newly-constructed health facility structures, including clinics and hospitals, remain unstaffed or understaffed throughout Sub-Saharan Africa, as general efforts to expand the network of such facilities have greatly outpaced efforts to build human resource capacity. For example, Lynch and Diallo (2001) and the USAID (2003) reports that despite vigorous efforts by the government of Mali to expand the number of its community health centres to 533, forty-three percent (43%) of these centres were not functioning as of January 2001, with the majority not operating because of a shortage of personnel to staff them. As it takes three to four years to train and deploy nurses and five or more years to train and deploy physicians, it is clear that without sufficient and aggressive training initiatives, this gap between physical infrastructure and human resources capacity will continue to widen and it is also compounded by the brain drain.

Given the desperate and growing demand for health workers and the loss of trained workers to better jobs in more well-to-do countries, many African nations have reportedly been encouraged to adopt human resource policies that lead to the deliberate overproduction of health workers to fill the growing gaps in human resource capacity. Schwab (2001), Puku (2002) and Narasimhan Et al. (2004) say that filling these gaps is not a simple task. However, as the African health sector's human resources crisis is multidimensional, it involves a complex set of underlying upstream and more-proximal causal factors. The problem encompasses not only the scarcity of well-trained health workers, but also generally poor morale and staff motivation, insufficient management, an imbalance between urban and rural workforces, and strain on human resources caused by infrastructure changes and new, unfamiliar practices and technologies.

The burden of HIV/AIDS, which amounts to nearly one-fifth of the disease burden in Sub-Saharan Africa, has not only dramatically increased the patient volume and associated workforce needs, but has also led to the death of many health workers. According to USAID (2003), AIDS-related mortality accounts for 19 to 53 percent of all deaths among government staff, including public-sector health workers, in most African countries. Moreover, the number of hours or days of work lost due to AIDS-related illness can be substantial, further reducing actual workforce capacity. Unfortunately quantitative data and objective analyses of the situation are scarce. Most available data come from only three countries, Malawi, Zambia and Zimbabwe, although these are by no means the only countries facing this critical problem. The lack of data is due in large part to a generally nonexistent personnel information system, which in itself is indicative of how seriously neglected the issue is.

The human resource crisis in the health sector of resource-constrained settings reflects the underlying crisis in tertiary education throughout the developing world, particularly in sub-Saharan Africa. The quality of such education tends to be low. Access is limited, and as most health professional training is conducted under the auspices of national governments through their ministries of health, there is not enough public money

available to fund the numbers and types of formal per service training programmes that are needed. This is an issue that is discussed further below. In short, the production of new workers has not kept pace with the growing demand for greater workforce capacity. A recent report indicates that when countries receive aid to build schools and training hostels, they often do not receive the funds needed to support the organisational programmes those facilities house. Malawi Ministry of Health and Population (MOHP 1999), for example, has reportedly closed medical and nursing schools at midterm because of lack of funds to support faculty and student services. Between 1996 and 1999 two of Zambia's public universities reportedly received only 45 percent of expected funds from the treasury (USAID 2003).

In addition to physicians, pharmacists, nurses and other health care workers directly involved in care and treatment of HIV/AIDS patients, laboratory technicians are essential for the actual diagnosis and monitoring of tests of HIV/AIDS patients on ART. For example, as noted above, Zambia has estimated that its initial ART scale up programme (for 10,000 patients) will require 32 FTE laboratory technicians in addition to an estimated 13 FTE doctors and nurses and 15 FTE pharmacists (Kombe and Smith 2003).

The important role of laboratory technicians in ART scale up suggests the need for more of these personnel and improvements in their training, for compliance with good laboratory practice which is critical for quality laboratory services. Generally, problems with inaccurate laboratory analyses fall into one of three categories:

- pre-analytical (i.e. improper labelling and specimen mix-ups),
- analytical, (i.e. when a test is done correctly) and
- Post-analytical (i.e. when a test is done correctly, but the results are recorded incorrectly).

It is essential to identify and evaluate deficiencies in training programmes for laboratory technicians whose correction would minimize these errors. In Sub-Saharan Africa, Bates and Maitland (2006) found that some factors that may be contributing to poor compliance should be addressed, such as not having clear laboratory policies and procedures in place. Kober and Van Damme (2004) also show 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.

2.5 ART Scale up Interventions

In Kenya the scale up of ART was going on well, fostered by clear political commitment at a high level in 2003. Strategic and operational plans were developed to support the 3 by 5 goal. A pragmatic public health approach to ARV provision was adopted based on development and application of national guidelines, standardisation and quality control. Staff training was recognised as essential for successful implementation. Sufficient funding was secured for strengthening of laboratory services in terms of human resource development, infrastructure requirement and supplies (Wachira Et al.2006). Furthermore, Denje Et al. (2004) conducted a study in Mombasa on the laboratory challenges to start scaling up the ART programme. The lessons learnt were that the development and implementation of appropriate guidelines for sample flow and record keeping significantly improved the performance of the laboratory. However, staff shortages and increased workload related to the ART programme together with semi-automated equipment and manual methods limited the number of tests done which could hinder the ART scale up.

According to the Economic Commission for Africa CHGS (2004) report, the strategy for scaling up of ART in Senegal was by training all human resources required including the laboratory staff. Funds were to be made available to provide for laboratory support to perform monitoring tests for patients on ART.

Chasombat Et al. (2006) report that by year 2005 in Thailand, ART programmes were well established and were a success story. The laboratories were fully functional with all the prerequisites for monitoring HIV/AIDS patients on ART. Lessons learnt from the initiation and scaling up of the ART programmes showed that local leadership,

comprehensive training, adherence and coordination were essential to the programme's effectiveness and sustainability.

2.6 Quality of Laboratory Systems

Bates and Maitland (2006) write in an editorial that "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 impinge on all those involved in delivering health care in poorer African countries." The question to be answered is that as part of the roll out of antiretroviral therapy, laboratory services are now being scaled up in many low and middle-income countries, will the efforts be enough to provide high quality monitoring of people with HIV on AR? Further research studies required to be conducted to answer this question.

HIV/AIDS/TB and malaria are among the major public health problems in the resource-poor countries of Sub-Saharan Africa that require efficient and quality-controlled laboratory services for their management (Mhalu 2005). Harries Et al. (1993) 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."

Medical laboratory services should have the capacity to assist in early and reliable diagnosis and treatment, investigate disease outbreaks and collect reliable surveillance data for disease control. Comprehensive data collection and analysis are essential to inform policy making and planning whilst knowledge generation through research is required to solve local and national health problems (Petti Et al.2006).

Petti Et al. (2006) found that the underlying reason for the gaps and weaknesses in laboratory services provision is historical. In many countries there has been little

evidence of an overall vision or clear communication of the critical role of the laboratory in health care delivery. Hence, investments in laboratories have been inadequate, resulting in a crumbling infrastructure and run-down service.

The HIV/AIDS epidemic has increased the demands on laboratory services and exacerbated the pre-existing weaknesses. With the greater realisation over the last few years that laboratories have a critical role to play in fighting HIV/AIDS and advocacy from funding sources to build capacity for laboratory systems, there have been encouraging signs that this situation is gradually changing. The advent of antiretroviral treatment programmes, the launch of the WHO 3 x 5 initiative in 2003 to get three million people on antiretroviral treatment by the end of 2005 (WHO 2006b) and the availability of major funding on a scale not previously seen, for example, from the Global Fund Against AIDS, TB and Malaria (GFATM 2006) and the President's Emergency Plan for AIDS Relief (PEPFAR 2005), have heralded a change in attitude. However, because of the emphasis on rapid scale up of services, laboratory strengthening has often focused on developing appropriate technologies and providing equipment, supplies and technical training. Whilst these are very important, the concurrent strengthening of management and leadership has not been sufficient to leverage these inputs effectively. Even to improve and sustain the overall quality of laboratory performance and to develop the laboratory systems capacity requires to ensure a long-term sustainability on the quality of HIV/AIDS, TB and malaria care (Harries Et al.2006).

The prevention, diagnosis, care and treatment of HIV/AIDS require quality-assured laboratory support. HIV testing, to determine serostatus, can be divided into four types:

- voluntary counselling and testing (VCT),
- diagnostic HIV testing,
- routine offer (provider-initiated testing) and
- mandatory HIV screening (for blood and blood products).

The need for HIV testing services continues to increase as the HIV infection rate rises and countries recognise the need for people to know their HIV serostatus. Those who are negative can be encouraged to maintain their status and remain disease-free, whilst those who are HIV infected can be assessed for various care interventions (WHO 2006c).

The limited laboratory capacity in resource-poor settings, particularly in Sub-Saharan Africa, represents an important barrier to the scale up of ART. The WHO has promulgated a public health approach for scaling up antiretroviral therapy in resource-limited settings (WHO 2003). The WHO guidelines lay out the criteria for starting treatment, and when to change or stop treatment. The criteria for clinical and laboratory monitoring are documented for primary health care centres (level 1), district hospitals (level 2) and regional referral centres (level 3). These recommendations were further modified in December 2004 (WHO, 2004) and are summarised in Table 1.

Table 1: WHO recommendations for tiered laboratory capabilities for diagnosis and treatment for HIV/AIDS in resource-limited settings.

Diagnostic and monitoring laboratory tests	Primary Health Care	District Level	Regional/ Central Level
HIV antibody testing	X	X	X
Haemoglobin	d	X	X
Pregnancy testing	d	X	X
Malaria microscopy	d	X	X
Sputum smear microscopy for TB	d	X	X
FBC and differential		X	X
CD4 + cell count		X	X
ALT		X	X
CSF analysis (including India ink for cryptoccocal meningitis)		X	X
Syphilis screening and other STI diagnostic tests		X	X
Hepatitis B, hepatitis C serology, bacterial microbiology and cultures Diagnostic tests and procedures for Cryptococcus, toxoplasmosis and other major opportunistic infections		d	X
Full chemistry (liver enzymes, renal function, glucose, lipids, amylase, electrolytes)			X
HIV viral load			d

Source: WHO 2002 **KEY:** X = to be provided; d = desirable.

In South Africa, a case study was conducted by Medicines sans Frontiers (MSF) in July 2003 on access to ART in a primary health care setting experience of the Khayelitsha programme which was feasible and replicable. The importance of monitoring tests for patients on ART was recognized. The eligibility for ARV depended on CD4 cell counts of less than 200/mm^3. The CD4 cell counts were done by sending specimens to the National Health Laboratory Services in Johannesburg. They had a good referral transport system and the results were received back at the centre within 2 days. The turnaround was short and fast (MSF 2003).

Bekker *Et al. (*2006) reports that the experience of Medicines sans Frontiers (MSF) in the rural township of Gugulethu of Cape Town, South Africa, who successfully used small, remote operating laboratories, presents proof of the concept that peripheralization, capacity development and community ownership, may be another approach to meet the laboratory services support required for monitoring tests for HIV/AIDS patients on ART in resource-poor settings.

In Uganda, the Ministry of Health (2002) developed an ART policy whose ultimate goal was to provide a framework that was to allow universal access to ART to all in need who were clinically eligible. Hence, the 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 (Ministry of Health, Uganda, 2004).

According to the WHO (2003), the situation in Brazil was different from other countries affected by the HIV epidemic, since Brazil was a middle income country. 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.

2.7 Clinicians' perceptions of the value of Laboratory Services for ART monitoring tests

In most low and middle-income settings, the decision regarding when to switch patients from a failing regimen remains challenging because there is little consensus on when to act on decreasing CD4 cell counts (if available) and clinical events are often only very late signs of failure. Viral-load counting is even less common than CD4 cell counting, and even when available, the test can greatly increase the cost of managing a person with HIV (WHO 2005). So how can a clinician working with limited laboratory resources recognise treatment failure in these patients on ART before they become seriously ill or develop high level resistance? Nevertheless, studies by PEPFAR (2006) suggest that strategic use of viral-load tests will still be necessary to confirm any suspicion of failure made on the basis of falling CD4 cell counts, clinical signs or algorithms, especially in children.

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. Treatment failure is usually recognised 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 a change in treatment necessary, in general, the goal is to switch treatments before CD4 cells slip significantly and put the patient at risk of clinical progression, and also before ongoing viral replication on the failing treatment permits the accumulation of drug resistance mutations which could impair responses to subsequent regimens. But 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 (Kent et al.2003). The UN Global Report on HIV/AIDS (2006), states that: "most

patients in low and medium-income countries will continue to be monitored clinically over the next few years."

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 Organisation 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 by Abimiku et al. at the PEPFAR (2006) Implementers' Meeting, held on 12-15 June 2006 in Durban, South Africa. The meeting found that clinical staging would miss up to half of the patients who would qualify for treatment on the basis of 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. In some cases, donors are assisting the scale-up of CD4 testing services and as access improves, the point at which people initiate ART should come more in line with what is considered best practice in industrialized countries (WHO 2006b).

The findings in Uganda by Haumba and Rippey (2006) were that "In 2002 there was a scarcity of qualified staff that was poorly deployed, there was low uptake of laboratory services due to lack of trust in results by clinicians, supplies were not regular, some basic equipment was lacking but existing equipment was not well maintained."

A team from the Institute of Human Virology (University of Maryland) working to develop quality assurance programmes for the laboratory infrastructure in Nigeria described shocking findings after visits to twelve laboratories between September 2005 and March 2006. Abimiku et al. (2006) reports that, "Over half of the laboratories had no record of the laboratory staff credentials; had limited inventory systems and had no programme for calibrating pipettes. A number had no policy on accidental exposure to

infectious agents and did not disinfect the bench tops of the laboratories daily". Nevertheless, thanks in part to price reductions and international donor assistance from PEPFAR, the World Bank and others, access to CD4 cell count (especially) and viral-load testing are being introduced into these settings anyway (Presentations at HIV/AIDS Implementing meeting of the PEPFAR 2006).

According to a recent review article by Petti e al. (2006), even the most basic laboratory services are often missing or unreliable in the most resource-constrained settings, the laboratory infrastructures in low-income countries generally lack basic essential equipment, have a limited number of skilled personnel, lack laboratory consumables such as sterile urine-specimen containers, lack educators and training programmes, have inadequate logistical support, suffer from a de-emphasis of laboratory testing by clinical staff, have insufficient monitoring of test quality, have decentralised facilities that have been set up as parallel and competing infrastructures where governmental, non-governmental organisations and commercial for-profit organisations operate independent laboratories, and have no governmental standards for laboratory testing.

At a PEPFAR meeting, Wachira e al. (2004) described how CD4 cell testing was integrated into the existing infrastructure at one public sector hospital in Mombasa, Kenya. And yet, according to Wachira, "the role of the laboratory in the ART programme at the hospital was really not fully appreciated until it became a major constraint to good patient management and care." As a result of all of these interventions, not only did CD4 cell monitoring become accessible, but the laboratory's capacity increased and the quality of the results and clinicians' confidence in them improved dramatically. Furthermore, Wachira said that "Testing for all tests, other than just for ART, patients increased tremendously and the image of the laboratory improved to the extent that private practitioners began sending requests to this public hospital."

Similar results were reported by Haumba and Rippey (2006), that after four years of comprehensive efforts to upgrade the laboratory infrastructure in Uganda, "Service utilisation statistics showed an increased uptake of the laboratory services and number of

tests for HIV, TB, malaria and syphilis increased from 288 269 tests in 2003 to 1 353 383 tests in 2005. Both projects demonstrated that CD4 cell testing, if integrated into the existing but improved public sector laboratory infrastructure, could be made available and result in improving laboratory services and care for all patients.

At the 2006 PEPFAR Implementers' meeting, a number of presentations suggested that there was a challenge if basic skills and equipment were often lacking at the referral hospital level, and whether primary health care level facilities could offer equitable monitoring of their patients on ART. However, Torpey et al. (2006) reported a successful effort to improve access at primary health level to a range of quality ART services in five provinces of Zambia.

In Zambia, as in Kenya, the basic laboratory infrastructure was weak, so the primary health centres were provided with basic haematology and chemistry analyzers and the training and systems to use them. Torpey et al.(2006) stated that they knew from experience that HIV patients were not immune to the background diseases that every community faces, so it was important that there be access to basic haematology and clinical chemistry which should improve the care received by all patients served by the facility. Flow cytometry to measure CD4 cell counts was, however, beyond the scope of what could be implemented at the primary health centres. So in order to offer CD4 cell monitoring for people with HIV at the primary health centre clinics, a sample referral system was set up, using motorcycles provided by USAID (and neatly branded with its logo) to transport samples from the outlying clinics to referral laboratories set up in strategic areas with CD4 cell monitoring equipment (Torpey et al.2006).

Sample transport from the clinics was coordinated on specific days in order to make the most efficient use of Zambia's limited laboratory equipment and staff. Torpey et al. (2006) said that, "So within the health centre, we are able to provide a level of service that you see in a hospital. We don't have the CD4 cell monitoring equipment on site, but we have access to almost everything through simple systems such as this." The outcome was that between May 2005 and March 2006 these outlying clinics were able to start 1

868 clients on ART on the basis of CD4 cell counts and clinical staging. Of course, not every primary health care clinic in Africa has been outfitted with its own motorcycle courier service by USAID. According to Wachira, (2004), many sites are transporting samples to the reference laboratories by putting couriers with cold storage boxes onto the same regular public mini-taxis (mini-vans) that many Africans use to get from place to place.

However, several studies have shown that this can be technically challenging. According to Petti et al. (2006), there is also a danger that AIDS funding could lead to the development of new laboratory facilities that exist parallel to and in competition with basic but necessary government services. To avoid developing parallel laboratory systems, HIV monitoring tests should be integrated into the existing laboratory services. In order to do this, the infrastructure must first be totally revamped.

Lessons learnt by the WHO in both developed and developing countries show that poor early treatment decisions without laboratory diagnosis, including CD4 count, can limit patients' future therapeutic options and alter the course of the disease and treatment responses. Therefore the use of ART without proper monitoring tests, including viral load, is associated with treatment failure as a result of the emergence of a resistant virus.

2.8 Conclusion

In conclusion, this chapter identified and reviewed the conceptual, theoretical and methodological dimensions of the literature survey. The literature review has unearthed areas of research questions that require researching in relation to the research problem statement in the later chapters on the challenges of scaling up and strengthening the laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART.

During the PEPFAR Implementers meeting (2006) in Durban, South Africa, it was agreed by Kenya, Uganda, Tanzania, Malawi, South Africa and Zambia that scaling up and strengthening of laboratory services for diagnosis and monitoring tests of HIV/AIDS

patients on ART will require basic inputs (infrastructure, equipment or supplies and qualified competent human resources) to support the ART services in the clinics.

CHAPTER III

METHODOLOGY

3.1 Introduction

The previous chapter was literature review of the challenges of scaling up and strengthening the laboratory services which are required and necessary for this study. This chapter describes the methodology in details that was used to collect the data to answer the research questions. The chapter discusses the methods and the tools used to collect data to study and investigate the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART according to the objectives of the study.

3.2 Study Design

The study design was a descriptive cross-sectional survey of ART centres in the public sector in Zambia. The cross-sectional study was to measure the capacity of ART centres with and without quality assured laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART (Bonita, Beaglehole and Kjelitrm. 2006).The study collected descriptive, exploratory, quantitative and qualitative data. Descriptive and qualitative data was used to review the policies, strategies and ART implementation plan documents. A retrospective review of the year 2007 data on patients' medical records in the ART centres was used. The study was carried out over a short period of one month to be able to provide information for planning. The study design provided a "snap shot" of the outcome and the characteristics associated with it, at a specific point in time. The information collected from this study design will be useful in generating hypothesis for future research.

In order to have a basis for comparison of the challenges of scaling up laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia, the survey reference period was for the year 2007.

The sample used in this cross-sectional study was taken from the whole population of 137 ART centres in Zambia. The survey on the challenges of scaling up laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia employed a three-stage approach to data collection. These included the preliminary or planning stage, pre-testing and the main survey. The study design collected both qualitative and quantitative data from 137 public ART centres.

The data was collected using three of research tools which were designed to solicit information from eligible respondents in all public institutions during the study, using a one-to-one interview method where possible.

The main respondents in the study included six selected Directors and Managers at the Ministry of Health headquarters in Lusaka and all the nine provinces; District Directors of Health, medical doctors/clinicians, laboratory staff in charge of ART Centres and the custodians of the Health Information Management Systems (HIMS) in the respective health institutions during the survey period.

The level of non-response was one concern, in that biased response, where one person was more likely to respond when they have a particular characteristic or set of characteristics. Bias occurred when the characteristic in question was in some way related to the probability of having the outcome. In order to improve and minimise on non response, three (3) reminders were sent to each ART centre which did not respond within the given period of time to ensure that all identified ART centres were included in the survey within the field-study work period.

The advantages of choosing this cross-sectional survey were that: less resource are required, took up little time to conduct and there was no follow up. There was an estimated outcome of interest because the sample was taken from the whole population of 137 ART centres. The data collected was useful for public health planning, and for the generation of hypotheses.

3.3 Study Setting

The study setting was the one hundred and thirty-seven (137) ART centres in the public sector of nine (9) provinces in Zambia.

3.3.1 Geographic, demographic, social and economic setting of Zambia

Zambia is a landlocked country in Central Africa and covers an area of 752,612 square kilometres. It shares borders with eight countries namely Malawi, Democratic Republic of Congo, Tanzania, Zimbabwe, Mozambique, Botswana, Namibia and Angola. The country is divided into nine provinces and has 72 administrative districts. The nine provinces are Lusaka, Copperbelt, Central, Northern, North-Western, Luapula, Western, Eastern and Southern.

Figure 3 shows the map of Zambia, showing provinces, major towns and neighbouring countries. The population of the country in the year 2009 was estimated at 12.9 million (Central Statistics Office 2009). The population has been growing steadily from 5.7 million in 1980 to 7.8 million in 1990 and 9.9 million in the year 2000. The annual growth rate in the year 2000 was 2.5 percent. The population density has increased from 7.5 people per square kilometres in 1980 to 10.4 in 1990 and 13.7 in 2000 as shown by ZDHS.

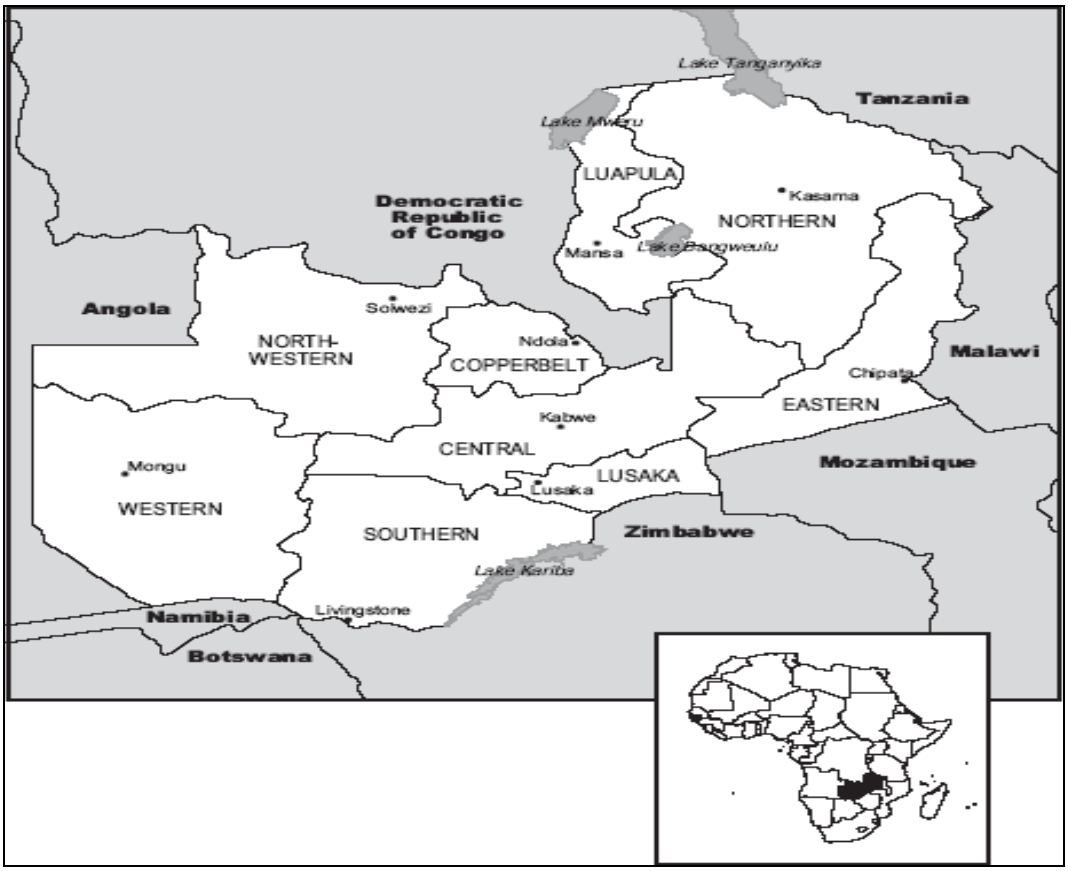

Figure 3: Map of Zambia.
Source: Zambia Demographic Health Survey (ZDHS) 2001-2002.

With an estimated per capita income of about $1,150 in 2009 (Zambia 2009), Zambia is classified as one of the poorest countries in Sub-Saharan Africa with over 70 percent of the population living in abject poverty (Ministry of Finance and Economic Planning 2002). The country's economy depends mainly on mineral resources and exports, in particular copper, which generates over 50 percent of the foreign exchange earnings of the country. Over the last three decades, the structure of the economy and composition of output changed perceptibly. The share of agriculture in the economy increased from around 15 percent in the 1970s to about 21 percent in the 1990s; manufacturing increased from 16 percent to 21 percent; services from 35 percent to 40 percent; and energy from 2.4 percent to 2.8 percent. On the other hand, the share of mining declined from 24 percent to about 11 percent and that of construction from 7.3 percent to about 4.5 percent (ORC Marco and Central Statistical Office 2002.). As of 2000, nearly half of the gross

domestic product (GDP) came from services, about 27 percent from agriculture, and about 13 percent from manufacturing. Mining contributed only about 3 percent of GDP (Ministry of Finance and Economic Planning 2002).

The health status as reflected by some indicators has also been deteriorating over the years. The Maternal Mortality Ratio for Zambia is 729 per 100 000 and the Under-Five Mortality Rate and Infant Mortality Rate now stand at 168 and 95 per 1000 respectively (Zambia Demographic Health Survey (ZDHS) 2002).

Table 2: Demographic Profile of Zambia.

Variable	**Figure**
Mid-year 2003 population	10.9 million
Infant Mortality Rate	95 per 1 000
Life expectancy at birth (Total)	41 years
Life expectancy at birth (Male)	41 years
Life expectancy at birth (Female)	40 years
Births	43 per 1 000 population
Deaths	21 per 1 000 population

Source: Population Research Bureau (PRB) 2003.

The study coverage targeted on a census basis, all public-owned health facilities in Zambia's nine (9) provinces with a total of seventy-two (72) districts. The map in Figure 4 shows the number of ART centres in Zambia in 2007 by province.

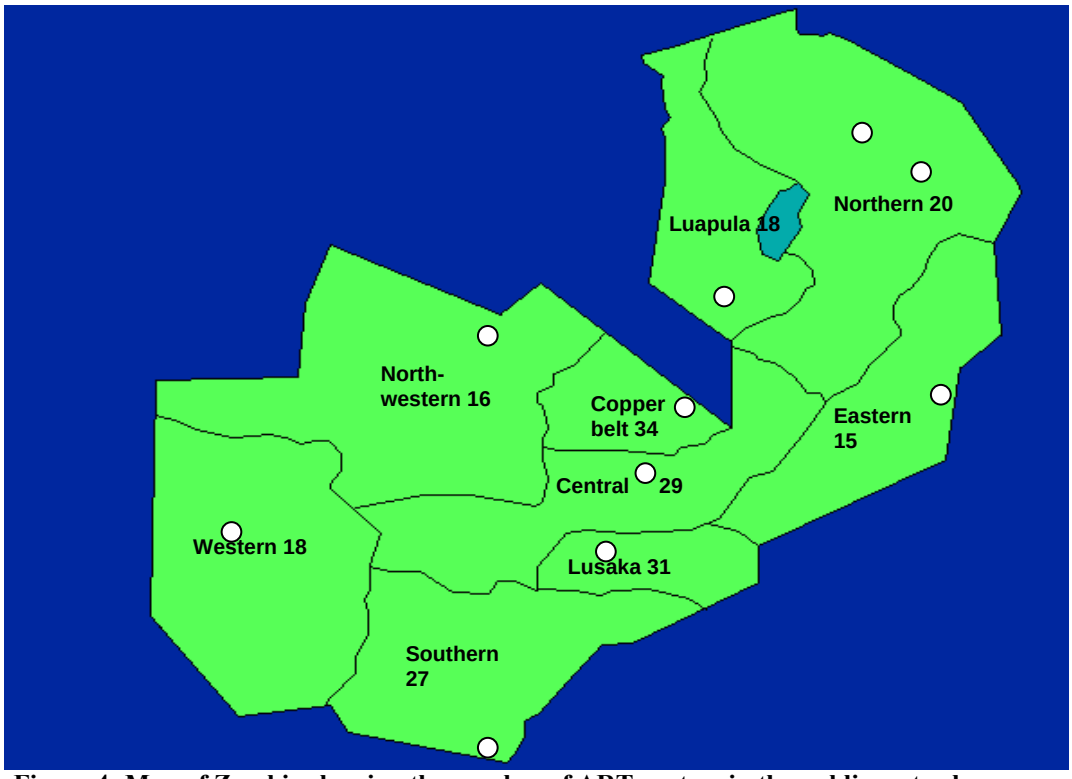

Figure 4: Map of Zambia showing the number of ART centres in the public sector by province, 2007 (Source: Ministry of Health (MOH), ART Sites in Zambia, 2007).

3.3.2 Health Related Facilities and Site Selection

Current 2008 Ministry of Health data indicates that there are total of 246 ART Centres in the Public Sector. The distribution of public owned ART Centres as indicated in Figure 4 by province are as follows; Central Province with thirty nine (29), Copperbelt Province with thirty four (34), Eastern Province with fifteen (15), Luapula Province with eighteen (18), Lusaka Province with thirty one (31), Northern Province with twenty six (20), North Western Province with sixteen (16), Southern Province with twenty seven (27), and Western Province with eighteen (18) (Ministry of Health 2007).

Most of the public owned ART Centres are located in Copperbelt 34 and Lusaka 31 provinces due to high population density, and the least being Eastern Province with 15. However, there are only 57 laboratories out of 208 ART Centres who have laboratory service to support the ART programme. Therefore, 151 ART Centres have no laboratory services to support the ART programme in Zambia.

3.4 Study Population

ART programme health workers were used as the target population for this study since their responsibilities are to diagnose, treat, monitor and evaluate patients on ART. The target populations used for this study were all medical doctors/clinicians, all persons in-charge of ART centres, all laboratory staff and all data-entry clerks responsible for HIMS from one hundred and thirty-seven (137) public ART centres in Zambia. At national level, Ministry of Health the target population was six (6) Directors and Managers, whose responsibilities are policy, planning and budgeting for the ART scale up programme.

3.5 Sample Selection

A List Frame of all public sector ART centres in Zambia (see Appendix 7.1) was obtained from the Ministry of Health. This was used as a sampling selection frame for the purpose of undertaking the survey. The study was a census survey of (137) public sector ART centres. This meant collecting data from all public sector ART centres in Zambia. However, in some instances where government institutions were not providing health facilities to the public, mission-owned health institutions were included in the study. The researcher aimed to study at National Level of Ministry of Health headquarters, the six directors and managers were purposively selected for interviews as they were involved in policy, planning, and budgeting and health management system of ART programme in Zambia. At ART Centres since there was only one staff for each cadre, all in-charge of ART services, all medical doctors/clinicians, all laboratory staff and all data-entry clerks responsible for HIMS were interviewed during the study.

The ART centres within a distance of 500 kilometres from Lusaka, the capital city of Zambia, included Central, Eastern and Copperbelt provinces a total number of fifty four (54) ART Centres were visited to administer the research instruments. For ART centres beyond 500 kilometres, Northwestern, Western, Northern, Southern and Luapula a total

number of eighty four (84) ART Centres self-administered questionnaires were posted or couriered with enclosed self-addressed pre-paid postage envelopes.

3.6 Data Collection Instruments

The researcher developed own research instruments for gathering data on the basis of literature review. The research instrument for this study used six sets of research instruments which had three questionnaires for Directors and Managers at national level, Medical Doctors/ Clinicians and Laboratory. The questionnaires were divided into sections.

3.6.1 Interview Guide

The structured interview guide of Directors and Managers at National level were developed by the researcher in consultation with dissertation supervisors. The structured interview guide covered six main sections: General Identification of socio-demographic data, Policy and Planning, Human Resource development, Laboratory Commodity management system, and Laboratory management information system in the scaling up of laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia (Appendix 7.1).

Section A was general identification of socio-demographic data; province, district, name of the facility, position of the respondent, title of the in-charge of the ART centre, and population catchment served. This section had open ended questions in order to encourage full and meaningful answers.

Coding for Section B: Policy and Planning.
The section had a total of 15 items.
Question 1, 4, 5, 7, 8, 10, 12, and 14: Yes = 1, No = 0

Coding for Section C: Human Resource Development (Training).

The section had a total of 10 items.

Question 16, 21, and 25: Yes = 1, No = 0

Coding for Section D: Laboratory Commodity Management System (procurement and distribution).

The section had a total of 8 items.

Question 26, and 30: Yes = 1, No = 0

Coding for Section E: Laboratory Commodity Management System.

The section had a total of 4 items.

Question 33 and 34: Yes = 1, No = 0

The data from the interview was analysed quantitatively to answer research question one (1) and presented in Chapter IV page 63 to page 64.

3.6.2 Health Facility Assessment Observation Checklist

The observation checklist was developed by the researcher in consultation with the dissertation supervisors. The observation checklist covered four sections: General Identification of socio-demographic data, Health facility staffing in ART Centres, Health Facility Assessment observation checklist of existence of policy regulations and standards and ART Centres with or without Laboratory facilities (Appendix 7.3)

Section A was general identification of socio-demographic data: province, district, name of the facility, position of the respondent, title of the in-charge of the ART centre, and population catchment served. This section had open ended questions in order to encourage full and meaningful answers.

Coding for Section B: Health facility staffing levels in ART Centres

Numbers and qualifications of health staff in ART Centres for the four types of cadres. The section had a table to fill in.

Coding for Section C: Observation assessment of existence of policies, regulations and standards.

The section had a total of 5 items.

Table 1, 2 and Question 3: Yes = 1, No = 0

Coding for Section D: ART centres with or without laboratory facilities

The section had a total of 3 items.

Question 1, 2 and 3: Yes = 1, No = 0

The data from the questionnaire was analysed qualitatively and quantitatively to answer research question one (1) and presented in Chapter IV page 66 to page 69.

3.6.3 Medical Doctors/Clinicians structure questionnaires

The questionnaire was developed by the researcher in consultation with the dissertation supervisors. The structured questionnaire covered four sections: general identification of socio-demographic data, laboratory and monitoring test of HIV/AIDS patients on ART, Tests for management for HIV/AIDS patients on ART and quality of service (Appendix 7.4).

Section A was general identification of socio-demographic data: province, district, name of the facility, position of the respondent, title of the in-charge of the ART centre, and population catchment served. This section had open ended questions.

Coding for Section B: Laboratory Diagnosis and Monitoring tests

The section had a total of 5 items.

Question 1: Yes = 1, No = 0

Coding for Section C: Tests for management of HIV/AIDS patients on ART.

The section had a total of 4 items.

Question 7: Always = 3, Frequently = 2, Occasionally = 1, Never = 0

Coding for Section D: Quality of Service.

The section had a total of 7 items.

Question 9: Excellent = 3, Good = 2, Fair = 1, Poor = 0

Question 10: Same day = 3, Next day = 2, More than 2 days = 1, More than a week = 0

Question 11: Always = 4, Frequently = 3, Sometimes = 2, Rarely=1, Never = 0

Question 12: Very satisfied = 2, Moderately satisfied = 1, Not satisfied = 0

Question 14: Yes = 1, No = 0

The data from the questionnaire was analysed qualitatively and quantitatively to answer research question two (2a) and presented in Chapter IV page 74 to page 87.

3.6.4 Laboratory Personnel structure questionnaires

The questionnaire was developed by the researcher in consultation with the dissertation supervisors. The semi structured questionnaire covered eight sections: General identification of socio-demographic data, Test profiles for diagnosis and monitoring of HIV/AIDS patients on ART, Quality Assurance, Equipment, Laboratory Commodity Management System, Human Resource Development and Supervision, and Challenges on scaling up of Laboratory for diagnosis for HIV/AIDS patients on ART in Zambia (Appendix 8.5)

Section A was general identification of socio-demographic data: province, district, name of the facility, position of the respondent, title of the in-charge of the ART centre, and population catchment served. This section had open ended question

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

The section had a total of 12 items.
Question 2 and 7: Yes = 1, No = 0
Question 5: Always = 2, Sometimes = 1, Never = 0
Question 6: In the last week = 2, In the last month = 1, in the last three months = 0
Question 8: Always = 2, Frequently = 1, Never = 0

Coding for Section C: Quality Assurance
The section had a total of 5 items.
Question 9 and 11: Yes = 1, No = 0

Coding for Section D: Equipment
The section had a total of 9 items.
Question 13, 14, 16, 19 and 25: Yes = 1, No = 0
Question 21: One week = 3, One month = 2, Up to three months = 1, More than three months = 0
Question 23: Very satisfied = 2, Moderately satisfied = 1, Not satisfied = 0

Coding for Section E: Laboratory Commodity Management System
The section had a total of 9 items.
Question 28: Weekly = 4, Monthly = 3, Every few months = 2, Rarely = 1, Never = 0
Question 29 and 30: Yes = 1, No = 0

Coding for Section F: Challenges.
The section had a total of 4 items.

Question 36: Yes = 1, No = 0

The data from the questionnaire was analysed qualitatively and quantitatively to answer research question two (2b) and presented in Chapter IV page 88 to page 99.

3.6.5 District Director of Health structured questionnaire

The structured questionnaire was developed by the researcher in consultation with the dissertation supervisors. The questionnaire covered two sections: General Identification of socio-demographic data, and Number and type of ART Centres with or without Laboratory facilities in the district (Appendix 7.6).

Section A was general identification of socio-demographic data: province, district, name of the facility, position of the respondent, title of the in-charge of the ART centre, and population catchment served. This section had open ended questions.

Coding for Section B: Number and type of ART Centres in the District

This section had open ended questions.

Numbers and type of health staff in ART Centres in the district.

The data from the record review form was analysed qualitatively to answer research question one (1) and presented in Chapter IV page 65.

3.6.6 Data extract sheet for retrospective review of patients' records in the ART centres

The record review form for patients on ART was developed by the researcher in consultation with the dissertation supervisors. The form covered a monthly retrospective review of medical records of CD4 count of HIV/AIDS patients on ART from January to December 2007. (Appendix 7.7)

The data from the record review form was analysed quantitatively to answer research question one (1) and presented in Chapter IV page 69 to page 73.

3.7 Data Collection Methods

The study tools were designed to collect both qualitative and quantitative data. Therefore the most appropriate data collection practices were used. Seven sets of research instruments were designed to capture information on the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia. The research instruments designed were for;

- Document review
- Directors and Managers at the Ministry of Health headquarters in Lusaka;
- Health Facility Assessment
- Medical doctors/clinicians;
- Laboratory personnel;
- District Directors of Health; and
- Retrospective record review of patients on ART from HIMS data clerks.

3.7.1 Document review

The researcher reviewed the policy documents for HIV and AIDS, laboratory policies, HIV/AIDS strategic plans, Laboratory Standard Operating Procedures, ART scale up plan, implementation plans for ART programme, ART budget, and management systems of the laboratory services at the national level. The reviewed documents provided the researcher with the national guidance picture in terms of policies and guidelines.

3.7.2 Interviews

Six directors and managers from the Ministry of Health at national level, the Director of Public Health, the Director of Clinical Care and Diagnostic services, the Director of Technical support, the Director of Policy and Planning, the ART Coordinator and the

Laboratory Services Manager were all interviewed using a semi-structured interview guide. The interview addressed the policy, implementation plan, budgeting, and management systems in the scaling up of laboratory services for the diagnosis of and monitoring tests for HIV/AIDS patients on ART in Zambia. The face-to-face interviews were of 45 minutes duration at a specific appointment time and were conducted in their offices. Participants' permission to participate in the study was obtained by requesting them to sign the consent form (refer to Appendix 7.2).

3.7.3 Health Facility Assessment observation checklist

The check list questionnaire was self administered to cover a wide area due to the vastness of the country. The questionnaire was completed by persons in-charge of all public ART centres in Zambia (refer to Appendix 7.3). The checklist was used to obtain information on the health facility background information, staffing, regulations, policies, standard operating procedures and human resource development.

3.7.4 Medical Doctor/Clinician Questionnaire

All medical doctors/clinicians working in the public sector ART centres were requested to complete the questionnaire. This questionnaire was used to assess the knowledge, attitude and practice (KAP) of medical doctors'/clinicians' capacity in requesting diagnosis and monitoring tests for HIV/AIDS patients on ART, and to assess how the clinicians perceived and valued the need for laboratory services in diagnosing and monitoring patients on ART in Zambia (refer to Appendix 7.4).

3.7.5 Laboratory Personnel Questionnaire

The self administered questionnaire was completed by the persons in charge of public-sector laboratories in health facilities in Zambia. The questionnaire had five major parts

to assess, the socio-demographics and work experience of laboratory staff, the quality of laboratory services for the diagnosis of HIV/AIDS provided to clients and providers, the knowledge, attitude and practice (KAP) of laboratory staff for performing laboratory diagnosis and monitoring tests for HIV/AIDS patients in the ART centres, planning and budgeting, laboratory information and commodity management systems and challenges regarding diagnosis and monitoring tests for HIV/AIDS patients in the ART centres in Zambia (refer to Appendix 7.5).

3.7.6 District Director of Health Questionnaire

The self administered questionnaire was completed by the District Director of Health in public-sector district health facilities in Zambia. The questionnaire had two major parts to assess, the socio-demographics and the number, type of facilities in the districts providing ART services for diagnosis and treatment of HIV/AIDS patients on ART (refer to Appendix 7.6).

3.7.7 Data extract sheet for retrospective review of patients' records in the ART centres

The self administered data extract sheet to review the records of patients retrospectively for the year 2007 in ART centres in Zambia was completed by the HIMS data clerks. The period for the retrospective record review study was from January to December 2007. The patients' record review was looking at numbers in order to obtain the required information on the total number of patients enrolled on ART, the number of patients initiated on ART with and without the CD4 count test and the number of patients on ART using the CD4 count test to monitor progress (see Appendix 7.7). Therefore there was no need to get informed consent from the patients.

The validity of the instruments was pre-tested by the researcher in two ART centres to ensure the appropriateness, clarity and completeness of questions. The pre-test was

explained to participants at the beginning of the interview and they were told that they were being given an opportunity to comment on the clarity of the questionnaires, the time required to complete the interview/questionnaire and to make suggestions for improvement. The validity and reliability of the pre-test/pilot findings were checked for logical flow, consistence/skip pattern, completeness, spelling, question and sentence construction by comparing the responses with the study objectives. The reliability test was performed on the qualitative data analysis (inter-ratters reliability). Quantitative analysis of the pre-test or pilot findings was done using a Statistical Package for Social Sciences (SPSS) version 14. Gaps which were identified during the pre-test or pilot stage were used to fine tune the study tools before the main survey. The two co-supervisors in Zambia acted as independent researchers and checked whether the data coding and grouping were correctly recorded and reflected the reliability of the information.

Three research assistants participated in the pre-test/pilot and the main survey for data collection. Two of the research assistants were involved in the overall receipt of questionnaires, coding, data entry and editing. The research assistants attended a one-week in-house training course on data-collection procedures which included five research tools designed for the study. The training excluded the questionnaire for the directors and managers at national level, as interviews were conducted by the researcher personally.

The study used face-to-face interview and the posted self-administered questionnaire methods in order to collect data from the target population.

The research team managed to collect a total of two hundred and ninety-four (294) questionnaires from 137 ART centres. The distribution of questionnaires by type was as follows;

- six (6) Directors and Managers at national level,
- seventy four (74) Health facility assessment,
- seventy four (74) Medical Doctors/Clinicians,
- sixty nine (69) Laboratory Personnel,

- forty two (42) District Director of Health, and;
- sixty nine (69) Retrospective Review of Patients Medical Records.

Table 3 shows the data collection schedules and dates per province.

Table 3: Pre-test and Main Survey Data-collection Schedule by Province.

Activity	**Province**	**Data Collection Dates**
1. Pre-test/Pilot	Lusaka	08/08/2008
2. Main Survey	Lusaka	08/09/2008
	Central	08/10/2008
	Copperbelt	13/08/2008
	Luapula	19/08/2008
	Western	21/08/2008
	N/western	28/08/2008
	Northern	14/08/2008
	Eastern	03/08/2008
	Southern	09/09/2008

Table 4 illustrates the summary data collection plan which includes the timeframe indicating the type of research questions and its objectives, activities which were done during data collection, the expected outcomes and timeframe involved.

Table 4: Summary of Data Collection for each research objective.

Objectives	Activities	Outcome	Time frame
1. To review the current national HIV/AIDS/STI/TB, laboratory policies and strategic plan in regard to the laboratory services to support the ART programme in Zambia.	Document review and data analysis	Availability of policies and strategic plan	2 weeks
2. To assess the knowledge, attitudes, and practices (KAP) of medical doctors/clinicians and knowledge and practice of laboratory staff in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.	Data Collection Conduct Interviews Posted and received self administered questionnaires Data analysis	Response rate above 75%	1 month
3. To assess the qualities of laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia compared to WHO standard guidelines.	Data Collection Conduct Interviews Post and receive self administered questionnaires Data analysis	Response rate above 75%	1 month
4. To determine the turn-around time for the CD4 count of results to reach the public sector ART centre in support of the ART programme in Zambia.	Data Collection Conduct Interviews Post and receive self administered questionnaires Data analysed	Response rate above 75%	1 month
5. To determine the difference between the knowledge, attitude and practice of medical doctors/clinicians in public sector ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?	Data Collection Conduct Interviews Post and receive self administered questionnaires Data analysis	Response rate above 75%	1 month
6. To determine the predictive value and discrimination power of performing diagnosis and monitoring tests for HIV/AIDS patients on ART in ART centres with and without laboratory services in Zambia.	Data Collection Conduct Interviews Post and receive self administered questionnaires Data analysis	Response rate above 75%	1 month

3.8 Study Limitations

The study was limited to only 74 medical doctors'/clinicians' responses in the 137 public sector ART centres, excluding the private sector ART centres in Zambia. Interviews at national level were conducted by the researcher to reduce bias. Self-administered questionnaires eliminated the problem of interview bias. Information gaps were a problem because records were not kept up to date in the public ART centres in Zambia. The qualitative aspect of data was taken care of during the questionnaire-designing stage, after pre-test and during the main survey of all the questionnaires. Quantitative data was pre-coded in order to reduce bias and the number of variables to be coded. Some of the problems associated with open-ended questions were data transcription, data entry, analysis. The research questions in the study were mainly close ended.

3.9 Ethical Considerations

Prior to the undertaking the study, the research proposal was submitted to the Research, Ethics and Publications Committee of the National School of Public Health, University of Limpopo, Medunsa Campus in South Africa for clearance (see Appendix 7.11) and to the Biomedical Research and Ethics Committee of the University of Zambia for approval (see Appendix 7.12). Official permission to access all public sector ART centres in Zambia was sought from the Permanent Secretary, Ministry of Health, Zambia (see Appendix 7.13).

Written informed consent was obtained from all study participants after oral explanation, and written instructions were posted together with self-administered questionnaires in English. The informed consent form was filled in and posted back with completed self-administered questionnaires (see Appendix 8.14). Confidentiality was maintained at all times, considering that the study involved sensitive issues for HIV/AIDS patients. Anonymity was maintained and the names of individual participants were not identified in any reports or publications. All records collected will be destroyed after three years in

accordance with the standards of the Census and Statistics Act of the Republic of Zambia.

3.10 Data Analysis

The essence of data analysis is to answer the study objectives. All collected data were subjected to a number of scrutiny procedures before data entry to check for completeness and accuracy and after data entry to counter check what was done during data analysis., The interpretation and analysis of data was presented using descriptive statistics (median, mode and mean) in the form of tables and charts by means of percentile and standard deviation. Inferential statistical methods compared between ART with and without laboratory services to support ART programme included Chi-square and T-tests.

In order to validate and ensure reliability of the study findings, tests of statistical significance and correlation analysis were undertaken on most of the derived estimates or variables. Statistical tools such as descriptive and inferential statistics were taken into consideration during data analysis. Descriptive statistics were used to measure the central tendency correlation of dependent and independent variables. Chi-square and T-tests were used to compare the KAP of medical doctors/clinicians and laboratory staff in order to determine variables/characteristics that were significant in predicting the success of the scaling up of laboratory services.

The qualitative data was grouped into themes and sub-themes and analysed using Tesch's method as described by Tesch (1990). The sub-themes were on the following; demography, health management system, policy and planning, human resource, laboratory commodity management system and laboratory information management system.

The qualitative and quantitative data were captured using SPSS Version 14. *Descriptive and inferential statistics* were used to describe the general findings of all variables in the

instruments. Frequency tables, graphs, and charts were used in exploring data and presentation. *Independent Samples t-test and chi-square* were used to compare the knowledge, attitudes and practices among the clinicians in ART centres with and without laboratory services. *Discriminant Analysis* was planned to be used to determine the predictive value and the discrimination power of medical doctors'/clinicians' KAP in ART centres with and without laboratory services in performing diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia. But the *Discriminant Analysis* was not used because there was no difference in the KAP of medical doctors'/clinicians' and no correlation of variables in ART centres with and without laboratory services to support the ART programme.

3.11. Conclusion

In conclusion, this chapter catalogued the methods used to collect the relevant data for the study. Each method was followed by a discussion of statistical data analysis method used. Finally the chapter ended with consideration of ethical issues. The next chapter looks at the findings obtained after analysing the data followed by discussion of each of the findings.

CHAPTER IV

RESEARCH FINDINGS

4.1 Introduction

The previous chapter discussed the methodology, research instruments, software and statistical tools used to collect and analyse data for the study. This chapter presents patterns of results in tables, graphs, charts of the data analysis which are relevant to the six (6) research questions namely;

1. Are there national HIV/AIDS/STI/TB policy, Laboratory policy, ART strategic plan and guidelines on the implementation of ART services in Zambia?
2. What are the levels of knowledge, attitude and practice (KAP) of Medical Doctors/Clinicians and knowledge and practice of laboratory staff in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?
3. What are the qualities of the laboratory services in performing diagnosis and monitoring tests for HIV/AIDS on ART in Zambia compared to World Health Organisation (WHO) standard guidelines?
4. What is the turnaround time (TAT) of CD4 count results to reach the public sector ART centres in Zambia?
5. Is there any difference between the knowledge, attitude and practices (KAP) of Medical Doctors/Clinicians in ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patient on ART? and
6. What are the predictive values and discrimination power of performing diagnosis and monitoring tests for HIV/AIDS patients on ART by using KAP of Medical Doctors/Clinicians with and without laboratory services?

Descriptive and inferential statistical methods were used to determine the general characteristic distribution of estimates using correlation, chi-square, t-test and confidence

intervals prior to logistic regression and discriminant analysis of dependent and independent variables. The source of tables and figures used in the analysis of the survey data are from survey findings unless specified otherwise.

4.2 Findings

Research Question 1. *Are there national HIV/AIDS/STI/TB policy, Laboratory policy, ART strategic plan and guidelines on the implementation of ART services in Zambia?*

Interviews were conducted with all the six Ministry of Health (MOH) directors and managers who are mainly involved in policy formulation, planning and budgeting. The respondents included the Director of Clinical Care and Diagnosis, the Director of Health Planning, the Director Technical Support, the Director of Public Health and Research, the ARV Programmes Coordinator and the Laboratory Specialist. Of the six respondents at national level, only MOH indicated that the policies, strategic plan and ART plan existed except none of them had a readily available copy in their offices as proof of existence of documentation during interviews. The other findings were that it was clear from the discussions that there were challenges in the implementation of the national HIV/AIDS strategic implementation plan including the ART scale-up plan.

The six (6) respondents clearly allude to the challenges on; policy, strategic plan, human resource, laboratory commodity and information management systems as follows;

1. The MOH target stipulated that at least two thirds (2/3) of a total of 350,000 people living with HIV/AIDS should be on ART by the year 2010 which requires strengthening of health systems in terms of infrastructure, laboratory equipment and supplies/reagents. The six respondents said that the challenge for the ministry of health to meet the target of starting 350,000 HIV/AIDS patients on ART is lack of basic inputs (proper infrastructure, equipment and reagents/supplies) to support the ART services.

Of the ART centres assessed, only sixty four (64) had laboratories which are less than 50% of ART centres. Eleven (11) out sixty four (64) laboratories had no capacity (CD4 machine, haematology and chemistry analysers) to support the ART services. The laboratory infrastructure in most of the laboratories was in a deplorable condition and would require renovation and refurbishment.

The results for the assessment of District Directors of Health indicated that there were between four to seven mobile ART clinics in each district operating once a week especially in far away areas from ART centres with Laboratory services. The ART mobile team comprised Medical Doctor/Clinician, Nurse, Pharmacy staff and Laboratory personnel (Appendix 7.6).

2. The human resource currently there is a crisis operating at only 50% capacity due to mortality mostly attributed to AIDS-related complications and departure of staff for "greener pastures" in the region and international markets. In addition to this there were the inadequate trained health personnel and high staff turnover to handle the increased disease burden related to HIV/AIDS.

   The staffing levels of seventy four ART centres assessed varies as shown in Table 5. The results also indicate that there was a critical shortage of Medical Doctors/Clinicians and Laboratory staff. Additional resources were required for training and recruitment of a significant number of staff to cope with the work load in the scale up of laboratory services.

Table 5: Health Facility Staffing Levels in ART Centres.

Cadre	Total number of Staff	Qualifications of In-Charge of ART Centres/Sections. 1. Diploma 2. Degree 3. Masters 4. Certificate 5. Other (Specify)	Average Years in Position
2.1. Laboratory staff			
- Scientists	18	12% Degree [1 & 2]	4 yrs
- Technologists	64	41% Diploma [1, 2 & 3]	6 yrs
- Technicians	66	38% Certificate [1, 2 & 3]	6 yrs
2.2. Clinicians			
- Medical Doctors	80	42% Degree [1, 2 & 3]	4 yrs
- Clinical Officers	123	70% Diploma [1, 2, 3 & 4]	4 yrs
2.3 Pharmacy			
- Pharmacists	30	12% Degree [1, 2, 3 & 4]	2 yrs
- Pharmacy Technician	50	31% Diploma [1,2 & 4]	2 yrs
2.4 Nurse			
- Registered Nurse	64	41% Diploma [1, 2 & 3]	4 yrs
- Enrolled Nurse	175	54% Certificate [1, 2 & 4]	4 yrs
2.5. Environmental Officers	30	31% Diploma [1 & 4]	4 yrs
2.6. Dispensaries	62	41% Certificate [1, 2 & 4]	3 yrs
2.7. Other (Specify)	18	7% Diploma [1, 2, 4 & 5]	5 yrs

Table 6 shows that almost all the laboratory staff at the assessed ART Centres with laboratories had been retrained on HIV testing CD4 count and clinical management for HIV/AIDS except for viral load testing which was not performed in all the ART centres. There was only one viral load testing centre in the public sector in Zambia.

Table 6: Frequency number of laboratory staff trained by subject area.

Nos.	Subject Area	Number of staff Trained	Percentage (%)
1.	HIV Testing	274	49
2.	CD4 Count	133	24
3.	Viral Load testing	14	3
4	Clinical Management of HIV/AIDS	139	25
	Total	**560**	**100**

3. There was poor information management system due to lack of standardised storage of data in retrievable format to assist in planning, forecasting, quantification and budgeting for commodities required for diagnosis and monitoring tests of HIV/AIDS patients on ART. In addition there was lack of information required for monitoring and evaluation of ART guidelines and policy implementation needed for the scale up plan of laboratory service.

4. There was inadequate and under developed Laboratory Commodity management systems unable to avert the frequent shortages and stock outs of reagents and consumables.

5. There has been overall inadequate financial resources to support the ART scale up programme.

At the local ART health facilities statements were assessed on the existence of the following documents; national HIV/AIDS policy, laboratory policy, laboratory SOPs, national health strategic plan and the ART scale up implementation plan in 74 public sector ART centres with and without laboratory services. The information gathered in this research question was on the physical check of the availability of the documents in the ART clinic office and laboratories.

Table 7: Frequency summary of availability of policies, guidelines, Standard Operating Procedures (SOPs) in all public sector ART centres.

Availability of documents in ART centres		ART Centres		Total
		With lab	Without Lab	
National Policy on HIV	Available	37	8	45
	Not available	18	11	29
Guidelines on management and care of HIV/AIDS patients	Available	48	14	62
	Not available	7	5	12
National ART implementation plan	Available	28	7	35
	Not available	27	12	39
Laboratory SOPs for ART program	Available	45	5	50
	Not available	10	14	24
Laboratory Implementation plan to support ART services	Available	22	2	24
	Not available	33	17	50

Table 7 indicates the availability of policies, laboratory SOPs, guidelines, national health strategic plan and the ART scale up implementation plan in public sector ART centres with and without laboratory services.

Figure 5 illustrates the percentage availability of policies, laboratory SOPs, guidelines, national health strategic plan, National ART implementation plan and the Laboratory implementation plan to support ART services in public sector ART centres with and without laboratory services. This implies that almost all ART centres with laboratory services had the necessary important documentation to support the implementation of ART program in order to provide quality services. While the existence of the documents was below 25% at those ART Centres without laboratory services, the quality of service can be said to be below WHO standards.

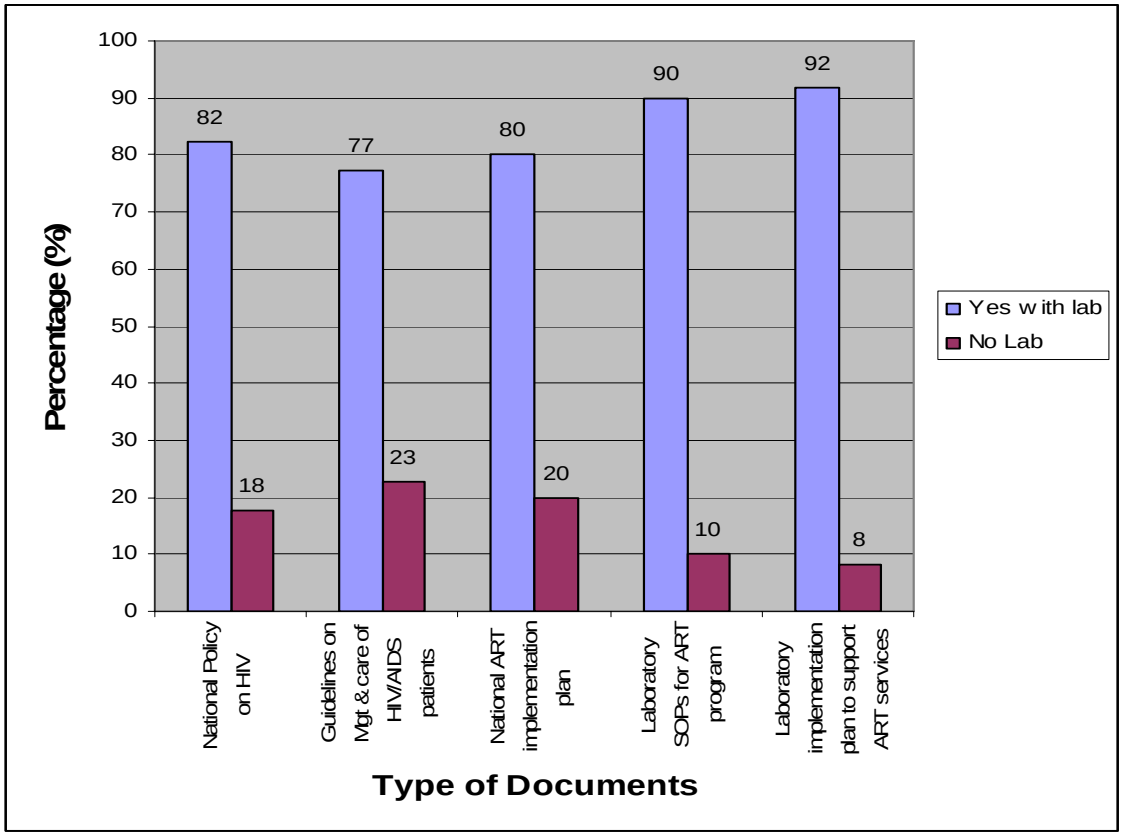

Figure 5: Percentage availability of policies, guidelines, SOPs in all public sector ART centres.

Table 8 provides a summary existence of policies, guidelines and SOPs documentation of 83% in ART centres with laboratory services, whilst existence of the same documentation in ART centres without laboratory services is 17%.

Table 8: Frequency summary of availability of policies, guidelines, SOPs in all public sector ART centres.

Availability of policies, guidelines and SOPs	ART Centres			
	With lab		Without Lab	
	n	%	n	%
Yes (available)	180	83	36	17
No (not available)	95	62	59	38

Table 9 indicates the retrospective review of patients records for the period of January to December 2007 in the 137 ART centres assessed. The findings were that the records were incomplete, not properly filled, there was no documentation (they used loose sheets of papers), data was irretrievable and unverifiable with no correlation with the laboratory register for CD4 count results. Out of 137 ART Centres only sixty – eight (68) had completed the required information. Table 9 shows the aggregated total number of patients enrolled on ART.

Table 9: Retrospective review of total number of patients in the ART Centres –Period January – December 2007.

Nos.	Patients/Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Number of patients enrolled on ART	3,771	3,459	3,693	3,617	3,896	3,491	3,510	3,732	3,657	4,385	4,306	3,712
2	Number of patients initiated on ART without CD4 count test	311	266	277	378	412	356	336	330	347	363	445	249
3	Number of patients initiated on ART with a CD4 count test	2,272	2,093	2,323	2,012	2,060	2,020	1,919	2,073	2,229	2,585	2,440	2,164
4	Number of patients on ART using CD4 count test to monitor progress	2,187	2,141	1,320	1,415	1,437	2,091	1,394	1,447	1,654	1,779	1,870	2,326

Table 10 illustrates the average number of the patients' record reviewed for sixty – eight (68) ART Centres with well completed documentation in ART Centres. The information requested is required for planning, budgeting and commodity management systems but unfortunately most of the ART centres seemed not to be aware of the importance of good record keeping.

Table 10 also shows constant monthly number of patients on ART with no increase or decrease due to poor record keeping. Retraining in information management systems was therefore of utmost important in the ART scale-up plan.

The reliability of the records depended on the patient records in the registers from records clerk in-charge of HMIS.

The validity of records showed that the mean score was not reliable except for the average number of patients initiated on ART without CD4 count test with a standard deviation equal to 1.90 or 2 within the expected range.

Table 10: Retrospective review of average number of patients in the ART Centres –Period January – December 2007.

Nos.	Patients/Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Average number of patients enrolled on ART	55	51	58	57	60	54	53	57	55	65	64	55
2	Average number of patients initiated on ART without CD4 count test	9	9	9	12	13	11	11	11	11	11	14	8
3	Average number of patients initiated on ART with a CD4 count test	42	39	43	37	37	37	35	37	40	46	44	39
4	Average number of patients on ART using CD4 to monitor progress	64	67	41	44	44	62	41	44	49	54	55	66

Table 11 indicates the summary survey findings on the estimated population mean, range, minimum, maximum values and the standard deviation/variance for HIV/AIDS patients' medical records from ART centres.

The table also illustrates the population mean and the standard deviations for each patient record type. Dispersion which is the statistic that measures the spread or variation in the data is measured using standard deviation, (square root of variance) and range.

Table 11: Summary mean scores and standard deviation of the ART Patient Medical Records.

Nos.	Patients/Month	Mean	Standard Deviation
1	Average number of patients enrolled on ART	57	4.31
2	Average number of patients initiated on ART without CD4 count test	11	1.90
3	Average number of patients initiated on ART with CD4 count test	40	3.38
4	Average number of patients on ART using CD4 count test to monitor progress	53	10.13

Research Question 2a. *What are the levels of Knowledge, Attitude and Practice (KAP) of Medical Doctors/Clinicians in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?*

The distribution of Medical Doctors/Clinicians in ART centres with and without laboratory services is shown in table 12.

Table 12: Distribution of the respondents by title in ART Centres with and without laboratory services.

Title of respondent	ART Centres			
	With Lab		Without Lab	
	n	%	n	%
Medical Doctor/ Clinical Officer	40	**72.0**	13	**68.5**
Other Health Workers	15	27.2	6	21.1
Total	**55**	**100**	**19**	**100**

The percentage distribution of Medical Doctors/Clinicians in ART centres with laboratory services was about 72.0% as compared to 68.5% of Medical Doctors/Clinical officers in ART centres without laboratory services. Although the table shows an increase of about 27.2% other health workers working mainly in ART centres with laboratory services whilst a reduced percentage of 21.1% were other health workers working in ART centres without laboratory services this alludes to inadequate competence of existing staff which affected the implementation of ART services. The ART centres without Laboratory services referred samples or patients to the nearest ART centre with laboratory services (in most cases more than 100 km in rural areas).

Table 13: Frequency of Medical Doctors/Clinicians responses about knowledge in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.

Variables on Knowledge	ART centres			
	With lab		Without lab	
	n	%	n	%
1. Knowledge of four(4) correct roles of laboratory services in management of HIV/AIDS patients on ART;				
• Diagnosis of Opportunistic infections	49	75.4	16	24.6
• HIV testing	53	74.6	18	25.4
• Laboratory tests prior to initiating a patient on ART	55	76.4	17	23.6
• Monitoring tests for patients on ART	53	77.9	15	22.1
• Prevention of transmission of HIV	9	16.4	3	15.8
2. Knowledge of when to start/initiate HIV/AIDS patients on ART;				
• CD4 count less than 350 cells/cubic mm	41	73.2	15	26.8
• WHO Stage 3 or 4	39	69.6	17	30.4
3. Knowledge of five(5) reasons requiring laboratory services in the management of HIV/AIDS patients on ART;				
• Full blood count	18	72.0	7	28.0
• Monitoring liver and Kidney function	15	60.0	10	40.0
• Diagnosis (knowing status)	15	60.0	10	40.0
• CD4 count test	27	79.4	7	20.6
• Diagnosis of Opportunistic infections	27	75.0	9	25.0
4. Knowledge of four(4) most important tests required to monitor HIV/AIDS patients on ART;				
• TB smear microscopy	37	74.0	13	26.0
• CD4 count	55	74.0	19	25.7
• Full blood count	55	75.3	18	24.7
• Liver function test	55	74.3	19	25.7

Table 13 illustrates the frequency of Medical Doctors/Clinicians' level of total knowledge on the diagnosis and monitoring tests for management of HIV/AIDS patients on ART in ART Centres with and without laboratory services in Zambia.

Table 14: Frequency of responses of Medical Doctors/Clinicians knowledge in the laboratory diagnosis and monitoring tests for management of HIV/AIDS patients on ART in ART centres in Zambia.

Variables	No. of correct answers	ART Centre	
		With Lab n (%)	**Without Lab n (%)**
1. Knowledge of four (4) correct roles of laboratory services in management of HIV/AIDS patients on ART.	4 roles	**46(83.6)**	**12(63.2)**
	3 roles	8(14.5)	4(21.1)
	2 roles	1(1.8)	1(5.3)
	1 role	0(0.0)	1(5.3)
	No correct answer	0(0.0)	1(5.3)
2. Knowledge of when to start/initiate HIV/AIDS patients on ART	2 correct answered	**40(72.7)**	**16(84.2)**
	1 correct answer	10(18.2)	3(15.8)
	No correct answer	5(9.1)	0(0.0)
3. Knowledge of five(5) reasons requiring laboratory services in the management of HIV/AIDS patients on ART	5 correct reasons	**9(16.4)**	**4(21.1)**
	4 correct reasons	14(25.5)	8(42.1)
	3 correct reasons	26(47.3)	6(31.6)
	2 correct reasons	5(9.1)	1(5.3)
	1 correct reason	1(1.8)	0(0.0)
	No correct answer	0(0.0)	0(0.0)
4. Knowledge of four(4) most important tests required to monitor HIV/AIDS patients on ART	4 most important tests	**37(67.3)**	**12(63.2)**
	3 most important tests	18(32.7)	7(36.8)

Table 14 outlines the frequency responses from Medical doctors/Clinicians on laboratory diagnosis and monitoring tests for management of HIV/AIDS patients on ART in ART centres in Zambia. The results indicate that about 84% Medical Doctors/Clinicians answered the four roles of laboratory services in management of HIV/AIDS patients on ART correctly. Only about 73% answered correctly on when to start/initiate HIV/AIDS patients on ART followed by 67% who answered correctly on the four most important tests required to monitor HIV/AIDS patients on ART. Few (about 16% and 21% working in ART centres with and without laboratory services respectively) answered correctly the five reasons requiring laboratory services in the management of HIV/AIDS patients on ART.

Table 15: Summary mean score comparison of Medical Doctors/Clinicians' level of knowledge in ART Centres with and without laboratory services.

Descriptive	**ART Centres**			
	With Lab		**Without Lab**	
Mean score	12.56		12.57	
Standard deviation	1.38		1.38	
Minimum	8		10	
Maximum	15		14	
Level of Knowledge *	**n**	**%**	**n**	**%**
Low knowledge (0-65%)	2	3.6	0	0.0
High knowledge (> 65 %)	53	**96.4**	19	**100**

Table 15 summarises the level of knowledge of Medical Doctors/Clinicians in ART centres (96.4%) mean score of 12.56 with laboratory services and (100%) and mean score of 12.57 without laboratory services to support ART programme. In both ART centres the level of knowledge was high meaning that they were able to manage HIV/AIDS patients well on ART. It was assumed that at ART centres without laboratory services to support ART programme, the laboratory services were provided on ambulatory basis.
The reasons cited for the use of the laboratory services in the management of HIV/AIDS patients on ART to support the demonstrated knowledge levels is as shown below:

> *"Monitoring organic damage (liver and kidney) and CD4 count" (88),*
>
> *"Monitor CD4 count staging "(43),*
>
> *"Know the status of the patient and diagnosis" (53),*
>
> *"Evaluate the patient before initiation" (43),*
>
> *"Assessing treatment failure, identify side effects (toxicity) and assessing resistance to drugs" (39).*

Table 16 outlines the frequency responses of Medical Doctors/Clinicians' rating of the quality of laboratory services in ART centres with and without laboratory services to support the ART programme in Zambia. The results indicate that about 70% of the Medical Doctors/Clinicians in ART with laboratory services had a positive perception of the performance and quality of the laboratory services.

Table 16: Frequency of Medical Doctors/Clinicians responses regarding the quality of service provided by the laboratories in Zambia.

Variables	Rating	ART Centre	
		With Lab n (%)	Without Lab n (%)
1. Rating results received from the laboratory	Excellent	**9(69.2)**	4(30.8)
	Good	41(74.5)	14(25.5)
	Fair	4(80.0)	1(20.0)
	Poor	1(100.0)	0(0.0)
2. Reliance on laboratory results for monitoring tests	Always	**28(75.7)**	9(24.3)
	Frequently	25(78.1)	7(21.9)
	Sometimes	1(25.0)	3(75.0)
	Never	1(100.0)	0(0.0)
3. Rating of performance of laboratory services	Very satisfied	**17(70.8)**	7(29.2)
	Moderately satisfied	36(80.0)	9(20.0)
	Not satisfied	2(40.0)	3(60.0)

Table 17: Summary mean score comparison of Medical Doctors'/Clinicians' rating towards the quality of performance of laboratory services in ART Centres with and without laboratory services.

Descriptive	**ART Centres**			
	With Lab		**Without Lab**	
Mean	6.85		6.63	
Standard Deviation	1.40		1.34	
Minimum	5		3	
Maximum	12		8	
Level of Attitude *	**n**	**%**	**n**	**%**
Negative (-3 to 5)	4	7.3	3	15.8
Positive (>5)	**51**	**92.7**	**16**	**84.4**

Table 17 summarises the total rating of the quality of performance of laboratory services by Medical Doctors/Clinicians in ART centres (92.7%) of ART with laboratories and (84.4%) without laboratory services to support ART programme have positive attitude meaning that the laboratory services performance is of high quality in the diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia.

The mean score of 6.85 and 6.63 in both ART centres with and without laboratory services respectively is slightly high this entails that Medical Doctors/Clinicians utilises laboratory services on daily basis as shown in Table 17.

The Medical Doctors/Clinicians' perceptions of the quality of performance of the laboratory service cited were as follows;

"Reliable results by machine" (26),

"Dedicated or experienced laboratory staff "(16),

"Shortage of laboratory staff" (22).

"Increased work load" (15),

"Testing sample timetable is adhered to and results same day" (6) and

"Results get lost" (5)

Table 18 outlines the frequency of Medical Doctors/Clinicians' practice in requesting laboratory tests for diagnosis and monitoring of HIV/AIDS patients on ART in ART centres with and without laboratory service to support the ART program in Zambia.

Table 18: Frequency of responses for requesting laboratory tests for diagnosis and monitoring of HIV/AIDS patients on ART by of Medical Doctors/Clinicians' practice in Zambia.

	ART Centres			
	With lab		Without Lab	
Variables	**n**	**%**	**n**	**%**
1 .Practice of when to start/initiate HIV/AIDS patients on ART;				
• CD4 count less than 350 cells/cubic mm	41	73.2	15	26.8
• WHO Stage 3 or 4	39	69.6	17	30.4
2. Practice of four (4) most frequent tests requested for monitoring patients on ART;				
• Full Blood Count	41	76.4	15	78.9
• CD4 count	67	82.0	20	95.0
• Liver function test	98	56.1	35	54.2
• Viral load	69	79.7	27	70.3

The frequency of Medical Doctors/Clinicians' practice in requesting laboratory tests for diagnosis and monitoring of HIV/AIDS patients on ART in ART centres with Laboratory services is much higher for CD4 counts and WHO Stages 3 and 4 compared to the ART centres without laboratory service to support the ART program in Zambia.

Table 19 outlines the frequency of responses for requests by the Medical Doctors/Clinicians' for laboratory tests for diagnosis and monitoring of HIV/AIDS patients on ART in ART centres with and without laboratory service to support the ART program in Zambia.

Table 19: Frequency of requesting for monitoring tests available in ART centre with laboratory services by Medical Doctors/Clinicians.

Nos.	Monitoring Tests	Always n(%)	Frequently n(%)	Occasionally n(%)	Never n(%)
1.	CD 4 Count	9(16.4)	21(38.4)	21(38.2)	4(7.3)
2.	Blood sugar	13(23.6)	11(20.0)	21(38.2)	10(18.2)
3.	Full Blood count	4(7.3)	14(25.5)	35(63.6)	2(3.6)
4.	Liver Function Test	9(16.4)	19(34.5)	19(34.5)	8(14.5)
5.	Viral Load test	6(10.9)	2(3.6)	2(3.6)	45(81.8)

Only 16% of Medical Doctors/Clinicians always requested monitoring tests available in the management of HIV/AIDS patients on ART. This indicates that majority of Medical Doctors/Clinicians use mainly the WHO clinical staging guidelines in management of HIV/AIDS patients on ART without the laboratory services support.

Table 20: Frequency of responses of Medical Doctors/Clinicians' practices in the management of HIV/AIDS patients on ART.

Variables	No. of Corrected answers	ART Centre	
		With Lab n (%)	Without Lab n (%)
1. Practice of when to start/initiate HIV/AIDS patients on ART	2 correct answers	**41(73.2)**	15(26.8)
	1 correct answer	39(69.6)	17(30.4)
2. Practice of four(4) most frequent tests requested for monitoring patients on ART	4 most frequent tests	**53(73.6)**	19(26.4)
	3 most frequent tests	53(74.6)	18(25.4)
	2 most frequent tests	53(74.6)	18(25.4)
	1 most frequent tests	13(65.0)	7(35.0)
3. Practice on requesting available monitoring tests	Always	**9(16.4)**	1(5.3)
	Frequently	21(38.2)	5(26.3)
	Occasionally	21(38.2)	8(42.1)
	Never	4(7.3)	5(26.3)

*Highlighted numbers are a good practice

Table 20 outlines the frequency of correct responses by the Medical Doctors/Clinicians' practices in requesting laboratory tests for the management of HIV/AIDS patients on ART in ART centres with and without laboratory service to support the ART program in Zambia. The Medical Doctors/Clinicians' working in ART centres with laboratory service answered correctly the laboratory tests frequently requested in the management of HIV/AIDS patients on ART.

Table 21 also indicates that the mean score of 13.29 and 13.26 in ART with and without laboratory services respectively is low even where Medical Doctors/Clinicians are using laboratory services on daily basis.

Table 21: Summary mean comparison of Medical Doctors/Clinicians' practices in requesting laboratory tests for diagnosis and monitoring of HIV/AIDS patients on ART in Zambia.

Descriptive	**ART Centres**			
	With Lab		**Without Lab**	
Mean	13.29		13.26	
Standard deviation	3.00		3.63	
Minimum	3		5	
Maximum	19		18	
Level of Practice *	**n**	**%**	**n**	**%**
Bad	37	67.3	12	33.2
Good	**18**	**32.7**	**7**	**36.8**

Key: Good Practice = >75% and Bad Practice = <75%

Table 21 summarises the total practices of Medical Doctors/Clinicians in all facilities with laboratory (32.7%) and without laboratory services to support ART (36.8%), which means that the difference in the availability of laboratory services to support ART scale up does not affect the Medical Doctors/Clinicians practices in requesting diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia. The Medical Doctors/Clinicians performing good practice are very few therefore this will require a retraining programme.

The Medical Doctors/Clinicians' cited reasons for the bad practices in requesting for the diagnosis and monitoring tests of HIV/AIDS patients on ART were poor performance and the quality of laboratory services. They answered as follows;

"Results take too long /turn around time" (17),

"Lack of supplies/reagents" (15),

"Lack of CD4 machine" (12) and

"Frequent break down of machine" (9).

Research Question 2b. *What are the levels of knowledge, attitude and practice (KAP) of laboratory staff in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?*

The distribution of laboratory staff and other health workers in ART centres with and without laboratory services is indicated in Table 22

Table 22: Distribution of the respondents by their position in ART Centres with and without laboratory services.

Title of respondent	ART Centres			
	With Lab		Without Lab	
	n	%	n	%
ART Officers	16	26.6	1	12.5
ART Coordinator	2	3.3	2	25.5
Laboratory Technician	32	52.2	5	62.5
Director	3	4.9	-	-
Medical Doctor	2	3.3	-	-
Registered Nurse	2	3.3	-	-
In charge	2	3.3	-	-
Not stated	2	3.3	-	-

The percentage distribution of laboratory staff in ART centres with laboratory services was about 52% where as in ART centres without laboratory services to support the ART programme was about 62%. Although the table shows an increased pattern of about 45%, some health workers worked mainly in ART centres with laboratory services whilst a reduced percentage of about 38 % are other health workers working in ART centres without laboratory services to support the ART programme. This alluded to inadequate competence of existing staff which affected the quality of laboratory services. The ART

centres without Laboratory services referred samples or patients to the nearest ART centre with laboratory services (in most cases more than 100 km away in rural areas).

Table 23 indicates the frequency responses of Laboratory Staff on the most important test profiles in the diagnosis and monitoring tests for management of HIV/AIDS patients on ART in Zambia.

Table 23: Indicates frequency of responses by Laboratory Staff on the five (5) most important test profiles for diagnosis and monitoring of HIV/AIDS patients on ART in Zambia.

Knowledge of five(5) most important monitoring tests for HIV/AIDS patients on ART	**ART CENTRES**	
	With Lab	**Without Lab**
	n (%)	**n (%)**
CD4 count	16(10.90)	2(10.52)
Full Blood Count(FBC)	35(23.97)	4(21.05)
Renal Function Test(RFT)	12(8.21)	1(5.26)
Creatinine Serum	16(10.51)	1(5.26)
Liver Function Test(LFT)	43(29.45)	8(42.10)
Not stated	24(16,43)	3(15.78)

The frequency of responses by Laboratory Staff on the most important test profiles in the diagnosis and monitoring tests for management of HIV/AIDS patients on ART is almost similar in both ART centres with and without Laboratory services.

Table 24 outlines Laboratory Staff responses on the most important test profiles in the diagnosis and monitoring tests for management of HIV/AIDS patients on ART in Zambia.

Table 24: Outlines frequency of responses by Laboratory Staff on the five (5) most important test profiles for diagnosis and monitoring of HIV/AIDS patients on ART in Zambia.

Variables	**No. of Corrected answers**	**ART Centre**	
		With Lab n (%)	**Without Lab n (%)**
Knowledge of five(5) most important monitoring tests for HIV/AIDS patients on ART	5 correct answers	**36(59.0)**	**7(87.5)**
	4 correct answers	19(31.1)	3(13.6)
	3 correct answers	5(8.2)	1(12.5)
	2 correct answers	1(1.6)	0(0.0)
	1 correct answer	0	0(0.0)

The majority of the respondents 59% and 87% identified correctly to the five most important monitoring tests for HIV/AIDS patients on ART respectively in ART centres with and without laboratory services respectively to support the ART programme. The results indicate that the majority of laboratory staff in ART centres without laboratory services to support the ART programme had a high score of correct answers even though they had no materials/equipment to practice on, compared to Laboratory Staff that had daily practice on performing monitoring tests in ART centres with laboratory services.

Table 25 summarises the total level of knowledge responses for Laboratory Staff in the diagnosis and monitoring tests for management of HIV/AIDS patients on ART.

Table 25: Summary mean comparison of Laboratory Staff level of knowledge in ART Centres with and without laboratory services.

Descriptive	**ART Centres**			
	With Lab		**Without Lab**	
Mean	4.48		4.75	
Standard deviation	0.72		0.01	
Minimum	2		3	
Maximum	5		5	
Level of Knowledge *	**n**	**%**	**n**	**%**
Low knowledge (0-65%)	6	9.8	7	12.5
High knowledge (> 65 %)	55	**90.2**	1	**87.5**

Majority 90 % of Laboratory Staff had a high level of knowledge of the most important test profiles for diagnosis and monitoring of HIV/AIDS patients on ART with laboratory services. About 87% of Laboratory Staff in ART centres without laboratory services had also a high level of knowledge as compared to Laboratory Staff with laboratory services that had daily practices on performing monitoring tests.

Table 26 indicates the availability of Standard Operating Procedure Manual for use in the laboratory to perform test profiles for diagnosis and monitoring tests of HIV/AIDS patients on ART in order to support the ART services in quality management of patient care.

Table 26: Frequency of the respondents on the availability of Standard Operating Procedure Manual to support the ART programme.

Availability of Laboratory SOPs	ART Centres			
	With Lab		Without Lab	
	n	%	n	%
Yes	51	85.0	6	75.0
No	9	15.0	2	25.0

The results illustrates that majority (85%) of laboratories have SOPs manual for use. Few respondents who did not have the Standard Operating Procedure Manual gave reasons as;

"Not established" (4),

"Not given" (3) and

"Not yet collected" (4).

The Figure 6 indicates the percentages of laboratories performing internal quality control on tests profiles as follows: majority of the laboratories perform internal quality control for HIV Test 71%, followed by CD4 count test 62%, Full Blood count test 59%, Liver function test 54% and Creatinine test 51%.

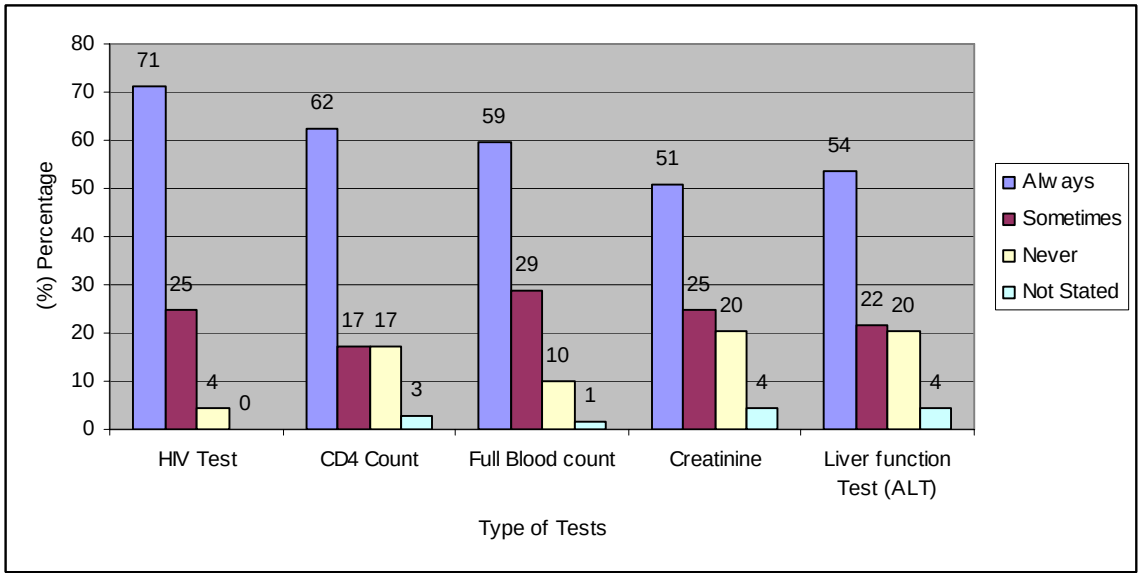

Figure 6: Percentage of laboratories performing internal quality control on tests profiles

This illustrates that there is an average performance of internal quality control on the five (5) most important test profiles in the laboratories, which is supposed to be done on a daily basis.

Table 27 outlines the frequency responses of Laboratory Staff practices in performing Internal Quality Control (IQC) for monitoring tests for HIV/AIDS patients on ART. The IQC is supposed to be done on daily basis always but unfortunately the results indicate that all the respondents said "sometimes." This compromised the quality of results provided for the management of HIV/AIDS patients on ART.

Table 27: Frequency responses of Laboratory Staff practices in performing Internal Quality Control for monitoring tests for HIV/AIDS patients on ART in Zambia.

Type of test	ART Centre	Always	Sometimes	Never
HIV test	With Lab	-	24.6	75.4
	Without Lab	-	25.0	75.0
CD4 Count	With Lab	-	19.7	80,3
	Without Lab	-	12.5	87.5
Full Blood Count	With Lab	-	31.1	68.9
	Without Lab	-	12.5	75.0
Creatinine	With Lab	-	27.9	72.1
	Without Lab	-	12.5	87.5
Liver Function Test	With Lab	-	24.6	75.5
	Without Lab	-	12.5	67.5

The Laboratory staff who indicated "**Sometimes"** in their responses as shown in Table 28 were then asked when they last had performed an IQC on the test profiles to support the ART services.

Table 28 outlines the frequency responses of Laboratory Staff practices the "sometimes" category in performing Internal Quality Control (IQC).

Table 28: Frequency of responses by Laboratory Staff who "sometimes" perform Internal Quality Control for monitoring tests for HIV/AIDS patients on ART in Zambia.

Type of test	In the Last week %	In the last month %	In the last 3 months %	Not answered %
HIV test	18.2	8.2	4.9	57.5
CD4 Count	12.5	12.5	12.5	62.5
Full Blood Count	21.3	8.2	1.6	68.8
Creatinine	21.3	9.8	3.3	65.6
Liver Function Test	16.4	9.8	3.3	70.4

The reasons given by the respondents for never performing Internal Quality Control were as follows;

"Need to service machinery" (14),

"Lack of staff" (4),

"No machines" (9),

"Lack of machine" (6),

"Lack of refresher course" (1) and

"No chemistry analyser" (3).

The majority of Laboratory staff gave a reason for not performing IQC as not having readily available quality control materials and lack of planned service/ maintenance contracts for the equipment.

Table 29 outlines the frequency responses of Laboratory Staff practices on the availability of four test profiles to perform in the management of HIV/AIDS patients in ART Centres with and without laboratory services respectively.

Table 29: Frequency of responses by Laboratory Staff on the availability of four test profiles to perform monitoring tests for HIV/AIDS patients on ART in Zambia.

Type of test	ART Centre	Always	Frequently	Never
Liver Function Test	With Lab	54.2	31.1	14.7
	Without Lab	37.5	12.5	50.0
CD4 Count	With Lab	72.2	21.3	1.5
	Without Lab	25.0	12.5	62.5
Full Blood Count	With Lab	80.3	18.0	1.6
	Without Lab	50.0	-	50.0
Creatinine	With Lab	50.8	34.4	14.8
	Without Lab	37.5	-	67.5

Figure 7 indicates the percentage availability of laboratory monitoring tests profiles for diagnosis and monitoring tests for HIV/AIDS patients on ART as follows: the majority of the laboratories reported that Liver function test (ALT) (77%) was not available for diagnosis and monitoring HIV/AIDS patients. The non availability of liver function test (ALT) can lead to pathophysiological damage and toxicity to therapy to patients on ART.

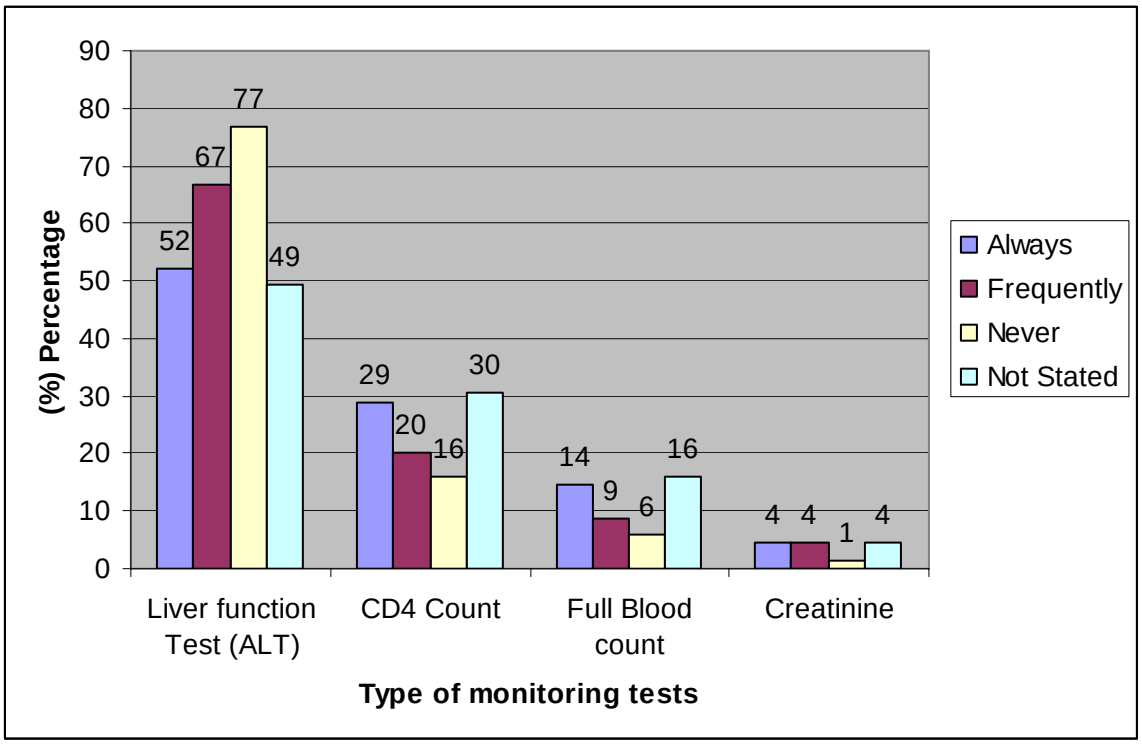

Figure 7: Percentage availability of laboratory monitoring tests profiles for diagnosis and monitoring HIV/AIDS patients on ART.

Table 30 summarises the total responses of Laboratory Staff level of practice in performing Internal Quality Control and test profiles for management of HIV/AIDS as Good 63.9 % and a mean of 13.83 in ART Centres with laboratory services whereas the ART Centres without laboratory services to support the ART program was good 37.5 % and a mean of 8.43. Laboratory Staff level of good practices was slightly less than WHO standard of 75%. This is due to non availability of equipment, reagents /supplies and lack of planned maintenance service contracts for equipment.

Table 30: Summary means comparison of Laboratory Staffs' level of practice in performing Internal Quality control tests in ART Centres with and without laboratory services.

Descriptive	**ART Centres**			
	With Lab		**Without Lab**	
Mean	13.83		8.43	
Standard deviation	4.24		7.34	
Minimum	2		1	
Maximum	18		18	
Level of Practice *	**n**	**%**	**n**	**%**
Bad	22	36.1	3	37.5
Good	39	**63.9**	5	**62.5**

Key: Good Practice = >75% and Bad Practice = <75%

Table 31: Summary comparison of Laboratory Staffs' Knowledge and Practice in ART Centres with and without laboratory services.

Variables	**Level**	**ART Centres**				**X^2 Chi-square**	**p-value**
		With Lab		**Without Lab**			
		n	**%**	**n**	**%**		
Knowledge	**Low**	6	9.8	1	12.5	**0.55**	**0.60**
	High	**55**	**90**	**7**	**87.5**		
Practice	**Bad**	22	36.0	5	38.5	**2.07**	**0.25**
	Good	**39**	**63.9**	**8**	**61.5**		

Table 31 summarises a comparison of Laboratory staffs' knowledge and practices. The majority (90%) and about (88%) of Laboratory staff working in ART centres with and without laboratory services respectively to support the ART program have high levels of knowledge. Similarly they have good laboratory practices of about 64% and 62% in performing diagnosis and monitoring tests for the management of HIV/AIDS patients on ART in ART centres with and without laboratory services respectively to support the ART program. Although the percentages are lower for the Laboratory Staff working in ART centres without laboratory services to support the ART program, this is mainly because they do not daily practice and perform tests profiles in their laboratory facilities due to lack of equipment and reagents/supplies.

However, the results indicate that there is no significant difference between Laboratory Staffs' knowledge and practices in the diagnosis and monitoring tests of HIV/AIDS patients on ART.

Research Question 3. *What are the qualities of the laboratory services in performing diagnosis and monitoring tests for HIV/AIDS on ART in Zambia?*

It is critical to have a fully functional quality assured laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia in accordance to WHO standard guidelines. This will enable quality, timely, early diagnosis, treatment and monitoring therapy of HIV/AIDS patients on ART.

The research findings indicate that the current number of laboratory staff was very low with 44 out of 69 (64%) with one (1) or two (2) persons managing the laboratory compared to an average estimated number of four (4) laboratory personnel in accordance with the MOH establishment register of the district facility (MOH 2007). Due to the increase in work load this has lead to poor quality of performance in laboratory diagnosis and monitoring tests of HIV/AIDS patients on ART. The laboratory staff also stated that

supervisory visits were conducted yearly by the national level from the Ministry of Health, Laboratory Services Manager to the peripheral levels. They said that the supervisory visits were useful and helpful in terms of technical support and updates in new methodologies.

Table 32 indicates the total number of Laboratory staff currently working in the ART centres. It also illustrates the frequency of Laboratory staff currently working in each ART centres.

Table 32: Frequency number of staff providing quality laboratory services per each ART centre.

Number of staff	ART Centres	
	n	Percent (%)
1	23	33.3
2	21	30.4
3	6	8.7
4	6	8.7
5	2	2.9
7	3	4.3
9	1	1.4
12	1	1.4

Figure 8 illustrates the percentage of equipment available in the laboratory for use in performing diagnosis and monitoring tests for HIV/AIDS patients on ART to support the ART program as follows; Haematology analyser 87%, CD4 count machine 72% and Chemistry analyser 75%.

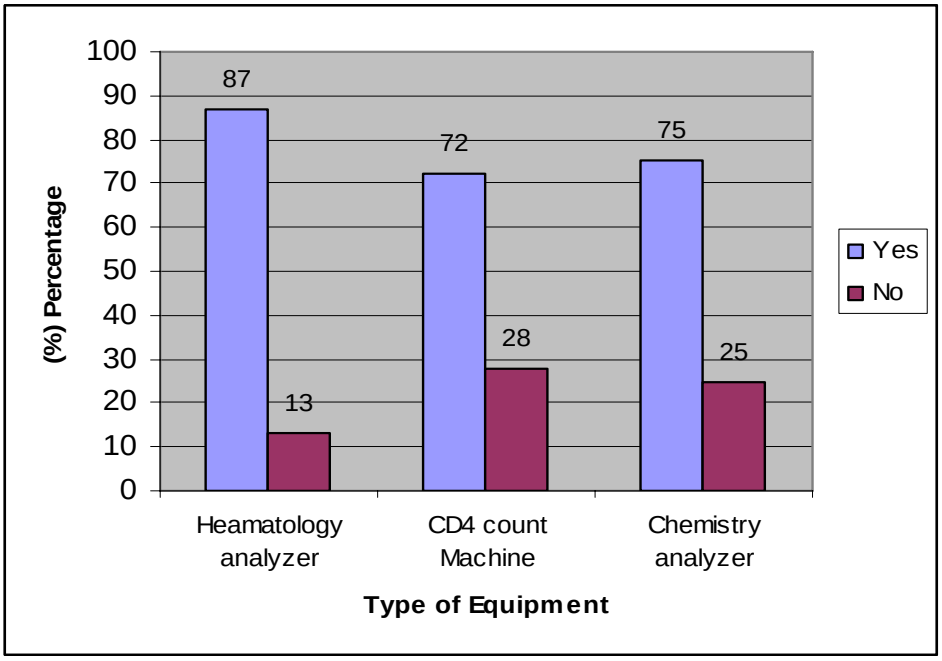

Figure 8: Percentage of available equipment for performing diagnosis and monitoring tests for HIV/AIDS patients on ART.

The study findings on the equipment used in the laboratories for performing diagnosis and monitoring tests for HIV/AIDS patients on ART revealed that most were of the equipment were more than fours years old, of various models, un-standardised and lacked planned service/maintenance contract. Once the equipment broke down it took more than one month to have it repair without service contract. Majority of the laboratories lacked services/maintenance contract this pose questions on the accuracy and reliability of the test results provide to Clinicians.

The study found that 41% of the laboratories had budgeted for service/maintenance contracts for the equipment and whilst only 25% of ART centres without laboratory services to support ART program had good equipment service.

Table 33: Frequency summary comparison of equipment service in ART Centres with and without service/maintenance contracts for laboratory equipment.

Level of Equipment Service	ART Centres			
	With lab		Without Lab	
	n	%	n	%
No service/maintenance contract	36	**59**	6	**75**
Yes With service/maintenance contract	25	**41**	2	**25**

Table 33 provides the summary comparison of equipment service in ART Centres with and without service or maintenance contracts for laboratory equipment. The table shows that the majority of the laboratories lacked equipment service/maintenance. This compromised the quality of tests performed.

In most cases the laboratory equipment was serviced on site by agents or suppliers. On average it took one (1) week to repair equipment with service/maintenance contracts.

The summary of the study findings indicated that the responsible officers involved in procurement of laboratory supplies/reagents were as follows; Head of Laboratory 29% and others 71% in ART centres with and without laboratory service to support the ART services. Poor quality of supplies/reagents was being procured by non laboratory personnel who were unable to quantify and specify the type of supplies/reagent required. As a result the respondents who were not satisfied with the current procurement system gave reasons such as receipt of wrong laboratory supplies/reagents, non receipt of

reagents /supplies, receipt of expired reagents/supplies and late delivery of laboratory requests.

Regarding the Laboratory commodity management systems to support the ART programme, respondents indicated that the laboratory supplies/reagents are mainly sourced from Medical Stores Limited and 58% of laboratories in the ART centres had experienced stock out of laboratory supplies/reagents in the last six (6) months prior to the survey.

Table 34 indicates that laboratories participation in External Quality Assessment (EQA) to support the ART services was not yet well established. Only 72% of the laboratories participated in the External Quality Assessment for TB smear microscopy. Performance results were documented and kept for future use and reference

Table 34: Frequency of the respondents on participation in External Quality Assessment to support the ART programme.

	ART Centres Laboratory services	
Participation in EQA	**n**	**%**
Yes	5	72
No	13	18

Only two respondents agreed in participating and kept records of EQA for diagnosis and monitoring tests of HIV/AIDS patients on ART to support the ART services. But majority responded that there is a to the need to;

"Improve quality control"(67)

The laboratories are affiliated to the National TB reference laboratory (Chest Disease Laboratory) and the National Tuberculosis Programme (NTP). The scaling up of the laboratory services requires quality management systems which are essential to the improvement of overall laboratory services and provides a blue print for sustainable quality. The findings clearly indicated an urgent need to establish EQA systems in the country.

The study found that 69% of the laboratories had planned for laboratory activities and 50% budgeted for laboratory activities in 2006 District Hospital Action Plan. Only 55% of the respondents in the laboratories attended senior management meetings. This reflected on poor laboratory management systems.

The respondents also stated that the five main challenges in performing diagnosis and monitoring tests for HIV/AIDS patients on the ART programme were as follows:

"Shortage of laboratory staff" (42),

"Shortage of reagents/supplies" (29),

"Lack of equipment" (20),

"Increased workload" (20) and

"Machine breakdown and frequent power interruptions (load shading)" (10).

All the above mentioned experiences and challenges stated by the Laboratory staff supported the study findings from the data gathered from the Medical Doctors/Clinicians, as well as from the findings of other researchers.

Research Question 4*. What is the turnaround time* (TAT) *of CD4 count results to reach the public sector ART centres in Zambia?*

The turnaround time is the time it takes to receive the CD4 count results after submitting the blood specimens to the laboratory from the ART Clinic. The ART Clinic may be defined as a health facility with a full complement of laboratory support (CD4, Chemistry and Haematology functions). It is of paramount importance to determine the turnaround time of CD4 count Laboratory results to reach the ART clinics in support of the ART programme in Zambia. A long turn around time for the results leads to reduced compliance to clinic attendances, drug uptake and consequently leads to development of drug resistance and adverse drug reactions. It is therefore necessary to have increased equity of access and provide fully equipped, functional, quality assured laboratory services and guidelines for storage and transportation of specimens for referral to support ART services in order to reduce turnaround time for the CD4+ Lymphocytes count results to reach the ART Clinics.

Seventy-four (74) ART centres with and without laboratory services were assessed on the time taken for CD4 count results from the laboratories to reach the ART clinic as shown in Figure 9.

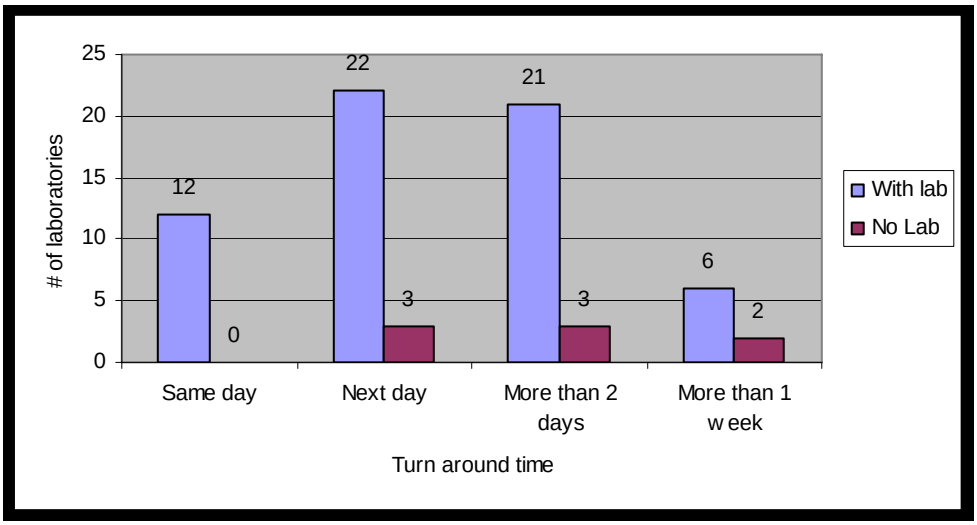

Figure 9: Comparison of turnaround time of CD4 count results in ART Centres with and without laboratory services.

The study findings on the TAT for CD4 count results to reach the ART clinic indicated that twenty-two (22) laboratories had a TAT of the next day, twenty-one (21) laboratories had TAT of more than two days, twelve (12) laboratories had TAT the same day and six(6) laboratories had TAT of more than one (1) week. This applied to ART centres with and without laboratory facilities on site.

Table 35 summarises the turnaround time. About 22% ART centres with laboratory services had short TAT of CD4 count results to reach the ART clinics, whereas all 100% ART centres without laboratory services had long TAT of more than 48 hours.

Table 35: Frequency summary of the turnaround time (TAT) of CD4 count results to reach the ART clinics in support of the ART in ART Centres with and without laboratory services.

Level of TAT *	ART Centres			
	With Lab		Without Lab	
	n	%	n	%
Long (after 24 hours)	43	78	19	100
Short (within 24 hours) Standard	12	22	-	-

Research Question 5; *Is there any difference between the KAP of Medical Doctors/Clinicians in ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia?*

The student t-test statistic was used to calculate of the difference between the KAP of Medical Doctors/Clinicians in ART Centres with and without laboratory services.

Table 36 illustrates the t-value of Medical Doctors/Clinicians' KAP in ART centres with and without laboratory services in order to statistically test whether there is difference in the means.

Table 36: Comparison of Medical Doctors/Clinicians' t-value in ART centres.

Variables	ART Centres	n	Mean	Standard Deviation	Degrees of freedom	t-value	p- value
Knowledge	With Lab	55	12.56	1.38	31	0.04	0.97
	Without Lab	19	12.57	1.39			
Attitude	With Lab	55	6.85	1.14	27	0.93	0.36
	Without Lab	19	6.52	1.39			
Practice	With Lab	55	13.29	3.00	27	0.03	0.98
	Without Lab	19	13.26	3.63			

The results indicate that the Medical Doctors/Clinicians KAP mean values are not different in ART centres with and without laboratory services to support the ART programme. Therefore the Medical Doctors/Clinicians level of KAP are of similar proportions in the diagnosis and monitoring tests for the management of HIV/AIDS patients on ART in ART centres with and without laboratory services.

Research Question 6: *What are the predictive values and discrimination power of performing diagnosis and monitoring tests for HIV/AIDS patients on ART by using KAP of Medical Doctors/Clinicians in ART centres with and without laboratory services in Zambia?*

The determination of the predictive values and discrimination power of performing diagnosis and monitoring tests for HIV/AIDS patients on ART was calculated using KAP of Medical Doctors/Clinicians in ART centres with and without laboratory services.

There is no difference in the Medical Doctors/Clinicians KAP in performing diagnosis and monitoring tests for the management of HIV/AIDS patients on ART in ART centres with and without laboratory service to support the ART programme.

Since there is no difference in the knowledge, attitude and practices of Medical Doctors/Clinicians in ART centres with and without laboratory services, there is no relationship in these variables. Therefore neither logistic regression nor discriminant analysis was done for the scaling up of laboratory services to support the ART programme.

Table 37 illustrates the analysis and summary of the study findings linking up all the research questions to the dependent variable.

4.3 Conclusion

In conclusion, the research findings have determined challenges within the components of the conceptual framework model. The counter measures or interventions required are basic inputs (infrastructure, human resources, equipment and supplies) with financial resources in order to scale up and strengthen the quality assured laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.

Table 37: Summary analysis of challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia

Research Question	ART Centres	Availability of Policy & Guidelines	KAP of Medical Doctors/Clinicians	KAP of Lab Staff	Quality of Lab Services	CD4Count results Turn Around Time
	With Lab	Good = 83%				
1	Without Lab	Poor = 17%				
	With Lab					
2a	Without Lab					
	With Lab			K =90%. P=63.9%		
2b	Without Lab			K=87.5% P=61.5%		
	With Lab				Availability of CD4 count machines =72% , QA=Not yet established Equipment Service contracts = 59%	
3	Without Lab				Availability of CD4 count machines (Poor=100%) QA=Not yet established Equipment service/maintenance contracts =75%	
	With Lab					Short(24hrs)=22% Long(>24hrs)=78%
4	Without Lab					Long(>48hrs)=100%
	With Lab		No difference			
5	Without Lab		No difference			
	With Lab		K(p=0.97) A(p=0.36) P(p=0.98)			
6	Without Lab					

Note: KAP =Knowledge, A=Attitude, P=Practice, *p*=Predictive, QA=Quality Assurance, Lab=Laboratory

CHAPTER V

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses based on the data collected and analyzed, further recommends and makes conclusions on the challenges relating to scaling up and strengthening laboratory services for diagnosis and monitoring tests for HIV/AIDS patients in Zambia.

5.2 Discussion

The research findings are discussed from the previous chapter's results within the context of the literature review in Chapter II. The discussions are on the data presented in answering to each research objective on the challenges of scaling up laboratory services for diagnosis and monitoring tests for HIV/AIDS patients in Zambia.

Research Objective 1. *To review the current national HIV/AIDS/STI/TB policy, Laboratory policy, ART strategic plan and guidelines for the implementation of ART services in Zambia.*

The Ministry of Health in Zambia have developed guidelines and disseminated for implementation on HIV/AIDS treatment and care, HIV/AIDS policy, laboratory policy, laboratory SOPs for HIV/AIDS diagnosis and monitoring tests and ART scale-up plan. In most developing countries where ART services have been scaled up there has been political commitment by the government to constituting a national AIDS Council for the formulation of policy (Ministry of Health, Uganda 2003). In Zambia, the national policy (National HIV/AIDS/STI/TB Council 2005) provides the framework and general

principles for the national response interventions for the prevention of infection, care and support of those infected and affected by the pandemic and mitigation of the situation. Zambia has adopted the UNAIDS (2006) global recognition of strengthening health systems for greater access to ART by scaling up ART services through the development of guidelines and their implementation. These guidelines have been instrumental in the successful implementation of the ART programme in Zambia.

The laboratory SOPs are written instructions that describe standard ways of doing things in the laboratory, how laboratory tests should be performed, how quality control should be done for each test and how equipment should be maintained. In Zambia laboratory SOPs to support the ART programme have been developed and disseminated in accordance with WHO guidelines (WHO 2003), and have been critical to quality-assured laboratory services. Zambia has done well in the development of these guidelines indicated in the study findings. Similarly, Kenya has piloted these guidelines in two regions. This has contributed to the successful implementation of further scale up of laboratory services provision (Denje et al. 2004).The study conducted in Kenya recognised the importance of development and implementation of the laboratory policy, SOPs and quality assurance guidelines in the implementation of ART services. Whilst Uganda and Rwanda (2003) have disseminated the SOPs in all the laboratories supporting their ART programmes, the actual implementation of SOPs is yet to be monitored and evaluated.

Challenges have also been noted in scaling up laboratory services in studies done by Petti et al. (2001). The studies indicate that the cost is high for scaling up laboratory services in developing countries and that slow progress has been attributed to lack of leadership at national level to spearhead the development, coordination and implementation of the laboratory policy, strategic plan and SOPs to support ART services. A well-functioning country-wide ART programme requires a significant investment to build the capacity of leaders to develop national strategies with laboratory components to support ART services. This is in agreement with the research findings.

PEPFAR (2005) funding is supporting countries to develop national strategies, and to build HIV/AIDS care and treatment networks which include the scale up and strengthening of laboratory services to support ART programmes. The effect of not having networks to support ART services will result in poor linkages in providing clinical support for laboratory services, training logistics, management systems, monitoring and reporting systems and other aspects of quality care treatment.

Research Objective 2a. *To assess the knowledge, attitudes and practices (KAP) of Medical Doctors/Clinicians in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.*

Results from a WHO (2003) survey report in Sub-Saharan Africa show that the human resource (health) capacity is generally weak in many places. This is a critical factor in providing access to ART services.

It correlates with the results of this survey conducted in 137 ART centres in the public sector in Zambia. The findings indicated that there were 53 Medical Doctors/Clinicians working in ART centres with and without laboratory services to support the ART programme. Only 40 of the medical doctors/clinicians were working in ART centres with laboratory services and 13 in ART without laboratory services to support the ART programme.

Results from the survey showed that medical doctors/clinicians who worked in ART centres with laboratory services had high levels of knowledge (96.4%) and 100% in ART centres without laboratory services to support ART programme, on when to start or initiate ART for HIV/AIDS patients and monitoring tests required for the treatment. A logical explanation of this is that the medical doctors/clinicians were trained in ART scale-up implementation of guidelines and had been provided with guidelines to use in the management of HIV/AIDS patients on ART.

Similarly, the WHO (2006a) reports that in developing countries (for example, Kenya, Uganda, Malawi and South Africa) building capacity in the health workers by training them in ART scale-up interventions (in-service training) provided adequate knowledge for the successful implementation of ART services. In Botswana, Kenya, Malawi, South Africa, Tanzania and Zambia, medical doctors/clinicians had a high level of knowledge of when to start or initiate ART for HIV/AIDS patients as well as monitoring tests required for treatment, but there was little evidence of an overall vision or clear communication of the critical role of the laboratory services to support the ART programme in health care delivery.

The medical doctors/clinicians in both ART centres 92%with and 84%without laboratory services to support the ART programme had high perception and valued the high quality performance of laboratory services in the diagnosis and monitoring tests of HIV/AIDS patient on ART. The medical doctors/clinicians felt that the performance of laboratory services was of high quality in the diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia. This was also supported by the studies conducted in Kenya by Wachira et al. (2004) which indicate that the role of laboratory services in supporting ART services at the hospitals was fully appreciated in patient management and care.

This survey looked at the practices (skills) of medical doctors/clinicians on when to start or initiate ART for HIV/AIDS patients and monitoring tests requested for the treatment. The study survey found that only 32.7% of medical doctors/clinicians working in ART centres with laboratory services, and 36.8% of medical doctors/clinicians working in ART centres without laboratory services to support the ART programme used both CD4 cell count test and clinical staging to determine when to start or initiate ART and to monitor HIV/AIDS patients on ART. The findings indicate that the majority of medical doctors/clinicians used only the WHO (2003) staging guidelines without the CD4 count test in the management of HIV/AIDS patients on ART in ART centres with laboratories and without laboratories to support ART services. This meant that there was no difference in medical doctors/clinicians' practices on when to start or initiate ART and when to request for monitoring tests for HIV/AIDS patients on ART. But recently the

WHO (2007) has updated its staging guidelines to encourage the widespread use of CD4 cell counts.

Other research studies presented at the International AIDS conference in Rio de Janiero (2007) and the PEPFAR (2006) implementers' meeting showed that many of the HIV/AIDS patients who would qualify for treatment on the basis of CD4 cell count were missed out when only clinical staging was used. It has become of paramount importance in accordance with WHO (2007) guidelines that the CD4 cell count is a standard test and part of the clinical management of patients with HIV/AIDS.

In summary, the majority of medical doctors/clinicians at ART centres had a high level of knowledge about the diagnosis and monitoring tests required for HIV/AIDS patients on ART. It was therefore critical that the laboratories should be strengthened and capacity built where ART services were provided, to avoid the use of only clinical staging to determine when medical doctors/clinicians should start/initiate HIV/AIDS patients on ART. It must be noted that clinical staging yields fewer patients to be started on treatment.

Research Objective 2b. *To assess the knowledge, and practices (KP) of laboratory staff in the diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.*

In addition to medical doctors/clinicians, pharmacists, nurses, and other health care workers directly involved in care and treatment for HIV/AIDS patients, laboratory technicians were essential to the actual diagnosis and monitoring tests for HIV/AIDS patients on ART. According to studies conducted by Puku et al. (2002), for example, Zambia had estimated that its initial ART scale-up programme (for 10 000 patients) would be 32 Full-Time Equivalent (FTE) laboratory technicians in addition to an estimated 13 FTE doctors and nurses and 15 FTE pharmacists to support the ART programme.

Studies have shown that laboratory technicians play an important role in the ART scale-up programme; hence the need for more of these personnel and the need to improve their training, as compliance with good laboratory practices are critical for quality-assured laboratory services. It is essential to identify and evaluate deficiencies in training programmes for laboratory technicians to minimise these errors. To support the findings in Sub-Saharan Africa, Bates and Maitland (2006) reported that some factors that may contribute to poor performance such as not having clear laboratory policies and strategies in place should be addressed. The studies are in consonance with other studies by Van Damme (2004), 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. This is clearly indicated in the study findings that the distribution of laboratory staff was only 52% in the ART Centres which is 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 competence in laboratory techniques. This can be achieved through continuing education or refresher courses.

The findings show a clear correlation between the quality of trained staff and the relative distance from the capital city. National Reference Laboratories (NRLs) are situated in the capital city and tend to have more qualified staff than provincial or district level laboratories. The severe lack of trained laboratory experts at provincial level and districts presented an additional layer of challenge to the rapid scale up of laboratory services in district health centres in areas where most of the population resided.

The responses from laboratory staff indicated that they had a high level of knowledge (about 88%) among those working in laboratories with limited capacity to support ART services on the most frequently requested tests for diagnosis and monitoring tests for

HIV/AIDS patients on ART in ART centres. The findings suggest that there is a need to strengthen the laboratories with the basic inputs such as equipment, human resource and reagents/supplies in order to support ART services.

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 practice (64%) and 62% those working in laboratories with limited capacity to support ART services in ART centres. Although the percentages of good practice seemed to be lower than the WHO (2006b) standard guidelines. This was mainly because they did not practice and perform test profiles on a daily basis in the laboratories due to lack of IQC materials, reagents/supplies and faulty equipment with no service maintenance plan. There had not been any studies previously conducted to compare or contrast to the observed findings.

The findings also indicated that there was low knowledge and practice on the type of disinfectant to use when there was blood spillage as well as inadequate safety laboratory practices which would be required to be enforced. These findings are in consonance with previous studies by Abimuku (2006) in Nigeria that highlighted that a number of developing countries had no policy on accidental exposure to infectious agents and did not disinfect the bench tops of their laboratories daily.

There was a need to retrain laboratory staff on standard universal precautions, in the use of various types of disinfectants, and good laboratory practice.

Research Objective 3. *To assess the qualities of laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia compared to WHO standard guidelines.*

A fully functional quality-assured laboratory requires an adequate number of laboratory staff at each level of care. Inadequate staffing can result in increased mistakes in

processing tests, which leads to inaccurate, unreliable results and safety measures in the laboratory may be ignored.

The survey found that the current number of laboratory staff was very low with only 64% of the laboratories with one or two persons managing the laboratory compared to an average of four laboratory staff in accordance with the Zambia Ministry of Health's establishment register of a district facility. The World Health Organisation (WHO 2004) recommends that at least two staff members be available for health centre laboratories and at least four for district level laboratories. Other studies by USAID (2003) that are comparable to the study findings have shown that laboratories across the health system appear to be understaffed, particularly at district and health centre level. However, understaffing in some instances is due to poor distribution of laboratory staff according to the workload, mortality of laboratory staff mostly attributed to AIDS complications and lastly the departure of laboratory staff for better opportunities (greener pastures).

These findings correlate with studies by Ojikutu et al. (2004) that even the most basic laboratory services are often lacking or unreliable in the most resource-constrained settings. The laboratory infrastructure in low-income countries generally;

- lack basic essential equipment,
- have a limited number of skilled personnel,
- lack laboratory consumables/supplies (such as sterile urine-specimen containers),
- lack educators and training programmes,
- have inadequate logistical support,
- suffer from a de-emphasis of laboratory testing by clinical staff,
- have insufficient monitoring of test quality,
- have decentralised facilities that have been set up as parallel and competing infrastructures (where governmental, non-governmental organisations and commercial (for-profit) organisations operate independent laboratories), and
- have no governmental standards for laboratory testing (SOPs).

The majority of medical doctors/clinicians who used the laboratory services in this study said that the performance of the laboratory services needed to be improved by employing more adequately trained staff, acquiring more equipment, ensuring a constant supply of reagents and providing refresher courses for the laboratory staff on new testing technologies to support the ART services. To support these findings, reports by Haumba (2006) in Uganda indicate that there is a scarcity of qualified laboratory staff that is poorly deployed. There is low uptake of laboratory services due to lack of trust in results by clinicians. It was noted that supplies were inconsistent, basic equipment was lacking and existing equipment was not well maintained. Petti et al.2006 demonstrate that CD4 cell testing, if integrated into the existing (but improved) public sector laboratory infrastructure, could be made available and would result in improved laboratory services and care for all patients.

It was also demonstrated that as a result of all of the above mentioned interventions, not only did CD4 cell monitoring become accessible, but the laboratories' capacity increased and the quality of the results (and clinicians' confidence in them), improved dramatically. Further testing for all tests, other than just for ART patients increased tremendously and the image of the laboratory improved to the extent that private practitioners began sending requests to the public hospital.

The study findings have shown that the distribution of laboratories to support the ART services was not proportionate to the number of ART centres in the provinces. To alleviate this problem some provinces implemented a referral system by having an ART mobile clinic where specimens were collected once a week and tests were performed at referral laboratories. The results were sent back by the same transport mechanism once a week. In this case, all CD4 count specimens were sent to the nearest laboratory and results were sent back to the ART Clinic within a week.

This is also well documented in the study conducted in Zambia by Torpey et al. (2006). In order to offer CD4 cell monitoring for people with HIV (at primary health centre clinics), a sample referral system was set up to transport samples from the outlying

clinics to referral laboratories set up in strategic areas with CD4 cell monitoring equipment. This transportation system of samples is comparable to and supported by Wachira et al. (2004) in Kenya where many sites were transporting samples to the reference laboratories by putting couriers with cold storage boxes onto the same regular public mini-taxis (mini-vans) that many people used for local transportation.

The lack of laboratory services in most developing countries was also highlighted in a survey conducted in 2000 by the WHO-sponsored African AIDS Vaccine programme (AAVP). 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.

Lessons learnt from the WHO (2006) both in developed and developing countries showed that poor initiating or starting of treatment without laboratory diagnosis, including CD4 count, could limit a patient's future therapeutic options and alter the course of the disease and treatment response. Therefore the use of ART without proper monitoring tests, including viral load, was associated with treatment failure as a result of the emergence of a resistant virus.

The External Quality Assessment (EQA) of public ART centres allows for evaluation of past performance of a laboratory on the various quality-assurance measures. It also provides an opportunity to improve performance of the laboratory. The study findings on participation in EQA indicated that it was not yet established for the laboratory tests to support the ART services. The only External Quality Assessment available was for TB smear microscopy. To support these findings a similar survey which was conducted by the WHO African Regional Office (AFRO) (2000), 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.

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 during routine laboratory work. The present study findings indicated that internal quality control was not performed on a daily basis. The reasons given by those laboratory staff for not including internal quality control when performing tests were lack of staff, too great a work load, lack of refresher courses, need of equipment for service/repair and lack of equipment. The absence of internal quality control has serious implications for the reliability of tests.

Comparable to results of this survey, other studies showed that Quality Laboratory Management and Quality Assurance (QA) had been an important part of Brazil's laboratory services support for their ART programme. External Quality Assessment (EQA) for CD4 count was conducted six times per year to ensure quality-assured performance of laboratories to support their ART programme (WHO 2004).

The study found that in most cases procurement of laboratory reagents and supplies were done by procurement officers without involvement or representation of the head of the laboratory in the quantification and tender evaluation. This had implications in that sub-standard, wrong specifications and poor quality of reagents/supplies were procured. This could lead to inaccurate laboratory results. There is a need to build capacity by re-training the laboratory person in charge in laboratory management systems and quality performance improvements.

The study established that the equipment used in the laboratories were of various models, not standardised and there was a lack of maintenance/service contracts. Once the equipment broke down it took more than a month to be repaired. A fully functional laboratory must have good working equipment and a maintenance plan in place in order to provide accurate reliable laboratory results.

To support the findings, reports by Nkengasang et al. (2008) have found that in developing countries it has been a challenge to ensure the consistent supply and provision of laboratory commodities to meet the demand created by rapid scaling up programmes. Timely availability of essential equipment, supplies and reagents is critical to ensure the

overall quality of laboratory testing and avoid disruptions in patient care. Standardisation of laboratory commodities offers unique opportunities to coordinate the maintenance of equipment, bulk purchases, training on common instrumentation, and contract service mechanisms. To overcome this challenge, when PEPFAR was created, USAID established a supply chain management system (SCMS) in order to standardise the procurement and distribution of laboratory commodities to support all PEPFAR countries. The system has however not yet been fully implemented and will require to be evaluated before being rolled out to all levels of care.

The findings also showed that basic procedures for recording and storing information were in place but these were often insufficient and not standardised among private/public sector laboratories to support the ART programmes. In some cases information was poorly stored and incomplete and therefore not suitable to be used for planning and decision- making. The scaling up of public sector ART services would need strengthening and capacity building in recording and reporting systems. There were no data by other researchers to compare and contrast to the study findings.

The quality of the laboratory services for performing diagnosis and monitoring tests for HIV/AIDS on ART in Zambia compared to WHO standard guidelines can be described as poor. This was evident from the fact that out of 246 of public ART centres only 57 offered a full complement package of laboratory services to support ART services . This showed that only 23 percent of laboratory services supported the ART programme in Zambia. The other fact is that distances between ART centres offering laboratory services in Zambia was not proportionate compared to the WHO (2004) guidelines.

In comparison to the proposed study conceptual framework, the study findings clearly showed that interventions were required to be put in place for fully-functional quality-assured laboratory services to support the ART programme. In accordance to the conceptual framework the key interventions elements or core functions required were;

- the structural capacity (planning and budgeting, policy and health systems management)
- human resources, infrastructure, equipment/supplies and
- organisation of the ART service.

The process of performing diagnosis and monitoring tests will provide quality, reliable accurate test results. The outcomes will be increased effective timely diagnosis and monitoring tests, efficiency of service, increased clinicians' confidence in laboratory performance and equity of access to laboratory services. The final overall result would be impact on patients; increased timely diagnosis and monitoring tests for patients on ART, early treatment and monitoring of treatment, early detection of drug resistance and treatment adherence problems.

Research Objective 4. *To determine the turnaround time of CD4 count Laboratory results to reach the ART centres in support of the ART programme in Zambia.*

The CD4 count machine is the critical equipment used for diagnosis before initiating therapy and monitoring therapy required for HIV/AIDS patients on ART. As the ART programme continues to be scaled up in developing countries, CD4 lymphocyte count testing has become critical in initiating ART and monitoring response to ART. However, WHO clinical staging alone does not always correspond to the degree of suppression.

According to the WHO (2004) recommendations, the TAT for CD4 count results to reach the ART clinics should be within the same day (12 hours), especially where the Laboratory is within the facility. Unfortunately the study findings show that due to the critical shortage of qualified, competent laboratory staff and lack of CD4 count machines in some laboratories, the targeted TAT of 12 hours will be extremely difficult to attain or achieve. Only 23% of ART centres had CD4 count machines. It took more than 48 hours to one week for CD4 count results to reach the ART centre with or without laboratory services. Currently this presents a number of challenges such as storage and transportation of blood samples to the referral laboratories that again have inadequate laboratory staff and frequent breakdowns of equipment due to frequent power outages

(electricity shutdown or load-shedding) which is currently a problem in Sub-Saharan Africa.

Even though the Ministry of Health's (1992) reform vision and aim was to improve health status of all Zambians through provision of equity of access to cost-effective quality health services closer to the family. This study finding clearly showed that there was no equity of access in terms of distribution of the laboratories to support ART services in Zambia.

To support the study findings in similar studies that had been conducted by the WHO (2006b) in Kenya, Uganda, and South Africa by *Medicines sans Frontier* (2003), it was observed that without the CD4 count machine, CD4 count results would delay;

- the initiation of therapy,
- monitoring therapy and
- the adverse reaction to drugs

This could consequently lead to treatment failure and HIV drug resistance. The findings of the study clearly indicate that, in terms of laboratory support for ART services, equity of timely access to CD4 count results is not available.

Reaction to delay is clear from the findings of the study that there is considerable variation in turnaround time for CD4 counts in Zambia. Prolonged results turnaround time delays the initiation of ART in appropriate patients and the monitoring of HIV/AIDS patients' reaction to drugs. It also affects the assessment of HIV drug resistance.

Research Objective 5. *To determine the difference between the Knowledge, Attitudes and Practices (KAPS) of Medical DoctorsCclinicians in the ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.*

The study findings indicated that there was no difference between the medical doctors/clinicians' knowledge, attitude and practices in ART centres with and without laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia.

The study indicated that the level of knowledge of medical doctors/clinicians of the diagnosis and monitoring tests for HIV/AIDS patients on ART was high on average (about 96%) in ART centres, both with and without laboratory services to support the ART programme. This clearly indicated that in ART centres both with and without laboratory services medical doctors/clinicians' level of knowledge was the same, mainly because they had been trained in the ART scale-up implementation plan guidelines and used the guidelines in the management of HIV/AIDS patients on ART.

Similarly, there was no difference in ART centres both with and without laboratory services in the perception and value of the laboratory services by Medical Doctors/Clinicians to support the ART programme. The medical doctors/clinicians (on average about 88%) had a high perception and valued the performance of laboratory services; they felt that the performance of laboratory services was of high quality regarding the diagnosis and monitoring tests of HIV/AIDS patients on ART in Zambia. This was supported by the studies conducted in Kenya by Wachira et al. *(*2004) which indicated that the role of laboratory services to support ART services at the hospitals was fully appreciated by the medical doctors/clinicians in the management of HIV/AIDS patients on ART.

However the practices of medical doctors/clinicians in ART centres both with and without laboratory services to support ART programme were the same. The study survey indicated that of the Medical Doctors/Clinicians, only about 35% used both CD4 cell count test and clinical staging on when to start or initiate ART and monitoring for HIV/AIDS patients on ART. It was assumed that the majority of medical doctors/clinicians used only the WHO (2003) staging guidelines without CD4 count test in the management of HIV/AIDS patients on ART in ART centres with laboratories and without laboratories to support ART services. This meant that there was no difference in medical doctors/clinicians' practices on when to start or initiate ART for HIV/AIDS patients and requesting for monitoring tests of HIV/AIDS patients on ART. But recently the WHO (2007) had updated its staging guidelines and recommended the widespread use of CD4 cell counts.

The researcher did not come across any credible literature for comparing and contrasting with the study findings.

Research Objective 6. *To determine the predictive value and discriminative power of performing diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy by using KAPs of Medical Doctors/Clinicians with and without laboratory services.*

The determination of the predictive value and discriminative power of performing diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy by using the KAP of medical doctors/clinicians with and without laboratory services could not be analysed. This because there was no difference in the KAP of medical doctors/clinicians in ART centres with and without laboratory services to support the ART programme. Hence there was no relationship between these variables. The prediction for scaling up laboratory services could not be determined using these variables.

The findings indicated that medical doctors/clinicians working in the ART centres with laboratories had better prognosis of diagnosis and monitoring tests in the treatment of

patients on ART. Hence the patients were less likely to have adverse effects on drugs as well as being resistant to HIV drugs, compared to those medical doctors/clinicians working in the ART centres without laboratories. Because in most cases HIV/AIDS patients on ART tended not to go back for their results due to non-availability of laboratory services and long distances to access the laboratory services. HIV/AIDS patients on ART in ART centres without laboratory services, were therefore likely to have a high mortality rate and adverse drug reactions which may lead to HIV drug resistance.

Furthermore, the study findings highlighted the need for interventions in the scale-up of laboratory services and medical doctors/clinicians' KAP especially those working in ART centres without laboratory services. There was also the need to retrain and update all medical doctors/clinicians working in ART centres with and without laboratory services so that they were at the same level of knowledge, attitude and practice in diagnosis and monitoring tests for management of HIV/AIDS patients on ART.

The researcher did not come across any credible literature for comparison and contrast with the study findings.

In summary the discussion was mainly on the six research objectives findings in comparison with the findings of other researchers. This study had limited literature review for discussion to compare and contrast the findings. Therefore the conclusion followed to discuss the challenges of scaling up and strengthening the laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART.

5.3 Conclusion

In conclusion, the study indicates that there are only 39%, laboratory service delivery points providing full complement package for diagnosis and monitoring tests of HIV/AIDS patients on ART in the 137 public ART centres in Zambia. The distance between laboratories with a full complement package to support ART services and the

ART centres is not proportioned in accordance with WHO guidelines. This was supported by the finding that the majority of Medical Doctors/Clinicians' KAP in ART centres were using clinical staging and management of patients based on WHO staging guidelines without laboratory services support.

The Zambian Ministry of Health ART scale-up plan target stipulates that at least two-thirds of 350 000 people living with HIV/AIDS should be on ART by the year 2010. In line with the Ministry of Health's health reform vision this will therefore require the provision of equity in access to laboratory services for HIV/AIDS patients on ART in order to ensure early detection of drug resistance, drug reactions and treatment of drug adherence problems. The challenges of scaling up laboratory services are real and require urgent and vigorous interventions to successfully support the implementation of the ART programme in Zambia.

The research findings indicate that the HIV/AIDS policy, Laboratory policy, Laboratory SOPs and guidelines on ART scale-up plan exist at national level but have not been fully disseminated to ART Centres. Therefore, there is an urgent need to develop a Laboratory services implementation plan. Guidelines for quality assurance should be developed towards laboratory accreditation to a regional body in the SADC to support the ART programme.

External Quality Assessment to support the ART services has not yet been established. Quality-assured laboratory services will increase medical doctors and clinicians' confidence in and satisfaction with the laboratory results.

Shortage of staff is the biggest challenge in performing laboratory tests, due to the high disease burden for HIV/AIDS/TB. The average number of laboratory staff at district hospitals surveyed was only one (1) qualified laboratory member of staff which is lower than the WHO recommendation of four (4) staff members per district hospital. To achieve rapid scale up of laboratory services, the training of laboratory staff is critical at all levels of the laboratory network.

This study's findings have also shown that there is a shortage of CD4 count machines to support ART services. In most cases the turnaround time of laboratory results was longer and could exceed one week. Non-availability of specimen transportation guidelines compromised the quality of specimens to perform the CD4 count tests as it took longer to transport the samples to referral laboratories.

The laboratories surveyed had no service or maintenance contracts and the staff had no basic knowledge of repairing non-functional equipment. Once the equipment was sent to the suppliers, it took almost one month to be repaired.

There is a need for the policy and decision-makers to improve and strengthen the quality of laboratory services by providing the required resources such as adequately trained laboratory staff, supplies/reagents, conducive working environments (infrastructure), equipment and finances.

The findings of the survey indicate that the current state of laboratories in Zambia cannot fully support the needs of the ART programme. To alleviate these challenges, the overall goal of scaling up laboratory services is a must in order to ensure sustainable, accessible, integrated laboratory capacity that can provide quality, accurate, reliable and affordable results in a predictably quick turnaround time for the effective implementation of lifesaving treatment and prevention programme. Thus, from a public health perspective, laboratory services need to be significantly strengthened and expanded for ART scale-up interventions to be successful.

5.4 Recommendations

On the basis of the present research findings on the scaling up of laboratory services in diagnosing and monitoring tests for HIV/AIDS patients on ART in Zambia, it is recommended that through the Ministry of Health, the Government of the Republic of Zambia should:

- Disseminate and distribute the national HIV/AIDS policy, Laboratory policy, Laboratory SOPs and guidelines on the ART scale-up plan from the Ministry of Health to the service providers of ART services and a mechanism be put in place to strengthen and periodically review the implementation of these documents;
- Accelerate the recruitment and improve on the redistribution of qualified staff which should be reviewed to accommodate the current high workload, range of tests performed and the increase in laboratory operations with the ART scale-up programme.
- There is a need to direct efforts to address the training challenges in at least three areas: in-service training and organisation of test-specific workshops to meet the immediate needs, increase pre-service training that includes the full spectrum of testing in the curriculum, and establishing a culture of effective quality management.
- Training should be accompanied by a strategy for recruitment and retention of staff.
- All laboratory staff working to support the ART programme should be trained through a system of continuing professional education in order to keep abreast of the new technologies to avoid frequent breakdown of machines due to use by untrained staff.
- Capacity should be built in the all the Laboratory staff by providing them with laboratory management training skills to enable them develop work plans and budgets for the activities in the laboratory;
- Develop guidelines and establish quality assurance systems to include IQC and EQA to support the ART programme and affiliate the laboratories to participate in the SADC regional EQA for accreditation such as the South African National Accreditation Systems (SANAS);
- Develop and establish standardised procedures and forms for recording, registering and storing information to ensure patient confidentiality at the Ministry of Health and implemented at facility level (ART Centre). This will be used to monitor and evaluate activities to support the ART programme. A

standard format of recording CD4 Count results should be either computerised or kept on a manual system. This should include the CD4 count for diagnosis before initiating ART and CD4 for monitoring therapy with a timeframe.

- Provide the laboratories which already have capacity for supporting ART services with a CD4 count machines. Draw up maintenance service contracts with manufacturers or distributors and a dedicated budget should be allocated for equipment maintenance and spare parts. Due to the frequent breakdown of equipment, the laboratories need to be provided with guidelines on service or maintenance contracts with suppliers on a yearly basis; and
- Increase equity of access by providing more fully functional laboratory service delivery points to support the ART programme in order to reduce turnaround time for the CD4 count results to reach the ART Centres.

5.5 Recommendations for Future Research

The study attempted to address challenges of scaling up and strengthening quality assured laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on ART. However, some issues could not be examined. Further research could therefore be conducted by taking these issues into consideration. The issues are as follows;

- A study should be conducted on the development of a model for scaling up and strengthening quality-assured laboratory services to support the ART programme in diagnosis and monitoring for HIV/AIDS patients on ART;

- The model should include a standardised, uniform and comparable way of capturing CD4 count result data for diagnosis before initiating treatment and for monitoring treatment of HIV/AIDS patients on ART. The model should also have a standardised format of capturing and storage of laboratory data; and

- Manufacturers of CD4 count machines should conduct studies on the possibilities of having a cheaper, reliable solar or battery-operated CD4 counting machine for

the sub-Saharan African region which is currently facing a lot of load-shedding (power outages).

In conclusion, this chapter discussed the six research objectives findings in comparison with the findings of other researchers but the study had limited literature. Conclusions and recommendations required as interventions to be put in place were made based on the study findings. Recommendations to policy makers and further future research was also addressed on the scaling up of laboratory services for diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia. This will widen the scope of research for future policy and planning development.

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7. APPENDIX

7.1 List Frame of Public Sector ART Centres in Zambia – 2007.

Province	District	Nos.	Dist	Art	ART Center
Central	Chibombo	1	11	111	Chibombo DHMT
CENTRAL	Chibombo	2	11	112	Liteta District Hospital
	Chibombo	3	11	113	Mwachisompola Demo Zone
	Kabwe	1	12	121	Kabwe District Hospital DHMT
	Kabwe	2	12	122	Kabwe General Hospital
	Kabwe	3	12	123	Kabwe Mine Hospital
	Kabwe	4	12	124	Mahatma Gandhi Health Centre
	Kabwe	5	12	125	ZNS Kabwe
	Kapiri Mposhi	1	13	131	Kapiri Mposhi District Office DHMT
	Kapiri Mposhi	2	13	132	Kapiri Mposhi District Hospital
	Kapiri Mposhi	3	13	133	Mpunde RHC (mobile)
	Kapiri Mposhi	4	13	134	Mukonchi RHC (mobile)
	Kapiri Mposhi	5	13	135	Nkole RHC (mobile)
	Kapiri Mposhi	6	13	136	ST. Paul's Mission RHC
	Kapiri Mposhi	7	13	137	Waya RHC (mobile)
	Mkushi	1	14	141	Mkushi District Office DHMT
	Mkushi	2	14	142	Masansa Health Centre
	Mkushi	3	14	143	Mkushi District Hospital
	Mumbwa	1	15	151	Mumbwa District Office DHMT
	Mumbwa	2	15	152	Kaindu RHC (Mumbwa Mobil Clinic)
	Mumbwa	3	15	153	Kanona
	Mumbwa	4	15	154	Lungobe RHC (Mumbwa Mobil Clinic)
	Mumbwa	5	15	155	Mumbwa District Hospital
	Mumbwa	6	15	156	Nalbanda RHC (Mumbwa Mobil Clinic)
	Mumbwa	7	15	157	Nampundwe RHC (Mumbwa Mobil Clinic)
	Mumbwa	8	15	158	Nangoma Mission Hospital
	Serenje	1	16	161	Serenje District Office DHMT
	Serenje	2	16	162	Chitambo Mission Hospital
	Serenje	3	16	163	Serenje District Hospital
Copperbelt	Chililabombwe	1	21	211	Chililabombwe DHMT
Copperbelt	Chililabombwe	2	21	212	Konkola mine Hospital (KCM)
	Chingola	1	22	221	Chingola DHMT
	Chingola	2	22	222	Chiwempala Health Centre
	Chingola	3	22	223	Kabundi East Health Centre
	Chingola	4	22	224	Nchanga North Hospital
	Kalulushi	1	23	231	Kalulushi DHMT
	Kalulushi	2	23	232	Kalulushi Government Clinic
	Kitwe	1	24	241	Kitwe DHMT
	Kitwe	2	24	242	Chimwemwe Clinic
	Kitwe	3	24	243	Kitwe Central Hospital
	Kitwe	4	24	244	Luangwa Clinic
	Kitwe	5	24	245	Ndeke Clinic

Province	District	Nos.	Dist	Art	ART Center
	Luanshya	6	25	252	Luanshya DHMT
	Luanshya	1	25	253	Roan General Hospital
	Luanshya	2	25	254	Thomson Hospital
	Lufwanyama	1	26	261	Lufwanyama DHMT
	Lufwanyama	2	26	262	Lufwanyama HC
	Masaiti	1	27	271	Masaiti DHMT
	Masaiti	2	27	272	Masaiti Boma Health Center
	Masaiti	3	27	273	Masaiti Council Health Center
	Mpongwe	1	28	281	Mpongwe DHMT
	Mpongwe	2	28	282	Mpongwe Mission Hospital
	Mpongwe	3	28	283	St Theresa Mission
	Mufulira	1	29	291	Mufulira DHMT
	Mufulira	2	29	292	Kamuchanga Health Center
	Mufulira	3	29	293	Kamuchanga Hospital
	Mufulira	4	29	294	Ronald Ross General Hospital
	Ndola	1	30	301	Ndola DHMT
	Ndola	2	30	302	Arthur Davison Hospital
	Ndola	3	30	303	Kavu Health Center
	Ndola	4	30	304	Lubuto Health Centre
	Ndola	5	30	305	Ndola Central Hospital
	Ndola	6	30	306	Zambia Flying Doctor Service
Eastern	Chadisa	1	31	311	Chadisa District DHMT Office
	Chadisa	2	31	312	Chadisa District Hospital
	Chama	1	32	321	Chama DHMT
	Chama	2	32	322	Chama District Hospital
	Chipata	1	33	331	Chipata DHMT
	Chipata	2	33	332	Chipata Hospital
	Chipata	3	33	333	Kapata Hospital
	Katete	1	34	341	Katete DHMT
	Katete	2	34	342	St Francis Mission
	Mambwe	1	35	351	Mambwe DHMT
	Mambwe	2	35	352	Mambwe District/Kamoto Mission Hospital
	Nyimba	1	36	361	Nyimba DHMT
	Nyimba	2	36	362	Nyimba Hospital
	Petauke	1	37	371	Petauke DHMT
	Petauke	2	37	372	Petauke Hospital
	Chiengi	1	41	411	Chiengi DHMT Office
	Chiengi	2	41	412	Puta RHC
	Kawambwa	1	42	421	Kawambwa DHMT
	Kawambwa	2	42	422	Kawambwa District Hospital
	Kawambwa	3	42	423	Mbereshi Mission
	Mansa	1	43	431	Mansa DHMT Office
	Mansa	2	43	432	Mansa General Hospital
	Mansa	3	43	433	Senama Urban Health Centre
	Milenge	1	44	441	Milenge DHMT Office
Luapula	Milenge	2	44	442	Milenge East 7

Province	District	Nos.	Dist	Art	ART Center
	Nchelenge	1	45	451	Nchelenge DHMT Office
	Nchelenge	2	45	452	Kashikishi
	Nchelenge	3	45	453	ST Paul Mission Hospital
	Samfya	1	46	461	Samfya DHMT Office
	Samfya	2	46	462	Lubwe Mission
	Samfya	3	46	463	Samfya stage II
	Mwense	1	47	471	Mwense DHMT Office
	Mwense	2	47	472	Lubwe Mission
Lusaka	Chongwe	1	51	511	Chongwe DHMT Office
	Chongwe	2	51	512	Chongwe RHC
	Chongwe	3	51	513	St. Luke Mission(Mpanshya)
	Kafue	1	52	521	Kafue DHMT Office
	Kafue	2	52	522	Kafue District Hospital
	Kafue	3	52	523	Kafue Estates UHC
	Kafue	4	52	524	Kafue Gorge RHC
	Kafue	5	52	525	Meru Health Centre
	Kafue	6	52	526	Mwembeshi
	Kafue	7	52	527	Nangongwe RHC
	Luangwa	1	53	531	Luangwa DHMT Office
	Luangwa	2	53	532	Katondwe Mission
	Lusaka	1	54	541	Lusaka DHMT Office
	Lusaka	2	54	542	Bauleni
	Lusaka	3	54	543	Chainama Hills Psychiatric Hospital
	Lusaka	4	54	544	Chawama
	Lusaka	5	54	545	Chelstone
	Lusaka	6	54	546	Chilenje
	Lusaka	7	54	547	Chipata
	Lusaka	8	54	548	George
	Lusaka	9	54	549	Kabwata
	Lusaka	10	54	550	Kalingalinga
	Lusaka	11	54	551	Kamwala
	Lusaka	12	54	552	Kanyama
	Lusaka	13	54	553	Makeni
	Lusaka	14	54	554	MateroMain
	Lusaka	15	54	555	MateroRef
	Lusaka	16	54	556	MoH clinc
	Lusaka	17	54	557	Mtendere
	Lusaka	18	54	558	Ngombe
	Lusaka	19	54	559	Railway clinic
Northern	Chinsali	1	61	611	Chinsali DHMT Office
	Chinsali	2	61	612	Chinsali District Hospital
	Kaputa	1	62	621	Kaputa DHMT Office
	Kaputa	2	62	622	Kaputa Health Centre
	Kasama	1	63	631	Kasama DHMT Office
	Kasama	2	63	632	Kasama General Hospital
	Kasama	3	63	633	Kasama Urban Health Center

Province	District	Nos.	Dist	Art	ART Center
	Luwingu	1	64	641	Luwingu DHMT Office
	Luwingu	2	64	642	Luwingu District Hospital
	Mbala	1	65	651	Mbala DHMT Office
	Mbala	2	65	652	Mbala General Hospital
	Mpika	1	66	661	Mpika DHMT Office
	Mpika	2	66	662	Mpika District Hospital
	Mporokoso	1	67	671	Mporokoso DHMT Office
	Mporokoso	2	67	672	Mporokoso District Hospital
	Mpulungu	1	68	681	Mpulungu DHMT Office
	Mpulungu	2	68	682	Mpulungu Rural Health Centre
	Mungwi	1	69	691	Mungwi DHMT Office
	Nakonde	1	70	701	Nakonde DHMT Office
	Nakonde	2	70	702	Nakonde Rural Health Centre
Northwestern	Chavuma	1	71	711	Chavuma DHMT Office
	Chavuma	2	71	712	Chavuma Mission Hospital
	Chavuma	3	71	713	Chiyeke Health Centre
	Kabompo	1	72	721	Kabompo DHMT Office
	Kabompo	2	72	722	Kabompo District Hospital
	Kasempa	1	73	731	Kasempa DHMT Office
	Kasempa	2	73	732	Kasempa District Hospital
	Mufumbwe	1	74	741	Mufumbwe DHMT Office
	Mufumbwe	2	74	742	Mufumbwe District Hospital
	Mwinilunga	1	75	751	Mwinilunga DHMT Office
	Mwinilunga	2	75	752	Mwinilunga District Hospital
	Solwezi	1	76	761	Solwezi DHMT Office
	Solwezi	2	76	762	Solwezi General Hospital
	Solwezi	3	76	763	Solwezi Urban Clinic
	Sambezi	1	77	771	Sambezi DHMT Office
	Sambezi	2	77	772	Sambezi District Hospital
Southern	Choma	1	81	811	Choma DHMT Office
	Choma	2	81	812	Choma General Hospital
	Gwembe	1	82	821	Gwembe DHMT Office
	Gwembe	2	82	822	Gwembe District Hospital
	Itezhi-tezhi	1	83	831	Itezhi-tezhi DHMT Office
	Itezhi-tezhi	2	83	832	Itezhi-tezhi District Hospital
	Kalomo	1	84	841	Kalomo DHMT Office
	Kalomo	2	84	842	Kalomo District Hospital
	Kazungula	1	85	851	Kazungula DHMT Office
	Kazungula	2	85	852	Kazungula Rural Health Center
	Kazungula	3	85	853	Mambova RHC
	Kazungula	4	85	854	Mukuni RHC
	Livingstone	1	86	861	Livingstone DHMT Office
	Livingstone	2	86	862	Dambwa Clinic
	Livingstone	3	86	863	Livingstone Hospital
	Livingstone	4	86	864	Maramba UHC
	Livingstone	5	86	865	Mosi-oa-Tunya Health Center

Province	District	Nos.	Dist	Art	ART Center
	Masabuka	1	87	871	Masabuka DHMT Office
	Masabuka	2	87	872	Masabuka Hospital
	Masabuka	3	87	873	Mbayamusuma
	Monse	1	88	881	Monse DHMT Office
	Namwala	1	89	891	Namwala DHMT Office
	Siavonga	1	90	901	Siavonga DHMT Office
	Siavonga	2	90	902	Siavonga District Hospital
	Sinazongwe	1	91	911	Sinazongwe DHMT Office
	Sinazongwe	2	91	912	Sinazongwe RHC
	Sinazongwe	3	91	913	Maamba Hospital
Western	Kalabo	1	92	921	Kalabo DHMT Office
	Kalabo	2	92	922	Kalabo District
	Kaoma	1	93	931	Kaoma DHMT Office
	Kaoma	2	93	932	Kaoma District Hospital
	Lukulu	1	94	941	Lukulu DHMT Office
	Lukulu	2	94	942	Lukulu District/Mission Hospital
	Mongu	1	95	951	Mongu DHMT Office
	Mongu	2	95	952	Lewanika General
	Mongu	3	95	953	Limulunga RHC
	Senanga	1	96	961	Senanga DHMT Office
	Senanga	2	96	962	Senanga District Hospital
	Sesheke	1	96	963	Sesheke DHMT Office
	Sesheke	2	96	964	Mwandi Mission
	Sesheke	3	96	965	Sesheke District Hospital(Yeta)
	Sesheke	4	96	966	Sichili Mission
	Sesheke	5	96	967	Yeta District Hospital (Sesheke)
	Shang'ombo	1	97	971	Shang'ombo DHMT Office
	Shang'ombo	2	97	972	Sioma Mission RHC

Note: U/RHC=Urban/Rural Health Centre DHMT=District Health Management Team

Serial Number:_____

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CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY SURVEY – 2008.

FORM 1:

7.2 Questionnaire - Directors and Managers.

Section A: Identification.

Province:_____ [ ]

District: _____ [ ][ ]

Name of institution: _____

Title/Position of Respondent: _____

Section B: Policy and Plan.

Q1. Is there a formal comprehensive national HIV/AIDS policy? 1.[ ] Yes 0.[ ] No>>***Q4***

Q2. If y**es,** attach the policy.

Q3. What are the challenges in implementing the policy? ***(Briefly explain)***

_____

_____

Q4. If **No**, Are there any tentative plans to formulate the national policy?

1.[ ] Yes 0.[ ] No

Q5. Is there an implementation plan for scaling up of ART services?

1.[ ] Yes 0.[ ] No

Q6. If **yes,** *(Attach the plan)*,

Q7. If **No,** Is there any tentative plan to develop the national strategic plan?

1.[ ] Yes 0.[ ] No

Q8. Are there any challenges in implementing the strategic plan? 1.[ ] Yes 0.[ ] No>>***Q10***

Q9. If **Yes,** What are the challenges? ***(Briefly explain)***

_____

Q10. Do you have any written guidelines for use in the scaling up of ART?

1.[ ] Yes 0.[ ] No***>>Q12***

Q11. If **yes,** briefly explain.

_____

Q12. Are there guidelines to monitor the quality of laboratory services to support the ART services? 1.[ ] Yes 0.[ ] No***>>Q14***

Q13. If **yes**, attach the guidelines

Q14. Are there any challenges in implementing quality assurance guidelines for the scale up of laboratory services to support ART? 1.[ ] Yes 0.[ ] No***>>Q16***

Q15. If Yes, What are the barriers in implementing quality assurance guidelines?

(Briefly explain)

_____

Section C: Human Resource Development (Training).

Q16. Has there been a training plan for laboratory staff in the scaling up of laboratory services in diagnosis and monitoring for HIV/AIDS patients on ART?

1.[ ] Yes 0.[ ] No***>>Q18***

Q17. If **yes**, briefly describe and attach a copy of the plan.

_____

_____

_____

_____

Q18. How often is the training conducted?

1.[ ] Quarterly
2.[ ] Annually
3.[ ] Biannually

Q19. How long is the training programme? ***(Tick and indicate the number)***

1.[ ] Days _____
2.[ ] Weeks _____
3.[ ] Months _____
4.[ ] Years _____

Q20. How does the training duration impact on the Laboratory Services? ***(Briefly explain)***

_____

_____

_____

Q21. Is there adequate number of laboratory staff to cover national needs?

1.[ ] Yes 0.[ ] No**>>*Q23***

Q22. If **Yes,** What is the establishment at each level of care? ***(Check and attach)***

Q23. If **No**, What are the challenges? ***(Briefly explain)***

_____

_____

Q24. What is the impact of human resources on the scaling up of laboratory services? ***(Briefly explain)***

Q25. Is there an establishment register of laboratory staff with training and experience in HIV/AIDS laboratory diagnosis and monitoring tests on ART?

1.[ ] Yes 0.[ ] No**>>*Section D***

Section D: Laboratory Commodity Management System (Procurement and Distribution)

Q26. Is there a strategic plan for the procurement and distribution of supplies and equipment for the scaling up of laboratory services to support the ART programme?

1.[ ] Yes 0.[ ] No***>>Q28***

Q27. If **yes**, please attach plan.

Q28. What was the budget for procurement and distribution of supplies and equipment for scaling up laboratory services to support the ART programme for last year 2007?

1.[ ] At Central level? ***(K'000)*** _____
2.[ ] At Provincial level? ***(K'000)*** _____
3.[ ] At District level? ***(K'000)***_____

Q29. Describe the laboratory commodity management system for laboratory services to support ART program?

_____

_____

_____

Q30. Is there a plan for preventive maintenance and repairs for equipment, including availability of spare parts for scaling up laboratory services to support the ART programme? 1.[ ] Yes 0.[ ] No***>>Q32***

Q31. If **yes,** attach the plan.

Q32. If **no,** how are the equipment maintained? (B***riefly explain)***

_____

_____

Section E: Laboratory Information Management System.

Q33. Are there guidelines available on Laboratory Information Management System for diagnosis and monitoring tests HIV/AIDS patients on ART? 1.[ ] Yes 0.[ ] No***>>Q35***

Q34. If **yes,** please describe and attach the forms used for Laboratory Information Management System of monitoring HIV/AIDS patients on ART. (***End of Interview!)***

_____

_____

Q35. If **no,** are there plans to develop the forms at national level and distribute to ART centres? 1.[ ] Yes 0.[ ] No

Q36. How is information captured now without the forms? ***(Briefly explain)***

_____

_____

End of Interview!

THANK YOU FOR YOUR TIME AND INFORMATION!

Serial Number:_____

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CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY SURVEY – 2008.

FORM 2:

7.3 Questionnaire - Checklist for Health Facility Assessment.

Section A: Identification.

Province:_____ [ ]

District: _____ [ ][ ]

Name of Facility (ART Centre): _____

Population Served ***(from HIMS)***: _____

Position of Respondent: _____

Title of in-Charge of ART Centre:_____

Section B. Health Facility Staffing (ART Sites)

Cadre	**Total number of Staff**	**Qualifications of In-Charge of ART Centres/Sections.** 1. Diploma 2. Degree 3. Masters 4. Certificate 5. Other (Specify)	**Years in Position**	**Remarks**
2.1. Laboratory staff				
- Scientists		[ ]	[ ]yrs	
- Technologists		[ ]	[ ]yrs	
- Technicians		[ ]	[ ]yrs	
2.2. Clinicians				
- Medical Doctors		[ ]	[ ]yrs	
- Clinical Officers		[ ]	[ ]yrs	
2.3 Pharmacy				
- Pharmacists		[ ]	[ ]yrs	
- Pharmacy Technician		[ ]	[ ]yrs	
2.4 Nurse		[ ]	[ ]yrs	
- Registered Nurse		[ ]	[ ]yrs	
- Enrolled Nurse		[ ]	[ ]yrs	
2.5. Environmental Officers		[ ]	[ ]yrs	
2.6. Dispensaries		[ ]	[ ]yrs	
2.7. Other (Specify)		[ ]	[ ]yrs	

Section C: Observation Assessment of Existence of Policies, Regulation and Standards.

Table 1: Operating Procedures - 2007 Data

Type of Document on;	**Present** *(Tick √ in the box)*	**Date of latest Revision**	**Location of document**	**Remarks**
1. National Policy on HIV?	1.[ ]Yes 0.[ ] No			
2. Guidelines on management and care of patients with HIV/AIDS?	1.[ ]Yes 0.[ ] No			
3. National ART implementation Plan?	1.[ ]Yes 0.[ ] No			
4. Laboratory SOPs for ART Program?	1.[ ]Yes 0.[ ] No			
5. Laboratory services implementation plan in support of ART Programme?	1.[ ]Yes 0.[ ] No			

Table 2: Training of Laboratory staff - 2007 Data.

Subject Area	**No. of staff trained**	**Any remarks?**	**If yes, Remarks**
1. HIV testing	[ ]	1.[ ]Yes 0.[ ] No>>n	
2. CD4 count	[ ]	1.[ ]Yes 0.[ ] No>>n	
3. Viral load testing	[ ]	1.[ ]Yes 0.[ ] No>>n	
4. Clinical Management for HIV/AIDS	[ ]	1.[ ]Yes 0.[ ] No>>n	

Section D: ART Centres with or without Laboratory facilities.

Q1. Does the ART centre have a laboratory facility to support the ART programme?

1.[ ] Yes **>>*Q3*** 0.[ ] No

Q2. If **No**, please indicate if you have plans to set up laboratory services at the ART centre? 1.[ ] Yes 0.[ ] No>>***End of Interview***

Q3. What are the appropriate responses and remarks on the laboratory infrastructure?

(Tick √ in the table below)

Type Infrastructure	**Is ….. Available?**	**Any remarks?**	**If yes, Remarks**
1. Designated laboratory structure/ space	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
2. Client waiting room / space	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
3. HIV testing room / space	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
4. Laboratory in charge 's office	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
5. Specimen collection room	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
6. Working bench for staining	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
7. Working bench for instrumentation	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
8. Working bench for recording / dispatch	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
9. Working bench for receipt of specimen	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
10. Safety cabinet / hood	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
11. Windows	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
12. Temperature monitor	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
13. Filing cabinet, lockable	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
14. Lockable storage Cabinet	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
15. Shelves/cupboard for storage	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
16. Running tap water with sink	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
17. Power supply with outlets	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
18. Gas supply outlets	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
19. Stand by generator	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
20. Space for expansion	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
21. Lab chairs stools	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
22. Wash up rooms	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
23. Store room with shelves	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
24. Sterilizing room	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
25. Night duty room	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	
26. Tea/reading room	1.[ ]Yes 0.[ ] No	1.[ ]Yes 0.[ ] No>>n	

End of Interview!

THANK YOU FOR YOUR TIME AND INFORMATION!

STRICTLY CONFIDENTIAL **Serial Number:_____**

For Official use

CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY SURVEY – 2008.

FORM 3:

7.4 Questionnaire - Medical Doctors / Clinicians.

Section A: Identification

Province:_____ [ ]

District: _____ [ ][ ]

Name of Facility (ART Centre): _____

Position of Respondent: _____

Title of in-Charge of ART Centre:_____

Section B: Laboratory diagnosis and monitoring of HIV/ AIDS patients.

Q1. Does this facility have a laboratory? 1.[ ] Yes 0.[ ] No

Q2. If **No**, how do you access the laboratory services? ***(Briefly explain)***

_____

Q3. Please tick the **four** roles of the laboratory services in the management for HIV/AIDS from the list below. ***(Tick all the correct answers)***

[1] In the diagnosis of opportunistic infections

[1] HIV Testing

[1] Laboratory tests prior to initiating a patient on ART

[1] Monitoring tests for patients on ART

[0] Prevention of transmission of HIV

Q4. When do you start/initiate HIV/AIDS patient on ART? ***(List below the two most common first)***

1._____

2._____

Q5. What are the **five** reasons why you require laboratory services in the management for HIV/AIDS patients on ART? *(Please indicate in spaces below)*

1._____

2._____

3._____

4._____

5._____

Section C: Tests for Management for HIV/AIDS patients on ART.

Q6. What are the **four** most important tests that you require to monitor HIV/AIDS patients on ART? ***(i.e. ones that you consider critical to your management of patients on ART)*** *(Please tick all appropriate boxes below)*

[0] TB smear microscopy
[1] CD4 count
[1] Full Blood Count
[1] Liver Function Tests
[1] Blood sugar

Q7. How often were these monitoring tests available to you in 2007? ***(Please indicate by ticking appropriate box)***

Nos.	**Monitoring Tests**	**Always [3]**	**Frequently[2]**	**Occasionally[1]**	**Never[0]**
1.	CD 4 Count	[ ]	[ ]	[ ]	[ ]
2.	Blood sugar	[ ]	[ ]	[ ]	[ ]
3.	Full Blood count	[ ]	[ ]	[ ]	[ ]
4.	Liver Function Test	[ ]	[ ]	[ ]	[ ]
5.	Viral Load test	[ ]	[ ]	[ ]	[ ]

Q8. Please select the **four** most frequent tests you request for the monitoring patients on ART (i.e. most frequently used) out of the five. ***(Tick √ all the correct answer)***

[1] Full Blood count

[1] CD4 count

[0] Blood sugar

[1] Liver Function test

[1] Viral load

Section D: Quality of Service.

Q9. How do you rate the results received from the laboratory? ***(Tick the appropriate response)***.

[3] Excellent

[2] Good

[1] Fair

[0] Poor

Q10. What is the turnaround time for the following tests? ***(Tick √ the appropriate response?***

Type of Test	**Same day [3]**	**Next day[2]**	**More than 2 days[1]**	**More than 1 week [0]**	**Other *(Specify time)***
CD4 count	[ ]	[ ]	[ ]	[ ]	
Full Blood count	[ ]	[ ]	[ ]	[ ]	
Liver function	[ ]	[ ]	[ ]	[ ]	
Blood Sugar	[ ]	[ ]	[ ]	[ ]	
Creatinine	[ ]	[ ]	[ ]	[ ]	

Q11. How often do you have to rely on the laboratory results for monitoring tests HIV/AIDS patients on ART?

[4] Always

[3] Frequently

[2] Sometimes

[1] Rarely

[0] Never

Q12. How do you rate the degree of satisfaction with the laboratory services at your centre? ***(Tick √ in the appropriate box)***

[2] Very Satisfied

[1] Moderately Satisfied

[0] Not Satisfied

Q13. Give **two** reasons for your answer.

1._____

2._____

Q14. Do you have any other comments on the performance of the laboratory services.

1.[ ] Yes 0.[ ] No ***>>End of Interview***

Q15. If **yes**, briefly explain.

_____

_____

End of Interview!

THANK YOU FOR YOUR TIME AND INFORMATION!

Serial Number:_____

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CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY SURVEY – 2008.

FORM 4:

7.5 Questionnaire - Laboratory Personnel.

Section A: Identification.

Province:_____ [ ]

District: _____ [ ][ ]

Name of Facility (ART Centre): _____

Position of Respondent: _____

Title of in-Charge of ART Centre:_____

Section B: Test profiles for diagnosis and monitoring of HIV/ AIDS 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 a Standard Operating Procedure Manual to support the ART programme? 1.[ ] Yes 0.[ ] No ***>>Q4***

Q3. If **Yes**, Check.

Q4. If **not**, briefly explain the reason 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[2]	Sometimes[1]	Never[0]	Remarks
1	HIV Test	[ ]	[ ]	[ ]	
2	CD4 count	[ ]	[ ]	[ ]	
3	Full Blood count	[ ]	[ ]	[ ]	
4	Creatinine	[ ]	[ ]	[ ]	
5	Liver function Test (ALT)	[ ]	[ ]	[ ]	

(If never go to Q7)

Q6. If **sometimes**, when did you last perform IQC on the following? ***(Check records of results and Tick √ in the appropriate box)***

Nos.	Type of Test	In the Last week[2]	In the last month[1]	In the last 3 months[0]	Remarks
1	HIV Test	[ ]	[ ]	[ ]	
2	CD4 count	[ ]	[ ]	[ ]	
3	Full Blood count	[ ]	[ ]	[ ]	
4	Creatinine	[ ]	[ ]	[ ]	
5	Liver function Test (ALT)	[ ]	[ ]	[ ]	

Q7. If **never**, tick √ in the appropriate box and state the reasons why you do not perform IQC on the above list of tests.

Nos.	Type of Test	Any reasons?	If yes, Reason.
1	HIV Test	1.[ ] Yes 0.[ ]No>>n	
2	CD4 count	1.[ ] Yes 0.[ ]No>>n	
3	Full Blood count	1.[ ] Yes 0.[ ]No>>n	
4	Creatinine	1.[ ] Yes 0.[ ]No>>n	
5	Liver function Test (ALT)	1.[ ] Yes 0.[ ]No>>n	

Q8. Please state the availability of the four listed tests requested for monitoring HIV/AIDS patients on ART. (***Tick √ in the appropriate box)***

Nos.	**Test**	**Always[2]**	**Frequently[1]**	**Never[0]**
1	Liver function Test (ALT)	[ ]	[ ]	[ ]
2	CD4 count	[ ]	[ ]	[ ]
3	Full Blood count	[ ]	[ ]	[ ]
4	Creatinine	[ ]	[ ]	[ ]

Section C: Quality Assurance.

Q9. Do you take part in External Quality Assessment programme? 1.[ ] Yes 0.[ ] No **>>*Q11***

Q10. If **yes**, which programme are you participating in? ***(Briefly explain)***

_____

_____

Q11. Are records of External Quality Assessment kept? 1.[ ] Yes>>***Check & attach*** 0.[ ] No

Q12. If **no**, why are you not participating? ***(Briefly explain)***

_____

_____

Section D: Equipment.

Q13. For each of the following equipment, indicate if it is available, type/make, functional to-date and indicate any remarks.

Type of Equipment	**Is it available?**	**Type /Make**	**How old is ….?** 1. Months 2.Years	**Is ….. functional?**	**If No, Remarks.**
1. Haematology analyser	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
2. CD4 count Machine	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
3. Chemistry analyser	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
4. Binocular Microscope	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
5. Haemoglobin meter	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
6. PCR	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
7. Viral Load	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	
8. Refrigerator	1[ ] Yes 0.[ ]No>>n		[ ] _____	1.[ ] Yes >>n 0.[ ]No	

Q14. If the above equipment is available are test done always 1.[ ] Yes ***>>Q16*** 0.[ ]No

Q15. If **No**, what are major reasons for this? ***(Briefly explain)***

_____

_____

Q16. Do you have a service/maintenance contract plan for your laboratory equipment?

1.[ ] Yes 0.[ ]No***>>Q18***

Q17. If **yes,** ***(Check for the plan)***

Q18. If **No**, why not? ***(Briefly explain)***

_____

_____

Q19. Did you budget for spare parts and maintenance of equipment in your 2006 Action Plan? 1.[ ] Yes 0.[ ]No

Q20. Where do you send your Laboratory Equipment for repair? ***(Briefly explain)***

_____

Q21. How long does it take on average to repair equipment? ***(Tick in the appropriate box)***

1.[ ] One week
2.[ ] One month
3.[ ] Up to three months
4.[ ] More than three months
5.[ ] Other (specify)_____

Section E: Laboratory Commodity Management System.

Q22. Where do you receive most of your Laboratory supplies and reagents?

1. [ ] From Central Medical Stores
2. [ ] Directly from Local suppliers/agents
3. [ ] Directly from cooperating partners
4. [ ] Other (Specify)_____

Q23. How satisfied are you with the present system for procurement of laboratory supplies and equipment? ***(Tick in the appropriate box)***

[2] Very satisfied **>>>Q16**
[1] Moderately satisfied ***>>Q16***
[0] Not satisfied

Q24. If you are not satisfied what are the **main** problems with current systems? ***(Briefly explain)***

_____

Q25. Do you have any suggestion on how to solve these problems? 1.[ ] Yes 0.[ ]No***>>Q18***

Q26. What are the suggestions? ***(Briefly explain)***

_____

_____

Q27. Who is the key person given responsibility for procurement of laboratory supplies in this facility? ***(Tick √ the correct answer)***

1. [ ] Administrator
2. [ ] Procurement Officer
3. [ ] Pharmacist
4. [ ] Head of Laboratory
5. [ ] Director of ART Centre
6. [ ] Other, (specify)_____

Q28. 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)***

Nos.	**Reagents and Supplies**	**Weekly[4]**	**Monthly[3]**	**Every few months[2]**	**Never[0]**	**Rarely[1]**
1	HIV Testing kits	[ ]	[ ]	[ ]	[ ]	[ ]
2	CD4 count reagents	[ ]	[ ]	[ ]	[ ]	[ ]
3	Haematology reagents	[ ]	[ ]	[ ]	[ ]	[ ]
4	Creatinine reagents/kit	[ ]	[ ]	[ ]	[ ]	[ ]
5	Liver function Test reagents / kits	[ ]	[ ]	[ ]	[ ]	[ ]
6	Viral load kits	[ ]	[ ]	[ ]	[ ]	[ ]
7	TB reagents	[ ]	[ ]	[ ]	[ ]	[ ]

Q29. What tests have you been unable to perform for monitoring HIV/AIDS patients on ART due to lack of reagents/supplies or equipment?

Type of test	**Is test done using.. ..?**	**Reasons for lack of test**		**Length unavailable**
		Equipment?	**Supplies?**	
1. HIV Testing	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	
2. CD4 count	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	
3. Full Blood Count	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	
4. Creatinine	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	
5. Liver function Tests	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	
6. Viral Load	1[ ] Yes >>n 0.[ ]No	1[ ] Yes 0.[ ]No	1[ ] Yes 0.[ ]No	

Q30. If test is not available where did you refer the samples / specimen?

Type of test	Specify, place referred to for Samples/Specimen?	Any remarks?	Remarks
1. HIV Testing		1[ ] Yes 0.[ ]No>>n	
2. CD4 count		1[ ] Yes 0.[ ]No>>n	
3. Full Blood Count		1[ ] Yes 0.[ ]No>>n	
4. Creatinine		1[ ] Yes 0.[ ]No>>n	
5. Liver function Tests		1[ ] Yes 0.[ ]No>>n	
6. Viral Load		1[ ] Yes 0.[ ]No>>n	

Section F: Human Resources Development and Supervision.

Q31. Please list ART training programs that you received in 2007.

Position held	Training Received	Sponsor	Duration

Q32. Please estimate your current and required staff for provision of quality laboratory services.

1. Current staff *(Number)*_____
2. Required Staff *(Number)*_____

Q33. What is the source of the estimate? ***(Briefly explain)***

_____

Section G: Challenges.

Q34. 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. _____

Q35. What countermeasures are needed to overcome these challenges? ***(Briefly explain)***

_____

Q36. Do you have any other comments? 1. [ ] Yes 0.[ ] No***>>End of Interview!***

Q37. If **yes,** what are the comments? ***(Briefly explain)***

_____

End of Interview!

THANK YOU FOR YOUR TIME AND INFORMATION!

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CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY SURVEY – 2008.

FORM 5:

7.6 Questionnaire - District Director of Health.

Section A: Identification.

Province:_____ [ ]

District: _____ [ ][ ]

Population Served ***(from HIMS)***: _____

Position of Respondent: _____

Section B: Demography of ART Centres in District.

Q1. How many ART Centres do you have in your District? ***(Fixed+Mobile)*** _____

Q2. How many are static? ***(Provide names)***

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

Q3. How many are mobile? _____

Q4. How often do you provide the treatment and diagnosis services in the mobile centres? ***(Tick √ in the appropriate box)***

[3] Weekly
[2] After two weeks
[1] After three weeks
[0] After a month
[ ] Other (specify)

Q5. Who is on the team of ART provision to mobile centres? ***(Please provide full Title/Position)***

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

End of Interview!

THANK YOU FOR YOUR TIME AND INFORMATION!

Serial Number:_____

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CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING TESTS FOR HIV/AIDS PATIENTS ON ANTI RETROVIRAL THERAPY IN ZAMBIA.

Form 6:

7.7 Questionnaire - Record Review.

Section A: Identification

Province:_____ [ ]

District: _____ [ ][ ]

Population Served ***(from HIMS)***: _____

Position of Respondent: _____

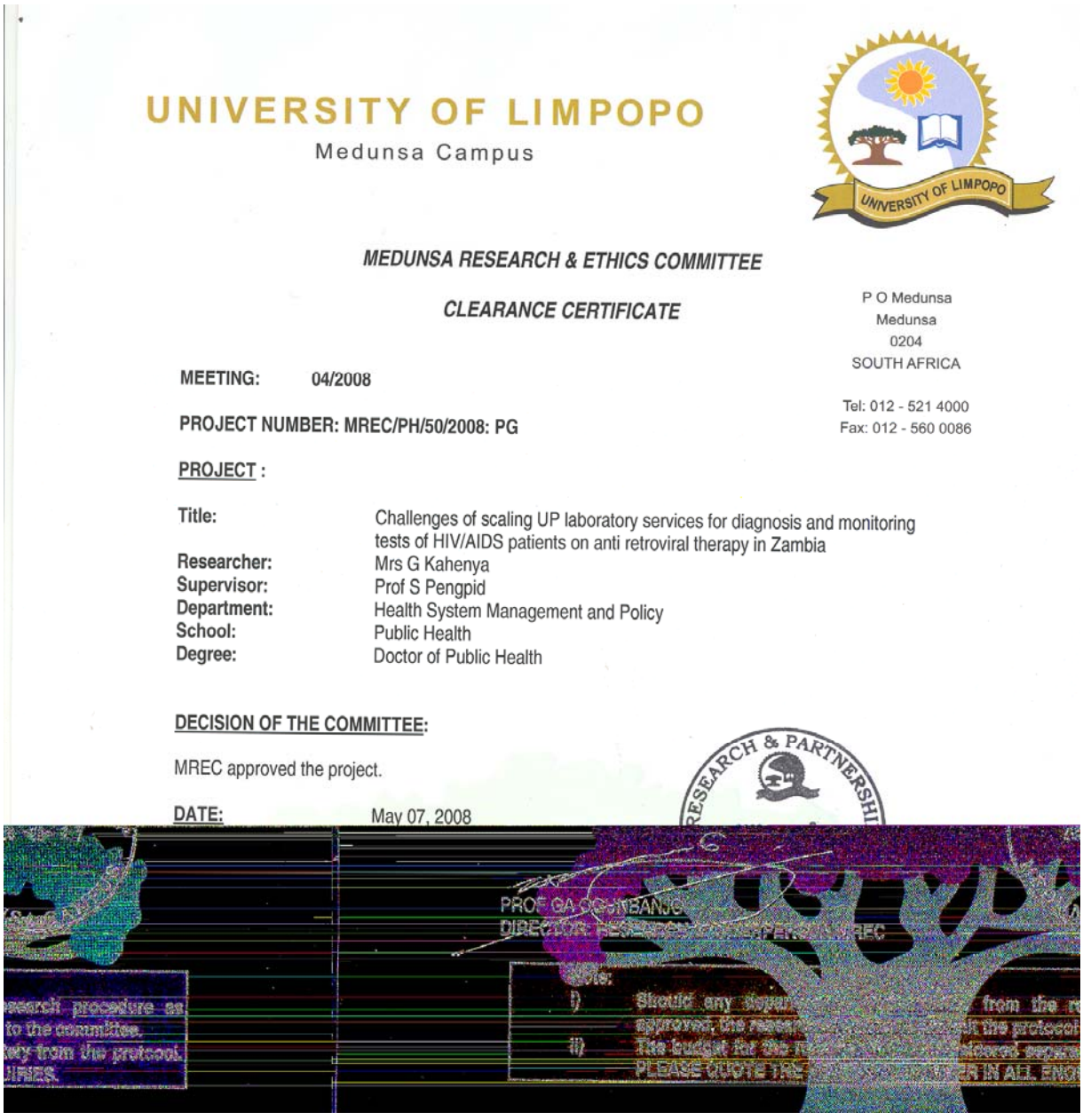
Section B: Retrospective Review of Patient Medical Records in the ART Centres – Period January – December 2007.

Patients/ Month	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Total**
1. Total Number of patients enrolled on ART.													
2. Number of Patients initiated on ART without CD4 count test.													
3. Number of Patients initiated on ART with a CD4 count test.													
4. Number of patients on ART using CD4 count test to monitor progress.													

End of Form

THANK YOU FOR YOUR TIME AND INFORMATION!

7.8 Clearance Certificate



UNIVERSITY OF LIMPOPO

Medunsa Campus

MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

P O Medunsa
Medunsa
0204
SOUTH AFRICA

Tel: 012 - 521 4000
Fax: 012 - 560 0086

MEETING: 04/2008

PROJECT NUMBER: MREC/PH/50/2008: PG

PROJECT :

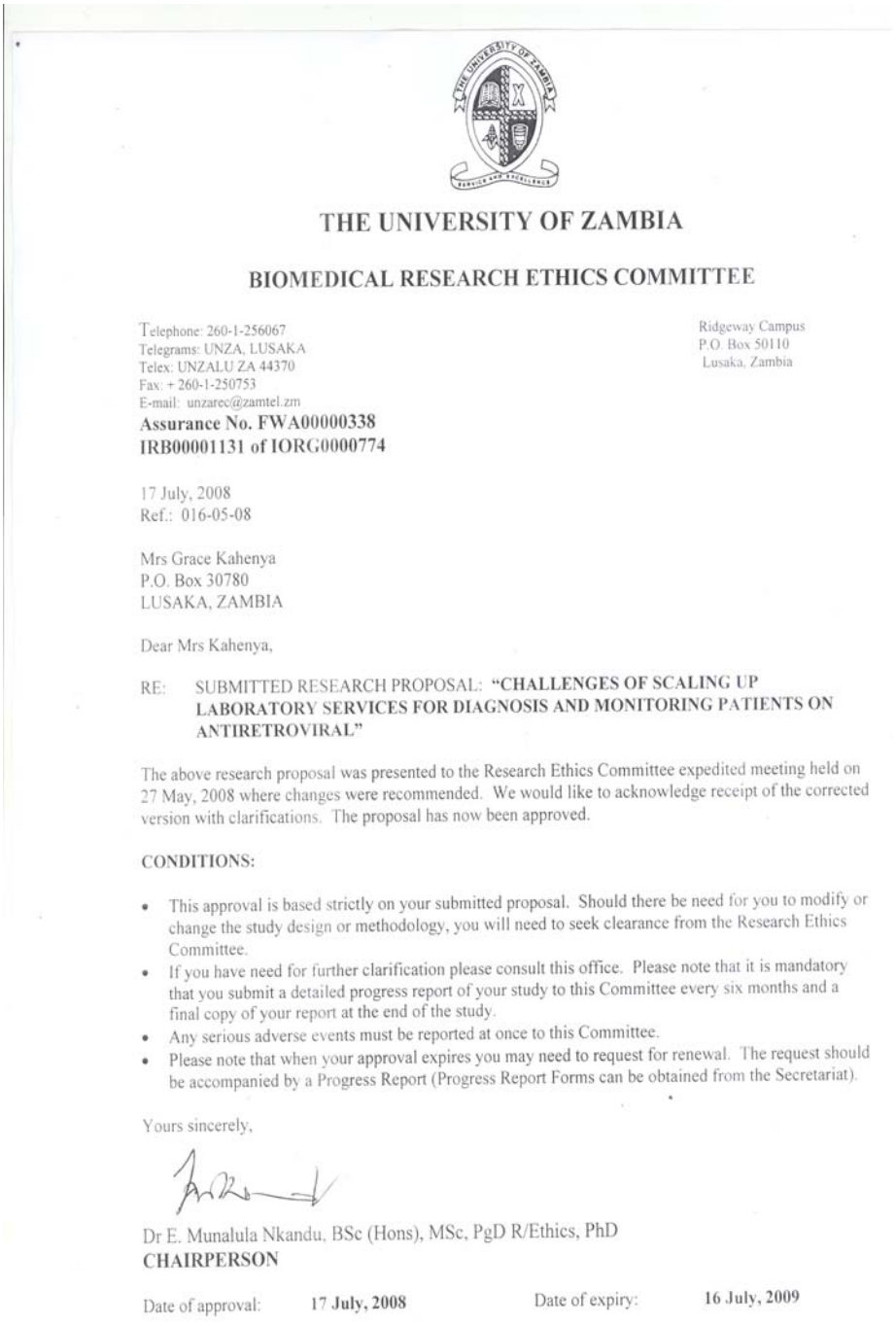
Title:	Challenges of scaling UP laboratory services for diagnosis and monitoring tests of HIV/AIDS patients on anti retroviral therapy in Zambia
Researcher:	Mrs G Kahenya
Supervisor:	Prof S Pengpid
Department:	Health System Management and Policy
School:	Public Health
Degree:	Doctor of Public Health

DECISION OF THE COMMITTEE:

MREC approved the project.

DATE: May 07, 2008

7.9 Approval Letter from UNZA Zambia



THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

17 July, 2008
Ref.: 016-05-08

Mrs Grace Kahenya
P.O. Box 30780
LUSAKA, ZAMBIA

Dear Mrs Kahenya,

RE: SUBMITTED RESEARCH PROPOSAL: **"CHALLENGES OF SCALING UP LABORATORY SERVICES FOR DIAGNOSIS AND MONITORING PATIENTS ON ANTIRETROVIRAL"**

The above research proposal was presented to the Research Ethics Committee expedited meeting held on 27 May, 2008 where changes were recommended. We would like to acknowledge receipt of the corrected version with clarifications. The proposal has now been approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).

Yours sincerely,

Dr E. Munalula Nkandu, BSc (Hons), MSc, PgD R/Ethics, PhD
CHAIRPERSON

Date of approval: **17 July, 2008** Date of expiry: **16 July, 2009**

7.10 Permission Letter from the Permanent Secretary

MINISTRY OF HEALTH

Republic of Zambia

24th July 2008

TO: All Provincial Health Director
All Executive Directors
All District Directors

Dear Sir /Madam,

Authority has been granted for Mrs. Grace Kahenya , Doctor of Public Health Student at University of Limpopo, Medunsa Campus, Pretoria, South Africa to conduct a research study on "Challenges of Scaling up Laboratory Services for diagnosis and monitoring tests of HIV/AIDS patients on antiretroviral therapy in the Public health institutions in Zambia".

Please support her with the necessary required information for the data collection for this study.

The information collected will be very useful contribution to efficiency and cost effective quality laboratory diagnosis and monitoring for patients on ART in Zambia.

Dr. S. K. Miti
Permanent Secretary
MINISTRY OF HEALTH

7. 11 Informed Consent

Dear Participant,

I am Mrs. Grace Kahenya, a student at the University of Limpopo, Medunsa Campus, South Africa undertaking a research study on the "The Challenges of Scaling up Laboratory Services for diagnosis and monitoring tests for HIV/AIDS patients on antiretroviral therapy in the ART centres, public health facilities in Zambia". The study is a thesis to be submitted to the University of Limpopo in fulfillment of the requirement for the degree of Doctor of Public Health.

The purpose of the study is to determine the challenges of scaling up laboratory services in diagnosis and monitoring tests for HIV/AIDS patients on ART in Zambia. Data collection will be done using structured questionnaires to interview all clinicians and laboratory staff working in the ART centres. The results of the study will be shared and used in the scaling up of laboratory services in diagnosis and monitoring tests for HIV/AIDS patient on ART. It is anticipated that the results of the study will contribute and provide additional information required by policy makers, planners, implementers, public health professionals and researchers on the need of laboratory services in the diagnosis and monitoring HIV/AIDS patients on ART.

I am therefore requesting your participation in the study**. Participation is voluntary and you have a right to withdraw from the study at any time.** Confidentiality will be maintained at all times and no other person will have access to the data considering that the study involves sensitive issues for HIV/AIDS.

Please for further clarification on this study contact the Chairman of Biomedical Research and Ethics Committee, University of Zambia, Ridgeway Campus.

Kindly fill in the slip on next page and sign.

I am willing/not willing to participate in the said study.

Full name:

Signature:

Date:

Witness

Full name:

Signature:

Date:

Contact Details: Grace Kahenya, Telephone: +260 97-777-2427

7.12 Study Timeline

(March 2008 – January 2009)

Activities	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan
Literature Review											
Designing Research Tools											
Submission/Approval to REPC/UNSA ethical committee											
Pre-test and preparation of final research tools											
Permission from Permanent Secretary MOH											
Training Research Assistants, Data Collection, Coding & Data capturing											
Data verification and analysis											
Data interpretation and presentation											
Write-up											
Submission of 1st Draft to Supervisor											
Corrections of 1st Draft											
Submit 2nd Draft to Supervisor											
Corrections and Final Submission											

7.13. Biography

Name: Grace Cecilia Musonda Kahenya

Date of Birth: 12th May 1954

Place of Birth: Chingola, Zambia

Fellowship: Chartered Scientist and Fellow of Institute of Biomedical Sciences

Institutions Attended:

1972 – 1975	Evelyn Hone College, Lusaka, Zambia (Diploma in Medical Laboratory Sciences)
1979 .	Royal Free Hospital, London, United Kingdom (Diploma in Teaching Biomedical Sciences)
1985 – 1987	Westminster University, London, United Kingdom (B.Tech HND Medical Laboratory Sciences Microbiology)
1991 – 1992	Brunel University of West London, United Kingdom. (Masters in Applied Immunology)
1992	Institute of Biomedical Sciences (Fellow of Institute of Biomedical Sciences)
2002	Sustainable Management Development Programme (SMDP) – CDC – Georgia, Atlanta (Certificate in Management for International Public Health, MIPH)
2005	Institute of Biomedical Sciences and the Science Council (Chartered Scientist)

Work Place: Ministry of Health, Lusaka, Zambia
Position Held: Director Public Health Laboratories

I am also an International Consultant expert in Medical Laboratory Services, I have worked with the following organisations; Management Sciences of Health, The Tuberculosis Control Assistance Program (TBCAP), United States Agency for International Development (USAID), World Health Organisation (WHO) and Howard University Technical Assistance Project (HUTAP).

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