IMPLEMENTATION OF QUALITY MANAGEMENT STRATEGIES IN HIV/AIDS CD4 TESTING LABORATORIES IN NAIROBI, KENYA

BY:

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DECLARATION

I, hereby declare that this is my original work and has not been presented for award of any degree or any other award in any institution.

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This research project has been presented for examination with my approval as the university supervisor

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DEDICATION

This is a dedication to all the upcoming researchers in strategic quality management of health systems who are driven by their self-ambition, determination and motivation to make health systems management a one-stop shop of quality management.

ABSTRACT

It is estimated that 1.5 million people in Kenya are infected with Human Immunodeficiency Virus (HIV). In persons with HIV, CD4 Testing is essential in their clinical management and in the determination of the appropriate time to initiate antiretroviral therapy (ART). CD4 counts are also used in monitoring HIV disease progression and the effectiveness of ART. Therefore, CD4 testing is a critical component of HIV/AIDS care and treatment and because of this; a strong need exists for good Quality Assurance (QA) strategies, incorporating both Internal Quality Control (IQC) and External Quality Assessment (EQA) for CD4 enumeration. Despite the importance of quality assurance in CD4 testing, most HIV/AIDS CD4 testing laboratories in Kenya do not adhere to quality assurance procedures such as internal quality control and external quality assessments which are important strategies in the management and treatment of HIV infected persons. These strategies either do not exist at all, and where such strategies exist, they are poorly implemented. A strong need therefore existed to assess the level of awareness and implementation of these quality practices. The main objectives of this study were to assess the implementation of quality management strategies (internal quality control and external quality assessment strategies) and establish the challenges of quality management strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya. A cross-sectional survey was conducted across HIV/AIDS CD4 testing laboratories in Nairobi Kenya where questionnaires were administered by face-face interviews with the laboratory personnel, laboratory supervisors/managers regarding the quality assurance procedures in the HIV/AIDS CD4 testing laboratories. A total of 21 HIV/AIDS CD4 testing laboratories were assessed, majority of which were clinical services laboratories, followed by research laboratories. With regard to the implementation of quality management strategies, more than half of the HIV/AIDS CD4 testing laboratories assessed in this study had implemented IQC strategies, while more than a third had not implemented the IQC strategies. Majority of these laboratories had implemented EQA strategies in HIV/CD4 testing while a quarter of these laboratories had not implemented EQA strategies. The major challenges of strategy implementation included the lack of knowledge on the quality management practices, procurement of IQC and EQA materials, management resistance and inadequate funding. Slow procurement process emerged as the most significant challenge to quality management strategy implementation in HIV CD4 testing laboratories in Nairobi Kenya. The findings of this study show that a large number of HIV CD4 testing laboratories have not implemented HIV/AIDS CD4 testing IQC and EQA quality management strategies. This non-adherence to good quality management procedures means poor quality and unreliable CD4 test results. In this regard there is a need to establish a monitoring system to laboratories performing CD4 testing for the purpose ensuring that activities related to quality assurance procedures are followed. Personnel doing HIV CD4 testing should be re-trained on the procedures of HIV CD4 testing and quality assurance strategies.

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ACRONYMS AND ABBREVIATIONS

AIDS :   Acquired Immunodeficiency Syndrome

ART :   Antiretroviral Therapy

EQA :   External Quality Assessment

IQA :   Internal Quality Assurance

IQC :   Internal Quality Control

HIV :   Human Immunodeficiency Virus

HuQAS: Human Quality Assessment Services

NHLS :   National Health Laboratory Service

SQM :   Strategic Quality Management

QA :   Quality Assurance

QASI :   Quality Assurance Systems International

UoN :   University of Nairobi

UKNEQAS : United Kingdom National External Quality Assessment

CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Today's organizations operate in a dynamic environment that is turbulent, confusing, threatening and often unpredictable. These organizations face dynamic environments characterized by substantial and often unpredictable social, technological, political and economic changes and in order to be successful, these organizations must be strategically aware. They must understand how changes in their competitive environment are unfolding. They should actively look for opportunities to exploit their strategic abilities, adapt and seek improvements in every area of the business, building on awareness and understanding of current strategies and successes. Organizations must be able to act quickly in response to opportunities and barriers (Papulova, 2006).

In order to succeed in the long term, organizations must compete effectively and out-perform their rivals in a dynamic environment. To accomplish this they must find suitable ways for creating and adding value for their customers. Strategic management is a highly important element of organizational success. The need to know what the business is about, what it is trying to achieve and which way it is headed, is a very basic requirement determining the effectiveness of every member's contribution. Every successful entrepreneur has this business self-awareness and every successful business seems to have this clarity of vision, even though it does not arise from a formal planning process (Pearson, 1990)

The word strategy has entered the field of management more recently. In the political and military context, the concept of strategy has a long history. At first, the word strategy was used in terms of military science to mean what a manager does to offset

actual or potential actions of competitors. In this context, strategy was concerned with the art of planning and directing the large military movements and operations of a campaign or war. The transfer of the word to business activities is understandable and appropriate, the market becoming the theatre of competition (Hill, 1998)

In management, the concept of strategy is taken in a slightly different form as compared to its usage in military form; it is taken more broadly. The 'design school' strategy theorists, who consider strategy to be a part of a well formed, logical planning process (Ansoff, 1965, Porter 1980, 1985), might define 'strategy' as moving from where you are to where you want to be in the future – through sustainable competitive advantage. Chandler (1962) has defined strategy as the determination of the basic long-term goals and objectives of an enterprise, and the adoption of courses of action and the allocation of resources necessary for carrying out these goals. Chandler subscribes to the view that is as much defining goals and objectives as it is about providing the means for achieving them.

Public and private health care organizations also operate in a dynamic environment that is turbulent, confusing, threatening and often unpredictable. It is therefore necessary for these organizations to be able to develop and implement plans to take advantage of their changing environment (Swayne et al., 2006). Strategic management, which is a technique commonly used in the business sector; has many benefits that can be applied to healthcare and public and private health arenas. In the recent years, these concepts have been customized and employed in the healthcare organizations and they does seem to provide the necessary processes for health care organizations to cope with the vast changes that have been occurring (Ginter et al., 2002).

HIV/AIDS CD4 testing laboratories in Kenya are on the rise, and the coverage is about 85% (NASCOP, 2011). The placement of CD4 testing equipment in Kenya is based on geographical location and distance from each placement with the patient load in sites being used as a guiding principal in placement of equipment.

Kenya has moved from a situation where the availability of HIV/AIDS CD4 testing laboratories was limited to a few referral laboratories to the current status where HIV/AIDS CD4 testing laboratories are present in each province (NASCOP, 2011). In total, there are 23 HIV/AIDS CD4 testing laboratories in Nairobi with the promise of more coming up especially in research settings (NASCOP, 2011).

One area in which the concept of strategic management can be applied to make significant impact in the quality of healthcare is in the area of HIV/AIDs and specifically in the provision of quality and reliable CD4 results. Quality management strategies in HIV/AIDS CD4 testing laboratories such as internal quality control and external quality assessment must be implemented and maintained to ensure quality and reliability of reported results.

1.1.1 Strategy Implementation

According to Aosa (1992), once strategies have been developed, they have to be implemented; they are of no value unless they are translated into action. Implementation of strategy is the process through which a chosen strategy is put into action. It involves the design and management of systems to achieve the best integration of people, structure, processes and resources in achieving organizational objectives. Once the creative and analytical aspects of strategy formulation have been settled, the managerial priority is one of converting the strategy into operationally effective action. Indeed a strategy is never complete, even as formulation until it gains

a commitment of the organization's resources and becomes embodied in organizational activities. Therefore, to bring the result, the strategy should be put to action because the choice of even the soundest strategy will not affect organizational activities and achievement of its objectives. Therefore, effective implementation of strategy is a must for the organization (Galbraith et al., 1986).

Strategy implementation involves institutionalization and operationalization of strategies. To institutionalize a business strategy, business leaders must develop a system of values, norms, roles and groups that will support the accomplishment of strategic goals. So, strategy is institutionalized if it is connected to the culture, the quality system, and the other driving forces in the organization. Operationalizing strategy is the translation of agreed upon long term objectives, the strategic plan into organizational action. To make this transition work well, four important things need to be done; translation of long term objectives into short term annual targets for action, translation of the business strategy into daily activities, communication of policies to people in the organization, and designing effective rewards aimed at rewarding desired actions and results.

1.1.2 Quality Management Strategies

Quality is defined as meeting and exceeding the customer's need and expectations and then continuing to improve (Demming, 1986). Quality has been recognized as critical to modern competition. High quality is achieved by continual improvement in terms of customers' expectations. The aim of continuous quality improvement is to meet the customer, not just the competition.

Quality management is the totality of functions involved in the determination and achievement of quality (American Society for Quality, 1983). Quality management

includes all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the quality system, of all these, quality assurance plays an important role.

Quality assurance (QA) refers to the planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled (Lee, 1989). These activities can be divided into two broad groups-namely, internal quality control (IQC) by which is meant the in-house procedures for continuous monitoring of operations and systematic day-to-day checking of the produced results to decide whether these are reliable enough to be released; and external quality assessment (EQA) which involves the objective evaluation of standards by an external agency and is very much concerned with comparisons among others service providers and the assessment of competence within a national or even global context (American Society for Quality, 1983). A good quality assurance program ensures accuracy, reliability and timeliness of reported results, services or products.

An important activity that is sometimes overlooked is the assessment of how well the quality-management program is working. The program team should periodically assess whether the planned strategies for measuring quality are being carried out and whether the expected improvements in quality are being seen. This assessment is important to ensure that the efforts and resources put into the program are achieving the desired outcomes.

It is important to note that quality, like any other dimensions of a business must be managed strategically. One factor above all others –Quality- drives market share. Businesses with superior quality products outperform those with inferior quality

(Omachonu and Ross, 2005). It has been noted that, when we start improving quality, it improves everything and the result is that you stay in business (Narasimhan et al., 2011).

There is a growing body of empirical research supporting a direct relationship between the adoption of quality management strategies and improved firm performance (Samson and Terziovski, 1999). Given the theoretical link that exists between competitive advantage and performance, it is perhaps not too surprising that it has been claimed that quality management practices can be used to generate a competitive advantage (Seawright and Young, 1996). It has also been seen that quality management leads to sustainability of advantage (Tilton, 1994). Five major specific performance objectives have been identified, that is, cost, speed, dependability, flexibility and quality and of these, many authorities believe that quality is the most important (Slack et al., 2004).

1.1.3 HIV/AIDS CD4 Testing Laboratories in Kenya

CD4 is a an important type of T-cell in the human body that is required for proper functioning of a person's immune system in helping protect the body from infection. When a person is infected with HIV, CD4 cells are greatly reduced. HIV attacks and destroys these types of cells and uses them to make more copies of itself. In so doing, HIV weakens the immune system, making it unable to protect the body from illness and infection. Antiretroviral drugs are used to treat HIV infection by restoring CD4 cells and reducing the viral load (amount of the virus in the body).

Assays that detect CD4 T cells in blood are relied on to determine the appropriate time to start antiretroviral therapy (ART) in HIV positive people. CD4 counts are also used as a tool to monitor HIV disease progression and the effectiveness of ART.

When a patient is not responding to treatment, CD4 data is used to determine whether to change from first-line to second-line therapy. Thus, CD4 testing is a very critical laboratory component of HIV and AIDS care and treatment, and the demand for CD4 testing is increasing as more patients, are living longer.

HIV/AIDS CD4 testing laboratories in Kenya are on the rise, and the coverage is about 85% (NASCOP, 2011). The placement of CD4 testing equipment in Kenya is based on geographical location and distance from each placement with the patient load in sites being used as a guiding principal in placement of equipment. Nyanza province and Nairobi province have the highest HIV prevalence in Kenya; 14.9% and 9% respectively, and therefore there are more HIV/AIDS CD4 testing laboratories in these regions. North eastern Kenya has the lowest set up of HIV/AIDS CD4 testing laboratories due to the low prevalence of HIV in the region (NASCOP, 2011). Kenya has moved from a situation where the availability of HIV/AIDS CD4 testing laboratories was limited to a few referral laboratories to the current status where HIV/AIDS CD4 testing laboratories are present in each province (NASCOP, 2011). Likewise, the country has tried to mainstream CD4 test monitoring through various activities that include setting up new laboratories with capacity to handle many CD4 tests per day using less human resource as more and more people are requesting for the CD4 test. In total, there are 23 HIV/AIDS CD4 testing laboratories in Nairobi with the promise of more coming up especially in research settings (NASCOP, 2011).

With the increase in the number of HIV/AIDS CD4 testing laboratories and more and more patients requesting for the CD4 tests, there is need to ensure that quality and reliability of CD4 test results, is maintained. In this regard, certain operational quality management strategies must be put in place and key among them are internal quality

control and external quality assessment strategies in these HIV/AIDS CD4 testing laboratories.

Internal quality control requires that every time that the patient samples are being tested, a quality control sample with known values and acceptable range be run concurrently with the patient samples. If at the end the test run you get the same results as you expected for the quality control sample; then you know that your patient results are reliable and accurate enough to be reported. Internal quality control samples must be run every day and every time the patient results are being tested.

The second important quality management strategy is external quality assessment. An external quality assessment scheme is designed to provide an independent check of laboratory results. The laboratory receives control samples from an external body (national, regional or international body). At the time of receiving these samples, the laboratory does not know the expected values for that sample, they are only expected to run the samples and submit the results back to the external quality assessment body. The external body then evaluates the submitted results to see if they are within the expected ranges and then marks them as pass or fail. Once the laboratory receives a pass feedback from the external quality assessment company, then they know that their methods, equipment, and personnel are competent; and the patient results that the laboratory is generating are precise, accurate and reliable enough to be reported. The external quality assessment scheme monitors the performance of each laboratory over time and identifies those laboratories that require training or corrective action to improve their performance.

1.2 Research Problem

Quality has been recognized as a critical component in modern competition. Therefore, quality, like any other dimension of business must be managed strategically for the organization to stay in business and in order to generate a sustained competitive advantage. Business with superior quality good outperforms that with inferior quality. In order for an organization to produce goods or services of high quality, then quality management strategies must be formulated and fully implemented.

In the area of HIV and CD4 testing in Kenya, quality management strategies such as internal quality control and external quality assessment are very key in ensuring that quality CD4 results are generated. However, despite the importance of these quality management strategies in CD4 testing, most HIV/AIDS CD4 testing laboratories in Kenya do not adhere to these quality management procedures. These strategies either do not exist at all, and where such strategies exist, they are poorly implemented. It is important therefore to assess how well these quality management strategies are being implemented in the HIV/AIDS CD4 testing laboratories so as to ensure that the efforts and resources put into the programs are achieving the desired outcomes.

Various empirical studies have studied the concepts of strategy implementation, Koske (2003) studied strategy implementation in Telkom Kenya Ltd and found out that Telkom Kenya Ltd had formulated strategies but the level of implementation was average. Gakenia (2008) studied strategy implementation in Kenya Commercial Bank (KCB) and found out that strategy implementation at the KCB follows the basic requirements of a successful strategy implementation. Nduva (2011) studied strategy implementation and associated challenges at the Kenya Bureau of Standards (KEBS)

and found out that strategy implementation at the KEBS is good although exposed to several challenges including poor internal communication, mismatch between strategy and organizational structure among other challenges. Empirical studies have also been conducted in quality management strategies. Thiong'o (2007) carried out a study to establish the extent of quality management practices in the Kenya's 3-5 star hotels in Nairobi Kenya. He found out that there was common appreciation and recognition of quality management as an important strategy for hotels competing in the tourism industry. She noted that most of the hotels have embraced quality management and that quality management has positive impact on operational performance of hotels. Komen (2011) conducted a study to investigate the critical quality management issues that pose challenges in the horticulture industry and to investigate the extent of awareness of and the use of quality management tools in the supply chain. He found out that information flow was not adequate especially at the upstream end. He argued that the flow of valuable information such as quality specifications is very important and especially to the suppliers. Komen (2011) also identified a need to meet quality management requirements as demanded by the customers.

There are very few studies that have been conducted to investigate the implementation of these quality management strategies in HIV/AIDS CD4 testing laboratories across the world and the few that have been done show that these strategies are not common (Mashauri et al., 2007, Yan et al., 2010, Mfinanga et al., 2007). Moreover, no single study has been conducted in Kenya to assess the implementation of quality management strategies in HIV/AIDS CD4 testing laboratories in Nairobi Kenya. This is the research gap that this study sought to fill. A strong need existed to assess the awareness, the level of implementation and the challenges of quality management strategies implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya.

The following questions needed to be addressed; Are there quality management strategies in HIV/AIDS CD4 testing laboratories in Nairobi Kenya? What are the challenges of quality management strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya?

1.3 Research Objectives

The objectives of this study were:

i. To assess the implementation of quality management strategies (internal quality control and external quality assessment strategies) in HIV/AIDS CD4 testing laboratories in Nairobi Kenya.

ii. To establish the challenges of strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya.

1.4 Value of the study

The value of the study lies in three main areas, i.e., theory building, improvement of managerial practices and in policy development. Firstly, this study adds on to the accumulated knowledge of the theory of strategic management, strategic quality management and operations quality management. It discusses how the theory of strategic management can be applied in the public and private healthcare sector. It explores specific concepts in strategic management that have led to success in the business sector and shows how these concepts can be customized and employed in the dynamic and uncertain public and private healthcare arenas in order to achieve long-term and short-term health related goals. The study also demonstrates how strategies can be linked or aligned with quality in order to achieve a desired outcome.

Secondly, research on quality management practices in HIV laboratories is scant; this study provides published information on laboratory quality management practices, the

data gathered from this study will help improve managerial practices of healthcare managers especially in the area of quality assurance (Internal quality control and external quality assessment strategies). This will in turn translate into better quality practices in medical laboratories and hence high quality results.

In terms of policy development, the findings of this study provide very useful information to healthcare policy makers, programme managers and other stakeholders in looking for a feasible means to improve the quality of HIV laboratory practices in Kenya and other parts of the world especially the sub Saharan African region which is home to more than 68% of the 34 Million people infected with HIV worldwide.

CHAPTER TWO: LITERATURE REVIEW

2. 1 Introduction

This chapter reviews related literature on the concept of strategy, strategy implementation, quality management, quality management strategies and the challenges of strategy implementation of in HIV/AIDS CD4 testing laboratories.

2.2 Concept of Strategy

The practice and concept of strategy has many varied meanings, yet it remains closely related to planning and planning models. The word "strategy" is now applied to almost every management activity. According to Johnson and Scholes (2002), strategy is the direction and scope of an organization over the long-term, which achieves advantage for the organization through its configuration of resources within a challenging environment, to meet the needs of markets and to fulfill stakeholder expectations.

According to Musyoka (2011), strategy is about where the business is trying to get to in the long-term; the markets it should invest in and the kind of activities involved in such markets; how the business can perform better than the competitors in those markets; the resources (skills, assets, finance, relationships, technical competence, facilities) required to enable it to compete; the external environmental factors that affect the business' ability to compete, and the values and expectations of those who have power in and around the business.

2.3 Strategy Implementation

Strategy implementation is often called the action stage of strategic management. It is often considered to be most difficult stage of strategic management and it requires

personal discipline, commitment and sacrifice. Strategy formulated but not implemented serve no useful purpose in an organization. According to Aosa (1992), once strategies have been developed, they need to be implemented; they are of no value unless they are translated into action. Poor implementation of an appropriate strategy may cause that strategy to fail (Kimuthi, 2011).

Koske (2003) did a study on strategy implementation on public cooperations at Telkom Kenya Limited with an objective of finding out the extent of strategy implementation and the challenges encountered. He found out that, Telkom Kenya Limited had formulated strategies but the strategies were averagely implemented.

Gakenia (2008) also conducted a study on strategy implementation at the Kenya commercial bank; he found out that strategy implementation process at Kenya commercial bank followed the basic requirements of a successful strategy implementation. He identified four factors that had greatly influenced strategy implementation process at the Kenya commercial Bank, that is; financial and human resources, management support, and organizational structure.

Achoki (2010) conducted a study on strategy implementation at the ministry of state for provincial and internal security. The objective was to determine the factors influencing strategy implementation at the ministry. He found out that strategy implementation at the ministry was met by several challenges such as inadequate and limited resource allocation, conflict of interest, bureaucracy, untimely communication, political interference and staff and public resistance to change.

Nduva (2011) conducted a study on strategy implementation challenges facing the Kenya Bureau of Standards (KEBS) and found that strategy implementation process at KEBS is good although exposed to several challenges which included poor internal

communication, unsound reward systems, mismatch between strategy and organizational structure and resource insufficiency. Nduva (2011) recommended that KEBS needed to look into strategy implementation issues with focus being to empowering and strengthening the implementation teams.

2.4 Quality management

Quality management has been widely viewed as a management paradigm that enables firms to gain a competitive advantage (Yeung et al., 2006). Empirical research shows that quality management practices positively affect firm performance (Hendricks and Singhal, 1996; Handfield et al., 1998; Das et al., 2000; Douglas and Judge, 2001; Kaynak, 2003). The ultimate goal of quality management is to establish a management system and an organizational culture that ensures customer satisfaction and continuous improvement (Sitkin et al., 1994; Kaynak, 2003).

According to Flynn et al., (1994), quality management is an integrated approach to achieving and sustaining high-quality output, focusing on the maintenance and continuous improvement of processes and defect prevention at all levels and in all functions of the organization, in order to meet or exceed customer expectations. Dean and Bowen (1994) conceptualized quality management in terms of principles, practices, and techniques. The principles are customer focus, continuous improvement, and teamwork. Each principle includes a set of practices, like direct customer contact, process analysis, group skills training, and collaboration with suppliers. These practices, then, are implemented through a number of techniques, like quality function deployment, control charts, cause and effect diagrams, team building, six-sigma, and so on. Anderson et al., (1994) perceived quality management as a holistic approach to organization-wide quality, operationalized through leadership, internal/external

cooperation, effective process management, product design, learning, customer focus and involvement, employee fulfillment, and continuous improvement.

Wacira (2007) in his study on the implementation of quality management systems and environmental management systems as an integrated system in Kenyan companies found that integrating quality management and environmental management systems yielded benefits which include reduction in resources required for implementing each system separately.

Komen (2011) conducted a study to investigate the critical quality management issues that pose challenges in the horticulture industry and to investigate the extent of awareness of and the use of quality management tools in the supply chain. He found out that information flow was not adequate especially at the upstream end. The exchange of information concentrated much more between customers and companies and suppliers. Flow of valuable information such as quality specifications is very important and especially to the suppliers. Komen (2011) also identified a need to meet quality management requirements as demanded by the customers.

Thiong'o (2007) carried out a study to establish the extent of quality management practices in the Kenya's 3-5 star hotels in Nairobi Kenya. She argues that, success in the industry is achieved through quality of service and this arose due to increased competition in in the tourism industry as a result of globalization. In her survey, Thiong'o (2007) found out that there was common appreciation and recognition of quality management as an important strategy for hotels competing in the tourism industry. She noted that most of the hotels have embraced quality management and that quality management has positive impact on operational performance of hotels.

2.5 Quality Management Strategies

Mfinanga et al., (2007) conducted a baseline survey on quality management strategies in 12 laboratories to assess the quality of HIV laboratory testing practices in Tanzania. He revealed the inadequacy in good laboratory practices and poor laboratory quality control process for HIV testing reagents, internal and external quality control. In this study only 14.3% of laboratories practiced internal quality control for CD4 count testing.

Mashauri et al., (2007) conducted a survey aimed at assessing quality management strategies in HIV testing in health facilities in Lake Victoria zone, Tanzania. In this study, 89 health facilities were surveyed. The findings of this study show that most of health facilities in the Lake Victoria zone do not adhere to quality assurance (including internal quality control and external quality assessments) procedures in HIV testing. It was notable that most of the internal quality control procedures were performed at hospital level 21/29 (63.6%). Internal and external quality controls were not common (37%) in the rest of the health facilities (health centers, dispensaries).

Yan et al., (2010), assessed the quality management strategies in the HIV laboratory network of China. In this study, of the 289 studies surveyed in 2009, 269 participated in an external quality assessment program. It was noted that, China has made significant progress in establishing a well-coordinated HIV laboratory network and quality management systems. However, the coverage and intensity of HIV testing and quality management programs needed to be strengthened.

2.6 Challenges of Strategy Implementation

Strategy implementation remains very critical yet the most difficult phase in strategic management process, even a good strategy would still fail if the implementation is not

thoroughly planned and executed well (Dwallow 2007). Much of the shortcomings in strategy are attributable to failures in the implementation process rather than in the formulation of strategy itself (Beer et al., 1990; Woolridge and Floyd, 1990). Wessel (1993) stated clearly that most of the individual barriers to strategy implementation that have been encountered fit into one of the following interrelated categories: too many and conflicting priorities, the top team does not function well; a top down management style; inter-functional conflicts; poor vertical communication, and inadequate management development.

Dwallow (2007) did a study on strategy implementation challenges in the firms in the packaging industry in Nairobi. From this study, it is clear that packaging firms in Nairobi perceive poor leadership style, wrong strategic choice, poor management of resources and global trends in the industry as the major challenges with significant effect during strategy implementation.

Ochanda (2005) investigated the challenges of strategy implementation at Kenya Industrial Estates Limited and discovered that Policies, procedures and support systems, the reward, and motivational structures, resource allocation and budgetary allocation continued posing a challenge to the successful implementation of the strategy.

Wangui (2007) also conducted a study in strategy implementation challenges. From her study; "strategy implementation challenges in the main stream churches in Kenya" it is evident that the way in which strategies implementation challenges were evident in organizational culture and poor communication back to top management were pertinent challenges with popular mechanisms used to cope with the challenges being teamwork and bringing all stakeholders on board in implementation of the strategy.

Musyoka (2011) conducted a study to investigate the challenges of strategy implementation in Jomo Kenyatta Foundation (JKF). In her study, the key challenge identified was related to changes in the operating environment such as stiff competition compounded by new entrance of important new competitors into the industry and un-anticipated new substitute or competing products. The government policies were also unfriendly to the business orientation. The industry forces, especially the buyers' power and rivalry within the industry, have led to increased costs in promotions, branding and efforts to enhance JFK's presence. Other challenges faced included behavior resistance to change, inappropriate systems, especially the structure, traditional public sector culture, unaligned organizational processes and resources used in the organization.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the research methodology and describes the research design that this study adopted and the reasons for choosing the design, the study population from which a sample was drawn and sample size of laboratories assessed. It also describes the data collection methods and the tools that were used in data collection and finally it describes the data analysis techniques and procedures that were done to achieve the study objectives and how the results are presented.

3.2 Research Design

This was cross-sectional descriptive study where questionnaires were used to elicit information on quality management strategies in HIV/AIDS CD4 testing laboratories in Nairobi Kenya. The descriptive design is a description of the state of affairs as it exists at present (Herve, 1988).

In this type of research design, either the entire population or a subset thereof is selected, and from these individuals, data are collected to help answer research questions of interest. The information that is gathered in a cross-sectional study represents what is going on at only one point in time.

3.3 Population of Study

The proposed study was carried out in Nairobi. The target population all HIV/AIDS CD4 testing laboratories in health facilities in Nairobi. There were an estimated 23 government and privately owned HIV/AIDS CD4 testing laboratories in Nairobi (NASCOP, 2011). In this study, all the 23 HIV/AIDS CD4 testing laboratories in Nairobi were considered and they comprised the sample size for this study.

3.4 Data collection

Primary data were used in this study. Data were collected using structured questionnaires. This allowed for collection of objective facts and the display of results as summary statistics. Closed ended and scaled items were carefully used because to generate information of influence, facilitates response since the questions are multiple choices and data can be categorized easily. The scaled items, according to Macmillan and Schumacher (2001) allow fairly accurate assessments of opinions. Similarly it has the ability to solicit information from several respondents within a short time (Gupta, 1999).

The questionnaire was divided into three parts, part one gathered general information about the laboratory, part two gathered information on implementation of quality management practices in the HIV/AIDS CD4 testing laboratories and part three gathered information regarding the challenges of strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi, Kenya.

3.5 Data Analysis

Data relating to demographic information of CD4 laboratories in Nairobi, CD4 testing quality management strategies, and challenges in strategy implementation in HIV/AIDS CD4 testing laboratories was reported. Descriptive statistics such as proportions were used to summarize categorical variables while measures of central tendency (mean, standard deviation, percentiles) for continuous variables.

The proportions of CD4 testing laboratories practicing internal quality control and external quality assessment strategies were reported. The challenges of strategy implementation in HIV/AIDS CD4 testing laboratories were reported in order of their magnitude. Data presentation was done using graphs and summary tables.

CHAPTER FOUR: DATA ANALYSIS, FINDINGS AND DISCUSSION

4.1 Introduction

The objective of this study was to assess the implementation of quality management strategies (internal quality control and external quality assessment strategies) in HIV/AIDS CD4 testing laboratories in Nairobi Kenya and to establish the challenges of quality management strategy implementation in these laboratories. A cross-sectional survey was conducted across HIV/AIDS CD4 testing laboratories in Nairobi Kenya where questionnaires were administered by face-face interviews with the laboratory personnel, laboratory supervisors/managers regarding the quality assurance procedures in the HIV/AIDS CD4 testing laboratories. A total of 21 HIV/AIDS CD4 testing laboratories were assessed out of the proposed 23 laboratories giving a response rate of 91%. This chapter records the general demographic characteristics of the assessed laboratories, the implementation of internal and external quality management strategies and the challenges of strategy implementation in HIV/AIDS CD4 laboratories. The chapter also records the data analysis steps and the data analysis outputs and then discusses the study findings in the context of the study objectives.

4.2 Demographic Profiles of HIV/AIDS CD4 Testing Laboratories

This section describes the general demographic information of the CD4 testing laboratories in Nairobi Kenya that were assed in this study. It captures information about the kind of the laboratory, type of the CD4 testing equipment used, the CD4 testing workload, the source laboratory funding, the cost of CD4 testing, the educational level and experience of the personnel in performing CD4 testing in the HIV/AIDS CD4 testing laboratories.

4.2.1 Kinds of HIV/AIDS CD4 testing laboratories in Nairobi Kenya

Majority of the laboratories assessed were those directly involved in clinical services of CD4 testing (47.6%). HIV Research laboratories accounted for 42.9% while 9.5 % were HIV reference laboratories where HIV persons and specimens are referred to for testing. (Table 4.1)

Tables 4. 1: Kinds of HIV/AIDS CD4 testing laboratories in Nairobi Kenya

Kind of HIV/AIDS CD4 Testing Laboratory Assessed		
Type of Laboratory	**Frequency**	**Percentage**
Clinical Services Laboratories	10	47.6
Research Laboratories	9	42.9
Reference Laboratories	2	9.5
Totals	**21**	**100**

Source: Research Data, (2012)

The clinical services laboratories comprised all the laboratories (both government and privately owned laboratories) whose day to day activities is to perform HIV/AIDS CD4 testing for HIV positive persons. This explains why the clinical services laboratories carried the highest percentage of the assessed laboratories. Research laboratories were defined as those directly involved in HIV research in persons infected with HIV/AIDS. The CD4 tests done in these laboratories are used for both clinical management of the HIV positive patients and for research purposes such as HIV vaccine research. Reference laboratories were defined as those whose mandate includes overseeing quality assurance activities in the regional labs; providing support supervision; mapping equipment placement in the region; validation of equipment and provision of services like CD4 testing to the public. The HIV Reference laboratories receive CD4 specimens from all over the country for testing. In this study two HIV reference laboratories were assessed.

4.2.2 Types of CD4 Testing equipment used in HIV/AIDS CD4 testing laboratories in Nairobi, Kenya

The most widely used CD4 testing equipment was the FACSCalibur (BD Biosciences) and the FACSCount (BD Biosciences), i.e. 2.4% and 42.9 % respectively. (Table 4.2)

Tables 4. 2: Types of CD4 Testing Equipment Used in HIV/AIDS CD4 testing laboratories

Types of CD4 Testing Equipment Used		
Equipment	**Frequency**	**Percentage**
FACSCalibur	11	52.4
FACSCount	9	42.9
Guava	1	4.8
Totals	**21**	**100**

Source: Research Data, (2012)

The FACSCalibur was the most widely used CD4 testing equipment. Many laboratories have opted to use the FACSCalibur because it is more stable, can handle a higher workload and can be fully automated so as to ease the CD4 testing workload on technicians especially in laboratories with very high daily workload. The FACSCalibur can run between 80 to 400 tests per day while FACScount has a workload of 30 tests per day.

4.2.3 Source of Funding for the HIV/AIDS CD4 Testing Laboratories

The majority of the HIV/AIDS CD4 testing laboratories were funded by individuals carrying out their research projects (33.3%). Other funding agencies included; private businesses (14.3%), USAID (14.3%) and CDC (14.3%), PEPFER and Clinton Foundation accounted for 9.5 % each and the MSF Belgium (4.8%). (Table 4.3)

Tables 4. 3:Source of Funding for the HIV/AIDS CD4 Testing Laboratories

Laboratory Funding for the HIV CD4 Testing Labs		
Funding Agency	**Frequency**	**Percentage**
Individuals HIV Research Projects	7	33.3
Private Businesses	3	14.3
USAID	3	14.3
CDC	3	14.3
PEPFER	2	9.5
Clinton Foundation	2	9.5
MSF Belgium	1	4.8
Totals	**21**	**100**

Source: Research Data, (2012)

The funding agencies provided funding in areas such as laboratory renovation, procurement and supply of the laboratory reagents and equipment, staff training and staff salaries and the maintenance of laboratory quality assurance standards. Majority of the laboratories assessed in this study were funded by individuals carrying out HIV research projects, however, these individual are donor funded projects from various research funding agencies across the world. These funding has greatly improved the quality standards of the CD4 testing laboratories.

4.2.4 CD4 Testing Workload in HIV/AIDS CD4 testing Laboratories

With regard to CD4 workload the median number of tests done per month was 735 ranging from 63-3150 tests per month. The mean number of tests done per month was 1,125 (SD 1, 035) tests per month. (Table 4.4)

Tables 4. 4: CD4 Testing workload in HIV/AIDS CD4 testing Labs in Nairobi Kenya

Number of CD4 Tests Done per month in HIV/AIDS CD4 Labs				
Statistic	Mean number	Standard Deviation	Median number	Range
Workload	1,125	1,035	735	63 - 3,150

Source: Research Data, (2012)

4.2.5 Cost of CD4 Testing in HIV/AIDS CD4 Testing Labs

The median CD4 test cost was Kshs 1,000 (Kshs 150 - 2, 760). The mean cost was Kshs: 1, 102.94 (SD 670.85) per test. (Table 4.5)

Tables 4. 5: Cost of CD4 Testing in HIV/AIDS CD4 Testing Labs

Cost of CD4 Testing (Kshs) in HIV/AIDS CD4 Labs				
Statistic	Mean Cost	Standard Deviation	Median Cost	Cost Range
Cost (Kshs)	1,102.94	670.85	1,000.00	150 - 2,760

Source: Research Data, (2012)

It was noted that, most of the donor funded laboratories did not charge the patients enrolled in their programs for performing the CD4 tests. However, those HIV positive patients who were not enrolled in these programs were required to pay a subsidized amount of money. The cost of CD4 testing was highest in privately owned HIV/AIDS CD4 testing laboratories. The CD4 cost was also lower in the laboratories using the FACSCount CD4 testing equipment and this was attributed to its low maintenance costs.

4.2.6 Education Level of Personnel Performing CD4 tests

All personnel performing CD4 testing and interviewed in this study had attained tertiary education and above. Diploma holder laboratory technicians comprised the highest percentage (66.7%), followed by Bachelor's degree holders and master's and above degree holders, that is; 19.1% and 14.3% respectively. (Table 4.6)

Tables 4. 6: Education levels of personnel performing CD4 testing Nairobi Kenya

Education Level of Personnel Performing CD4 Test		
Qualification	**Frequency**	**Percentage**
Diploma Level	14	66.7
Bachelor's Degree Level	4	19.1
Master's degree level and above	3	14.3
Totals	**21**	**100**

Source: Research Data, (2012)

An appropriately trained and well-organized laboratory staff is essential for the successful operation of a CD4 testing facility. The required qualifications for laboratory personnel performing CD4 testing should be determined by the ministry of health and governing body in charge of regulating health care professionals. The qualifications of the laboratory staff must be adequate to perform, interpret, and troubleshoot the CD4 assay.

4.2.7 Laboratory Experience of Personnel Performing CD4 Tests

The mean experience of personnel performing CD4 testing was 5 years (SD 2.6) and the median experience was 5 years ranging from (1-11years). (Table 4.7)

Tables 4. 7: Experience of personnel performing CD4 testing Nairobi Kenya

Experience in years of Personnel Performing CD4 Test in HIV/AIDS CD4 Labs				
Statistic	Mean Experience	Standard Deviation	Median Experience	Range of Experience
Experience (years)	5	2.6	5	1 - 11

Source: Research Data, (2012)

4.3 Implementation of Quality Management Strategies in HIV/AIDS CD4 testing laboratories

The main objective of this study was to assess the implementation of quality management strategies (internal quality control and external quality assessment

strategies) in HIV/AIDS CD4 testing laboratories in Nairobi Kenya. This section presents data on the level of quality management strategy implementation, that is, internal quality control strategy implementation, the types of internal quality control materials used, monitoring of internal quality control results, external quality assessment strategy implementation and the external quality assessment schemes used in HIV/AIDS CD4 testing laboratories.

4.3.1 Implementation of Internal Quality Control in HIV/AIDS CD4 testing laboratories

In this study, 61.9% HIV/AIDS CD4 testing laboratories had implemented internal quality control (IQC) strategies, while 38.1% had not implemented internal quality control strategies in CD4 testing. (Table.4.8)

Tables 4. 8: Internal Quality Control strategy implementation in HIV HIV/AIDS CD4 testing laboratories in Nairobi Kenya

Implementation of IQC Strategy in HIV/AIDS CD4 Testing Labs		
Strategy	**Frequency**	**Percentage**
Have Implemented CD4 testing IQC Strategies	13	61.9
Have not Implemented CD4 testing IQC Strategies	8	38.1
Totals	**21**	**100**

Source: Research Data, (2012)

Good Internal Quality Control requires daily testing of quality control samples with established target values and acceptable ranges must be done at each CD4 testing laboratory to ensure the quality of CD4 results on patient specimens. The results from daily control sample testing will identify abnormal trends and problems with the instruments and reagents, this allows problems to be addressed or corrected as soon as possible. With 38.1% of HIV/AIDS CD4 testing the laboratories not implementing

the internal quality control procedures, it means poor quality and unreliable CD4 test results from these laboratories.

4.3.2 Types of IQC materials used in HIV/AIDS CD4 testing Laboratories

Among those who had implemented IQC strategies, majority of them were using BD Trucount controls (61.5%) which is a quality control sample sold by the manufacturer of the FACSCount CD4 testing machine. Other materials used for internal quality control included the LymphoSure and Multicheck controls (15.4 %) and the Cytomax controls (7.7%). (Figure 4.1)

Figure 4. 1:Types of Internal Quality Control materials used in HIV/AIDS CD4 testing Laboratories
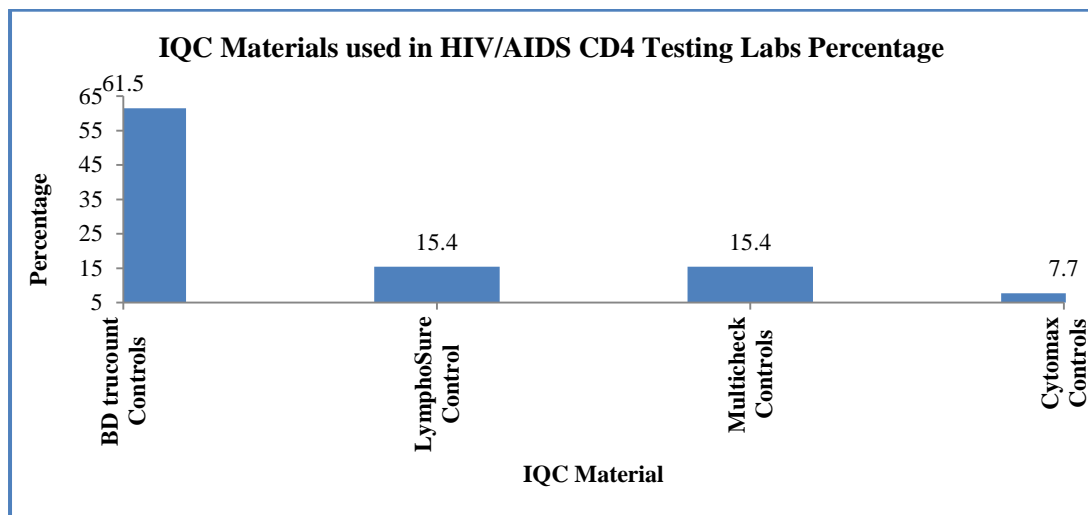
Source: Research Data, (2012)

4.3.3 Monitoring of Internal Quality Control results

Each day of testing patient specimens, IQC results should be entered on Levy-Jennings charts, and, ideally, results for each control should fall within ±2 SD from the mean established in each laboratory. Patient results should not be reported if control values are more than ±3 SD from the mean. Levey-Jennings charts should be reviewed monthly to check for and follow up on abnormal trends.

In this study, only 3 (14.3%) laboratories monitored and reviewed their IQC results overtime. Majority of the laboratories (82.7%) were not familiar with Levy- Jennings charts and how they could be used to monitor quality of CD4 results being provided to the patients.

4.3.4 Implementation of External Quality Assessment strategy in HIV/AIDS CD4 testing laboratories

Of the laboratories assessed in this study, 76.2% had implemented EQA strategies while 23.8% had not. (Table 4.7)

Tables 4. 9: External Quality Assessment strategy implementation in HIV HIV/AIDS CD4 testing laboratories in Nairobi Kenya

Implementation of EQA Strategy in HIV/AIDS CD4 Testing Labs		
Strategy	**Frequency**	**Percentage**
Have Implemented CD4 testing EQA Strategies	16	76.2
Have not Implemented CD4 testing EQA Strategies	5	23.8
Totals	**21**	**100**

Source: Research Data, (2012)

An External Quality Assessment (EQA) scheme is designed to provide an independent check of laboratory results. EQA is the most widely used approach to monitor the quality of CD4 testing, and each testing facility should participate in an external EQA program. Demonstration of proficiency in these EQA provides information to health care providers on the quality of testing in each laboratory and builds confidence in the accuracy of results on patient specimens. The performance of a testing facility in an EQA program should be reviewed over time by testing facility management and any affiliated external agencies. With 23.8% of the HIV/AIDS CD4 testing laboratories not enrolled in an EQA scheme, it means that

there is no confidence in the quality of reported CD4 count results from these laboratories.

4.3.5 Types of EQA Schemes used in HIV/AIDS CD4 Testing Laboratories in Nairobi Kenya

The most widely used EQA scheme was the Human Quality Assessment Services (HuQAS) (31.3%) and the National Health Laboratory Services (NHLS) (31.3%).

Figure 4. 2:Types of EQA Schemes used in HIV/AIDS CD4 Testing Laboratories in Nairobi Kenya
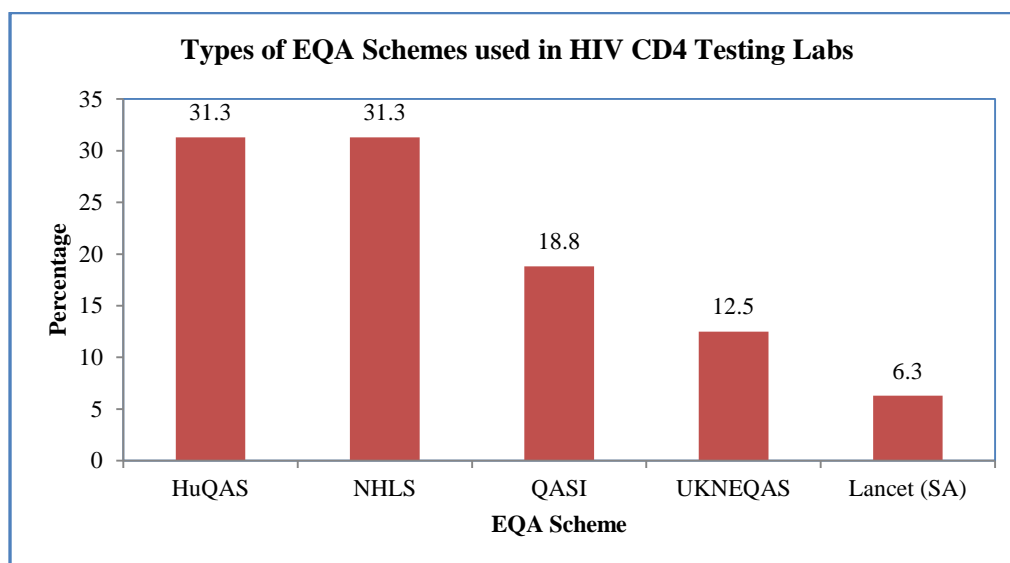
Source: Research Data, (2012)

External quality assessment schemes in HIV/AIDS CD4 counting play an important role. Several EQA schemes are in operation in the Nairobi Kenya, with the purpose to improve the accuracy and precision of CD4 counting. Laboratories can benefit from participation in an EQA scheme. It confirms the competency of the laboratory, identifies problems with test methods, monitors participant improvement of performance over time, educates staff, generates confidence, monitors competency of staff, determines accuracy and precision of test methods and can satisfy local auditing and accreditation organizations, depending on the type of scheme used by a laboratory.

4.4 Challenges of quality management strategy implementation in HIV/AIDS CD4 testing Laboratories in Nairobi Kenya

In this study, the main challenges of quality management strategies implementation included the lack of knowledge on internal quality control and external quality assessments (9.5% to a large extent), inadequate funding (4.8% to a large extent and 9.5% to a very large extent), the slow procurement process of the quality control materials (38.2% to a large extent and 4.8% to a very large extent) and management's resistance to implementing the quality management strategies (15% to a large extent). (Table 4.10).

Tables 4. 10: Challenges of strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya

Challenge	Response	Frequency	Percentage
Knowledge of IQC and EQA Strategies	Not at all	19	90.5
	Least Extent	0	0
	Moderate Extent	0	0
	Large Extent	2	**9.5**
	Very Large Extent	0	0
	Totals	**21**	**100**
	Response	**Frequency**	**Percentage**
Procurement of IQC and EQA Materials	Not at all	12	57
	Least Extent	0	0
	Moderate Extent	0	0
	Large Extent	8	**38.2**
	Very Large Extent	1	**4.8**
	Totals	**21**	**100**
	Response	**Frequency**	**Percentage**
Management Resistance	Not at all	17	85
	Least Extent	0	0
	Moderate Extent	0	0
	Large Extent	3	**15**
	Very Large Extent	0	0
	Totals	**20**	**100**
	Response	**Frequency**	**Percentage**
Inadequate Funding	Not at all	18	85.6
	Least Extent	0	0
	Moderate Extent	0	0
	Large Extent	1	**4.8**
	Very Large Extent	2	**9.5**
	Totals	**21**	**100**

Source: Research Data, (2012)

The results reveal that besides the above listed challenges of strategy implementation, others included, high cost of the quality control testing materials, questionable quality and integrity of the quality control testing materials, instability of the internal quality control and external quality assessment materials, human personnel limitations, poor laboratory information management systems, and unreliable specimen transport systems. Of all the challenges of strategy implementation, procurement of internal quality control and external quality assessment materials emerged as the most

significant challenge to quality management strategy implementation in HIV HIV/AIDS CD4 testing laboratories in Nairobi Kenya.

4.5 Discussion

Strategy implementation remains very critical yet the most difficult phase in strategic management process, even a good strategy would still fail if the implementation is not thoroughly planned and executed well. Further, without proper strategy implementation, even the most superior strategy is useless. According to Aosa (1992), once strategies have been developed, they need to be implemented; they are of no value unless they are effectively translated into action. This is necessary if such organizations are to remain competitive and relevant to current market trends. In HIV/AIDS treatment and control, the implementation of internal quality control and external quality assessment strategies in CD4 Count testing in very critical if quality and reliable CD4 count results are to be provided. Prior to the recent expansion of HIV/AIDS CD4 testing laboratories, CD4 testing was often conducted at central laboratories with the resources and technical skills required to help ensure that test quality procedures were adhered to. These procedures include, amongst others, running of internal quality control samples on every test day, regular calibration of the instruments, participation in external quality assessment schemes, and adherence to standard operating procedures and CD4 operator competency checks. With the proliferation of HIV/AIDS CD4 count laboratories in many resource-limited settings, it has not been easy to ensure that the same quality standards are established at all new laboratories.

In this study, 38.1% of the HIV/AIDS CD4 testing laboratories had not implemented internal quality control strategies in CD4 count testing. These findings are higher as

compared to those found by Mfinanga et al., (2007) who conducted a baseline survey on quality management strategies in 12 laboratories to assess the quality of HIV laboratory testing practices in Tanzania. Mfinanga et al., (2007) revealed the inadequacy in good laboratory practices and poor laboratory quality control process for HIV testing reagents, internal and external quality control. In this study only 14.3% of laboratories practiced internal quality control for CD4 count testing. However, the finding of this study are similar to those of Mashauri et al., (2007) who conducted a survey aimed at assessing quality management strategies in HIV testing in health facilities in Lake Victoria region, Tanzania. In this study, (Mashauri et al., 2007) internal quality control was not common to 37% of the HIV CD4 testing health facilities.

Until recently, many laboratories in Kenya were not enrolled in external CD4 quality assessment (EQA) programs such as HuQAS, QASI or UKNEQAS. In this study, 23.8% of the HIV/AIDS CD4 testing laboratories had not implemented external quality assessment strategies for CD4 count testing. This was contrary to what was observed by a study conducted in China (Yan et al., 2010), where only 7.1% of the CD4 testing laboratories had not implemented external quality assessment strategies in CD4 count testing. However, the finding of this study are lower as compared to those found by a study conducted in Tanzania (Mashauri et al., 2007) where 37% of the CD4 testing laboratories had not implemented external quality assessment for CD4 count testing. The positive impact of EQA on HIV/AIDS CD4 testing laboratory performance has been well demonstrated. However, lack of knowledge and the common perception that EQA is costly or unnecessary has hindered the widespread enrolment of laboratories into such programs. The strengthening of national laboratory quality programs provides an opportunity to ensure that all HIV/AIDS

CD4 testing laboratories conduct routine internal control procedures and enroll and participate in external quality assurance programs. EQA programs require a national coordinator with the authority and resources to send out EQA samples to each laboratory, receive results in a timely fashion, and to make firm recommendations based on the results.

The regular monitoring of daily QC (Levy-Jennings plots) and EQA performance is also essential to establish. Individual competency should be periodically assessed, especially for high-throughput CD4 testing equipment, which require advanced skills for their operation. This study found out that, only 14.3% of the HIV/AIDS CD4 testing laboratories monitored and reviewed their IQC results overtime. Majority of the laboratories (82.7%) were not familiar with Levy- Jennings charts and how they could be used to monitor quality of CD4 results being provided to the patients. Other empirical studies have not looked at this problem in detail but our findings raise a need for a further a retraining of laboratory stuff to enable them fully understand this important process.

This study also established that there were many challenges of strategy implementation in HIV/AIDS CD4 testing laboratories. One of these challenges was lack of knowledge of internal quality control and external quality assessment strategies, which showed a need for personnel training in this area. This was in agreement with a study done by Awino (2010) on challenges of strategy implementation in Mumias Sugar Company where he identified personnel training as one of the major challenges. This study also established that management resistance to change was one of the challenges to strategy implementation. This was similar to the findings of one of the empirical studies conducted to establish the challenges of strategy implementation in Jomo Kenyatta Foundation (Musyoka 2011). Another

challenge of strategy implementation identified in this study was that of procurement of internal quality control and external quality assessment materials. Quality procedures for CD4 counting are not commonly used, possibly because they are less understood than those for other tests. Much of this has to be addressed via training and ensuring regular maintenance of instruments. In addition, it is important to ensure access to quality assurance material to run internal and external controls. Laboratories often do not have daily access to control materials; these are purchased separately from testing kits and often viewed as unnecessary and expensive by many laboratories. The standard inclusion of internal control kits in procurement lists for CD4 reagents will help improve laboratory practice.

CHAPTER FIVE: SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

In this chapter, a summary of the findings of the study are provided and conclusions drawn. In addition, recommendations for policy and practice, limitations of the study and suggestions for further research have been provided.

5.2 Summary of Findings

The main objectives of this study was to assess the implementation of quality management strategies (internal quality control and external quality assessment strategies) in HIV HIV/AIDS CD4 testing laboratories in Nairobi Kenya and to identify the challenges of strategy implementation in HIV/AIDS CD4 testing laboratories in Nairobi Kenya. A total of 21 HIV CD4 testing laboratories were assessed, 10(47.6%) were clinical services labs, 9(42.9%) were research labs and 2(9.5%) were HIV reference laboratories. The median number of CD4 tests done was 735 CD4 tests per month (63-3150) at a median cost of Kshs 1,000 per test (Kshs 150 -2,760). With regard to implementation of quality management strategies, 61.9% of the HIV/AIDS CD4 testing laboratories had implemented IQC strategies, while 38.1% had not. 76.2% had implemented EQA strategies while 23.8% had not. The major challenges of strategy implementation included the lack of knowledge on the quality management practices, procurement of IQC and EQA materials, management resistance and inadequate funding. Slow procurement process emerged as the most significant challenge to quality management strategy implementation in HIV CD4 testing laboratories in Nairobi Kenya.

5.3 Conclusion

The main aim of this study was to assess the implementation of quality management strategies (internal quality control and external quality assessment strategies) in HIV HIV/AIDS CD4 testing laboratories in Nairobi Kenya and to identify the challenges of strategy implementation in HIV/AIDS CD4 testing. The study findings study show that a big number of HIV/AIDS CD4 testing laboratories in Nairobi Kenya do not adhere to quality management procedures in CD4 count testing and that the implementation of quality management strategies in HIV/AIDS CD4 testing laboratories is still low. Non adherence to quality management procedures means poor quality and unreliable CD4 test results.

There is therefore an urgent need to scale up the implementation of CD4 testing quality management strategies. The challenges of strategy implementation should be dealt with by training of laboratory personnel on quality management strategies, involvement of external funding agencies, improvement on procurement processes, improvement of laboratory infrastructure and storage systems to ensure good storage conditions and hence the stability of quality control materials.

5.4 Recommendations for Policy and Practice

The findings of this study gave empirical evidence that have implications for policy and practice. The study has provided insights into the current status of the implementation of quality management strategies in HIV CD4 testing laboratories in Nairobi Kenya. These quality management strategies are intended for use by clinical laboratory staff, governmental and nongovernmental organizations, clinicians, and program managers involved in provision, management, or financial support of CD4 testing.

In this regard there is a need to establish a monitoring system to laboratories performing HIV CD4 testing for the purpose ensuring that activities related to quality management procedures are followed. The study recommends that in order to overcome challenges related to core competence, personnel performing HIV CD4 testing should be re-trained on the procedures of CD4 testing and quality management strategies. To overcome the challenges related to finances, the study recommends more involvement of external partners such as World Bank, PEPFER, MSF, Clinton foundation among others to aid in financing operations and in purchasing of quality control materials.

Procurement of internal quality control materials and external quality assessment materials should be improved; the study recommends installation of laboratory information management systems (LIMS) to help in monitoring laboratory consumables, reagents and the expiry of quality control materials. The study recommends that the government and the various HIV/AIDS treatment and management agencies should develop a HIV/AIDS CD4 count testing policy that should address the issues of quality management of CD4 count testing across all HIV/AIDS CD4 testing laboratories. This will ensure confidence in the quality of the reported CD4 count patient results.

5.5 Limitations of the Study

The findings of this study should be interpreted within the limitations of the study. At the outset, there are limitations of measurement, which are common to social science researchers. Interviewee's perception of good quality management practices may change over time and vary with personal inclinations based with their individual experiences. Also interviewees may express prejudiced views or offer insincere

responses. The data were collected through face to face interviews at the respondent's places of work. The interviewee's would have felt like the researcher was monitoring their laboratories shortcomings or poor laboratory practices.

Equally, some of the questions asked regarded as to how well the laboratory offered quality results to their patients. These were sensitive questions with potential of tainting the image of the laboratory. However, the respondents were assured of anonymity and confidentiality of their responses. Due to inadequacy of resources, the researcher conducted this research under the constraints of finances and therefore collected data from Nairobi region only. This could limit the generalizability of the findings to other parts of the country and the sub-Saharan African at a large.

5.6 Suggestions for Further Research

The fundamental components of a laboratory quality management program include providing a functional and safe laboratory environment, trained and competent personnel, maintained equipment, adequate supplies and reagents, testing of appropriate specimens, internal monitoring of quality, accurate reporting, and external quality assessments strategies. These components are necessary to provide accurate and precise CD4 T-cell counts, an essential test to evaluate start of and monitor effectiveness of antiretroviral therapy for HIV-infected patients.

In this study, internal quality management strategies and external quality assessment strategies in HIV/AIDs CD4 testing laboratories were evaluated. The study has confirmed that a large number of HIV/AIDS CD4 testing laboratories in Nairobi Kenya do not adhere to good quality management strategies in CD4 testing. It has also firmly established the challenges of strategy implementation in these HIV/AIDS CD4 testing laboratories. However, large scale studies should be conducted across the

47 counties in Kenya to assess the implementation of quality management strategies and the challenges of strategy implementation in HIV/AIDS CD4 testing laboratories. It will also be very important to study the level of implementation of the other components of laboratory quality management strategies in HIV/AIDS CD4 testing laboratories. This will l help understand the problems in depth.

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Appendix I: Letter of Introduction

John Gatimu
Reg. No. D61/60089/2011
P.O Box: 19586-00100
Nairobi, Kenya

Dear Sir/Madam:

<u>Re: Completion of the Questionnaire on Implementation of Quality Management Strategies in HIV/AIDS CD4 Testing Laboratories in Nairobi, Kenya</u>

I am a student pursuing Master of Business Administration in Strategic Management in the school of business, University of Nairobi. The title of my project is IMPLEMENTATION OF QUALITY MANAGEMENT STRATEGIES IN CD4 TESTING LABORATORIES IN NAIROBI, KENYA.

The project seeks to assess implementation of quality management strategies (internal quality control and external quality assessment strategies) in CD4 testing laboratories in Nairobi Kenya and to identify the challenges of strategy implementation in CD4 testing laboratories in Nairobi Kenya.

I therefore kindly request you to give me the most appropriate response to the questions based on your experience and knowledge.

Your participation is crucial to the study as it will enhance our knowledge of strategic management and quality management practices in Kenya and particularly in the health sector and HIV CD4 testing.

I hereby assure you that all the information in respect to this research will be treated with utmost confidence and will only be used for academic purposes and under no circumstances will your name and or identity be mentioned in the report without your prior consent.

A copy of the findings may be sent to you on request.

Yours sincerely

……………………

John Gatimu- Student

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Dr. Vincent N. Machuki- Supervisor

Appendix II: Study Questionnaire
IMPLEMENTATION OF QUALITY MANAGEMENT STRATEGIES IN HIV CD4 TESTING LABORATORIES IN NAIROBI, KENYA

<u>**Introduction**</u>

The main objective of this questionnaire is to collect data on the implementation of quality management strategies (Internal Quality Control (IQC) and External Quality Assessment (EQA) strategies) in CD4 testing laboratories in Nairobi Kenya and to identify the challenges of strategy implementation in CD4 testing laboratories in Nairobi Kenya.

Your support in completing this questionnaire objectively will be greatly appreciated.

<u>**PART I: INFORMATION ABOUT THE LABORATORY TO BE ASSESSED**</u>

1. **Date and Time of assessment:**

   Date:_____   Time: _____

2. **Person who assessed the site:**
   a. Name (Optional)_____
   b. Position:_____

3. **Interviewee:**
   a. Name (Optional)<u>:</u>
      _____
   b. Designation._____
   c. Position:_____

4. **Basic information on the CD4 testing laboratory to being assessed**
   a) Laboratory **Name**:_____
   b) **Location** (City, Province):_____
   c) **Kind of Lab:** eg (Clinical Lab, Reference Lab, Research Lab)_____
   d) Type of **Equipment:** (e.g. FACSCalibur, Count, Guava) :_____
   e) **Workload**/No. of test Performed Per day:
      _____

f) Laboratory funding: (e.g. PEPFER , USAID)

    _____

g) **Cost** of CD4
(Kshs):_____

PART II: INTERNAL QUALITY CONTROL (IQC)

1. Is there a national guideline (or protocol) of quality assurance for CD4 testing?
   (1) Yes☐
   (2) No☐

2. Does the laboratory use any system for internal quality controls?
   (1)   Yes☐
   (2)   No☐
      i. If yes, which
         one?_____
      ii. If no, why
         not?_____

3. What IQC samples are being run? Meaning:
   (1) Low
   (2) Normal
   (3) High

4. Are internal control samples included in each test run?
   (1)   Yes☐
   (2)   No☐

   i. If yes, is the performance of these internal controls recorded and monitored over time?
   (1) Yes☐
   (2) No☐

   ii. If yes to 4 (i) above, what system of monitoring is used, eg use of Levy-Jennings
   plots_____
   _____
   _____

   iii. If no to 4 (i), why not?

   _____
   ___
   _____
   ___

   iv) What criterion is used to explain/interpret the control charts? eg the Westgard
   rules_____
   ___

v) Is the corrective action taken after IQA failures?

           (1) Yes□
           (2) No□

a) If yes, which one?

_____

b) If no, why not?

_____

vi) Is there an SOP for the corrective action on IQA or EQA failure?

           (1) Yes□
           (2) No□

5. How often are your internal quality control (IQC) reports/ results reviewed?

_____

6. Do you run calibrations of your equipment?

    (1) Yes□
    (2) No□
    i. If yes, how often?_____
    ii. If no, why?

_____

7. What other IQC checks are available; that are internal to the particular laboratory (e.g Reproducibility tests and how often, Inter laboratory checks and how often)_____

PART II: EXTERNAL QUALITY ASSESSMENT (EQA)

1. Does the laboratory participate in any external quality control assurance or proficiency testing schemes?

        (1)   Yes□
        (2)   No□

i. If yes, which one?_____

ii. If no, why not?

_____

2. What IQC samples are being run? Meaning:

    (1) Low
    (2) Normal
    (3) High

3. Are the EQA feedback reports available for review?

        (1) Yes□

        (2) No□

4. Are there mechanisms to ensure that corrective actions are taken and sustained after the feedback?

        (1) Yes□

        (2) No□

5. What is the average EQA performance in the last one year, consistent failure or pass?

_____

_____

_____

_____

6. Describe if any the problems you have encountered with the EQA programs, (eg consistent failure of say, CD3s or CD8…)

_____

_____

_____

7. <u>PART III: STAFF EDUCATION AND EXPERIENCE</u>

1. What is the education level of the staff performing CD4 count?

        (1) Certificate

        (specify)_____

        (2) Diploma

        (specify)_____

        (3) Degree

        (specify)_____

        (4) Student

        (specify)_____

        (5) Other

        (Specify)_____

2. What is the experience (years) of the laboratory personnel performing CD4 count?_____

___

3. Is there a laboratory training plan for CD4 testing?

(1) Yes□

(2) No□

        a. If yes how often is the refresher training in CD4 counting?

_____

     ___

i.   Who provides the training?

_____

___

ii.   Where is it conducted?

_____

___

PART IV: POLICY

1. Is there a national guideline or SOP for CD4 testing?
   - (1) Yes□
   - (2) No□
   - a. If yes, is the guideline/SOP available and in use for this lab?
     - (1) Yes□
     - (2) No□
2. Are there international partners involved in the laboratory development plans, such as WHO, Global Fund, World Bank, etc?
   - (1) Yes□
   - (2) No□
   - a. If yes, which ones?

     _____

   - b. What part of the laboratory effort do they provide? (renovation, procurement, training, QA,

     etc)_____

PART III: CHALLENGES OF STRATEGY IMPLEMENTATION IN CD4 TESTING LABORATORIES

The following are the identified challenges of strategy implementation in CD4 testing laboratories in Nairobi, Kenya.

On a scale of 1 to 5 please kindly indicate to what extent you agree with the following statements.

Kindly Use the following levels.

1. Not at all

2. Little extent

3. Moderate extent

4. Large extent

5. Very Large extent

Part III: Challenges of strategy implementation in cd4 testing laboratories

Challenge	Level of Agreement					
	1	2	3	4	5	
Inadequate finances has lead us to not implement Internal Quality Control (IQC)						
Inadequate finances has lead us to not implement External Quality Assessment (EQA)						
I am not aware of the existence of Internal Quality Control (IQC) strategies						
I am not aware of about the existence of external Quality assessment (EQA) strategies						
Management does not want to implement Internal Quality Control (IQC)						
Management does not want to implement External Quality Assessment (EQA)						
Kindly Identify and grade any other challenges that you face in the implementation of quality management strategies in your CD4 testing laboratory						
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

……….*End of the Questionnaire*…………

Thank you very much for taking the time to answer my questions. Once again, any information you have given will be kept completely confidential.

Appendix III: List of Laboratories Assessed

List of laboratories assessed on the study on the implementation of quality management strategies in HIV/AIDS CD4 testing laboratories in Nairobi, Kenya

1. Armut Kangemi Flow cytomety Laboratory
2. AMREF Headquaters Flow Laboratory
3. CDC KEMRI laboratory
4. Coptic Hospital Flow Laboratory
5. AMREF Kibera Flow Laboratory
6. KAVI UoN Immunology Lab
7. KEMRI Immunology Lab
8. Kibera Heath Center Laboratory
9. KNH CCC laboratory
10. Lancet Laboratories
11. Mathare North Hospital Flow Laboratory
12. Mbagathi District Hospital Flow Laboratory
13. Nairobi KEMRI Faces Project Lab
14. National HIV Reference Laboratory
15. Nyumbani Flow Laboratory
16. Obs/ Gyn (Pips) Research laboratory
17. Pathcare Ltd Laboratory
18. Peads Diagnostic Lab
19. University of Manitoba Research Laboratory
20. University of Nairobi Immunology Lab
21. University of Washington Flow Research Laboratory