ASSESSING HIV EARLY INFANT DIAGNOSIS COMMODITY STOCK OUT FREQUENCY IN SELECTED PUBLIC HEALTH FACILITIES IN ZAMBIA

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DECLARATION

I, Charles Nyambe, do declare this piece of work, Master of public health (MPH), represents my own work, and that it has never been previously submitted for a degree at the university of Zambia or any other university.

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APPROVAL

This dissertation by Charles Nyambe is approved as a fulfilment of the requirement for the award of the degree of master of public health in the school of medicine at the University of Zambia.

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ABBREVIATIONS AND ACRONYMS

ADCH	Arthur Davison Children's Hospital
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
CIDRZ	Centre for Infectious Disease Research in Zambia
CAP /CTM	Cobas ampliprep/CobasTaqman
DBS	Dried Blood Spot
DNA	Deoxyribonucleic acid
EGPAF	Elizabeth Glaser Paediatrics AIDS Foundation
EID	Early Infant Diagnosis
HIV	Human immunodeficiency virus
IDI	In Depth Interview
GHSC	Global Health Supply Chain
ISO	International Organisation of Standards
JSI	John Snow Incorporation
LMIC	Low-and Medium-Income Countries
LMU	Logistics Management Unit
LMIS	Logistics Management Information System
NAT	Nucleic Acid Test
NHRA	National Health Research Authority
MoH	Ministry of Health
MSL	Medical Stores Limited
PCOE	Paediatric Centre of Excellence
PCR	Polymerase Chain Reaction
PMTCT	Prevention of Mother to Child Transmission
POC	Point of Care
RDT	Rapid malaria Diagnostic Test
SARS	Severe Acute Respiratory Syndrome
SCMS	Supply Chain Management System
TAT	Turn Around Time
TB	Tuberculosis
UNICEF	United Nations International Children's Emergency Fund
UNAIDS	United Nations Programme on HIV/AIDS
UNZABREC	University of Zambia Biomedical Research Ethics Committee
UNZAREC	University of Zambia Research Ethics Committee
USAID	United States Agency for International Development
UTH	University Teaching Hospital
WHO	World Health Organisation
ZPCT II	Prevention, Care and Treatment Partnership

ABSTRACT

Since 2006, low-to medium-income countries in Sub Saharan Africa have been adopting molecular methods for testing for Early Infant Diagnosis (EID) of Human Immunodeficiency Virus (HIV) in infants. Such molecular methods require a number of inputs such as; airconditioned laboratories, training of human resource, regular procurements of reagents and commodities and a robust logistics information management system among other things.

Various studies conducted in Low-to Medium-Income Countries (LMIC) have shown that most laboratories in these countries have difficulties providing access to Early Infant Diagnosis of HIV in children. In 2012, 39%of eligible infants in Zambia were not tested for HIV. One reason for this situation was the frequent occurrence of reagent and commodity stock-outs. The frequency of stockouts is a measure of the robustness of the supply chain. This study conveniently selected the following laboratories to assess the frequency of EID reagents stock outs; University Teaching Hospital (UTH) and Centre for Infectious Disease Research in Zambia (CIDRZ) laboratories in Lusaka, Arthur Davison Children's Hospital (ADCH) laboratory in Ndola and Livingstone central hospital (LCH) laboratory in Livingstone.

This was a cross sectional mixed method study. Quantitative data in form of binary data (0 = stock out, 1= in stock) for each day, was collected using a Checklist; the binary data was entered into excel then transferred into *Stata13*for analysis to obtain Frequencies, Mean stockouts and stock out durations.

Quantitative results were presented in form of pie charts and graphs to show the stock fluctuations over the 2-year period. Qualitative data was obtained from in-depth interviews with key informants using a structured interview schedule. Their responses were processed into major themes, subthemes and categories to come up with the various reasons in the EID supply chain which cause stock outs.

The study revealed that Stock out frequencies (incidents) for the period of the study (24 months), were few (Mean; 2.4 SD 1.1). However, the durations of the stock out periods were long (30% of 24 months). This translated to the test not being available for reasons of commodity stock outs for 4 months of each year.

There were many reasons which led to EID commodity stock outs, prominent amongst which was the non-allocation of funds by the MoH. This created a persistent funding gap which was accentuated by other deficiencies in the supply chain of EID commodities.

Keywords: Early infant Diagnosis, EID reagent stock out, Point of care testing.

CHAPTER I

INTRODUCTION

1.1 Introduction

In 2014, there were an estimated 36.9 million peopleworldwide living with the Human Immunodeficiency Virus (HIV) and about 2 millionpeople werenewly infected with the HIV virus, which causes Acquired Immunodeficiency Syndrome (AIDS). Since the beginning of the AIDS epidemic, 78 million people have been infected with the HIV virus and 35million people have since died from AIDS-related illnesses (UNADS,2017).

Out of the global total number of people living with the Human Immunodeficiency Virus, 1.8 million were children (UNADS,2017). Most of these children got the infection from their HIV-positive mothers during pregnancy, at the time of childbirth or during breast feeding. The greatest number (1.3 million) of these HIV positive children were in Eastern and Southern Africa(UNADS,2017).

The majority of people living with HIV are found in low-to medium-income countries with most of themoccurring in the region south of the Sahara. These Sub-Saharan low-to medium-income countries were the worst affected by the HIV epidemic, with an estimated 25.6 million people living with HIV in 2015, of these 190 000 were children in sub Saharan Africa(UNAIDS, 2016).

By 2016, the number of people living with HIV in East and Central Africa was estimated at 19.4 million. The percentage of people living with HIV accessing antiretroviral therapy was about61% adults and only 51% children. In the same year, there were 420,000 deaths from AIDS- related illnesses (UNADS,2017).

The first case of AIDS was diagnosed in Zambia in 1984 (GARPR,2014). Zambia has since had one of the highest prevalence of HIV in Sub-Saharan Africa.The national prevalence rate of HIV among adults (15 to 49years) stands at 13% (ZHDS, 2014)with a Mother to child Transmission rate of 13% (UNICEF, 2015). There were approximately 1.2 million people living with HIV in Zambia in 2016 (NASF 2017-2021), 94,000 of these individuals were children under the age of 15 years. Each year, an estimated 7,500 children are newly infected

with HIV, however only 28% of infected children were receiving ART as of 2011(MOH 2012). The country recorded 21,000 AIDS-related deaths in 2016 (UNADS,2017).

The HIV and AIDS disease progression in infants is different from adults. In this age group the disease progression is rapid and if left untreated 20% of infected infants die within 3months and 50% of the affected infants do not live to see their second birthday (Ghadrshenas et al., ., 2013). Early Infant Diagnosis (EID) is the testing of infants to determine their HIV status, given that HIV can be acquired during pregnancy, during delivery, through breastfeeding, or via parenteral exposure(WHO, 2015).

Currently, there is no HIV test which is able to detect the presence of the virus in the blood within 7 days of infection (WHO 2012). For individuals that are over 24 months of age, serological tests are used to diagnose HIV through the detection of HIV antibodies or HIV Protein (p24) components of the virusfrom the blood(saliva or urine may be used for RDTs) after 21 days (WHO 2012). Available serological based tests include; Rapid Diagnostic Tests (RDT), Western Blot (WB), Enzyme Immunoassays (EIA), Electrochemiluminescence immunoassays(ECL), Chemiluminescence immunoassays (CLIA) etc. The immunoassays are limited to the detection of antibodies or protein components from HIV1 and HIV2 after about 14 days (WHO, 2012).

Apart from serological HIV tests, HIV Nucleic Acid tests (NAT) are available and are widely used in facility-based laboratories. These tests are based on the detection of HIV RNA or DNA in a blood sample. They are able to detect Viral Nucleic Acid after 10 days of infection (WHO 2012).

In Zambia HIV laboratory diagnosis is routinely done through RDTs in individuals who are over 18 months of age. Because maternal HIV antibodies are able to cross the placenta, which could lead to false positive results in HIV exposed infants, RDTs are not used to test for HIV in infants (UNICEF, 2008).After this age, the mother's antibodies are no longer present in the infant's blood and the routine rapid serological methods could be employed to indirectly test for the presence of the virus in the infant(WHO, 2015).

Nucleic Acid Tests (NAT) are used instead to test for HIV in infants.The common NAT employed for the identification of HIV infection in infants utilises dried blood spots (DBS)

samples which are used for Polymerase Chain Reaction (PCR), a molecular method of testing for HIV DNA or RNA (WHO,2015).

The HIV DNA polymerase chain reaction has been the method of choice for EarlyInfant Diagnosis of HIVin Zambia.

It is critical to promptly test and link infants that test positive, within 4 to 6weeks after birth, to care and treatment, because it has been shown to reduce infant mortality by 76%(Ghadrshenas et al., ., 2013).The test is repeated at 6months for HIV exposed infants. Persistent testing for Early Infant Diagnosis of HIV in infants can only be achieved by a meticulous implementation of policies intended to strengthen theEID commodity supply chain. The execution of policies which envision the EID supply chain as more than just a pipeline of warehouses, trucks and carton boxes but as a network of organisations, people, technology, activities, information and resources to ensure the availability of reagents and commodities from the point of manufacture to the service delivery point in a cost effective manner(Yadav, 2015).

Zambia, like most resource-limited countries which have undertaken to test infants using PCR methods, are frequently faced with varied operational challenges such as poor equipment maintenance, regular power failures, *commodity stock-outs*, unfavourable ambient temperatures and machine down times (Nkengasong, 2010). The other notable challenge to unlimited access to HIV early infant diagnosis is the overall cost of inputs, including the cost of reagents (Ciaranello, 2011).This has led to a notable decline in the number of HIV exposed babies tested. In 2012 and 2013, around 70% of HIV- exposed babies were tested. In 2014 the number of HIV-exposed babies tested dropped to 37% (GARPR,2014).

Early infant diagnosis of HIV involves a complex system requiring a robust and carefully managed supply chain system. Equipment and consumables used in EID testing are manufactured overseas. The supply chain for such a system designed to ensure the availability of the reagents and consumables for EID in Zambia has faced many challenges.
One of the challenges has been the failure to consistently maintain adequate EID testing reagents and the auxiliary commodities. This has manifested in regular disruptions in EID testing due to stock outs of such prerequisites.

1.2 Problem Statement

Rapid HIV test kits which are usually more ubiquitous, cannot be used for Early infant diagnosis. Molecular methods using PCR are used to test for HIV in infants. PCR laboratories are usually centralised and DBS samples have to be collected on special filter papers and dispatched to these, usually distant, molecular laboratories.In order to perform an HIV test on an infant using PCR, nine testing items (reagents and auxiliary commodities) are required. Stocking out of any one or more of the testing items results in cessation of testing.

PCR testing platforms require a constant flow of huge amounts light and bulky items produced by various overseas based manufacturers, to be shipped into the country. Such an undertaking demandsa well-co-ordinated *supply chain system*. A supply chain is a network of facilities (warehouses, factories, terminals, ports), vehicles (trucks, planes and ocean vessels) and logistics Information systems (LIS) by which commodities flow from suppliers to finalend users (Frazelle, 2002). The EID supply chain system in Zambia has been beleagueredbychallengesat almost every stage.

Firstly, as in other low-to medium-income countries, there has been a knowledge gap in the understanding of the root causes of the suboptimal performance of the EID commodity supply chain (Yadav, 2015). Much of the available supply chain operational literature is based on experiences drawn from commercially oriented supply chain systems. Such Supply chains presupposes a dedicated, committed, self-motivated and accountable workforce. When supply chains based on such assumptions are superimposed on supply chains which fall under public service control, they underperform resulting in frequent stock outs or rationing of reagents and other commodities (Yadav, 2015).

With the ever-attendant risk of counterfeit reagents and products, the public-sector supply chains in resource-constrained countries such as Zambia, are compelled to tighten and safe-guard against counterfeits reagents and commodities.However, the down side of these stringent measures has been the slowing down of the movement of reagents and commodities prolonging the lead times to the point of exhausting buffer stocks and therefore creating periods of reagent stock outs.

Weaknesses exist in the commodity supply chain information system as well. The accuracy of the information used to plan for the procurement of the commodities is usually unrepresentative of the actual consumption. Inaccurate data has frequently led to either overstocking and increased waste or understocking and increased stock out frequency.

Further, the management of EIDcommodity distribution system has had challenges. Deliveries of the commodities are scheduled for every month. However, when distribution errors occur, where large quantities of EID reagents are delivered to a site which does not have a PCR laboratory and proper storage facilities, a time period (at least a month) elapsesbefore the next distribution cycle which enablesthe redistribution of misplaced reagents. Such distribution challenges have led to early expiries and stock outs.

The other gap in the availability of EID reagents has been in the timely and effective coordination of the pooling of finances from various supporting partners. Timely and adequate funding is critical to ensure prompt procurements of reagents. Inadequate funding has been a major reason for under procurement of reagents and commodities. This has led to frequent cessation of testing across the laboratories in Zambia.

Zambia has been testing for the HIV virus in infants using molecular methods (PCR) since 2006. Current WHO guidelines call for all HIV-exposed infants to be tested at t 4 to 6 weeks of age or at the earliest opportunity thereafter (Murtagh,2011). However, this service in Zambia has not been without frequent interruptions mainly due to stock outs of the commodities used in testing. As a result, in 2012 approximately 39% of HIV exposed infants were not tested and therefore werenotlinked to treatment and care (UNAIDS 2013). About 70% of the infants who acquire the virus from their mothers, if not tested and linked to treatment, die within two years. (Ghadrshenas, 2013).

The performance assessment of the laboratory commodities *supply chain* in most LMIC has been constrained by the lack of data on the operations of the system. LMIC countries do not routinely monitor and report on their Supply chain performance. The lack of frequent monitoring and reporting on the performance of the supply chain is an indication of the suboptimal performance of the system (Dowling,2011).

The most common metric of supply chain performance in developing countries is the *Stock out frequency* (Dowling,2011). The purpose of this study is to highlight the *stock out frequency* of early infant diagnosis reagents and commodities and further explore the reasons associated with such stock outs in Zambia. It is hoped that the findings of the study would be utilised by appropriate policy makers in order to strengthen the EID supply chain and ensure consistent availability of reagents and testing of infants for HIV and ultimately improve access to paediatric HIV treatment.

1.3 The Stock Outs Conceptual Framework

The causes of EID commodity stock outs are multifaceted and not just related to supply chain performance. The conceptual frame work below in Figure 1, adopted from *(Hare,2004),* shows the three major categories which affect the availability or non-availability of EID commodities.

The frame work describes the three major factors which are involved in determining stock unavailability.At the centre of the conceptual framework is a stock out. The stock out is surrounded by three circles representing; Funding challenges, capacity challenges and coordination challenges. These challenges all feed into a stock out.

The three major challenges which bring about a stock out, are affected by the level of commitment by policy implementers to stipulated policies, programmes and established systems; such as the logistics management information system, supply chain management systems, inventory systems, policy implementation plans etc. At the outer most peripheral of the framework lies the context. This consists of country-specific policies, regulations, social economic environment etc, which affect test uptake, stock consumption rates and ultimately stock outs.

Funding challenges affect the incidence and duration of stock outs the most. Such challenges occur in the mobilisation of resources from governments, development partners, households and any third parties to finance the procurement and distribution of the commodities (Hare, 2008).

Coordination challenges in the causation of stock outs refer to the operational harmonisation of various stakeholders to make sure the utilization of resources is effectively applied through consultative planning and implementation of the EID programme.

A strong capacity is needed to perform the critical functions such as; quantification and forecasting, procurement and in- country commodity distribution and monitoring and system evaluation.
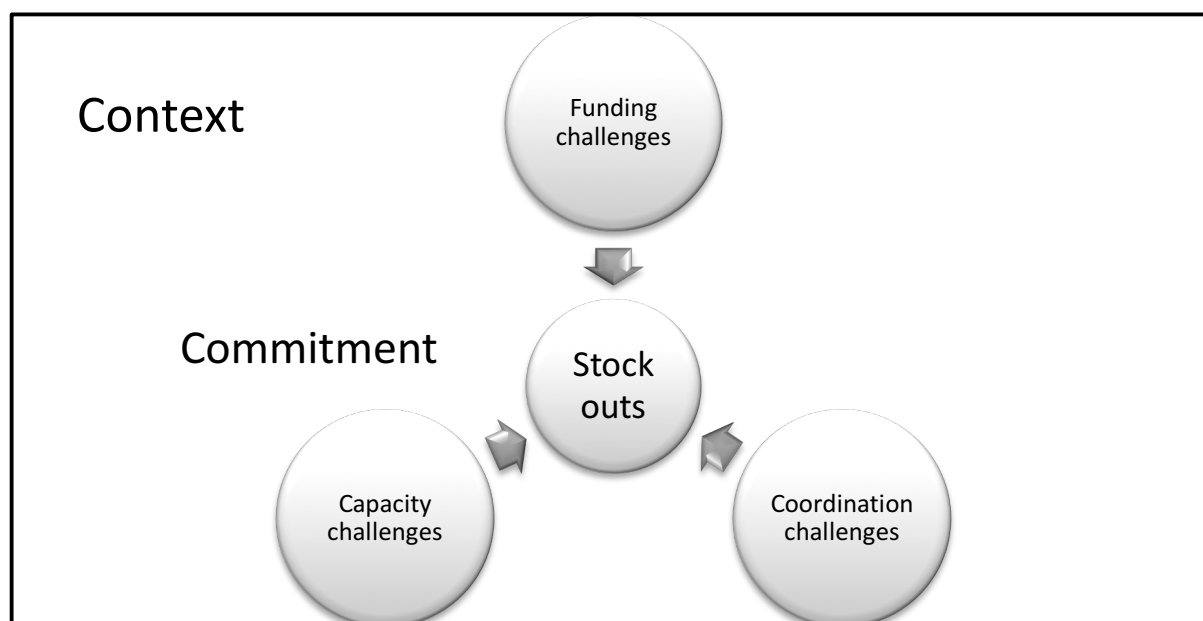
Figure 1. Stock out conceptual framework(adapted from *Hare,2004*).

Consistent stock availability or commodity security is said to existwhen every person is able to have access to reliable, basic diagnostic services using quality essential medical laboratory products and equipment whenever he or she needs them. Proper stock management includes logistics activities and the coordination and collaboration of staff. This includes global manufacturers and suppliers and demand dynamics. A properly functioning supply chain in such a system is a critical part in ensuring commodity availability(Kumurya, 2015).

Early Infant Diagnosis testing laboratories, which heavily depend on an effective supply chain, have been established in the following health institutions in the country: Arthur Davison Children's Hospital in Ndola, CIDRZ laboratory in Lusaka, UTH laboratory in

Lusaka, Livingstone Central Hospital, Lewanika Central Hospital in Mongu, Chipata Central Hospital, Kabwe Central Hospital, Kasama Central Hospital, Mansa Central Hospital and Solwezi Central Hospital.

This study focused on four laboratories and the Central Medical Stores. The Laboratories were: University Teaching Hospital Paediatrics Centre of Excellence PCR laboratory, Livingstone Central Hospital PCRlaboratory, CIDRZ central laboratory and Arthur Davison Children's Hospital PCR laboratory.

It is hoped thatthe information generated from this study will inform national policy on the management of HIV EID commodity supply and explore other alternative test systems to ensure persistent EID commodity availability and thereby improve access to testing of HIV exposed infants so that they are initiated early on treatment and care, ultimately saving their lives.

1.4 Rationale

The high national prevalence of HIV in Zambia has meant that there are more (69,000) (UNICEF, 2014) HIV positive pregnant women who subsequently expose their unborn children to the virus. In addition, while some infants with undetected HIV infection die within 5 years after their birth, others survive and remain undetected and grow into sexually active adolescents who may become pregnant, adding to the pool of exposed infants (WHO, 2015). Moreover, in 2012 fewer than one of every five girls aged between 15–19 years in WHO Africa, were aware of their HIV status (WHO, 2015). In Zambia, 33.6 percent of young people aged between15 – 19 years reported to have tested for HIV and knew their status (UNICEF, 2010). Some of these adolescents were HIV positive females and when they become pregnant, they could consequently provide exposure to their infants.

Prolonged infant exposure to HIV, delayed infant referrals and delayed laboratory testing of the infant ultimately delays enrolment of the infant into care (Kebede, 2012). When this happens because the laboratory is unable to perform the test at the scheduled appropriate time and the mothers are given a fresh laboratory appointment, the mothers or care givers usually never come back for testing (Sutcliffe, 2014).

Early infant diagnosis is being scaled up in many countries, but in 2011 only 35% of the Infants born to mothers living with HIV received an HIV test within the first two months of life (UNAIDS, 2013). In Zambia, approximately 39% of HIV exposed infants in 2012were not tested and therefore were denied linkage to treatment and care (UNAIDS 2013).

The frequency of EID commodity stock-outs and long stock-out durationshas a negative effect on the number of tests performed in a specific period thus limiting test utilisation and consequently failure to meet the demand for the test.
Studies in other LMICs have shown frequent commodities stock-outs due to weaknesses in the supply chain (WHOUNICEF UNAIDS, 2013).

The effect of such stock-outs is that eligible HIV positive infants are either delayed or denied treatment and care.
Not much is known in Zambia on the magnitude of HIV EID commodity stock-outs. However, testing proportions were still low (South Africa 85%, Swaziland 81%, Zambia 61%) in Zambia.
This studyassessed the HIV EID stock-outs frequency, duration, and performed a document review of the documents used in EID for the purposes of Data collection and policy direction. It is hoped that the information from the study would inform the review of national policy in order to strengthen the supply chain of EID reagents andminimise the stock-outs.

1.5 Research Question

What was the frequency of HIV EID commodity stock-out and stock-out durations from June 2014 to May 2016in the selected public health facilities?

1.6 General Objective

To assess HIV Early Infant Diagnosis commodity stock-outs frequency from June 2014 to May 2016 in selected public health facilities.

1.7 Specific Objectives

i. To determine the frequency and duration of HIV EID commodities stock-outs during the study period.
ii. To identify factorsassociated with HIV EID stock- outs.

1.8 Organisation of the dissertation

The dissertation proceeds, after the preliminaries, by providing the background to the study in the introduction. Chapter two explores similar studies, in the literature review, that have been conducted prior to this study and recognises the study gaps and the unique contribution that this study would fill in the supply chain of HIV logistics system. Chapter three is a presentation of the methodology followed in the conduct of the study, including the way both quantitative and qualitative data was collected and collated. Chapter four shows the results obtained and how data was analysed. The final chapter was essentially a discussion of the results obtained and the study recommendations.

CHAPTER II

LITERATURE REVIEW

Reagents and commodities for early infant diagnosis of HIV are expected to be available before the HIV test for an infant is requested (National Health Strategic Plan 2011-15). This is to ensure that the test can be performed whenever it is required so that the infected infants are linked to treatment and care as soon as possible. In poor resource settings, EID commodity security has been a big challenge. Frequent stock-outs continue to plague the health system in many countries (WHO UNICEF UNAID, 2013).

Unless the supply chain is adequately funded, health commodities will not get to the people who need them (Dawlinget al., 2004).Apart from funding gaps, there are also disruptions and vulnerabilities in many systems which are expected to ensure EID commodity availability leading to frequent stock outs. These systems need to work well, work together, and have the resilience to adapt to sudden changes to ensure that supplies are available to the clients when and where they need them (Hare, 2004).

Reagent availability needs to be strengthened to meet the ever-growing EID testing demand to avoid test disruptions in the system.Concurrentstudies conducted in Cambodia and Senegal showed a dramatic workload increase of more than 100 EID samples per quarter from 2006 to 2009. In Uganda, the study showed a sudden rise in EID sample volumes to more than 7,000 samples per quarter and in Namibia, the abrupt rise was more than 2,000 samples per quarter (Chatterjee,2011).

Instances where laboratory personnel are omitted from trainings in Logistics Management Information Systems (LIMS) has often lead to inappropriate types of reagents and equipment being selected and therefore leading to stock outs, stock imbalances, and wastage (USAID | DELIVER PROJECT,2009). Thus, the risk of omitting wider stakeholders is that information quality could be compromised causing oversupplies or commodity stock outs.

Furthermore, the Linkage of commodity usage *reporting*to commodity *resupply*by the Central Medical Stores (USAID | DELIVER PROJECT, 2009)has contributed to frequent stock outs due to infrequent reporting by end users. In the absence of electronic reporting systems, reports are conveyed through road transport. However, trucks might break down and

roads might wash out (Owens, 2003). When facility monthly reports are not received by the central stores, there is no commodity resupply for such defaulting facilities and thus an eminent stock out.

A significant factor for the frequency of EID HIV stock outs is the short shelf life of the reagents used for this test. Given an average lead time of three months, EID test reagents have approximately 6–9 months of shelf life once they arrive in country (Ghadrshenas, 2013). This means that reagent batches have to be manufactured on order and no buffer stocks are kept by the suppliers. In addition, end users cannot maintain a large *buffer* stock without running the risk of reagent wastage due to expiries.

There have been a number of studies conducted in Zambia, which analysed the turnaround time for EID samples. There is hardly any research, which has specifically looked at the magnitude of EID stock-outs and the association of such stock-outs to respective EID policies and other commodity stock-out drivers.

For an HIV EID test to be performed, a combination of reagents and commodities has to be available (see appendix 9). A stock-out of any one of the needed components would render the testing for EID not possible.

A longitudinal study conducted in Mozambique on the magnitude of stock outs of Essential Health Products in Sofala Mozambique, revealed a stock out rate for supplies of up to 44% and these were predominantly laboratory commodities such as Syphilis testing kits and rapid HIV testing kits (Wagenaaret al., 2014).The study was well conducted, except that the number of days sampled (only 3days in 3years) were insufficient to represent stock out rates over the study period.

In a descriptive study conducted in Ivory Coast, on the *Challenges for early infant diagnosis of HIV in the GbekeHealth Region,*(Mulluh2014) an improvement in the supply chain and Logistics system having *impacted* positively on the rate of stock outs of EID commodities is cited. The reason attributed to the improvement was that all the EID commodity items were packaged in one kit. The innovation is agreeable given the logistical challenges faced by the Supply Chain in Low and Medium Income Countries in Africa.

HIV EID stock outs are a frequent occurrence in resource -limited setting and may indirectly show inform of long turnaround times for the EID results. A descriptive Assessment of Bottlenecks Affecting Early Infant Diagnosis of HIV Infection through Dried Blood Spot Testing In Rural Church Health Institutions in Zambia, revealed that 64% of the samples had suffered delays of their results reaching the final caregiver (Shempela et al., 2014). However, the study only implied that the delay was more than two months and gave no specific duration. The turn around time is frequently affected by commodity stock-out durations.

In a similar study conducted earlier in Macha, a rural Mission Hospital in the southern province of Zambia, on the *Turnaround Time for Early Infant HIV Diagnosis in Rural Zambia: A Chart Review*, The total median time from sample collection to return of results to the caregiver was 13weeks (Sutcliffeet al., ., 2014). The WHO recomended time is up to 6 weeks. It is noteworthy to observe that these studies presesented significant variations in turnaround times and therfore, the possibility of being affected by variations in commodity stock-out durations at the testing site could have affected the findings.

Other studies have attempted to reddress the long turn around time for EID. One of such studies was on *Early infant diagnosis of HIV infection in Zambia through mobile phone texting of blood test results,* it was observed that the turn around time in EID showed a reduction from from 44.2 days to 26.7 days (Seidenberget al., . 2012).

Using estimates for *lost consumption (consumption not met due to stock-outs) percentage*as a quantitative measure of stock-outs, a longitudinal cross-sectional study in Cabo Delgado in Mozambique demonstrated an RDT stock out rate of about 78% (Hasselback 2014). This was a better way of assessing stock-outs, assuming that the Average Monthly consumption data were accurate. In addition, the sampled days (120time points) were limited as this is usually the *lead time* for commodity procurement.

A study was conducted in Ethiopia titled Assessment of Laboratory Logistics Management Information System Practice for HIV/AIDS and Tuberculosis (TB) Laboratory Commodities in Selected Public Health Facilities in Addis Ababa(Desale 2014), revealed that stock-out of commodities were due to poor inventory management. The study was quite extensive covering a wide range of health commodities. However, both the qualitative and quantitative

data collection was based on interviews. This approachneeded precautions against issues of *information bias*.

Provision of health care in resource-constrained countries is challenging and complex. Many governments in sub-Saharan countries have formulated policies to direct the management of HIV EID services. Some governments have policies on the expected number of EID tests to be performed for each exposed infant and when the tests are to be undertaken. Policies also exist on the selection of medical products, how they are procured, stored and distributed.

However, most policy makers in sub-Saharan countries, frequently fail to understand that diagnosis is essential to the prevention and treatment of disease. Access to reliable diagnostic testing is severely limited in Sub saran Africa, and misdiagnosis commonly occurs (Pettiet al., 2005).

On the other hand, the supply chain for health care commodities including EID commodities is vulnerable to various types of disruptions. Civil wars as happened in Ivory Coast (Muluh 2014), unpredictable disasters, including terrorist attacks, earthquakes, economic crises, devaluation of currencies, SARS, Tsunamis, strikes, computer virus attacks, etc (Tang2006) could occur and disrupt health commodity supply including EID HIV commodities.Policies which anticipate such risks must be designed to mitigate the consequences of such disruptions and ensure uninterrupted service delivery.

CHAPTER III

METHODOLOGY

3.1 Study design

This was a cross sectional mixed methodsstudy. The two-year study period was chosen in order to cover at least six commodity procurement periods, given a standard commodity procurement lead-time of three months, and allow for a two months contingency period.

3.2 Study setting

The study setting covered four EID testing sites and MSL in Zambia.

3.3 Study population and target population

The selected PCR laboratories for the study were; University Teaching Hospital-Paediatrics Centre of Excellence, Centre for Infectious Disease Research in Zambia, Arthur Davies Children's Hospital, Livingstone Central Hospital and Medical Stores Limited (commodity storage and distribution).

The University Teaching Hospital-Paediatrics Centre of Excellence PCR laboratoryis situated at the Paediatrics Hospital, within the largest referral hospital in the country. It is in the city of Lusaka in the province of *Lusaka* with a population of 2.1million (CSO, MOH, ICF, 2014). EID samples are received from inpatients as well as from the health facilities in the province. It was the first Public Service (donor supported) EID laboratory in Zambia having been established in 2006.

Livingstone Central Hospital, located in Zambia's tourist capital, is the largest referral hospital in thesouthern province of Zambia. The southern province has a population of 1.5 million (CSO, MoH, ICF, 2014). The PCR laboratory at Livingstone Central Hospital receives EID samples from Livingstone urban as well as Livingstone rural Health institutions. The EID laboratory at Livingstone was operational by 2012.

The centre for Infectious Disease Research in Zambia (CIDRZ) is a research institution situated in Lusaka's Kalingalinga compound, about 5km from the University Teaching Hospital. It was one of the earliest three EID testing centres in Zambia and received samples from; western, southern, eastern and Lusaka provinces. Currently, theCentre for Infectious Disease Research in Zambia (CIDRZ) collects EID samples from selected facilities in Lusaka province.

The Arthur Davison Children's Hospital PCR laboratory is situated at the largest children'shospital in the city of Ndola in the Copperbelt province of Zambia with a population of 2.0 million (CSO, MoH, ICF, 2014). The Zambia Prevention Care and Treatment (ZPCT), a nongovernmental organisation, mainly supports this laboratory, The PCR laboratory at Arthur Davison Children's Hospital (ADCH) was second after the PCR laboratory at the Paediatrics centre of excellence at the UTH was established. The ADCH PCR laboratory previously collected EID samples from; Northern, Muchinga and Luapula provinces of Zambia before these provinces had their own EID equipment. Presently, the laboratory receives samples from Copperbelt based health facilities. It often serves as a*back up* for other provinces when their equipment breakdown or the samples overwhelm the testing capacity.

The Medical Stores Limited (MSL), situated in Lusaka the capital city of Zambia, serves as the country's central medical stores. It is the main medical warehouse in Zambia. It stores and distributes medical supplies around the country.

Targeted key informantsincluded PCR laboratory managers, PCR operators, Chief Biomedical Scientists, EID laboratory coordinator at the Ministry of Health Headquarters, Deputy Director-Laboratory services (MoH), Laboratory supplies Managers at Medical stores andUSAID Global Health Supply Chain (GHSC) Programme- Procurement and Supply Management.

3.4 Data collection

3.4.1 Data collection instruments
These included stock checklist (Appendix 7), stock control cards, Usage reports and results output log sheets for quantitative data collection.

The Stock Checklist: This is a ruled sheet indicating every working day of the month with a check box. Each day checked as either stocked (1) or out of stock (0).

The data was entered on to a spread sheet and later transferred on to a *stata*[13] data sheet for further analysis.

The stock control card: The stock control card is practically a *bin card*. The card is used to capture data about the commodities received in the stores, the commodities issued out of the stores, loses and adjustments and the balance in stock, if any.

The usage report: The Usage report is a more detailed form indicating the average monthly commodity consumption for previous three months, the consumption for the immediate past month, the loses and adjustments and the Physical stock count at hand. This report is submitted monthly to the MoH/LMU based at MSL. Based on the monthly consumption, MSL dispatches the commodities to restock to a three months maximum stock holding. Facilities which do not send the usage report do not receive commodities.

Results log sheets: These are records of the test results obtained from the machines. They are kept both in electronic and hard copies. They show the daily number of tests performed. Stocked out days show no test entries.

Data collection fromStock control cards.

    i.   The *stock control cards*were checked for stockout dates for each of the nine EID test commodity items (see appendix 9).

    ii.   Each testing day was entered on the stock checklist as either in-stock (1) or stocked-out (0).

    iii.   The data was*triangulated* with the number of EID tests done during the period indicated as stock-out on the stock control card and in the results log sheets.

    iv.   The data was entered in an excel sheet and then transferred into *Stata*[13] for analysis to obtain Frequencies and Mean stock-outs and stock out durations.

Medical Stores Limited was in the same way quantitatively analysed after extracting the same data from their inventory.

3.4.2 Qualitative data

Qualitative data was collected from key informants using a semi-structured interview schedule.

*Semi-structured Key informant interview schedule:*This was a form with ten questions which were used to provide guidance on what to ask the key informants during the interview.This form was used for the collection of qualitativedata (appendix 6).

Data phone: This was a portable electronic voice recording device. It was used to supplement the physical transcription of the responses from the key informants.

The interviewwas conducted by the researcher in a private room, in acalm, non-confrontational and non-judgemental manner, with Key informants as follows:

i. The semi structured interview schedule (with 10 questions) was administered to two key informants at each laboratory facility, MSL, Ministry of health headquarters and GHSC.

ii. Their responses were written down and were also audio recorded using the data phone recorder.

iii. The recordings by the data phone were later transcribed verbatim.

3.4.3 Sampling technique and sample size

The sample size was calculated using the formula for calculating sample size for the *Mean* as follows:

Where:

$$n = \frac{Z^2 \, \sigma^2}{e^2}$$

n = sample size

e = margin of error (+/- 5)

δ = standard deviation (assuming SD =70, due to lack of identicalstudies)

Z= 1.28 for CI 90%

$$n= \frac{(1.28)^2 (70)^2}{5^2}$$
$$n= 321 \text{ days}$$

The minimum sample size coincided well with three commodity procurement *lead times*. In order to increase on the power of the findings, the calculated minimum sample size was more than doubled (726 days) to cover six procurement cycles equivalent to two years study period.

3.4.5 Inclusion criteria

Zambia has nine PCR testing platforms distributed across the provinces. This study was conducted at four conveniently selected testing sites and the Central Medical Stores Limited. The four facilities were conveniently selected because they are easily accessible and have been in operation for more than 2 years. They also have well established testing support systems and infrastructure.

The key informant research participants had served for not less than two years in EID Management or Operations.

3.4.6 Exclusion criteria

PCR laboratories which were located in distant sites and not easily accessiblewere not included in the study. In addition, PCR laboratories which had not been in operation for more than 2 years were excluded. At the time of the study the PCR laboratories which had not been operating for more than two years had not yet established strong support systems such as adequate staff, alternative power supply, sample courier systems and adequate infrastructure.

3.4.7 Data storage
Data was protected under lock and key in a personal cabinet. Electronic data was kept in a folder stored on the hard drive of a password secured computer. Back up data was stored on a secure external hard drive.

3.5.1Quantitative data Analysis
The study variables to be analysed were; stock out frequency and stock out duration.

Data entries were made on the stock checklist (appendix 7) for each day of the two study years, '1' represented a stocked day and '0' represented a stocked-out day. The data was then entered on to an *Excel spread sheet*and exported to *Stata[13] Statistical software* for analysis. The stock out Mean (SD,Max and Min.),stock out frequencies (incidences) and stock out durations (percentage days in 24moths) were obtained and pie charts generated.

The common causes of the stock outs were identified throughkey informant interviews, using a semi structured interview schedule.

3.5.2 Qualitative Data Analysis

The emerging views from key informant interviews were thematically grouped, into Major Themes, Subthemes and Categories. They were manually studied and triangulated with Quantitative data to see if they provided any insights into the reasons for the frequency and duration of EID commodity stock-outs. Any explanations that emergedwere noted and manually classified into one of the groups stated above.

3.5.3 Study Limitations

The study depended on the accuracy of secondary data and verbal submissions from structured interviews. This type of data sources is likely to be affected by information bias which may lead to inaccuracies. To minimize this bias quantitative data was triangulated with other records such as Stock Control Cards, Commodity Usage reports and EID results registers.

Inclusion of all provincial PCR laboratories would have enhanced the strength of

the findings.

3.5.4 Potential ethical issues

Participant information and consent forms (Appendix3and4) were given to the eligible research participants a day before the interview. In-depth interviews (see appendix 6), expected to last one hour or less, were conducted with key informants in a quiet, comfortable and secluded room. Research participants had the right not to answer questions they feel uncomfortable with and were free to withdraw from the study at any stage.

3.5.6 Risks

The study had the potential of being misunderstood to be an investigation about a range of issues ranging from staff levels of competence to laboratory commodity pilferage. Such fears were addressed by reemphasising the purpose of the study and reminding the research participants that the researcher was a student at the University of Zambia and has no links with any other agency whether public or private.

Key informant interviews were conducted in a private, secured and quiet room away from work areas to provide confidentiality.

3.5.7 Benefits

The participantswere informed that they would benefit for participating in the study by being acknowledged as having contributed to the study and therefore their contribution to minimise stock outs of EID commodities or to the provision of a sustained EID testing and improved utilisation, would be recognised.

3.5.8 Results dissemination

The study findings would be disseminated to the following major stakeholders: Ministry of Health policy makers, Supply Chain Management System laboratory commodity managers, Medical Stores Limited laboratory commodity managers, other stakeholders (e.g. UNITAID/EGPAF), University of Zambia library and the study will be published in a peer reviewed journal.

CHAPTER IV

RESULTS

4.1 Quantitative Results

The results presented below are for the 24 months study period (from May 2014 to June 2016) for the selected EID PCR laboratories and the Central Medical Stores.

Table 1. Stock out Duration, Stock out dates and Stock out Frequency

Facility	Stock out dates	Stock out duration	Stock out observations	Stock out Rate
UTH - PCOE	October 2015 to December 2015	79 days	1	11%
Livingstone Central Hospital	June 2014 to February 2015 September 2015 to December 2015 *Total stock out days*	274 days 119 days *393 days*	2	54%
CIDRZ	March 2015 to May 2015 August 2015 to December 2015 *Total stock out days*	92 days 143 days *235 days*	2	34%
Arthur Davison Children's Hospital	February 2015 April 2015 to May 2015 August 2015 to November 2015 March 2016 *Total stock out days*	17 days 44 days 108 days 11 days *218 days*	4	30%
Medical Stores Limited	March 2015 July 2015 to December 2015 February 2016 to April 2016 *Total stock out days*	31 days 184 days 90 days *305days*	3	42%

Note: total number of days sampled=726 (2years) from June 2014 to May 2016

4.2 UTH –PCOE PCR laboratory total stock status
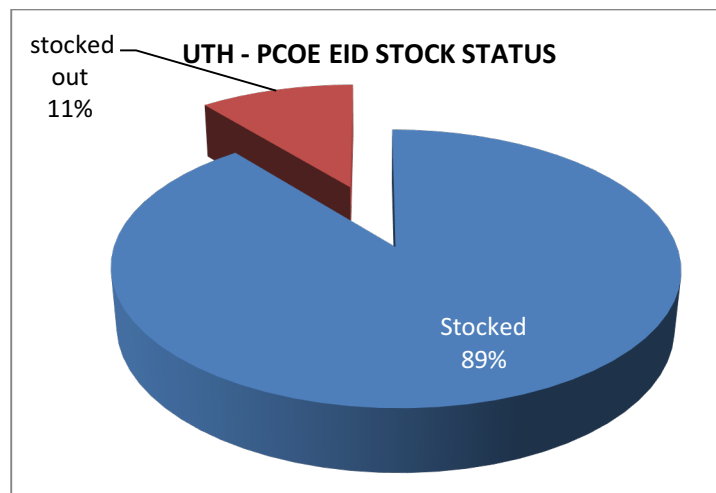
Figure 2. UTH-PCOE EID commodity stock status from June 2014 to May 2016.

UTH-PCOE had the least number (01) of stock out observations (frequency) as shown Table 1, and total stock-out duration of 11%, as shown in Figure 2 above. This was largely due to partner direct support coupled with a ***drastically reduced sample uptake and sample testing.*** The number of days stocked out was 79 days in 2years.
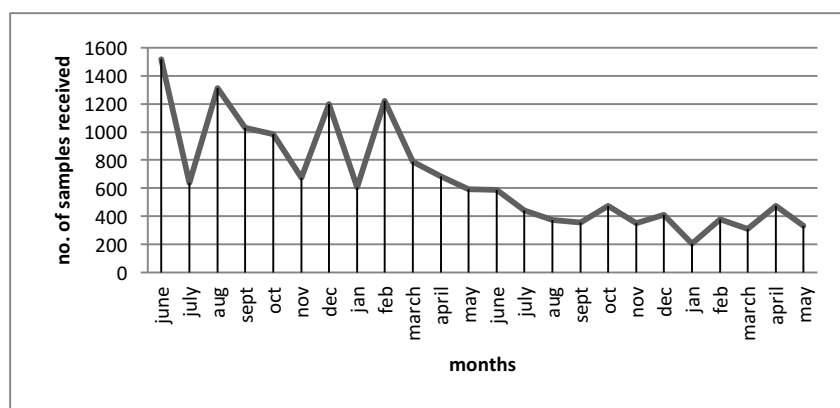
Figure3. UTH – PCOE Received EID samples from June 2014 to May 2016

The gradual reduction in the number of received samples, as plotted in Figure 3 at the UTH-PCOE was partly due to the commencement of EID testing in the respective provinces, which were formerly referring their samples to the UTH-PCOE and not due to a stock out.
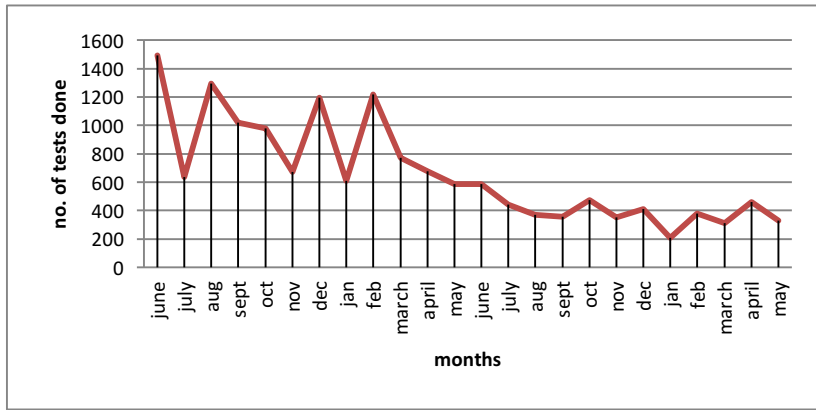
Figure4. UTH – PCOE Tested EID samples from June 2014 to May 2016.

Bothpreceding graphs i.e.Figure 3 and Figure 4 appear nearly identical. Normally, where testing disruptions occur, there is a build-up of received samples (backlog) with a drop in the number of tests done. However, this did not show because the number of test requests continued to fall to suboptimal levels, from March 2014 because of the redirecting of samples as stated earlier.

4.3 CIDRZ EIDPCR total stock status
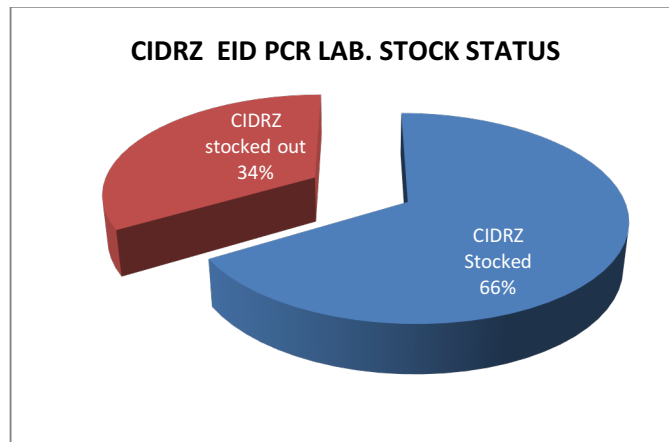
Figure 5. CIDRZ EID Stock status from June 2014 to May 2016.

The CIDRZ EID PCR laboratory observed stock outs (frequency)and total stockout duration of 34%, see Figure 5. The laboratory had a Mean stock out duration of 118 days (SD; 36 days). The Minimum stock out duration was 92days, the Maximum duration was 143days.
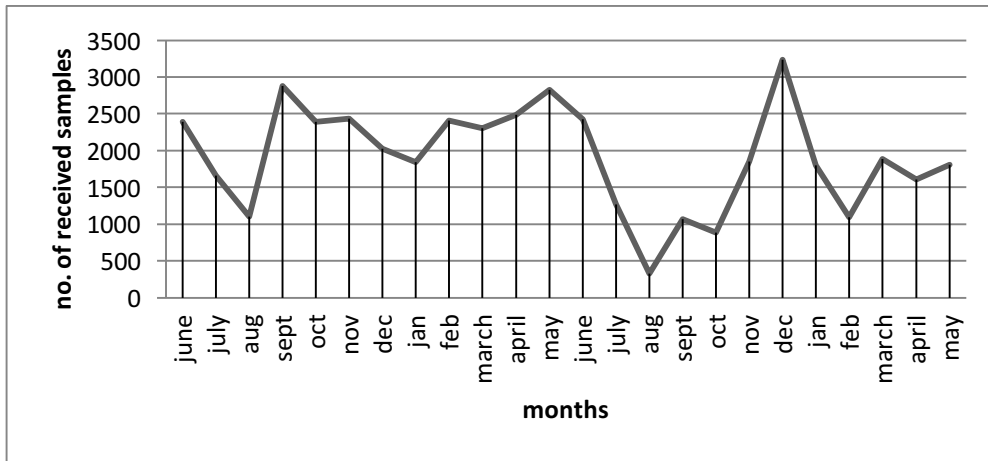
Figure 6. CIDRZ PCR laboratory - received samples from June 2014 to May 2016.

The CIDRZ EID PCR laboratory samples received and samples tested graphs,Figure6 and Figure7, clearly indicate the back-logbuild-up of received samples during periods of stock outs which subsequently get cleared when restocked with testing reagents, which rapidly run out and plunge the laboratory again intoanother stock out as indicated in Figure 6, between July to October, 2015. This signified an actively testing laboratory with a high rate of commodity consumption.
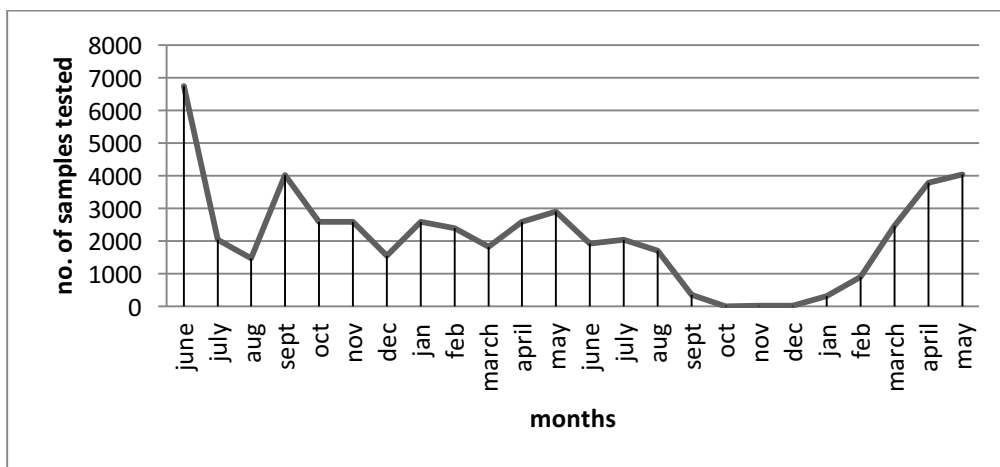
Figure7. CIDRZ PCR laboratory – tested samples from June 2014 to May 2016.

4.4 ADCH EID total stock status
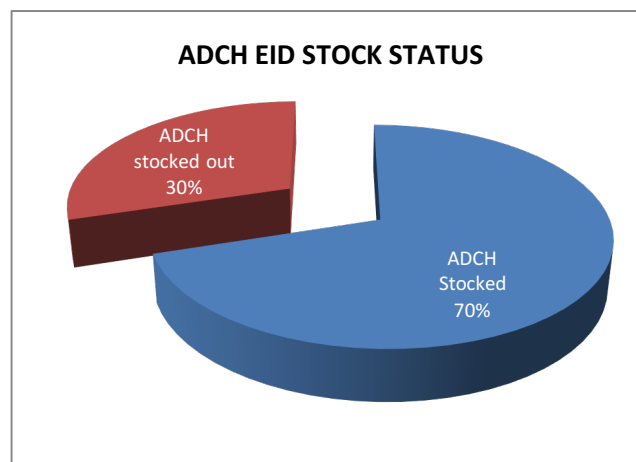
Figure8.ADCH EID Stock status from June 2014 to May 2016.

The ADCH laboratory HIV total stock out status had a high number of observed stock out incidents (4) table 1. The total stock out duration (Figure 8)stood at 30%. The Mean stock out duration was 45 days (SD; 44, Min; 11days, Max; 108 days).
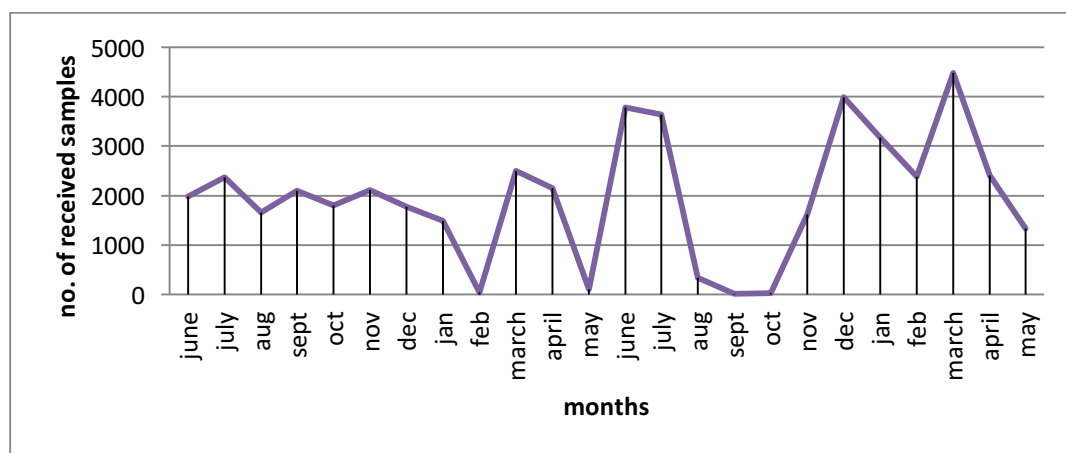
Figure9. ADCH EID Samples received from June 2014 to May 2016.

The number of samples received by ADCH (see Figure 9) followed the same pattern as the number of tests done (see Figure 10). This means that during periods of *no testing (i.e. stocked out)*, the laboratory stopped receiving samples and resumed when testing started again. The ADCH laboratory had a *high testing through put*indicating that despite the frequent stock outs, the backlog samples build ups were *cleared* when testing resumed (seeFigure 9; Dec. 2015 and March 2016).
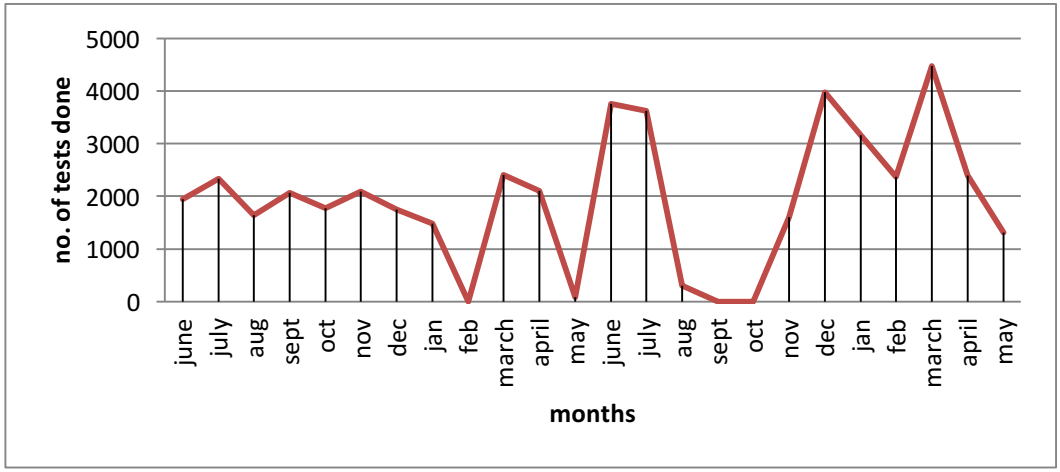
Figure10.ADCH EID samples tested from June 2014 to May 2016.

4.5 Livingstone Central Hospital EID PCR Laboratory total stock status
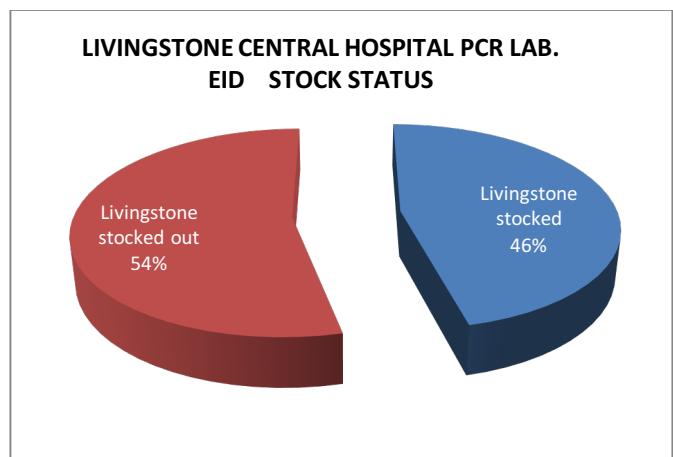
Figure11. Livingstone EID Stock status from June 2014 to May 2016.

The Livingstone EID PCR laboratory had 02 stock outincidents (frequency), see Table 1,but had the longest stock out duration at 54%, see Figure 11,*Direct Partner support notwithstanding*. The Mean stock out days was 197 (SD; 109days, Min;119, Max;274).
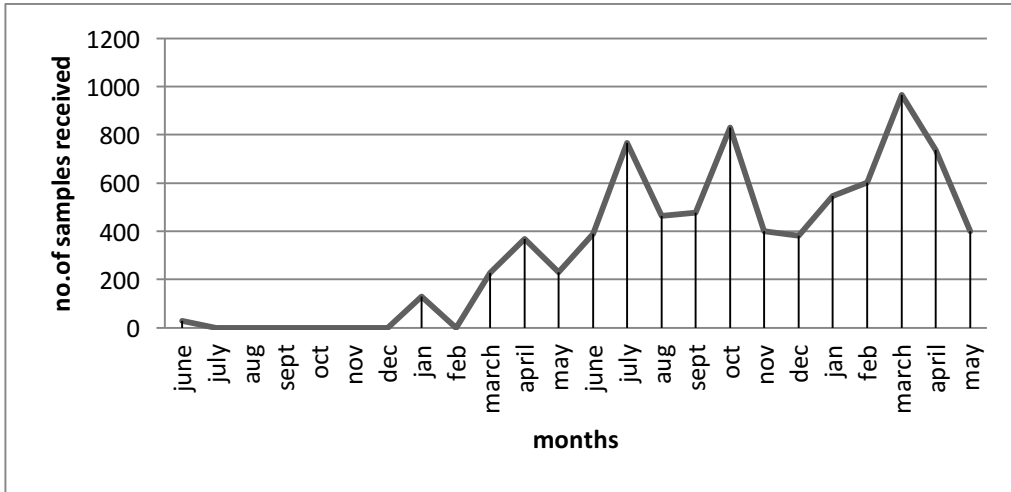
Figure12.Livingstone EID samples received from June 2014 to May 2016.

The Livingstone EID laboratory had only 02 observed stock out incidents, albeit with very long durations adding up to 54% of the sampled period (Figure 11). The Mean stocked out days was 197 (SD; 110, Min; 119, Max; 274).

The Livingstone EIDlaboratory (Figure 12 below)was not receiving samples during the stock out periods stretching from June 2014 to December 2014. Testing briefly resumed in December 2014. From September to December 2015, there was a nationwide stock out and a back log of received samples developed, Figure 12.
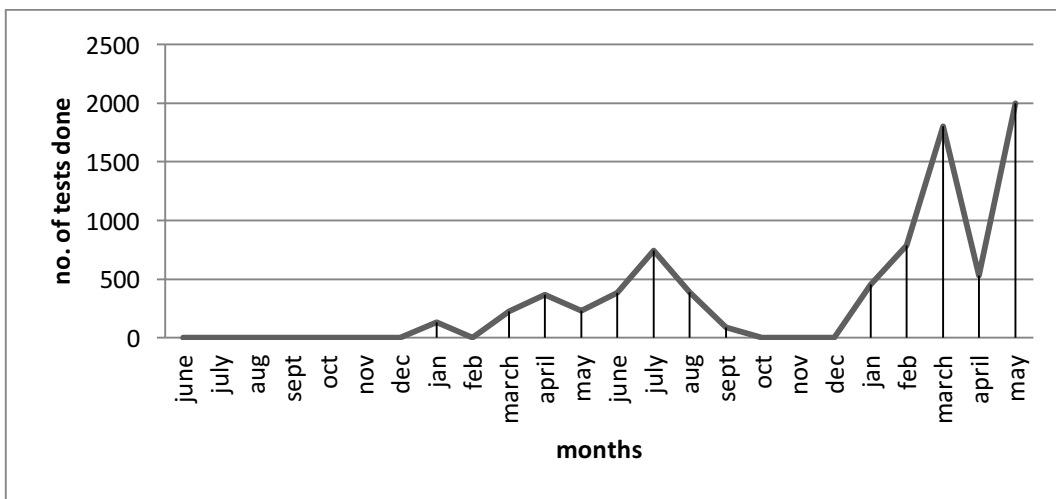
Figure13. Livingstone EID tests done from June 2014 to June 2016.

4.6 The EID commodity total stock status at the Central Medical Stores
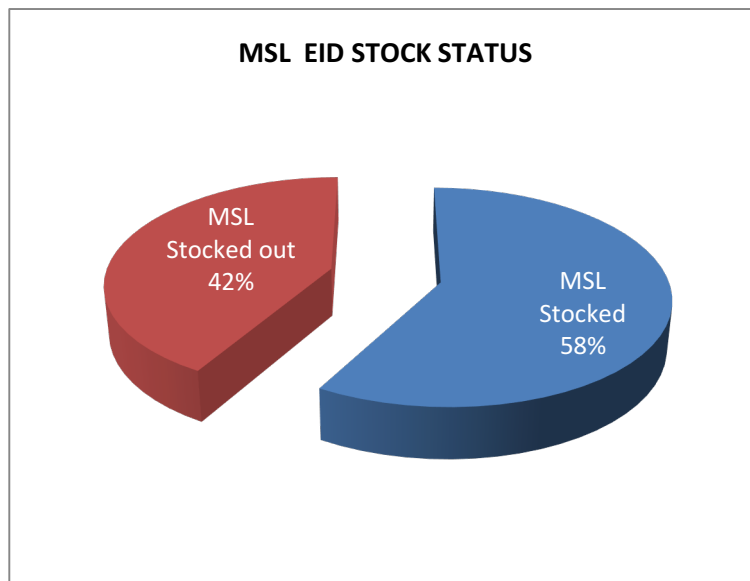
Figure14. MSLEID Stock status from June 2014 to May 2016.

The Central Medical Stores had 03 observed stock out times (frequency) see Table1, which added up to 42% (See Figure 14) of the sampled period. The stocked-out days was 102 (SD;77, Min;31, Max;184).
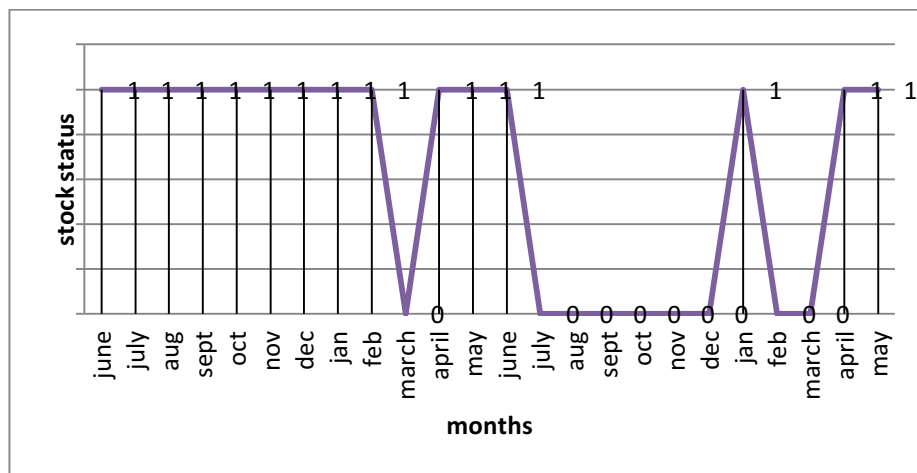
Figure15. MSL Stock status from June 2014 to May 2016. 1= stocked, 0=stock out.

For the period July to December 2015(see Figure 15), MSL stocked out of EID, commodities for Six months but facilities stocked out for three months on average. This is because facilities hold a 3 months buffer stock, which is supplemented by direct partner commodity support to varying degrees.

4.7 The number of EID tests done per facility sampled from May 2014 to June 2016.

Number of EID Tests done per Facility
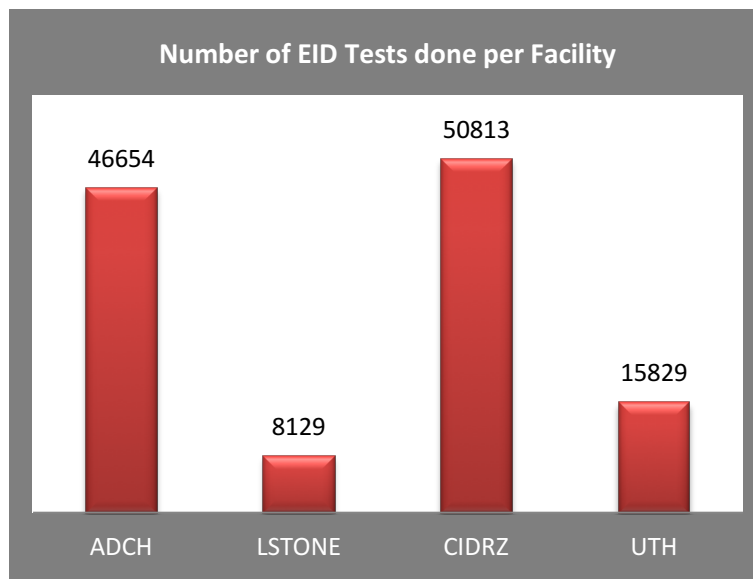
Figure16. Number of EID Tests done from June 2014 to May 2016 for the four labs.

Figure 16, shows the number of tests done in the four sampled HIV EID PCR testing facilities. Livingstone EID PCR laboratory and UTH- PCOE EID PCR laboratory tested few samples. The main reason for sub-optimal testing for Livingstone was poor EID commodity availability. UTH PCOE PCR laboratory was adequately stocked most of the time but tested few samples. Samples which used to be referred to UTH- PCOE were being referred to their respective provincial PCR labs.

Mean EID stock out duration for the 4 labs sampled
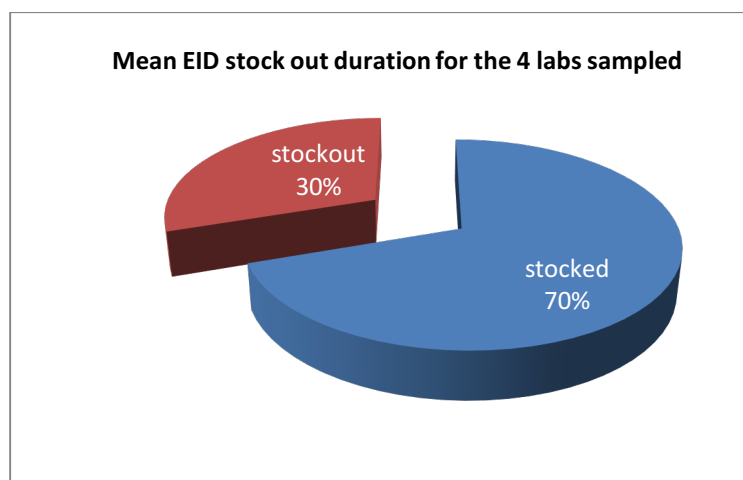
Figure17.The Mean stock out duration for EID commodities from June 2014 to May 2016 in four laboratories sampled was 30%, (SD;17.6, Min; 11, Max;54).

The chart in Figure 17 is a summary EID commodity stock out rate in the four sampled HIV EID PCR testing facilities. No EID testing occurred for the equivalent of one quarter of each year due mainly to frequent and long periods of commodity stock outs.

4.8 Qualitative Data Analysis

Causes of Early Infant HIV laboratory diagnosis commodity stock outs
In-depth interviews with fourteen key informants from the selected facilities were conducted to find out their views regarding the causes of EID commodity stock outs. Their observations fell within the following categories:

4.8.1Capital related challenges
The study revealed that the EID programme was a relatively new programme and it was strongly overshadowed by the Adult ART programme. Consequently, EID structures and systems were still evolving and therefore weak. The situation manifested in the following ways:

4.8.1.1 Early Infant Diagnosis funding

The EID programme was totally *donor dependent*. The Ministry of Health did not have a budget line specifically dedicated to support the laboratory diagnosis of HIV in infants. One of the interviewees stated;
"How much has the Government procured from 2014 to 2016, tell me ...Zero.
It has always been partner supported. So, its SCMS will buy, CHAI will buy, Global Fund will buy. GRZ zero."
"... they need to have a deliberate policy ... that can support even may be 15% of EID,
to cover those gaps when the donors are not coming forth." IDI Respondent #05, suggested.

This left a gap in the financing of EID commodity procurements and was a major factor in causing stock outs.

4.8.1.2Unfulfilled procurement commitments

It was not uncommon for some partners to suddenly indicate that they could no longer continue with the procurement, even after they had made commitments that they would procure the commodities when their turn comes around. Such impromptu withdrawals put pressure on the government to quickly find a replacement donor. The attendant delay could translate into a stock out period. One key informant said;

"There are cases where people pledge to buy then at the time of procurement, someone backs out and says 'we are unable to proceed with the procurement'.
So it means, even though everyone is readily available to ensure there is a full supply chain, but because the principle procurement person or the principle funder who should have funded that procurement has withdrawn, for you to make a replacement it will not happen in 24hours, it will take probably a minimum of 6 week. So that also pushes the whole system into stock outs". IDI Respondent #07.

4.8.2 Capacity related challenges

The study brought out various shortcomings in the EID system related to capacity as outlined below:

4.8.2.1 EID Quantification and forecasting

With the introduction or migration from one Technology to another, service statistics data are usually inadequate. Early Infant Diagnosis was initially performed on **the Roche AMPLICOR 1.5** with its own unique set of reagents and consumables. When the **CAP/CTM**was later introduced and the earlier version phased out, quantification and forecast of the new Reagents and consumables had to be undertaken, albeit with insufficient service statistics data. This lead, in most cases to under quantification and ultimate stock outs.

When a new product comes, or a new system comes or a new method comes on the market, mostly the Forecasting and quantification is not supported by logistics data like consumption data, you don't have service statistics data.So in the absence of Consumption data and test numbers, you find that even the Quantification that you are doing can either under quantify or over quantify. So in cases where we underestimated the need, that resulted in the stock out.IDI Respondent #05.

4.8.2.3 Data collection system

It was observed that there was no standard data collection tool. This affected the harmony and the quality of the data collected from various facilities, e.g. the order unit was differently understood by facility staff and central stores staff;

"... they said they wanted about 150,000. They were ordering for about 150,000 tests but them, they forgot to put that 'tests', so we were about to give them about 130,000 of the Kits. But then we realised that if we give these, then it means that as a Central store, we won't have anything.The facilities may be reporting in terms of tests, us we interpret that to mean kits. So as a result, we may end up over supplying one facility".IDI Respondent #11.

4.8.2.4 Specialised laboratory staff at Central Medical Stores

For the period under study, the staff who handled EID commodities at the Central stores had no Technical knowhow of these commodities. The commodities were not effectively managed with regard to the maintenance of the cold chain, location placements and accurate commodity availability information. For instance, facilities would be told that a particular item was available when not.

"Then even at the issuance stage, when they are available at MSL, sometimes the people, the pickers within MSL do not have the right expertise to pick the right commodities. So, you have this guy who has no idea what a Cup-G Wash buffer is. So, you'll find that even if it is there centrally, you'll find that the site is not given the Wash Buffer, because the people who are picking these are non-lab". IDI Respondent #04.

4.8.2.5 Staff attitude towards work

Closely linked to the issue of poor data quality was the staff attitude towards work. Despite several trainings in Logistics Management Information System, two out of four facilities had poor inventory keeping with data entries not done in real time. One supervisor remarked;

"But it takes so long to correct issues. You will be going through the same issues year in year out. Right now, am collecting data for quantification, and am seeing the same mistakes as we were having at the last quantification. Nothing has changed.
You have all these young people who don't want to do their work. There is a lot of short cuts ... I think for me the issue is, people know what is supposed to be done and how to manage inventory, I think the issue for me is just the attitude".IDI Respondent # 06.

4.8.2.6 Alternative Energy source

The period 2014 to 2016 suffered frequent power outages which lead to abortive testing runs on the machines and subsequent waste of costly EID reagents. In addition, this situation posed a challenge on the maintenance of the cold chain compromising the quality of the test kits in facilities which did not have alternative sources of energy. A PCR operator elaborated;

"Firstly, because most of the waste is because of power cuts, a generator would actually prevent waste. I will give an example; on Tuesday they lost 80 tests, Tuesday this week... 80 tests lost because of power, if there was a backup generator that would have been prevented".IDI Respondent #02.

4.8.2.7 Reagent Complexity

EID reagents and consumables must be assembled into a cocktail before a test can be performed. This means that the more than nine items have to be available in usable form simultaneously. This *reagent complexity* has been a challenge. The items are sourced from different manufacturers and bear a different range of Lead times and expiry dates. A Key Informant summed it thus;

"The only challenge that we have is that these reagents are not in a kit form. They come as individual components. So you have each of these reagents coming in as a standalone commodity. That is a threat. If these things could be packaged in one kit in the right ratios, then it would work well but now we do procurement for each one of them as a separate entity. So you'll find that Specks runs out, the actual reagent is still there or the Bundles runs out or the buffer runs out, because they have different expiry dates. So you find that should you stock out of any of these things, then you are down, you can't operate, you can't run the test".IDI Respondent #05.

4.8.2.8 Undersupply of orders

The in-country distribution of EID commodities has its own challenges accounting for frequent stock outs. Facilities were frequently under supplied due to rationing of commodities by MSL. In country commodity distribution employs the Pull system. Some facilities exploit this system and over order commodities beyond their consumption information and resist redistribution to facilities in need, hence creating an artificial stock shortage.

"For EID we use a Pull System, and you find that a facility which uses may be 10 kits in a month, they will say they will use thirty, but all they do is to go and stock themselves when others stock out they still have this bulk of reagents that they are keeping when others can't use them".IDI Respondent #03.

4.8.2.9 Supply chain Disruptions

Disruptions in the supply chain for EID commodities would be caused by; delayed shipments by the vendor to MSL, delayed delivery schedules by MSL and long procurement processes by some donors.

"The second one was Delayed shipments, once we planned the shipment with the vendor, the vendor ... so this is a closed system; we only get the reagents from one manufacturer (from one representative). So, we have had the vendor failing to deliver the reagents on time, so that resulted into stock outs".IDI Respondent #05.

4.8.2.10 Distance to MSL

EID testing Facilities that are located in the same city as the Central Medical Stores have a comparative advantage over distant facilities and are likely to collect their emergency orders quickly. This prolongs the stock out duration for distant laboratories.

"Only if you use a PUSH system whereby you tell the facilities to say do an Emergency order. Then they have to make their own arrangements to come and collect".IDI Respondent #11.

4.8.2.11 EID commodity demand

The study noted that there was a persistent use of old data to quantify and forecast for future needs despite a growing demand. One operator put it succinctly;

"I will say ok we did 38 tests, but that is because there was no sensitisation, those are people who were just willing. What happens the moment you release the results people get encouraged to send more tests. So, you find that your 38 tests in the next months because you released the results the previous month, automatically just goes up to 78 but they would have supplied your reagents for 38 tests". IDI Respondent #02.

4.8.2.12 Over stating commodity orders

Some facilities deliberately inflate their orders resulting in a rapid depletion of EID commodities at the central stores and in the process deprive other needy facilities.

"For EID we use a Pull System, and you find that a facility which uses may be 10 kits in a month, they will say they will use thirty but all they do is to go and stock themselves when others stock out they still have this bulk of reagents that they are keeping when others can't use them".IDI Respondent #03.

4.8.2.13 Currency regulations

The Government of the Republic of Zambia, in 2012 released a Statutory Instrument directing that all business transactions in the country were to be conducted in the local currency (the Zambian Kwacha).

Because of the huge difference in the exchange rate, the resultant large number of digits in the local currency was incompatible with the Dollar based software used to procurement commodities.
This led to a long stock out duration, after all the buffer and emergency stocks dried up. One Manager recalled;

"That time the Statutory Instrument (STATUTORY INSTRUMENT NO. 33 OF 2012)
came in to say; now we are to deal in Kwacha. The zeros were too many; the system couldn't work with the zeros that were there. So, we were stocked out. We were stocked out of EID because of the Software that we use to procure. We waited for four months to sort out that thing before we could receive".IDI Respondent #05.

4.8.3 Coordination related challenges
EID commodity availability requires effective resource mobilisation among major players such as host governments, Donors or Development partners and the Private Sector.
The coordination is particularly critical among other inputs, the harnessing of funds. A veteran EID Manager observed:

"We have a lot of partners that are pushing this EID programme but there is very little that they do in terms of procurement of reagents and I think it's time they also get engaged in the procurement.
They get al., l these grants that somehow there is money that is loose which can be used to support MoH with such procurements. You can have the main funder but in terms of gaps you can say, ok what are you bringing on board, what you are bringing on board and you can use those funds to push for stock gaps".IDI Respondent #03.

4.8.3.1Vertical EID programme

The EID commodity quantification and procurement system had been independently managed, that is separate from other laboratory supplies. This posed an intervention difficulty in the event that the programme experienced some challenge. A key informant stated thus;

"So, EID commodities in the initial they used to beprocured separately. There used to be a part that was specifically dealing with EID commodities. They will quantify, Procure and bring them in the country for distribution. So, in the long term that was very unsustainable".
IDI Respondent #06.

CHAPTER V

FINDINGS AND DISCUSSION

The aim of this project was to determine the number of times and the duration of each EID commodity stock out episodes from June 2014 to May 2016, and identify the factors associated with the stock outs. A brief documentary review was also conducted to identify any gaps related to EID commodity security.The purpose of the ART Laboratory Logistics System is to ensure that reagents and other laboratory supplies are continuously available to the people (*infants)* who need them *when* and *where* they need them (MoH 2009).The Stock out frequencies (incidents) for the period of the study (24 months), were few (Mean; 2.4 SD 1.1). However, the durations of the stock out periods were long (30% of 24 months). This translates to the test not being available for 4 months of each year.

Worthy of note however, is that non-availability of the test when and where it was required did not mean that the test was therefore never performed. This is because under normal circumstances, the requesting facilities continue to collect and send samples to the testing facilities (fig.6, Dec.2015 CIDRZ and fig.12, Oct. Nov. Dec.2015 Livingstone).The result is a build-up of untested samples (backlog) which is subsequently tested but only as a delayed test and result. The testing of huge sample backlogs plunges the facilities into the next stock out. This is one reason for prolonged turnaround times for EID testing as other studies have demonstrated (Mainza D, 2015, Seidenberg P, 2012).

Arthur Davison Children's Hospital PCR laboratory showed the highest number of observed EID commodity stock out events (04 in 24months, Table1). On the contrary, the laboratory conducted one of the highest numbers of EID tests (46,654, fig.16) only second to the CIDRZPCR laboratory (50,813, fig 16). This indicates that the frequency of observed stock out incidents does not necessarily reflect badly on the performance of the laboratory, the opposite could be the case, indicating an active laboratory that has an efficient restocking*backup* system (fig.10, Feb. and May). The graph (fig.10) shows a rapid recovery from a stock out for February and May 2015. However, there was a prolonged stock out duration from August to November of the same year. This was a nationwide stock crisis emanating from anational financial regulation, referred to earlier.

The study also revealed that EID commodities were principallydonor funded and the funding, never covered the total procurement cost estimate. The problem of insufficient funding for such medical supplies was also identified by a similar study conducted in Uganda (The BMAU briefing paper [15/15], Uganda 2015). In addition, prominent (43% of Key informants) amongst the causes of EID commodity stock outs wasthe infidelity of the data submitted for quantification from the facilities. The poor quality of the data completely rendered the essence of the quantification activity *null and void*. This state of affairs could lead to inadequate or over estimation of the needed quantity of commodities and a further exaggeration of the funding gap. It is therefore important to *identify the causes of poor data quality* and rectify them to ensure rational use of the persistently limited EID commodity

funding.The study also highlighted the need for the Logistics Management Unit (LMU) based at the Central Medical Stores to verify the consumption/test datasubmitted from testing facilities. This could be done by triangulating the data submitted with the numbers emanating from the registers at the specimen delivery hubs as well as the facility registers.

During the period of the study, there were a number of test runs which were aborted not least due to power outages. Such wastage was never quantified and cost to inform subsequent quantification exercises in order to factor in the necessary measures to ameliorate the impact of such waste on commodity stocks.It was also observed that consumption data was not always *captured*on Stock Control Cards in*real time*. The hard copy Stock Control Cards at two laboratories visited, showed frequent deletions and *superimposed record alterations,* with data omissions and non-chronological date entries. This made logistics data fidelity and commodity accountability untrustworthy.Another reason for the stock outs was attributed to the nature and complexity of EID reagents. EID reagents, nine in all, need to be brought together and mixed in varied proportions for the test to be performed; the absence of a single item halts the process. However, these items are procured from various suppliers and frequently one or the other item would not be available. When this happens, the other reagents continue to lose their potency (exacerbated by their short shelf lives) to the point of being rendered expired and discarded. Huge commodity volumes were lost in this way, the study observed.

The study had also reviewed eleven EID related documents to identify commitment statements to guarantee EID commodity security. *The Standard Procedure Manual (MoH 2009)* was adequately crafted to guide the Management of Laboratory Commodity Logistics System except for a Standard tool for data collection for purposes of quantification. The Viral Load and Early Infant Diagnosis Testing Scale up Implementation Plan2016 to 2020 (Ministryof Health, 2016) was a recent attempt to improve Early Infant diagnosis. The road map to reach this goal demonstrates intent to redress the persistent occurrence of EID commodity stock outs. Specific EID funding commitment remained obscure.

The study covered a period of 24 months and showed that the Mean frequency of stock outs was 2.4 (SD 1.1) times in 24 months. The Total Duration of the stock outs was 30% of the 24 months, which translated to 04 months of stock outs of EID commodities per year.
Periods of EID commodity stock out delayed EID sample testing and ultimate linkage to treatment.The ideal EID stock out status, according to the Supply Management guidelines, should always be at zero stock outs. As this study demonstrated, all the sampled facilities experienced stock outs to varying degrees. The total testing activity during the study period (with all back-logs cleared) was 121,425 tests. At 13% mother to child transmission of HIV in Zambia, this ultimately translated to 2,631 positive infants not tested during the 4 months of commodity stock-out and therefore denied treatment and care, 20% of such infants die within 3months.

In 2012, the government issued a statutory instrument number 33, banning the use of the United States Dollar in all local transactions. The move created a crisis in the supply chain

system which led to a four months stock out of EID commodities in the country translating to more than two thousand (2,631) HIV exposed infants not receiving the test where and when they needed it.This move by government revealed a lack of wider stake holder consultation before such an important pronouncement is undertaken. It is the position of this study that policy makers at such high levels of governance should make an open call to all stake holders to make their submissions before such policies take effect.

The study found that amongst many other factors that led to the occurrence of the stock-outs, was the fact that EID commodities were principally donor funded and that such a funding source never covered the total commodity procurement cost estimate.While other causes of EID commodity stock-out such as incorrect quantification due to invalid data,unfulfilled procurement commitments, supply chain Disruptionsetc impact on the frequency and duration of EID stock-outs, the non-allocation of a budget line for EID commodities by the Ministry of Health, is worthy of note.

5.1 Conclusion

The non-allocation of funds by the ministry of health to the EID program guarantees the persistence of a funding gap which translates to a period of a non-availability of EID commodities. It is therefore important that policy makers at the ministry of health take cognisance of the downstream implications of such policy decisions such as not to create a dedicated budget line to supplement donor support to ensure the success of the EID program.A successfully uninterrupted EID commodity supply chain would ultimately lead to the prevention of 7,200 HIV new mother to child infections in the four sampled facilities. It is therefore important that the frequency and causes of EID testing commodities stock outs are urgently redressed.

5.2 Recommendations

The study recommends the following:

i. The Ministry of Health should create a dedicated budget line for EID testing commodities

ii. The Ministry of Health, in collaboration with the partners and other EID stake holders, should strengthen the system used for EID stock management in order to eliminate the causes of poor data quality.

iii. TheEID reagents should be supplied in complete pre-packed usable *cocktails* with a more extended *shelf life*.

iv. The use of EID point of care devices should be urgently pursued by the Ministry of Health.

Further research could be done to measure the impact of each identified independent variable on the stock out frequency and duration.

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APPENDICES

APPENDIX 1

PARTICIPANT INFORMATION SHEET FOR LABORATORY COMMODITY MANAGERS, CHIEF BIOMEDICAL SCIENTISTS, PCR LABORATORY MANAGERS AND LABORATORY SCIENTISTS

Most low-and medium-income countries like Zambia have undertaken to test infants for HIV using molecular methods such as PCR (Polymerase chain Reaction). However, they are frequently faced with various operational challenges such as poor equipment maintenance, regular power failures, **commodity stock outs**, unfavourable ambient temperatures and machine down times.

This research is aimed at assessing the frequency of **stock outs of Early Infant Diagnosis test commodities** that are required to perform the test.

The implications of the frequent non-availability of the commodities are that a number of infants either are lost to follow up or are not tested at all. This means that such infants are subsequently denied the linkage to treatment and care.

The Selected Study sites

The analysis will sample a two-year period, assess the frequency of stock-outs, and stock-out durations experienced from June 2014 to May 2016 respectively at four selected sites and Medical Stores Limited. The sites are:

- University Teaching hospital
- Livingstone Central Hospital
- Centre for Infectious Disease Research in Zambia Central laboratory
- Arthur Davison children's hospital

Furthermore, the study will review exiting Early Infant Diagnosis documents about the testing of infants for HIV.

Early Infant Diagnosis (EID) test availability

The high national prevalence of HIV in Zambia (13.0%) has meant that there are more HIV positive pregnant women who subsequently expose their unborn children to the virus.

A series of delays following the birth of an infant, hinder early infant diagnosis of HIV and linkage to treatment and care. Delayed laboratory testing happens when the laboratory is unable to perform the test at the scheduled appropriate time. This means that the mothers are given fresh laboratory appointments. In poor rural setting, with long distances to the health facilities, the mothers are often held back by a lack of transport, anticipated long waiting hours and awkward working hours at the health facility and decide not to fulfil the appointments.

With so much vertical HIV exposure to the unborn children, the need for a responsive clinical laboratory to conveniently provide early HIV infant diagnosis so that the infants are promptly initiated on ART is of the essence. Given such a massive EID work load in form of DBS samples from various referring health facilities to often distant testing centralised laboratories; the study wishes to assess whether or not the laboratory service has adequately responded to the challenge, in terms of clear guidelines that would guarantee a well-managed commodity supply chain system so that the HIV EID testing kits are always available and in usable form. A well-managed functioning system would ensure that there are no significant periods of disruption in EID testing attributable to the non-availability of testing commodities.

The consistent availability of such EID requisites could be realised where specific guidelines designed to guarantee their regular availability, not only exist but are rigorously implemented. This study seeks to review such documents.

The information identified from the study, it is hoped, would help to review the various stages and activities of the supply chain for HIV EID products, the tools and methods used in the quantification of the HIV EID products and other qualitative variables affecting early infant diagnosis commodity security with an overarching view of improving service delivery.

Justification

Early infant diagnosis commodity security exists when every exposed infant is able to have access to reliable, diagnostic services whenever they needthem.

Currently, molecular methods are used to test for HIV in infants who are less than 18 months old. Molecular methods employ a higher level of technology and a complexity of supplies is required to perform the test. Studies in other Low-and Medium-Income Countries have shown frequent commodities stock-outs (WHO UNICEF UNAIDS, 2013).

The effect of such stock-outs is that eligible HIV positive infants are either delayed or denied linkage to treatment and care.

Not much is known in Zambia on HIV EID stock-outs. However infant testing proportions are still low (South Africa 85%, Swaziland 81%, Zambia 61%) in Zambia.

It is hoped that the information from the study would inform the review of national policy in order to reduce on the frequency of stock-outs, and improve utilisation of EID testing.

Study questions

This study intends to address the following questions:

i.   What was the frequency of HIV EID commodity stock-out and stock-out durations from June 2014 to May 2016 in the two study provinces?

ii. What are the views of the staff involved in HIV EID?

Study Objectives

The main objective of this study is to assess HIV Early Infant Diagnosis commodity stock-outs frequency from 2014 to 2016 in selected public health facilities.

The **specific objectives** are:

i. To determine the frequency and duration of HIV EID commodities stock-outs during the study period

ii. To identify **factors** associated with HIV EID stock- outs

APPENDIX 2

University of Zambia School of Medicine,Department of Public Health

PARTICIPANT INFORMED CONSENT DOCUMENT FOR LABORATORY COMMODITY MANAGERS, CHIEF BIOMEDICAL SCIENTISTS, PCR LABORATORY MANAGERS AND LABORATORY SCIENTISTS

Study Title: Assessing HIV Early Infant Diagnosis commodity stock-outs frequency in selected public health facilities in Zambia

Principle investigator (UNZA): Charles Nyambe

UNZAREC No.   ....

Purpose of research project

This study is part of my research for the Master in Public Health with The University of Zambia. The purpose of this research is to establish the frequency and duration of stock outs for HIV early infant diagnosis (EID) test commodities in a two-year period; 2014 and 2016 at the University Teaching Hospital, CIDRZ Laboratory, Arthur Davison Children's Hospital and Livingstone central hospital. In this study, I will also review the current Early Infant Diagnosis documents and highlight any strengths or gaps for the information of policy makers seeking to strengthen the EID system.

Why you are being asked to participate

Research participants in this study are all directly involved in the management and use of EID commodities. The participants play strategic roles in infant diagnosis of HIV either as commodity mangers or as actual performers of the test. The managers are familiar with the procurement and stock management systems whereas the test performers or biomedical scientists are familiar with commodity inventory management and use of EID commodities.

You are one of the selected research participants because you are familiar with the conditions indicated above and therefore you qualify to take part in this research.

One manager and two scientists will be interviewed from each testing centre and one Manager and two desk officers from *Supply chain management Systems* (JSI-SCMS) under USAID will also be interviewed. This means that fifteen participants will be interviewed to obtain the qualitative data.

Procedures

If you agree to participate in this interview, I will administer a semi structured interview schedule. The interview shall take about 30 minutes. With your permission, I will audio record the interview to help me capture all the details of our interview. I will also ask for your permission to write some notes during the interview. My questions will revolve around EID commodity security. Your name will not be indicated on both audio tape and hard copy notes.

Risks/discomforts

The study poses no conceivable physical or professional risks to you as a research participant. However, I take cognisance of the fact that some information you may divulge to me may be complimentary or critical in nature to other stake holders in the EID commodity and testing system. I therefore want to assure you that the information will not be shared to anyone outside of the faculty.

Benefits

If you agree to participate in this study, you will be contributing to a body of information about the challenges facing EID and to the effort in solving the issues surrounding improved access to EID and linkage to treatment by HIV exposed infants.

Payment

There is no payment for participating in this study. However, participants may be provided with transport to their preferred destinations if the work hours are exceeded.

Protecting data confidentiality

I have put necessary measures to protect the information I will obtain from all participants. Access to my computer, where some of the data will be stored, will be password protected; your name will not be specified throughout the study. The hard copies of our interview will be secured and locked away. The audio tapes will be uploaded on to secured files on my computer.

What happens if you do not want to participate in the interviewed?

You are free to decide whether you want to participate in this study or not. You are allowed to stop your participation in this study at anytime without any adverse consequences on you. Further, you are free to refrain from answering any questions you may not be at ease with or any questions you may consider personal.

Who do you contact in case of any questions or problems?

Should you have any queries or problems; PLEASE feel free to call me at Charles Nyambe 0977 57 2327 or E-mail; charlericks @yahoo.com

Or

Contact or call the University of Zambia Biomedical Research Ethics Committee office for any ethical concerns. The Ethics Committee can be contacted at;

The Chairman
Zambia Biomedical Research Ethics Committee
Ridgeway Campus
P.O. Box 50110

Lusaka, Zambia.
Telephone: +260 1 256067
        Fax: +260 1 250753
        E-mail: unzarec@zamtel.zm

What does your signature on this consent form mean?

Your signature on this form means the following

1. You have been clearly informed about the study's purpose, procedures, possible benefits and risks.
2. You have been given the opportunity to ask questions for any clarifications before you sign.
3. You have voluntarily agreed to participate in this research

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Print code number of participant   date

---   -----------------------------------   ---------------
Print name of person obtaining consent   signature of person obtaining consent date

Ethical clearance

Clearance for the study was sought and granted from the University of Zambia Biomedical Research Ethics Committee (UNZABREC). Permission to conduct the research was obtained from the National Health Research Authority (NHRA). Further, Requests for authorization to conduct the research were asked for and granted by all institutions that participated in this study.

APPENDIX 3

Document review summary

Document review data: A document checklist was used to collect the documents, (policy, guidelines, tools), study their content and make summary notes.

Data collection: Each EID document was described and its distribution noted. The content summaries of each document were then generated.

Data Analysis: *Document*review data analysis was done through; Document description, document distribution &document content analysis.

Data synthesis: The findings from document analysis were triangulated with Quantitative and qualitative data.

Document review: In the context of this study an EID related document is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals, charts, posters, manuals,memoranda, software, drawings, plans, Registers, forms and documents of external origin such as regulations, standards or examinationprocedures related to EID. (ISO 15189:2007).

The document review was conducted as outlined below:

i.   Document Selection: All documents available and fitting the criteria were selected.

ii.   Sampling: Policy documents on HIV EID, Guidelines and tools were sampled.

iii.   Data collection: The Document checklist was used to collect the documents, study their content and make summary notes (see appendix 8).

iv.   Data management: Summary notes (Data) were collected, entered into a table with the following column headings; document description, document distribution and document analysis.

Document Description	Document Distribution	Document analysis
Viral Load & Early Infant Diagnosis Testing Scale up Implementation Plan 2016to 2020, Ministry of Health	Laboratory Managers Nation wide	An EID and Viral Load Expansion Implementation plan. Sets the target for EID to 75% in 2017(from 21% in 2015). Assumes an uninterrupted supply of EID commodities. EID commodity stock out rates will be monitored. Consideration of EID Point of Care devices will be given.
National Health Strategic Plan 2011-2015	Health Facilities Managers	A plan based not on the WHO health systems building blocks and prioritization of interventions. The plan commits to support laboratory services by proving adequate supplies and ensure their proper storage, distribution and usage.
National Medical Laboratory Policy, 1997. Ministry of Health	Laboratory Managers Nation wide	The Policy stipulates the Vision and the Goals of the laboratory Service. Thus; the provision of sustained Lab. Services as close to the family as possible, Improvement of Logistics and supply systems etc. The positive role of the Lab. in maternal and child health was recognized.
Zambia National Logistics System Evaluation Report, 2012	MoH headquarters	The evaluation acknowledges the proficiency of the Logistics system in Zambia. It however points out some attendant challenges including poor data fidelity.
Zambia National Laboratory Forecasting and Quantification Review Report 3rd Quarter 2010	MoH Headquarters	Three forecasting methodologies were discussed before the quantification for the next quarter. Quantification by Logistics data, service stats. and demographic data. The pros and cons. Also highlighted the persistent funding gap.
Standard Operating Procedures Manual For Management of the National ART Laboratory Commodity Logistics System, 2009	Laboratory Managers Nationwide	The Manual provides guidelines on the extensive operations of the ART commodity logistics system. Descriptions and functions of various critical forms are outlined.
DNA PCR Test Laboratory Requisition form	Health facilities Nation wide	An elaborate EID test request form. Currently under revision. The number of requests may indicate test utilization. Currently under review.

PCR Lab EID Register	PCR Laboratories	Logs in all samples received and tested with respective dates/times.
Guideline for Filling out the DNA PCR Laboratory Requisition Form	Health facilities Nation wide	Explains how to complete the requisition form. Information must include repeat and repeat test dates, which impact on stock consumption.
Laboratory commodity Stock Control Card	Health facilities Nation wide	This Card is used to indicate the stock status of commodities in a store room at any given time. It must be completed in real time.
Usage Report for Laboratory Commodities	Health facilities Nation wide	This form is used to submit monthly commodity consumption, stock levels etc reports to the MoH/LMU for resupply purposes. Without the report, there is no resupply. The form is Currently electronic.

APPENDIX 4

Assessing HIV Early Infant Diagnosis commodity stock-outs frequency in selected public health facilities in Zambia

Semi structured Questionnaire for Key informant in-depth interview

Name of interviewer ....   Date: **...........................**

Code no. of key informant: ....

Code no. of title of key informant: ....

Name of facility Laboratory: ....

Site: ....

Type of facility: ....

Assessing HIV Early Infant Diagnosis commodity stock-out frequency in selected public health facilities inZambia

Questionnaire for Key Informant In-depth Interview

1. Studies conducted in various countries have shown regular periods of EID commodity stock-outs; what do you think are the reasons for that?

2. What type of policies, guidelines and tools are in place to ensure that HIV EID commodities do not go out of stock and are always available in usable form?

3. How would you describe the current supply chain for EID commodities?

4. What is the average lead-time for each EID commodity for your facility?

5. To what extent do you receive the exact quantities you order? Do you have alternative suppliers?

6. What measures have you put in place to mitigate for the occurrence of a stock out?

7. How do you keep track of EID commodity waste? How can rational use of commodities be improved? How can inventory of EID commodities be improved?

8. How is the PCR operators staff strength at your laboratory?

9. What are the qualifications of the staff that carry out PCR testing? Are they trained in Logistics Information System?

10. Are there any important issues you think we have left out which we should have discussed?

    Would you like to be acknowledged in the final write up?

APPENDIX 5

Qualitative Data Analysis summary

Major themes	Sub-themes

Capacity related challenges

EIDforecasting andQuantification
- o Under quantification
- o Lack of Technical EID knowledge at MSL
- o Introduction of new technology lacking logistics data
- o Reagent waste due to power outages
- o Fluctuating workloads leading to poor forecast
- o Unsatisfactory work attitude
- o Poor data collection systems – poor data quality
- o Not documenting data in real time.

Capital Related challenges

EID funding

- o No dedicated budget from MoH
- o Exclusive Donor funding
- o Unfulfilled donor commitments – sudden withdrawals
- o High cost of EID
- o Inadequate funding advocacy
- o Technology switch to more reagent-demanding expensive methods

Coordination Related challenges

EID Commodity Supply

- o EID reagent complexity (cocktail of items) impact on lead time and different expiry times
- o Undersupply of EID commodities
- o Central level coordination challenges
- o Supply chain disruptions
- o Varying Partner procurement turnaround times
- o MSL delivery schedules
- o Commodity rationing at the central stores
- o Distance to MSL in case of emergency orders (UTH,CIDRZ located in Lusaka have advantage)
- o MSL staff not familiar with EID commodities (now redressed)
- o Short reagent expiry dates

EID Commodity Demand
- o Growing test uptake with improved laboratory testing

- Increased waste due to power cuts
- Need for improved sample referral system
- Facilities Ignore Test *numbers calculator*

EID Policy
- Need to formalize policies e.g. integration of EID into General Laboratory commodities procurement
- Need for guide lines on logistical terminology e.g. *unit of issue*.
- Lack of standardized tools for data collection
- Distribution safe guards; over ordering of supplies
- Indiscriminate distribution of EID commodities
- Instrument Service intervals - *Instrument stress*
- No accounting for consumption and Test numbers
- Need to record data in *real time*.
- Government currency regulations

APPENDIX 6. SAMPLEHIV EID STOCK CHECKLISTSAMPLE
July 2014 to June2016

2014																															
July	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															
August	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															
Sept	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29		
s/status																															
o/s item																															
Oct	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															
Nov	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
s/status																															
o/s item																															
Dec	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															
2015																															
Jan	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															

o/s item																															

Feb	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			
s/status																															
o/s item																															

March	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															

April	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
s/status																															
o/s item																															

May	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
s/status																															
o/s item																															

June	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
s/status																															
o/s item																															

key : s/status = stock status,   o/s = out of stock item code no. (1-9 see list of HIV EID reagents and supplies)

Note: Both qualitative and quantitative data will be collected on each visit.

APPENDIX 7

EID Document checklist.

no.	EID document	available	Not available	Comment
1	Policy			
2	Standard Operating Procedures			
3	Equipment Manuals			
4	Specifications			
5	Calibration tables			
6	Biological Reference intervals			
7	Soft ware			
8	Plans			
9	Drawings			
10	International regulations			
11	Standards			
12	Guidelines			
13	Tools			
14	Contracts			

APPENDIX 8

List of HIV EID critical reagents and supplies which must be available and in usable form before the test can be performed.

EID Reagents (CobasTaqman)
1	Cobas AMP/Taq specimen pre Extraction Reagent
2	COBAS,Taqman, AmpliPrep, HIV-1, Qualitative, 48Tests
3	DBS Bundles 50 Pcs
4	CAP - G Wash Buffer
5	CAP K tips
6	CAP SPU Flapless
7	COBAS, TaqMan, K-Tubes, 12 Racks of 96
8	COBAS, TaqMan,Ampliprep, Input S-tubes
9	Pipette tips,DNA/RNA free filtered 200-1000microlit

APPENDIX 9

The distribution of PCR machines for EID in provincial centres of Zambia.
Facilities conveniently selected for the study are indicated by a check mark.

sno.	Facility	Selected facilities
1	Arthur Davison Children's Hospital (ADCH)	✓
2	CIDRZ (Kalingalinga Lab)	✓
3	University Teaching Hospital (UTH)	✓
4	Livingstone central hospital	✓
5	Lewanika central hospital	
6	Chipata central hospital	
7	Kabwe central hospital	
8	Ndola Central Hospital	
9	Kasama central hospital	
10	Mansa central hospital	
11	Solwezi central hospital	