IMPACT OF OFFERING CD4 TESTING AT THE POINT OF CARE IN TANZANIA

(A CASE OF THE COASTAL REGIONS)

by

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May God bless you all

DECLARATION

I declare that **Impact of offering CD4 testing at the point of care in Tanzania,** is my own work and that all sources that I have used or quoted have been indicated and acknowledged by means of complete references.

Signature:  Date: 20/8/2013

SHAYO Caroline Paschal

DEDICATION

I dedicate this research thesis to my Husband Bernard Hezron Munubi and my Son Bencarl Bernard Munubi for their genuine love, sacrifices and confidence entrusted in me. You made my entire stay in Japan for my Master degree at APU a happy and fruitful moment. I also wish to dedicate this research thesis to my mother Agatha Mzee Macha who made me the way I am today, and my in-laws Mr. and Mrs. Hezron Munubi for supporting my family when I was away. May God continue to guide, protect and bless them for their massive contribution towards this work.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

LIST OF TABLES

LIST OF FIGURES

LIST OF ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase- a key maker of liver function test
ANC	Antenatal Care
ART	Anti-Retroviral Therapy
ART	Antiretroviral Treatment
ARV	Antiretroviral
AZT	Zidovudine
CD4	Cluster 4 differentiative 4 is a glucoprotein found on the surface of immune cells such as T helper cells, monocytes/macrophages
CHAI	Clinton Health Access Initiative
CTC	Care and Treatment Centres (for HIV)
HAART	Highly Active Antiretroviral Therapy
Hb	Haemoglobin
HIV	Human Immunodeficiency Virus
HRH	Human Resources for Health
HTC	HIV Testing and Counselling

LTFU	Loss to Follow-up in HIV Infected patients on Antiretroviral Therapy
MDG	Millennium Development Goal
MOHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department Store
NACP	National AIDS Control Program
NVP	Nerapine
OI	Opportunistic Infection
PEPFAR	The President's Emergency Plan for AIDS Relief
PIMA	A novel device used to test CD4 count of people living with HIV
PLWHIV	People living with HIV
PMTCT	Prevention of Mother to Child Transmission (of HIV-AIDS)
POC	Point of Care
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir Disoforoxyl Fumarate
WHO	World Health Organization

ABSTRACT

As Tanzania government is planning to expand point of care services to all primary health clinics, it is important to assess the current situation of implementing CD4 testing at the point of care, which is likely to be repeated under similar conditions in other clinics. Hence the developments of coherent strategies for Pima rollout for optimal utilization of the device which corresponds to patient care outcomes. This study looks specifically at what seems to be the result of offering CD4 testing at the Point of Care (POC) in Tanzania with introduction of Pima device. This thesis is related to one of the biggest problem of Tanzania health care HIV/AIDS staging.

The study analyzes both qualitatively and quantitatively observed results, demonstrates potential for POC CD4 testing to improve staging of disease and as consequence clinical care and timely treatment. It also shows that the introduction of the Pima device dramatically reduced the number of patients turned away. Though significant improvements in clinical outcomes were observed after the introduction of the Pima device, these improvements were mitigated by the implementation challenges leading to the benefits being compromised.

The results of the thesis have the potential for immediate application in the healthcare system in Tanzania and will help to show the benefits of quick and reliable new type of CD4 detection equipment. This in turn would be beneficial to the HIV positive people seeking treatment.

CHAPTER ONE

1.1 Introduction

Tanzania is formally twelfth-highest HIV prevalence in the world, with 5.6% of the population infected, the epidemic has stabilized in the last ten years, and begun to decline (UNAIDS, 2010). It is estimated that nationally, approximately 1.4 million people live with HIV, with an expected increase in cases in rural areas due to systemic poverty (UNAIDS, 2011). The majority of these people are adults in childbearing age (UNAIDS 2010, 180-186). The number of Tanzanian women living with HIV is higher than their male counterparts, with 730,000 representing the former and 470,000 the latter. African women have a risk 1.3 times higher than African men in contracting HIV, due to cultural and biological factors (MoHSW, 2007, 2). The main modes of transmission include heterosexual sex, and mother-to-child-transmission (UNAIDS, WHO, UNICEF, 2011).

A range of factors including poverty, inequitable gender norms and early marriage has fuelled the spread of the epidemic (USAID, 2012). Poor Tanzanians are particularly at risk because they often lack knowledge of HIV treatment and prevention. In 2003 the government developed Health Sector Strategy on HIV/AIDS for 2003–2008. The strategy was geared towards scaling up antiretroviral therapy to the district level and enables the enrolment of up to 15,000 clients on care and treatment (NACP, 2008). In response to rising numbers of People Living with HIV (PLWHIV) with low enrolment rates into care and treatment, the government developed and implemented a plan for providing ART services to all eligible patients by the end of 2008. The plan was aimed to place 440,000 HIV patients on ART and 1.2 million people on care by December 2008 (NACPT, 2009). To accomplish this goal, the MOHSW decentralized care and treatment services from district hospitals to

primary health clinics. By the end of 2010, a total of 1100 health facilities had begun providing care and treatment services. Of those, 220 are hospitals and the remaining 880 are primary health facilities (UNGASS, 2010). This decentralization has increased the demand for ART services, and consequently, the demand for CD4 tests, both for initiation into care and treatment, and monitoring of ART-initiated patients. Currently on average, 52% of persons with HIV infections who are receiving care and treatments are receiving ARVs (UNGASS, 2010). It is clear that the country need to improve access to ART and by improving CD4 access may help. Prior to the introduction of point of care, Tanzania had limited CD4 test capacity available only at the hospital level which was inaccessible to the rural communities (Zachariah R. *et al*, 2011).

The introduction and expansion of POC testing can therefore help to overcome logistical and geographic barriers to full-scale roll out of HIV treatment and care, increasing the number of patients on ART and reducing HIV-related morbidity and mortality. Therefore this work intends to assess the impact of introducing POC for CD4 testing in primary health clinics in Tanzania.

1.2 Facts about Tanzania

1.2.1 United Republic of Tanzania Country profile

The United Republic of Tanzania is located in East Africa and is the largest east African country when measured in land area. Tanzania is bordered by Kenya, Uganda, Rwanda, Burundi, the Democratic Republic of Congo, Mozambique, Malawi and Zambia (see figure 1.1)

Figure 1.1: Map of Tanzania

Source: http://www.tanzania-consulate.dk/map.htm (accessed online November 10, 2012).

The United Republic of Tanzania is the outcome of a union between two former African states, Zanzibar and Tanganyika. Tanganyika became an independent state in 1961, and Zanzibar got hers in 1963. On the 26th of April 1964 the two nations united to form the United Republic of Tanzania.

Despite the merger 49 years ago, Tanzania still has two-tier government: the Zanzibar Revolutionary Government and the Union Government. Dodoma acts as the country's political capital, while Dar es Salaam is considered the country's commercial capital. Its political system is based on a multiparty democracy. The country has 26 administrative regions, subdivided into 130 administrative districts (The United Republic of Tanzania National Website 2011). In Tanzania tribal languages are

widely spoken, however, Swahili serves as the lingua franca (Mrisho *et al*. 2007, 863).Tanzania has a tropical climate with one wet and one dry season, which occur at different times of the year in different parts of the country (The United Republic of Tanzania National Website 2010). The rainy season has a sizable effect upon the accessibility of the roads and therefore to the health facilities.

1.2.2 Demography

1.2.2.1 Socio- demographic Characteristic

Table 1.1 Tanzania Mainland demographic indicators with HIV assumption

Statistics	**2012**	**2005**	**2015**	**2025**
Annual population (000)	43,726,471	35,746,092	47,521,276	61,753626
Growth rate %	2.85	2.89	2.73	2.61
Total fertility rate (births per women)	5.34	5.66	5.21	4.74
Crude Birth rate (per 1000 population)	41.4	44.9	39.3	35.9
Crude death rate (per 1000 population)	13.5	16.4	12.6	10.1
Life expectancy at birth (years)	52	49	52	56
Infant mortality rate (per 1,000 births)	70.5	82.1	65.9	50.1
Under 5 mortality rate (per 1,000 births)	51 (2010 estimate)	**68**	88 (1995 Estimate)	

Maternal Death per 100,000live births	Slight decrease in maternal mortality rate from 578/100,000 live birth to 454/100,000 live birth (2009/10)

Source: (NBS, 2006) Tanzania Bureau of statistic, population division, national projection (2006).

HIV/AIDS is a demographic issue as it has effect on mortality and fertility which leads to the changes in the other demographic indicators like population growth and size. The total fertility rate of the women aged 15-45 in Tanzania decline from 6.3 in 1992 to 5.7 in 2005 and to 5.4 in 2010 (THDS, 2010). The main reasons for the decline were due to death before the childbearing age, physiological means, use of condom and women empowerment.

Death from AIDS will mean a small proportion of the population surviving to childbearing age, with HIV/AIDS assumptions the projection indicate that Tanzania population growth rate will decrease by 2% by 2025 (NBS, 2006). Death and decreasing of fertility rate will have general effect on population growth and size, negative population growth with absolute decrease in population number, which will eventually affect population pyramid. Therefore mortality, change in fertility and behaviour have impact on current predicted data for population. Although the prevalence of major diseases appears to be declining, the current HIV/AIDS prevalence rate may have been one of the major contributors to the slow increase of life expectancy in Tanzania. However, with substantial decline in child mortality, it is projected that on average, people in Tanzania have improved their life expectancies significantly. Reduction of child mortality rate estimated to increase life expectancy by 5-10 years (Demographic Surveillance Site 1999-2007). Using National Bureau of Statistics (NBS) projections, it is now estimated that life expectancy in 2012 is around 57 for males and 59 for females (NBS, 2012).

1.2.2.2 Human Development Profile

A. Education

Table 1.2: Tanzania Education Profile

Indicator	Year	Values
Adult literacy rate (both sexes above the age of 15)	2002-2007	72%
Education attainment between males and females	2009/10	Male 27%, Females 18%
Median number of years of schooling	TDHS 2009/10	Female 3.6, Males 4.6 years
Attend in school by age of 20 years	TDHS 2009/10	Males 27% , Female 10%
Attendance rate peak at age of 11	TDHS 2009/10	9 in 10 male and female attending school
Human development index, ranking 2011	2010	148

Source: Tanzania Demographic and Health Survey, 2010

In Tanzania there is a gap in education attainment between females and males; 27% of females have never attended school compared to 18% of males. This is because culturally education is more important to males than females. The median number of years of schooling is differing among males and female, female had 1 year less than males. Attending school also differ between male and female with age. 27% of male attend the school compared with only 10% of female by the age of 20. Education attainment vary across the regions and it's based on wealth quintiles e.g. 7% of females from wealthier households have never been to school compare to 46% of the

poorest household (TDHS, 2010).

B. Economy:

Table: 1.3 Tanzania Economic Profiles

Statistic		% Or Number	Year
GDP	Per Capita	$ 552	2010
	Real growth rate	6.4%	
GDP: Composition by sector	Agriculture	27.8	2011
	Industry	24.2	
	Services	48%	
Labour force		24.06 million	2011
Labour force by occupation	Agriculture	80%	2002
	Industry	20%	
	Services		
Unemployment rate	2.3 million (12.9 of labour force)		

Source: World Fact book. Tanzania economy 2012

HIV/AIDS is closely related to economic development. HIV/AIDS is negatively affecting economic growth which limits the country to fight against it. HIV related mortality and morbidity rate have economic effect at all levels of society, from the individual through to the government level. For example individual level economic repercussion may include the allocation of resources to the healthcare and funeral. The study done in Tanzania showed that 8% of the total household expenditure was allocated to medical care and funerals in a household that had an adult death in the preceding 12 months (Mead Over *et al*. 1996). Reduced in labor force as a result of

death, care of the patients and funeral duties hence reduced productivity and increased cost for companies, reduction in household income due to increased AIDS related expenditure and increase in government budget deficit due to increased health spending (Bollinger L, Stover J, & Riwa P, 1999).

C. Poverty

Table: 1. 4 Incidence of Poverty in Tanzania (Poverty Head Count Index)

Item	Year	Dar-es Salaam	Other Urban areas	Rural areas	Tanzania Mainland
Food	2000/1	7.5	13.2	20.4	18.7
	2007	7.4	12.9	18.4	16.6
Basic needs	2000/1	17.6	25.8	38.7	35.7
	2007	16.4	24.1	37.6	33.6

Source: International Monetary Fund. (2010). *Tanzania: Poverty Reduction Strategy Paper.*Washington, D.C. International Monetary Fund.

It is estimated that approximately 50% of the population in Tanzania is living below the poverty line (The United Republic of Tanzania National Website 2012). Poverty in Tanzania occurs predominantly in rural areas. However, poverty in the urban areas, mostly due to unemployment and employment in informal sectors, is growing rapidly (The United Republic of Tanzania National Website 2011). The poverty is associated with the lack of quality education, capital and human assets. Other factors include large families, a large part of the population suffering from poor health, and a high vulnerability to diseases, including HIV/AIDS.

D. Health

Table: 1.5 Health systems indicator

Item		Amount	Comment
Financial Resources	Proportional of national budget spend on health	Increase from 13.45% in 2006/07 to 13.87% in 2008/09	increase in government spending on health does not reflect the good performance of health care system
	Total Government and Donor on Budget Allocation to health capita	increased from 17,474.55 to 24,791.25in 2008/09	per capita health spending is still low compared with 2015 HSSP III and MKUKUTA target which is 52,800.25
	Proportion of population enrolled in CHF/TIKA	6.6% of Tanzanian slight increase from previous year which was 5.6%.	The MOHSW has a long way to reach the target of enrolling 80% of Tanzanian population by 2015
Human resource status in the Health sector	By December 2010 the total number of health workers was 52,637 which is 64% of the actual requirement. The deficit was 29,650 (36%) of the actual requirement		Acute lack of medical personnel is a national issue

Source: Tanzania Ministry of Health and Social Welfare 2010

HIV/AIDS has increased burden to the health care system of all the countries worldwide but sub Saharan Africa region is mostly affected. The disease has reduced the resources for solving other health related problems, which had an effect of overall quality of health services. In Tanzania where by human and financial resources are constrained, additional HIV care and management services has added challenges to the health system. Today more than 80% of hospital admissions are HIV related

conditions (NACP, 2012). HIV has also affected health care workers and thus an additional burden has been felt.

E. Medicines and laboratories

Essential medicines are supposed to be available in all primary health care facilities but unskilled personnel who have low knowledge on quantification and forecasting manage most of these facilities. Sometimes the zonal medical store does not have all essential drugs for facilities. The introduction of push system makes the situation even worse.

Laboratories are supposed to be available in level two of primary health care but not all the health centres have laboratories and it's due to shortage of laboratory technicians and laboratory equipment. At Districts, Regional and National level laboratory equipment and machines are not enough, which leads to long cue and waiting time (THDS & ICF Macro, 2009/10).

1.2.3 Overview of the health care system in Tanzania

The health care system in Tanzania is built hierarchically, with the following levels: Village health services, health dispensaries, health centres, district hospitals, regional hospitals and referral hospitals. Health workers who are given a short training provide village health services, and the services are provided within the home (The United Republic of Tanzanian National Website 2011). The health dispensaries are numerous and are located within villages to facilitate easy access. These facilities are intended to serve between 6,000 and 10,000 people. Dispensaries provide various services, ranging from dressing of wounds to infant delivery. Health centres are larger units intended to cater to more than 50,000 people. Many health centres have wards for

patients to stay in and labour rooms. Each district has a district hospital, and all regions in the country have a regional hospital. There are four referral hospitals which provide the highest degree of hospital services in Tanzania. Not all facilities offer HIV related care and treatment services. Patients in need of this service are referred to facilities having a care and treatment clinic (CTC), which among other services provides HIV drugs, counselling on infant feeding etc. (Ministry of Health and Social Welfare 2010, 10).

1.2.4 Overview of Point-of-Care Testing in Tanzania

In January 2012, the National AIDS Control Program (NACP) implemented a plan to standardize and expand the use of POC CD4 testing in Tanzania. POC CD4 testing is rollout in phases, beginning with the Alere Pima, which was introduced after a successful technical evaluation, and initial pilot in Lindi and Mtwara carried out by the Clinton Health Access Initiative (CHAI) and the NACP. Devices have been placed at 254 sites as of September 2012, in 21 regions across Tanzania, with the largest number of devices in Tanga, Tabora, Mbeya, Kagera and Kilimanjaro regions. Current guidelines in Tanzania recommend prioritizing Pima rollout to sites with high patient volumes, to impact the greatest number of patients and take advantage of scaled cost-savings. However, many devices were rolled out prior to the publication of this protocol, and these POC CD4 devices were placed primarily in rural areas, which have the highest rates of LTFU. There is a significant rural bias to the placement of Pima devices in Tanzania, which is reflected in the sites chosen for this study.

According to the most recent census, 26% of Tanzanians live in urban centres, with the remaining majority of the population in rural areas and villages (CIA, world fact

book, 2011). However, HIV prevalence is higher in urban areas than rural areas (8.7% and 4.7%, respectively (USAID, 2012). As of 2010, the most recent year for which data is available, there were seven FACSCalibur and 74 FACSCount units in Tanzania. Currently referral hospitals in Tanzania have the highest-throughput device (the FACSCalibur), while regional and district hospitals have FACSCount machines. The Ministry of Health and Social Welfare had a plan of rolling out Pima services to 5 to 10 sites at regional level, 100 sites at district level and 600 sites at primary health clinics.

1.2.5 Health care financing in Tanzania

Previously Tanzania health care system was purely financed by the central government. The public financing was not enough to maintain the existing health structure and in 1993 the government introduced user fees with the aim of increasing resources available for health care system while removing the notion that health care is free, to help to avoid unnecessary visits and informal payments. The user fees made access to health care services relatively more expensive for poorer people than for richer people. Although exemption and waiver were in place to ensure access of services to the poor, the reviews of those polices indicated that the desired effect were not met (Mtei and Mulligan 2007, 47–48). The reviewers found that the system favoured well off people rather than the poor. A household survey conducted by the SHIELD project estimated that 44% of those who were eligible for exemptions pay user fees for outpatient care; 70% pay for inpatient care. For those not eligible for exemptions, 89% pay for outpatient care and 86% for inpatient care (Borghi, Mtei, and Ally 2011, 39). Thus, exemptions are somewhat effective in reducing out-of-pocket payments. With respect to waivers, the poorest often do not have access because of a lack of information, denial of the waiver by a provider, loopholes that

allow misuse and sometimes abuse of the system, and a lengthy and cumbersome identification process that often deters people from applying for waivers (Mtei and Mulligan 2007, 6). Identification of the poor is a major problem, because there are no clear guidelines and no money has been set aside by the government to compensate facilities for waivers. In addition to exemptions and waivers, other systems were developed to address the highly regressive aspects of user fees, thus enabling people to access medical treatment when needed through prepayment and risk pooling. The mechanisms included voluntary public community health funds organized at the district level, voluntary micro-health schemes organized at the community level, private health management organizations, private health insurance, public mandatory social health insurance through the NHIF, and voluntary health benefits through the NSSF. Whereas the NSSF itself is mandatory, members must sign up separately for the SHIB health benefit but most do not. Since then the health financing system of Tanzania is highly fragmented with many financers and mode of financing. HIV/AIDS is mainly funded by development partners and services such as diagnostics and drugs are provided free of charge. In summary, the health financing landscape in Tanzania is quite fragmented, with a large number of funding sources covering different aspects of the costs of health services. The HSSP III has as a major priority the development of a comprehensive health financing strategy to determine the appropriate mix of financing modalities and to develop a road map for improving financial and physical access to health services by all Tanzanians. Criteria should therefore be developed for identification of poor people who are in need of waiver and exemption to access health care services.

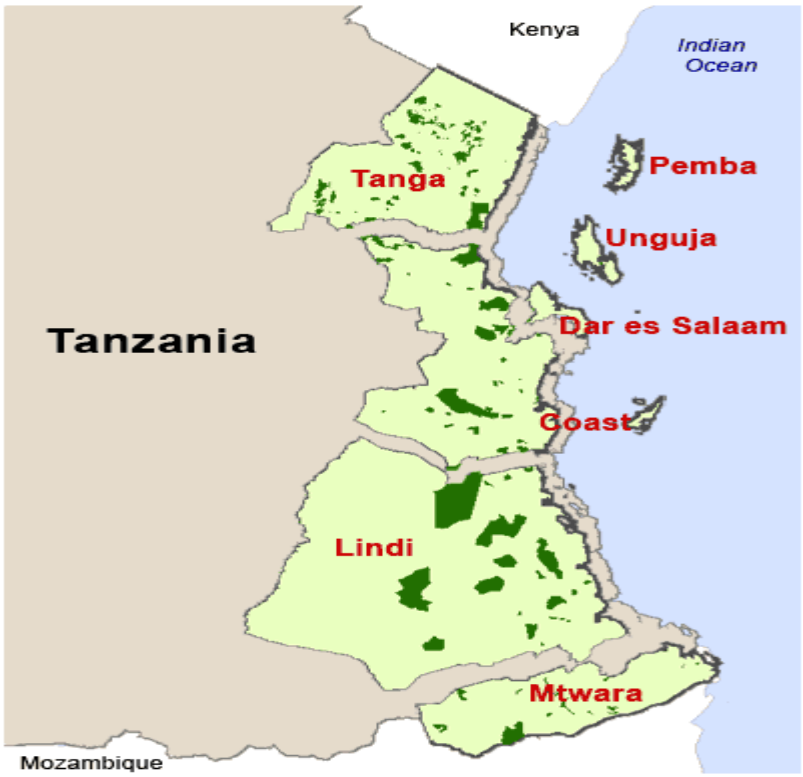
1.2.6 Coastal Regions

There are 26 administrative regions in Tanzania, with a population estimated to be 43, 726,471 in 2010(NBS, 2012). The regions are divided into districts of which each region has between 6 to 8 districts. The poverty situation differs from one region to another. According to poverty and welfare rankings, Lindi region is ranked as one of the most deprived regions in Tanzania together with Dodoma, Kagera, and Pwani Regions (The Government of Tanzania, 2011). There are few paved roads rural areas of most of the regions. Some roads are not passable during rainy seasons and some others are too steep for cars to get through at all (Mrisho, Mwifadhi, Joanna A, Schellenberg, Adeil k. Mushi, Brigit Obrist et al, 2007). All regions have regional hospitals and all districts have district hospitals and within the districts there are primary health clinics (health centres and dispensaries) with about 90 percent of the population living within 5 kilometres away from a primary health facility (Tanzania MoHSW, 2008). There are 4 referral hospitals in Tanzania and the regions supported by those hospitals are divided by zones. For example all the coastal regions of Tanzania are served by Muhimbili National Hospital located in Dar es Salaam. The study was within five coastal regions of Tanzania Mainland which are Tanga, Pwani, Dar es Salaam, Lindi and Mtwara. The five coastal regions of Tanzania mainland encompass about 15% of the country's total land area. Approximately 25% of the country's populations live in these regions (NBS, 2010). Most of the coastal communities are very poor with less than US$100 per capita GDP at current prices (NSGR, 2005). The HIV prevalence vary from one region to another with 9.3% in Dar es Salaam, 3.8% in Lindi, 3.6% in Mtwara, and 6.7% in Pwani and 4.8% in Tanga (TACAIDS, 2008). Based on the selection criteria, the researcher managed to visit 4 out of the five regions (Lindi, Mtwara, Pwani and Tanga).

Why the study has to focus on the coastal region?

The study focused on the coastal regions because it is the area where Pima device has been placed in the clinics at least six month ago, with a big volume of patients. The regions are also easily accessible.

Figure 1.2: Map of Coastal Regions



Source: http://coastalforests.tfcg.org/images/tz-regs.gif

1.3 Problem Statement

Though CD4 testing is the entry point to HIV/AIDS care and treatment, still there are considerable barriers to access in resource limited settings. Testing facilities are centralized and require highly trained and specialized infrastructure (UNITAID, 2012). Primary health care workers who wanted to order CD4 test were faced with a lots of challenges. As a result, patients were often lost due to repeated visits to the

health facilities as well as delays in returning results (MOHSW, 2010). A study in Mozambique found that CD4 staging on a traditional CD4 machine could take up to 4 to 6 weeks (Jani *et al*, 2011). To address this challenge, the MoHSW introduced at primary health care levels, Pima point of care for CD4 testing so that those found positive can be appropriately managed. Pima point of care was introduced about one year back; this was done after it was confirmed that its tests were accurate in comparison to traditional CD4 machine. There has not been a tangible evaluation since they were introduced. This reality made the government to hesitate to continue the rollout of the device. This is a major gap and there is a need to collect evidence whether PIMA is successful or not. The outcomes of this particular study will fill this gap by providing a fair and timely evaluation of the impact of implementing CD4 testing at the point of care on HIV case management in primary health clinics. The thesis tries to provide an answer for what one such intervention has led to. It will also help to gain knowledge of which conditions have led to the results found, and what actions can be taken in future in order to make such interventions successful.

1.4 Rational of the study

This study will provide evidence as to whether the introduction and use of PIMA point of care for CD4 testing in primary health clinics has improved HIV case management. The report will be widely disseminated and meetings will be held in all study regions of Lindi, Mtwara, Pwani and Tanga. Based upon the data, discussion with relevant stakeholders will be conducted to adopt new direction if needed regarding PIMA. Additionally the Tanzania Ministry of Health and Social Welfare – Director of Curative Services, NACP Manager and partner organizations will also receive the report and recommendations. The aim is to provide a platform for developing new or modifying policies regarding HIV case management. The report

will also provide critical information to service providers and planners that will help them in selection of technology, design services and allocate resource efficiently.

1.5 Research questions

i. To what extent point of care CD4 testing affects the rate of CD4 count at initiation and time to antiretroviral therapy initiation?
ii. To what extent point of care CD4 testing affects patient retention before immunological staging and treatment initiation?
iii. Does CD4 testing at the point of care affect patient schedule and waiting time?
iv. Are there any barriers to the implementation of Pima POC CD4 testing in primary health clinics?

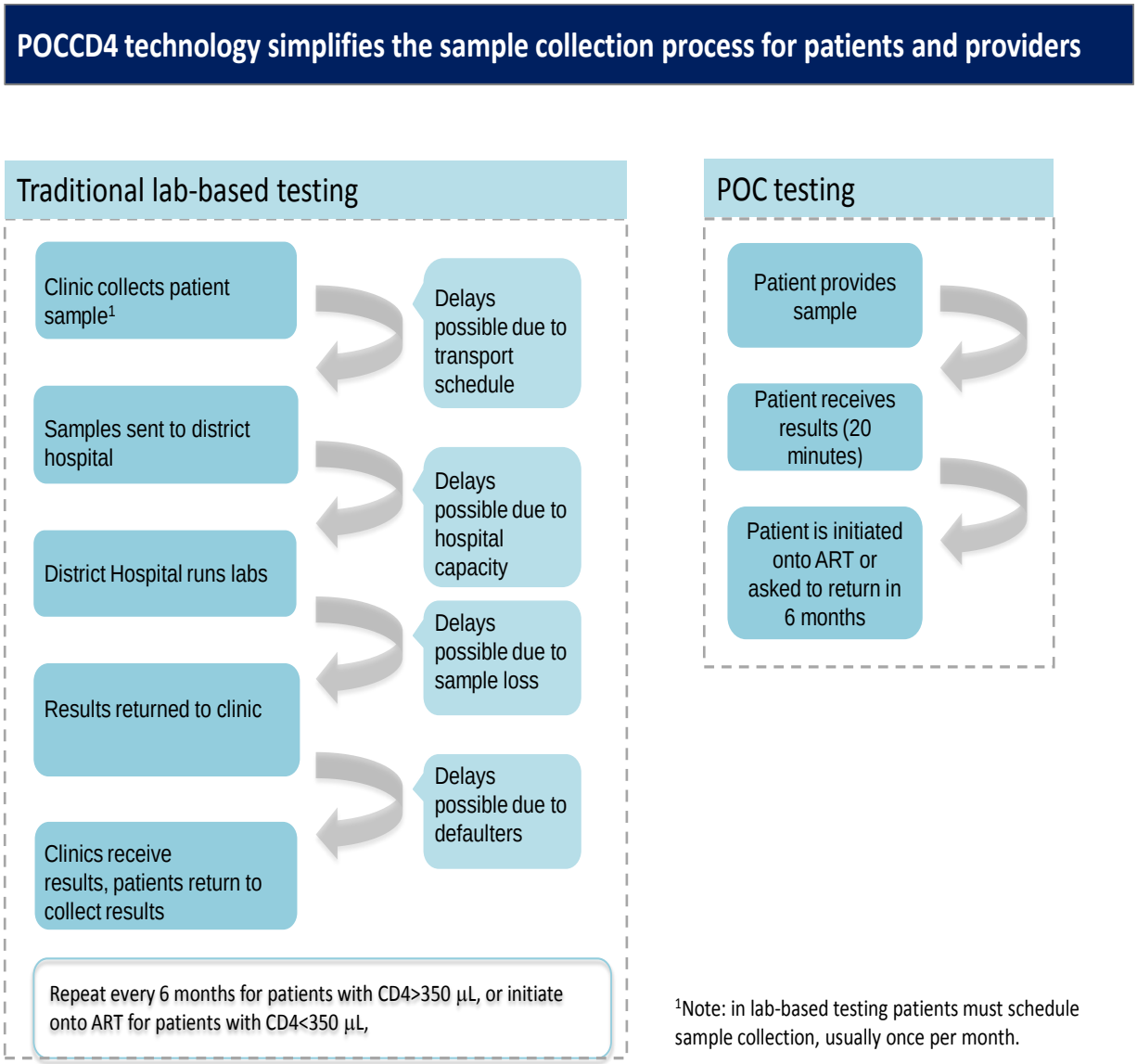
1.6 Main objective

To assess the impact of implementing CD4 testing at the point of care on HIV case management in primary health clinics in Tanzania

1.6.1 Specific objectives

i. To assess the effect of point of care CD4 testing on rate of CD4 count at initiation and time to antiretroviral therapy initiation.
ii. To assess the effect of point of care CD4 testing on loss to follow up before immunological staging and treatment initiation.
iii. To determine the impact of CD4 testing at the point of care on patient schedule and waiting time.
iv. To identify barriers to the implementation of Pima in primary Health clinics

Figure 1.3: Conceptual Framework of POC testing in comparison to tradition laboratory base testing and its impact



Source: Researcher's own design

In Tanzania individuals walk for over five hours to get to a comprehensive primary health clinic in the remote areas. No paved roads and the public transport systems are almost inexistent with the majority using bicycles and motorcycles as the means of transport and anyway unaffordable. When the HIV positive individuals are in need of CD4 count, they are scheduled for blood collection which is usually done once or twice per month at a clinic level. Then clinic collects patient samples and sent away using existing means of transport (can be bus, private car, bicycle or motorcycle). The

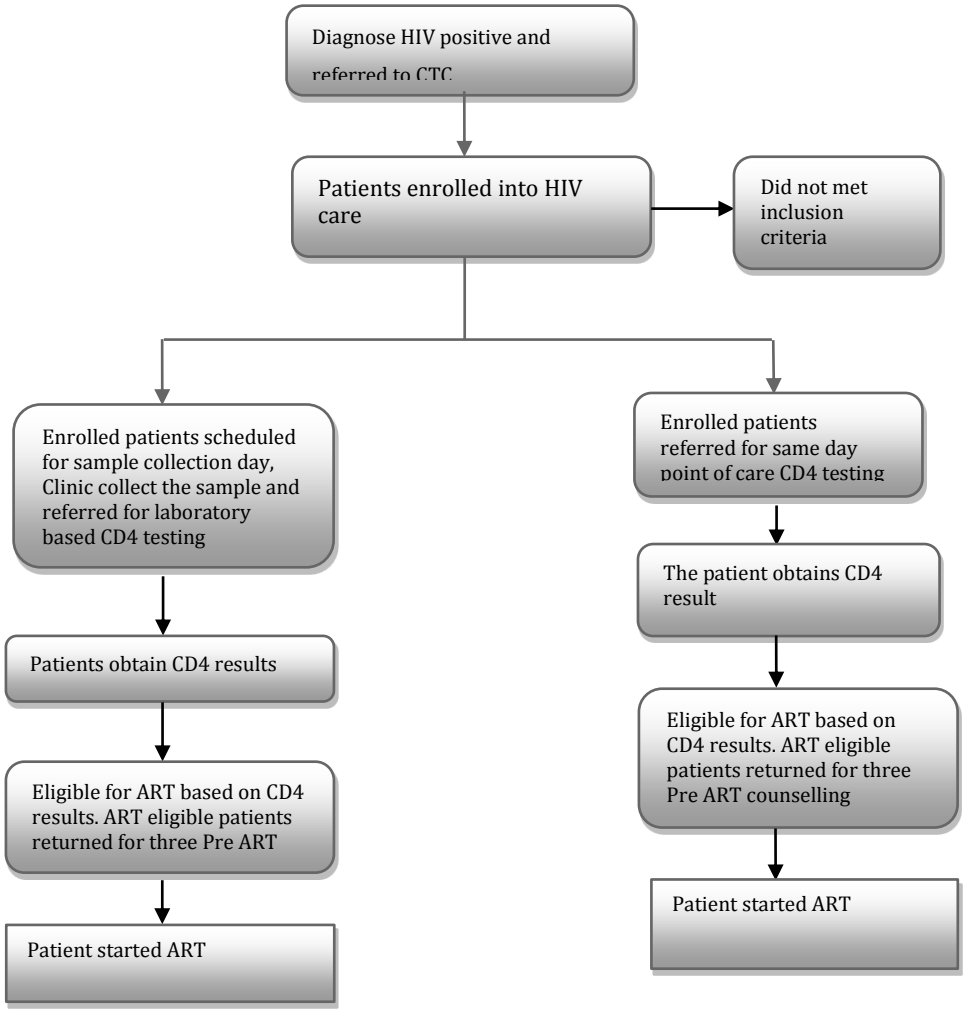
HIV patients are told to come back 2 weeks later to get results. A study in Mozambique found that CD4 staging on a traditional CD4 machine could take up to 4 to 6 weeks (Jani IV *et al*, 2011).

The samples are sent to the district hospital and delays are possible due to Machine malfunction as a result of poor maintenance, breakdown, and shortage of staff and lack of reagents due to stock outs or financial constraints. They had many additional challenges such as blood specimen being damaged or unsuitable for testing because of delays in sample reaching the CD4 count laboratory, poor handling, or lose of the results due to unclear records management system.

Patients getting CD4 testing require repeated visits to the health facilities leading to delays in accessing ART and in most cases lost to follow up due to lack of transport and financial constraints. By the time the results are ready the patient is too sick to return to the clinic or overwhelmed due to disturbances. Such individuals are usually impossible to track them again, thus they end up being declared as "lost to follow up," which exceeds 50% in low-income settings, and it is a significant barrier to the scale-up of HIV treatment (Jani IV *et al*, 2011). This is the situation for Tanzania, a country that ranks 25th on the scale of highest HIV prevalence in the world. This means the traditional CD4 technology used was inappropriate technology that was inaccessible for rural communities (Zachariah R. S, 2011).

The Alere Pima device enables clinicians to provide patients with an absolute CD4 count within twenty minutes and therefore can initiate them into ART within the same day or asked to return in six months (Mtapuri Zinyowera, S. *et al* 2010 & Zachariah R.S, 2011).

Figure 1.4: Research Framework



Source: Researcher's own design (Diagram was contracted based on patient flow at the clinic level).

All patients found to be HIV positive at the clinics are referred for enrolment into HIV Care and Treatment Clinics (CTC). After enrolment, patients are referred on the same day to point of care for CD4 testing and obtain the results within 20 minutes. Then patients who are eligible for ART based on the CD4 test results have to come back for three pre ART counselling, hemoglobin and liver function test before initiation of antiretroviral therapy. Before the introduction of point of care test, blood samples were collected once or twice per month and sent to nearby laboratories. Patients were then asked to return for a staging visit after the test results were

available. If eligible as a result of CD4 cell count or clinical sign, a patient usually has three counselling visits, hemoglobin and liver function test before initiation of antiretroviral therapy.

CHAPTER TWO

LITERATURE REVIEW

2.1 Global situation of HIV/AIDS

The world today is facing serious challenges regarding the HIV/AIDS epidemic. In 2010 worldwide 34 million people were living with HIV (UNAIDS, WHO, UNICEF, 2011). Several indicators have demonstrated the improvement in combating the AIDS epidemic (UNAIDS, 2010). Despite the improvement, still the world is facing some challenges of low levels of enrolment into treatment. The global HIV burden is unevenly shared with an estimated 23.5 million people living with HIV found in sub Saharan Africa, among them 1.9 million were newly infected in 2010. Sub Saharan Africa is home to only 10% of the world's population (UNAIDS, 2010). Great inequalities occur in prevalence rate among nations within the sub Saharan Africa, from the Comoros with 0.1% to Swaziland with 25.9% (UNAIDS, 2010). Despite the notable global effort to improve access to ART, approximately 50% of the people who are in need do not receive it (WHO, 2012). Access to antiretroviral medicines is needed for preventing morbidity and mortality including mother to child transmission, access to CD4 testing may improve the situation.

2.2 Laboratory test for HIV and AIDS

A person with HIV needs a comprehensive clinical care which requires health care personnel to have appropriate clinical knowledge, experience and laboratory support to identify patients with gross features of HIV disease. Laboratory testing is an integral part of HIV and AIDS care and treatment. These tests provide additional information on individual status, the level of disease progression, treatment eligibility, response to treatment and drug adverse reactions. A package of affordable diagnostic

tests, performed at the point of service delivery is needed for further rollout of HIV testing. This would help reduce instances of late initiation of antiretroviral therapy and ensuring adequate monitoring of lifelong HIV therapy in particular in primary health clinics (UNITAID, 2012).

2.2.1 Test for HIV diagnosis

The HIV diagnosis for adult and children above 18 month is done by the detection of antibodies to HIV using rapid tests. The national rapid alogarism for Tanzania is made up of the following rapid tests: - Determine HIV ½ and Uni-Gold HIV. Rapid test can be done using whole blood, serum or plasma sample and can be performed in laboratory and non-laboratory settings such as hospitals, clinics and in the community by trained staff (Kedrick *et al*, 2005). Rapid HIV testing are available in Tanzania and accessible to the rural communities. For distant communities the testing is done through mobile clinics.

2.2.1.1 Diagnosis of children under 18 month

Diagnosis of HIV infection in children below 18 month to determine whether he/she has been exposed is done by detection of viral nucleic acid (RNA or pro viral DNA) or viral antigens. HIV DNA polymerase chain reaction (PCR) is used in Tanzania to confirm HIV infection in infants by the age of four weeks and children below 18 month. Capacity for PCR testing is limited in the national level and it is a challenge to paediatric enrolment into care and treatment in Tanzania. The recent point of care of dried blood spots for quantifying viral load and early infant diagnosis has demonstrated promising results (UNAIDS, 2011).

2.2.2 CD4 testing for disease staging and monitoring responses to ART

Patients are supposed to receive CD4 test immediately after testing HIV positive to check ART eligibility and after ART initiation to assess the treatment outcome. In adolescents and adults, CD4 counts are reported in absolute numbers while for children under six years are reported in % (WHO, 2010). WHO recommends ART initiation if CD4 counts are below 350 and for under-five years old if the CD4% of lymphocytes is less than 15-25% (WHO, 2010). Once the patient is eligible for treatment they are planned to have their CD4 count routinely every 3 to 6 months, and those who are not yet eligible are monitored in every 6 to 12 months. Perhaps Patients on ART are received up to 50 CD4 counts (Peter T *et al*, 2008). Therefore the demand for CD4 count test will continue to increase as the government continues to scale up ART services to the rural community. International and national guidelines recommend the use of CD4 count for treatment decision and marker for treatment outcomes in both adult and children (WHO, 2006), (NACP, 2012). When available, viral load may be considered in addition to clinical and immunologic measurements to diagnose treatment failure earlier. However, capacity for viral load measurements is currently limited (NACP, 2012).

Table 2.1: Laboratory monitoring before, during and After Initiating ART

Phase of HIV management	Recommended test	Desirable test
AT HIV diagnosis	CD4	HBsAg
Pre-ART	CD4	
At start of ART	CD4	Hb for AZT creatinine clearance for TDF, ALT for NVP

On ART	CD4	Hb for AZT, creatinine clearance for TDF, ALT for NVP
At clinical failure	CD4	
At immunological failure	Viral Load	
Women exposed to PMTCT interventions with sd-NVP with a tail within 12 months and without a till within six month of initiating ART	Viral load six months after initiation of ART	

Source: Tanzania HIV Care and Treatment guideline- 2012.

2.2.3 Tests for Monitoring Antiretroviral Treatment Toxicity

Though ART has the potential to control HIV and save lives, the drug cocktails can also cause serious side effects, which must be monitored. AZT can cause anaemia, which can be monitored with regular Hemoglobin testing (currently available in POC form with the Hemocue device). TDF can cause renal function, necessitating creatinine testing. NVP can cause hepatotoxicty, which can be monitored with ALT tests. Baseline testing is a vital indicator of which regimen to choose, and continuous monitoring testing can preserve health status for patients, while preventing the development of life-threatening complications. It is vital, therefore, to ensure that these complementary tests are occurring regularly. Capacity for testing haematology indices and clinical biochemistry has been developed at the laboratories of all hospitals with a CTC in the country but not in all primary health clinics (NACP, 2012).

2.3 Pima Device

The Alere Pima device enables clinicians to provide patients with an absolute CD4 count within twenty minutes. Designed for use in the resource-constrained setting, the device can be operated with an external power source, rechargeable battery, or solar charger. The unit uses disposable test cartridges with sealed reagents, ensuring safety and effectiveness.

The Pima test consists of a disposable test cartridge containing dried reagents, and the Pima analyzer (Vanjari *et al*, 2011). Approximately 2μL of capillary or venous whole blood is collected into the test cartridge, and the sealed sample is then processed. The test result displays on the front of the unit when the test has been completed, and the results are saved on an on-board archive that can be retrieved and downloaded by the user at any time after the test (Boyle SD, Hawkins RK, Steele SM, Singhal M, Cheng X, 2012).

Table 2.2: Comparison of Pima POC CD4 to Conventional Testing

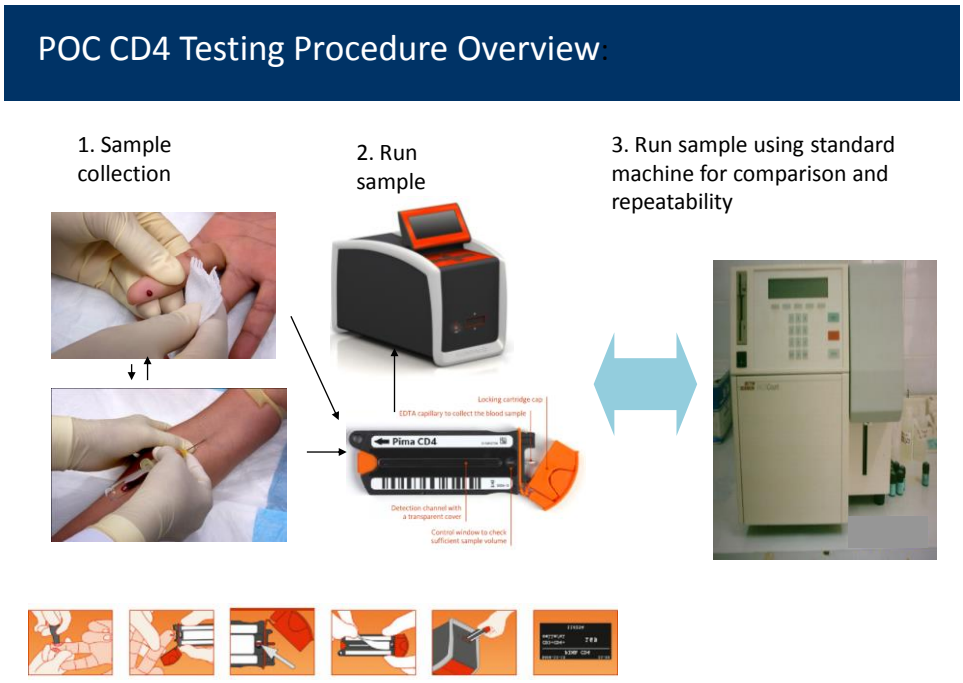
Category	Conventional Lab Testing	Pima POC Testing
Turnaround Time	1 day – 2 weeks	20 minutes
Throughput	50-300 tests per day	20 tests per day
Amount of Training Required	2-30 days	½-3 days
Electricity Required	Yes	No
Refrigeration Required	Yes	No
Sample Transportation Required	Yes	No
Supply Chain Requirements	Many consumables	Few consumables
Sample Type	Venous blood	Capillary or venous blood
Instrument Cost	$20,000-$75,000	$5,000
Test Cost	Typically $6-10 per test	$10 at high-volume sites $20 at low-volume sites
Visits Required for Single Test	2	1
Loss-to-follow-up prior to initiation onto ART	Up to 64% in resource constrained setting	33%[27]
Loss-to-follow-up during CD4 Staging	57%[27]	21%[27]
Instrument Downtime	Up to 30% in some labs	Low

Note 27: Massambu, C. Mwangi, C. The Tanzania Experience: Clinical Laboratory Testing Harmonization and Equipment Standardization and Different Levels of a Tiered Health Laboratory System

2.3.1 PIMA CD4 testing

Based on clinical observations in Pima testing, patients provided blood samples either through finger prick or venous blood. "*After sample collection through Pima cartridge, the cartridge is capped and inserted immediately into Pima analyzer to run the test. During the analysis process, the blood is automatically mixed with freeze-dried fluorescently labelled antibodies (anti-CD3 and anti CD4) contained in the cartridge and transferred to a detection chamber were images are taken of the labelled cell to calculate the number of CD4 cell per μL of blood. The results are then printed and recorded after each test" (Mtapuri Z. S. et al. 2010)*

Figure 2.1 Point of care CD4 testing procedure overview



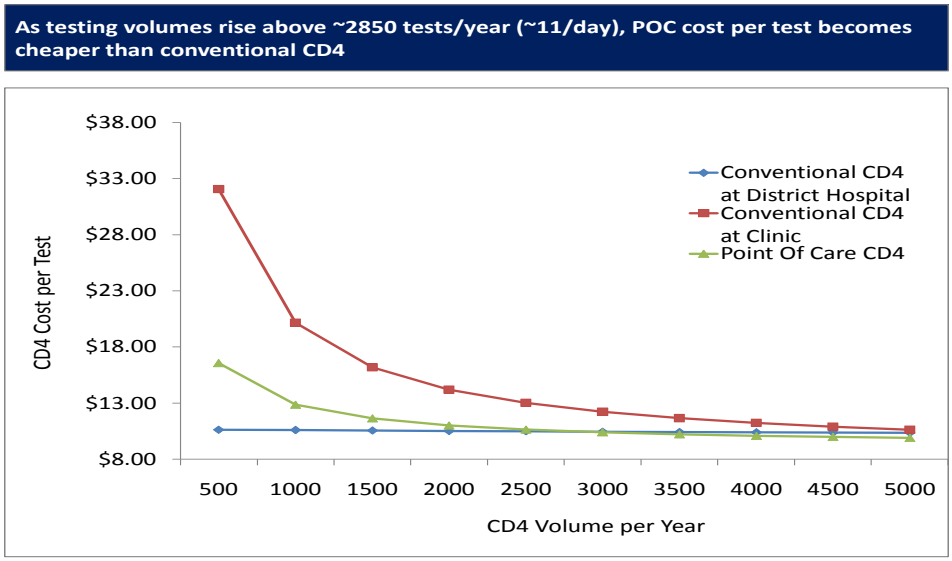
Source: Tanzania Ministry of Health and Social Welfare, 2011

2.3.2 Cost Discussions

Reagent costs for POC CD4 testing slightly exceed those for traditional laboratory-based testing, but analysis has shown that at average testing volumes, the cost of POC

CD4 testing is comparable to traditional CD4 testing. Based on Clinton Health Access Initiative (CHAI) Laboratory Service Team analysis in 2011 conducted over several countries in the developing world, when testing volumes rise above 2850 tests/year (11 tests per day), POC cost per test is less than conventional CD4 testing.

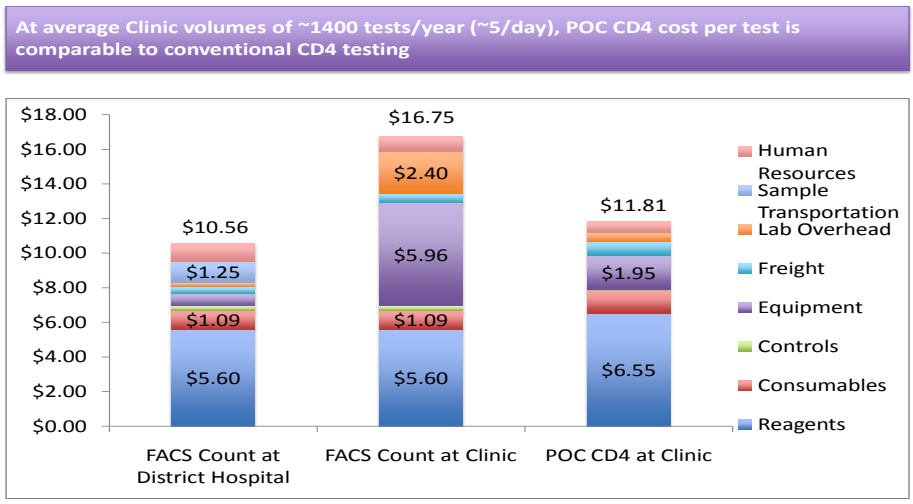
Figure 2.2: Point of care cost per test



Source: CHAI Laboratory Service Team analysis in 2011

The same study showed that with average volumes of 1,400 tests per year (~5/day), POC CD4 tests cost $11.81 per test, as compared to $10.56 for FACSCount testing at the district hospital, and $16.75 for FACSCount at the clinic level. The one-time overhead costs of acquiring a POC unit are thus spread over an increasing number of tests, while conventional laboratory-based testing has a fixed cost. POC testing can take advantage of economies of scale, while conventional testing cannot.

Figure 2.3 Point of care cost as comparable to conventional CD4 testing



Source: CHAI Laboratory Service Team analysis in 2011

2.4 Emerging of new technologies for point of care CD4 count cell

Some devices are available now and current studies suggest more devices will be released in future. Non point of care machine remain viable in urban and new technology which are rapid, easy and cost effective should be developed for rural areas and their rollout should accompany with the availability of ART drugs. While the development of the new technology continues, capital equipment and human resources cost should be assessed for easy adoption and uptake in the resource-constrain settings. The development of the technology provides support to the rollout of HIV care and treatment program. Evidence based research is needed showing challenges faced by the decision and policy makers when making procurement and implementation decision (Boyle SD, Hawkins RK, Steele SM, Singhal M, Cheng X, 2012). WHO, UNAIDS and other partners are in the process to determine the ideal package of point of care diagnostics in identify challenges in developing and delivering of new technology and speed up the critical path towards making them available (UNAIDS, WHO, UNICEF, 2011) . UNITAID committed more than USD

140 million to project implementation of point of care services by different partners in low income countries. This aims to improve access of diagnostic services to patients. The support targeted 3 critical diagnostic tests for HIV such as CD4, early infant diagnosis and viral load. In planning to implement point of care services it is crucial to consider some of the challenges the program might face especially in the rural clinics (Peter T *et al*, 2008). Therefore the development of the device should be consistence with the implementation process.

2.5 Performances of Pima

Point of care eliminates the challenges faced with the conventional laboratory based services and its utility is not limited to the rural areas. Most of the developing countries like Zimbabwe, Mozambique, Uganda, South Africa etc are using Alere Pima technology and their performance is good as compares to conventional laboratory based technology (Mtapuri Z. S. *et al*, 2010; Jani I.V. *et al* , 2011; Manabe YC. *et al*, 2012; Herbert S. *et al*, 2012; Glencross DK. *et al*, 2010; Thakar M. *et al*, 2012). Pima performance is highly correlated when using venous blood but if the finger prick blood sample are correctly collected and tested there is also high correlation (Glencross *et al*., 2012; Alassane PD. *et al*, 2011; Sitoe N. *et al*, 2011). Skilled health staffs are highly needed for proper sample collection (Herbert S. *et al*, 2012; Mtapuri Zinyowera, S. *et al*, 2010; Kafufu Fred, 2010). Point of care can be done by either laboratory technicians or nurses, there is no significance difference between the test run by a nurse or laboratory technician, this justify the increase of human resources available for Pima services and possibility of implementing it in a standalone clinic such as VCT, PMTCT (Mtapuri Zinyowera, S. *et al*, 2010). Pima correctly identified 93% of pregnant women eligible for ART, hence with Pima we can reduce mother to child transmission by early initiation of ART to pregnant

mothers and promote early initiation based on 2010 WHO recommendations that women are supposed to start their ART at early stage of 14 week of their gestation (Myani CN, Mclintyre JA, Myer L, 2012). Pima is also good in identifying clients eligible for ART as it is highly correlated, with low biases (Sukapirom K. *et al*, 2011). When rapid point of care CD4 testing is provided through mobile clinics, it increases linkage to care and patients are likely to visit referral clinics and their results are accurately determined with non-clinical bias (Larson AB *et al*., 2012; Schaik NV *et al*, 2011). In general Pima is highly accepted by the clients as it provides rapid results which reduce lost and time to the clients (Herbert S. *et al*, 2012). Efforts is needed for the development of new point of care technology especially those which are still relying on complicated laboratory infrastructure like DNA-PCR and HIV viral load which limit access to rural communities (Anderson AD, Crowe MS, Garcia M, 2011). Despite of shortcomings identified, Pima device may be one of the suitable instruments for rural communities (Bergeron M, 2012; Kafufu Fred, 2010; Glencross *et al*., 2012). However, proper training and support is highly needed for the operators to reduce those shortcomings.

2.6 HIV Prevention and Treatment

The government efforts need to focus on both HIV prevention and treatment. Antiretroviral treatment has now been seen as having crucial impact on AIDS response but this is only true when prevention and treatment interact in synergy. Currently we have seen the global impact of promotion and support combination HIV prevention that leads to the decline of transmission rate (UNAIDS, 2010). Behavioural change is the crucial factor for the decline. The government investment on comprehensive and correct knowledge about HIV and condom use and condom distribution is crucial. Correct and consistent use of condoms has proven effective in

reducing 90% of transmission rate (UNAIDS, 2010). The investments of substantial efforts to programming and funds to prevent high risk such as drug users and sex workers is highly needed to reduce the infections. Currently the challenge is the planners and implementers are reluctant to focus their prevention effort where they produce maximum impact (UNAIDS, 2010). New methods for prevention should be continued to be adopted such as male circumcision and use of microbicide gel by women. Universal access to prevention of mother to child transmission in antenatal and postnatal care could eliminate the transmission. Availability of CD4 testing for HIV infected individuals is crucial for early initiation of ART and monitoring of drug results. Early initiation of antiretroviral prophylaxis to pregnant women can reduce HIV transmission from mother to child (WHO, 2010). The government efforts on prevention should continue by allocating more resources on prevention to reduce the burden caused by high incidence of HIV infection which will include the reduction of cost for treatment and diagnostic services.

Most of the studies mentioned are based on assessment of the accuracy of point of care tests and its development. A good number of them are experimental in nature, focusing mostly on comparison with the tradition technology, very little was said about its impact on HIV case management. However the strength of these studies is the fact that they are multi-sited and the study has been done from different under developing countries which have almost the same context with Tanzania.

2.7 Need for and Potential Benefits of Point-of-Care Testing

Measuring the concentration of CD4+ T-cells in the blood is essential to quantifying the level of immune suppression among HIV patients. CD4 count is the most commonly used indicator of disease progression, and is a more reliable indicator than clinical staging. In settings where CD4 testing is available, it is used to determine

eligibility for antiretroviral therapy (ART) initiation and monitoring of ART-initiated patients. For all patients older than 5 years of age, CD4 absolute count is recommended, measured as the number of CD4 cells per μL of blood (WHO, 2009).

Constrained access to CD4 testing results in late initiation onto ART, which imposes costs on patients including additional morbidity and mortality, and poor treatment prognosis once initiated onto ART (Larson *et al*. 2009). Studies have shown that a low CD4 count (<100 cells/ μl) at initiation is a major predictor of HIV/AIDS mortality (Lawn *et al*. 2008; Lawn *et al*. 2009). Immune system recovery after 3 years on ART is also positively correlated with a patient's CD4 cell count at initiation (Robbins *et al*. 2007). A study in Mozambique showed that the expansion of rapid-response and point-of-care testing increased the percentage of HIV-infected persons on ART. The same study found that the introduction of POC CD4 testing decreased LTFU from 57% to 21% (Jani *et al*. 2011). The median time to enrolment on ART fell from 48 to 20 days, and the proportion of patients initiating ART increased from 12% to 22% (Jani *et al*. 2011). Current WHO ART guidelines recommend initiation onto ART for all patients with a CD4 cell count at or below 350 cells per μL. However, a recent review of eight sub-Saharan African countries found that median CD4 cell count at initiation was 136 cells per μL (Nash *et al*. 2011). POC CD4 testing may enable more patients to initiate ART with cell counts closer to 350 by increasing the number of patients who are successfully staged, and by decreasing LTFU prior to initiation onto ART (Jani *et al*. 2011).

The expansion of POC testing can therefore help to overcome logistical and geographic barriers to full-scale rollout of HIV treatment and care, increasing the number of patients on ART and reducing HIV-related morbidity and mortality.

The potential benefits of POC CD4 testing are as follows:

Cost & Resource Needs

i. Reduced delivery frequency due to long shelf life and high-heat stability
ii. Reduced device cost as compared to traditional laboratory instruments.
iii. Reduced training and staff requirements due to ease of use and training.
iv. Reduced infrastructure requirements e.g. smaller space required for device, solar charger and battery capability.
v. Permit task shifting and the use of unspecialized staff.
vi. Timing.
vii. Reduced patient burden by eliminating multiple visits for a single test.
viii. Reduced turnaround time (<20 minutes) by providing same-day test results.
ix. Eased capacity shortages and backlogs at central labs by diverting samples customarily referred for conventional testing.

Quality of Care

i. Improved patient outcomes by enabling faster treatment decisions.
ii. Reduced patient LTFU between HIV diagnosis and CD4 staging, as well as between eligibility for and initiation of ART.

Prior to the availability of POC CD4 devices, CD4 testing was based at Zonal, Regional and district hospital laboratories. There are currently 170 sites with labs offering conventional CD4 testing, including regional hospitals, district hospitals, and some health centres (MoHSW, 2011).

CHAPTER THREE

METHODOLOGY

3.1 Study Design

This study was a cross sectional explorative study to evaluate the impact of implementing CD4 testing at the point of care on HIV case management in primary health clinics in Tanzania. The study was conducted using both qualitative and quantitative methods. For quantitative approach a pre-post evaluation was done, to compare beneficiary before and after introduction of Pima to see their changes. Qualitative approach was undertaken to explain the relation between the intervention and the perceived effects by the participants.

3.2 Study area

This study was done at eleven public primary health clinics in four regions of Tanzania namely Tanga, Lindi, Mtwara and Pwani. The regions were selected based on geographical location criteria and that they had implementing point of care service for CD4 testing in not less than a year.. The sites were selected from a range of settings: - accessible by road, patient volumes of at least 50 patients per week[1], pima device placed in clinics at least six months ago, rural setting, voluntary and provider initiated HIV tests and antiretroviral therapy services were routinely available at all clinics. Currently, the overwhelming majority of Pima devices have been placed in rural sites, and the sample therefore is rural-based.

3.3 Study Period

The study was conducted from October 10th through November 10th 2012 from 11 public primary health clinics. During clinic visits, the data was collected from May to

[1] Not all clinics met these criteria.

September 2012 following the placement of the Pima device and the pre intervention data was retrospectively collected for the same period in 2011. This was purposely done so that there would be minimum effects of season or other confounders.

3.4 Study Participants

The research population included patients older than five years who were newly diagnosed and found to be positive during the period of study. Health care workers were also purposively selected based on criteria that they attended Pima training and were operating the device. The staffs were mainly from the laboratory and CTC.

3.4.1 Inclusion criteria

- HIV newly diagnosis
- HIV positive older than 5 years old
- Trained health care providers

3.4.2 Exclusion criteria

- Patients whose records were transfer to another facility
- Patients under five years old
- Untrained staff on Pima and all supervisors who are not directly related to Pima

3.5 Sample size

The study aimed to estimate the difference in proportions between two independent populations, that is, to estimate the risk difference. The formula used to determine sample size in each comparison group was as follows:-

$$n_i = \left[p_1(1-p_1) + p_2(1-p_2)\right]\left(\frac{z}{E}\right)^2$$

Where n, is the sample size required in each group, (i=1, 2), z is the value from the standard normal distribution reflecting the confidence level that will be used (e.g. z=1.96 for 95%), E is the desired margin error in which the 95% confidence interval for difference in proportions has a margin error of no more than 0.05 or 5%. P1 and P2 are the proportions of success in each comparison group. In this study the researcher used national adult HIV incidence rate which is 0.7 as a P1 & P2. The calculated required sample size was 645. As a precaution the sample size was increased by 20%. This gave the total sample size of 806. Based on this sample size 50% was allocated to pre Pima and 50% to post Pima introduction. Thus 403 patients were enrolled when Pima was not available and another 403 when Pima was available.

3.6 Data Collection tools

3.6.1 Quantitative data collection

For quantitative approach a structured questionnaire was used to extract patient level clinical data from medical records. Simultaneously a checklist was used to collect observational data.

3.6.2 Qualitative data collection

For qualitative approach in-depth interviews were done (see interview guide in appendix 1.4) for health care workers. A total of 22 in-depth interviews were conducted involving health workers and 55 study participants (unstructured). After these interviews the researchers noted that additional information would not result into new valuable information. The selection of the clients was based on convenient

sampling for those who were available at the clinic upon the visit of the researcher and the clinics providers were purposeful selected based on the fact that they had been trained and were operating Pima at the clinics. The researcher chose this type of sampling because it was difficult to arrange appointments beforehand, and as a majority of the health workers and patients did not have telephones, e-mail or other ways of being contacted. A problem encountered at two of the selected sites using this type of sampling was that there was only one person working that day, so an in-depth interview was not possible to conduct due to a large number of clients waiting to be attended to. All questionnaires were pre-tested (piloted) outside the study area.

3.6.3 Observations

The researcher conducted observations in addition to the in-depth interviews to provide a means of triangulating the data gleaned from the in-depth interviews, and to gain additional information that did not get in the interviews. One of the first things that the researcher must do when beginning fieldwork is to clarify what a role he/she will take on as an observer (Chambliss and Schutt 2006, 169). The researcher identifies the role and develops a checklist base on her role. Entering the field is a crucial stage in fieldwork and the researcher must therefore pay much attention and consideration to this stage (Chambliss and Schutt 2006, 172). The researcher was familiar with field environment and before going to the field the researcher meets with regional and district health management teams as a preparation stage.

3.7 Data analysis

3.7.1 Qualitative

The transcription of each interview was carried out within a few days after the interview was conducted. In the process of analyzing the data the researcher primarily used grounded theory, which is mainly inductive. The purpose is to generate theory based on the collected data (Chambliss and Schutt 2006, 218). An inductive approach allows themes to emerge from the collected data (Chambliss and Schutt 2006, 185). Through in-depth interviews and observations the researcher generated much data. In analysis process the researcher worked through all of the interviews and identified codes. Continued this process until no new codes emerged then placed these codes within main categories. Then discussed and analyzed each category and compared with the notes from observations. In the analysis process of the observation notes the researcher identified key themes and compared them with the information from the interviews. Then identified possible aberrant information to see if there were differences in what people said and actually did in the field. The researcher continued with this process until no new themes emerged.

3.7.2 Quantitative

Data analysis was done using excel software, mechanism was put in place to ensure quality control. Descriptive statistics such as means, standard deviation and proportions were calculated. Frequency tables and charts were generalized for relevant variables. All extracted data were dissociated from personal identifiers and remained anonymous and unlinked throughout the study.

3.8 Validity and reliability

At the end of each day all the forms were reviewed by the interviewer and mistakes were immediately corrected.

3.9 Ethical consideration

The researcher is affiliated with both the Ritsumeikan Research Centre for Asia Pacific Studies (RCAPS) and Tanzania National Institute for Medical Research (NIMR). The letter of approval from RCAPS and research proposal was submitted to Tanzania's NIMR for approval. Also the partner organization Clinton Health Access Initiative in collaboration with the Ministry of Health and Social Welfare authorized the researcher with an introductory letter. Informed consent was obtained from each participant.

CHAPTER FOUR

FINDING AND DISCUSSION

4.1 Impact of Pima on HIV case management

When Pima was not available a total number of 1105 patients were enrolled at the 11 sites (see table 4.1). Of these 407 were selected based on inclusion criteria to meet the sample size. When Pima was available a total of 996 were enrolled at the 11 sites. Of these patients 407 were selected based on inclusion criteria. There was no difference in age, sex between the participants before and after the introduction of point of care testing as per table 4.1.

Table 4.1: Study participants before and after the introduction of point-of care CD4 testing at primary health clinics in Tanzania

	Pre POC CD4 test	Post- POC CD4 test
All patients Enrolled	**1105**	996
Kabuku	102	96
Kisiju	96	112
Kitomanga	92	86
Mahuta	98	72
Mchichira	106	103
Mkamba	96	96
Mkuzi	109	98
Mwera	94	86
Nanyamba	105	83

Rutamba	95	76
Nanguruwe	112	88
Study participants	**407**	**407**
Kabuku	37	37
Kisiju	37	37
Kitomanga	37	37
Mahuta	37	37
Mchichira	37	37
Mkamba	37	37
Mkuzi	37	37
Mwera	37	37
Nanyamba	37	37
Rutamba	37	37
Nanguruwe	37	37
Younger than 18 years of age	29	33
Female %	310	280

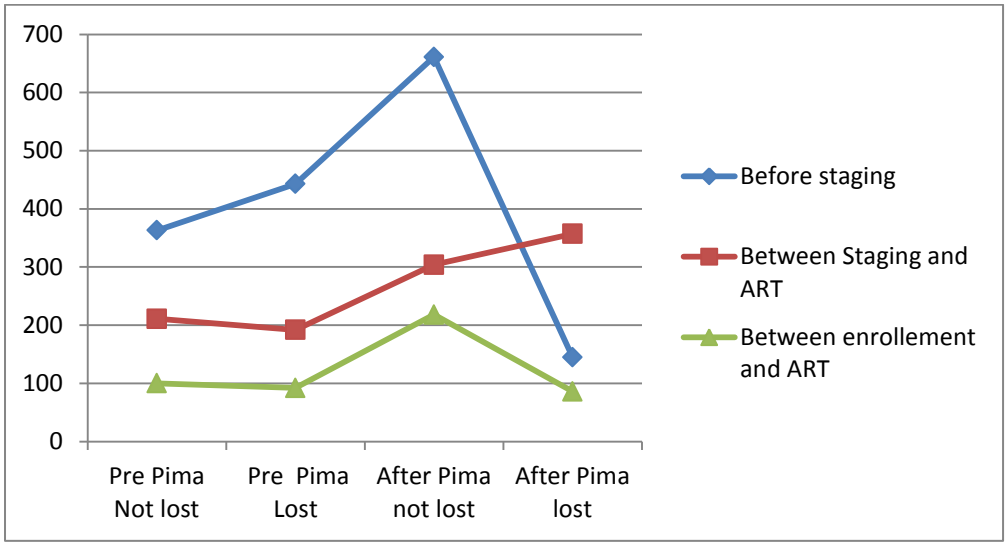
Source: Author

4.1.1 Lost to follow before staging, between staging and ART initiation and between enrolment and ART initiation

The introduction of POC CD4 testing helped to reduce lost to follow up. Total losses between enrolment and antiretroviral therapy initiation dropped from 90% to 73%.

This effect was due mainly to a reduction in loss to follow-up before completion of CD4 staging, which decreased from 55% to 18%. Loss to follow up between staging and antiretroviral therapy initiation for treatment eligible patients did not change after the introduction of point of care CD4 testing.

Figure 4.1: Lost to follow before staging, between staging and ART initiation and between enrolment and ART initiation



Source: Author

4.1.2 The effect of point of care CD4 testing on the rate of CD4 count at initiation and time to antiretroviral therapy initiation

On average, patients' CD4 count at first CD4 test raised 24.7 cells after the implementation of Pima, from an average of 255.6 cells/μL to 280.3 cells/μL of blood. This can be attributed largely to HIV patients being tested closer to diagnosis, and therefore earlier in their disease progression.

This study found substantial differences in timing of ART initiation before and after the implementation of Pima. On average, clinics saved 77 days in time between diagnosis and CD4 testing after the introduction of Pima testing, reducing time by

86%, to 12 days from an average of nearly three months (89 days) prior to Pima implementation. In total, averages of 63 days were saved in time between diagnosis and initiation onto ART, with 22 days saved in time between eligibility for and initiation onto ART. Time between diagnosis and initiation onto ART fell from 88 days to 25 days after the implementation of Pima. Time between eligibility and initiation fell from 33 days to 11 days.

While the majority of clinics reduced time and increased CD4 count at initiation, there were outliers in each category. Clinics in this category included Rutamba, Kitomanga, Mwera, and Kisuju who all reduced their Time to first CD4 test by more than 90%. Rutamba, and Mkuzi also reduced their ART Time by more than 90%. Though it is hard to quantify, clinics that were judged to have consistence supply of Pima logistics and daily provision of Pima services reduce their times by upwards of 80%. In some clinics, CD4 count at initiation fell after the implementation of Pima, which the researcher speculate may be due to a backlog of patients needing CD4 tests, inconsistence supply of Pima suppliers, breakdown of Pima machine and changing of schedule for providing Pima services from daily to once per week. Hence the disease status of those patients has progressed in the absence of a CD4.

Table 4.2: Clinical Outcomes Before and After Introduction of Pima, Site by Site

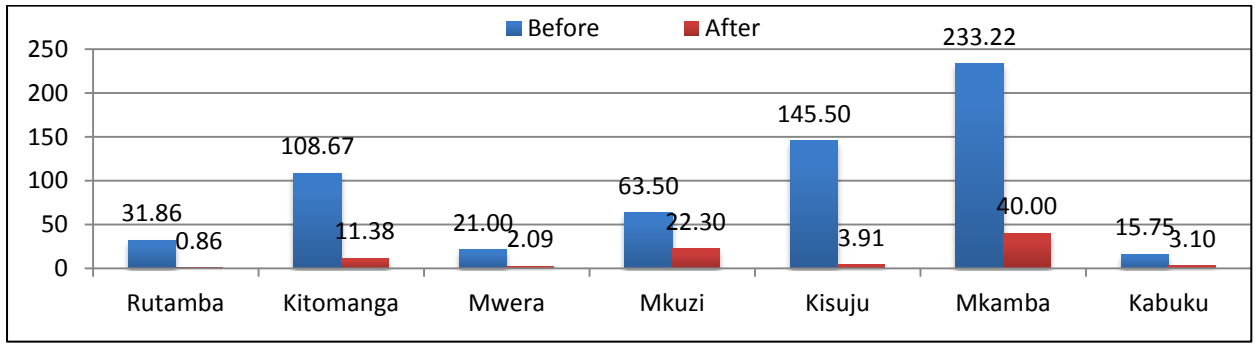
Region	Clinic	CD4 Count at Initiation		TAT to CD4 Test		TAT from Eligibility for to Initiation on ART		TAT from HIV Diagnosis to ART Initiation	
		Before	After	Before	After	Before	After	Before	After
Mtwara	Nanyamba	158.50	0	0	0	23.08	3.00	117.00	28.47
	Nanguwere	356.60	233.91	0	0	38.25	20.75	55.75	55.38
	Mchichira	402.00	356.67	0	0	30.50	13.33	84.50	13.33
	Mahuta	119.875	126.88	0	0	33.44	1.33	100.44	25.89
Lindi	Rutamba	303.75	425.33	31.86	0.86	4.00	0.00	30.00	0.00
	Kitomanga	183.56	257.29	108.67	11.38	28.67	23.00	197.44	27.29
Tanga	Mwera	161.50	263.36	21.00	2.09	26.50	9.75	45.75	12.00
	Mkuzi	150.33	328.60	63.50	22.30	102.33	4.20	112.00	23.57
	Kisuju	375.56	278.09	145.50	3.91	47.25	18.38	58.40	20.63
Pwani	Mkamba	187.78	236.60	233.22	40.00	26.56	18.43	149.00	55.29
	Kabuku	412.25	296.20	15.75	3.10	4.00	5.40	13.00	10.60

Source: Author

Table 4.3: Clinical Outcomes before and after Introduction of Pima, Averages (Source: Author)

Indicator		Before	After	% Change
Pre- Initiation	CD4 Count at First Test	255.61	280.29	19.39%
	Time between diagnosis to first CD4 test	88.50	11.95	-86.04%
Post- Initiation	Time between staging to ART initiation	33.14	10.69	-56.42%
	Time between Diagnosis to Initiation	87.57	24.77	-65.43%

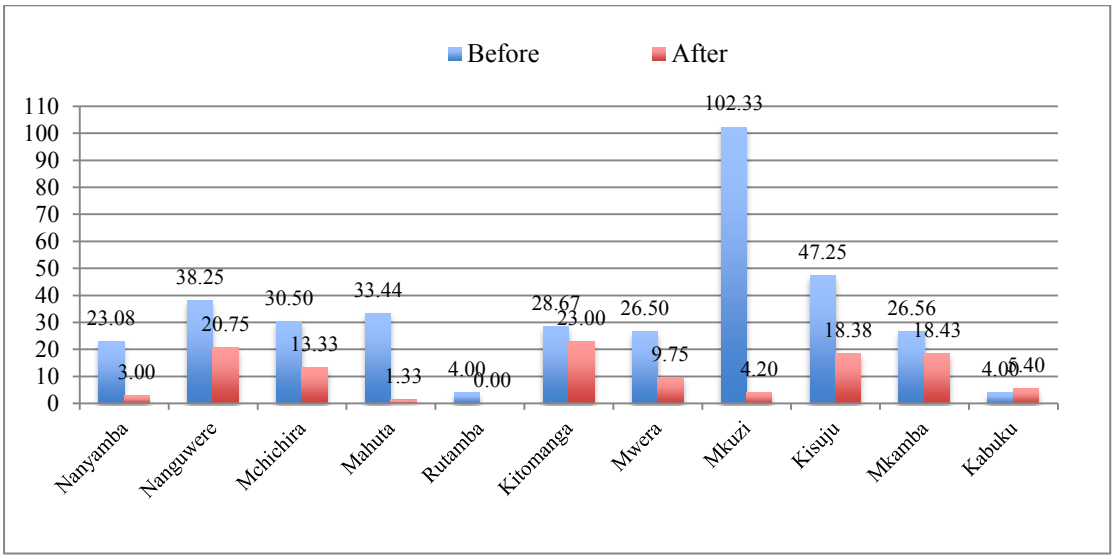
Figure 4.2: Time between diagnosis and first CD4 test before and after Pima (Source: Author)



[2]

[2] Time to CD4 test was not available in Mtwara clinics (Nanyamba, Nanguwere, Mchichira & Mahuta), due to poor record keeping

Figure 4.3: Time between eligibility for and initiation onto ART

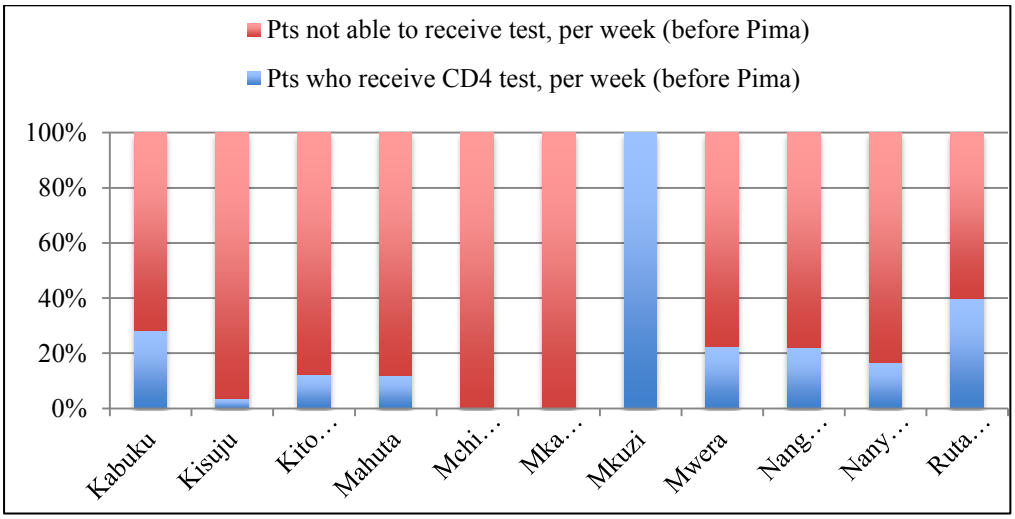


Source: Author

4.1.3 Impact of Point of care on patient schedule to receive CD4 testing

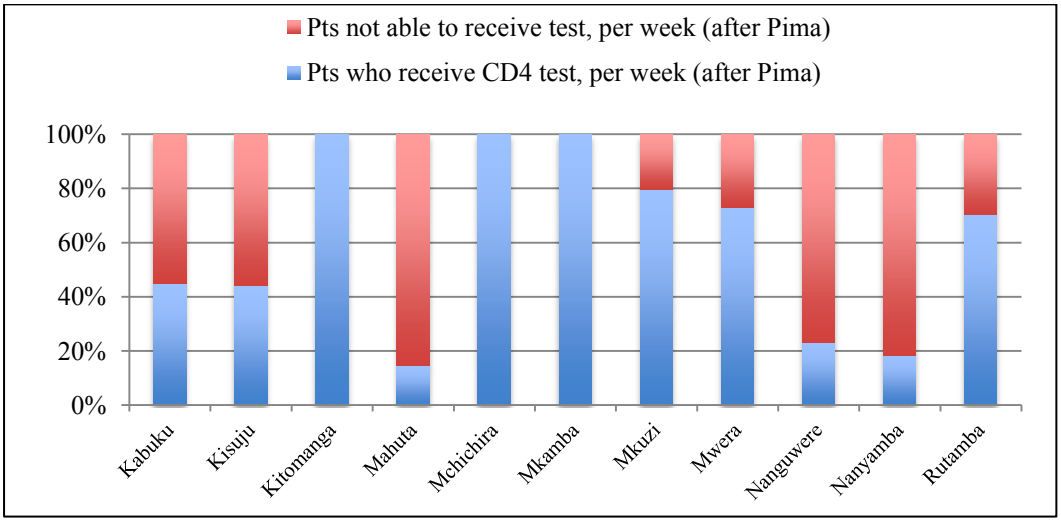
Before the introduction of Pima, clinics had scheduled patients for CD4 testing twice per month while some once per month. After the introduction of Pima there was a drastic change in this schedule. There was still a fair amount of variation. Almost 50% of the clinics had testing available throughout the week including weekends. While another 50% followed the clinics days' timetable of testing twice per week which resulted into attrition. This finding raises major concerns.

Figure 4.4: CD4 Testing as a share of need, before Pima (Source: Author)



Source: Author

Figure 4.5: CD4 Testing as a share of need, After Pima (Source: Author)



Source: Author

On average, clinics reduced the number of patients turned away each week by 50.98%, from 76.24% to 25.26%. Weekly CD4 testing need was calculated based on the number of active pre-ART and ART-initiated patients, and WHO testing guidelines. Some clinics exceeded the projected weekly need, as seen on the graphs below. These clinics may have a CD4 testing backlog from sample transport or other logistical challenges. Though clinics expanded CD4

testing, after Pima implementation, on average, clinics still only met 74.76% of CD4 testing need. This may be due to insufficient patient demand or loss to follow up due to capacity limit (use of previous system of scheduling the patient and devise challenges such as stock out and breakdown).

Also clinics increased the volume of patients tested per month by an average of 244.71% over their pre-Pima volumes. The specific results can be seen below.

Table 4.4: Average patients tested per month

	Pts who need testing per month	Avg pts tested per month, pre-Pima	Total pts tested in sample period (2011)	Avg pts tested per month, post Pima	Total pts tested in sample period (2012)	Increase in % of patients tested
Kabuku	133.08	37.80	189	59.80	299	58.20%
Kisuju	54.46	2.00	10	24.00	120	1100.00%
Kitomanga	45.54	5.60	28	62.60	313	1017.86%
Mahuta	118.15	14.00	70	17.40	87	24.29%
Mchichira	4.00	0.00	0	5.60	28	100.00%

Mkamba	23.08	0.00	0	40.60	203	100.00%
Mkuzi	38.62	40.00	0	30.80	154	-23.00%
Mwera	27.38	6.20	31	20.00	100	222.58%
Nanguwere	56.77	12.60	63	13.20	66	4.76%
Nanyamba	82.92	13.80	39	15.40	77	11.59%
Rutamba	44.92	18.00	90	31.60	158	75.56%

Source: Author

4.1.4 Effect of Point of care on waiting time

When Pima is available the standard waiting time should be 20-30 minutes. Before Pima introduced the interview with the staff revealed that testing was done twice per month and patients had to wait almost more than 8 weeks to get their results. This scenario changed, after Pima, results were now returned in 30 minutes in most cases. There were instances when for some social reasons patients left immediately after blood collection, in this case the delay in giving the feedback was less than 24 hours. Additionally due to increase volume of patients there were instances results were given the next day. Overall the waiting time after Pima did not exceed 24 hours.

4.1.5 Impact of POC CD4 testing on gender

The number of women tested is more than 60% higher than men; this may be due to higher number of Tanzania women with HIV than their male counterparts (MoHSW, 2007, 2). Health workers and clients we spoke with at the facilities reported that positive male involvement was an important motivating factor for participation in the different services. At the majority of sites we visited, there were low rates of male participation in the CD4 testing programs, while other facilities had a higher number of men participating. We questioned health workers at the sites with high male involvement regarding what had made the difference in motivating men to participate in the services. According to these interviewees, the most important factor motivating men to participate in the services was previous education and information, and understanding regarding the program among men. Suzan said, "Men that get proper education come for testing". The interviewees emphasized that the men needed information and motivation specifically aimed at men, such as books, brochures and art groups. Some health workers at facilities that had previously educated men when they visited the facilities believed that these men passed the learned information on when they met other men in the streets. However, most of the health education was given at the facilities, and as previously discussed; most men did not regularly visit the facilities so reaching these men with health information constituted a challenge.

Other possible reasons for low male involvement in HIV related services. Health workers at one hospital told us that only a few men came in for HIV testing because they feared that it may take much time and they could not afford to lose a day of work. While others said that few men knew their HIV status because they did not understand why they had to go for testing. Several others told us that some men believed that they would have the same results of an HIV test as their wives and therefore felt that they did not need to be tested themselves. One interviewee indicated that men sometimes refused to accept the results of a positive

HIV test. Neha was of the opinion that men did not come for testing because they were afraid: “They [the men] are mainly afraid because they have many partners.”

The interviewees described initiating different types of interventions in order to attract men and encourage them to be more involved in the HIV related services. The health care workers told that most of the women were told to bring their husbands; some were providing an invitation letter.

When we asked clients and community members about suggestions how to effectively reach more men, some people mentioned going from home to home providing education and information, while others suggested the use of mobile services (services that are offered outside the health facilities, e.g., in the villages or in people's homes). Benjamin expressed his suggestions as: “Men need motivation. Women that go to the clinic should motivate them to go. Also NGOs and nurses should motivate men to go. They should go from house to house and teach the men about the importance.

4.2 Barriers to the implementation of Pima

4.2.1 Delay due to Chemistry and Haematology test

Clinicians reported that though POC CD4 testing relieved some delays in ART initiation, a bottleneck remained due to the need for laboratory-based baseline testing. For initiation of ARVs, three sets of laboratory results are mandatory i.e. CD4, Creatinine and hemoglobin. In the study site only 1 Health centre namely Rutamba had Point of Care for both CD4, Creatinine and Hemoglobin test and the results were available and treatment was initiated timely. In other site point of care for creatinine test were not available, they are relying on sample transportation thus treatment initiation was delayed. Clinicians who want to order cretinine test faced with challenges of not only transporting the blood specimen to and off site laboratory but also getting the result back to the patient. They had many additional challenges

such as blood specimen being damaged or unsuitable for testing as the result of delays in sample reaching to the district laboratory, losing of the result due to unclear system. Patients are often lost due to repeated visits to the health facilities as well as delays in returning results Hence 90% of the clinics initiated ARVs without laboratory result for creatinine. This finding raises major concerns.

Figure 4.6: Total testing volumes across all sites, before the introduction of Pima (**Source:** Author)

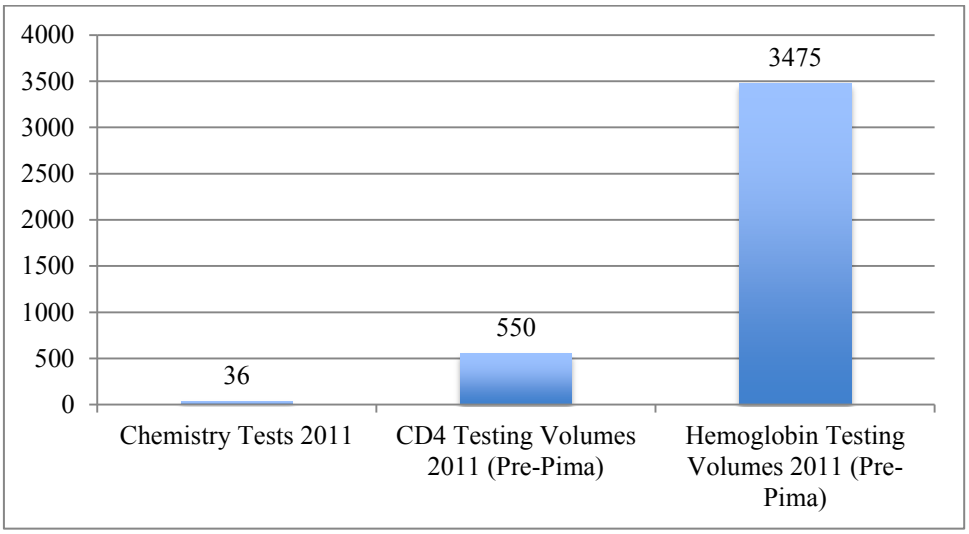
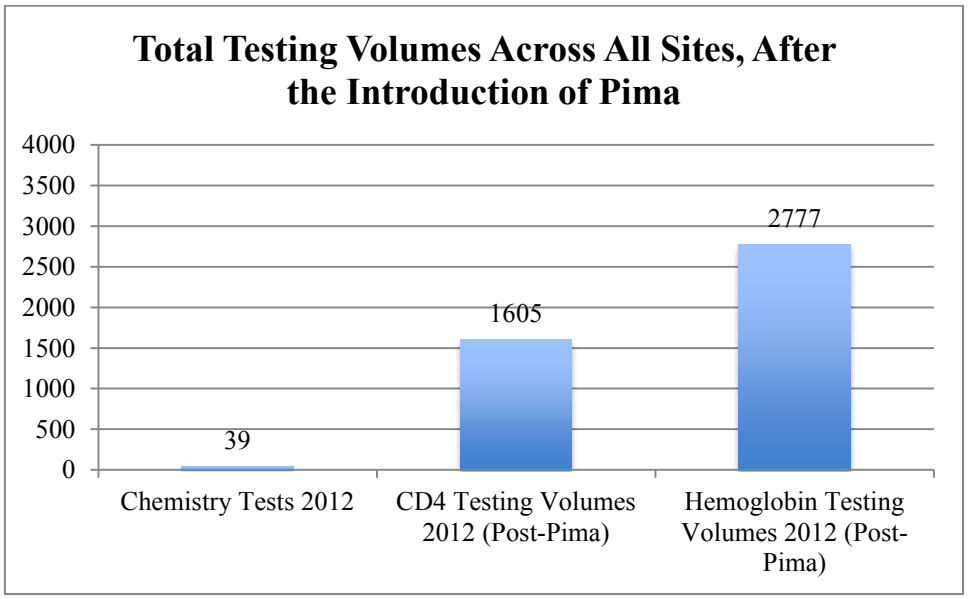


Figure 4.7: Total testing volumes across all sites, after the introduction of Pima (**Source:** Author)



4.2.2 Staff Shortage

A majority of the clinicians and clients reported staff shortage as a big problem, as Bakari clearly expressed, “Shortage of staff is a problem, an important problem.” Many of the facilities we visited only had a few health workers employed. The study observe shortage of staff in term of numbers and skills, more than 90% of the clinic visited does not have laboratory technician. Laboratory assistants who are available are medical attendants who were recruited through on-the-job training. The health workers were supposed to complete many different tasks such as providing different services, providing health education, attending follow-up appointments at the patient’s homes, cleaning the facility and fetching water. As Zuwena stated, “We need more staff, so we can be able to follow-up the patients. There is a nurse assistant here, but she can’t do follow ups because of other activities.” Some facilities had expert patients or volunteers helping, but most health workers said that there were too few volunteers and community health care providers to do follow-ups of patients and provide health education. Some facilities we visited had long lines of people waiting outside and only one or two health workers present. As Anna stated, “We are only three health workers and lots of patients, so they have to wait a long time to get the services.” People we spoke with reported that some people faced problems spending so much time waiting at the facility, as they had various tasks waiting at home. Most people reported that they were paid per day’s work, and that many could not afford to go to the facility when it was so time consuming. Many of the health workers we interviewed indicated that they were unmotivated because they often had to work overtime with no compensation. One female health worker at a health centre, Silvia, said that she sometimes worked for three days straight without any time to rest or sleep, and with no overtime payment. They emphasized that with such a shortage of staff their working conditions were arduous and they became

tired of having to bear so much responsibility alone. Mohamad said that poor management of health workers was also a problem which was caused by shortage of staff and that they often did not have the chance to follow up with workers. Through conversations and interviews with these health workers and through our observations of their work, the study found that none of the health workers talked to were pleased with his/her job situation.

4.2.3 Distance and transportation

The visited regions are expansive and many people live far from the health facilities. The study found that the clinics visited are not offering mobile clinic services due to lack of transport. At some facilities, results from CD4 tests took some time before they were ready. This meant that the persons tested had to come back to the facility another day to get the result. In such case the time aspect can be a challenge, as people reported that this long waiting period was a reason patients sometimes did not return to the facility to receive the result for their CD4 test. The study also found that some of the health care workers are sending patients away for non-same day testing. Hence the need to visit the facility several times was frequently mentioned as a barrier, and the different obstacles to accessing the facilities may lead to discontinuance of services when extra visits are required.

However, the study found that only a few areas had available buses, and only a minority of people had available vehicles, including bicycles. To access the health facilities most people's only option was to walk. Lack of transportation and far distances were two important factors that may have affected the decision to use Pima services. The study found that spending such amounts of time in accessing the facilities created other challenges in a client's everyday life including what to do with the children, the possibility of losing a day of work and income, and the fact that many people had other tasks they needed to prioritize at home. Some emphasized that transportation was especially difficult in the rainy season when

the roads flood and become difficult to travel on. Mwajuma explained a consequence of this reality: “In the rainy season, they are not affording to go to the facility. For the facilities which are not offered creatinine testing patients were referred to other facilities which were farther away; this could have been a potential factor for why they did go for testing. A few health workers said that they had cars available for transport, and stated the offered transportation services acted as a motivating factor for patients. Several health workers, however, expressed a need for means of transportation for mobile clinics. Some of the facilities that had available vehicles reported frequent lack of funding for fuel and maintenance of the vehicle**.** The study observes an example for this: a facility had been provided with several motorbikes in order to reach out to patients in need, however, these were not in use due to the lack of funding for maintenance and fuel.

As distance could be a hindrance to seeking services for those who lived far from their local health facility, living within close proximity of the facility was reported as a motivating factor to use the services provided. As one female dispensary health worker, Naomi, suggested, “Most people who use the clinic live close to it. Also health care workers are unable to follow patients due to workload at the clinic, distance and lack of the transport, so most of clients who lost to follow when Pima was not available have not been traced and returned back to the facilities for continuation of services.

4.2.4 Lack of space

The researcher observed and was informed by different people that for a majority of facilities, lack of space for privacy were a problem. Paul stated, “It is hard to give the services privately because of lack of space.” The study found that some facilities did not have a separate room for testing or for giving test results. Some of the people reported that the lack of privacy made the facility undesirable for seeking services. From observation the researcher discovered that

CD4 testing at the point of care created a risk of involuntary disclosure due to the lack of privacy space. Interventions that contributed to privacy was said to motivate the uptake of services. As we continue to introduce new point of care devices we should also think of multifunction devices to reduce space.

4.2.5 Training and Skill

The initial training from Both Region was held by the Trainers of Trainees from the Ministry of Health and Social welfare, CHAI and RHMT at their regions. One of their trainers noted a lot of variation between what the participants knew from before. Some were fast, some had inquiries. The training was aimed to a specific department; about 2 people from each clinic were trained one from Care and Treatment clinic and the other one from Laboratory. According to the trainer this was done to ensure the device can be operated by both lab and CTC staff to avoid long cure, 80% of the trained staff are operating the device but when they are not around the device are operated by other staff who have been learn from trained staff. Trainers generally reported that they were satisfied with the content and amount of training, but error reports, failure to order Pima suppliers, unclear with the plan preventive maintenance issues, poor recording of CD4 logbook and unclear information about Pima revealed that many providers did not achieve the training objective and hence incorrectly using of Pima device. See Appendix 1.4 for complete description of training protocol from National Implementation Plan for POC CD4 Testing.

4.2.6 Use of Pima

Most of the health staffs that are using Pima are medical attendants. At each clinic, error reports and testing volumes were extracted from the Pima device using a USB stick. From this information, the researcher was able to assess the frequency and types of errors. On average, 21.5% of Pima tests performed had an error. The clinic with the highest error rate

had errors in 40% of tests performed. The best performing clinic had errors in only 2% of tests. 50% of errors occurred in May, the month after Pima placement. The next-highest months for errors were August and September, with 16.77% of errors in each. Some clinics experienced a stock out of controls and reagents in August and September; the lower error rates in these months may be due to lower testing volumes, rather than improvement in operator skills. Among the error occurred in August and September, error rate was 6.5 among sites that used venous blood, 5.5 among sites that alternate between finger prick and venous blood and 4.8 among sites that use finger prick blood sample.

4.2.7 Supply Chain Management

Of the eleven sites visited, six reported stock challenges, and four additional sites reported stock outs of Pima supplies (controls and reagents). None of the sites visited were able to show us ordering forms for Pima supplies; most of the clinics had supplies delivered to them ("push system") from the regional or district hospital, Medical Department store or local partners. The pushing system has disadvantages as the facility are receiving the supplier's which are not of their choice and in less or additional amount. In Tanga Region the Medical Department Store (MSD) supply Pima supplies through pushing system and they end up supplying to the sites which they don't have Pima machine. 90% of the clinics are using the old form for request and ordering (R&R) which did not integrate Pima suppliers. Logistics/supply chain was a challenge at 100% of facilities- all facilities had either not placed an order for reagent or placed an order that went unfulfilled. Need to improve the communication capabilities between facilities and districts authority and MSD for reliable supply chain.

4.2.8 Electricity supply (inconsistent electrical and mechanical services)

Of the clinics surveyed, eight relied on solar power, and reported rainy season outages that constrained testing capacity. The remaining clinics (Mahuta, Mkuzi, and Kabuka) had access to grid power, and reported power rationing. Among 11 sites 8 sites reported having problem with Pima battery, it does not last long and breakdown of the machine.

4.2.9 Security

Security is poor in the entire clinic visited that why most of Pima machine are located in the laboratory and not at the entry point like VCT, PMTCT and CTC due to lack of security. The study observes poor security in most of the entry point such not having doors, windows, locks etc. In future these things needs to be taken into account as they will assist to have a good patient flow and reduced lost follow up between diagnosis and enrolment.

4.2.10 Cost effectiveness

As we are providing Point of Care for CD4 testing, cost control is very important for efficiency delivery of the services. Current the implementation is not cost effective due to the fact that the clinics needs high control and supervisions, they are not able to manage on their own, frequently supervision and mentoring is needed for capacity building, the devices has been placed in the clinics with low patients volume although one of the criteria for implementation was to the sites with high patients volume, therefore sample ratio is small which makes them to have unused expired suppliers. Though clinics expanded CD4 testing, after Pima implementation, on average, clinics still only met 74.76% of CD4 testing need. This limited opportunity for economic of scale due to fixed test volumes per unit of infrastructure and staff.

Other findings

i. More factors impact Pima utilization and the impact on CD4 access than just patient volumes.

ii. Clinics days: Facilities with more than 2 clinic days per week increase testing rate than those with one or two clinic days.

iii. Facility leadership: having strong leadership improve documentation rate over 90% also the Pima training help to improve documentation by more than 80%.

iv. The facilities using finger prick increases testing rate while those using venous blood decrease by 5%.

v. Documentation of the CD4 result improved when compares with the period before the introduction of Pima as their documentation were very poor with incorrect and incomplete filling of the logbook and most of the clinics they were not available.

vi. 80% of the facilities using venous blood with limited of the same day results which eliminating the point of care advantage.

vii. Utilization of the machine within was differ from one site to another due to machine breakdown, scheduling of patients, inconsistence of power supply and inconsistence supply of Pima supplies.

viii. Supervision, feedback and support to the health facilities.

ix. In some facilities the study found poor communication and coordination among entry points.

x. Most of the facilities we found that they run control but the program do not monitor the quality of the clinic with high testing rate.

xi. The program needs training of many operators due to high staff turnover.

xii. In general staffs are committed as 80% of the trained staffs are operating the device.

Contextual Observations

There were many factors that influenced the use of the Pima in Tanzania, and impacted the results of the study. Successful use of the Pima device and effective implementation relies upon well-trained nurses and clinicians, timely delivery of supplies, reliable power and infrastructure, and leadership from local authorities. Below are some observations on how these factors interacted and the impact they had upon findings.

	Category	Issue	Impact
Infrastructure	Facility Infrastructure	Power sources and reliability were not assessed prior to the placement of a Pima device.	Long testing outages due to power instability were common, with several clinics reporting outages of one month or more due to power.[3]
	Human Resources	Only 2 clinicians were trained per site; all others trained through on job training	Staff shortage and turnover, majority who are working has been trained through on job training, leads to miscommunication about the correct use of Pima device. High error rates (up to 40%) resulted.
Communication	District Level	Inconsistent messaging from district officials and local partners on the correct use of Pima, and the accuracy of the device and lack of support from regional and district authority	One clinic reported that the DMO felt the Pima results were inaccurate, and told the clinic not to use these results for clinical decision-making. Many other clinics reported confusion over whether to use finger sticks or venous blood draws and patient scheduling.
Supply Chain Mgmt	PIMA—cartridge Ordering	Inconsistent or incorrect ordering of supplies including reagents, cartridges, and finger stick kits. Many clinics had never ordered supplies, and did not know how.	Many clinics stocked out of Pima supplies as soon as their initial supplies ran out, usually in July or August. Some clinics had never re-stocked after the initial supplies ran out, and therefore had only used their Pima device for 6 weeks. Currently they are using pushing system to receive the suppliers.

[3] Though solar chargers are available for the Pima device, none of the clinics we visited reported receiving one.

	Category	Issue	Impact
	PIMA—cartridge delivery	Push system from district to clinics	Clinics reliant on local officials to deliver supplies. Delays at district or regional level led to stock outs.
	Forecasting	Clinics do not order their own supplies and do not forecast their need based on consumption.	Testing volumes fluctuated highly from month to month due to availability of supplies, and clinics did not correctly assess their consumption. Stock outs resulted at four clinics; with six others reporting stock challenges for Pima supplies.
Testing Procedures	Sample Transport	Many clinics profited from the sample transport system.	Some clinics maintained the sample transport system and continued to send CD4 samples to the district hospitals after the placement of Pima devices.
	Chemistry Tests	Many clinics were not performing any chemistry or hematology testing.	Patients are not being properly monitored for side effects of ART medications.
	POC Hematology	Stock outs and power failures prevented POC Hb (Hemocue) machines from functioning effectively.	Patients are not receiving Hb tests prior to initiation on ART.
	PPM	Staff do not have any clue regarding the plan preventive maintenance, when they had a breakdown they are just staying with the machine without taking any action	Services are not provided and patient are turned away for next visit

Source: Author

4.3 Discussion of Research Findings:

4.3.1 Patient retention

The overall evaluation of Pima introduction in the study sites reveals a positive contribution. This study shows that the positive impact of Pima is related to many factors. The study found positive impact on attrition rate. The proportion of patients lost to follow-up before completion of CD4 staging decreased from 55% to 18%. Total losses between enrolment and antiretroviral therapy initiation dropped from 90% to 73%. Time between diagnosis and initiation onto ART fell from 88 days to 25 days the improvement may be due to the reduction of time taken to stage patient from nearly 3 month to 12 days, which reduce the opportunities for lost to follow up and increase the number of treatment eligible patients who progressed to treatment. Similar outcome were shown Jani *et al*. (2011) that after the introduction of POC CD4 testing the proportion of patients loss to follow up before completion of CD4 dropped from 57% to 21% and loss to follow up before initiation of ARVs fell from 64% to 33% and the proportion of patients initiating ART increased from 12% to 22%. The median time from enrolment to antiretroviral therapy initiation reduced from 48 days to 20 days primarily because of reduction in the median time taken to complete CD4 staging, which decreased from 32 days to 3.Lost to follow up between staging and ART initiation did not change this may due lack of laboratory-based baseline testing for creatinine and hemoglobin. It may also be due to lack of transport or time to visit the clinic to attend 3 ART counselling session before initiation. Further research is needed to investigate the cause.

4.3.2 Time to initiate ARVs and CD4 counts closer to 350

This study also demonstrates a two way benefit- the substantial differences in timing of ART initiation before and after the implementation of Pima and proves that POC CD4 testing enable more patients to initiate ART with cell counts closer to 350. This can be attributed

largely to HIV patients being tested closer to diagnosis, and therefore earlier in their disease progression. Current WHO ART guidelines recommend initiation onto ART for all patients with a CD4 cell count at or below 350 cells per μL. However, a recent review of eight sub-Saharan African countries found that median CD4 cell count at initiation was 136 cells per μL (Nash *et al*. 2011). POC CD4 testing may enable more patients to initiate ART with cell counts closer to 350 by increasing the number of patients who are successfully staged, and by decreasing LTFU prior to initiation onto ART (Jani *et al*. 2011). Constrained access to CD4 testing results in late initiation onto ART, which imposes costs on patients including additional morbidity and mortality, and poor treatment prognosis once initiated onto ART (Larson *et al*. 2010). Studies have shown that a low CD4 count (<100 cells/ μl) at initiation is a major predictor of HIV/AIDS mortality (Lawn *et al*. 2009& Lawn, *et al*. 2008). Immune system recovery after 3 years on ART is also positively correlated with a patient's CD4 cell count at initiation (Robbins *et al*. 2007).

4.3.3 Convenience and easiness to get tested

The questionnaire part of the study revealed that patients now had more satisfaction in terms of convenience and easiness to get tested. The same sentiments were expressed by health workers. Similar outcomes were shown by Zachariah R S. (2011) that POC CD4 testing remains a vital entry door to accessing ART, improving immediate decision making, patient management and referral, reduced visits, waiting time for patients and accessible to the rural community. This study also found that POC CD4 testing reduced waiting time and visits for patients. The expansion of POC testing therefore help to overcome logistical and geographic barriers to full-scale roll out of HIV treatment and care, increasing the number of patients on ART and reducing HIV-related morbidity and mortality.

4.3.4 Facilities Infrastructure

This study also reflects issues about infrastructure. The results indicate that a supportive infrastructure is very essential for Pima testing these supportive infrastructures include other support test like cretinine and hemoglobin, staff, sufficient training, reliable supply chain, quality assurance, space, and security, consistent electrical and mechanical service. Similar findings were shown by Peter T *et al*. (2008) that in planning to implement point of care services its crucial to consider some of the challenges the program might face especial in the rural clinics such as shortage of staffs, uncommitted staff, lack of space, security, inconsistent electrical and mechanical service, poor communication system, poor documentation of medical records, unreliable supply chain, high risk of unused expired supplies, fixed test volumes per unit of infrastructure and staff, training of many operator due to staff turnover and monitor of quality at clinics with high testing rate. Many of this challenges can be solved with a good strategy of implementation.Though significant improvements in clinical outcomes were observed after the introduction of the Pima device in Tanzania, these improvements were mitigated by implementation challenges including human resource shortages, inconsistent power, inconsistent supplies, insufficient knowledge on the use and maintenance of the Pima, and incorrect use of the device. Patient flow, or a good workflow is been control by the location of Pima machine. Currently most of the machines are located at the laboratories for security issues with few located at CTC. Most of the laboratories visited are far from the entry point and the patient had to cue for services. Having Pima machine at the entry point like VCT, CTC or PMTCT will maximize utilization of Pima device and reduce lost to follow up between diagnosis and enrolment which is also high in Tanzania**.** Serious supply chain issues exist at the clinic level. There was a generally poor understanding of the ordering process for obtaining new reagents and cartridges for the Pima device, with many clinics reporting that they had never placed an order for Pima supplies. Also the study

found that there is serious shortage of ARV drugs and ceprin. The study from Northern Tanzania found that the health facilities often lacked basic equipment and medication (Plummer *et al*. 2006, 463). Harms *et al*. (2005, 263), found that together with fear, the most frequently reported cause for not taking HIV tests was lack of treatment, both for men and women. Other studies have also found a serious shortage of drugs for different purposes (Mrisho *et al*. 2008, 674-675; Schellenberg *et al*. 2008).

4.3.5 Sub optimal utilization of Pima

The observation part of the study showed that several clinics are using the Pima in a way that does not take full advantage of the benefits of POC CD4 testing, including sending patients away for non-same day testing and using venous blood draws. Most of the facilities visited are not capable of using finger-prick blood sample. According to Pima SOP test operators should be trained on both venous blood and finger-prick blood sample collection, as both are viable options for POC CD4 testing and may be appropriate under different circumstances. Proper training on sample collection of both venous and finger prick blood sample resulted to reliability of CD4 count by Pima, this will also reduced errors identified. Adequate training for correct use of finger prick blood sample is highly needed for proper collection of finger prick to avoid multiple pricks (Herbert *et al*, 2012; Mtapuri Zinyowera *et al*, 2010; Kafufu Fred, 2010). Without the improvement of finger prick blood collection the reliability of the CD4 count by Pima analyzer is questionable (Thakar *et al*, 2012). Pima performance is highly correlated when using venous blood but if the finger prick blood sample are correctly collected and tested there is also high correlated (Glencross *et al*., 2012). In this study high rate of error observed in clinics used venous blood rather than finder pricks which means the perfomance depend on capability of staff in collecting both venous and finger prick blood sample.

4.3.6 Health worker constraints

Also the observation part of the study showed that most of clinics the device are operated by Laboratory attendant or nurse assistant who has been train through on job training by other staff. This situation is due to staff shortage in term of number and skills including staff turnover. According to Pima SOP in the event that a test operator is transferred to another facility and a new operator needs to be trained, this training should be conducted only by official trainers who have received the TOT module from the supplier, rather than one operator training another. Studies from southern Tanzania found that staff shortage was common in this area (Schellenberg *et al* 2008; Mrisho *et al*. 2009. Simba *et al*. (2010, 25) state in their article, that Tanzania had a staff gap of 33% in the health workforce. The study showed variation in the staff workload among health providers at various facilities. The workload at hospitals was lower than the workload for health providers in primary health care facilities. This study also experienced shortage of staff at several of the facilities visited. Almost all interviewees stated that they needed more human resources to be able to take care of all the patients, in addition to all the different tasks they had at the facility. We found that staff shortages created challenges in several ways: not having enough people to attend to all the patients that were in need of services; not having enough trained staff led to decreased quality of the services; the shortage of staff created a pressure for the existing health workers due to higher workload; and health workers felt unmotivated. As in accordance with the broader literature, many of the health workers reported a lack of motivation in their work. The reasons given for these feelings included overtime hours without compensation, feeling too much responsibility and not enjoying their work. As there were many facilities with only a few health workers employed, most facilities had massive amounts of work to complete each day. As most of the Lindi region is rural area, the majority of health workers lived close to the facility where they work, and many of them were on duty 24 hours per day. As other

studies also found, our data indicate that these feelings of discomfort and unhappiness could have had a negative impact upon their performance as health workers.

4.3.7 Mobile clinics (outreach)

The questionnaire part of the study revealed that clinics are not conducting outreach/ mobile clinics to the nearby community or clinic without Pima due to lack of transport and funding for fuel. Some of the clinics that had available vehicles reported frequent lack of funding for fuel and maintenance of the vehicle**.** The study observes an example for this: a facility had been provided with several motorbikes in order to reach out to patients in need, however, these were not in use due to the lack of funding for maintenance and fuel. Currently clinic with Pima act as point of referral which limit the coverage and uptake.

Several previous studies have explored distance from the health facility as a barrier for uptake of health services (Myer and Harrison 2003, 268-270; Van Eijk *et al*. 2006; Mrisho *et al*. 2007, 863+870; Schellenberg *et al*. 2008, Creek *et al*. 2009, 357; Mrisho *et al*. 2009). Additionally, lack of reliable transport is described in other studies from the area as a problem (Mrisho *et al*. 2008, 675). (Mrisho *et al* 2007, 863) write that distance and transportation were two factors affecting the decision to go to the health facility. (Schellenberg *et al*. 2008) investigated both of these aspects and found that large distances and lack of transport was difficult in relation to referrals to other facilities. Patients reported there were poor infrastructure related to transport and roads in both regions long distance and lack of transport option was widely reported as obstacles for accessing health facilities. This clearly challenges uptake of CD4 testing. Most of the health workers spoke with said that the majority of people had to access the facilities by using bicycles or on foot, which underlines the impact of distance on the uptake of CD4 testing. Focus on mobile clinic is very crucial.

4.4 Study Limitation

These study findings are limited by poor record keeping at the clinic level, especially in the comparison (pre-Pima) period. Few clinics kept official/standard records of sample transport, CD4 tests, or chemistry tests.[4] Due to inconsistent record keeping at the clinic level, it was often difficult to follow a single patient through the treatment process for HIV. Patients identified at diagnosis often cannot be tracked through baseline CD4 tests, monitoring, and initiation onto ART. In other cases, patients could be tracked, but the records were not comprehensive. As in many resource-constrained settings, data availability and accuracy was poor. The study focuses on an area that is mainly rural, and impact of point of care CD4 testing in a more urban setting could turn out to be different. There are many differences between urban and rural settings e.g. people in urban settings may have easier access to information, and it may also be easier to attract human resources in these areas. Additionally, urban settings may have better infrastructure which can contribute to better accessibility of health services. To minimize error records with implausible error for example impossible dates were either corrected in consultation with the clinic or excluded from the specific analyses.

[4] With the exception of clinics in Pwani, who kept this information in standard MOHSW testing books. Pwani clinics nonetheless had very haphazard record keeping, and the books were incomplete.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 Summary of Findings

The results observed during the assessment demonstrate the potential for POC CD4 testing to improve clinical care, case identification, and timely treatment of HIV+ and ART-eligible patients in Tanzania. After the introduction of Pima 50% of the clinics had testing available throughout the week including weekends, which reduced the number of patients turned away each week from 76.24% to 25.26%. The rate of patient CD4 count at initiation increased from an average of 255.6 cells/μL to 280.3 cells/μL of blood, proportion of patients lost to follow-up before completion of CD4 staging decreased from 55% to18%. Total losses between enrolment and antiretroviral therapy initiation dropped from 90% to 73%. Time between diagnosis and initiation onto ART fell from 88 days to 25 days the improvement may be due to the reduction of time taken to stage patient from nearly 3 month to 12 days, increased the volume of patients stage per month by an average of 244.71% over their pre-Pima volumes and the proportion of patients initiated ART from 13% to 26%. Though significant improvements in clinical outcomes were observed after the introduction of the Pima device, these improvements were mitigated by implementation challenges including human resource shortages, inconsistent power supply, inconsistent supplies, insufficient knowledge on the use and maintenance of the Pima, and incorrect use of the device.

5.2 Overall conclusion

This study shows that there are numerous clinical benefits of the Pima device. It also shows that the current implementation of Pima in Tanzania is deficient leading to the benefit being compromised.

If a coherent strategy is developed for Pima rollout, including improved training, clear forecasting, provision of solar chargers, and mentoring, the Pima device can play a crucial role in improving HIV care and treatment in Tanzania. However, the current approach to implementing the Pima device has resulted in haphazard and patchy use of the Pima, with corresponding patient outcomes. It is important to engage local and national leaders, as well as partners and clinicians to devise and communicate a cohesive POC strategy moving forward. Support from the regional, district authorities and implementing partner is crucial for reliable supply chain.

5.3 Recommendations

Although this study shows numerous clinical benefits of the Pima device, the current implementation of Pima in Tanzania prevents these benefits from being fully realized. Therefore the devices must be deployed effectively. POC CD4 must be integrated into the existing health care system, with systems and policies in support of it.

The following factors will need to be considered when deploying POC CD4 testing:

a) ***Device Placement (within the clinic):*** Devices should be placed at strategic patient entry points to minimize the burden placed on patients to receive testing. These entry points include the CTC area, VCT area, maternity ward, and ANC clinic.

b) ***Device Placement (targeting clinics):*** Because POC CD4 testing provides an important benefit to ANC patients; clinics with high volumes of PMTCT patients should be targeted as high-priority areas for Pima expansion.

c) ***Availability of Space and Infrastructure:*** The Pima device can be operated from anywhere with a flat surface and space to place the reagents and consumables. Pima devices may also be deployed in other settings, including mobile outreach for rural villages and bedridden patients. Clinics, which need solar chargers, e.g. those with large outreach areas, should be identified, and units provided.

d) ***Clinic Workflow:*** It is important that staff at the facility understand patient flow and develops systems to optimize patient flow and referrals. This will inform device placement, balancing patient volumes with patient confidentiality.

e) ***Eligible Patients for POC CD4 Testing:*** POC CD4 testing should be available daily for all HIV clients, including newly diagnosed individuals, those in the CTC clinic receiving routine CD4 testing to determine eligibility for ART, and those on ART receiving routine immunological monitoring.

f) ***Human Resources:*** POC testing represents an increased burden of work for clinic-based staff. The staffing patterns and capabilities of clinics must be assessed prior to the placement of a Pima device, in order to ensure that the clinic will operate smoothly and tests will be completed on time.

5.3.1 POC Pipeline & Multiplex POC Testing Systems

Moving forward, POC CD4 testing should be part of a broader POC testing strategy. The benefits of POC testing detailed previously are particularly relevant to Tanzania, given the rural-based population and long travel time to district-level laboratories. These challenges would be largely alleviated by moving to a system with POC testing as the standard of care.

Currently, there is Hb, viral load, and creatinine POC tests on the market, enabling HIV monitoring and treatment to be conducted entirely at the clinic level. This presents an unprecedented opportunity to resolve existing logistical challenges and would improve patient care.

The POC market is rapidly diversifying beyond the Alere Pima device. There has been an increasing emphasis on POC technology in the developing world, including POC viral load testing. In conjunction with CD4 count, viral load provides a complete picture of a patients' immune response to the virus. Viral load can inform timing of ART initiation, and provides information on the patients' response to ART, once therapy has begun. POC viral load testing should work in conjunction with, and complement, existing POC CD4 systems.

POC CD4 testing can be incorporated as a part of broader POC strategy and the introduction of other POC tests.

5.3.2 Supportive Supervision and Mentoring

As Pima devices continue to be rolled out in Tanzania, it is vital to ensure that clinicians are correctly and consistently ordering Pima supplies including cartridges, reagents, and finger stick kits. Given our experience in the field, it is apparent that there is currently a lot of confusion surrounding the ordering process; the resulting delays and stock outs have caused serious interruptions to patient care. Emphasizing the ordering process during training, using of the revised R&R forms and if possible, integrating of Pima system in the existing supportive supervision checklist will be helpful to ensure consistent supply and provision of high quality services. Regional, district authorities, mentors and implementing partner should provide technical assistant as needed.

5.3.3 Testing Incentives

Many clinics were previously profiting from the sample transport system, and are therefore reluctant to switch to a POC device. It is important to engage local providers and clinic leaders to discuss the potential for providing incentives, and clearly communicate the benefits of POC testing to ensure its appropriate use.

5.3.4 Improved Training

Given the number of errors observed in the use of Pima (>50% in some sites), it is clear that existing training may need to be re-evaluated, or "topped up" after several months of using the device. We should engage the manufacturer (Alere) as well as national and local authorities to devise a training curriculum that best addresses these needs. Also needs to assess the performance of those trained through on job training.

5.3.5 Opt-in Placement of Devices

It is important to consider the criteria for placing devices as Pima use is expanded in Tanzania. Given the lack of interest in POC testing observed at some sites (some clinics had never removed the device from its box), we may want to consider an opt-in (Pull) system for POC CD4 testing, ensuring buy-in from the clinic side. While there are ethical concerns with prioritizing clinician demand, this will ensure that devices are utilized. Clinics that opt-in to program would be invested in the use of the device, having identified their prior sample transport system as problematic. We can look to other countries that have implemented new technologies using this model.

5.3.6 Supply chain Management

Though POC protocol has been developed, there is not a clearly articulated policy around the procurement and distribution of PIMA units and cartridges, or the training of clinicians, and the monitoring of results. PIMA devices do not need to be routinely serviced, and represent a one-time acquisition cost for the clinic. PIMA cartridges, however, need to be acquired at least once annually.[5] These cartridges come in packs of 100, and are not currently a part of the national distribution plan. Poor ordering by clinic staff and poor communication between local health centres, district hospitals, and the MOHSW have resulted in delayed deliveries, and stock outs of cartridges at the clinic level. It is imperative to articulate responsibility for distribution, as well as a clear transportation plan/schedule, to ensure timely delivery of supplies. Potential solutions include:

i. ***Partnerships with NGO partners.*** Orchestrate a system that piggybacks on existing plans by tasking partners to visit clinic sites, e.g. as part of mentoring programs, supportive supervision etc.

ii. ***District-level distribution.*** The District Hospital could be given responsibility for transporting supplies from the hospital level to the clinics, or supplies could be delivered directly to them from the central stockroom on a regular schedule. This would establish a push system, which is already in place in some areas.

iii. ***Procurement of a buffer supply.*** If Tanzania is to move forward with Pima rollout, the acquisition of a buffer supply of all testing reagents and Pima cartridges is of paramount importance.

iv. ***Quarterly forecasting and delivery of cartridges with appropriate expiry dates.*** Regardless of the method of transportation chosen, a dedicated forecasting and

[5] PIMA cartridges have a 12 month shelf life

procurement effort will be necessary. Ensuring the timely delivery of sufficient supplies will prevent waste and improve efficiencies. Distribution of the revised R&R form and training of staff on how to use the form and mentoring is highly needed.

Next Steps

1. ***Health Systems Strengthening***
    a. *Human Resources.* Clinics must meet HR requirements and adhere to the basic staffing pattern of ART clinics as set out by the MOHSW. Staff shortage and turnover was main concern by the clinician, it is understood that POC testing increases the burden on clinic-based staff. It is imperative, therefore, that HR allocation and shortages be addressed prior to the placement of a Pima unit at a given clinic.
2. ***Distribution and Supervision***
    a. ***Procurement Plan and Ownership.*** If POC CD4 testing becomes the standard of care, a sustainable plan for the procurement and financing of units and cartridges will be necessary. Integrating of Pima supplies into a clinic supply chain is necessary.
    b. ***Supply Chain Strengthening.*** Rural clinics will still face transportation challenges with respect to the delivery of cartridges and potential servicing of units. Timely delivery of cartridges is essential to minimize waste and ensure continuity of care at the clinic level. Utilizing the regional or district authority, or partner organizations to deliver these supplies will be necessary.
3. ***Stock Management.*** It will be necessary to define and adhere to a delivery schedule for Pima cartridges. The timely and consistent delivery of cartridges is necessary to

minimize waste and ensure consistency of results at the clinic level. Training on forecasting is needed to all staff at the clinic.

4. ***Maintenance and Backup*.** It will be necessary to keep several machines in a central location to be loaned out when units break. It will also be crucial to design and implement a clear "breakdown" plan to be communicated to clinics, to minimize downtime during breakages and maintenance.

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APPENDICES

Appendix 1.1: The situation in Tanzania before the implementation of point of care

In Tanzania HIV positive individual walked for over four hours on a hot and humidity day to get to a comprehensive primary health clinic in the remote areas. No paved roads and the public transport are almost inexistent with the majority using bicycles as the means of transport and anyway unaffordable. When the HIV positive individual are in need of blood test (the enumeration of the absolute number of T helper cells commonly refers to as the CD4 count, to make decision on whether or not they can start antiretroviral treatment (ART), or for monitoring of the drug results. HIV positive individual are schedule for blood collection, usually at the clinic level is being done once per month. A blood specimen is collected and sent away using any existing transport (it can be a bus, private car, bicycle or motorcycle). The HIV individuals are told to return 2 weeks later to get result. The health care workers in primary health clinics who wish to order CD4 test were faced with challenges of not only transporting the blood specimen to and off site laboratory but also getting the CD4 result back to the patient. They had many additional challenges such as blood specimen being damaged or unsuitable for testing as the result of delays in sample reaching the CD4 count laboratory, specimen damage, losing of the result due to unclear system. Machine malfunction as a result of poor maintenance, breakdown, shortage of staff and lack of reagents due to stock outs or financial constrain. For patient getting a CD4 testing means repeated visits to the health facilities leading to the delays in accessing ART and lost to follow up due to financial constrains. By the time the results are ready the patient is too sick to return to the clinic or overwhelmed due to disturbances, such individual are frequent impossible to find again and end up declare as a lost to follow up. This is means the previous CD4 technology used was inappropriate technology that was inaccessible for rural communities.

Appendix 1.2: Clinic List

1. Tanga
    a. Mkuzi
    b. Mwera
    c. Kabuku
2. Mtwara
    a. Nanyamba
    b. Nanguwere
    c. Mchichira
    d. Mahuta
3. Lindi
    a. Rutamba
    b. Kitomanga
4. Pwani
    a. Mkamba
    b. Kisuju

Appendix 1.3: Informed consent form

Dear Respondent

I am a Tanzanian student studying international cooperation policy, specializing in the field of Public Health Management at Ritsumeikan Asia Pacific University in Japan. As part of the program prerequisite for completion and award of a master's degree, a comprehensive research thesis is mandatory.

I have chosen to research on HIV Diagnostics focusing on CD4 testing as there are still considerable barriers to access in Tanzania. Below are set of questions which would help in the analysis of my research topic. I will appreciate your participation in answering these questions and the information provided shall be used for the sake of the academic research work and improve the work of Tanzania Ministry of Health and Social welfare and their collaborating partners.

Your participation is voluntary, and you can withdraw your participation at any time.

There will be no costs for you in participating in the research.

Date _____ Place _____

Printed name of participant _____

Signature of participant _____

Appendix 1.4: Data Collection Tools and Interview Guide

Interviewer name: _____ Date: *(dd/mm/yy)*_____

_____

Health Facility:_____Implementing Partner: District:_____

Facility In-Charge:_____ Contact information:_____

Lab staff interviewed:_____ Contact information:_____

ART staff interviewed:_____ Contact information:_____

Triage staff interviewed:_____ Contact information:_____

ART Day ☐ YES ☐ NO

NB: This questionnaire is accompanied by a Facility data collection Excel tool where answers can be inputted and analyzed with the tool.

General Facility Information

	Basic Facility Information		**Notes**
1	Date of ART accreditation	|_____|_____| _____| dd / mm / yy .	
2	Rural/Urban	Rural ..... 1 Urban 2	
3	Facility catchment population	_____ people	
4	Average distance patients have to travel	_____ km	
5	Number of clinic days per week	_____ days	
6	Which days are clinic days? *(Circle multiple if more than one clinic day)*	Monday ..... 1 Tuesday ..... 2 Wednesday ..... 3 Thursday ..... 4 Friday ..... 5 Saturday ..... 6 Sunday 7	

	If applicable, which days are outreach days? *(Circle multiple if more than one day)*	Monday..... 1 Tuesday..... 2 Wednesday..... 3 Thursday..... 4 Friday..... 5 Saturday ..... 6 Sunday 7	
	If applicable, do you bring the Pima device on outreach visits?	Yes ..... 1 No..... 2	
7	Which days are patients able to receive a Pima CD4 test? *(Circle multiple if more than one clinic day)*	Monday..... 1 Tuesday..... 2 Wednesday..... 3 Thursday..... 4 Friday..... 5 Saturday ..... 6 Sunday 7	
8	How many hours a day is Pima available?	_____ hours	
9	Are you able to initiate every eligible patient?	Yes ..... 1 No..... 2	

10	*If not, what percentage do you enrol?*	0-25% ..... 1 25-50% ..... 2 50-75% 3 75-100% 4	

Lab Staff

Please identify a lab staff who has experience using the Pima machine to answer the following questions:

	Basic interviewee information		**Notes**
14	Person interviewed	Lab technologist ..... 1 Lab technician ..... 2 Lab assistant ..... 3 Other (specify) ..... 9 Specify_____	
15	How many people are currently staffed at this facility? *(Write the number of each type of staff, if no staff, write 0)*	2a. _____ Lab technologist 2b. _____ Lab technician 2c. _____ Lab assistants	
16	Date staff trained on Pima machine	|_____|_____| _____| dd / mm / yy .	
17	Date of first use on Pima machine	|_____|_____| _____| dd / mm / yy .	

18	Where is the Pima machine located? *(Circle all that apply)*	Triage ..... 1 ART clinic ..... 2 ART clinician..... 3 Lab..... 4 Other (specify) ..... 9 Specify_____	
Sample Referrals			
19	What was your previous sample referral method?	Sent to nearest health centre..... 1 None ..... 2 Other (specify) ..... 9 Specify_____	
20	How many kilometres was the referral site (or nearest CD4 machine)	_____ km	
21	How long did it take for results to return to the clinic?	_____ days	

	On which days did you collect samples?	Monday..... 1 Tuesday..... 2 Wednesday..... 3 Thursday..... 4 Friday..... 5 Saturday ..... 6 Sunday 7	
	How many samples did you collect per week	_____ samples	
	Were there more tests required than could be performed per week? If so, how many tests were required.	Yes ..... 1 No ..... 1 #_____	
24	Was there any time you couldn't use the sample referral system?	Yes ..... 1 No ..... 1 Specify_____	
25	Did you have a CD4 logbook to record previous CD4 results?	Yes ..... 1 No 2	
26	Are you currently still using the sample referral method?	Yes ..... 1 No 2	

27	If yes, why are you still using the sample referral method? (*Circle all that apply, mark the most important with an arrow)*	High patient volumes ..... 1 Broken Pima machine..... 2 More reliable and accurate ..... 3 More familiar..... 4 Other (specify) ..... 9 Specify_____	
CD 4 Patient Flow and Volume			
28	Can you tell me how the Pima machine is used today starting with when a patient first arrives?		
29	Describe patient flow for PMTCT patient		
30	Describe patient flow for a patient from the CTC clinic		
31	Describe patient flow for a newly diagnosed HIV+ patient		

33	How many patients do you receive each day **currently?**	**Clinic day**	**Non-clinic day**	
	How many Pima tests do you perform each day?	_____ tests		
Quality Control				
35	When do you run the controls?	Always before testing patients ..... 1 A few times a week ..... 2 Never ..... 3 I don't know..... 8 Other (specify) ..... 9 Specify_____		
36	Any issues with running controls?	No ..... 1 Takes too long ..... 2 Machine not passing standards ..... 3 I don't know..... 8 Other (specify) ..... 9 Specify_____		
CD4 Patient Flow				

37	Who determines whether a patient needs a CD4 test?	Triage.....1 ART clinic.....2 Lab.....3 OPD.....4 Maternity.....5 I don't know.....8 Other (specify) .....9 Specify_____	
39	Do patients have their HIV blue cards when they see the lab?	Yes.....1 No .....2 Specify_____	
	When a patient comes for a CD4 test, how long does the visit take?	Specify_____	

41	How do patients know their results are ready?	Lab calls patient name.....1 Lab waits for patient to return .....2 Triage staff finds the patient.....3 Next appointment day.....4 I don't know.....8 Other (specify) .....9 Specify_____	
42	What is done with the CD4 result print-outs?	Inserted into patient exercise book .....1 Stapled into patient's file.....2 Inserted into patient's file .....3 Given to ART staff .....4 Given to triage nurse .....5 I don't know.....8 Other (specify) .....9 Specify_____	

43	What do you do with the results if other staff are not available?	Inserted into patient exercise book ..... 1 Stapled into patient's file ..... 2 Inserted into patient's file ..... 3 Given to ART staff ..... 4 Given to triage nurse ..... 5 I don't know ..... 8 Other (specify) ..... 9 Specify_____	
44	Who explains the CD4 results to the patient for same-day results?	Triage nurse ..... 1 ART clinic ..... 2 ART clinician ..... 3 Lab staff ..... 4 Records staff ..... 4 I don't know ..... 8 Other (specify) ..... 9 Specify_____	

45	Who explains the CD4 results for **non**-same-day results?	Triage nurse.....1 ART clinic.....2 ART clinician.....3 Lab staff.....4 Records staff.....4 I don't know.....8 Other (specify) .....9 Specify_____	
46	Who records CD4 results into patient HIV blue cards?	Triage nurse.....1 ART clinic.....2 ART clinician.....3 Lab staff.....4 Records staff.....4 I don't know.....8 Other (specify) .....9 Specify_____	
CD4 Resulting			
47	How often do you take samples using venous blood?	Never .....1 Sometimes.....2 Always 3	

48	Do you have a limit to how many patients you can test in day? If so, how many?	Yes.....1 No .....2 Specify_____	
49	How many patients do you have to turn away?	_____ patients	
50	How many patients are rescheduled for a different test date?	_____ patients	
51	Do patients leave due to waiting too long? If so, how many?	Yes.....1 No .....2 Specify_____	
52	Who receives same-day results?	Everyone.....1 Urgent patients .....2 Outside patients.....3 Nobody .....4 Specify_____	

53	What do you do when a patient cannot receive a CD4 test that day?	All patients receive CD4 test.....1 Reschedule for non-clinic day.....2 Take venous blood and… Perform Pima test on a different day..3 Use previous referral system.....4 Ask to come on another day .....5 Other (specify) .....9 Specify_____	
54	Does the facility correctly use the CD4 logbook? If not, why?	Yes.....1 No .....2 Specify_____	
55	Did patients have to pay for CD4 tests before Pima?	Yes.....1 No 2	
56	Did patients have to pay for CD4 tests after Pima (currently)?	Yes.....1 No 2	
Supplies			
57	How many Pima tests do you use per month?	_____ cartridges	
58	What was your initial supply of Pima kits? (Pima reagents + Pima supply)	_____ cartridges	

59	What is your current supply of Pima reagents?	_____ cartridges	
60	What are the expiry dates of your Pima supplies?	1. 2. 3. 4. 5.	
61	How often does the Pima machine not operate due to stock issue?	Never ..... 1 Sometimes..... 2 Always 3	
62	Do you know how to order Pima supplies	Yes..... 1 No 2	
63	*If they have ordered before, did the lab staff order correctly?*	Yes..... 1 No ..... 2 N/A..... 3	
	What are the stocks of the following supplies?		
11	HIV test kits	Consistent stock ..... 1 Stock challenges..... 2 Stock-outs..... 3	

12	Cotrimoxazole (Ceptrin)	Consistent stock .....1 Stock challenges.....2 Stock-outs.....3	
13	ARV drugs	Consistent stock .....1 Stock challenges.....2 Stock-outs.....3	
64	Do you use a stock card for Pima supplies?	Yes.....1 No 2	
65	*Did the lab staff use the stock card correctly?*	Yes.....1 No .....2 N/A.....3	
66	Has the Pima machine required troubleshooting?	Yes.....1 No 2	
67	Has the Pima machine needed to be swapped out for repairs?	Yes.....1 No 2	
68	*If yes, how many days did it take?*	_____ days	
69	How many times has the Pima machine required servicing?	_____ times	
70	How many days a week does the **facility** have power?	_____ days	

71	How many days a week does the **lab** have power?	_____ days	
72	What type of power does the lab have?	Grid.....1 Solar .....2 Generator.....3 None .....4 Other (specify) .....9 Specify_____	
	Do have a solar charger for the Pima?	Yes.....1 No 2	
73	Where do you charge the Pima machine?	Lab.....1 ART clinic.....2 Computer room.....3 Other (specify) .....9 Specify_____	
74	How often does the Pima machine not operate due to power issues?	Never .....1 Sometimes.....2 Always 3	
75	Is the Pima machine fully charged every day?	Yes.....1 No 2	

76	*If not, why?* (*Circle all that apply, mark the most important with an arrow)*	Lack of consistent power .....1 Lack of coordination.....2 Too many patients .....3 I don't know.....8 Other (specify) .....9 Specify_____	
77	How many hours does the Pima machine last?	_____ hours	
78	How many days has the Pima machine been non-operational since you received it?	_____ days	
79	*If so, what were the dates?*	_____ dates	
Training			
80	Please describe the Pima training		
	How many people were trained to operate the Pima machine?		

81	Who was trained on how to operate the Pima machine?	Triage nurse.....1 ART clinic.....2 ART clinician.....3 Lab staff.....4 I don't know.....8 Other (specify) .....9 Specify_____	
82	Who actually operates the Pima machine?	Triage nurse.....1 ART clinic.....2 ART clinician.....3 Lab staff.....4 I don't know.....8 Other (specify) .....9 Specify_____	

83	Why doesn't everyone who is trained to operate Pima actually operate the machine?	Not part of job description.....1 Training was not sufficient .....2 Does not feel comfortable taking blood.....3 Politics (Pima should be in lab).....4 I don't know.....8 Other (specify) .....9 Specify_____	

Staff Perspectives						
		Circle the correct response				
	Do you agree with the following statements?	Strongly Agree ***1***	Somewhat agree ***2***	Somewhat disagree ***3***	Strongly disagree ***4***	
85	The training was sufficient to use the Pima	***1***	***2***	***3***	***4***	
86	The Pima is easy to use	***1***	***2***	***3***	***4***	
87	I am satisfied with having the Pima in this facility	***1***	***2***	***3***	***4***	
88	Patients have been impacted by having the Pima here	***1***	***2***	***3***	***4***	
89	The results from Pima are correct	***1***	***2***	***3***	***4***	
90	Using the Pima is preferable to the old system	***1***	***2***	***3***	***4***	
Ask the following questions but not the answer choices. ***Circle the ones that apply and mark with an arrow the most important***						

91	What are some of the technical challenges to using the Pima machine? (*Circle all that apply, mark the most important with an arrow)*	Throughput too low ..... 1 Takes too long to shut down ..... 2 Won't turn on ..... 3 Doesn't stay charged ..... 4 Too many errors ..... 5 Don't trust the results ..... 6 Difficult to collect finger-prick samples ..... 7 None ..... 8 Other (specify) ..... 9 Specify_____	
92	What would you need in order to run more same-day tests each day? (*Circle all that apply, mark the most important with an arrow)*	More staff ..... 1 More training ..... 2 More consistent power ..... 3 Fewer other tasks ..... 4 Second Pima machine ..... 5 Better coordination ..... 6 Schedule patients throughout week ..... 7 None ..... 8 Other (specify) ..... 9 Specify_____	

Pima vs. Previous Referral System			
93	What are the strengths of using Pima for CD4 testing as compared to the referral system? (*Circle all that apply, mark the most important with an arrow)*	Same-day results ..... 1 Easy to use ..... 2 Very fast ..... 3 Portable ..... 4 Other (specify) ..... 9 Specify_____	
94	What did you like about the referral system that is missing from Pima? (*Circle all that apply, mark the most important with an arrow)*	More tests per week ..... 1 Less complicated ..... 2 Less work ..... 3 Better documentation ..... 4 Referral incentive ..... 5 More reliable results ..... 6 Fewer invalid tests ..... 7 None ..... 8 Other (specify) ..... 9 Specify_____	

95	What challenges of the previous referral system were solved by the use of Pima? (*Circle all that apply, mark the most important with an arrow)*	Same-day results.....1 More tests per week .....2 Less complicated .....3 Less work.....4 Better documentation.....5 Clearer processes.....6 None .....7 Other (specify) .....9 Specify_____	
96	What gaps still exist that neither system addressed? (*Circle all that apply, mark the most important with an arrow)*	Not enough tests run per day.....1 Too complicated .....3 Too much work .....4 Not enough documentation.....5 Ambiguous processes .....6 None .....7 Other (specify) .....9 Specify_____	

97	Are there any other issues you'd like to see addressed?		

Interviewer Notes:		
98	Was this facility successful in implementing Pima?	Yes.....1 No .....2 Explain:
99	Did the patient flow work to optimize Pima testing?	Yes.....1 No .....2 Explain:
100	Was the facility successful in documenting CD4 results?	Yes.....1 No .....2 Explain:

101	Has Pima helped to increase access to CD4 testing in this clinic?	Yes.....1 No .....2 Explain:
102	What qualities contributed to the success/failure of the facility to implement and use Pima?	

ART Staff

Please identify an ART staff who has experience using the Pima machine to answer the following questions:

	Basic interviewee information		**Notes**
103	Person interviewed	ART Clinician .....1 ART Nurse .....2 ART Nursing Assistant .....3 Other (specify).....9 Specify_____	

104	How many people are currently staffed at this facility? *(Write the number of each type of staff, if no staff, write 0)*	69. _____ ART Clinicians 70. _____ ART Nurses 71. _____ ART Nursing Assistants 72. _____ Mentor Mothers 73. _____ Facility-based expert clients 74. _____ Clinicians 75. _____ Records staff 76. _____ Total Facility Staff		
CD4 testing				
105	How many patients do you usually have who need to see an ART clinician?	**Clinic day**	**Non-clinic day**	
106	Can you tell me how the Pima machine is used today starting with when a patient first arrives?			

107	Who determines whether the patient needs a CD4 test?	Triage.....1 ART nurse.....2 ART clinician.....3 Lab.....4 I don't know.....8 Other (specify).....9 Specify_____	
108	Who is responsible for recording CD4 results in patient's HIV blue card?	Triage nurse.....1 ART clinic.....2 ART clinician.....3 Lab staff.....4 I don't know.....8 Other (specify).....9 Specify_____	

129	Who counsels the patient after receiving the CD4 results?	Lab staff .....1 Triage nurse .....2 Clinician.....3 I don't know .....8 Other (specify).....9 Specify_____	
111	What do you do when a patient cannot receive a CD4 test that day?	Reschedule for non-clinic day .....1 Ask patient to come a different day .....2 Referred to other health clinic .....3 I don't know .....8 Other (specify).....9 Specify_____	
112	How did patients receive CD4 results with the previous sample referral system?	Triage nurse enters into patient file .....1 ART nurse enters into patient file .....2 Lab staff enters into patient file .....3 Records staff enters into patient file .....4 I don't know .....8 Other (specify).....9 Specify_____	

113	How often do patients receive same-day results?	Never.....1 Sometimes .....2 Always.....3 I don't know 8				
Staff Perspectives						
	Do you agree with the following statements?	*Circle the correct response* Strongly Agree ***1***	Somewhat agree ***2***	Somewhat disagree ***3***	Strongly disagree ***4***	Don't know or decline to answer
114	The training was sufficient to use the Pima	***1***	***2***	***3***	***4***	***5***
115	I am satisfied with having the Pima in this facility	***1***	***2***	***3***	***4***	***5***
116	Patients have been impacted by having the Pima here	***1***	***2***	***3***	***4***	***5***
117	The results from Pima are correct	***1***	***2***	***3***	***4***	***5***
118	Using the Pima is preferable to the old system	***1***	***2***	***3***	***4***	***5***
Ask the following questions but not the answer choices. Circle the ones that apply and mark with an arrow the most important						

119	What will help you to test more patients under current Pima constraints? (*Circle all that apply, mark the most important with an arrow)*	More staff .....1 More training .....2 More consistent power .....3 Fewer other tasks.....4 Second Pima machine .....5 Better coordination .....6 Schedule patients throughout week .....7 None .....8 Other (specify).....9 Specify_____	
Pima vs. Previous Referral System			
120	What are the strengths of using Pima for CD4 testing over the referral system? (*Circle all that apply, mark the most important with an arrow)*	Same-day results .....1 Easy to use .....2 Very fast.....3 Portable.....4 Other (specify).....9 Specify_____	

121	What did you like about the previous referral system that is missing from Pima that you would like to see? (*Circle all that apply, mark the most important with an arrow)*	More tests per week.....1 Less complicated .....2 Less work.....3 Better documentation .....4 Referral incentive .....5 More reliable results.....6 Fewer invalid tests .....7 None .....8 Other (specify).....9 Specify_____	
122	What challenges from the previous referral system was solved by Pima? (*Circle all that apply, mark the most important with an arrow)*	Same-day results .....1 More tests per week.....2 Less complicated .....3 Less work.....4 Better documentation .....5 Clearer processes.....6 None .....7 Other (specify).....9 Specify_____	

123	What gaps still exist that neither system addressed? (*Circle all that apply, mark the most important with an arrow)*	Not enough tests run per day.....1 Too complicated.....3 Too much work.....4 Not enough documentation.....5 Ambiguous processes.....6 None .....7 Other (specify).....9 Specify_____	
124	Are there any other issues you'd like to see addressed?		

IF HIV POSITIVE						IF ART ELIGIBLE							
Patient ID	Patient Type (ART, PMTCT, …)	Date HIV Rapid Test Performed	Date Enrolled in CTC	CD4 count at time of diagnosis	Date CD4 Sample Collected	ART Eligible?	Was patient initiated?	If so, date of ART Initiation	TAT (Initiation-Diagnosis, in days)	LTFU (ART eligible, not initiated)	TAT from CD4 Sample Given to ART Initiated (If Eligible)	CD4 Count at Initiation onto ART	WHO Clinical Staging at Initiation onto ART
date confirmed HIV	Pre-ART/ ART #	Date of Pre-ART/ ART #	Date of request	Date test performed	Date result received	CD4 Result	date medically eligible	date eligible and ready	Date of ART initiation	Date of last visit			

Appendix1.5: Clinic Profiles.

Basic Information				*Pima Implementation*				
Clinic Name	**Location Information**	**Partner**	**Visit Date**	**Supplies**	**Staff**	**Infrastructure**	**Complementary Testing**	**Notes**
Nanyamba HC	Located in Mtwara Rural district, 100km from the nearest standard CD4 machine. Catchment population of 6,710. On average, patients travel three hours by bicycle to reach the clinic.	THPS	9 Oct 2012	Controls stocked out June 18, local officials were unresponsive to requests for resupply. Initial and only delivery of Pima supplies occurred during the training. Staff has poor understanding of ordering process, has never placed an order for Pima supplies.	Facility is understaffed; Staff requested more training esp. on supportive supervision, R&R forms, use of the CD4 logbook, and supply requisition	Facility has both grid and solar power and has not experienced electrical-related delays for the Pima	Clinic performs creatinine and Hb tests on-site, but has had stock problems with reagents.	

Mchichira Dispensary	Located in Tandahimba district, 25 km from the nearest standard CD4 machine. Catchment population of 9,147 On average, patients travel one hour by bicycle to reach the clinic.	THPS	9 Oct 2012	Initial and only delivery of Pima supplies occurred during the training. Staff has poor understanding of ordering process, has never placed an order for Pima supplies but has not stocked out because patient volumes are so low. Stock outs out of HIV test kits, Ceprin syrup, reagents, tubes, and ARVs.	Critically understaffed, with 3 staff members and no laboratory staff. Staff report Pima training insufficient to cover necessary information.	The facility uses solar power and has electricity except during the rainy season.	Clinic ceased sample transport for liver function and creatinine testing when Pima device was placed.	
Rutamba HC	Located in Lindi Rural district, 45km from nearest standard CD4 machine. Catchment pop. of 8,011. On average, patients travel three hours by bicycle to reach the clinic.	EGPAF	11 Oct 2012	Staff has poor understanding of ordering process for obtaining new reagents and cartridges. The clinic has never placed an order for Pima supplies but has not stocked out because the district delivers supplies routinely (push system).	Facility is understaffed Staff report Pima training insufficient to cover necessary information particularly R&R, ordering, and correct use of the Pima (clinic running controls only weekly).	The facility uses solar power and has electricity except during the rainy season.		Clinic was part of Pima pilot study in 2011.

Basic Information				*Pima Implementation*				
Clinic Name	**Location Information**	**Partner**	**Visit Date**	**Supplies**	**Staff**	**Infrastructure**	**Complementary Testing**	**Notes**
Nanguwere	Located in Mtwara Rural district, 32 km from the nearest standard CD4 machine. Catchment population of 10,949. On average, patients travel one hour by bicycle to reach the clinic.	THPS	10 Oct 2012	Initial and only delivery of Pima supplies occurred during the training. Staff has poor understanding of ordering process, has never placed an order for Pima supplies and has stocked out of Pima supplies, HIV test kits, reagents, tubes, and ARVs.	Staffing pattern sufficient. Staff reported that Pima training did not cover necessary information particularly R&R, ordering, and correct use of the Pima (clinic running controls only weekly).	The facility uses solar power and has electricity except during the rainy season.	Clinic using sample transport for CD4 and biochemistry; logbook and results not available.	DMO ordered clinic to use both FACS Calibur and Pima tests because MOH records supporting Pima placement at clinic unavailable. Pima only used for 6 weeks; nurses do not want to use two tests.
Mahuta HC	Located in Tandahimba district, 100 km from the nearest standard CD4 machine. Catchment population of 15,185. On average, patients	THPS	10 Oct 2012	Staff has never placed an order for Pima supplies but receives supplies routinely from district officials. Seven month stock out of cartridges resulted after initial supply complete.	Staffing pattern sufficient. Two staff trained on use of Pima, reported training session was too short to cover necessary	The facility uses grid power and has had persistent problems with electrical supply. Local electricity company routinely	Clinic ceased sample transport for liver function and creatinine testing when Pima device was	Clinic had excellent data collection as compared to nearby clinics. Clinic received Pima

	travel 2 hours by bicycle to reach the clinic.			Stock outs out of HIV test kits, Ceprin syrup, reagents, tubes, and ARVs.	information.	cuts power.	placed.	in September 2011.
Kisuju HC	Located in Mkuranga district, 45 km from the nearest standard CD4 machine. Catchment population of 6,685. On average, patients travel 2 hours by bicycle to reach the clinic.	THPS	24 Oct 2012	Clinic initially received supplies through push system from implementing partner. Clinicians aware of ordering process and will begin forecasting and ordering this quarter. HIV commodities and Pima supplies in stock.	Staffing pattern sufficient. Reported training session was too short to cover necessary information.	The facility uses solar power. Six month period of electricity failure led to complete stop of all POC testing in facility (Hemocue, Pima).	Clinic received hematology and biochemistry POC machine. Current stock out of Vacuatainer tubes and prior electricity failure prevented device from being used.	Clinic kept excellent records, including standard CD4 logbook produced by MOHSW. Clinic had excellent support from partner and local authorities.

Basic Information				*Pima Implementation*				
Clinic Name	**Location Information**	**Partner**	**Visit Date**	**Supplies**	**Staff**	**Infrastructure**	**Complementary Testing**	**Notes**
Mkamba HC	Located in Mkuranga district, 60 km from the nearest standard CD4 machine. Catchment population of 17,174. On average, patients travel 1 hour by bicycle to reach the clinic.	THPS	24 Oct 2012	Clinic initially received supplies through push system from implementing partner. Clinicians aware of ordering process and expected to begin forecasting and ordering this coming quarter. Pima has never been non-operational due to stock issues; other HIV commodities in stock.	Staff shortages. Staff reports that Pima training was sufficient; they have yet to perform on-the job training for remaining staff.	The facility uses solar power and has electricity even during the rainy season. Six month power failure this year resulted from solar battery failure.	Clinic received hematology and biochemistry POC machine. Current stock out of Vacuatainer tubes and prior electricity failure have prevented device from being used.	
Mkuzi HC	Located in Muheza district, 10 km from the nearest standard CD4 machine. Catchment population of 16,329.	AIDS Relief	18 Oct 2012	Clinic initially received stock through push system from MSD. Staff has since been educated on ordering process, expected to forecast and order own supplies	Staff shortages; all staff initially trained to use Pima have since left the facility. Staff requested four-day Pima training, and clarification on	The facility uses grid power. Due to power rationing they have inconsistent	Clinic ceased sample transport for liver function and creatinine testing when Pima device was	

	On average, patients travel 1 hour by bicycle to reach the clinic.			moving forward. Clinic has already placed order for new supplies. Consistent stock of Pima and HIV supplies.	supportive supervision, R&R, record keeping, and ordering.	electricity.	placed.	
Mwera HC	Located in Pangani district, 11 km from the nearest standard CD4 machine. Catchment population of 7,791. On average, patients travel three hours by bicycle to reach the clinic.	AIDS Relief	18 Oct 2012	Clinic initially received stock through push system from MSD. Staff has since been educated on ordering process, expected to forecast and order own supplies moving forward. Clinic has already placed order for new supplies. Consistent stock of Pima and HIV supplies.	Staff shortages. Staff requested four-day Pima training, and clarification on supportive supervision, R&R, record keeping, and ordering.		Clinic ceased sample transport for liver function and creatinine testing when Pima device was placed. Clinic refers patients to hospitals for testing.	

Basic Information				*Pima Implementation*				
Clinic Name	**Location Information**	**Partner**	**Visit Date**	**Supplies**	**Staff**	**Infrastructure**	**Complementary Testing**	**Notes**
Kabuku HC	Located in Handeni district, 78 km from the nearest standard CD4 machine. Catchment population of 46,213. On average, patients travel 3 hours by bicycle to reach the clinic.	AIDS Relief	17 Oct 2012	Clinic receives stock through push system from MSD. One-month stock out of controls resulted in August 2012. Staffs do not understand ordering or process for obtaining new reagents and cartridges for Pima device. Staff has never placed an order for Pima supplies.	Staffing pattern sufficient. Staff requested longer Pima training, including clarification on supportive supervision, R&R, record keeping, and ordering. Trained staff provided on-the-job training to all remaining staff.	The facility uses grid power. Due to power rationing they have inconsistent access to electricity.	Clinic ceased sample transport for liver function and creatinine testing when Pima device was placed, refers clients to hospital for testing.	