MORTALITY AND ITS DETERMINANTS DURING PRE-TREATMENT PERIOD AMONG HIV ADULT PATIENTS IN TANZANIA

Bonita Kilama, DDS

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MORTALITY AND ITS DETERMINANTS DURING PRE-TREATMENT PERIOD AMONG HIV ADULT PATIENTS IN TANZANIA

By

Bonita Kilama

A Dissertation Submitted in (Partial) Fulfillment of the requirements for the Degree of Master of Public Health of the Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that she has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled **Mortality and its determinants during pre-treatment period among HIV adult patients in Tanzania submitted** in partial fulfillment of the requirement for the degree of Master in Public Health of the Muhimbili University of Health and Allied Sciences.

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Dr Candida Moshiro

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Bonita Kilama**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: …….. Date: ……..

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Last but not least, I would like to extend my appreciation to my parents Professor Wenceslaus and Mrs. Anatolia Kilama, my siblings, in laws, fellow MPH students, friends and colleagues for their support and assistance during my studies.

DEDICATION

This write up is dedicated to my family. I thank you for your love, support and endurance. May the Almighty bless you more and guide you in all you do.

ABSTRACT

Background: HIV Care and Treatment services are guided by the National Care and Treatment Guideline. A recording and reporting system (paper and electronic) was developed to track those receiving services. Limited information is available on patients prior to the start of anti-retroviral therapy (ART), as most monitoring and evaluation of care and treatment programs concentrates on patients from ART initiation. Early initiation of antiretroviral therapy is desirable both in decreasing HIV transmission and having better treatment outcomes. In poor resource countries like Tanzania, delays in initiating ART is the reality. Greater understanding of the pre ART phase is crucial to help improve outcomes in HIV Care and determinants that affect the outcomes.

Objective: The aim of this study was to assess the level of mortality and its determinants among HIV infected adults prior to ART initiation.

Methods: A retrospective longitudinal analysis of more than 500,000 HIV infected adults enrolled in care was done from November 2004 and December 2011 using Stata 12. Patient characteristics at time of enrolment were described. Mortality rates and their 95% confidence intervals were estimated. Cox Proportional Hazard models were used to assess determinants of death before they access ART.

Results: From 348 health facilities, a total of 526,059 clients (67% females) enrolled for HIV Care services were assessed in the pre ART phase. Majority (85%) had working functional status, 82% had done a CD4 test by 3rd month since enrolment and TB screening was done in 93% of all visits. Overall mortality among adult pre ART care patients was 37.6 deaths per 1000 person years (95% CI 36.9 - 38.3). Independent predictors of pre ART mortality were WHO stage 3 (adjusted hazard ratio [AHR] = 2.37; 95% CI 1.94-2.90), WHO Stage 4 (AHR= 4.53; 95 % CI (3.64-5.64). Female sex, CD4 ≥200 and weighing more than 45kg were significantly associated with a lower hazard of death.

Conclusion and Recommendations: Mortality among patients who were eligible for ART before they accessed ART was high. Using routine electronic information to understand mortality and its predictors is resourceful for patient and program improvement. There is need to establish effective interventions targeting patients in the pre ART phase.

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LIST OF ABBREVIATIONS

ART	Antiretroviral Therapy
CTC	Care and Treatment Clinic
IeDEA	International epidemiological Database to Evaluate AIDS
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HAART	Highly Active Anti retroviral therapy
LICs	Low Income Countries
MDG	Millennium Development Goals
NACP	National AIDS Control Program
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organisation

OPERATIONAL DEFINITIONS

Pre ART Care	A phase where all services are provided to patients between testing positive for HIV and before anti-retroviral therapy (ART) initiation.
Enrollment in pre ART Care	Active (intentional) registration by a patient in any form of the pre ART Care regardless of whether this occurs before or after initial eligibility assessment
ART eligibility assessment	The process of determining if a patient should be referred to or continue in pre ART care or should initiate ART, typically determined through CD4 count or on the basis of WHO stage
Adherence to national HIV Care Guideline/Protocol	In this dissertation write up proxy measures are used to assess adherence to national HIV Care and Treatment Guideline. These are CD4 testing and TB screening documentation. As per guideline the following are defined: 1) CD4 testing frequency: Is CD4 testing done to every client every six months as per Care and Treatment guideline. If not what's the frequency of CD4 testing. 2) TB screening documentation: Is TB screening done on every visit as advocated in the guideline.

CHAPTER ONE

1.0 INTRODUCTION

This chapter presents an introduction to the write up of the dissertation. It is structured under following sub sections: Background to the problem, problem to the statement, research question, objectives, rationale and definition of terms.

1.1 Background

According to UNAIDS report of 2012, worldwide the number of People Living with HIV is estimated to be 33.3 million people by 2011. Of these, 2.5 million are children under 15 years of age and 30.8 million are adults' aged above 15 years old. HIV still affects more females (52%) than males among the adult population. In 2011 new HIV infections amounted to 2.5 million across all age groups. It is currently estimated that, the sub-Saharan Africa (SSA) region has (68%) of all people living with HIV, that totals to 22.5 million of the 2011 UNAIDS estimate. In Tanzania, a total of 1.5 million were estimated to be living with HIV in 2012 based on the UNAIDS approximation[1].

Through the Millennium Development Goals (MDGs), the response to the pandemic has included prioritizing HIV Care among the MDGs- MDGs 6a and b). Goal number six targets to provide access to antiretroviral therapy to half of those in need and halt as well as reverse the spread of HIV by 2015. However, reaching the target set requires coordinated efforts to have universal access to HIV testing, prevention, care, treatment and support to PLHIV and their surrounding communities and in return capture those in need of HIV Care and Treatment services[1,2].

In recent years, numerous country level HIV Care and Treatment Programme have been rolled out in middle and low income countries through support of global initiatives mostly PEPFAR and GFATM to rapidly increase access to treatment for those who need it [3,4].

Huge investments in infrastructure, equipment and workforce in the health sector has occurred with establishment of Care and Treatment programs thus contributing to the Health System

Strengthening agenda. Evidence from ART programmes in resource limited countries have shown remarkable improvements in survival of HIV infected patients on ART, decrease in opportunistic infections, decrease in morbidity and decrease in mother to child transmission. These programmes are facing several challenges of operational and clinical management including staff shortages, infrastructural deficits and inequitable access to care in rural areas, ART toxicity and treatment failure as well as poor use of routinely collected data for health determinants, health system performance and health status[5,6]. The health sector HIV response in Tanzania is coordinated by National AIDS Control Program, it was established in 1985 with a mission of working in partnership with other public sectors, private sectors, civil society and communities to play a leading role in the prevention of further spread of HIV and mitigate its impact by providing essential interventions and quality care[7].

In 2000, UN Member States, through the adoption of the Millennium Development Goals, committed to work toward a safer, healthier and more equitable world with a series of targets to be reached by 2015. The sixth goal of the MDG commits the global community to use every resource possible to halt and reverse the spread of HIV[8]. In 2001 Member States gathered for the first-ever United Nations General Assembly Special Session on HIV/AIDS, unanimously embracing a series of time-bound targets in the 2001 Declaration of Commitment on HIV/AIDS[9]. A political declaration was agreed upon in 2006 to move towards universal access to HIV prevention, treatment, care and support by 2010, the main aim was to establish a national platform for action[10]. Global institutions have provided strategic guidance and leadership to countries in need of various assistance towards the HIV response and thus save lives from new infections or HIV related deaths[11].

Although progress has been achieved in some countries in provision of HIV Care and Treatment services it is only 9.7 million people who are on ART worldwide, many countries are hindered by insufficient progress in addressing the underlying social and economic determinants of HIV risk and vulnerability. The main being, high levels of discrimination against People Living with HIV, women and girls, Men having Sex with Men (MSM), People Who Use Drugs and Sex Workers. In addition to these, punitive laws, policies and practices

continue to promote more stigmatization and discrimination which are likely to hinder effective national response efforts that include HIV Care and Treatment services[12]. For Tanzania, the recently UNAIDS released treatment update report of June 2013 show the country to have treatment coverage of 69% for adults (those above 15 years), 25% for children(under 15 years of age) , and 77% for pregnant women. Therefore, Tanzania falls in the group that has yet to attain universal ART coverage of 80% as wanted globally[13].

1.2 Statement of the Problem

Global initiatives have assisted middle and low income countries to develop their own care and treatment programs. There are has huge investment in infrastructure, equipment and workforce in the health sector that has happened with establishment of Care and Treatment services in the Low Income Countries (LICs). The Care and Treatment Programs has brought achievements that include prolonged life upon use of ART, decrease in Opportunistic infections (OIs) after use of low cost antibiotics as OIs prophylaxis agent, decreased mother to child HIV transmission following implementation of PMTCT strategies and many other interventions. However, challenges do exist, they include high attrition rates of PLHIV enrolled in HIV Care programs, poor tracking mechanisms, stock outs of essential medicines and testing reagents for PLHIV, work fatigue of Health Care workers providing care and treatment services, as well as poor recording and reporting performance of services provided. However, measurement and evaluation of care and treatment outcomes have sparsely been done globally for or during pre ART phase and therefore little information is available on Pre ART clients as evaluation of care and treatment programs is mostly evaluated based on patients who start and remain on treatment[5,6,14,15,16].

It was important to note that good sound health care provision in Pre ART state is a precursor to adherence to ART services. It was thus necessary to understand the characteristics of these patients[17,18,19].

WHO recommends a minimum package of care for PLHIVs enrolled in HIV care services in LICs to include, frequent visit to the health facility for clinical monitoring, cotrimoxazole prophylaxis for both adults and children as well CD4 test monitoring of which Tanzania has adopted[20].

This study assessed level of mortality among adult HIV pre-ART Care enrollees and its determinants using routinely collected information from electronic CTC sites that regularly export their patient level data to higher levels that include implementing partners and central level (NACP).

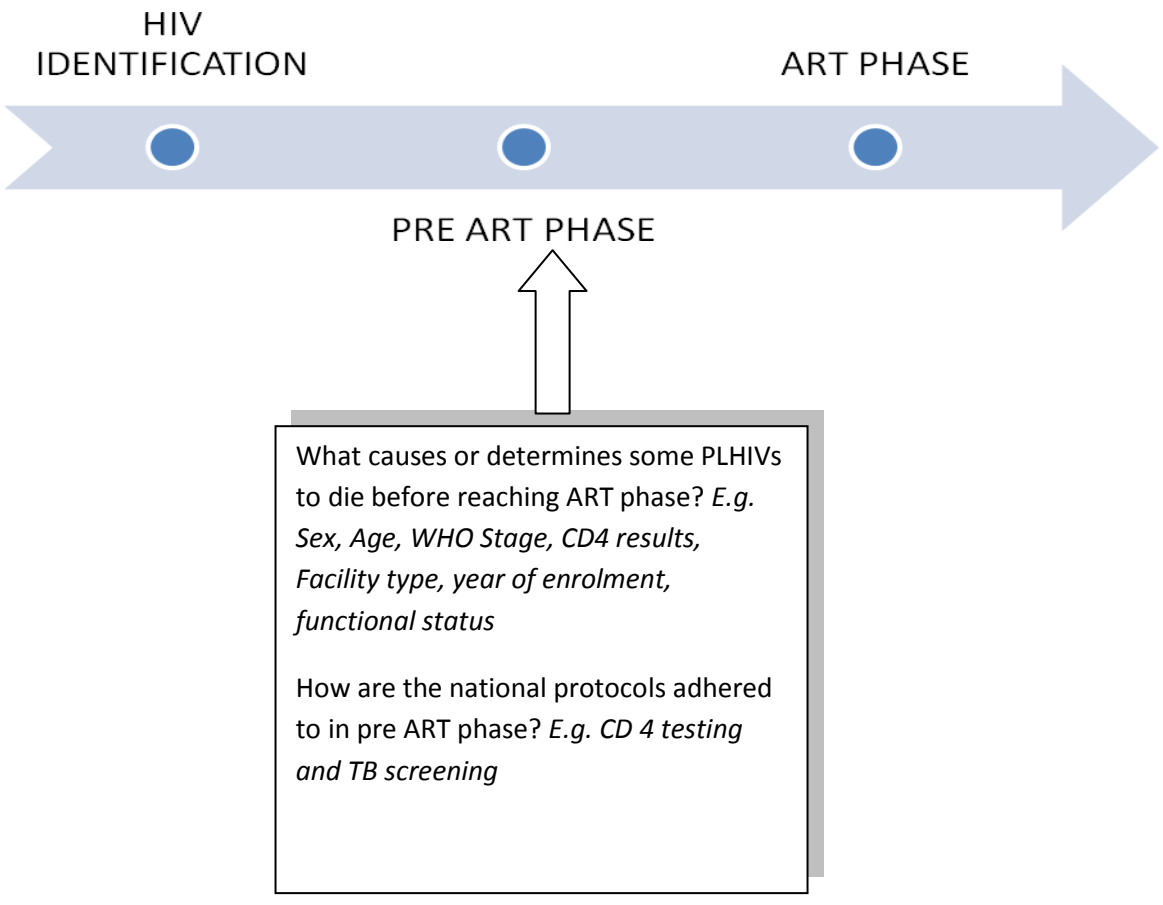
1.3 Rationale of the Study

This study provides information on determinants of mortality before initiating ART and thus guides implementers and decision makers of HIV Care and Treatment services in the country.

For Tanzania to reach universal treatment coverage, retention in pre ART and on ART phases needs to be strengthened. Findings from the study will inform stakeholders what needs to be revised for better tracking of clients' retention before they start ART.

1.4 Conceptual Framework: Treatment Cascade of Adult PLHIVs in Tanzania

This study was conducted basing on a problem diagram shown in Figure below which depicts a cascade from HIV identification, phase before ART initiation and ART phase were clients become eligible to consume ARVs. Focused attention was paid for pre ART phase to determine what factors show high mortality in period. The figure also revealed examples of factors that may determine mortality during pre treatment period. Adherence to national protocol was also assessed using CD4 testing and TB screening frequencies in the pre ART phase.



1.5 Research Questions

1) What is the level of mortality among adults living with HIV who have not initiated ART?

2) What are the determinants of mortality among Adult pre-ART HIV care enrollees?

1.6 Objectives

1.6.1 Broad Objective

To assess the level of mortality and its determinants among adult HIV Care enrollees before starting ART.

1.6.2 Specific Objectives

1) To estimate the overall mortality rate of HIV care enrollees before they start ART

2) To determine the level of adherence to national protocols among Pre ART patients by looking at:

    1. CD4 testing frequency

    2. TB screening documentation

3) To compare mortality rate of pre-ART HIV care enrollees by socio-demographic and clinical characteristics, and by adherence to the national protocols.

CHAPTER TWO

2.0 LITERATURE REVIEW

This chapter narrates literature review. It first documents HIV and AIDS pandemic and response, second- HIV and AIDS Epidemic and response in Tanzania and lastly the Pre ART mortality and adherence to national protocols for HIV Care provision.

2.1 HIV/AIDS Pandemic and Response

As the world has passed 30 years of AIDS, it is estimated 34 million [30.9 million–36.9 million] People are Living with HIV and nearly 30 million [25 million–33 million] people have died of AIDS-related causes since the first case of AIDS was reported on 5th June 1981. Sub Saharan region is the hardest hit by the pandemic with 22.5 million making 68% of people living with HIV in the world[21].

Although progress has been achieved in some countries in provision of HIV Care and Treatment services it is only 9.7 million people who are on ART worldwide, many countries are hindered by insufficient progress in addressing the underlying social and economic determinants of HIV risk and vulnerability[13]. The main being, high levels of discrimination against people living with HIV, women and girls, Men having Sex with Men (MSM), people who use drugs and sex workers. In addition to these, punitive laws, policies and practices continue promote more stigmatization and discrimination which are likely to hinder effective national response that include HIV Care and Treatment services[13].

2.2 Tanzania HIV Epidemic and Response

With estimated 1.5 million people living with HIV in Tanzania, the country falls under the region with the greatest HIV burden with 22.5 million infected in Sub Saharan Africa. From the population based survey titled 'Tanzania HIV and Malaria Indicator survey-THMIS' the national prevalence of HIV was computed to be 5.1%, disproportionately affecting women than men, urban setting than rural, wealth people than poor ones[22,23].

In response to this pandemic, Tanzania has had several actions being implemented by the Government and other stakeholders aiming to roll back the epidemic and mitigate its impact. These actions which constitute the national response to HIV/AIDS, have grown over time from the initial health sector response between 1985 and 2000 to a broad stakeholder response that has received a special multisectoral emphasis in recent years following the formation of the Tanzania Commission for AIDS in the year 2000[24].

However challenges do exist as availability of core HIV and AIDS interventions is far from becoming universally accessible to all. Most interventions for HIV and AIDS prevention, care and support are delivered through the health care system and their coverage is yet to reach most primary health care facilities. Furthermore, the fact that most interventions are delivered in health facilities, their uptake by certain population groups which are most vulnerable to HIV and which play a major role in the spread of the epidemic, is limited. These groups include among others, men who have sex with men, commercial sex workers, injection drug users as well as women and youth in general[25].

In collaboration with other partners, the HIV response has been able to complete several strategic documents to serve its mandate. The documents include HIV/AIDS policy, National Multisectoral Strategic Framework, Health Sector HIV/AIDS Strategic Plan, Care and Treatment Guideline, HIV/AIDS Prevention Strategy [8,21,24,25].

For the health sector response, of importance to our study is the HIV Care and Treatment guideline. The document provides clear guidance to implementers at all levels of the health care system on what to do in providing HIV Care and Treatment services. Tanzania

established its HIV Care and Treatment Programme in November 2004 after a bill was passed by the parliament in 2003. The HIV Care and Treatment Programme started with support from Clinton foundation, PEPFAR and GFATM. From 2004, the national initiative started in 23 facilities to 1156 facilities by December 2011. The sites include public and private health facilities with different capacities and types[7,26].

From literature, an increase in number of data generated from African ART Treatment programmes has been documented including Tanzania, this data mostly covers outcomes for clients already on HAART[5,6,14,15,16,17].

Typically, poor tracking mechanisms, stock outs of medicines and testing reagents, inequitable and low ART services coverage, late presentation to health delivery points with advanced HIV disease, work fatigue of health care workers providing HIV Care and Treatment services, poor recording and reporting of routinely collected data as well as little analysis of data collected are the challenges facing HIV Care and Treatment program in Tanzania and other resource constrained countries with same HIV endemicity[25,26,27].

2.3 Pre ART Mortality

Few studies have been done to document characteristics of clients enrolled in HIV Care and Treatment Programs before they start HAART (pre ART). In spite of frequently observed high early mortality in Pre ART clients, not much has been done to understand the characteristics of clients and thus know their adherence to set standards(national protocols)[27,28]. There is an enormous gap in knowledge with regard to PLHIVs identified who are known to have died before they initiated ART. Dearth of data shows high early mortality in clients initiated on ART which indicate there is even higher pre treatment mortality[29,30]. With increase in ART access and coverage, pre ART mortality is expected to decrease with time as fewer clients with advanced HIV disease seek treatment. From studies conducted in Low Income Countries (LICs), very little is known of pre ART mortality from health facility setting routinely collected data, many of references observed are from research setting. Evaluation in a community based ART program in South Africa, findings show program

evaluation done assessing only clients initiated on ART is underestimating mortality. The evaluation therefore advices early initiation on ART before WHO Stage 4 is reached[31]. A systematic review paper from sub Saharan Africa show eligible clients for ART were more likely to die than those ineligible, loss to ART programme was more to men, patients with low CD4 cell counts and low social economic status[32]. Findings from Rwanda, with a retrospective of cohort of 31,033 enrolled in HIV Care services revealed male gender, low CD4 count of 100, WHO stage 3 and 4 to be associated with mortality during pre ART phase[33]. From a outcome study conducted in Free State Province of South Africa revealed individuals with CD4 cell count below 25 and men were more likely to die in the pre ART phase[34]. Only one paper was retrieved for Tanzania which prescribed mortality before ART programs started and none was found after ART services started in Tanzania to assess pre ART mortality[35].

2.4 Adherence to National Care and Treatment Protocols

A recent systemic review of pre ART retention in care in Africa revealed substantial loss of patients at every step, starting with patients who do not return for their initial CD4 count results and ending with those who do not initiate ART despite eligibility[5]. In sub Saharan Africa, few countries have documented studies that show adherence to set standards (national protocols or guidelines). Evaluation findings from South Africa, Ethiopia and Swaziland, reveal improvements in the assessment for ART eligibility, management of Opportunistic Infections and timeliness of initiation of treatment for patients with HIV if pre ART service provision follow national guidelines as prescribed by World Health Organisation [29,36,37,38]. Limited information is available from Tanzania looking at adherence to national care and treatment protocols from few selected sites.

CHAPTER THREE

3.0 METHODOLOGY

This chapter narrates methods used in this study. It is structured under the following sections: study area, study design, study population, power calculations and sampling technique, research instrument, variables and definition, data management and analysis, study limitation and ethical considerations.

3.1 Study Area

Health facilities providing CTC services and have electronic CTC database in Tanzania were eligible for the study. Up to December 2011, there were a total of 1156 health facilities providing HIV Care and Treatment services in 21 regions of Tanzania Mainland. Only 570 of the health facilities providing CTC services have the electronic database out of which 348 have exported patient level data recently to National AIDS Control Program and therefore available for analysis. The National Data is accessible at NACP via the data server located at the premises. Data available was collected in the last quarter of 2012 and is from 18 regions

3.2 Study Design

A longitudinal analysis was done for records available of pre-ART patients enrolled into HIV Care and Treatment between November 2004 and December 2011 from electronic sites that have reported to NACP.

3.3 Study Population

The study population is adult Pre ART patients enrolled in HIV Care Program aged 15 and above in Tanzania from Care and Treatment Centers that have electronic CTC database and have longitudinal data reported to NACP between November 2004 and December 2011. In health provision individuals aged 15 and above are categorized as adults in Tanzania.

3.4 Power Calculations and Sampling Technique

All records pertaining to the defined study population and duration were included in the analysis. From the available dataset, there are a total of 526,059 clients aged 15 years and above. We estimated the power of the proposed study to detect significant differences. Previous reports show that mortality among pre-ART patients ranges from 14% to 20% [27,36,37]. Therefore, a size of 526,059 was adequate to detect a minimum of 6% absolute difference in mortality between pre-ART patients with and without risk factor with power greater than 90% taking into account 10% lost to follow up and 5% significance level (see table 1 below).

Table1: Power (in %) to detect a range of differences in risk of mortality

Mortality among pre-ART	**HR=1.5**	**HR=1.8**	**HR=2**
14%	100%	100%	100%
16%	100%	100%	100%
20%	100%	100%	100%

Note: HR=hazard ratio

3.5 Research Instrument

The source document for this study was electronic database that was imported from the CTCs with electronic capacity and reported to NACP. The primary source is the facility held card available at the CTC called CTC2 card (see appendix I). The card is the foundation for both paper and electronic CTCs as it documents all details of the patients enrolled in HIV Care and Treatment programme. The details in the CTC2 card include basic health information and follow up information required for patient and program monitoring.

3.6 Variables and Definitions

Mortality before start of ART was the dependent variable. Sex, age, WHO stage at enrolment, CD4 cell count and adherence to national protocol are independent variables for the study. Other variables extracted included date of enrolment to CTC, ART start date, facility type, weight and TB screening results.

3.7 Data Management and Analysis

Electronic information from sub-national level has built in checks in the system that correct for errors when data was entered at the facility CTC2 microdatabase. Upon data exportation to national level CTC3 macrodatabase there were hardly errors to work on. Data was transferred from MS Access to Stata version 12. Data analysis was done using Stata 12. Patient characteristics at the time of enrolment were described using frequencies and percentages for categorical variables. For continuous variables means (standard deviations) or median (interquartile range) were calculated.

Computation of person years lived following enrolment to CTC was calculated using the starting date as the enrolment date to CTC. The follow up time was defined until the date of death (if the person died without starting ART), or, the date the patient started ART (for those who started ART) or the date the patient was last seen in the clinic (for those who have not died or started ART). Mortality rates were obtained by dividing the number of deaths by the total time at risk, and presented with 95% confidence intervals. Hazard ratios, 95% confidence intervals and corresponding p-values were obtained from Cox proportional hazard models. P-values of less than 0.05 were considered as statistically significant. The following is a summary of analytical processes conducted by objective.

Objective: To estimate the overall mortality rate of HIV care enrollees before they start ART
Data Analysis Process; Mortality rates were obtained by dividing the number of deaths by the total time at risk, and presented with 95% confidence intervals. Total time at risk was the follow up time between enrolment and death prior to ART initiation, date the patient was last seen in the clinic or date of ART initiation.

Objective: To determine the level of adherence to national protocols among Pre ART patients by looking at CD4 testing and TB screening documentation. **Data Analysis Process; *CD4 testing*:** Descriptive analysis was done to look at when is the first CD4 test done to each clients before ART initiation. ***TB Screening Documentation*:** Looking at all visits and the first visits in the data set, descriptively frequencies for TB screening were counted.

Objective: To compare mortality rate of pre-ART HIV care enrollees by socio-demographic and clinical characteristics. **Data Analysis Process;** Univariate, Bivariate and Multivariate analysis (Cox regression Model) were used to determine mortality rate of pre-ART HIV Care enrollees by socio-demographic and clinical characteristics

3.8 Study Limitations

This study has the following limitations;

1. Verification of data collected then entered into the database cannot be done as we are using electronic routinely collected data available at higher level with no identification tags attached.

2. Data available for analysis comes from care and treatment centers with electronic database and have reported to higher levels. This could lead to information bias as electronic sites are well supported by implementing partners.

3. As this study depends on already collected data, addition of new variables to current database cannot be done.

3.9 Ethical Considerations

The proposal was approved by the MUHAS Research and Publications Committee.

The names of patients were dropped from the database upon exporting from the facility, only key variables of clinical and program importance were exported to the macro database located at higher levels (district, region partner and national).

All those who had access to the data signed the Data Transfer Agreement (DTA) that abides the data handler to be careful in using the data. The authorization note from Chief Medical Officer is attached as appendix II.

CHAPTER FOUR

4.0 RESULTS

This chapter documents results from analysis using information from 348 HIV Care sites with electronic database.

4.1 Description of the study participants

The data consisted of 526,059 clients enrolled in the 348 health facilities with electronic monitoring system. Socio demographic and clinical characteristics are shown in Tables 2 and 3. Two thirds of clients enrolled were females (67%). Most of clients were enrolled into HIV Care services were aged 30 to 34 years (21%). Majority of clients were enrolled with CD4 greater than 200 cells/µliter (55%) and a third in WHO stage 3 (38%). About 85% of clients enrolled into HIV Care services with a working functional status.

Mortality rate calculations were based on the known deaths that had been reported to the CTC clinic and documented on the patient record forms. Among the patients who were enrolled, 429,476 patients had available follow-up data and were included in the survival analysis, 10,362 deaths were recorded. The overall mortality was estimated to be 37.6 deaths per 1000 person years with 95% CI (36.9-38.3). Table 2 shows mortality rates by socio-demographic and clinical characteristics. High mortality was observed in males, those aged above 50 years old, single marital status, enrolled in hospital and faith based by ownership. Through the calendar years, mortality ranged from 32.0 deaths to 41.0 deaths per 1000 person years with exception of 2011 were it is 60.4 deaths per 1000 person years. For clinical characteristics high mortality was seen in those weighing less than 45 kilogrammes, BMI less than 20 kilogrammes/metre^2, bedridden functional status, those confirmed to have Tb and WHO stage 4 (Table 3).

Table 2: Socio demographic characteristics of enrolled adult clients in HIV Care Services

Characteristics	Category	Total	Percent	Deaths	1000 Person-years	Mortality rate per 1000 person years (95% CI)
Sex	Male	171,228	33	4217	63.34	66.6 (64.6 - 68.6)
	Female	354,831	67	5283	183.39	28.8 (28.0-29.6)
Age (years)	15-19	12,596	2	175	6.23	27.9 (24.1-32.4)
	20-24	43,610	8	625	24.83	25.2 (23.3-27.3)
	25-29	88,925	17	1474	46.75	31.5 (30.0-33.2)
	30-34	110,530	21	1983	46.745	36.8 (35.1-38.6)
	35-39	98,887	19	1792	43.62	41.1 (39.2-43.0)
	40-45	67,995	13	1261	28.86	43.7 (41.4-46.2)
	45-49	46,510	9	908	19.54	46.5 (43.5-49.6)
	50+	56,870	11	1282	22.73	56.4 (53.4-59.6)
Marital status*	Single	106,580	23	2092	47.83	43.7 (41.9-45.7)
	Married	255,905	56	4403	131.56	33.5 (32.5-34.5)
	Cohabiting	7,013	2	98	3.48	28.2 (23.1-34.3)
	Divorced	45,560	10	789	18.63	42.3 (39.5- 45.4)
	Widowed	44,061	10	658	22.53	29.2 (27.1-31.5)
Facility level*	Hospital	378,530	70	7362	170.84	43.1 (42.1-44.1)
	Health Centre	85,410	16	1124	38.17	29.5 (27.8-31.2)
	Dispensary	71,588	13	855	30.85	27.7 (25.9-29.6)
	Other	8,401	1	115	5.79	19.9 (16.5-23.8)
Facility type*	Private	39,348	7	514	20.23	25.4 (23.3-27.7)
	Government	341,494	69	5719	149.94	38.1 (37.2-39.1)
	FBO/ Voluntary	118,667	24	2371	56.95	41.6 (40.0- 43.3)
Year of enrollment	≤2005	26,144		655	20.5	32.0 (29.5 - 34.4)
	2006	50,407		1,535	38.5	40.0 (38.0 - 41.9)
	2007	76,193		2,209	54.4	41.0 (39.0 - 41.9)
	2008	91,367		2,169	57.9	37.5 (35.9 - 39.1)
	2009	103,787		1,797	52.0	33.3 (31.8 - 34.9)
	2010	97,750		1,209	37.4	32.3 (30.5 - 34.2)
	2011	80,411		788	13.0	60.4 (56.4 - 64.8)

* Do not add up to total due to missing data

Table 3: Clinical characteristics of enrolled clients in HIV Care Services

Characteristics	Category	Total	Percent	Deaths	1000 person-years	Mortality rate per 1000 person years (95% CI)
Weight (kgs)	<45	78,902	16	2966	27.07	109.6 (105.7-113.6)
	45-54	4,747	35	3313	82.21	40.3 (39.0-41.7)
	55+	245,030	49	2271	126.08	18.1 (17.3-18.8)
BMI (kg/m2)	Underweight	23,914	19	671	9.15	73.3 (68.0-79.1)
	Normal	5,181	59	536	42.36	12.7 (11.6-13.8)
	Overweight	28,734	22	96	20.24	4.7 (3.9-5.8)
CD4 cell count (cells/µlitre)	<50	10,376	18	738	2.83	260.7 (242.6-280.2)
	50-199	15,512	27	580	6.77	85.7 (79.0-93.0)
	≥200	30,888	55	520	57.76	9.0 (8.3-9.8)
Functional Status	Working	45,601	85	5771	214.93	26.9 (26.2-27.6)
	Ambulatory	6,288	12	1856	10.91	170.2 (162.6-178.1)
	Bed-ridden	1,605	3	1057	1.70	620.5 (584.2- 659.0)
Pregnancy	Yes	26,353	7	179	11.08	16.2 (14.0-18.7)
	No	340,623	93	4941	170.07	29.1 (28.3-29.9)
TB Status	Confirmed TB	2,601	1	291	2.87	101.3 (90.3-113.6)
	Unconfirmed TB	68,800	99	9210	243.86	37.8 (37.0-38.6)
TB Screening	Screened	73,248	13	8647	223.60	38.7 (37.9-39.5)
	Not screened	98,154	87	854	23.14	36.9 (34.5-39.5)
WHO Stage	1	06,110	21	932	73.60	12.7 (11.9-13.5)
	2	128,729	25	1404	76.08	18.5 (17.5-19.5)
	3	90,936	38	3241	52.06	62.3 (60.2-64.4)
	4	83,601	16	2797	9.39	297.9 (287.2-309.2)

4.2 Adherence to National Protocols among Pre ART Patients

Two components from the national HIV Care Protocol were selected for assessment is using existing electronic routine information from HIV Care Patient Monitoring System namely, CD4 testing and TB screening documentation prior to ART initiation.

4.2.1 CD4 Testing Frequency

Findings from the dataset show a huge variation in CD4 testing. On average, the first CD4 test was done by the 74th day upon enrolling in HIV Care. Table 4 below shows that 45% of clients were tested on the first day and in total 82% of pre ART clients had their CD4 test done and documented by the third month since enrolment. However, about 6% received their first documented CD4 test after one year since enrolment.

Table 4: CD4 testing since enrolment (n= 397,288)

CD4 testing since enrolment	Frequency	Percent
On enrolment day	178,003	45
One month since enrolment	104,933	26
Two months since enrolment	29,561	7
Three months since enrolment	14,598	4
4-6 months since enrolment	24,171	6
7-12 months since enrolment	24,268	6
After 12months since enrolment	24,503	6

4.2.2 TB Screening Documentation

According to the HIV Care Treatment Guideline, clients are to be screened at all visits. Of the 7.2 million visits done by clients in the pre ART phase, TB screening was done or at least documented in 93% of the visits. Further assessment on first visit on enrolment also reveal the same scenario were 91% of clients were screened for TB on first visit. Tuberculosis being the commonest opportunistic infection among clients enrolled in Care, this achievement is a huge stride.

Table 5: TB screening by all visits made and 1st visit on enrolment

TB Screening	Number of visits (%)	
	All Visits	On 1st Visit
Not screened	508,583 (7.0)	48,433 (8.9)
Screened	6,762,526 (93.0)	498,397 (91.1)

4.3 Multivariate Analysis for Factors Associated with Adult Pre ART Mortality

Multivariate analysis was done to determine the influence of socio demographic and clinical factors on mortality of adult pre ART HIV Care clients. Cox regression model was used as this is a time to event analysis. The model contained eight independent categorical variables: sex, first CD4 test done to client, BMI and Weight at enrolment, WHO stage, Functional Status, Tb Screening and Tb status as indicated in Table 6.

Females had significantly a lower hazard (risk) of death than males. The adjusted hazard ratio was 0.62 indicating that females had 38% lower hazard (risk) of death than males. Accounting for sampling variability, the decrease in risk for females could be as large as 44% or as small as 30% (95% CI for the hazard ratio 0.56 -0.70). After adjusting for other variables, clients with 1st CD4 count of more than 200 cells/µlitre had a lower risk of death than those with 50 cells/µlitre (AHR=0.17, 95 % CI 0.15-0.20). Clients weighing more than 45 kilogrammes had significantly a lower hazard of death than those below (weighing 45-54 kgs AHR=0.77, 95 % CI 0.68-0.87) and (weighing ≥55kgs AHR=0.53, 95 % CI 0.46-0.62)).

It was also found that pre ART adult clients enrolling with WHO Stage 3 and 4 had a significantly higher risk of dying than those enrolled with stage one after controlling for all other factors It appears also that, Pre ART adults clients with working functional status had a significantly lower hazard (risk) of death than those with bedridden status after controlling for all other factors (AHR=5.56, 95 % CI (4.70-6.57)).

Table 6: Factors associated with Mortality in Pre ART Clients

Characteristic	Category	Unadjusted HR 95% CI	P-value	Adjusted HR 95% CI	P-value
Sex	Male	Ref		Ref	
	Female	0.47 (0.42-0.51)	<0.001	0.62 (0.56 -0.70)	<0.001
Age at enrolment	15-19	Ref		Ref	
	20-24	0.69 (0.47-1.01)	0.06	0.96 (0.62-1.49)	0.85
	25-29	0.91 (0.64-1.29)	0.56	0.98 (0.66-1.47)	0.94
	30-34	1.09 (0.77-1.54)	0.62	1.07 (0.72-1.59)	0.73
	35-39	1.37 (0.97-1.93)	0.07	1.16 (0.78-1.78)	0.47
	40-45	1.29 (0.91-1.84)	0.15	1.02 (0.68-1.53)	0.92
	45-49	1.48 (1.04-2.11)	0.03	1.24 (0.83-1.88)	0.30
	50+	1.78 (1.26-2.52)	<0.001	1.36 (0.91-2.03)	0.13
1st CD4 count (cells/µlitre)	<50	Ref		Ref	
	50-199.9	0.34 (0.31-0.38)	<0.001	0.46 (0.40-0.52)	<0.001
	>200	0.07 (0.07-0.08)	<0.001	0.17 (0.15- 0.20)	<0.001
BMI at enrolment	Underweight	Ref		Ref	
	Normal	0.26 (0.23-0.29)	<0.001	0.73 (0.50-1.07)	0.11
	Overweight	0.13 (0.10-0.16)	<0.001	0.75 (0.38-1.47)	0.4
WHO Stage at enrolment	1	Ref		Ref	
	2	1.48 (1.36-1.61)	<0.001	1.42 (1.14 -1.76)	0.001
	3	3.86 (3.59-4.15)	<0.001	2.37 (1.94-2.90)	<0.001
	4	13.17 (12.22-14.19)	<0.001	4.53 (3.64 -5.64)	<0.001
Weight at enrolment (kilogram)	<45	Ref		Ref	
	45-54	0.53 (0.47-0.59)	<0.001	0.77 (0.68-0.87)	<0.001
	>55	0.25 (0.22-0.28)	<0.001	0.53 (0.46- 0.62)	<0.001
Functional Status	Working	Ref		Ref	
	Ambulatory	4.40 (3.91-4.95)	<0.001	1.90 (1.66-2.17)	<0.001
	Bedridden	18.55 (16.14-21.33)	<0.001	5.56 (4.70-6.57)	<0.001
TB Screening	Not screened	Ref		Ref	
	Screened	0.81 (0.69-0.94)	0.01	1.25 (1.04-1.52)	0.02

HR - Hazard ratio, Ref - Reference

CHAPTER FIVE

5.0 DISCUSSION

This chapter presents discussion of the results obtained from the study of analyzing the national HIV Care dataset from 348 sites in Tanzania Mainland. This study is one of the few from a resource limited-setting to describe the factors associated with mortality among a pre-ART population of PLHIV. This group of patients has not been well studied compared to PLHIV who are receiving ART.

5.1 Baseline Characteristics of Pre ART Clients

This study examined socio-demographic and clinical baseline characteristics and found that of those enrolled in HIV Care, 2/3 (67%) were female adults. This may be due to opportunities women have of reproductive child health services when they themselves attend or when they bring their infants or children for health services. Due to this, their HIV serostatus is identified earlier and they enroll into HIV Care services with better health than men. Similar findings are seen in other Sub Saharan Countries to name a few Ethiopia[38], Swaziland[29], Mozambique[39]. However, in contrast a study done in India showed a different aspect. Of those enrolled, 60% were male client and this could be due to HIV transmission dynamics or health seeking behaviour patterns outside Sub Saharan Africa are different[40]. Similar with other studies done in Africa, majority of clients were enrolled into HIV Care services in their thirties. Findings from North West Ethiopia show about half (44%) of clients enrolled with CD4 greater than 200 cells/μlitre and most were in in stage 3 (42%)[38]. From our study, 55% of pre ART clients had CD4 greater than 200 cells/μlitre 38% had WHO stage 3 as majority and 85% had working functional status on pre ART enrolment. With progress in scaling up HIV Care provision majority of clients enroll to services when not immunocompromised.

5.2 Adherence to National Protocols

Findings from the study indicate that only 45% had their first CD4 test done upon enrolment into HIV Care services, while by the third month about 82% of those enrolled had done their first CD4 test. For the first documented CD4 test, about half of those tested had more than 200 cells/μlitre. Similar findings are also seen in resource limited settings as in Gambia[27], Swaziland[32] and Ethiopia[38]. Low testing on enrolment is mainly due to type of CD4 machine used. The machines are high volume type and to be cost effective, CD4 testing is not done daily. Strategic thinking needs to be considered to improve documentation of CD4 tests done and facilitate ART initiation upon eligibility[41].

From the study, TB screening was done to majority of clients on every visit. This is a huge stride in TB/HIV Collaborative activities. A previous analysis from Tanzania on TB events at first visit in HIV Care and at start of ART showed a high TB burden among enrolled patients waiting to start ART and a drastic decline just three months after ART initiation[42,43]. Historically, Tanzania is a good model country for TB control where case notification rates have fallen in the last decade and are likely to represent falls in TB incidence[44]. Despite the good emerging evidence, there is need to have initiatives with greater focus on TB screening of clients attending HIV Care clinics on every visit and when on suspicion have proper confirming mechanisms at site or offsite with sound referral systems[45].

5.3 Pre ART Mortality and its Determinants

The results from this study show overall mortality to be 37.6 deaths per 1000 person years among enrolled HIV Care adult clients in the pre ART phase. Findings from elsewhere in Africa for instance Gambia show a pre ART mortality of 21.9 deaths per 100 person years [27]. Looking at specific calendar years, mortality is about the same ranging from 32 to 41 deaths per 1000 person years from 2004-2010 and conspicuously very high in 2011 (61 deaths per 1000 person years). The mortality rate observed in 2011 may be due to all deaths recorded, but incomplete person years documentation. However, this time is overlapping with the famous "kikombe cha babu" time 2010/2011 were it was reported a lot of people sought treatment for

health problems they faced. Unfortunately, a good number of PLHIVs enrolled in HIV Care were part of it. They dropped from receiving services for their own monitoring. Due to this, all HIV Care Services implementing partners were guided by Ministry of Health and Social Welfare to have back to care advocacy initiatives so as to identify, document those lost to follow up and return them for HIV Care services[46].

Through the Cox regression model, mortality in the pre ART phase was shown to be affected by gender, WHO staging, Functional Status and CD4. Few findings are available that assess mortality of clients before ART initiation in SSA with different predictors. Elvin Geng and his IeDEA team in Uganda identified CD4 level less than 200cells/µlitre, malnourishment, and travel time to clinic as factors associated with mortality[36]. A study done in Gambia recognized CD4 level less than 100cells/µlitre and WHO stage 3 and 4 as predictors of mortality in pre ART phase[27,47]. This study findings show those immunocompromised have a higher risk of dying i.e. low CD4 count, WHO stage 3 and 4 and a functional status of bedridden. Similarly, findings show females had a lower risk of death than males (AHR 0.62; 95% CI (0.56-0.70). From Rwanda, Mugisha and team, also saw females to have low risk of death than males in pre ART phase[33]. This trend is observed due to varying health seeking behavior between males and females and thus better outcomes for females.

In this study, BMI was not significantly associated with mortality among patients in pre-ART phase. This is in contrast to findings from a study from Malawi which showed individuals who had BMI less than 16 kg/m^2 had six times risk of dying than those with normal nutritional status[48]. BMI is an anthropometric measure for patient nutritional status and can be influenced by late stage AIDS such as wasting syndrome and opportunistic infections. Findings from our study may be influenced by factors mentioned above[49].

These findings suggest not all ART eligible patients (54%) are initiated on HAART and being the most important finding it needs strategic interventions. Findings from Swaziland show a similar scene (59%) as in this study before moving from fragmented acute care model to a

more comprehensive service to those in pre ART phase[29]. Tanzania still has fragmented acute services in the pre ART phase, learning from Swaziland model is crucial to facilitate timely initiation on HAART of all HIV Care enrollees.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

From findings a conclusion and several recommendations are documented in this chapter.

6.1 Conclusion

Mortality among adult pre ART Care Patients is high in Tanzania Mainland. Clients who enroll with low CD4 less than 50 cells/μlitre, WHO stage 3 and 4, bedridden functional status, and who do not access ART are at higher risk of dying. Overall, TB Screening was done and documented in majority of patients visits in the pre ART phase.

Also majority of clients had received a CD4 test to assess their ART eligibility. However, only 71% had received it in the first month of being enrolled in HIV Care services, 88% received it in their first six months of enrolment. The need of strategic planning for CD4 testing is clearly important for clients in pre ART HIV Care.

6.2 Recommendation

There is need to develop specific interventions for clients as they enroll in pre ART phase. The interventions should focus on targeting the most at risk groups of clients to die in the pre ART phase and fast track them to ART initiation upon ART eligibility assessment. In addition, there is a need to ensure all pre ART clients have CD4 tests result by end of first month and they are screened for TB on every visit.

REFERENCES

1. United Nations. MDG Goal 6: Combat HIV / AIDS , malaria and other diseases. 2012:2012-2013.

2. (UNAIDS). *The road towards universal access: ' Scaling up access to HIV prevention, treatment, care and support ' UNAIDS Concept Paper 2006*.; 2006.

3. Walensky RP, Kuritzkes DR. The impact of the President's Emergency Plan for AIDS Relief (PEPfAR) beyond HIV and why it remains essential. *Clin Infect Dis*. 2010;50(2):272-5. doi:10.1086/649214.

4. GFATM. *THE GLOBAL FUND STRATEGY 2012-2016 : INVESTING FOR IMPACT*.; 2012.

5. Rosen S, Fox MP. Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. *PLoS Med*. 2011;8(7):e1001056. doi:10.1371/journal.pmed.1001056.

6. Akileswaran C, Lurie MN, Flanigan TP, Mayer KH. Lessons learned from use of highly active antiretroviral therapy in Africa. *Clin Infect Dis*. 2005;41(3):376-85. doi:10.1086/431482.

7. TANZANIA Ministry of Health and Social Welfare. Health Sector HIV/AIDS Strategic Plan II (2008-12).

8. UN. General Assembly: UN Millenium Declaration. 2000;(September).

9. UNITED NATIONS. *Declaration for Commitment on HIV/ AIDS. United Nations Special Assembly on HIV/AIDS*.; 2001.

10. UNAIDS. *UN Political Declaration 2006*.; 2006:1-8.

11. UNAIDS. *Annual Report 2009*. International Food Policy Research Institute; 2010. doi:10.2499/9780896297852.

12. UNAIDS. *UNAIDS World AIDS Day Report 2011. How to get zero: Faster. Smarter. Better*.; 2011.

13. WHO, UNAIDS. *Global update on HIV treatment 2013: results, impact and opportunities*.; 2013.

14. Chalamilla G, Hawkins C, Okuma J, et al. Mortality and Treatment Failure among HIV-Infected Adults in Dar Es Salaam, Tanzania. *J Int Assoc Physicians AIDS Care (Chic)*. 2012;11(5):296-304. doi:10.1177/1545109711406733.

15. Nuwagaba-Biribonwoha H, Kilama B, Antelman G, et al. Reviewing progress: 7 year trends in characteristics of adults and children enrolled at HIV care and treatment clinics in the United Republic of Tanzania. *BMC Public Health*. 2013;13(1):1016. doi:10.1186/1471-2458-13-1016.

16. Wringe A, Floyd S, Kazooba P, et al. Antiretroviral therapy uptake and coverage in four HIV community cohort studies in sub-Saharan Africa. *Trop Med Int Health*. 2012;17(8):e38-48. doi:10.1111/j.1365-3156.2011.02925.x.

17. Hoffmann CJ, Fielding KL, Charalambous S, et al. Reducing mortality with cotrimoxazole preventive therapy at initiation of antiretroviral therapy in South Africa. *AIDS*. 2010;24(11):1709-16. doi:10.1097/QAD.0b013e32833ac6bc.

18. Geng EH, Nash D, Kambugu A, et al. Retention in care among HIV-infected patients in resource-limited settings: emerging insights and new directions. *Curr HIV/AIDS Rep*. 2010;7(4):234-44. doi:10.1007/s11904-010-0061-5.

19. Nsigaye R, Wringe A, Roura M, et al. From HIV diagnosis to treatment: evaluation of a referral system to promote and monitor access to antiretroviral therapy in rural Tanzania. *J Int AIDS Soc*. 2009;12(1):31. doi:10.1186/1758-2652-12-31.

20. MINISTRY OF HEALTH AND SOCIAL WELFARE NACP. *National Guidelines for the clinical management of HIV and AIDS, 4th Edition*.; 2012.

21. *UNAIDS Report on the global AIDS epidemic | 2012*.; 2012.

22. TACAIDS. HIV/AIDS and Malaria Indicator Survey 2011-12. 2011.

23. NACP. *THE UNITED REPUBLIC OF TANZANIA MINISTRY OF HEALTH AND SOCIAL WELFARE TANZANIA MAINLAND National AIDS Control Programme SURVEILLANCE OF HIV AND SYPHILIS INFECTIONS AMONG ANC ATTENDEES*.; 2008.

24. TACAIDS. *NMSF III MASTER FINAL DRAFT 9 DOCUMENT 04 JULY 2013*.

25. UNAIDS. UA Aide Memoire: A Review of HIV and AIDS Universal Access in Tanzania UNGASS 2006 Targets.

26. NACP. Implementation of HIV Care and Treatment Services in Tanzania 2009. 2009;2.

27. Togun T, Peterson I, Jaffar S, et al. Pre-treatment mortality and loss-to-follow-up in HIV-1, HIV-2 and HIV-1/HIV-2 dually infected patients eligible for antiretroviral therapy in The Gambia, West Africa. *AIDS Res Ther*. 2011;8(1):24. doi:10.1186/1742-6405-8-24.

28. Ivers LC, Kendrick D, Doucette K. Efficacy of antiretroviral therapy programs in resource-poor settings: a meta-analysis of the published literature. *Clin Infect Dis*. 2005;41(2):217-24. doi:10.1086/431199.

29. Burtle D, Welfare W, Elden S, et al. Introduction and evaluation of a "pre-ART care" service in Swaziland: an operational research study. *BMJ Open*. 2012;2(2):e000195. doi:10.1136/bmjopen-2011-000195.

30. Hoffmann CJ, Lewis JJ, Dowdy DW, et al. Mortality associated with delays between clinic entry and ART initiation in resource- limited- settings: results of a transition-state model. *J Acquir Immune Defic Syndr*. 2013;63(1):105-111. doi:10.1097/QAI.0b013e3182893fb4.Mortality.

31. Lawn SD, Myer L, Orrell C, Bekker L, Wood R. Early mortality among adults accessing a community- based antiretroviral service in South Africa : implications for programme design. 2005;(August).

32. Mugglin C, Estill J, Wandeler G, et al. Loss to programme between HIV diagnosis and initiation of antiretroviral therapy in sub-Saharan Africa: systematic review and meta-analysis. *Trop Med Int Health*. 2012;17(12):1509-1520. doi:10.1111/j.1365-3156.2012.03089.x.

33. Mugisha V, Teasdale C a, Wang C, et al. Determinants of mortality and loss to follow-up among adults enrolled in HIV care services in Rwanda. *PLoS One*. 2014;9(1):e85774. doi:10.1371/journal.pone.0085774.

34. Ingle S, May M, Uebel K, et al. Outcomes in patients Waiting for Antiretroviral Treatment in the Free State Province, South Africa: Prospective Linkage Study. *AIDS*. 2010;24(17):2717-2725. doi:10.1097/QAD.0b013e32833fb71f.Outcomes.

35. Todd J, Balira R, Grosskurth H, et al. HIV-associated adult mortality in a rural Tanzanian population. *AIDS*. 1997;11(6):801-7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/9143613.

36. Geng EH, Bwana MB, Muyindike W, et al. Failure to Initiate Antiretroviral Therapy , Loss to Follow-up and Mortality Among HIV-Infected Patients During the Pre-ART Period in Uganda. 2013;63(2):64-71.

37. Bassett I V, Wang B, Chetty S, et al. Loss to Care and Death Before Antiretroviral Therapy in Durban , South Africa. 2009;51(2):135-139.

38. Ahmed I, Gugsa ST, Lemma S, Demissie M. Predictors of loss to follow-up before HIV treatment initiation in Northwest Ethiopia: a case control study. *BMC Public Health*. 2013;13(1):867. doi:10.1186/1471-2458-13-867.

39. Palombi L, Marazzi MC, Guidotti G, et al. Incidence and Predictors of Death, Retention, and Switch to Second- Line Regimens in Antiretroviral- Treated Patients in Sub- Saharan African Sites with Comprehensive Monitoring Availability. *Clin Infect Dis*. 2009;48(1):115-122. doi:10.1086/593312.

40. Alvarez-uria G, Midde M, Pakam R, Naik PK. Predictors of Attrition in Patients Ineligible for Antiretroviral Therapy after Being Diagnosed with HIV : Data from an HIV Cohort Study in India. 2013;2013.

41. WHO. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach June 2013.*; 2013.

42. Ph D, Lugoba S, Fitzgerald DW, Downs JA. Initiation of Antiretroviral Therapy : a Case-Control Study. 2013;16(8):1047-1051. doi:10.5588/ijtld.11.0772.Predictors.

43. Bonita K, Jan van den H, Jim T, Swai R, Geoffrey Somi. Five Years (2004-2009) Antiretroviral Treatment for HIVAIDS in Tanzania TB, Outcomes and TB events. In: ; 2011.

44. TANZANIA Ministry of Health and Social Welfare. Report of the United Republic of Tanzania National Tuberculosis and Leprosy Programme External Review. 2014.

45. Naidoo K, Baxter C, Karim SSA. When to start antiretroviral therapy during tuberculosis treatment. *Curr Opin Infect Dis*. 2013;26(1):35-42. doi:10.1097/QCO.0b013e32835ba8f9.When.

46. National Bureau of Statistics. Tanzania in Figures 2010. In: ; 2011.

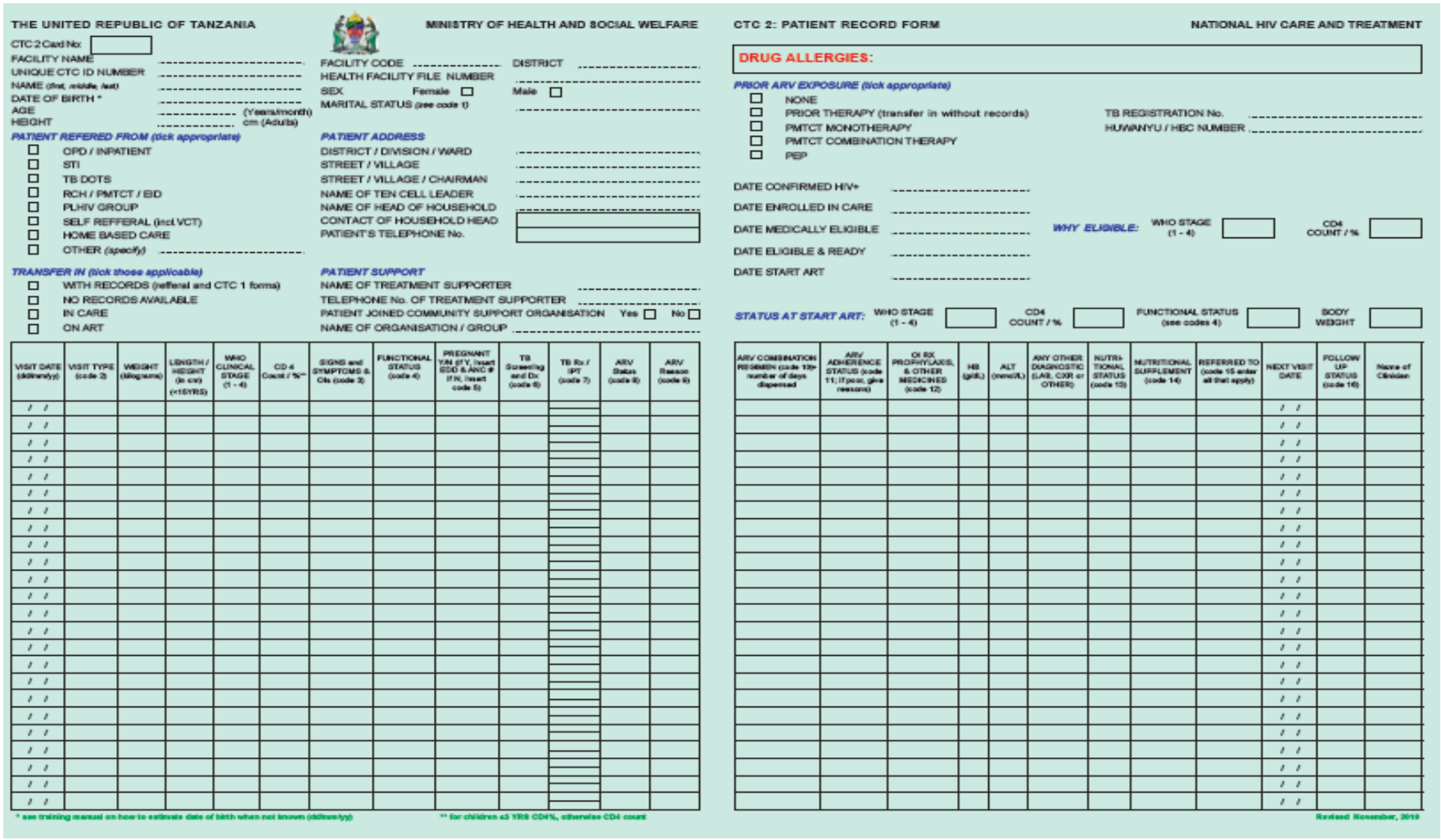
47. Amuron B, Namara G, Birungi J, et al. Mortality and loss-to-follow-up during the pre-treatment period in an antiretroviral therapy programme under normal health service conditions in Uganda. *BMC Public Health*. 2009;9:290. doi:10.1186/1471-2458-9-290.

48. Zachariah R, Fitzgerald M, Massaquoi M, et al. Risk factors for high early mortality in patients on antiretroviral treatment in a rural district of Malawi. *AIDS*. 2006;20(18):2355-60. doi:10.1097/QAD.0b013e32801086b0.

49. Van der Sande M a. B, van der Loeff MFS, Aveika A a, et al. Body Mass Index at Time of HIV Diagnosis. *JAIDS J Acquir Immune Defic Syndr*. 2004;37(2):1288-1294. doi:10.1097/01.qai.0000122708.59121.03.

APPENDICES

Appendix I: CTC 2 CARD



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

CTC 2: PATIENT RECORD FORM

NATIONAL HIV CARE AND TREATMENT

CTC 2 Card No:

FACILITY NAME

UNIQUE CTC ID NUMBER

NAME (first, middle, last)

DATE OF BIRTH *

AGE (Years/month)

HEIGHT cm (Adults)

FACILITY CODE

DISTRICT

HEALTH FACILITY FILE NUMBER

SEX Female ☐ Male ☐

MARITAL STATUS (see code 1)

PATIENT REFERED FROM (tick appropriate)

- ☐ OPD / INPATIENT
- ☐ STI
- ☐ TB DOTS
- ☐ RCH / PMTCT / EID
- ☐ PLHIV GROUP
- ☐ SELF REFFERAL (Incl VCT)
- ☐ HOME BASED CARE
- ☐ OTHER (specify)

PATIENT ADDRESS

DISTRICT / DIVISION / WARD

STREET / VILLAGE

STREET / VILLAGE / CHAIRMAN

NAME OF TEN CELL LEADER

NAME OF HEAD OF HOUSEHOLD

CONTACT OF HOUSEHOLD HEAD

PATIENT'S TELEPHONE No.

TRANSFER IN (tick those applicable)

- ☐ WITH RECORDS (referal and CTC 1 forms)
- ☐ NO RECORDS AVAILABLE
- ☐ IN CARE
- ☐ ON ART

PATIENT SUPPORT

NAME OF TREATMENT SUPPORTER

TELEPHONE No. OF TREATMENT SUPPORTER

PATIENT JOINED COMMUNITY SUPPORT ORGANISATION Yes ☐ No ☐

NAME OF ORGANISATION / GROUP

DRUG ALLERGIES:

PRIOR ARV EXPOSURE (tick appropriate)

- ☐ NONE
- ☐ PRIOR THERAPY (transfer in without records)
- ☐ PMTCT MONOTHERAPY
- ☐ PMTCT COMBINATION THERAPY
- ☐ PEP

TB REGISTRATION No.

HUWANYU / HBC NUMBER

DATE CONFIRMED HIV+

DATE ENROLLED IN CARE

DATE MEDICALLY ELIGIBLE

DATE ELIGIBLE & READY

DATE START ART

WHY ELIGIBLE: WHO STAGE (1 - 4) CD4 COUNT / %

STATUS AT START ART: WHO STAGE (1 - 4) CD4 COUNT / % FUNCTIONAL STATUS (see codes 4) BODY WEIGHT

VISIT DATE (dd/mm/yy)	VISIT TYPE (code 2)	WEIGHT (kilograms)	LENGTH / HEIGHT (in cm) (<15YRS)	WHO CLINICAL STAGE (1 - 4)	CD 4 Count / %**	SIGNS and SYMPTOMS & Dis (code 3)	FUNCTIONAL STATUS (code 4)	PREGNANT Y/N (FY, Insert EDD & ANC # if N, Insert code 5)	TB Screening and Dx (code 6)	TB Rx / IPT (code 7)	ARV Status (code 8)	ARV Reason (code 9)
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ARV COMBINATION REGIMEN (code 10)+ number of days dispensed	ARV ADHERENCE STATUS (code 11; if poor, give reasons)	OI RX PROPHYLAXIS, & OTHER MEDICINES (code 12)	HB (g/dL)	ALT (mmol/L)	ANY OTHER DIAGNOSTIC (LAB, CXR or OTHER)	NUTRI-TIONAL STATUS (code 13)	NUTRITIONAL SUPPLEMENT (code 14)	REFERRED TO (code 15 enter all that apply)	NEXT VISIT DATE	FOLLOW UP STATUS (code 16)	Name of Clinician
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* see training manual on how to estimate date of birth when not known (dd/mm/yy)

** for children ≤3 YRS CD4%, otherwise CD4 count

Revised November, 2010

CTC 2 DISCUSSION TOPICS AND CODES

Discussion topics for follow-up education and counseling (group or individual, pre- and post ART)
Coose one to three priority topics each visit

Topic	Date	Comments	Date	Comments	Date	Comments	Date	Comments
Basic HIV / AIDS and prevention								
Disclosure and identifying treatment supporter								
Coping and planning the future								
Promoting Testing within household								
Pregnancy, MTCT and family Planning								
Adolescent Issues								
Disease progression and role of ART								
Prevention of diseases; environmental hygiene, hand washing, bednets and nutrition								
CTX and INH prophylaxis								
Importance of adherence, how to remind, plan, what to do when travel, sick etc. Refer to checklist								
How to use CTC1 for exemptions								
Importance of HBC and PLHA support group								
Self Care								
Importance of appointments, dates and time, planning transport								
Provide patient leaflets / brochures								

1. MARITAL STATUS
S = SINGLE
M = MARRIED
CO = COHABITING
D = DIVORCED/SEPARATED
W = WIDOW/WIDOWED

2. VISIT TYPE
S = Scheduled visit at this clinic
US = unscheduled visit at this clinic
TK = Traced back after LTFU
TS = Treatment supports drug pick up
O = Visit other clinic (refill / outreach or transit)
IP = In-Patient Consultation

3. SIGNS, SYMPTOMS AND OIs
ABDOMINAL PAIN
ANAEMIA
BN BURNING, NUMB,TINGLING
CNS DIZZY, ANXIETY, NIGHTMARE, DEPRESSION
COUGH *
DB DIFFICULT BREATHING
DEMENTIA
DIARRHOEA
ENC- HIV ENCEPHALOPATHY
FAT CHANGES
FATIGUE
FEVER *
GUD GENITAL ULCER DISEASE
HEADACHE
HM HEMOPTYSIS*
IRIS IMM. RECONST. INFLAMM SYNDROME
ITCHING
JAUNDICE
MOLLUSCUM
NIGHT SWEATS*
NAUSEA
PE PAROTID ENLARGEMENT
PID PELVIC INFLAMMATORY DISEASE
PNEUMONIA
PPE PAPULAR PRURITIC ERUPTIONS
RASH
THRUSH ORAL / VAGINAL
UD URETHRAL DISCHARGE
ULCERS MOUTH OR OTHER
WEIGHT LOSS*
ZOSTER
If other, specify:
OPPORTUNISTIC INFECTIONS
CM CRYPTOCOCCAL MENINGITIS
KS KAPOSIS SARCOMA
OC OESOPHAGEAL CANDIDIASIS
PCP Pneumocystis Pneumonia
** These are TB Symptoms*

4. FUNCTIONAL STATUS
W = WORKING A = AMBULATORY
B = BEDRIDDEN

5. FAMILY PLANNING
O = NOT USING P = PILLS
J = DEPO INJECTION M = IMPLANTS
Z = STERILIZATION C = CONDOM
T = TRADWITHDRAWAL L = IUD

6. TB SCREENING / DIAGNOSIS
Screen –ve = Answered NO to all 5 TB screening questions
TB Susp = Answered Yes to 1 or more of TB screening questions
SS + = Sputum Sample Positive
SS – = Sputum Sample Negative
CXR + = Chest X-Ray suggestive of TB
CXR - = X-Ray NOT suggestive of TB

9. ARV REASON

NO START
51 DOES NOT FULFILL CRITERIA
52 FULFILLS CRITERIA BUT COUNSELING FOR ARVS ONGOING
53 FULFILLS CRITERIA BUT NO ARVS AVAILABLE
54 FULFILLS CRITERIA BUT IS NOT WILLING
55 FULFILLS CRITERIA BUT IS ON TB RX
57 FULFILLS CRITERIA BUT AWAITS LAB RESULTS
58 FULFILLS CRITERA BUT HAS OI AND IS TOO SICK TO START
99 FULFILLS CRITERIA BUT NO START - OTHER

ARV START
101 ADULT CD4 < 200
102 ADULT WHO STAGE IV
103 ADULT WHO STAGE III, IF CD4 < 350
104 CHILDREN PEDIATRIC WHO STAGE III
105 CHILDREN BETWEEN 12-59 MONTHS CD4%<20%
106 INFANTS UNDER 12 MONTHS
107 CHILDREN ≥ 5 YEARS CD4 < 15%
108 PREGNANT WOMEN FOR PMTCT (PLUS)
109 OTHER REASON TO START

CHANGES OR STOP ARVS BECAUSE OF TB OR ADVERSE REACTIONS
110 START TB TREATMENT
111 NAUSEA / VOMITING
112 DIARRHOEA
113 HEADACHE
114 FEVER
115 RASH
116 PERIPHERAL NEUROPATHY
117 HEPATITIS
118 JAUNDICE
119 DEMENTIA
120 ANAEMIA
121 PANCREATITIS
122 CNS ADVERSE EVENT
123 OTHER ADVERSE EVENT (SPECIFY)

CHANGE OR STOP ARVS BECAUSE OF TREATMENT FAILURE
131 TREATMENT FAILURE, CLINICAL
132 TREATMENT FAILURE, IMMUNOLOGICAL

CHANGE OR STOP ARVS, OTHER REASON
141 POOR ADHERENCE
142 PATIENT DECISION
143 PREGNANCY
144 END OF PMTCT
148 STOCK OUT
149 OTHER REASON (SPECIFY)
151 RESTART ARV AFTER 3 OR MORE MONTHS NOT ON ARV

10. ARV COMBINATION REGIMEN

1ST LINE

1a	d4T, 3TC+NVP	Paeds
1a (30)	d4T(30)+3TC+NVP	Adults
1a(30)L	d4T(30)+3TC+NVP	Adults Loading dose
1b	ZDV(AZT)+3TC+NVP	Adults and Paeds
1c	ZDV(AZT)+3TC+EFV	Adults and Paeds
1d	d4T+3TC+EFV	Paeds
1d (30)	d4T(30)+3TC+EVF	Adults
1e	TDF+FTC+EFV	Adults
1f	TDF+FTC+NVP	Adults
1g	TDF+3TC+EFV	Adults
1h	TDF+3TC+NVP	Adults
1x	Other first line	Adults and Paeds

2ND LINE

2a	ABC+ddI+ LPV/r	Adults and Paeds
2b	ABC+ddI+ SQV/r	Adults and Paeds
2d	ABC+ddI+ ATV/r	Adults
2e	TDF+3TC+LPV/r	Adults
2f	TDF+FTC+LPV/r	Adults
2g	ABC+3TC+LPV/r	Paeds
2x	other second line	Adults and Paeds

7. TB TREATMENT (Rx) / IPT

START TB	= START TB Rx	(Insert date)
CTN TB	= CONTINUE	
CPLT TB	= COMPLETE	(Insert date)
STOP TB	= STOPPED	(Insert date)
RES TB	= RESTART	(Insert date)

Restart screening after Completion TB Rx

START IPT	= START IPT	(Insert date)
CTN IPT	= CONTINUE	
CPLT IPT	= COMPLETE	(Insert date)
STOP IPT	= STOPPED	(Insert date)
RES IPT	= RESTART	(Insert date)

Restart screening after client stops IPT

8. ARV STATUS
1 = NO ARV 2 = START ARV
3 = CONTINUE 4 = CHANGE
5 = STOP 6 = RESTART

11. ARV ADHERENCE
G (good) = fewer than 2 missed days
P (poor) = 2 or more missed days

REASONS FOR POOR ARV ADHERENCE
1 = TOXICITY
2 = SHARE WITH OTHERS
3 = FORGOT TO TAKE DRUGS
4 = FELT BETTER
5 = TOO ILL
6 = STIGMA
7 = PHARMACY DRUG STOCK OUT
8 = PATIENT LOST / RAN OUT OF PILLS
9 = DELIVERY / TRAVEL PROBLEMS
10 = INABILITY TO PAY
11 = ALCOHOL
12 = DEPRESSION
13 = OTHER (SPECIFY)

12. OI TREATMENT / PROPHYLAXIS AND RELEVANT CO-MEDICATIONS
1 = COTRIMOXAZOLE
2 = FLUCONAZOLE
3 = OTHER ANTIBIOTICS
4 = ANTIMALARIAL
5 = OTHER

13. NUTRITIONAL STATUS
OK = NOT MALNOURISHED
MOD = MODERATE MALNOURISHED
SEV = SEVERELY MALNOURISHED

14. NUTRITIONAL SUPPLEMENT
TF = THERAPEUTIC FOOD
SF = SUPPLEMENTAL FOOD
NA = NOT APPLICABLE

15. REFERED TO
1 = PMTCT
2 = HBC
3 = PLHIV SUPPORT GROUP/CLUB
4 = ORPHAN AND VULNERABLE CHILDREN GROUP
5 = MEDICAL SPECIALITY
6 = NUTRITIONAL SUPPORT
7 = LEGAL
8 = TB CLINIC
9 = FP SERVICES
10 = OTHER (SPECIFY)

16. FOLLOW UP STATUS
MISSAPP = 1 OR 2 missing APPOINTMENTS
LTF = LOST TO FOLLOW-UP (Not seen for 3 or more months since last scheduled appointment [ART patients], OR 3 or more missing appointments [pre-ART patients] with 2 attempts to follow-up)
TO = TRANSFER OUT, if TO, to where?
DEAD = PATIENT DIED
OPT OUT = PATIENT OPTED OUT

Appendix II: The authorization note from Chief Medical Officer

MINUTE SHEET

Dokezo No.

CMO 24/1/13

YAH: NAFASI NA CHANGAMOTO ZA TAKWIMU ZIKUSANYWAZO NA MPANGO

Mpango wa Taifa wa kudhibiti UKIMWI umekuwa ukiratibu na kutengeneza mfumo wa kurekodi na kurepoti kwa huduma za tiba na matunzo kwa watu waishio na na VVU. Tangu 2004, mfumo huu umewezesha mpango kukusanya takwimu (paper and electronic) ambazo zinatumika kurepoti kitaifa na kimataifa. Mpango umeweza kuandika repoti mbili kwa kutumia takwimu inazokusanya kwa kusaidiwa na project iliyokuwa inawezeshwa kifedha na Pharmaccess International na kiufundi na London School of Hygiene and Tropical Medicine(LSHTM).Ufadhili wa kifedha wa Pharmaccess uliisha Desemba 2011.

Takwimu tuliyonayo ina taarifa za mahudhurio yote ya wagonjwa wote wapatao huduma kwa mfumo elektroniki kwa vituo 424. Taarifa hizi zaweza kujulisha mengi kwa wadau mbalimbali na kuna nafasi ya wadau mbali mbali kupata nafasi ya kujifunza "***analysis kwa dataset***" kubwa sana ***(longitudinal analysis of huge datasets***). Katika kupanga hili, mwezi wa Juni 2012, mpango uliitisha warshakuwezesha wadau katika kufanya analysis kwa kuangalia ripoti zilizopita kwa kusaidiwa na LSHTM. Katika warsha hii wadau waliofundishwa walitoka MUHAS- School of Public Health and Social Sciences - 3, wanafunzi kutoka FELTP - 2 na KCMC - 6 wadau wa tiba na matunzo (Implementing Partners) - 20, NACP - 8, NIMR Mwanza - 4.

Katika warsha ilikuwa dhahiri, kuna muhimu wa kuwezesha wadau zaidi na kuendelea kuwashirikisha waliofika kwa warsha. Katika hili tunapendekeza yafuatayo:-

1. Kuwezesha wazawa watumie takwimu hizi kwa ruhusa maalumu kufanyia (Masters, PhD, post doc) na hata waalimu au watafiti wanaotafuta taarifa za kufanyia kazi ili wapande vyeo kikazi au kwa makongamano.

2. Tunaomba kutumia form ya "***Data Transfer Agreement***" iliyotengenezwa na NIMR ili wazawa wawezeshwe ipasavyo, ili kuzuia wageni wasitumie takwimu bila mkataba wowote. Takwimu ziwezeshe wazawa zaidi.

3. Kufanya uhakiki wa wagonjwa waliohama au wanaopata huduma katika kituo zaidi ya kimoja. Mpango unaweza kufanya hili sababu unatakwimu za wagonjwa zaidi ya laki nane ambazo unaweza kufanyia upembuzi. Ruhusa inaombwa ili tuweze tumia software iliyotengenezwa na mdau Futures group – IQ tool, mdau ametumia IQ tool kwa mkoa wa Tanga, Mara, Musoma na Mwanza kutambua wagonjwa wanaopata huduma zaidi ya sehemu moja, waliohama na kwenda kwingine. Tunaamini zoezi hili litatuwezesha kujua wanaoacha kutumia dawa au kupotea ***(attrition).***

Ninawasilisha kwa hatua zaidi.

Dkt. Robert M.Josiah
KAIMU MENEJA MPANGO-NACP
24 Januari, 2013

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Appendix III: Ethical Clearance Approval Letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

Directorate of Postgraduate Studies

P.O. BOX 65001
DAR ES SALAAM
TANZANIA.

Website: http://www.muhas.ac.tz

Tel: +255-(0)22-2150302 Ext 207.
Tel (Direct): +255-(0)22-2151378
Telefax:255-(0)22-2150465
E-mail: *dpgs@muhas.ac.tz*

Ref. No. MU/PGS/SAEC/Vol.IX/

19th December, 2013

Ms. Bonita Kilama
MPH-Executive Track
MUHAS.

Re: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED "MORTALITY AND ITS DETERMINANTS AMONG ADULT PRE-ART HIV CARE PATIENTS IN TANZANIA"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has on behalf of the Senate approved ethical clearance for the above-mentioned study.

Thus ethical clearance is granted and you may proceed with the planned study.

Prof. O. Ngassapa
DIRECTOR, POSTGRADUATE STUDIES

/emm

c.c. Dean, School of Public Health and Social Sciences - MUHAS