Factors Associated with Delayed Antiretroviral Therapy Initiation among Tuberculosis/
Human Immunodeficiency Virus Co-infected Patients in Lupane District, 2015

By

John Manyara

Dissertation Submitted in Partial Fulfillment of

Master in Public Health Degree

University of Zimbabwe

Faculty of Health Sciences
Department of Community Medicine
University of Zimbabwe

Harare

August 2015
DECLARATION

I certify that this dissertation is my original work and submitted for the Master in Public Health Program. It has not been submitted in part or in full to any University and or any publication.

Student:
Signature __________________________Date __________________________

John Manyara

I having supervised and read this dissertation. I am satisfied that this is the original work of the author in whose name it is being presented. I confirm that the work has been completely satisfactory for presentation in the examination.

Academic Supervisor:
Signature __________________________Date __________________________

Dr. G. Shambira

Chairman:
Signature __________________________Date __________________________

Professor S. Rusakaniko
Acknowledgements

I extend my sincere gratitude to my field supervisor, Dr N. Masuka for his guidance and to the staff and management at Matabeleland North Provincial Medical Directorate for their support. Special thanks go to Dr G. Shambira for his guidance in the preparation of this dissertation. I am grateful for the dedicated support I got from staff at Department of Community Medicine and Health Studies Office. I would like to thank the study participants who consented to participate in this study. My family and colleagues also supported me during the conduct of this study and I am so thankful.

John Manyara

University of Zimbabwe, August 2015
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**Abbreviations**

ART- Antiretroviral Therapy

ATT- Anti-Tuberculosis Treatment

CPT- Cotrimoxazole preventive therapy

DEHO- District Environmental Health Officer

DMO- District Medical Officer

DNO- District Nursing Officer

HIV- Human Immunodeficiency Virus

TB- Tuberculosis

WHO- World Health Organization
Abstract

**Background:** Antiretroviral therapy (ART) should be given to all Human Immunodeficiency Virus (HIV)-positive Tuberculosis (TB) patients within the first eight weeks of commencing anti-tuberculosis treatment (ATT), to reduce risk of mortality. In 2012 and 2013, Lupane district initiated 62% and 37% respectively of TB/ HIV co-infected patients on ART against a target of 100%. The study was conducted to determine the prevalence of delayed ART initiation in 2015 and to identify factors associated with the delays.

**Methods:** An analytic cross sectional study was conducted at seven health facilities in Lupane district. Two hundred and ten study participants were recruited into the study. A checklist was used to assess for quality of care at the health facilities. Key informant interviews were held with program Managers and health workers.

**Results:** Among the 210 patients studied, 19 % (n= 39) delayed ART initiation. The median delay between starting ATT and ART was 23 days (Q1= 18 days, Q3= 30 days). Independent factors associated with ART initiation were marital status; separated (AOR 6.21, 95% CI 1.63-23.71), single (AOR 9.58 95% CI 2.39 – 38.36) and widowed (AOR 14.23 95% CI 1.72 – 117.76), first HIV treatment at health centre (AOR 0.35 95% CI 0.13-0.94), transport cost more than US$1 (AOR 5.69, 95% CI 1.87-17.34), fear of medicine toxicity (AOR 7.68, 95% CI 2.63-22.41), and having a family member on TB treatment (AOR 0.22, 95% CI 0.07-0.67). ART follow up and outreach was not being done at all the facilities. Communication on referred TB/ART patients was not complete between facilities.

**Conclusion:** Intensifying ART preparation, streamlining clinic visit schedule protocols, follow up on defaulting patients and outreach clinics are vital in averting delays. Health workers should communicate on referred ART patients to expedite linkage in care.

**Key words:** Human Immunodeficiency Virus, Antiretroviral therapy, Tuberculosis, Anti-Tuberculosis Treatment, Lupane
Introduction

1.1 Global situation and trends
Globally, between 33.2 and 37.2 million people and an estimated 0.8% of adults aged 15–49 years were living with Human immunodeficiency virus (HIV) at the end of 2013\(^1\). Sub-Saharan Africa has the highest prevalence, with approximately one in twenty adults living with HIV, contributing 71% of the people living with HIV (PLHIV) globally\(^1\).

Tuberculosis (TB) remains one of the world’s most serious communicable diseases\(^2\). In 2013, an estimated 9 million people developed TB and 1.5 million died from the disease, 360 000 of whom were HIV-positive\(^2\). TB is declining slowly every year and between 2000 and 2013 an estimated 37 million lives were saved as a result of effective diagnosis as well as treatment\(^2\).

1.2 Global Collaborative TB/HIV Activities
TB is the most frequent illness occurring in people living with HIV, inclusive of those on antiretroviral treatment (ART). In 2013, approximately 1.1 million HIV positive new TB cases were reported, 78% of which live in sub-Saharan Africa\(^3\). An estimated one-third of 35 million PLHIV globally have latent TB. PLHIV are 29 times more likely to contract active TB than those not HIV infected\(^3\).

HIV both increases the likelihood of progression from infection with \textit{M. tuberculosis} to active tuberculosis and changes the clinical presentation of TB disease (PLHIV are more likely to present with extra pulmonary or sputum smear-negative TB than HIV-uninfected TB patients, especially as immune suppression advances)\(^4\). Knowing a TB patient’s HIV status, therefore, has very important bearing on his or her TB care. Cotrimoxazole prophylaxis and ART reduce morbidity and prolong survival following successful TB treatment\(^4\).

According to the World Health Organization (WHO), patients with presumptive or diagnosed TB as well as their partners and family members should be offered routine HIV testing. TB
patients who are found to be HIV-positive should be provided with Cotrimoxazole preventive therapy (CPT) and ART should be given to all HIV-positive TB patients as soon as possible within the first eight weeks of commencing anti-tuberculosis treatment (ATT), regardless of their CD4 cell-counts². Those HIV-positive TB patients with profound immune-suppression, for example CD4 counts less than 50 cells/mm³, should receive ART immediately within the first 2 weeks of initiating TB treatment⁵.

In 2013, forty eight percent of the 2.9 million TB patients (2.9 million) were tested for HIV; an increase from 46% in 2012. ART initiated early within two to eight weeks after commencement of ATT is critical in reducing the risk of mortality. The interaction of TB with HIV causes extra problems to TB control. It is imperative to improve and fortify TB/HIV collaborative activities to decrease the occurrence of TB among people living with HIV (PLHIV) and decrease the occurrence of HIV in TB patients⁶.

The WHO has the following activities recommended for TB/HIV collaboration⁵:

- Establish and strengthen the mechanisms for delivering integrated TB and HIV services
  - Setting up and strengthening a body to coordinate TB/HIV collaborative activities at different levels
  - To determine the prevalence of TB and HIV among TB patients and the HIV infected
  - To integrate TB and HIV planning and delivery services
  - The monitoring and evaluation of TB/HIV collaborative activities⁵

- Decrease the burden of HIV in presumptive and diagnosed TB patients
  - Providing HIV counseling and testing services to TB patients
- Providing interventions towards HIV prevention for TB patients

- Providing CPT for TB patients PLHIV

- Ensuring interventions for HIV prevention, care and treatment for HIV infected TB patients

- Providing ART for TB patients living with HIV

There has been significant progress in global implementation of this package, which contributed to an estimated 1.3 million lives saved between 2005 and 2011. It is important that the implementation and scale-up of these collaborative activities and evaluation of their impact be continuously monitored.

1.3 Zimbabwe context

Zimbabwe is a high burden TB and HIV country with an estimated prevalence of HIV, according to the National AIDS Council, 2014. In 2013, the estimated incidence rate for TB was 552 per 100,000 population. A total of 22,442 (69%) of TB patients were HIV positive, of which 17,267 (77%) were on ART. HIV testing for TB patients is an entry point to other HIV services. Nationally, there has been a gradual increase in HIV testing rate among TB patients from 27% in 2008 to 92% in 2013. There were HIV testing rate variations across the provinces over the years, and in 2013 they varied from 78-99%, with Matabeleland North Province achieving 88%. Over the years, national ART coverage for co-infected patients has been increasing annually, but it is still below the 100% target. It has increased from 30% in 2009 to 78% in 2013. However, Mashonaland West and Matabeleland North provinces were below 70%, with the later reporting 68% in 2013. Zimbabwe adopted the International Standards for TB Care (ISTC) which stipulates that HIV testing and counseling should be recommended to all patients of all ages with TB or suspected of having TB. Because of the close relationship between TB and HIV infection, integrated approaches to prevention and treatment of both infections are recommended.
1.4 Lupane district
Lupane district is located in Matabeleland North province. It has a total population of 105046 and has 13 health facilities. According to Provincial TB Reports, the district has reported the highest number of TB patients in the province over the years; however these have been declining from 1047 in 2011 to 469 in 2013. Of the 469, 89.8% were tested for HIV and 306 (72.7%) individuals were found to be HIV positive. The district has reinforced its coordination and integration of TB and HIV activities through capacity building including training and supervision of health workers, joint resource mobilization for TB activities and HIV activities, ensuring coherence of communications about TB/ HIV and monitoring and evaluating progress toward locally set targets for TB/HIV activities. Surveillance of HIV prevalence among tuberculosis patients has also been practiced in the district through provider initiated HIV testing and counseling using the opt-out method.

1.5 Problem Statement
In Matabeleland North Province, Lupane district was consistently initiating the least proportion of TB patients who test HIV positive on ART from 2011 to 2013. There was a sharp decline in ART initiation among TB/HIV co-infected patients from 62% in 2012 to 37% in 2013 against a target of 100%. There was no corresponding decline in the provincial rate of ART initiation; see Figure 1. This was suggestive of some barriers in the implementation of, and access to the program.
Figure 1 Trends in ART initiation among TB/HIV co-infected patients in Matabeleland North Province, 2011-2013

The ART guidelines for HIV prevention and treatment in Zimbabwe recommend treating all HIV positive TB patients as soon as possible within the first 8 weeks of commencing regardless of CD4 cell count. The Public health implications of delayed ART initiation among TB/ HIV co infected patients are that health service providers and community members incur human and financial resources costs due to HIV/AIDS morbidity and mortality.

1.6 Research question
What are the factors associated with delayed initiation of ART among TB patients who test HIV positive in Lupane district?
2 Literature Review
Several studies have identified varying barriers to ART initiation among people living with HIV, but a few have focused on ART initiation among TB/HIV co-infected patients. The literature search is conceptualized into individual and health system factors associated with delayed ART initiation among TB/HIV co-infected patients; and bottlenecks in processes leading to ART initiation.

2.1 Health system factors
In a study carried out in Nigeria, delayed initiation of ART was associated with higher CD4+ counts, lower functional status, clinic of attendance, and later dates of enrollment among ART-eligible clients\textsuperscript{10}. The findings provide targets for quality improvement efforts that may help reduce attrition and improve ART uptake in similar settings.

Anticipated stigma or perceived discrimination in the health care system is likely to be a barrier in seeking care. A study on perceived discrimination in care revealed that 26% of adults with HIV reported having been discriminated in one way or another by health providers including the eight percent who were denied service. It concluded that many HIV infected adults believe that their clinicians have discriminated against them\textsuperscript{11}.

A study in Uganda revealed health system-related factors associated with very late ART initiation as stock-outs of antiretroviral medicines, competition from traditional and spiritual healers, and absence of pre ARV care\textsuperscript{12}.

In Tanzania, in a study of barriers to ART initiation, it was found out that accessibility was limited by patients fearing transportation and food costs, referral hospitals’ unfriendly and confusing reputation, and difficulties in sustaining long-term treatment\textsuperscript{13}. Fear of stigma posed challenges for getting in touch with referrals who did not want status disclosed\textsuperscript{13}.

The findings of a study in South Africa revealed that patients in rural health facilities or clinics with low staff complement had lesser rates of initiating treatment as compared to
patients in urban clinics, or clinics with better staff compliment. Patients at clinics with lower staff-to-patient ratios had lower rates of starting ART treatment than those with higher staff-to-patient ratios.

The capacity of the health care system in the district in terms of resource availability, to respond to the burden of HIV has a bearing on the timing of ART initiation. In eight sub-Saharan African countries the program-level factors associated with low-median CD4+ cell count in cohorts of persons initiating ART included urban setting, lower provider-to-patient ratio, no PMTCT program, outreach services for ART patients only versus both pre-ART and ART patients, fewer versus more adherence support services and smaller cohort size.

The predictors of delayed ART initiation in an Indian study were TB diagnosis, homelessness, lower CD4 count, prolonged pre-ART care, coming from disadvantaged communities, being widowed, and living far from a town were associated with delayed initiation of ART.

In Nigeria, delayed initiation of ART was associated with higher CD4 counts, lower functional status, clinic of attendance, and later dates of enrollment among ART-eligible clients.

Linkage to care and treatment for TB patients diagnosed with HIV is also critical. In a study in a South African hospital, among 486 HIV-infected TB patients, 38.3% failed linkage to HIV care, and 32% of the 61.7% who linked to care presented late. One in six HIV-infected patients failed linkage to both TB and HIV care. Risk factors for failed linkage to HIV care were antiretroviral-naive status, and absence of referral letter with HIV or CD4 cell count.

A long time lag between HIV diagnosis and initiation of ART is synonymous with delayed initiation. In a study in Malawi, 14% of participants eligible for ART at their first screening visit defaulted before starting ART. Participants with less education, difficulties in dressing,
a more delayed ART initiation appointment, and mid-upper arm circumference (MUAC) < 22 cm were significantly less likely to have visited the clinic subsequently\(^{19}\). Where CD4 counts were not available, MUAC and reported difficulties in dressing provided useful screening indicators to identify sicker ART-eligible patients at high risk of dropping out of the program.

Transport costs can also be increased by the behavior of some patients. Patients may leave their nearest health facility and would rather prefer to go and enroll in care at a facility further away where they are not recognized by clinic staff and neighbors. This increases the transport problem\(^ {20} \).

Some programmatic practices by health facilities have a bearing in patient behavior in care. These include active testing and the provision of ancillary patient support services such as adherence support, peer education, and outreach for patients who miss clinic visits\(^ {15} \).

2.1.1 Patient flow in ART initiation
Patient flow within institutions has an effect on the timeliness of ART initiation. The patient flow pathway includes TB diagnosis and starting TB treatment, such patients require HIV testing, blood CD4 cell count measurement, referral for ART, enrolment in the ART clinic, reassessment for ART eligibility, preparation for ART and finally starting ART. In a South African study, the prolonged delays observed for patients referred from TB clinics reflected the many steps in the care pathway for such patients\(^ {29} \). Lack of integration of TB and ART services represented a major obstacle to timely initiation of ART in patients with HIV-associated TB.

In another study, some patients stated that they did not receive any preparation for ART; hence they feared ART initiation during TB treatment\(^ {31} \). It was not clear from this study how this could have happened given the specific process that aimed to ensure that all patients accessed all components of the treatment regime.
In a study in Uganda, participants identified initial difficulties with communication between the trial team and service providers such as lost files or lost or absent referral forms.\textsuperscript{34} Occasional interruptions in ART services for a few weeks were reported, but this was usually because of holiday periods, rather than lack of drug supply. Occasionally personnel shortages resulted in a delay.\textsuperscript{34} Another study in three Sub Saharan countries asserted that to ensure steady ART uptake, it is important to minimize challenges to improve patient flow by proficient staff allocation to suitable clinical duties, streamlining clinic visiting protocols.\textsuperscript{35}

### 2.1.2 Client centeredness of care

A study conducted in SSA concluded the need to provide support and the development of structures in order to minimize clients from dropping out of care. Computerized record management systems are essential for accurate ART inventory, dispensing records, quality assurance monitoring, client enrollment records, visit scheduling and effective organizational management. Human resource policies are crucial for maintaining a high job performance, satisfaction and averting burnout.\textsuperscript{35}

In a Zambian study, it was observed that when livelihood problems and low perceived quality of care coalesced, incentives to stay on treatment diminished.\textsuperscript{36} For some PLHIV, long waiting time and frequent trips to the clinic presented enormous opportunity costs which they were not willing to forego. The long clinic appointments; often lasting almost a whole day, non-availability of some drugs and laboratory test results, and perceived rudeness of some clinic staff frustrated and dissuaded other PLHIV from seeking ART care.\textsuperscript{36}

### 2.2 Patient level factors

Individuals’ characteristics such as demographics, socioeconomic status, mental disorders and substance abuse may affect the timing of each stage in the path to ART initiation.

A study in Uganda reported that younger clients had a greater risk of late ART initiation as compared to older clients.\textsuperscript{12} Clients with less education were 14 times more likely to initiate
ART late as compared to well educated clients\textsuperscript{12}. Unmarried clients were 5 times more likely to initiate ART late as compared to married clients. Communal farmers were eight times more likely to initiate ART late as compared to non farmers. Clients who lacked family support were seven times more likely to initiate ART late as compared to those with the support of the family\textsuperscript{12}.

The logistic and financial difficulties that patients encounter in visiting health centers to collect ATT drugs and then hospitals to collect ART drugs are a major reason for the poor access of co infected patients to ART. In countries with good TB-HIV programs, less than a third of patients access ART\textsuperscript{21}.

Initiation of ART in HIV-infected patients with active tuberculosis is complicated and close monitoring is needed when initiating ART in these patients. These concerns include Immune reconstitution inflammatory syndrome (IRIS), high pill burden, overlapping adverse drug effects, drug-drug interactions and risk of HIV drug resistance\textsuperscript{22}. In a study by Mongkontida et-al (2010), early ART initiation within four months of TB treatment and disseminated TB were found to be significant risk factors for the occurrence of TB-IRIS. Patients who were initiated ART within four months of TB treatment are five times more likely to develop TB-IRIS\textsuperscript{23}. It is therefore prudent to investigate the existence of IRIS and its associated fear, more so in any setting where ART initiation is low.

Patients with high HIV treatment related knowledge may be less likely to initiate ART late. In a study in South Africa, individuals with higher levels of HIV-related “health literacy,” or knowledge concerning HIV disease (the importance of CD4 monitoring and ART regimens) were less likely to initiate ART late and this can be influenced by clinic level factors such as peer education programs\textsuperscript{25}. The barriers to treatment were transport costs, time needed for treatment, and logistical challenges, whereas stigma around HIV/AIDS, and side effects associated with ART were less influential\textsuperscript{25}.
An individual’s perception of need is an important determinant of their decision to use care. One South African study showed that being referred for testing by a provider was associated with a lower likelihood of linking to long-term HIV care compared with patients who made their own decision to test26.

In a study in Kenya, the main predictors of willingness to accept an HIV test offered in hospital were self-perception of HIV risk and attitude towards routine offer of HIV testing, knowledge about the routine HIV testing, age, level of education32.

In a study in Malawi, most people believed that attending ART clinic for treatment was tantamount to declaring their HIV status openly. A minority said they were better able to hide their status in their home village by starting treatment quickly33.

In a Ugandan study, the most prominent factors were expression of fear of side effects in those who delayed and positive beliefs about ART (such as improvement in health) in those who started early34. Many of those who delayed mentioned witnessing illness and side effects after starting ART in relatives, friends or acquaintances34.

Well documented in the literature is that family and social support are associated with better psychological adjustment, medication adherence, and slower progression to AIDS27.

A review of studies in Sub Saharan Africa on ART initiation revealed that anticipated stigma was a barrier to HIV testing and may also be a barrier to enrolling in care once tested, and experienced stigma might be related to dropping out of care28.

Financial challenges, competing work, mobile populations and employment status contribute to delaying care. In a study in Kenya, patients who were lost to follow up were three times as likely to be men (RR, 3.1; 95% CI, 1.1-8.1; p=0.028) and nearly 4 times as likely to have a primary education or less (RR, 3.8; 95% CI, 1.3-10.6; p=0.013)20. Overall, the most common
reason for LTFU was moving residence, predominantly due to job loss or change in employment\textsuperscript{28}.

\textbf{2.3 Delays in Processes}

Non integration of TB and ART services is likely to be a substantial obstacle to timely initiation of ART. A study in a South African township found out that, among 893 TB patients studied (median CD4 count, 81 cells/μL), the delay between starting TB treatment and starting ART was prolonged (median, 95 days; IQR = 49-155). Delays were shorter in more recent calendar periods and among those with lower CD4 cell counts. However, the median delay was almost three-fold longer for patients referred from separate TB clinics compared to patients whose TB was diagnosed in the ART clinic (116 days versus 41 days, respectively). Delays in starting ART were prolonged, especially for patients referred from separate TB clinics\textsuperscript{29}.

A study in Cape Town revealed that the time between starting TB treatment and starting ART was highly variable with a median of 2.66 months (IQR, 1.58-4.17). Delays were shorter among younger patients, those with a first episode of TB, sputum smear-positive disease, lower CD4 cell counts and treatment in later calendar periods\textsuperscript{30}. The level of integration of TB and HIV services as well as patient related factors impact on speed of initiating ART in TB/ HIV co infected patients.

In conclusion, from literature, health system related factors associated with delayed ART initiation were found to be; higher CD4 counts, lower functional status, clinic of attendance, and later dates of enrollment. Anticipated stigma or perceived discrimination in the health care system, stock-outs of antiretroviral medicines, competition from traditional and spiritual healers, and absence of pre ARV care, fearing transportation and food costs, referral hospitals’ unfriendly and confusing reputation, and difficulties in sustaining long-term treatment were significant factors. Other factors for delayed ART initiation were found to be fear of stigma, disclosure, low staff complement, urban setting, no PMTCT program,
outreach services for ART patients, support services and smaller cohort size, distance to clinic; later dates of enrollment, adherence support, peer education, outreach for patients who miss clinic visits, patient flow to ART initiation, patients referred from separate TB clinics and lack of integration of TB and ART services. Patient related factors associated with delayed ART initiation were demographics, socioeconomic status, mental disorders and substance abuse; Immune reconstitution inflammatory syndrome (IRIS), high pill burden, overlapping adverse drug effects, drug-drug interactions and risk of HIV drug resistance, knowledge on HIV, transport costs, perception on HIC care, witnessing illness and side effects after starting ART in relatives or friends, lack of family and social support, anticipated stigma, financial challenges, competing work, mobile populations and employment status.
2.4 The Conceptual framework

**Contextual level**

**Setting and population**
- urban/ rural
- population density- socioeconomic status
- cultural factors
- HIV related stigma
- knowledge of HIV

**HIV burden and health system care capacity**
- HIV prevalence
- testing coverage
- Health care workforce per capita
- ART coverage relative to need
- National ART guidelines

**Health system**

**Policies and practice**
- Cost sharing requirement
- Clinic days and hours
- Record keeping practices

**Programs**
- Active testing
- Ancillary patient support services
- Outreach for missed visits

**Capacity**
- Types of providers
- Patient flow etc
- Provider to patient ratio
- ART waiting lists

**Effectiveness of pre-ART care**
- Retention
- Appointment adherence
- Frequency of CD4 monitoring

**Individual level**

**Pre-disposing factors**
- Demographics
- Cultural
- Household SES
- Clinical status
- Depression
- Substance abuse

**Enabling factors**
- Social support
- Perception of stigma
- Distance to clinic
- Availability of transport
- Employment or family responsibilities
- Interaction with health care system
- Health beliefs

**Perceived need**
- Testing circumstances
- Reasons for testing

- Late diagnosis
- Late enrolment
- Primary outcome late ART initiation
To determine the patient related factors, The Health Belief Model (HBM) was used to predict the behavior of TB/HIV co-infected patients’ decision to initiate ART, see figure 2.

Figure 2 The Conceptual Framework: Adapted from Multi-level factors associated with late HIV diagnosis, late enrollment into care, and late Antiretroviral Therapy (ART) initiation

2.5 The Conceptual framework

- **Individual Perceptions**
  - Demographic factors
  - Socioeconomic factors
  - Knowledge of HIV and ART, and consequences of delaying ART
  - Cultural pressures
  - HIV medical history

- **Modifying Factors**
  - Perceived susceptibility to and perceived severity of consequences of delayed ART initiation

- **Likelihood of Action**
  - Perceived benefits (better health of TB/HIV co-infected patients, longer life, minus perceived barriers (fear of drug toxicity, lack of access, prohibitive costs, fear of stigmatization, misconceptions) ART initiation while on ATT
  - Self efficacy (confidence in TB patient diagnosed HIV positive’s ability to initiate on ART) leading to
  - Cues to action to promote use of family planning and reproductive services
    - Education to remove misconceptions
    - Media
    - Conducive environment
    - IEC materials
  - Likelihood of behaviour change of TB/HIV co-infected patients to initiate on ART with no delay
Figure 3: Conceptual Framework of Health Belief Model

The Health Belief Model (HBM) is a socio-psychological model which helps to address the potential to take the recommended health related action. 37, 38

2.6 HBM Constructs

The following constructs of the Health Belief Model will be measured:

- Perceived susceptibility – the perception of one’s risk of contracting a health event.; do TB/HIV co-infected patients see themselves as susceptible to any health issues if they are delayed to be initiated on ART
- Perceived severity- , feelings concerning the seriousness of contracting an illness or of leaving it untreated; are the consequences of delaying ART severe enough to make TB/HIV co-infected patients want to be initiated on time
- Perceived benefits- the perceived effectiveness of various strategies designed to minimize risk; are the benefits of not delaying ART sufficient to convince TB/HIV co-infected patients want to be initiated on ART with no delay
- Perceived barriers- feeling a nuisance as someone who takes particular health actions or results from the actions; are there barriers that are preventing TB/HIV co-infected patients want to be initiated on ART with no delay
- Cues to action- the belief of having the potential to successfully execute the expected behavior; what makes TB/ HIV co-infected patients take actual steps to be commenced on ART with no delay

Participants will be asked to respond to each statement on an ordinal scale by stating whether they;

1: Strongly agreed 2: Agreed 3: Undecided 4: Disagreed 5: Strongly disagreed
Table 2-1 below shows examples of the different components (constructs) of the Health Belief Model that will be used to predict likelihood of intention to initiate ART without delay with examples of statements that will be asked.

**Table 2-1 Constructs and statement of the HBM**

<table>
<thead>
<tr>
<th>Construct</th>
<th>Statement (Example)</th>
</tr>
</thead>
</table>
| Perceived susceptibility | People who are TB/HIV co-infected can start ART whenever they feel like doing so  
If I do not commence ART within 2 months of ATT, I could be very ill due to HIV infection  
I am healthy enough to commence ART within 2 months of ATT, as ATT is curing me  
I do not need ART counseling when taking ATT |
| Perceived severity    | If I do not commence ART within 2 months of ATT, I could die early due to HIV  
If I do not commence ART within 2 months of ATT I could suffer from some opportunistic infections |
| Perceived benefits    | If I commence ART within 2 months of ATT, I will live longer  
If I commence ART within 2 months of ATT, I will not suffer from serious illness/ opportunistic infections |
| Perceived barriers    | I do not like ART because I am already taking too many pills and I will forget ART  
I will suffer from side effects due to drug toxicity  
It is difficult to get ART because the health centre is far and I cannot walk the distance or afford the transport fares  
My religion demands that I do not use ART |
| Cues to action        | If health workers have time to counsel me I will commence ART  
If I hear about the benefits of ART in TB/HIV co-infected patients, I am more likely to use it  
If I read about the benefits of ART in TB/HIV co-infected patients on posters and in the newspaper, I am more likely to initiate ART |
2.7 Operational definition
Delayed ART initiation in this study is defined as ART initiation later than 8 weeks of ATT commencement in TB/HIV co-infected patients. According to WHO\textsuperscript{6} and the ART guidelines for HIV treatment and prevention in Zimbabwe\textsuperscript{4}, ART should be started in all TB patients living with HIV irrespective of their CD4 count. ATT should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment\textsuperscript{6}.

2.8 Justification of the Study
About 63\% of TB/HIV co-infected patients who were eligible for ART were not commenced on treatment in Lupane district. They were therefore predisposed to increased risk of HIV related morbidity and mortality. Evidence from randomized controlled clinical trials in persons living with both HIV and TB demonstrate superior outcomes if ART is started early, within the first 8 weeks of ATT\textsuperscript{4}. Thus Zimbabwe adopted the WHO guidelines which recommend early initiation of ART. However, despite concerted investment and effort in TB/HIV collaboration activities in the country and province, Lupane district managed to initiate on ART just 37\% of its targeted TB/HIV co-infected patients. There are very limited studies which have looked at factors associated with delayed ART initiation among TB patients who test HIV positive, both locally and abroad, yet this continued to be a problem in this setting. Available literature was predominantly on initiation of ART among people living with HIV, and not co-infected with TB. There was therefore need to investigate these factors so as give evidence based recommendations on improving access to timely HIV care and treatment by TB patients in the district and country at large.
3 Objectives

3.1 Broad objective
To determine factors associated with delayed ART initiation among TB/HIV co infected patients in Lupane district.

3.2 Specific objectives:
- To determine the prevalence of delayed ART initiation among TB/HIV co infected patients in Lupane district, 2014
- To determine patient related factors associated with delay in initiation of ART
- To assess health system factors associated with delay in initiation of ART
- To determine the socio-economic factors associated with delay in initiation of ART
- To determine time intervals in processes leading to ART initiation among TB/HIV co infected patients.
4 Methods and Materials

4.1 Study Design
An analytic cross sectional study was conducted.

4.2 Study Setting
The study was conducted at seven health facilities in Lupane district comprising 1 hospital and 6 RHCs.

4.3 Study Population
The study population comprised of TB/HIV co infected patients and key informants namely District Medical Officer (DMO), District Nursing Officer (DNO), District Environmental Health Officer (DEHO), Provincial TB Coordinator, District TB Coordinator, Provincial HIV Officer, Matrons and Sisters in Charge.

4.4 Inclusion Criteria
Patients initiated on anti TB treatment in Lupane district who were co-infected with HIV, had completed the first 8 weeks of anti TB treatment and were willing to participate in the study (see operational definition of delayed ART initiation).

4.5 Exclusion Criteria
Patients initiated on anti TB treatment outside Lupane district; not yet completed first 8 weeks of anti TB treatment; developed TB whilst already on ART and/ or who were not willing to participate in study were excluded from the study.

4.6 Sample size and sampling
Using the Dobson formula

\[ n = \frac{z^2pq}{d^2} \]
Where \( n \) = sample size,

\( z \) = maximum allowable error risk,

\( p \) = expected prevalence (assuming that 17.3\% of respondents have the reason for delayed ART initiation as, being on TB treatment or having other medical treatment\(^3\)).

\( q = 1-p \), and

\( d \) = absolute precision

Using a 95\% confidence interval (\( z = 1.96 \)) and absolute precision of 5\% and 10\% provision for attrition, a sample size of 239 TB/HIV co infected patients was calculated.

4.7 Sampling of study sites
St Lukes hospital, which had a high enrolment of TB/ HIV co-infected patients, was purposively sampled into the study. Six initiating sites out of the remaining 12 health facilities were randomly selected into the study. The health facilities were entered into Excel and the Excel RAND function was then used to select a random sample. Proportionate sampling of patients was then done from the selected health facilities.

4.8 Selection of study participants
The sampling frame was all TB/HIV co infected patients. All eligible TB/HIV co-infected patients attending TB/ART clinics at health facilities were recruited into the study.

4.9 Data Collection and Processing
A pretested interviewer administered questionnaire was used to collect data from patients. Pretesting was done at Lupaka clinic. We checked for availability of respondents, schedules, willingness of respondents to answer questions, acceptability and validity of questions, time to
administer data collection tools and sampling procedure. Appropriate modifications on data collection tools and sampling procedures were carried out.

Key informant interviews were done with key informants with the aid of an interview guide. Records review of patients’ treatment cards was done to check type of TB diagnosed treatment category, date of commencement of ATT, HIV testing, CD4 tests, counseling and commencement of ART.

Observation with the aid of a checklist was also done to check on health worker performance and quality of care issues. Results were triangulated with findings from clients and health worker interviews.

4.10 Data Capturing and Data Analysis
Data were entered into Epi info 7, which was used to generate means, frequencies, proportions, odds ratios of study variables, and tests for statistical significance were done at 95% confidence interval. Stratified and logistic regression analysis was done to check for effect modification and control for confounding.

4.11 Data storage and safety
Safety and confidentiality of completed questionnaires was maintained and this was only shared with the University of Zimbabwe and the Ministry of Health And Child Care (MoHCC). They were kept under safe lock and key in a lockable steel cabinet in the office. Only the investigator had access to the data. Confidentiality of data was assured and maintained throughout the study and afterwards by not recording the names and addresses of the respondents. Information will only be shared with the Supervisor or the University of Zimbabwe, if the need arises. If the research is published, no names of study participants will be published.
4.12 Permission to Proceed
Permission to carry out the study was sought from the Health Studies Office, Medical Research Council of Zimbabwe, Matabeleland North PMD and the DMO for Lupane district.

4.13 Ethical Considerations
Informed written consent was sought from all study participants. Confidentiality was assured and maintained throughout the study. The choice on whether to participate or not was respected. In the case of refusal to participate in the study, another respondent was selected and no negative consequences arose from the refusal. Anonymity was guaranteed by not recording the names or addresses of the respondents on the questionnaires. Information collected was treated with strict confidentiality, and was kept under lock and key for the duration of the study and thereafter. The information was used for the purpose of the study only. Ethical approval was sought from the Joint Research Ethics Committee (JREC)

4.14 Study variables
The outcome variable was delayed ART initiation. Delayed ART initiation is defined as failure to be initiated on ART during the first 8 weeks of ATT, in TB/HIV co-infected patient. The independent variables are listed in the table below.
<table>
<thead>
<tr>
<th>Conceptual definition of variable</th>
<th>Operational definition</th>
<th>Scale of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Age at last birthday</td>
<td>Continuous in years</td>
</tr>
<tr>
<td>Religion</td>
<td>As reported by informants</td>
<td>Nominal: Christian, Traditional, Moslem, etc</td>
</tr>
<tr>
<td>Site of tuberculosis</td>
<td>Location of TB in patient</td>
<td>Categorical: pulmonary or extra-pulmonary</td>
</tr>
<tr>
<td>Perceived need for ART</td>
<td>Whether patient perceive the need for ART as important</td>
<td>Categorical</td>
</tr>
<tr>
<td>Distance to nearest health facility</td>
<td>The distance travelled from home to nearest health facility</td>
<td>Continuous, in days</td>
</tr>
<tr>
<td>Distance to ART initiating site</td>
<td>Distance travelled from home to ART initiating site</td>
<td>Continuous in days</td>
</tr>
<tr>
<td>Cost of travelling to ART initiating site</td>
<td>The amount of money spent in travelling to ART initiating site</td>
<td>Continuous, in United States Dollars</td>
</tr>
<tr>
<td>Congestion at health facility</td>
<td>Availability of congestion at health facility</td>
<td>Categorical</td>
</tr>
<tr>
<td>Perceived stigma</td>
<td>Patient’s perception of the existence of stigma</td>
<td>Categorical</td>
</tr>
<tr>
<td>Interval between ATT and HIV test</td>
<td>The time from the start of TB treatment to HIV testing</td>
<td>Continuous, in days</td>
</tr>
<tr>
<td>Interval between HIV test and ART counseling</td>
<td>The time from HIV testing to start of ART counseling</td>
<td>Continuous, in days</td>
</tr>
<tr>
<td>Interval in ART counseling</td>
<td>The time from start to end of ART counseling</td>
<td>Continuous, in days</td>
</tr>
<tr>
<td>Interval between ART counseling to ART initiation</td>
<td>The time from end of ART counseling to ART initiation</td>
<td>Continuous, in days</td>
</tr>
<tr>
<td>Interval between ATT initiation to ART initiation</td>
<td>The time from start of ART initiation</td>
<td>Continuous, in days</td>
</tr>
</tbody>
</table>
5 Results
This chapter presents the results under the following sections; demographic characteristics, prevalence of delay to ART initiation, socio demographic, patient related and health system factors, and time intervals in the pathway to ART initiation.

5.1 Demographic characteristics of study participants
The demographic characteristics of the study participants are shown in Table 5-1 below.

A total of 210 participants were recruited into the study, giving a response rate of 88%. Fifty one percent were female while 48% of the study participants were married. The majority, 83% (n=175) were from the rural setting. One hundred and twenty five (59.6%) had an education level of primary and below and 60% (n=126) were unemployed.
### Table 5-1: Demographic characteristics of study participants, Lupane district, 2014-15

<table>
<thead>
<tr>
<th>Variable</th>
<th>Stratum</th>
<th>Frequency, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Female</td>
<td>107 (50.9)</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>103 (49.1)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>0-14</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td></td>
<td>15-29</td>
<td>36 (17.1)</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
<td>109 (51.9)</td>
</tr>
<tr>
<td></td>
<td>40-54</td>
<td>59 (28.1)</td>
</tr>
<tr>
<td></td>
<td>55+</td>
<td>5 (2.4)</td>
</tr>
<tr>
<td>Median age (years)</td>
<td>Delayed</td>
<td>39 (Q₁=34; Q₃=45)</td>
</tr>
<tr>
<td></td>
<td>Not delayed</td>
<td>36 (Q₁=33; Q₃=40)</td>
</tr>
<tr>
<td>Marital status:</td>
<td>Married</td>
<td>101 (48.1)</td>
</tr>
<tr>
<td></td>
<td>Single</td>
<td>11 (5.2)</td>
</tr>
<tr>
<td></td>
<td>Separated/ divorced</td>
<td>40 (19.1)</td>
</tr>
<tr>
<td></td>
<td>Widowed</td>
<td>14 (6.7)</td>
</tr>
<tr>
<td></td>
<td>Cohabiting</td>
<td>44 (21.0)</td>
</tr>
<tr>
<td>Occupation</td>
<td>Formally employed</td>
<td>11 (5.2)</td>
</tr>
<tr>
<td></td>
<td>Informal employment</td>
<td>45 (21.4)</td>
</tr>
<tr>
<td></td>
<td>Unemployed</td>
<td>154 (73.3)</td>
</tr>
<tr>
<td>Place of residence</td>
<td>Rural</td>
<td>201 (95.7)</td>
</tr>
<tr>
<td></td>
<td>Urban</td>
<td>9 (4.3)</td>
</tr>
<tr>
<td>Religion</td>
<td>Christianity</td>
<td>169 (80.5)</td>
</tr>
<tr>
<td></td>
<td>Traditional</td>
<td>39 (18.5)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Education</td>
<td>Tertiary</td>
<td>10 (4.8)</td>
</tr>
<tr>
<td></td>
<td>Secondary</td>
<td>75 (35.1)</td>
</tr>
<tr>
<td></td>
<td>Primary</td>
<td>115 (54.8)</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>10 (4.8)</td>
</tr>
</tbody>
</table>

#### 5.2 Prevalence of delay in ART initiation

Table 5-2 below shows the prevalence of delayed ART initiation among TB/HIV co-infected patients.
Eighty one percent (n=171) of the study participants did not delay, whereas 19% (n=39) delayed ART initiation.

5.3 Socio-demographic factors
The socio-demographic factors for delaying ART initiation of the study participants are shown in Table 5-3 below.
### Table 5.3 Socio-demographic factors Associated with Delayed ART Initiation in Lupane District, 2014-2015

<table>
<thead>
<tr>
<th>Variable</th>
<th>Stratum</th>
<th>OR (95% CI)</th>
<th>95%CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex:</strong></td>
<td>Male</td>
<td>1 (reference level)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>0.6</td>
<td>(0.30-1.24)</td>
<td>0.089</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>0-30 years</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥31 years</td>
<td>1.03</td>
<td>(0.41 – 2.55)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status:</strong></td>
<td>Married</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cohabiting</td>
<td>2.63</td>
<td>(0.96-7.16)</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Separated/divorced</td>
<td>4.38</td>
<td>(1.67-11.47)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single</td>
<td>5.84</td>
<td>(1.43-23.84)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Widowed</td>
<td>5.68</td>
<td>(1.56-20.63)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td>Formal employment</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Informal employment</td>
<td>3.24</td>
<td>(0.37 – 28.2)</td>
<td>0.417</td>
</tr>
<tr>
<td></td>
<td>Unemployed</td>
<td>2.12</td>
<td>(0.26 – 17.31)</td>
<td></td>
</tr>
<tr>
<td><strong>Place of residence</strong></td>
<td>Urban</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rural</td>
<td>1.87</td>
<td>(0.23-15.36)</td>
<td>0.304</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td>Christianity</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Traditional/other</td>
<td>2.99</td>
<td>(1.40- 6.47)</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>Primary and below</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secondary and above</td>
<td>1.46</td>
<td>(0.70 – 3.10)</td>
<td>0.161</td>
</tr>
</tbody>
</table>

On marital status; being separated, single and widowed were the significant socio-demographic factors associated with delayed ART initiation in Lupane district. Those who were single (OR 5.84, 95% CI 1.43-23.84) or widowed (OR 5.68, 95% CI 1.56-20.63) were six times more likely
to delay ART than those who were married. Those who belonged to traditional religion were three times more likely to delay ART initiation than those who belonged to Christianity (OR 2.56, 95% CI 1.15-5.71).

### 5.4 Patient related factors

The patient related factors for delayed ART initiation are shown in Table 5-4 below.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Yes</th>
<th>No</th>
<th>POR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family/community support</td>
<td>24 (61.5%)</td>
<td>129 (78.2%)</td>
<td>0.44 (0.21 – 0.93)</td>
<td>0.031</td>
</tr>
<tr>
<td>Belongs to support group</td>
<td>5 (12.8%)</td>
<td>40 (23.7%)</td>
<td>0.47 (0.18 – 1.26)</td>
<td>0.138</td>
</tr>
<tr>
<td>Had family member on TB treatment</td>
<td>7 (18.4%)</td>
<td>81 (47.9%)</td>
<td>0.25 (0.11 – 0.58)</td>
<td>0.001</td>
</tr>
<tr>
<td>Disclosed HIV status</td>
<td>24 (61.5%)</td>
<td>143 (84.6%)</td>
<td>0.29 (0.14 – 0.62)</td>
<td>0.002</td>
</tr>
<tr>
<td>Had family member on HIV treatment</td>
<td>15 (38.5%)</td>
<td>127 (75.2%)</td>
<td>0.21 (0.10 – 0.43)</td>
<td>0.001</td>
</tr>
<tr>
<td>TB treatment supervised</td>
<td>11 (28.2%)</td>
<td>131 (77.5%)</td>
<td>0.11 (0.05 – 0.25)</td>
<td>0.001</td>
</tr>
<tr>
<td>Perceived stigma</td>
<td>24 (61.5%)</td>
<td>67 (39.6%)</td>
<td>2.44 (1.20 – 4.94)</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Those who had perceived stigma were two times more likely to delay ART initiation (OR 2.44, 95% CI 1.20 – 4.94) than those who did not have perceived stigma. Those who were treatment supervised were 89% less likely to delay ART (OR 0.1195% CI 0.05 – 0.25) than those who were not supervised while those who had had a family member on TB treatment were 75% less
likely to delay (OR 0.25, 95% CI 0.11 – 0.58) than those who did not have a family member on TB treatment.

5.5 Health system related factors
The health system related factors are shown in Table 5-5 below.

Table 5-5: Health system related factors Associated with delayed ART initiation among TB/HIV co-infected patients, Lupane, 2014-2015

<table>
<thead>
<tr>
<th>Variable</th>
<th>Delayed ART Initiation</th>
<th></th>
<th>POR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n= 39 (%)</td>
<td>n=171 (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance to health facility</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-10 km</td>
<td>15 (38.5)</td>
<td>35 (79.0)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>&gt;11 km</td>
<td>24 (61.5)</td>
<td>36 (21.1)</td>
<td>6.00 (2.88–12.51)</td>
<td>0.001</td>
</tr>
<tr>
<td>Transport cost of &gt;US$1</td>
<td>27 (69.33)</td>
<td>56 (33.9)</td>
<td>6.49 (3.01-13.95)</td>
<td>0.001</td>
</tr>
<tr>
<td>Sought medical care elsewhere</td>
<td>22 (56.41)</td>
<td>48 (28.6)</td>
<td>3.24 (1.59 – 6.57)</td>
<td>0.007</td>
</tr>
<tr>
<td>Feared medicines toxicity</td>
<td>21(43.8)</td>
<td>27 (56.3)</td>
<td>6.14 (2.89 – 13.02)</td>
<td>0.001</td>
</tr>
<tr>
<td>Pulmonary TB</td>
<td>38 (97.4)</td>
<td>158 (80.6)</td>
<td>0.34 (0.04 – 2.52)</td>
<td>0.475</td>
</tr>
<tr>
<td>Treated for TB for first time</td>
<td>34 (87.9)</td>
<td>147 (86.0)</td>
<td>1.11 (0.40 – 3.92)</td>
<td>0.539</td>
</tr>
<tr>
<td>Registered for ART at facility</td>
<td>15 (9.6)</td>
<td>142 (90.5)</td>
<td>0.12 (0.16 – 0.67)</td>
<td>0.001</td>
</tr>
<tr>
<td>CD4 count done</td>
<td>14 (35.9)</td>
<td>108 (63.2)</td>
<td>0.33 (0.16 – 0.68)</td>
<td>0.003</td>
</tr>
<tr>
<td>Suffered from chronic condition</td>
<td>14 (34.1)</td>
<td>27 (65.9)</td>
<td>2.99 (1.38 – 6.47)</td>
<td>0.004</td>
</tr>
<tr>
<td>Suffered from serious illness</td>
<td>12 (9.8)</td>
<td>111 (90.2)</td>
<td>0.24 (0.11 – 0.51)</td>
<td>0.001</td>
</tr>
<tr>
<td>Perceived health worker stigma</td>
<td>9 (5.39)</td>
<td>3 (7.69)</td>
<td>1.46 (0.38 – 5.68)</td>
<td>0.404</td>
</tr>
</tbody>
</table>
Health system related factors associated with delayed ART initiation were transport cost of above US$1 (OR 6.49, 95% CI 3.01-13.95), sought medical care elsewhere (OR 3.24, 95% CI 1.59-6.67), fear of medicines toxicity (OR 6.14, 95% CI 2.89 – 13.02). Those who had to pay US$1 or more in transport cost were six times more likely to delay ART initiation than those who paid less than US$1. Those who suffered from a serious illness were 76% less likely to delay ART initiation (OR 0.24, 95% CI 0.11-0.51) than those who did not suffer serious illness.

5.5.1 Quality of HIV Care at Health Facilities
All the health facilities were offering HTC and initiating ART. ART follow up was not being done in all the seven health facilities. Five health facilities had no CD4 count machines and one facility, had no Primary Care Counselor.

Table 5-6 illustrates the frequency of heath facilities by quality of care variables in this study.
Table 5-6 Quality of HIV Care at Health Facilities, Lupane District, 2014/5

<table>
<thead>
<tr>
<th>Quality of Care at Health Facility</th>
<th>Frequency, n=7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV Testing and counselling</strong></td>
<td></td>
</tr>
<tr>
<td>Staff obtains informed consent from each client before testing.</td>
<td>7</td>
</tr>
<tr>
<td>Organization respects the confidentiality of test results.</td>
<td>7</td>
</tr>
<tr>
<td>Organization provides pre-test and post-test counseling.</td>
<td>6</td>
</tr>
<tr>
<td><strong>Provision of ART</strong></td>
<td></td>
</tr>
<tr>
<td>Organization follows standard diagnostic protocols for suspected HIV cases.</td>
<td>7</td>
</tr>
<tr>
<td>Organization follows clinical management protocols based on guidelines.</td>
<td>7</td>
</tr>
<tr>
<td>Clients are monitored for adverse effects and drug toxicity.</td>
<td>7</td>
</tr>
<tr>
<td>Provides support to ART clients in order to promote adherence to treatment.</td>
<td>7</td>
</tr>
<tr>
<td><strong>Uninterrupted supply of drugs and diagnostics for antiretroviral therapy and opportunistic infections</strong></td>
<td></td>
</tr>
<tr>
<td>Readily available stocks of OI/ART medicines</td>
<td>5</td>
</tr>
<tr>
<td>Health center has a monitoring process to warranty a constant flow of Antiretroviral and opportunistic infection medicines and a definite plan to protect medicines from misuse, loss or theft.</td>
<td>7</td>
</tr>
<tr>
<td><strong>Secured and confidential clinical record system</strong></td>
<td></td>
</tr>
<tr>
<td>Staff obtains a basic health record for each client suspected of having HIV.</td>
<td>7</td>
</tr>
<tr>
<td>Health center maintains the confidentiality, security and integrity of data and information.</td>
<td>7</td>
</tr>
<tr>
<td>Test results are communicated to clients who would have consented.</td>
<td>7</td>
</tr>
<tr>
<td>Clinical records contain sufficient and updated information.</td>
<td>2</td>
</tr>
</tbody>
</table>

One health facility did not have a Primary Care Counselor. Two facilities recorded stock outs of nevirapine during the period under review. Although individual patients’ records were up to date in all the facilities, the registers were not updated in 5 out of the 7 facilities. All the health centers had at least one health worker who had undergone training in HIV care. According to key informants, in house training and mentorship was reported to have cascaded to the other cadres. No machines were available for monitoring patients for drug toxicity and adverse effects at all the facilities. However health workers were using the clinical diagnosis for monitoring. Some
key informants reported that there was work overload at some facilities, although this was not substantiated. Two hundred and four (99.3%) of the respondents were satisfied with the quality of care provided at the health facilities.

5.6 Independent factors associated with ART initiation among TB/HIV co-infected individuals, Lupane, 2014

The independent factors associated with delayed ART initiation are shown in Table 5-7.

Table 5-7 Independent factors associated with ART initiation among TB/HIV co-infected individuals, Lupane, 2014

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted OR</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital status: Separated</td>
<td>6.21</td>
<td>1.63 - 23.71</td>
<td>0.01</td>
</tr>
<tr>
<td>Single</td>
<td>9.58</td>
<td>2.39 - 38.36</td>
<td>0.001</td>
</tr>
<tr>
<td>Widowed</td>
<td>14.23</td>
<td>1.72 – 117.76</td>
<td>0.01</td>
</tr>
<tr>
<td>Fear medicine toxicity</td>
<td>7.68</td>
<td>2.63 - 22.41</td>
<td>0.00</td>
</tr>
<tr>
<td>First HIV treatment at health centre</td>
<td>0.35</td>
<td>0.13 - 0.94</td>
<td>0.04</td>
</tr>
<tr>
<td>Transport cost of &gt;US$1</td>
<td>5.69</td>
<td>1.87 - 17.34</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Have family member on TB treatment</td>
<td>0.22</td>
<td>0.07 – 0.67</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Independent factors associated with delayed ART initiation were marital status separated (AOR 6.21), single (AOR 9.58 CI 2.39 – 38.36) and widowed (AOR 14.23 CI 1.72 – 117.76), fear of medicine toxicity (AOR 7.68, 95% CI 2.63-22.41), first HIV treatment at health centre (AOR 0.35 95% CI 0.13-0.94), transport cost more than US$1 (AOR 5.69, 95% CI 1.87-17.34) and having a family member on TB treatment (AOR 0.22, 95% CI 0.07-0.67).
5.7 Time intervals in patient pathway to ART initiation

Table 5-8 below shows the time intervals from HIV testing through to ART initiation among TB/HIV patients in Lupane.

Table 5-8 Time intervals in processes leading to ART initiation, Lupane district 2014

<table>
<thead>
<tr>
<th>Process intervals</th>
<th>Median delay (days)</th>
<th>Q1;Q3 (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV testing to start of ART counseling</td>
<td>8</td>
<td>4; 14</td>
</tr>
<tr>
<td>Start to completion of ART counseling</td>
<td>8.5</td>
<td>6; 14</td>
</tr>
<tr>
<td>Completion of ART counseling to Initiation of ART</td>
<td>3</td>
<td>2; 5</td>
</tr>
<tr>
<td>Initiation of TB treatment to ART initiation</td>
<td>23</td>
<td>18; 30</td>
</tr>
</tbody>
</table>

The median delay from HIV diagnosis to ART initiation among TB/HIV infected patients was 23 days ($Q_1=18$ days, $Q_3=30$ days). Fifty percent of the TB patients were taking between 18 and 30 days from HIV testing to ART initiation.
6 Discussion

The prevalence of delayed ART initiation among TB/ HIV co-infected study participants was 18.6% in 2014, while in 2013, 63% of eligible patients were not initiated on ART in Lupane district. This increase in coverage could be attributable to the intensification of TB/ HIV collaboration activities in the district. Training of health workers in HIV care and the full adoption of new guidelines in which there was ART initiation among all TB/ HIV co-infected patients regardless of CD4 count could also explain this trend. St Lukes hospital is the referral centre for Lupane district and is a health facility of choice for residents from neighboring districts. Incomplete reporting and ineffective record keeping for patients in 2013 could also have exaggerated the proportion of those not initiated on ART. This implies that updating treatment outcome records and effective record keeping is vital in reflecting the actual program performance. St Lukes Hospital has adopted the electronic Patient Management System (ePMS) for managing TB and HIV records. This system has been proven to improve the ability to track patients and follow up, and its roll out may improve patient management.\textsuperscript{41}

In this study, first HIV treatment at health facility where one is collecting medication was associated with earlier ART initiation. Those patients who were referred from other facilities for HIV care were more likely to delay ART initiation. This is similar to the findings of a study in South Africa where prolonged delays observed for patients referred from TB clinics reflected the many steps in the care pathway for such patients.\textsuperscript{29} In another South African study risk factors for failed linkage to HIV care were antiretroviral-naive status and absence of referral letter with HIV or CD4 cell count.\textsuperscript{18} In this study, it was noted that the patient flow pathway was prolonged due to lack of communication between referral and local sites. Although patients were being given referral letters, no communication was made with the local site, neither was there follow up on
those patients who failed to register. As a result, patients took long to register for ART since there was no follow up mechanism to track these patients. Patients could have responded well to ATT and cotrimoxazole prophylaxes hence were reluctant to commence ART early.

Transport cost of ≥ US$1 to access health facility was an independent risk factor for delaying ART initiation. The majority of people in Lupane district lives in the rural areas and are subsistence cattle owners and their earnings are well below the poverty datum line. Although ART initiation has been decentralized to all health facilities in the district, some patients still travel long distances of more than 10 kilometers to their nearest health facilities. This is similar to the findings of a study in Malawi where the higher the cost of transport to the hospital, the less probable it was that a TB patient accepted ART; distance to the hospital facility was not significantly associated with ART uptake. In a study of barriers to ART initiation, patients feared that transportation and supplementary food costs and difficulties in sustaining long-term treatment limited accessibility.

Marital status (single, separated and widowed) was an independent risk factor for delayed ART initiation. This is similar to the findings of a study in Uganda where unmarried clients were five times more likely to be initiated on ART late as compared to the married. In a study in India being widowed was significantly associated with delayed ART initiation. Community health workers should therefore target this group in offering ART support services. Single or widowed patients should also be encouraged to disclose their status and share their challenges so as to get support and encouragement to initiate ART early.

Those who feared drug toxicity were more likely to delay ART initiation. This is similar to the findings of a study in Uganda where the majority of those who delayed ART initiation
mentioned witnessing relatives and friends experiencing side effects.\textsuperscript{34} In a study to enquire the reasons why patients refuse ART before completing ATT in Swaziland, the fear of adverse outcomes being precipitated by combining ART with TB medicines was implicated.\textsuperscript{31} Some patients also stated that they did not receive any preparation for ART; hence they feared ART initiation during TB treatment\textsuperscript{31}. In Uganda, lack of pre ARV care was associated with delayed ART initiation.\textsuperscript{12} It is therefore imperative that patients undergo comprehensive ART preparation so as clarify all the fears associated with ART initiation during ATT.

Having TB treatment supervised and a family member on TB treatment were significant protective factors. This is plausible as the support from the treatment supervisor and the experience garnered in the successful treatment of the family member would allay any fears and encourage one to seek care early. Evidence has it that social support is associated with better psychological adjustment and medication adherence\textsuperscript{27}.

Suffering from another chronic condition was a significant risk factor for delaying ART. Pill burden could be a possible explanation as in addition to chronic condition medication, ATT and cotrimoxazole prophylaxis, the client was expected to commence ART. The benefits of ART should therefore be emphasized to encourage these patients to commence ART early.

Those who sought care elsewhere were more likely to delay ART initiation. A study in Uganda revealed competition from traditional and spiritual healers as a factor associated with very late ART initiation\textsuperscript{12}. In this study, while the majority of study participants were satisfied with the quality of care in the health centers, it is the choice by others to seek HIV care elsewhere which is worrisome. This implies that an information gap still exists amongst this group, and pre ART counseling should address this habit of patients leaving the conventional health care system for
other alternatives. At the same time there is also need to engage the faith and traditional healers so as to avert the delays that they cause.

Fear of stigma and non disclosure of HIV status were significant risk factors for delayed ART initiation. This is consistent with the findings of a study in Tanzania where fear of discrimination and stigmatization summed all concerns.\textsuperscript{13} In a study in Malawi, most people believed that attending ART clinic for treatment was as good as declaring their HIV status openly\textsuperscript{33}. Only a minority said they were better able to hide their status in their home village by starting treatment quickly\textsuperscript{33}.

Early initiation of ART among TB/HIV co-infected patients results in optimal outcomes. An indicator in the reporting system on the interval between ATT and ART initiation among TB patients will help to monitor program performance.

\section*{6.1 Study limitations}
The calculated sample size could not be reached due to limited number of patients who met the inclusion criteria and time to conduct the study. This could have reduced the power of the study and precision of estimation of measures of associations. Distances to health centers were based on estimations as obtained from the study participants.
7 Conclusions and Recommendations

7.1 Conclusion
The proportion of TB/ HIV co-infected patients who delayed ART initiation in 2014/15 was 18.6%. Lack of follow up and outreach to defaulting patients, and ineffective linkage to care in health facilities prolonged the patient flow pathway to ART initiation. The independent risk factors for delaying ART initiation among TB/ HIV co-infected patients were marital status, fear of medicine toxicity and transport cost of US$1 or more. Having had a family member on TB treatment and first treatment at health facility where one was receiving ART were significant protective factors. The median time interval from HIV testing to ART initiation in TB/ HIV co-infected patients was 23 days ($Q_1=18$ days, $Q_3=30$ days).

7.2 Recommendations

7.2.1 Immediate
There is need for health workers to communicate on referred ART patients to expedite linkage in care. [Sister in Charge, District HIV/AIDS Focal Person]

Health workers should intensify ART preparation with a comprehensive package emphasizing on benefits of early ART initiation. [Matron, Primary Care Counselor]

Health workers are to keep TB/ HIV records up to date. The electronic Patient Management System (ePMS) should be rolled out to all the facilities. [DHE, PHE]

Delaying eligible ART patients should be followed up by the health workers so as to initiate them timely. [Community Sister, Village Health Worker]

There is need to streamline clinic visit schedule protocols in order to reduce clinic visits made by the patients and the associated transport costs. [DNO, Matron, SIC]
7.2.2 Short term
ART outreach clinics should be conducted to remote areas where patients would normally find it difficult to reach the health facilities. [Sister in Charge, DHE]

Community awareness campaigns should be conducted to promote early diagnosis and treatment of TB/HIV. [District Health Promotion Officer, DHE]

Health workers should engage traditional and faith healers so as to come up with appropriate strategies to avert their role in delaying ART initiation in eligible patients. [District HIV/ AIDS focal Person, Sister in Charge]

7.2.3 Long term
The addition of an indicator on interval between ATT and ART initiation among TB patients in the TB/ HIV Collaborative activities will be instrumental in continuous monitoring of ART initiation among TB patients. [Health Information]
8. **References**


5. WHO policy on collaborative TB/HIV activities: Guidelines for national programs and other stakeholders; World Health Organization, 2012


doi:10.1097/QAI.0b013e31829ceaec.


16. Alvarez-Uria, Gerardo et al. “Predictors of Delayed Antiretroviral Therapy Initiation, Mortality, and Loss to Followup in HIV Infected Patients Eligible for HIV Treatment:


34. Ratanshi RP et-al. Barriers to starting ART and how they can be overcome: Individual and operational factors associated with early and late start of treatment. Tropical Medicine and International Health. Volume 15 no 11 pp 1347–1356 November 2010


\url{http://www.jiasociety.org/index.php/jias/article/view/17366} | \url{http://dx.doi.org/10.7448/IAS.15.3.17366}


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9. **Appendices**

   a. **Appendix 1: English Questionnaire**

   **Questionnaire for study participants**

   **Questionnaire Number …………**

   **Name of Health Facility  ……………………………… Date of Interview**

   ….../…../…..

   **Socio-demographic Information**

   1. **Sex**
      - Male [ ]
      - Female [ ]

   2. **What is your date of birth? ….../…../…..**

   3. **Where do you live? Township [ ] Rural [ ] Urban [ ] other, specify ………………….**

      - Separated [ ]

   5. **What is your occupation? Formal [ ] Informal [ ] Unemployed [ ] Housewife [ ]**
      - Student [ ]

   6. **What is the highest level of education you have achieved? Tertiary [ ] Secondary [ ]**
      - Primary [ ] None [ ]

   7. **What is your religion? Traditional [ ] Christianity [ ] Moslem [ ] Judaism [ ] Other**
      - [ ] specify……………….

   **Patient Treatment Record**

   8. **What type of TB, were you diagnosed?( Verify with records) Pulmonary [ ] Extra pulmonary [ ]**

   9. **What category of treatment are you in? (check with records)1 [ ] 2 [ ] MDR TB [ ]**
10. When were you commenced on anti-TB treatment? …/…/…

11. When were you tested for HIV? …/…/…

12. Have you had a CD4 count test done on you? Yes [ ] No [ ] if no, skip to 15

13. If yes to 13, when was it done? …/…/…

14. What was the result? .......... (check records)

15. Are you registered for ART? Yes [ ] No [ ] if no, skip to 18

16. If yes to 16, when were you registered for ART? …/…/…

17. Was your initial registration for ART in this district? Yes [ ] No [ ]

18. Are you taking cotrimoxazole prophylaxis? Yes [ ] No [ ]

19. If No to 18, why are you not taking cotrimoxazole? ............................................................

20. If yes to 18, when were you initiated on cotrimoxazole? …/…/…

21. Were you pre-ART counseled? Yes [ ] No [ ] if no, skip to 24

22. If yes to 21, when was pre-ART counseling started? …/…/…

23. When was ART counseling completed? …/…/…

24. Are you on ART now? Yes [ ] No [ ] if no, skip to 26

25. If yes to 25, when were you initiated on ART? …/…/…(record date and tick applicable) During intensive phase [ ] after intensive phase [ ]

26. Do you suffer from any other chronic condition that requires collecting medication regularly? Yes [ ] no [ ]

27. Did you suffer from any serious illness before or starting TB treatment? Yes [ ] No [ ]

   Patient, Socio economic determinants

28. Do you have any fears of being on ART during TB treatment? Yes [ ] No [ ]
29. If yes to 29, what are the fears? ………………………………………………………………………

30. Do you think TB and HIV treatment should be taken concurrently? Yes [ ] No [ ]

31. In your opinion, are there any benefits for you being on ART? ……………………………
……………………………………………………………………………………………………

32. Do you think people suffering from TB/HIV are stigmatized in your family/community?
   Yes [ ] No [ ] If yes, give reasons………………………………………………………………………

33. Whom were you staying with at the time of starting TB treatment? Alone [ ] Relative [ ]
   other [ ] specify ……………………………

34. Who supervises you when taking your TB treatment? Family member [ ] VHW [ ]
   Health worker [ ] Nobody [ ]

35. Do you have any support group where you participate as a member? Yes [ ] No [ ]

36. To who have you disclosed your TB and HIV status? Nobody [ ] Relative [ ] friend [ ]
   other [ ] specify ………

37. If no to 37, what are the reasons for not disclosing?
…………………………………………………………………………………………………….

38. Do you have any family member who was on TB treatment before? Yes [ ] No [ ]

39. Do you have any family member who was on HIV treatment before? Yes [ ] No [ ]

**Issues affecting behavior to initiate ART**

(Tick appropriate box using key below)

**Key**

Strongly agree (SA) = 5

Agree (A) = 4

Undecided (U) = 3
Disagree (D) = 2
Strongly disagree (SD) = 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perceived susceptibility</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>SA</td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>3</td>
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<tr>
<td></td>
<td>U</td>
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<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>40. People who are TB/HIV co-infected can start ART whenever they feel like doing so</td>
<td></td>
</tr>
<tr>
<td>41. If I do not commence ART within 2 months of ATT, I could be very ill due to HIV infection</td>
<td></td>
</tr>
<tr>
<td>42. I am healthy enough to commence ART within 2 months of ATT, as ATT is curing me</td>
<td></td>
</tr>
<tr>
<td>43. I do not need ART counseling when taking ATT</td>
<td></td>
</tr>
<tr>
<td><strong>Perceived severity</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
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<tr>
<td></td>
<td>SA</td>
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<tr>
<td></td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>44. If I do not commence ART within 2 months of ATT, I could die early due to HIV</td>
<td></td>
</tr>
<tr>
<td>45. If I do not commence ART within 2 months of ATT I could suffer from serious opportunistic infections</td>
<td></td>
</tr>
<tr>
<td><strong>Perceived benefits</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
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<tr>
<td></td>
<td>SA</td>
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<td></td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>46. If I commence ART within 2 months of ATT, I will live longer</td>
<td></td>
</tr>
<tr>
<td>47. If I commence ART within 2 months of ATT, I will live a healthy life</td>
<td></td>
</tr>
<tr>
<td>48. If I commence ART early, I will be able to look after my family</td>
<td></td>
</tr>
<tr>
<td>Perceived barriers</td>
<td>5</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>SA</td>
</tr>
<tr>
<td>49. I do not like ART because I am already taking too many pills and I will forget ART</td>
<td></td>
</tr>
<tr>
<td>50. I will suffer from side effects due to drug toxicity</td>
<td></td>
</tr>
<tr>
<td>51. I have seen people suffer from side effects, therefore I am afraid too</td>
<td></td>
</tr>
<tr>
<td>52. It is difficult to get ART because the health centre is far and I cannot walk the distance or afford the transport fares</td>
<td></td>
</tr>
<tr>
<td>53. The health workers discriminate people on ART so I do not like</td>
<td></td>
</tr>
<tr>
<td>54. The queues are too long and I cannot wait</td>
<td></td>
</tr>
<tr>
<td>55. My religion demands that I do not use ART</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Cues to action</td>
<td>SA</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>56. If health workers have time to counsel me I will commence ART</td>
<td></td>
</tr>
<tr>
<td>57. If I hear or read about the benefits of ART in TB/HIV co-infected patients, I am more likely to use it.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Health system determinants</td>
<td>SA</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>58. How much do you pay for services you get here? $ …….</td>
<td></td>
</tr>
</tbody>
</table>
59. How long do you travel to get to the health facility where you collect medicines? …… km

60. How much do you pay in transport costs to get to the hospital? $…….

61. How far away from your home is your nearest health facility? ……………

62. Did you face any problems in ART enrolment and initiation? Yes [ ] No [ ]

63. If yes to 39, what where the problems? Long waiting time [ ] No ARV medicines [ ]
    other [ ] specify …………………………………………………………………………………

64. Before you registered for ART, did you seek for medical care elsewhere? Yes [ ] No [ ]
    if no, skip to 67.

65. If yes to 64, where did you seek care? Private medical care [ ] Traditional healer [ ]
    Faith healer [ ] other [ ]Specify …………………

66. If yes to 64, what were the reasons for seeking care elsewhere? ……………………..
    …………………………………………………………………………………………………

67. Do you think health workers stigmatize people with TB/HIV? Yes [ ] No [ ]

68. How would you rate the quality of care you receive from health workers here? Poor [ ]
    Fair [ ] Good [ ]

69. Are you satisfied with the quality of service you receive in OI? Yes [ ] No [ ]

70. If no to 41, can you explain ……………………………………………………………………….
PARTICIPANTS INFORMED CONSENT

PROTOCOL TITLE: Factors Associated with Delayed ART Initiation among TB/HIV Co-infected Patients in Lupane District 2015

NAME OF RESEARCHER: John Manyara

PHONE: 0772429162

PROJECT DESCRIPTION:
You have decided to take part in the research study named above. The study will collect your information about your age, gender and income, place of residence and risk factors for delayed ART initiation in Lupane District. This consent form gives you information about the collection, storage and future use of data collected from you. Please ask if you have any questions. You will be asked to sign or make your mark on this form to indicate whether or not you agree to participate in the study. You will be offered a copy of this form to keep and will keep the other form for at least 3 years.

YOUR RIGHTS
Before you decide whether or not to volunteer for this study, you must understand its purpose, how it may help you, the risks to you, and what is expected of you. This process is called informed consent.

PURPOSE OF RESEARCH STUDY
The study seeks to determine Factors Associated with Delayed ART Initiation among TB/HIV Co-infected Patients in Lupane District 2015. The factors being looked at are divided into
health system related, clients/patient related economic and cultural factors. You will also be asked on your perceived benefits of presenting early for HIV treatment.

**PROCEEDURES INVOLVED IN THE STUDY**

Data will be collected using an interviewer administered questionnaire and checklists. The questionnaire you will respond to consists of open ended and closed ended questions and also a closed-ended rating scale question.

**DISCOMFORTS AND RISKS**

There are ethical risks related to storing your information. It is possible that if others find out information about you in the questionnaire, it could cause you problems of stigmatization. To minimise this risk your information will be strictly put under lock and key. Information collected from you will be used only for academic purposes.

**POTENTIAL BENEFITS**

There are no immediate benefits to you from having your information stored. You and others could benefit in the future from research done on you.

**STUDY WITHDRAWAL**

You may choose not to enter the study or withdraw from the study at any time without loss of benefits entitled to you.

**CONFIDENTIALITY OF RECORDS**

Completed questionnaires and checklists will be kept under lock and key for at least 3 years after which they may be destroyed. To keep your information private, your name will not be written on the questionnaire.
PROBLEMS/QUESTIONS

Please ask about this research or consent now. If you have any questions in future please ask.

AUTHORIZATION

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know being in this study is voluntary. I choose to be in this study. I know I can stop to be in this study and I know I will not lose any benefits entitled to me. I will get a copy of this consent form

__________________________________________________________________________

Client Signature or Mark       Date

___________________________________________________________

Client Name (Printed)

__________________________________________________________________________

Researcher Signature                      Date

__________________________________________________________________________

Witness Signature                      Date
d. Appendix 4: Ndebele Consent Form

Isivumelwano

PROTOCOL TITLE: Imbangela yokuphuza ukuqala ukwelatshwa kubagulibo fuba/ingculaza esiqintini seLupane.

NAME OF RESEARCH ER: John Manyara

PHONE : 0772429162

PROJECT DESCRIPTION:
Ukhethe ukuphatheka kulokhu kucubungula, ngicela ukwazi iminyaka yakho yokuzalwa, ubulili, inzuzo yemali lekheli lakho kanye lezizatho zokuphuza ukuqala ukwelatshwa ingculaza esiqintini seLupane. Lesi sivumelwano sikupha ulwazi mayelana lokuqoqwa, lokugcinwa kwempumela langokusetshenziswa kokutholakeleyo. Uzacelwa ukuthi ukuphela ukuthi yavumelana lokuphatheka kulokhu kungcubungula. Uzanikwa leliphepha ukuba ulugcine lami ngizagcina elifananayo okweminyaka emithathu.

Amalungelo akho
Ungakazinikeli qala uzwisise izizatho zalokhu kucubungunga, ukuthi zingakunceda njani, ingozi ezingakuvelela lokuthi wena kumele wenzeni. Lokhu kuthiwa yisivumelwano sozwisisileyo okumunyethweyo.

Injongo yokucubungula
Ukucubungula lokhu kujonge ukuveza izizatho eziphathelane lokuphuza ukwelatshwa kwezigulane ezilomkhuhlane woufuba/ingculaza esiqintini seLupane. Imibuzo izabe iphathelane lezemplakahle, ezomnotho lezamasiko. Uzabuzwa njalo ngokuqakatheka kokuthola ukwelatshwa ngokuphangisa.
**Indlela ezalandelwa ekucubunguleni**


**Ukungaphatheki kahle lengozi**


**Okungakunceda**

Akula ongakuthola ngokuphangisa ngokunika ulwazi kumbengokuphatheka kulokhu, kodwa wena labanye lingancedakala ngezikhathi ezizayo.

**Ukungaphatheki ekucubunguleni**

Ungakhetha ukungaphatheki kulokhu kucubungula lobanini.

**Ukugcinwa kwalezi ngwalo**

Ingwalo ezilemibuzo egcwalisiweyo ziza ngcinwa ziyimfihlo, njalo zikhiyelwe okweminyaka emithathu besezitshabalaliswa ngendlela yakhona. Ibizo lakho alizikubhalwa kulezingwalo.

**Inkinga/Imibuzo**

Nxa ulemibuzo khathesi loba ngesikhathi esizayo uvunvelwe ukubuza.
Imvumo


____________________________________
Client Signature or Mark       Date

____________________________________
Client Name (Printed)

____________________________________
Researcher Signature       Date

____________________________________
Witness Signature       Date
e. Appendix 5: Interview guide for key informants

Interview Guide

1. Designation ………………………………………………………………………………………………………

2. Years of experience ……………………………………………………………………………………………

3. Have health workers undergone training in TB/HIV care? Yes [ ] No [ ]

4. What proportion is trained at this institution? …………

5. Do you have adequate human resources for the program? Yes [ ] No [ ]

6. Do you have adequate medicines? Yes [ ] No [ ]

7. Do you have adequate medical supplies for testing patients? Yes [ ] No [ ]

8. Do you offer any outreach services for TB/HIV care? Yes [ ] No [ ]

9. Can you briefly explain how a TB patient diagnosed with HIV proceeds from diagnosis to ART initiation in this institution? (Take note of linkages in care, time and number of appointments)

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10. What is the average time lag between HIV diagnosis and ART initiation in TB patients in this institution? …………

11. What are some of the challenges impacting on the performance of the program? ……………………………………………………………………………………………………………
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12. In your opinion, what causes delay in ART initiation in eligible TB/HIV co infected patients?
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13. Do you have any solutions to avert the delays? Yes [ ] No [ ] Explain you answer
### Appendix 6: Checklist for Quality of Care at Health Facilities

#### HIV Testing and counselling

1. The organization establishes and follows an HIV testing policy that reflects national laws and guidelines and the WHO guidelines on rapid testing.

2. The staff obtain informed consent from each person tested, and test subjects and staff attest to the voluntary nature of HIV testing.

3. The organization respects the confidentiality of test results.

4. The organization provides pre-test and post-test counseling.

#### Provision of ART

5. The organization follows standard diagnostic protocols for every person suspected of having HIV infection.

6. The organization follows clinical management protocols based on national or WHO guidelines for all people living with HIV/AIDS.

7. The trained and/or certified caregivers and health professionals monitor people receiving therapy for drug toxicity and adverse effects.

8. The organization provides support to people receiving therapy to facilitate their adherence to the prescribed treatment.

#### Uninterrupted supply of drugs and diagnostics for antiretroviral therapy and opportunistic infections

9. The organization stocks medicines for antiretroviral therapy and opportunistic infections listed in the national or WHO antiretroviral therapy guidelines and has them readily available.

10. The list of medicines stocked in the organization includes other drugs, such as methadone for substitution therapy, appropriate for the services offered by the program.

11. The organization has an established monitoring process to ensure a continuous flow of supplies of key antiretroviral and opportunistic infection drugs and a process in place to protect drugs from loss, theft or misuse.

#### Secured and confidential clinical record system

12. Staff obtains a basic health inventory for each person suspected of having HIV or AIDS.

13. The organization maintains the confidentiality, security and integrity of data and information.

14. The organization communicates test results to other people only with the consent of the person being tested, and only health-care professionals with a direct role in managing the person being tested have access to the results on a need-to-know basis.

15. Clinical records contain sufficient and updated information to identify the person receiving treatment, support the diagnosis, justify the treatment, document the course and results and promote continuity of care among health care providers.
g. Appendix 7: Joint Ethics Review Committee Approval Letter
APPROVAL LETTER

Date: 28th July 2015

Name of Researcher: John Manyara
Address: University of Zimbabwe, Department of Community Medicine

Re: Factors Associated With Delayed Antiretroviral Therapy (ART) Initiation Among Tuberculosis (TB)/ Human Immunodeficiency Virus (HIV) Co-Infected Patients In Lupane District, 2015.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ approval and if required by the nature of your study, RCZ approval as well, before you commence the study.

- APPROVAL NUMBER: JREC/172/15
- APPROVAL DATE: 28th July 2015
- EXPIRY DATE: 27th July 2016

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

a) Completed application form
b) Full Study Protocol
c) Informed Consent in English and/or appropriate local language
d) Data collection tool version:

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

a. A Progress report
b. A Summary of adverse events.
c. A DSMB report

OHRR IRB Number: IORG 00068914
PARIYENYATWA GROUP OF HOSPITALS FWA: 00019350

72
REF: MRCZ/B/896

12 August 2015

John Manyara
University of Zimbabwe
Department of Community Medicine
College of Health Sciences
P. Box A 179
Avondale

RE: Factors associated with Delayed Antiretroviral Therapy Initiation Among Tuberculosis/ Human Immunodeficiency Virus C-infected patients in Lupane District, 2015

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has reviewed and approved your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:-

a) Study proposal
b) Informed Consent Form (English, Shona and Ndebele)

- TYPE OF MEETING: Expedited
- EFFECTIVE APPROVAL DATE: 12 August 2015
- EXPIRATION DATE: 11 August 2016

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted three months before the expiration date for continuing review.

• SERIOUS ADVERSE EVENT REPORTING: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices or website.

• MODIFICATIONS: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).

• TERMINATION OF STUDY: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices or website.

• QUESTIONS: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

Other

• Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
• You’re also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH