MAGNITUDE AND PREDICTORS OF ANTIRETROVIRAL (ART) TREATMENT FAILURE AMONG WOMEN ON OPTION B PLUS ATTENDING PMTCT CLINICS IN DAR ES SALAAM, TANZANIA

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By

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A Dissertation Submitted in (Partial) Fulfillment of requirements for the Degree of Master of Public Health of

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CERTIFICATION

The undersigned, certifies that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled "***Magnitude and predictors of ART treatment failure among women on option B plus attending clinics in Dar Es Salaam region***" in (partial) fulfillment of the requirements for the degree of Master of Public Health (MPH) of Muhimbili University of Health and Allied Sciences.

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Dr. Rose Mpembeni

(Supervisor)

_____

Date

DECLARATION ANDCOPYRIGHT

I, **Ally M. Kaduma**, 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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I give thanks to God for giving me the ability, strength and courage to pursue my studies and complete this dissertation.

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Last but not least my special thanks goes to beloved wife Juliana Joachim and my sons for their moral support and providing conducive environment for conducting my work.

DEDICATION

I would like to dedicate this work to my beloved wife Juliana Joachim and my sons Jayson & Jaydan May the almighty God grant them long life with this piece of work be a motive for them to accomplish higher than this in future.

ABSTRACT

Background: In 2010, the world Health organization (WHO) published prevention of mother to child transmission (PMTCT) guideline, to initiate ART to all HIV +ve pregnant/ breastfeeding women regardless of their CD 4 or WHO clinical Stages. Tanzania adopted this new guideline in September 2013 called PMTCT option B plus (PMTCT Option B+). The implementation of PMTCT B+ option has already begun to show impressive results and many pregnant and breastfeeding women have been put on ART. However the challenges of, adherence to ART, retention and ART treatment failure are yet to be clearly understood**.**

Objective: To assess the magnitude and predictors of ART treatment failure among women on option B+ attending PMTC clinics in Dar es Salaam region.

Material and Methods: A cross sectional study conducted among 410 HIV +ve women who access PMTCT option B + services in Dar es Salaam. A two stage cluster random sampling method was used to select 410 participants of this study and 15 health facilities; First stage was to select Health facilities for study and second study for selection of participants of study. Ethical approval pursued from MUHAS ethical committee and informed consent from study participants. Structured questionnaire were used for data collection. And summarization of data was done through descriptive statistics; Chi square was used to test association between independent and dependent factors and multiple logistic regression were used to determine independent predictor of ART treatment failure after controlling for potential confounding variables. The study was conducted between April and May 2017. ART treatment failure were considered in this study when women on ART for more 6monthsand have viral load of more than 1000copies after repeat viral test and CD4 cells drop of more than 50% from high peak value or baseline.

Results: The overall ART treatment failure for women on PMTCT option B+ was at 26.6%; Those who had immunological failure were about at 8%, virological failure was at 11.5% and those with both immunological and virological failures were at 6.8%. Findings showed that women who had not disclosed their HIV status to partner or relatives had higher odds of

developed treatment failure compared to those disclosed their HIV status, women with poor adherence to ART medication has higher odds of develop failure compared to those with good adherence to ART medication and women who experienced ART related side effects had higher odds of developing treatment failure compared to those with no history of ART related side effects.

Conclusion: This study findings show that overall ART treatment failure was 26.6% and were strongly associated with poor adherence, Lack of disclosure HIV status and ART related side effects. It is recommended that health workers be trained .on identifying patients with ART failure for timely intervention which may include both targeted adherence interventions and better preservation of efficacy of second-line regimens.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retrieval Treatment
ARV	Anti-retroviral
CTC	Care and Treatment Centre's
HIV	Human Immunodeficiency Virus
PMTCT	Prevention of Mother to Child Transmission
MoHCDEC	Ministry of Health, Community Development, Gender, Elderly & Children
MTCT	Mother to Child Transmission
RCH	Reproductive and child health
SPSS	Statistical Package for Social Scientists
TACAIDS	Tanzania commission for AIDS
UNAIDS	United Nations Programme on HIV and AIDS
WHO	World Health Organization

DEFINITION OF KEY TERMS

- **Immunological failure:** - Fall of CD4 count to baseline (or below) or50% fall from on- treatment peak value or Persistent CD4 levels below 100 cells/mm3
- **Clinical failure:** - New or recurrent WHO stage 4 condition or new or recurrent WHO stage 3 with pulmonary TB and/or severe bacterial infections
- **Virologic failure:** - When the plasma viral load is 1000 copies/ml or above[(1)].
- **Overall Treatment failure** is considered in this study as all patients who failed clinically, virologically and immunologically[(1)].
- **Predictor's of ART failure**: is considered as identifier that helps to suspect treatment failure and for intervention. Especially, earlier detection of virological failure allows both targeted adherence interventions and better preservation of efficacy of second-line regimens

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The World is determined to achieve the 90–90–90 treatment target by 2020, whereby 90% of people living with HIV know their HIV status, 90% of people who know their HIV-positive status are accessing treatment and 90% of people on treatment have suppressed viral loads not failed[2].

HIV continues to be a major global public health issue, having claimed more than 35 million lives so far. In 2016, 1.0 million people died from HIV-related causes globally. There were approximately 36.7 million people living with HIV at the end of 2016 with 1.8 million people becoming newly infected in 2016 globally. And 54% of adults and 43% of children living with HIV are currently receiving lifelong antiretroviral therapy (ART) globally[1]. And Worldwide Global ART coverage for pregnant and breastfeeding women living with HIV is high at 76%. The WHO African Region is the most affected region, with 25.6 million people living with HIV in 2016. The African region also accounts for almost two thirds of the global total of new HIV infections.

Mother to child transmission (MTCT) of HIV remains the primary mode of infection in children under 15 years[3].Timely access to quality lifesaving antiretroviral (ARV) drugs during and after pregnancy is a proven intervention to preserve maternal health and virtually eliminate the risk of MTCT of HIV[4]

In 2010, the world Health organization (WHO) published prevention of mother to child transmission (PMTCT) guideline, the guideline specify to initiate ART as lifelong treatment to all HIV pregnant women regardless of their CD 4 OR WHO clinical Stages. In 2013 Tanzania adopted the new WHO guideline and they named it as PMTCT Option B+. The PMTCT Option B+ is a strategy on which all newly diagnosed HIV-positive pregnant women are counseled to initiate combination anti-retroviral therapy (ART) immediately upon diagnosis regardless of CD4 count and to continue treatment for life. The rationale of Option

B+ was to achieve the elimination of new pediatric HIV infections by 2015 and ensuring that all ART-eligible pregnant women receive triple ARVs for their own health [5,6)(7)]. This approach is believed to contribute to the target of ending the AIDS epidemic by 2030[8]

Option B+ may be a more effective PMTCT strategy, as it helps overcome some barriers (like poor access to CD4 testing) associated with achieving high coverage of treatment [9]. This approach ensures that most HIV-positive women are placed on treatment immediately following diagnosis, which leads to further reduction of MTCT([9]. Moreover, the simplification of drug regimen options could make adherence easier for both mother and healthcare provider, which is likely to facilitate higher retention rates[10,11] Additionally, Option B+ provides an excellent opportunity to begin roll-out of ‘‘treatment as prevention,’’ which can have a significant impact in reducing new HIV infections due to sexual transmission among sero discordant partners [11].

The implementation of Option B+ has already begun to show impressive results in resource-constrained settings dramatically increasing the numbers of pregnant and breast- feeding women enrolled on ART[11]. But it is facing several potentials challenges including adherence to ART, immunological and virologial failures. These challenges might result with higher viral loads which in turn increase risk of MTCT, maternal disease progression and a high risk of drug resistance. Thus it’s very important to understand the magnitude of viral suppression and their predictors among pregnant women and breastfeeding women who are on PMTCT option B+. Identification of these predictors will help to define early predictors of treatment efficacy that permit better use of these potent drugs, avoid unnecessary side effects of drug, prevent drug resistance, and decrease economic burden, especially in a resource-limited setting like Tanzania due to the expensiveness of drug. The results of this study will provide important information to, stakeholders on how to implement and monitor predictors for ART failures among women attending care in PMTCT programs.

1.2 Problem statement.

Globally its indicated that, the percentage of infants born from HIV infected women or HIV exposed infants who becomes HIV infected is at 15% (UNAIDS 2016)[12] and this it's too far from global target of eliminating Mother to child HIV transmission. UNAIDS concern is to achieve 90% of patients on ART to suppress viral load maximally, which means only marginal of 10% are on failure zone [1]. PMTCT is known to reduce MTCT to about less than 2%. But the gains sought by PMTCT Option B+ depends on the proportion of women who adhere to treatment and are retained in care. Treatment failure, development of drug resistant which is associated maternal disease progression and hence an increased risk in MTCT to attain the global targets.

Poor adherence, undisclosed HIV status and low CD4 count were postulated as the major predictors of ART treatment failures among adult on HIV care[13][14][15].

The magnitude and predictors for ART treatment failure has not been thoroughly assessed in Tanzania, particularly among pregnant mothers who are enrolled to PMTCT, there are only few studies on the assessment of the ART services which discussed on predictors of immunologic failure and on retention of ART patients in care.[16][17]

It has been found that chances of Virological and Immunological failures increases with the increase in Time on ART.[16]. But there is a lack of information on virological and immunological failures among women utilizing PMTCT Option B + since it was started in 2013.

Studies have shown that even for ART clients with good adherence, there is still a possibility of treatment failure[18]. A study done in Ethiopia showed that the magnitude of ART treatment failure in the public health sector in Ethiopia ranges from 20.4% [19][20]

Thus to achieve the three 90-90-90 target of reaching 90% HIV care of viral suppression there is need to understand the magnitude and predictors of ART treatment failures among HIV Infected women utilizing PMTCT Option B +. In Tanzania there is scarcity of information on the magnitude and factors influencing ART treatment failure among pregnant women on

PMTCT using Option B Plus. Knowledge of the magnitude and factors influencing treatment failure will be a bridge to develop interventions to reduce treatment failure. Thus this study seeks to assess the magnitude and predictors that account for treatment failure among HIV Infected women utilizing PMTCT Option B + in Dar es Salaam.

1.3 Conceptual Framework:

Assessment of factors and predictors of antiretroviral treatment (ART) failure among women on option B plus attending PMTCT clinics in Dar es Salaam, Tanzania.

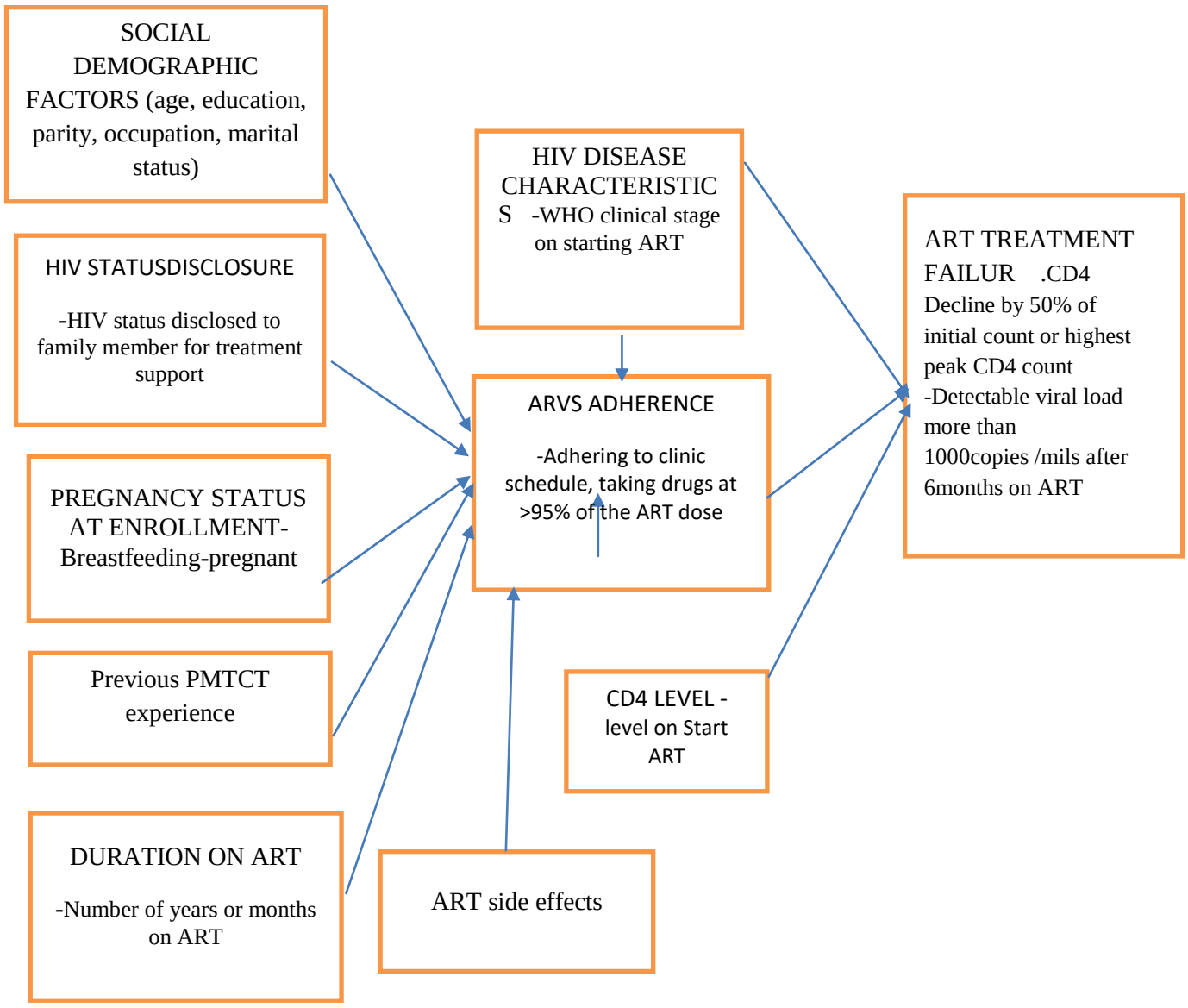

Figure 1 : Conceptual frame work

This conceptual frame work illustrate how factors may be associated with ART treatment failures. Knowing the magnitude and predictors of ART treatment failure is a crucial on elimination of MCT and maternal health. There several factors which associated with ART treatment failure which include ART adherence which influenced by :HIV status disclosure, status of women at enrollment, previous exposure to ART, Duration of women on ART, history of ART related side effects,CD4 level at joining or start PMTCT and all HIV diseases characteristics (WHO clinical stages) at start PMTCT these all there effect to adherence to ART can be linked to treatment failure indirectly. And all these independent variables guided on formulation of specific objective, literature review and development of research tools.

1.4 Rationale

In September 2013 Tanzania launched Option B as national policy to prevent MTCT. This ART policy was implemented, prioritizing Health centers that provide both PMTCT and ART services. Prevention mother to child HIV transmission through PMTCT option B+ has been postulated be the most efficient way of reaching and achieve the 90–90–90 treatment target by 2020, whereby 90% of people living with HIV know their HIV status, 90% of people who know their HIV-positive status are accessing treatment and 90% of people on treatment have suppressed viral loads not failed [(2)]. The implementation of option B+ has already begun to show impressive results such as increasing the numbers of pregnant and breastfeeding women enrolled on ART and promising chance of reducing MTCT. The gains sought by expanding ART access through Option B+ depends on the proportion of women who adhere to treatment and are retained in care. However, the gains are being challenged by treatment failure, development of drug resistant which is associated maternal disease progression and increased risk in MTCT.

To date less has been studied to assess the magnitude and predictors that results to viral logical failure, development of drug resistant among PMTCT Option B+ clients. Thus this study sought to assess the magnitude and predictors of ART treatment failure among women utilizing PMTCT under Option B plus is a warrant.

The findings from this study will be used to develop evidenced based interventions for early detection of ART treatment failure, such that the health benefits of Option B plus can be fully realized.

1.5 Research questions:

1. What is the magnitude of ART treatment failures among HIV positive women on PMTCT Option B+ attending clinic in Dar es Salaam?
2. What are the predictors for of ART treatment failures among HIV positive women on PMTCT Option B+ attending clinic in Dar es Salaam?
3. What proportion of women who adhered to ART who developed treatment failure?

1.6 Study objectives

1.6.1 Broad Objective

To assess the magnitude and predictors of ART treatment failure among women on option B plus attending PMTC clinics in Dar es Salaam region.

1.6.2 Specific Objectives

1. To determine the prevalence of ART treatment failures among HIV positive women on PMTCT Option B+ attending clinic in Dar es Salaam?
2. To determine the predictors for ART treatment failure among HIV positive women on PMTCT Option B+ attending clinic in Dar es Salaam.
3. To determine factors associated with treatment failure among women who are adherent to ART

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Prevalence of ART treatment failure among women in option B plus.

2.1.1 Overview of ART treatment failure

ART Treatment failure is defined in three ways; Immunological failures, clinical failure and Virological failures.; Immunological treatment failure is decrease in CD4 cell count to base line or below base line (initial CD4 count), 50% decrease of CD4 cell count from the peak value during ART treatment, or persistent CD4 cell counts after at least 12 months of ART[21].

Clinical failure is the emerging of new opportunistic infection or recurrent of WHO stage 3 or stage 4 conditions like pulmonary TB or severe bacterial infections[22].

Virologic failure is primarily defined as 2 consecutive viral load measurements of more 1000 copies/mL after at least 6 months of ART. But this definitions used when want to switch to second line (programmatic)[21], for this study we defined Virologic failure as on resource limited country as viral load measurements for more 1000 copies/mL after at least 6 months of ART treatment and viral load test repeated[23].

In meta-analysis of 17 ART programs in resource-limited settings we found that patients with access to viral load monitoring were more likely to switch to second-line therapy earlier and at higher CD4 cell counts than those enrolled in programmes without viral load monitoring, and delays in switching will increase the time on low CD4 cell counts, and may promote treatment failure and development of resistant strains and thus affect long-term prognosis of clients[24].

To understand the concepts and predictors of treatment failure and timing of identifying treatment failure, will reduce the chance of delaying to detect failure. The delay of detect failure might increases the chance for drug toxicity and accumulation of drug resistance associated mutation, and further more will limit treatment options might higher the goal of eliminating MCT[23][25].

2.1.2 Magnitude of ART Failure

A study done in Ethiopia found that, overall treatment failure was 19.8% with incidence rate of 8.46 failures per 1000 person-months[20]. Even though the overall treatment failure is in line with the magnitude of treatment failures in resource limited settings[26][27] sensitivity and specificity of immunologic and clinical failures were discussed to be low [28], it has to be further accompanied by viral load tests to confirm true treatment failure and to take optimal decision of switching and avoiding misclassification of treatment failures[23]

Study conducted in Kenya[29] show that the clinical failure exceeded the virological and immunological failures, the results from this study[29] showed that the magnitude of treatment failure as defined by immunological criteria was high (15%); followed by the clinical failure (6.3%) and by virologic failure (1.3%). Furthermore study done in Ethiopia revealed most of the ART failed cases were those who were in age groups 25–49 (77.9%), married (36.7%), had primary education (43.6%), disclosed their HIV status (76%) with clinical characteristics observed 62.5% of the failures were those in WHO stage 3 or 4 at start[20]. Study conducted in Nigeria showed that immunologic criteria missed more than half of patients with virologic failure[30].

2.2 Determine predictors for ART treatment failures among women access option B plus

2.2.1 Adherence to ART treatment

Adherence to ARVs has been a key stone for success to ART services as well as PMTCT. Proper adherence to treatment is a challenge worldwide, in both resource-rich and resource-limited settings. Women may be particularly vulnerable to disruptions in adherence during pregnancy and breastfeeding. In a systematic review and meta-analysis[31]which including 53 studies from over 20 countries found that adequate adherence (>80%) was shown to drop from 75.7% (CI 71.5–79.7) during pregnancy to 53% (CI 32.8–72.7) postpartum among women on ART. And also meta-analysis done on adherence to ART during and after pregnancy showed that ART drug adherence is higher during the antenatal period (74%) compared to postnatal period (53%)[32].

Several studies done in Sub Saharan Africa on adherence to PMTCT has shown large variation of adherence level among HIV pregnant and breastfeeding women ranging from 41 %[33]to 68.2%[34]at 12 months of being on PMTCT services.

Studies done in Swaziland shows that there is no different in viral suppression between those who underwent enhancing Adherence counselling and those who did not get adherence counselling.[35]. In study done in Urban setting HIV clinics show that 58 clients were poorly adherent to ART treatment and among of them 40 (69%)patients developed treatment failure during the study follow up[36].

In study done in South Africa found that virologic failure is associated with incomplete adherence and adherence is most predictor of treatment failure and resistance[37].

2.2.2 Socio demographic factors in relation to adherence

Study conducted in Zimbabwe on pregnant women has shown that maternal age below 24 years as identified risk factors for not adherence ART as prophylaxis during pre-delivery [38].

And also a study done Kenya has shown women with age less than 20 years of age and women who are single were less likely to swallow their ART prophylaxis[31]hence poor adherence.

Study conducted in Kenya shows that level of education among pregnant women has influence on adherence on utilizing PMTCT services[32], similar study conducted in Zambia on predictors of non-adherence on single dose Nevirapine showed maternal non-adherence was associated with no high school education [38]. And similar results finding has been documented by Zimbabwe study where non- adherence to the maternal dose of Nevirapine was associated with lack of maternal secondary education and multi-parity[39].

2.2.3 Time on ART initiation at pregnancy in relation to adherence

Studies shows that majority of women initiated on ART during pregnancy failed to stay on treatment despite needing it for their own health. A meta-analysis on adherence to ART during and after pregnancy showed that drug adherence was higher during the antenatal period (74%) compared to postnatal period (53%) [31]. Long-term follow up in a community-based ART program another study in South Africa showed that women who initiated ART during pregnancy had a significantly higher risk of loss to follow-up compared to non-pregnant

women [40]while another study from 6 resource-limited SSA countries found similar retention rates and CD4 count responses in HIV-infected women who initiated ART during pregnancy and other adults. However, even during pregnancy, adherence is lower than is thought to be required in order to attain the maximum viral suppression and prevention of drug resistance study shown[41].

2.2.4 Disclosure of HIV status in relation to adherence

Previous studies have suggested that on the pattern and determinants of antiretroviral drug adherence revealed that patients who disclosed their HIV status had better adherence to therapy as well as receiving support from the family members[42].In study conducted in Tanzania shows that women who disclosed HIV status to the partner, relative/family or friend were significantly adherent than women who did not disclosed their HIV status [43].

When patients take medicines without having the fear of being stigmatized it means that the medications can indeed be taken even at their work places, as well as in front of their relatives and other family members including their sexual partners. Lack of disclosure related to stigma and lack of male partner involvement could result in interrupted treatment.

In many studies have reported that disclosure of HIV status was linked to better adherence with the ultimate better viral load suppression (VLS) and immunological improvement[44]. Disclosure status play as key factors associated with high ART adherence reported in several studies were disclosure of HIV status as well as social support, in agreement with other studies in the general population[41].

2.2.5 Previous PMTCT experience in relation to adherence

In Study conducted in Zimbabwe shows that there are improvement on ART adherence to all pregnant women who had prior history of maternal exposure to PMTCT and ART services[39].

2.3 Factor associated with treatment failure among women who adhere to ART

2.3.1 WHO clinical stage at enrolment in relation to ART treatment failure

A study done in Mozambique showed that starting ART at later stages of WHO (3 and 4) had a risk of poor outcomes and end up with treatment failure and as a result it recommended initiation of ART at early stages[45][46]. Other study findings demonstrate that patients who begin ART when HIV disease is far advanced and CD4 cells count is extremely low experience a clinical benefit that improves their ability to perform activities of daily living compared to treatment-naive participants were more likely to attain viral suppression than were treatment-experienced participants.

Adherence to PMTCT is also influenced by HIV disease status during PMTCT service as stipulated in United States studies where patients who had lower WHO clinical staging had significantly higher chance to adherence than those who is HIV infected pregnant women with AIDS with late WHO clinical stage[47]

2.3.2 CD4 count level at start ART in relation to treatment failure

Study conducted in South Africa on f rates and predictor of failure of first line show that one cohort had a substantially lower failure rate compared with the others. And for those with le CD4 count less than 100 at ART initiation cells per microliter was associated with a 60% increased risk of failure compared with those with CD4 level more than 100 cells per microliter[14]. In study conducted on relationship between CD4 count and Viral load monitoring shows that a CD4 cell counts may remain stable for months or years, provided that the viral load does not exceed 10,000 copies/mL[25]. In Study done in cohort of 17517 asymptomatic HIV infected people's shows that the evidence of supporting initiation of therapy increases as CD4 cell count greater than 500/mm3 decreased mortality by 94%, and initiating it at a CD4 cell count between 351 and 500/mm3decreased mortality by 69%[21].

2.3.3 Viral load

Though viral load testing is very limited in low income countries, it has confirmed treatment failure for many of those suspected of failure. From those suspected of treatment failure , 11 patients with viral load tested, seven of them were confirmed as having treatment failure (63.7%)[20]. The treatment failure magnitudes computed using all, two or one of the three criteria, alert that there should be cautious and frequent monitoring and evaluation of the ART treatment outcomes by health care providers. Studies show s that in most of resource limiting countries clinical and immunological criteria were found to perform relatively poorly in predicting virological failure of ART[29]

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

Study is a descriptive cross-sectional study designed for assessing magnitude and predictors of ART treatment failure among women accessing PMTCT option B plus services. This study was conducted in 15 health facilities from 5 Dar es Salaam municipal between April and May 2017.

3.2 Study area

This study was conducted in Dar es Salaam City, which is a major commercial city in Tanzania. Dar es Salaam is among the regions with high HIV prevalence which is above national prevalence where for age group 15-49 years prevalence is at 6.9%. Females have higher HIV prevalence with a prevalence of 8.2% while males are at 5.3%. Dar es Salaam region comprised of total of 256 RCH facilities with 88% of facilities supported by MDH and 98% of the facilities are providing PMTCT-Option B + services. And a total of 25 health facilities which offered PMTCT option B plus were engaged in this study from five municipals (Ilala, Temeke, Kinondoni, Ubungo and Kigamboni) in Dar es salaam. From this health facilities only 4 are hospitals, 10 health centres and 11 are dispensaries and clinics.

There are estimated to be 134,000 pregnancies per year and HIV testing and counseling (HTC) is above 95 %and more than 10,000 pregnant women who tested positive for HIV. (MDH-DSM RHMT CDC report September 2015, *APR report)*[58]

3.3 Study population

The study population comprised of HIV positive women (pregnant or breast feeding) enrolled in PMTCT option B+ clinics in Dar es Salaam Region.

3.4 Inclusion Criteria

The following criteria were used to select participants of the study

- Must have consented to participate
- Resident of Dar es Salaam
- HIV positive women on PMTCT Option B+ attending clinic in Dar es Salaam has CD4 & viral load results.
- Has been attending clinic for more than 6 months.
- HIV infected women (Pregnant, in labor or breastfeeding women) who have started PMTCT option B+ Services in Dar es Salaam health facilities. Women in labor were interviewed after delivery.

3.5 Sample size estimation and sampling methods

3.5.1 Sample size Estimation

Sample size was estimated by using the formula for estimating a single proportion

$n= Z^2 P (100-P) / E^2$

Where by: n= minimum required sample size

Z=standard normal deviate at 95% confidence level (1.96)

E= accepted margin of error on P (set at 5%)

P= estimated proportion of pregnant women with optimum viral suppression (41%)[48][49]

n= (1.96)2 X 41 (100-41) / (5)2

n = 377

The minimum sample size was 377, and 10% was added for case of non-response; the sample size was 415. We have managed to reach 410 and completed interview.

3.5.2 Sampling method

Two stage cluster random sampling method was used to select participants for the study.

Stage 1: MDH supported HIV care and Treatment Clinics/ PMTCT in Dar es Salaam were listed. From this list, records checked and clinics which attend at least 10 PMTCT clients daily formed the sampling frame, the study was conducted in 30% of the clinics as per the WHO recommendation in assessment of the district health services[(50)]

The total number of MDH supported CTC/PMTCT clinics in Dar es Salaam region from five municipals is 198, and among these clinics with heavy PMTCT client load were82. A simple random sampling technique was used to select 5 clinics from each of the 5 municipalities in Dar es salaam.

Stage 2: From each selected health facilities, all PMTCT clients who meet the inclusion criteria were listed from the daily clinic register with the help of CTC staff (using CTC2 data base). All patients in the list had their clinic schedules examined to know when they are expected in the clinic. When they showed up for their clinics, they were consented and all those who agreed were interviewed using a questionnaire with structured questions.

3.6 Study variables.

3.6.1 Dependent variables

1. ART treatment failure
    i. ART Treatment failure is defined as when HIV +women on ART for 6 months or more has either of the following
2. Their CD4 count decrease by 50% from their initial value or High peak CD4 count ever recorded or persistence CD4 count below initial value
3. Viral load greater than 1000 copies/ml 3.6.2 Independent variables

1. Social demographic Characteristics
    - Age
    - Parity/
    - gravidity
    - Marital status
    - Occupation
    - Level of education
2. Adherence status (Adherence is define as good (>95% adherence), or poor (<95% adherence).
3. HIV disclosure Status
4. WHO clinical HIV clinical stage (1, 2, 3&4). Clinical stage at start of ART and the current clinical stage will be recorded for analysis
5. CD4 count at ART initiation. All patients with a baseline CD4 cell count, High peak of CD4 level and the recent one.
6. ART enrolment status (Start before this pregnant or during this pregnant)
7. Previous PMTCT experience

3.7 Data collection technique and tools.

3.7.1 Data collection procedures

The Principal investigator recruited 5 research assistants with counselling skills on HIV/AIDS and PMTCT background. Preliminary training was conducted by the Principal investigator on the familiarization of the research purpose and tools, which included on how to conduct interview and how to administer the tools in order to get accurate data. And research ethics and logistic information were introduced.

3.7.2 Data collection tools

A structured questionnaire developed in English and translated to Swahili was used to obtain data from the study participants (Appendix II). Data collected using the questionnaire were information on social demographic characteristics, Adherence status, HIV disclosure Status,

Partners HIV status, ART enrolment status (Start before this pregnant or during this pregnant), Previous PMTCT experience, Pregnancy status (gestation age) at enrollment of Option B+, Duration on ART treatment (years)

And Secondary data which were collected from the participant's clinic files were: treatment status including WHO (clinical HIV clinical stage (1, 2, 3&4), CD4 count at ART initiation&CD4 at last visit, Viral load result was obtained from the CTC card.

Participants were counseled to be recruited into the study by the nurse counselor in the last desk (last point for a patient in the clinic before leaving the CTC) and directed to a room which was prepared for the interview.

3.7.3Pre testing of the questionnaires

Before data collection started pretest of questionnaire was done to check for clarity and logic flow of questions by using the sample of HIV positive women accessing PMTCT services and meet study criteria in Temeke hospital and then data collection tools reviewed based on the pre testing experience

3.8 Ethical consideration

Ethical clearance obtained from the Muhimbili University of Health and Allied Sciences Senate Research and Publications Committee. And permission to conduct the study obtained from all the Municipal Health director and from the facility in charge, in charges of RCH services.

Women who met criteria were informed on study objectives and informed that its voluntary participation. And only participants who agreed to participate and signed informed consent form were enrolled into the study. For participants who didn't know how to read, the research assistant read for them and they asked to put a thumb prints to show acceptance to participate in the study.

Confidentiality of information collected from all study participants was ensured to the fullest extent possible. Study participants were not identified by name on their responses. All study records kept in a locked cabinets with limited access

3.9 Data processing and Analysis

3.9.1 Data Quality checks, Entry & Cleaning

Data collected by research assistants was checked daily for assurance of completeness and consistency by the Principal investigator. Then Data was entered and stored in a computer that has password or limited assess using SPSS version 20. And data were doubly entered and quality control checks done whereby cross frequency and cross tabulation of two entrants files was done after every 30 entries for cross check and error noted were corrected by referring to specific questionnaire number.

3.10 Data Analysis

Data collected was then analysed based to objectives of study and using a statistical program for Social Scientists (SPSS) version 20.

- At first basic characteristics including clinical characteristics were summarized by using descriptive statistics.
- Basic characteristics variables were cross tabulated with ART treatment failure to find magnitude and association using chi square to test. A p-value of < 0.05 was considered statistically significant.
- Multiple logistic regression was used to determine independent predictors of ART treatment failures among HIV positive women on PMTCT Option B+ while controlling for confounders and adjusted odds ratios calculated and presented with 95% confidence intervals and P value of <0.05 were considered statistically significant. All covariates with p value of≤ 0.2 in the bivariate analysis were incorporated in the multivariate model
- Measurement of Adherence based on to Adherence PMTCT protocol:
  In order to achieve maximum viral suppression adherence should be more than 95% which means missing only one dose in a month (Clients reported missing at most 3 tablets in last 3 months or missing one tablet per month). Hence the one who reported missing one or none per month has more than 95% adherent. And for Women with poor adherence with less than 95% adherent to PMTCT protocol reported missed more than 3 tablets in the last 3 months.

3.10 Plan for Utilization and Dissemination of information.

- These research findings will be presented in Ministry of Health (MoHCDEC)PMTCT technical working groups, PMTCT implementing partners technical meeting, Dar es salaam region and Council Health Management teams
- And the results of this study will also be published in international scientific journals and presented in National and international conferences

CHAPTER FOUR

4.0 RESULTS

4.1. Demographic characteristics of the respondents

Table 1 describes the demographic characteristics of women who participated in the study. We approached 420 and 410(98 %) completed the study questionnaire. The age of respondents ranged from 20 to 46 years with median age of 35 years. Half (50%) of study participants were aged 36years and above and more than three quarters (77.8%) were enrolled while they are pregnant. Over half (52.7%) had primary education, and more than half were married or living with a partner, 61.4% of women interviewed were employed or doing business. Over two thirds (69.5%) of respondents had previous exposed to ART with majority (78.8%) of them having had previous pregnancies.

Table 1: Basic characteristics of the study population (n=410)

Characteristics	n (%)
Age groups, years	
<25	24 (5.9)
25 -<35	181 (44.1)
36 and Above	205 (50)
Level of Education	
No formal Education	115 (28.1)
Primary Education	216 (52.7)
Secondary Education and Above	79 (19.2)
Marital status	
Married or Cohabiting	325 (79.3)
Divorced, Separated, widow &single	85 (20.7)
Occupation	
With employment	252 (61.5)
Without employment	158 (38.5)
Patients status at PMTC enrolment	
Pregnant	319 (77.8)
Breast feeding	91 (22.2)
Gravidity	
1st pregnancy	87 (21.2)
2nd pregnancy & above	323 (78.8)

4.2 Clinical characteristics of respondents

Table 2 describes the Clinical assessment of respondents, it show that majority of women were enrolled into PMTCT option B plus with WHO clinical stage I (63.7%) and 58.3% had CD4 less than 350 on enrolment. Few respondents (16%) reported to have experienced side effects and majority the respondents (78.3 %) show good adherence to ART (no history of stopped using ART). Although big proportion of women (97.3%) in this study accessed counselling on disclosure of their HIV sero status, only few of respondent's (26.1%) disclosed their HIV sero-status to their partners and others disclosed to any member of a family (74.9%).Majority of respondents(93.7%) had viral load results and CD4 results six months after enrollment.

Table 2: Clinical characteristics of the study population (n=410)

Characteristics	n (%)
Pre exposure to ART Before PMTCT enrolment	
Yes	285 (69.5)
No	125 (30.5)
HIV status Disclosure to any family member	
Yes	307 (74.9)
No	103 (25.1)
HIV status disclosure to partner	
Yes	107 (26.1)
No	303 (73.9)
Ever change time to take ART	
Yes	114 (27.8)
No	296 (72.2)
ART Adherence Status	
Yes	321 (78.3)
No	89 (21.7)
Experience ART side effects	
Yes	65 (16)
No	345 (84)
WHO stage at enrolment to PMTCT Option B+	
I	258 (63.7)
II	143 (35.4)
III	3 (0.7)
****CD4 Level at start PMTCT**	
<350	230 (56)
350 to <500	100 (24)
500 and Above	63 (15.)
Viral load results (copies/ml)	
Yes	384 (93.7)
No	26 (6.3)

*** 4 % of respondents missing CD4 results at start PMTCT*

4.3 Prevalence of ART treatment failures among HIV positive women on PMTCT Option B+ attending clinics.

This study shows that a proportion of women in PMTCT option B plus with immunologic failure were 34(8.3%) and virological failure was 47(11.5%) and women who found to have both immunological and virologica failure were 28(6.8%).

The overall ART treatment failure among women on PMTCT option B plus services was higher 109 (26.6%) as summarized in **figure 2**

Furthermore in table 3 show that the age group 35+ had highest proportion (29.6%) with treatment failure compared to other age group but the difference was not significant (p=0.08), Women who are cohabiting or married also had highest percentage (29.3%) with treatment failure compared to those who divorced, widow or single and the difference was significant(p=0.02). Patients who reported to have previous ART exposure also had higher percentage (69.7%) with treatment failure compared to those with no previous ART exposure and the difference was statistically significant (p=0.02) .Patients who did not disclosed HIV sero-status have higher proportion (51.6%) with treatment failure compared to those who disclosed their HIV status and the difference was significance (p=< 0.0001). Also patients who had experienced ART side effects has higher percentage (80%) with treatment failure compared to those with no history of ART side effects and the difference was significance (p=< 0.0001).

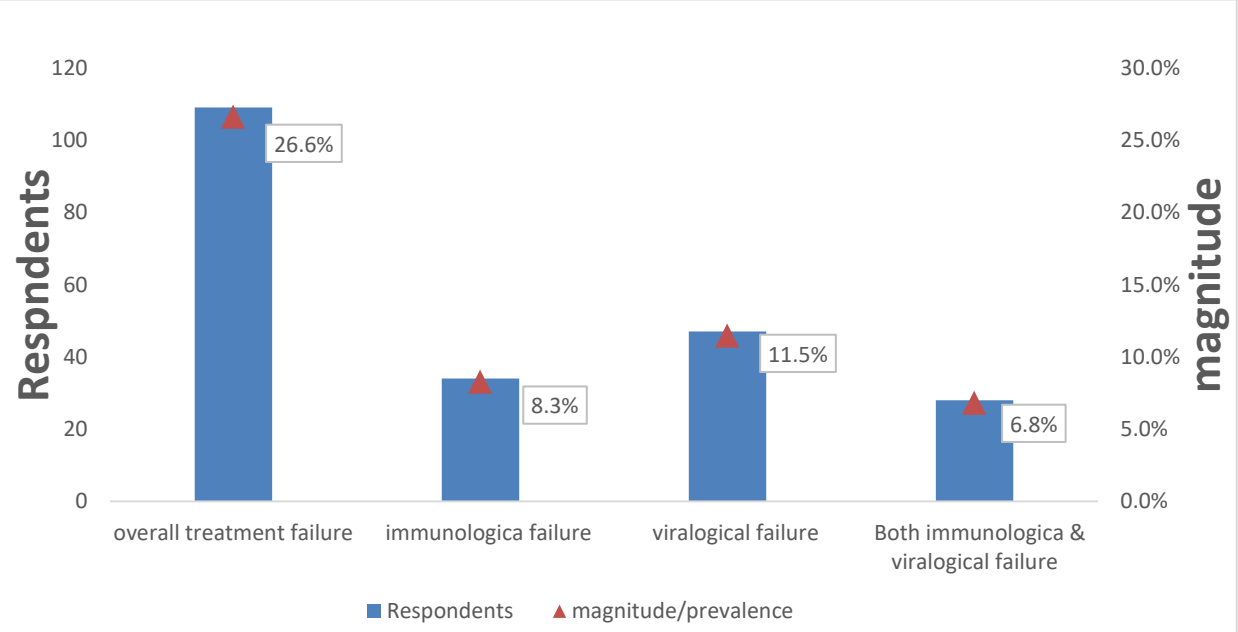

Figure 2: Magnitude of ART treatment failure among women accessing PMTCT option B plus (n=410)

Table 3: magnitude of ART treatment failures by social demographic factor among women access PMTC option B plus. (n=410)

Basic Characteristics	ART treatment failure (410)		
	Failure	No Failure	P-Value
Age groups, years			
<25	2 (8.3%)	24 (91.7)	
25 -<35	47 (26%)	134(74%)	0.08
36 and Above	60 (29.6%)	143 (70.4%)	
Level of Education			
No formal Education	30 (24.4%)	86 (75.6%)	0.38
Primary Education	62 (29.3%)	153 (70.7%)	
Secondary Education and Above	17 (21.5%)	62(78.5%)	
Marital status			
Married or Cohabiting	95(29.4%)	226(70.6%)	0.02
Divorced, Separated, widow &single	14 (13.8%)	75 (86.2%)	
Occupation			
With employment	60 (24.8%)	190(75.2%)	0.27
Without employment	49 (29.8%)	111 (70.2%)	
ART Pre Exposure enrolment			
Yes	76 (69.7%)	195(72%)	0.02
No	33 (24.1%)	106 (75.9%)	
Gravidity			
1st pregnancy	19 (22.8%)	68 (78.2%)	0.25
2nd pregnancy & above	90 (27.80%)	233 (72.20%)	
HIV status Disclosure			
Yes	43 (15.30%)	239(84.70%)	< 0.0001
No	66 (51.6%)	62(48.4%)	
ART Adherence			
Yes	85 (26.6%)	236(73.4%)	0.006
No	24 (27%)	65 (73%)	
Experience ART side effects			
Yes	80 (80%)	20 (20%)	<0.0001
No	29 (9.40%)	281(90.60%)	
WHO stage at enrolment to PMTCT			
Stage I	43 (16.70%)	214(83.30%)	
Stage II	63 (44.6%)	85 (55.4%)	<0.0001
Stage III	03 (60%)	02(40%)	
CD4 Level at start PMTCT(cells/mm3)			
<350	55 (23.1%)	183 (76.9%)	
350 to <500	32 (29.6%)	76 (70.4%)	0.11
500 and Above	22 (34.4%)	42 (65.6%)	
Women status at PMTCT enrolment			
Pregnant	76 (23.9%)	242 (76.1%)	0.02
Breast feeding	33 (35.7%)	59 (64.3%)	

4.4 Predictors for ART treatment failure among HIV positive women on PMTCT Option B+ attending clinics.

In bivariate analysis it was found that women who were not married/cohabiting (single, divorced or widow) had lower odds of developed ART treatment failure compared to those who Married and the different was statistically significant (COR=0.47, 95% CI (0.25 – 0.88)). And women who had no history of pre ART exposure before joining PMTCT option B plus has lower odds of developed ART treatment failure compared to those who has history of ART exposed before and the different was statistically significant (COR=0.55,95% CI (0.33 – 0.92)), Women on PMTCT who did not disclosed HIV status has higher odds to ART treatment failure compared to those who disclosed their HIV status and the different was statistically significant (COR=2.60,95% CI (1.61– 4.18)),women who had history of change time to take pills has higher odds to ART treatment failure compared to those who had no history of change time to take pills and the different was statistically significant (COR=2.67,95% CI (1.68– 4.27)),Also women who had poor adherence to ART has higher odds of developed treatment failure compared to those with good ART adherence and the different was statistically significant (COR=2.20,95% CI (1.24– 3.92)).

But other factors like age, level of education, employment status, gravidity, WHO clinical stage &CD4 Level at enrolment on PMTCT option B plus were found not to have a statistically significant association with ART treatment failure. Table 4

Multivariate Analysis

In multiple logistic regression analysis only factors with P-value of less than 0.2 in bivariate analysis were in cooperated in the model. And the analysis results revealed several factors to be independent predictors of ART treatment failures among women access PMTCT option B plus. Factors found to be independent predictors include HIV status Disclosure where those who did not disclosed HIV status were more likely(higher odds)of develop ART treatment failures compared to those who disclosed HIV status and the different was statistically significant (AOR=2.35,95%CI (1.55-6.06)), Women with poor adherence to ART were more likely of develop ART treatment failure compared of those with good adherence to ART the

different was statistically significant (AOR=1.03,95%CI (0.14 0.62)) ,Despite women with history of ART side effects has higher odds of develop ART treatment failure compared to those with no history of ART side effects the different was statistically significant (AOR=1.78, 95%CI (1.25 -3.83)). As Table 4 summarized

However women who were Divorced, separated & widow had low odds of developing ART treatment failure (AOR=0.28, 95% CI (0.03 -2.46)) compared to those who Married or cohabiting women on PMTCT option B plus but statistically was not significant. As Table 4 summarized below.

Table 3: Factor associated with ART treatment failures among women access PMTCT option Plus in Dar Es Salaam (n=410)

Basic Characteristics	ART failure(n=109)	COR(95%CI)	AOR(95%CI)	P-value
Age groups, years				
<25	2 (8.3%)	0.22(0.05 – 0.95)	0.09(0.01 -5.47)	0.51
25 -<35	47 (26%)	0.84 (0.53 – 1.31)	0.90 (0.29–2.86)	
36 and Above	60 (29.6%)	**1**	**1**	
Level of Education				
No formal Education	30 (24.4%)	**1**		
Primary Education	62 (29.3%)	1.22(0.73 – 2.03)		
Secondary Education +	17 (21.5%)	0.80 (0.41 – 1.59)		
Marital status				
Married or Cohabiting	95(29.4%)	**1**	**1**	
Divorced, Separated, widow &single	14 (13.8%)	0.47(0.25 – 0.88)	0.28(0.03-2.46)	0.25
Occupation				
With employment	60 (24.8%)	1.28(0.82 – 2.01)		
Without employment	49 (29.8%)	**1**		
Pre ART exposure				
Yes	76 (69.7%)	**1**	**1**	
No	33 (24.1%)	0.55(0.33 – 0.92)	1.55(0.01-2.71)	0.98
Gravidity				
1st pregnancy	19 (22.8%)	0.72(0.41 – 1.26)		
2nd pregnancy & above	90 (27.80%)	**1**		
HIV status Disclosure				
Yes	43 (15.30%)	**1**	**1**	**0.03**
No	66 (51.6%)	2.60(1.61 – 4,18)	**2.35(1.55-6.06)**	
ART Adherence				
Yes	85 (26.6%)	**1**	**1**	
No	24 (27%)	2.20(1.24 – 3.92)	**1.03(1.14 -1.62)**	**0.04**
Experience ART side effects				
Yes	80 (80%)	2.41(3.32 – 6.40)	**1.78(1.25-3.83)**	**0.03**
No	29 (9.40%)	**1**	**1**	
WHO stage at enrolment				
PMTCT	43 (16.70%)	**1**		
Stage I	63 (44.6%)	3.97(2.49 – 6.32)		

Stage II	03 (60%)	4.99(0.01 – 7.13)		
Stage III				
CD4 start PMTCT				
(cells/mm3)	55 (23.1%)	**1**		
<350	32 (29.6%)	1.40(0.84 – 2.34)		
350 to <500	22 (34.4%)	1.83(1.01 – 3.34)		
500 and Above				
Status at PMTCT enrolment				
Pregnant	76 (23.9%)	**1**	**1**	0.64
Breast feeding	33 (35.7%)	1.84 (1.12 – 3.04)	0.70(0.16-3.12)	

4.5 Proportion of women who had ART treatment failure among those who are adhering to ART

Findings of the Study showed that more than three quarter of study respondents 321(78.3%) adhered to ART provided in PMTCT option B plus clinics. Among the respondents who adhered to medication (ART), 85 (26 %) had developed ART treatment failure.

4.6 Factors associated with Treatment failure among women who are adherent to ART

This study found that 85(26%) respondents who adhered to ART developed ART treatment failure. ART adherent women who had no history of been exposed to ART had lower odds of develop treatment failure compared to those exposed to ART before and the different was statistically significant (COR=0.50,95% CI(0.28 – 0.90)), And also ART adherent women who were not married or cohabiting (single, divorced or widow) had lower odds of treatment failure compared to those who were Married or cohabiting and the difference was statistically significant (COR=0.44, 95% CI (0.21 – 0.90)). ART adherent women who did not disclosed HIV status to their partners had higher odds of treatment failure compared to those who disclosed their HIV status and the difference was statistically significant (COR=1.14, 95% CI (1.08– 1.98)),Also ART adherent women who were enrolled to PMTCT during her 1st pregnancy has lower odd of developed ART treatment failure compared to those who enrolled while it's their 2nd& above pregnancies and the difference was statistically significant (COR=0.54,95% CI(0.28 – .86)), as summarized in table 5 below

And other factors such as age, level of education, occupation status, WHO clinical stage &CD4 Level at enrolment on PMTCT option B plus were found to be not statistically significant as Summarizes in table 5 below.

All factors with P-value of less than or equal to 0.2 in bivariate analysis were in cooperated in multivariate analysis. And results show that among women on PMTCT option B who adhered to treatment but did not disclosed HIV status to their partners had higher odds to have treatment failure compared to those who disclosed HIV status and the difference was statistically significant (AOR=2.44, 95%CI (1.14-3.17)),ART adherent women who were enrolled while on WHO disease Stage 2 had higher odds of developing ART treatment failure compared to those enrolled on WHO stage 1 and the difference was statistically significant (COR=3.30,95% CI (1.57-6.94))

And other factors assessed did not show a statistically significant difference with ART treatment failure among ART adherent women. These variables include marital status in which single, separated & widow had lower odds compared to married and cohabiting women and other factors. Table 5summarized below.

Table 4: Factors associated with treatment failure among women who are adherent to ART (n=321)

Basic Characteristics	Adhere & failed (n=85)	COR(95%CI)	AOR(95%CI)	P-value
Level of Education				
No formal Education	18(19 %)	**1**		
Primary Education	51 (33 %)	1.67(0.92 – 3.01)		
Secondary Education +	16 (22%)	1.37(0.65 – 2.88)		
Marital status				
Married or Cohabiting	75(31 %)	**1**	**1**	
Divorced, Separated, widow &single	10 (13%)	0.44(0.21 – 0.90)	0.33(0.04-2.96)	0.32
Pre ART exposure				
Yes	63(31 %)	**1**	**1**	
No	22 (19%)	0.50(0.28 – 0.90)	0.33(0.01-5.1)	0.99
Gravidity				
1st pregnancy	12 (15 %)	0.54(0.28 – .86)	0.61(0.69-1.15)	0.10
2nd pregnancy & above	73 (30 %)	**1**	**1**	
HIV status Disclosure				
Yes	62(23 %)	1	1	**0.04**
No	23 (46 %)	1.14(1.08 – 1.98)	2.44(1.04-3.17)	
WHO stage at enrolment PMTCT				
Stage I	36 (16 %)	**1**	**1**	
Stage II	48 (55%)	3.12(1.90 – 5.11)	3.30(1.57-6.94)	**0.007**
Stage III	1 (25 %)	3.08(0.27 – 34.89)	0.82(0.01-5.89)	
Status at PMTCT enrolment	60(27%)	**1**		
Pregnant	25(25%)	1.63 (0.95 – 2.80)		
Breast feeding				

CHAPTER FIVE

5.0 DISCUSSION

This study conducted to assess the magnitude and predictors of ART treatment failure among women access PMTCT option B plus in Dar es Salaam region. ART treatment failure is describe as Immunological failure, Clinical failure and Virological failure. The proportion of women who experience both immunological and virological failure was 6.8% and the overall ART treatment failure was 26.6%.And the proportion of women with immunological failure were 8.3% and that of virological was 11.5%. Also this study revealed there are strong relationship between HIV status disclosures, adherence and ART related side effects with ART treatment failure development.

5.1. Prevalence of ART treatment failures among HIV positive women on PMTCT Option B+ attending clinics

In this study the magnitude of Immunological failures was.8.3%, this magnitude is a lower than the observed virological failures (11.5%). It is different from the findings from a study conducted in Ethiopia (29)where by virological failure (1.3%) was lower compared to immunological failures (15%). The difference in results may be different setting area and study population where by study conducted in Ethiopia was done among Adults patients on ART at private facilities while this study conducted in both private and public health facilities providing PMTCT services to pregnant and breast feeding women.

On the other hand, the overall magnitude for ART treatment failure in this study was 26.6% which is similar to the finding of a another study conducted in south Africa(37)(29)with proportions ranging from 33.3% to but different from study conducted in Ethiopia(20)which found the overall treatment failure to be much lower (19.8%). This study also revealed only 28(6.8%) respondents had both immunological and virological treatment failure which is different from a study conducted in Ethiopia(20).This finding is also less compared to a finding from Mitra plus study conducted in Tanzania which showed the proportion of women

who failed both immunologically and virologicaly to be 19% for women at 12 months postpartum (16)

Most of the failed cases were those who in age groups 35 years & above (55.10%), married (87.2%), had primary education (56.7%), women with employment(56.4%), with more than 2 pregnancies (82.6%), women with history on pre exposure of ART before (69.2%), those who did not disclosed their HIV status (60.6%), who had history of ART side effects before (73.4%) and women who started PMTCT with WHO stage 2 (57.8%)&CD4 level of less than 350 cells/mm3this findings were in line with studies conducted in other resource limited countries(29)(13).

5.2. Predictors for ART treatment failure among HIV positive women on PMTCT Option B+ attending clinics

Adherence to medication, Disclosure HIV status and ART side effects have been identified as most important factors for predicting ART treatment failures among women accessing PMTCT services and same factors have been mentioned in several other studies as most important factor for ART treatment failures among women [20][16][14].

Furthermore the probability of women to developed ART treatment failure increased several times among women who reported non-perfect adherence to ART compared to those who are adhere to take ART medication this also portray what have been stipulated with other studies in resources limited countries that Poor adherence was a major determinant of virological failure in people taking ART [20][16][29][51].

Failure to take the prescribed doses of antiretroviral drugs leads to ongoing viral replication in the presence of drug and the selection of drug-resistant HIV[52].

Disclosure to HIV status has strongly linked to ART treatment failures, Women who did not disclose their HIV status to their partners or any member of family or friends had increased chance to developed ART treatment failure compared to those who disclosed, And the results of this study supported by several studies[16][20][13][29][53][30].

Disclosure of HIV status help in social coping which leads to higher rates of ART adherence and absence of social coping patients end up with poor adherence to ART and this association may result of multiple factors, including social stigma, social isolation and depression lead not to take medication properly.

Despite the facts few women on ART had experience severe side effects, but in this study only 100 (24.4%) respondents had reported to have history of developed ART side effects among them 80(80%) developed ART treatment failure, this may due to some point fear to take medications. This finding is supported by findings of a study conducted on barriers to ARV adherence among HIV/AIDS positive persons taking anti-retroviral therapy in Dar es salaam & Arusha[54]

5.3. Proportion of women who had ART treatment failure among those who are adhering to ART

WHO strongly recommends adherence support interventions for all people receiving ART because it's a major setback in PMTCT option B plus[55].In this study more than quarter of respondents 321(78.3%) adhered to ART medication. This portrays what have been shown in Mitra plus study which shown drug adherence was higher during the antenatal period (74%) compared to postnatal period (53%) [16].

However unexpectedly, 85(26.4%) of women who adhered to medication developed ART treatment failure. This could be due to other confounding factors not captured in this study like ART resistance HIV strains and stipulated on study conducted in San Francisco USA which revealed that there are type of ART resistance occurs most frequently at moderate to high levels of adherence[52].

5.4. Associated factors for Treatment failure among women who are adherent to ART

This study show few factors which are independently associated with treatment failure among women who adhered to ART. They included patients HIV status disclosure and the WHO stage of women at PMTCT/ART enrollment.

Disclosure HIV status has link with perfect ART adherence because it relieved women psychosocial stress and make to get psychological and material support from their partner, friends and relatives[56]. This study found that women who adhere to ART and had not disclosed their HIV status to their partners had a high chance of develop ART treatment failure compared to those who disclosed their status. When women/partner disclosed their HIV status also reduce the chance of keeping reinjection from each other which end up with resistance to ART[52]. Hence even if they adhere to ART they keep exposed to new strains of HIV from their partners. Same picture have been seen the association of disclosure HIV status and adherence to ART, these also described in number of studies conducted in Tanzania[43], Zimbabwe[57], South Africa and Malawi[58].

Furthermore this study found women who enrolled while on WHO stage 2 or 3 had aa big chance of treatment failure this may due to the slow responding of lymphocytes cells as explain in study conducted in San Francisco USA[52] .

5.5 Study Limitation

- Adherence to Medication was difficult to ascertain because we depended on what's the patients reported. As Study respondents, they tend to answer questions in a manner that will be viewed favorably by others this can take the form of over-reporting "good behavior" or under-reporting "bad", or undesirable behavior this called social desirability. We tried to minimize this by using skilled and experienced health care workers as Research assistants.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The study has shown the magnitude of ART treatment failure among HIV positive women accessing PMTCT option B plus services was 8.3% immunological failure, 11.5% virological failure and 6.8% who has both immunological and virological ART treatment failures. And the overall ART treatment failure for HIV positive women access PMTCT option B plus service was 26.6%.

Factors that predicting ART treatment failure among HIV positive women who accessed PMTCT option B plus services were age, incomplete/poor adherence, disclose HIV status and history of ART side effects.

Also findings of this study has highlighted that 26.6% of HIV positive women who accessed PMTCT option B plus services and adhered to treatment developed ART treatment failures. History of ART side effects and lack of disclosed HIV status to partners or any member of family or friends were found to be significantly associated with ART treatment failure among the adherent women. For the success of PMTCT program, all factors such as history of pre exposure to ART, duration of women on ART, history of ART related side effects, gravidity, ART adherence and WHO clinical stage & CD4 at start or joining PMTCT should be considered as the key important factor for screening in every visit to make sure that ART treatment failure is picked early.

6.2 Recommendation

1. Health care workers should be oriented on screening for ART treatment failure through workshop or mentorship based on the National guideline.
2. PMTCT program should develop strategies to support early identification of ART treatment failure among women accessing PMTCT services. And this strategies based on most at risk including who did not disclosed HIV status & married, who has history of ART related side effects, pregnancy more than one, more duration on ART for more than a year and those with history of imperfect or non-adherence to medication.
3. Facilities should develop or use *patients provider tie model* where by patients who had risk or develop treatment failure are tied with provider, hence every provider would have certain number of patients to follow. This will improve early identification of failure and also improve adherence

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58 (MDH-DSM RHMT CDC report September 2015, *APR report)*

APPENDICES

Appendix I: Interview questionnaire (English Version)

Title: Magnitude and predictors of antiretroviral (ART) treatment failure among women on option B plus attending PMTCT clinics in, Dar Es Salaam.

Questionnaire no…….. Date of interview…….

District:…… Name of RCH/Health facility:……..

SOCIO-DERMOGRAPHIC CHARACTERISTICS.

1. How old are you? ……. (In complete years)
2. What is the highest level of education you have attained?

a. NO formal education	1
b. Primary Education	2
c. O level secondary school education (“O” Level).	3
d. A level secondary school(“A” Level)	4
e. Level of college certificate	5
f. Diploma	6
g. Degree level	7
h. Masters level and Above	8

3. What is your current occupation status?

a. House wife/ un employed	1.
b. Students	2
c. Employed	3
d. Business woman	4
e. Casual labor's	5
f. Others (specify) ……	6

4. What is your Monthly income?

a. None, just depend from My partner	1
b. 10,000 - 20,000 Tanzania shilings	2
c. 30,000 - 50,000 Tanzania shillings)	3
d. 60,000 - 100,000 Tanzania shillings	4
e. 110,000 - 200,000 Tanzania shillings	5
f. 210,000 - 300,000 Tanzania shilings	6
g. More than 300,000 Tanzania shilings	7

5. What is your marital status?

a. Single	1
b. Married	2
c. Cohabiting	3
d. Divorced	4
e. Separated	5
f. Widow	6

Patients STATUS at Enrollment on PMTCT option B plus

6. When did you join PMTCT option B plus?

a. Six month ago	1
b. More than six month ago _____	2

7. What is your status at enrollment in this facility?

a. Pregnant	1
b. Breast feeding	2

8. Did ever access ART or CTC services before join PMTCT?

a. Yes	1
b. No (go to Q10)	2

9. If ever use ART before enrolled to PMTCT for how long?

a. Six months	1
b. For twelve months	2
c. For 24 months	3
d. For 36 months (three years)	4
e. More than 36 months (more than 3 years)	5

10. How many pregnancies have you ever had prior to this?

a. 1st pregnancy	1
b. 2nd pregnancy	2
c. 3rd pregnancy	3
d. 4th pregnancy and more	4

Previous PMTCT experience

11. When were you diagnosed with HIV infection? _____ (write year)

12. When did you enroll for ART after HIV diagnosis?

a. Before any pregnancies	1
b. Previous pregnancies	2
c. During breast feeding	3
d. Current pregnancy	4

13. Je How long did you take to Start ART after HIV diagnosis?

a. Immediately after being diagnose(within a Month)	1
b. More than a months	2

14. When did you enrolled to PMTCT option B plus? ____ (mention month and year).

15. Je, Is it your First time to Joint PMTCT services?

a. Yes	1
b. No	2

HIV Status DISCLOSURE

16. Did you receive any counselling in connection with HIV test results disclosure?

a. Yes	1
b. No	2

17. Have you shared your HIV status with anybody?

a. Yes	1
b. No (22)	2

18. Did you share/disclose HIV status to your partner?

a. Yes	1
b. No	2

19. Did you disclose HIV status to your any family member?

c. Yes	1
d. No	2

20. Did you disclose HIV status to your any family member?

a. Yes	1
b. No	2

21. How long after learning your HIV status, did you first disclose your HIV status?

a. Immediately after HIV results (within a month's)	1
b. After 2 to 5 months after HIV diagnosed	2
c. After 6 months after HIV diagnosed	3
d. After 12 months after HIV diagnosed	4
e. More than a year	5

22. Do you know your partner's HIV status?

a. Yes	1
b. No (go to q24)	2

23. What is your partner's HIV status?

a. HIV positive	1
b. HIV negative	2

PREVENTION MEASURE

24. Do use condom with having sex with your partner?

a. Yes	1
b. No (go to Q26)	2

25. What is your frequent of condom use?

a. Regularly/ always	1
b. Some time	2

ADHERENCE STATUS

26. Do you take ARV as Doctor's /Nurse Counsellor prescribed to you?

a. Yes	1
b. No	2
c. I don't know	3

27. Do you know your ARVs medication you're using?

a. Yes (mention_____		1
b. No		2

28. How many times you're taking your medication per day?

a. Once (time_____)	1
b. Twice per day (from _____to_____)	2

29. Have you ever change time to take you ARVs pills?

a. Yes	**1**
b. No (go to Q31)	**2**

30. IF you ever change time to take PILLS how many times per months?

a. once	1
b. twice	2
c. more than three times	3
d. I don't remember	4

31. Do you believe that ARV will have a good effectiveness for your health?

a. Yes	1
b. No	2
c. I don't know	

32. Do you believe that ARV would be ineffective if you take them not properly?

a. Yes	1
b. No	2
c. I don't know	3

33. Have you ever missed to come to this health facility/any clinic to pick your ARVs?

a. Yes	**1**
b. No	**2**

34. From when you started PMTCT option B plus have you ever missed your ARV dosage either because you forgot or you were travelled away from your drugs?

a. Yes	1
b. No (go to Q37)	2

35. For the last 3 months how many days did you miss your ARV s dosage

a. 1 to 2 days	1
b. 3 to 4 days	2
c. 5 days	3
d. More than 5 days	4
e. I don't remember	5

36. How many tablets did you missed per month for the past 3 month?

a. 1- 2 pills	1
b. 3-4 pills	2
c. 5 pills	3
d. More than 5 pills	4

37. Have you ever experienced any ARVs side effects since you started to use it?

e. Yes	**1**
f. No (go Q41)	**2**

38. Which ARVs side affects you ever experienced (Remember that this can have multiple responses So each is a Yes/No question)

a. Vomiting	1
b. Diarrhoea	2
c. Severe abdominal pain	3
d. Dizziness	4
e. Vivid dreams	5
f. Severe headache	6
g. Skin rashes	7
h. Skin itching	8
i. Others specify _____	9

39. Did you stop took your pills after experience ARVs side effects?

a. Yes	**1**
b. No	**2**

40. For how many days did you stop using you medication after experience side effects _____days

END OF INTERVIEW

TO BE CROSS CHECKED ON THE CTC2 FILE, CTC2 DATA BASE & ART REGISTER

41. Did she Missed appointment for more ≥ 7days since enrolled on PMTCT option B plus?

a. Yes	**1**
b. No	**2**

42. Check duration on ART or PMTCT option B plus

a. Six months	1
b. 6 to 12 months	2
c. 24 months	3
d. More than 24 months	4

43. Check CD4 Levels:
    a. Initial when enrolled on PMTCT option B plus_____
    b. CD4 level at 6 months later after enrolled on PMTCT option B plus_____
    c. CD4 level at 12 months later after enrolled on PMTCT option B plus_____
    d. Check for highest level of CD4 ever patients reached _____
44. Check Viral load level at
    a. 6 months later after enrolled on PMTCT option B plus_____
    b. at 12 months later after enrolled on PMTCT option B plus_____
    c. viral load result after repeated (After EHC)_____
    d. **CTC ID # for those with Viral load more than 1000COPIES_____
45. Check for WHO HIV clinical stage on starting option PMTCT option B plus _____
46. Check for WHO HIV clinical stage at 6 months after started option PMTCT option B plus _____
47. Check for current visit the WHO HIV clinical stage for this clients attending this clinic of PMTCT option B plus _____
48. Check for type of ART She is currently using?_____
49. Check if ever changed

a. Drug_____ date switched _____reasons_____

b. Drug_____ date switched _____reasons_____

Appendix II: Interview questionnaire (Swahili Version)

Title: Magnitude and predictors of antiretroviral (ART) treatment failure among women on option B plus attending PMTCT clinics in, Dar Es Salaam.

(Kujua ni kwakiwango gani na ni visababishi gani vinaweza kuzorotesha dawa za kupunguza makali ya UKIMWI katika Mkoa wa Dar Es Salaam'')

Dodoso namba:_____ Tarehe ya mahojiano: _____

Jina la RCH/Kituo cha huduma za afya: _____Wilaya: _____

MAELEKEZO YA UJAZAJI 'ZUNGUSHIA KIDUARA au WEKA ALAMA YA VEMA KWENYE NAMBA MBELI YA JIBU,AU JAZA TARAKIMU ULITAKIWA KUWEKA''

TAARIFA BINAFSI ZA MSHIRIKI

1. **Tafadhali naomba unitajie umri wako (**Andika miaka iliyokamilika**)** _____

2. **Je una elimu ya kiwango gani? (Zungushia kiduara Au weka Alama ya VEMA kwenye namba)**

a. Sikusoma elimu ya darasani (elimu rasmi).	1
b. Elimu ya msingi	2
c. Elimu ya kidato cha nne ("O" Level).	3

d. Elimu ya kidato cha sita (“A” Level)	4
e. Elimu ya cheti	5
f. Stashahada	6
g. Shahada ya kwanza	7
h. Shahada ya pili au zaidi	8

3. Je kwa sasa unafanya kazi gani au unajishughulisha na nini?

a. Mama wa nyumbani / Sijaajiriwa	1.
b. Mwanafunzi	2
c. Nimeajiriwa.	3
d. Mfanyabiashara / Mjasiriamali.	4
e. Kibarua (au kazi isiyo rasmi)	5
f. Kazi ya aina nyingine (taja): ……	6

4. Je kipato chako cha mwezi chaweza kuwa ni kiasi gani?

a. Sina kipato kabisa Namtegemea mwenza	1
b. 10,000 -20,000Tanzania shilings	2
c. 30,000 mpaka 50,000 Tanzania shillings)	3
d. 50,000 mpaka 100,000 Tanzania shillings	4
e. 110,000 mpaka 200,000 Tanzania shillings	5
f. 210,000 mpaka 300,000 Tanzania shilings	6
g. Zaidi ya 300,000 kwa mwezi	7

5. Je, kwa sasa upo kwenye mahusiano gani ya ndoa?

a. Sijaolewa	1
b. Nimeolewa	2
c. Ninaishi na mpenzi	3
d. Nimeachika (nimetalikiana) na mwenza wangu	4
e. Nimetengana na mwenza wangu	5
f. Nimefiwa na mume wangu	6

Hali ya Ujauzito na Kujiunga na Huduma za Kuzuia Maambukizi ya VVU kutoka kwa Mama kwenda kwa Mtoto (PMTCT)

6. Je umejiunga lini kwenye huduma hii ya Kuzuia maambukizi ya mama kwenda kwa mtoto

a. Miezi sita iliopita	1
b. Zaidi ya miezi sita iliopita _____	2

7. Je wakati unajiunga katika kituo hiki kupata huduma ya maambukizi ya Virusi vya ukimwi ulikua mjamzito au ulikuwa unanyonyesha ?

c. Mjamzito	1
d. Mama anayenyonyesha	2

8. **Je kabla ya kujiunga na kituo Hiki cha Afya na huduma hii ulishakua unapata huduma ya ARV sehemu nyingine?**

a. Ndio (kama ndio nenda swali la 9)	1
b. Hapana (nenda swali la 10)	2

9. **Kama ndio,e, umetumia ARV kwa muda gani?**

a. Kwa miezi Sita	1
b. Kwa mwaka mmoja	2
c. Mika miwili	3
d. Miaka mitatu	4
e. Zaidi ya mika Mitatu	5

10. **Je umepata ujauzito mara ngapi ukijumlisha na ujauzito huu wa mwisho? (Hakikisha kwenye card ya klinik)**

a. Mjamzito mara moja	1
b. Mjamzito mara mbili	2
c. Mjamzito mara tatu	3
d. Zaidi ya mara tatu	4

UZOEFU WA KUPATA HUDUMA ZA KUZUIA MAAMBUKIZI YA VVU KUTOKWA KWA MAMA KWENDA KWA MTOTO

(Previous PMTCT experience)

11. Je ni lini ambapo uligundulika kuwa na maambukizi ya virusi vya UKIMWI? _____ (andika mwaka)

12. Je ulipogundulika una maambukizi ya Virusi vya UKIMWI ilikuwa? (Msomee majibu)

a. Kabla ya ujauzito wowote	1
b. Ujauzito uliopita	2
c. Kipindi na nyonyesha	3
d. Ujauzito huu?	4

13. Je baada ya kugundulika kuwa una maambukizi ya VVU, ulichukua muda gani kujiunga na matibabu ya kupunguza makali ya VVU?

a. Mara moja baada ya kugundulika kuwa nimeambukizwa VVU (ndani ya mwezi)	1
b. Zaidi ya mwezi	2

14. Je, uliwahi kutumia dawa za ARV zinazopunguza makali ya VVU kabla ya kujiunga na mpango wa kuzuia maambukizi ya VVU/UKIMWI kutoka kwa mama kwenda kwa mtoto?

a. Ndio	1
b. Hapana	2

15. Je, ni lini ulijiunga na "Chaguo la B Plus" la mpango wa kuzuia maambukizi ya VVU/UKIMWI kutoka kwa mama kwenda kwa mtoto? ____(taja mwezi na mwaka).

16. Je, hii ni mara yako ya kwanza kujiunga na huduma hizi za mpango huu wa kuzuia maambukizi ya VVU/UKIMWI kutoka kwa mama kwenda kwa mtoto? (swali hili linafaa kwa wanawake waliowahi kupata ujauzito Zaidi ya mara moja).

a. Ndio	1
b. Hapana	2

KUIELEZA JAMII KUHUSU HALI MAAMBUKIZI YA VIRUSI VYA UKIMWI (HIV Status DISCLOSURE)

17. Je ulipata ushauri wowote kutoka kwa washauri nasaha kuhusu kuwaeleza watu wengine kwamba umeambukizwa virusi vya UKIMWI?

e. Ndio	1
f. Hapana	2

18. Je, umewahi kumweleza mtu yeyote kwamba una maambukizi ya virusi vya UKIMWI?

c. Ndio	1
d. Hapana (NENDA SWALI 22)	2

19. Je, ulimweleza mwenza wako kwamba una virusi vya UKIMWI?

c. Ndio	1
d. Hapana	2

20. Je, uliieleza mtu yeyote familia yako kwamba umeambukizwa virusi vya UKIMWI?

g. Ndio	1
h. Hapana	2

21. Je, ulipita muda gani tangu kugundulika kuwa na VVU hadi ulipoamua kuweka wazi kwa mara ya kwanza kwamba umeambukizwa virusi hivyo?

f. Mara baada ya vipimo kugundua kwamba nimeambukizwa VVU	1
g. Baada ya miezi 2 hadi 5 tangu nigundulike kuwa na VVU	2
h. Baada ya miezi 6 tangu nigundulike kuwa na VVU	3
i. Baada ya miezi 12 tangu nigundulike kuwa na VVU	4
j. Zaidi yam waka mmoja	5

22. Je unafahamu kama mwenza wako ameambukizwa au hajaambukizwa virusi vya UKIMWI?

c. Ndio (kama jibu ni ndio, nenda swali 23)	1
d. Hapana	2

23. Je, mwenza wako ana maambukizi ya VVU?

c. Anamaambukizi ya VVU	1
d. Hanamaambukizi ya VVU	2

24. Je unapokutana mwezi wako kimwili yaani sex mnatumia njia ya kujikinga na maambukizi (yaani mnatumia kondomu)

a. Ndio (kama ndio nenda swali la 25)	1
b. Hapana (kama Hapana nenda swali la 26)	2

25. Unaweza kusema matumizi yako ya kondomu ni ?

a. Mara zoote	1
b. Mara chache sana	2

KUFUATA USHAURI NA TIBA YA KUPUNGUZA MAKALI YA VVU (ADHERENCE)

26. Je unatumia dawa za kupunguza makali ya virusi vya UKIMWI, yaani ARV, kama ulivyoshauriwa na Daktari, Muuguzi, au Mshauri Nasaha?

d. Ndio	1
e. Hapana	2
f. Sijui / hakuna jibu	3

27. Je unaijua aina/Jina ya dawa(ARVs) unayoitumia ?

c. Ndio(Unaweza kuitaja_____		1
d. Hapana		2

28. Je Dawa za ARVs umeelekezwa kumeza/kunywa mara ngapi kwa siku?

a. Mara moja kwa siku (saa _____)	1
b. Marambili kwasiku (saa_____na saaa_____)	2

29. Je umeshawai kubadilisha muda wa kumeza dawa zako/ARVS?

a. Ndio (Kama ndio nenda swali namba 30)	**1**
b. Hapana (nenda swali namba 31)	**2**

30. Kama ndio mara ngapi ndani ya miezi mitatu iliyopita ?

a. Mara moja	1
b. Marambili kwa kipindi za miezi mitatu	2
c. Zaidi ya mara tatu	3
d. Sikumbuki	4

31. Je, unaamini kwamba dawa hizo za ARV zinasaidia kuimarisha afya yako/Afya ya mtoto wako?

a. Ndio	1
b. Hapana	2
c. Sijui	

32. Je unakubali kwamba dawa za ARV zinaweza kushindwa kufanya kazi kama inavyotakiwa iwapo hutozitumia kama ulivyoelekezwa na wataalamu wa afya Yaani usugu?

a. Ndio	1
b. Hapana	2
c. Sijui / hakuna jibu	3

33. Je umewahi kukosa kuhudhuria hapa kituoni au kliniki yoyote ili kuongeza dawa zako za kupunguza makali ya VVU, yaani ARV?

c. Ndio	**1**
d. Hapana	**2**

34. Je, umewahi kuacha kutumia dawa za ARV kwa sababu ya kusahau au kusafiri mbali na zilipo dawa zako tangu ujiunge na "Chaguo la B Plus" ili kuzuia maambukizi ya VVU kutoka kwa mama kwenda kwa mtoto?

c. Ndio	1
d. Hapana(Nenda swali la 37)	2

35. Je, ni siku ngapi umeacha au umeshindwa kutumia dawa za ARV katika miezi 3 iliyopita?

f. Siku **1 hadi 2**	1
g. Siku 3 hadi 4	2
h. Siku tano	3
i. Zaidi ya siku tano	4
j. Sikumbuki	5

36. Je, kila mwezi ni vidonge vingapi ulivyoacha kunywa katika kipindi hicho cha miezi 3?

g. Vidonge 1- 2	1
h. Vidonge 3-4	2
i. Vidonge 5	3
j. Zaidi ya vidonge 5 (vitano)	4

37. Je umewahi kupata matatizo yoyote ya kiafya wakati unatumia hizi Dawa za ARVs (dawa ya kupunguza makali ya virusi vya UKIMWI?)

a. Ndio	**1**
b. Hapana (Nenda swali la 41)	**2**

38. Je ni matatizo gani uliopata ambayo unadhani yalisababishwa na hizi dawa za kupunguza makali ya virusi vya UKIMWI? (Remember that this can have multiple responces So each is a Yes/No question)

a. Kutapika sana	1
b. Kuharisha sana	2
c. Tumbo kuuma sana	3
d. Kusikia kizunguzungu	4
e. Kuota ndoto za ajabu sana	5
f. Kichwa kuuma sana	6
g. Kutoka na vipele	7
h. Kuwashwa ngozi sana	8
i. Nyinginezo , Nitajie _____	9

39. Je uliacha kunywa dawa zako baada ya kupata tatizo la dawa za ARVS?

a. Ndio	**1**
b. Hapana	**2**

40. Je uliacha kunywa dawa zako ARVS kwa muda gani baada ya tatizo? Zitaje siku au miezi _____

MWISHO WA MAHOJIANO,JE UNASWALI LOLOTE LA KUULIZA

NAKUSHUKURU SANA KWA USHIRIKIANO WAKO ASANTE SANA

TAARIFA ZIHAKIKIWE KWA KUTAZAMA TAARIFA ZILIZOMO KWENYE MAJALADA YA TAARIFA ZA MGONJWA YA CTC2, KANZIDATA (DATABASE) YA CTC2 & REJESTA YA WAGOJNWA WALIO KWENYE MPANGO WA MATIBABU YA KUPUNGUZA MAKALI YA VVU

41. Je, mgonjwa alikosa kuhudhuria siku 7 au zaidi tangu ajiunge na "Chaguo B Plus" la mpango wa kuzuia maambukizi ya VVU kutoka kwa mama kwenda kwa mtoto?

c. Ndio	**1**
d. Hapana	**2**

42. Tazama muda mteja alikuwa tangu ajiunge Huduma Ya ARVs au "Chaguo B jumlisha " la mpango wa kuzuia maambukizi ya VVU kutoka kwa mama kwenda kwa mtoto

e. < 6 (chini ya miezi sita)	1
f. MIEZI 6 hadi Mwaka mmoja	2
g. Miaka miwili	3
h. Zaidi ya mika miwili	4

43. Tazama kiwango cha chembe hai nyeupe (CD4) wakati:
    e. Mgonjwa alipojiunga na PMTCT "Chaguo B Plus"_____
    f. Miezi 6 baada ya mgonjwa kujiunga na PMTCT "Chaguo B Plus" _____
    g. Miezi 12 baada ya kujiunga na PMTCT "Chaguo B Plus" _____
    h. Tazama kujua kiwango cha juu kabisa cha kiwango cha chembe nyeupe za damu alichofikia mgonjwa huyu _____
44. Tazama kujua kiwango cha wadudu wa VVU kwenye damu ya mgonjwa katika kipindi cha:
    i. Miezi 6 baada ya kujiunga na PMTCT "Chaguo B Plus" _____
    j. Miezi 12 baada ya kujiunga na PMTCT "Chaguo B Plus" _____
    k. Angalia idadi ya VVU baada ya kurudia baada ya kuonekana juu_____
    l. Kama vvu vipo juu ya 1000 andika namba ya ctc_____

45. Angalia kwenye faili la mteja ni lini alianza dawa za ARVs. Andika ni MUDA gani umepita tangu alipoanza ARVs mpaka leo _____
46. Kwa kutumia kigezo cha Shirika la Afya Duniani (WHO), tazama hatua ya maambukizi ya VVU ambayo mgonjwa alifikia kipindi alipojiunga na mpango wa kuzuia maambukizi ya VVU kutoka kwa mama kwenda kwa mtoto, yaani PMTCT "Chaguo B Plus" _____
47. Kwa kutumia kigezo cha Shirika la Afya Duniani (WHO), tazama hatua ya maambukizi ya VVU ambayo mgonjwa alifikia miezi 6 tangu alipojiunga na PMTCT "Chaguo B Plus" _____
48. Kwa kutumia kigezo cha Shirika la Afya Duniani (WHO), tazama hatua ya maambukizi ya VVU ambayo mgonjwa alifikia mara ya mwisho alipohudhuria kliniki ya matibabu ya mpango wa PMTCT "Chaguo B Plus" _____
49. Angalia aina ya Dawa za ARVS alizowai kutumia na sababu za kubadilshiwa dawa?

a. Dawa _____tarehe ya kubadidili_____sababu ya kubadili_____
b. Dawa _____tarehe ya kubadidili_____sababu ya kubadili_____

NAKUSHUKURU SANA KWA USHIRIKIANO WAKO ASANTE SANA

Appendix III: Informed consent form (Swahili Version)

IDARA YA UTAFITI NA MACHAPISHO

FOMU YA RIDHAA

ID NO:……

Salaam,

Jina langu naitwa ……. Ni mwanafunzi katika Shule ya Afya na Sayansi za Jamii katika Chuo Kikuu cha Tiba na Sayansi shirikishi cha Muhimbili.Dar es Salaam.

Madhumuni ya Utafiti

Ndugu mhojiwa napenda kukujulisha kuwa somo hili la utafiti lenye jina "Tathmini ya Ridhiko la Madaktari 'juu ya Habari na Mawasiliano kwa ajili ya matumizi ya mojawapo ya huduma za maabara katika huduma za uchunguzi katika hospitali za manispaa za Dar es Salaam, Tanzania."

Usiri

Sisi tutalinda na kuziweka taarifa zako kwa usiri wa hali ya juu na kadri ya uwezo wetu. Sisi hatutaandika jina lako katika ripoti yoyote/nyaraka ambazo zinaweza kuruhusu mtu kukutambua wewe. Jina lako halitakuwa na mahusiano na habari za utafiti kwa njia yoyote.Watafiti watatunza takwimu na taarifa zitakazo kusanywa. Hata hivyo matokeo ya utafiti yatawasiliswa kwa ajili ya uchapishaji katika majarida ya kisayansi.

Haki na uondoaji mbadala

Ushiriki wako ni wa hiari. Unaweza ukajiondoa katika ushiriki katika utafiti wakati wowote, wakati wa mahojiano hata kama ulikuwa umekubali kushiriki. Uamuzi wako wa kushiriki hautahusishwa na haki yako ya kuendelea na matibabu katika kituo. Hakuna adhabu ya kukataa kushiriki katika utafiti. Hutapata hasara yoyote kama ukikataa kushiriki katika utafiti huu.

Faida:

Utafiti huu utawawezesha watu wa Afya na wasimamizi kuweza kujua ni wakati gani ya za kupunguza maambukizi ya VVU kwenda kwa watoto zaweza kutengeneza usugu au kushindwa kufanya kazi

Hatari:

Hakuna madhara kwa kushiriki katika utafiti. Hata hivyo wewe uko huru katika kuacha kushiriki kwa wakati wowote katika mjadala huu katika tukio unalojihisi kuwa na wasiwasi.

Endapo utapata madhara:Hutegemei kupata madhara yoyote kutokana na ushiriki wako katika utafiti.

Nani wa kuwasiliana naye:Kama una maswali kuhusiana na utafiti huu tafadhali wasiliana na mtafiti mkuu, Ally Kaduma simu 0755091157 wa Chuo Kikuu cha Tiba na sayansi Muhimbili,S.L.P 65001,Dar es Salaam.

Kama una swali juu ya haki zako za msingi kama mshiriki, unaweza kuwasiliana na Dr Joyce Masalu ambaye ni mkurugenzi wa Tafiti na machapisho katika Chuo Kikuu cha Tiba na sayansu shirikishi cha Muhimbili. ***Simu namba simu namba 22 2152489***Je unakubali

Mshiriki anakubali……Mshiriki hakubali……...

Mimi …… nimesoma maelezo ya fomu hii. Nakubali kushiriki katika utafiti huu.

Saini ya mshiriki……

Saini ya Mtafiti…….

Tarehe ya kusaini ……

Appendix IV: Informed consent form (English Version)

INFORMED CONSENT FORM

ID NO: …….

Greetings,

My name is ……working for school of public health and social sciences at Muhimbili University of health and allied sciences in Dar Es Salaam.

Purpose of the study

Dear respondent, I would like to inform you that this is a research study titled "To assess the magnitude and predictors of ART treatment failure among women on PMTCT option B plus attending PMTC clinics in Dar es Salaam region."

This study seeks to assess the magnitude and factor associated with ART treatment failure, and the good results will health workers on how and when to identifies failures before Drug resistance emerge. Kindly be honest and true for good results that could lead to better intervention and recommendations in future.

Confidentiality We will protect and treat information you will provide with high confidentiality to the best of our knowledge. We will not write your name on the questionnaire or in any reports/documents that might let someone identify you. Your name will not be linked to research information in any way.

The investigator will take care of information to be collected. However, final results after the analysis will be shared with national stakeholders and I will submit the manuscript for publications in scientific journals.

Right and withdraw alternatives

Your participation is voluntary. You may decline from participation from participation to the study at any time even if you have consented to participate. Your decision to participate or not to participate will be associated with the right to get services in the facility. There is no penalty for refusing to participate in the study. You will not experience loss of your refusal to participate in this study

Risks

There is no harm for participating in the study. However, you are free to stop participating as the respondent at any time during the discussion in the event you feel uncomfortable.

Person to contact

If you have any questions about this study you should contact the principal investigator, (Ally Kaduma Mob: 0755091157) of MUHAS, Dar es Salaam.

If you have any questions about your participation rights please contact, Doctor Joyce Masalu Director of Research and Publication, Mob: ***022 2152489*** MUHAS Dar Es Salaam.

DECLARATION

I have read or being read by the researcher and understood the contents in this form. My questions have been answered. Do you agree?

Participant agreed ☐ Participant disagreed ☐

The above document describing benefits, risks and procedures for research titled "To assess the magnitude and predictors of ART treatment failure among women on PMTCT option B plus attending PMTC clinics in Dar es Salaam region" I certify that the nature and purpose, the potential benefits and possible risks associated with participating in this study have been explained to me.

Signature or stamp of the respondent……Date……...

Signature of the researcher ……..……Date……...

Appendix V: Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

P.O. Box 65001
DAR ES SALAAM
TANZANIA
Web: www.muhas.ac.tz

Tel G/Line: +255-22-2150302/6 Ext. 1015
Direct Line: +255-22-2151378
Telefax: +255-22-2150465
E-mail: dpgs@muhas.ac.tz

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

18th April, 2017

Mr. Ally Kaduma
Master of Public Health
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED "MAGNITUDE AND PREDICTORS OF ANTIRETROVIRAL (ART) TREATMENT FAILURE AMONG WOMEN ON PMTCT OPTION B PLUS ATTENDING PMTCT CLINICS IN DAR ES SALAAM."

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. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 19th April, 2017 to 18th April, 2018. In case you do not complete data analysis and dissertation report writing by 18th April 2018, you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. E. Balandya
DEPUTY DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publication
cc: Dean, School of Public Health and Social Sciences

Appendix VI: Research permit Temeke and Kigamboni

THE UNITED REPUBLIC OF TANZANIA
President's Office
REGIONAL ADMINISTRATION AND LOCAL GOVERNMENT

DAR ES SALAAM REGION
Phone Number: 2203158
Fax number: 2203158
email: ras@dsm.go.tz
website: www.dsm.go.tz

In reply please quote:
Ref. No. .....

REGIONAL COMMISSIONER'S OFFICE,
3 RASHID KAWAWA ROAD,
P.O. BOX 5429,
12880 DAR ES SALAAM

17.05. 2017

District Administrative Secretary,
TEMBKE – KIGAMBONI
P. O. Box .....
DAR ES SALAAM.

RE: RESEARCH PERMIT

Prof/Dr/Mrs./Mr/Miss ALLY ISADUMA is student/Research from MUHAS has been permitted to undertake research on MAGNITUDE AND PREDICTORS OF ANTIRETROVIRAL (ART) TREATMENT FAILURE AMONG WOMEN ON PMTCT OPTION B+ ATTENDING PMTCT CLINIC IN DAR-ES-SALAAM.

From 17.05. 2017 to 17.08. 2017.

Kindly request your good assistance to enable her/his research.

For: REGIONAL ADMINISTRATION SECRERTARY
DAR ES SALAAM

Copy: Municipal Director,
TEMBKE
DAR ES SALAAM.

Principal/Vice Chancellor
MUHAS

Appendix VII: Research permit Kinondoni and Ubungo

THE UNITED REPUBLIC OF TANZANIA
President's Office
REGIONAL ADMINISTRATION AND LOCAL GOVERNMENT

DAR ES SALAAM REGION
Phone Number: 2203158
Fax number: 2203158
email: rasdsm@dsm.go.tz
website: www.dsm.go.tz

In reply please quote
Ref. No. .....

REGIONAL COMMISSIONER'S OFFICE
3 RASHID KAWAWA ROAD,
P.O. BOX 5429,
12880 DAR ES SALAAM

17/05/ 2017

District Administrative Secretary,
KINONDONI - UBUNGO.

P. O. Box .....,

DAR ES SALAAM.

RE: RESEARCH PERMIT

Prof/Dr/Mrs./Ms/Miss ALLY KADUMA ..... is student/Research from MUHAS ..... has been permitted to undertake research on MAGNITUDE AND PREDICTORS OF ANTIRETROVIRAL (ART) TREATMENT FAILURE AMONG WHEN ON PMTCT OPTION B+ ATTENDING PMTCT CLINICS IN DAR-ES-SALAAM

From 19/05/ ..... 2017 to 17/06/17 .....2017.

I Kindly request your good assistance to enable her/his research.

For: REGIONAL ADMINISTRATION SECRERTARY
DAR ES SALAAM

Copy: Municipal Director,
KINONDONI
DAR ES SALAAM.

Principal/Vice Chancellor
MUHAS

Appendix VIII: Research permit Ilala

THE UNITED REPUBLIC OF TANZANIA
President's Office
REGIONAL ADMINISTRATION AND LOCAL GOVERNMENT

DAR ES SALAAM REGION
Phone Number: 2203158
Fax number: 2203153
email: ras@dsm.go.tz
website: www.dsm.go.tz

In reply please quote:
Ref. No. .....

REGIONAL COMMISSIONER'S OFFICE,
3 RASHID KAWAWA ROAD,
P.O. BOX 5429,
12880 DAR ES SALAAM

17. 05 2017

District Administrative Secretary,
ILALA
P. O. Box 20950,
DAR ES SALAAM.

RE: RESEARCH PERMIT

Prof/Dr/~~Mrs~~/Ms/~~Miss~~ ALLY KADUMA is student/Research from MUHAS has been permitted to undertake research on MAGNITUDE AND PREDICTORS OF ANTIRETROVIRAL (ART) TREATMENT FAILURE AMONG WOMEN ON PMTCT OPTION B+ ATTENDING PMTCT CLINIC IN DAR-ES-SALAAM

From 19/05 2017 to 17.08 2017.

Kindly request your good assistance to enable her/his research.

For: REGIONAL ADMINISTRATION SECRETARY
DAR ES SALAAM

Copy: Municipal Director,
ILALA
DAR ES SALAAM.

Principal/Vice Chancellor
MUHAS