.

PREVALENCE OF ADVERSE NEONATAL OUTCOME AND ASSOCIATION WITH HIV INFECTION AMONG POSTNATAL WOMEN IN MTWARA REGIONAL HOSPITAL-TANZANIA

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DECLARATION

I hereby declare to the best of my knowledge that the work presented in this dissertation has not been presented for any award in any institution and has never been published anywhere. All the work is original unless otherwise stated. I'm therefore presenting it for the award of Degree of Master of Science (Clinical Epidemiology and Biostatistics) of Makerere University, Kampala, Uganda

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DEDICATION

Dedicated to my beloved wife Dr. Frida W. Mghamba

To my son Chris Junior

To my parents Mr. Hokororo Christopher and Mrs. Hokororo Imelda for bringing me up as a potential academician.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Ante natal clinic
ARV	Anti retrovirus
BMI	Body Mass Index
GA	Gestation age
HIV	Human Immune Deficiency Virus
IPD	Intra partum death
IUFD	Intrauterine fetal death
IUGR	Intrauterine growth retardation
LBW	Low Birth Weight
MDG	Millennium Developing Goal
MoH(T)	Ministry of Health of Tanzania
NACP (T)	National Aids Control Program of Tanzania
PMTCT	Prevention of Mother to child Transmission
SGA	Small for Gestation Age
STDS	Sexual Transmitted Diseases
UNAIDS	Joint United Nations Programs on HIV/AIDS
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

OPERATIONAL DEFINITIONS

1. **Adverse neonatal outcome** is mortality and severe morbidities of the offspring (1)
2. **Low birth weight** is Birth weight less than 2500gm (1)
3. **Preterm delivery** is delivery of the new born before 37 weeks GA (1)
4. **IUGR (SGA)** is birth weight below 10^{th} percentile for GA (1)
5. **Intra uterine fetal death** is mortality of a newly growing child within the 2^{nd} and 3^{rd} trimesters
6. **HIV Positive** people is a person infected with the Human Immuno deficiency virus and who has seroconverted .
7. **Post- natal period** is the duration (42 days) immediately after childbirth.
8. **Neonatal mortality** is the number of babies who die during the first 28 days of life per 1,000 live births based on the birth cohort
9. **Stillbirth** is the fetus that shows no evidence of life (heartbeat, respiration or independent movement) at anytime later than 22 weeks after conception (WHO), in Tanzania 28 weeks of gestation (1).
10. **Perinatal** defines the period occurring around the time of birth (5 months before and 1month after).The perinatal period commences at 22 completed weeks (154 days) of gestation (the time when birth weight is normally 500 g), and ends seven completed days after birth. (WHO - World Health Organization).Legal regulations in different countries include gestation age beginning from 16 - 22 weeks (5 months) before birth.

ABSTRACT

Background

It is estimated that a global average of NMR is 30 neonatal deaths per 1000 live births. In 1995, 20.5million LBW were born and 16% of all new born in developing countries had LBW. Tanzania's NMR is 32 deaths per 1000 deliveries. Preterm deliveries and LBW rate is 27% and 13% respectively. In Tanzania the prevalence of HIV/AIDS among pregnant women varies from 4-32%.

General objective

The objective of this study was to establish the prevalence of adverse neonatal outcomes and their association with HIV infection among postnatal women in Mtwara Regional Hospital

Methods

A cross sectional study was conducted between February and March 200 in Mtwara Reginal hospital (South east of Tanzania mainland). A total of 480 health postnatal women were selected by consecutive sampling. Data was collected from the participants using semi-structured questionnaire. EPI-DATA and SPSS computer packages were used for analysis of the data. Estimation of risk was done by computing Odd's Ratio. Confounding and interaction between independent variables and the main independent variable (HIV) were assessed using logistic regression

Results

The overall prevalence of adverse neonatal outcome (neonatal death, low birth weight and preterm delivery) was (28%, n=132), 95% CI= 24.0-32.0). In this study it also was found

postnatal women with HIV infection had about (OR=3.6, CI 2.2-5.7) more than four times risk of getting adverse neonatal outcome than among postnatal women of no HIV infection. Other predictors which independently associated with adverse neonatal outcome were History of adverse neonatal outcome in prior pregnancy (OR=2.64, CI 1.6-4.8), history of other diseases during pregnancy e.g. malaria (OR=2.64 CI, 1.5-4.4) and residence in rural area (OR=1.75, 1.05-2.9). Some independent variables confounded the main predictor HIV infection, these were drinking alcohol (OR=1.69, CI 1.01-2.9), non education (OR=4.68, CI 1.2-17.9) and high blood pressure (OR=2.29, CI 0.7-5.9).

Conclusions

This study has found postnatal women in Mtwara regional hospital are at high risk of getting newborns with adverse outcome. Three in every ten postnatal women have a risk of getting a newborn with at least one adverse outcome in a year. Postnatal women of Mtwara Regional Hospital with HIV infection are at about four times more risk of getting newborn with adverse outcome as compared to non infected ones.

1.0. CHAPTER ONE

1.1. Introduction

Adverse neonatal outcomes are among the health burden challenges globally. It is estimated that each year 4 million children die in the first 4 weeks of life, giving a global average of 30 neonatal deaths per 1000 live births(2) . In 1995, 20.5million LBW neonates were born and 16% of all new born in developing countries had LBW (1). In Sub Saharan Africa approximately 30 million women become pregnant in a year. Of those, about 1 million deliveries are stillborn, at least 1million babies die in their first month of life and 0.5 million die on the first day. About 4 million LBW babies and others with neonatal complications may live but not reach their full potential. Africa accounts for 11% of world's population but more than 25% of the worlds' new born deaths. Of the 20 countries with the highest risk of neonatal death, 15(75%) are in Africa. Tanzania is among the African countries constituting 50% of Africans' newborn death. It ranks number four (4) in African countries with the most newborn deaths .It has 44900 neonatal death per year (NMR 32 death per 1000 deliveries). Preterm deliveries and LBW rate constitute 27% and 13% respectively (2)

Viral infections in pregnancy are major causes of morbidity and mortality for both mother and the fetus. The infections can occur in uterus transplacentally, perinatally or postnataly. Traditionally the only viral infections of concern during pregnancy were those caused by rubella, cytomegalovirus, herpes simplex, etc, other viruses now also known to cause congenital infections include parvovirus (B19), varicella-zoster, measles and HIV. Worldwide congenital HIV infection is now taken as the major cause of infant and childhood morbidity and mortality with an estimated 4 million deaths occurring since the start of the pandemic. Maternal HIV status

affects new born survival by causing an increased risk of morbidity and mortality in the neonatal period and even among those babies who do not become positive. The interaction of HIV with other infections and the indirect effects of HIV such as poverty and maternal illness, malnutrition, also contribute to adverse neonatal outcome (3). HIV- infection pandemic has increased a health burden globally. About 40 million people (adults and children) are living with HIV /AIDS world wide. Sub Saharan Africa is the world's most severely affected part of the world. It hosts about two thirds of the global total population living with HIV and AIDS. One in 12 adults in this region is reported to be infected with HIV(4). In Tanzania the prevalence of HIV/AIDS among adults is 7% estimating to 2.2 million people. Prevalence among pregnant women in Tanzania varies from 4-32% and Mtwara Region is about 7.5%(5).

Although the number of new born deaths worldwide is roughly equal to the number of HIV/AIDS and malaria death combined, the deaths of new born babies have received remarkably little consideration in the international policy. Ministry of Heath of Tanzania targets to reduce the burden of disease, infant mortality and increase life expectancy through the improvement of health services and disease control including HIV/AIDs. This study is going to be carried out at Mtwara Regional Hospital which is at remote area and a more resource limited where probably prevalence of adverse neonatal outcome is high. It has limited ante natal, intra partum and post natal care. In order to achieve the Ministry of Health goal at this region the burden of adverse neonatal outcome should be known. Hence the aim of this study was to establish the prevalence of adverse neonatal outcome and its association with HIV infection among post natal women in Mtwara Regional Hospital.

1.2 Literature Review

1.2.1. Introduction

Adverse neonatal outcomes include mortality and morbidities of the new born. Virtually all countries in WHO African Region have generalized HIV/AIDS epidemics with at least 1% of pregnant women attending antenatal clinics in the urban areas are HIV infected(6). Since the start of the pandemic of HIV/AIDS the adverse neonatal outcomes have been found to be increased.

1.2.2. The prevalence of adverse neonatal outcome

Globally infant deaths are ranging from 4-5 to more than 100 per live births. It is estimated that 20.5 million LBW infants were born in 1995. Prevalence of infant mortality per 1000 live birth ranged from 6 to 77 in developed countries including United Kingdom, United States. LBW in the same counties ranged from 5.2% to 28.2% where as the pre term delivery ranged from 4.6% to 24% of all live births(1) A snapshot of progress since 2005 showed each year at least 4 million new born die world wide which is unacceptably high number given that low cost solutions exist to save these lives. Neonatal mortality account for 40% of all under fives deaths. The time of birth and first days of life are the riskiest period in human life span. Each year 3 million babies die in the first week of life and up to two third (2/3) of these die in the first 24 hours of life. In India alone, more than 1 million newborns die every year(7). The study which was carried out at King Fahad showed the perinatal mortality rate was 34.9% (65/186)(8). In another study from Guatemala found among 671 infants born in 4 rural ladino villages, 15.2% had birth weights < 2500 g. The prevalence of LBW of 41.3% among 415 live, singleton births (9).

Sub Saharan Africa remains the most dangerous region in the world for the baby to be born as 1.16 million babies die each year in the first 28 days of life. About 0.5 million Sub Saharan Africa babies die on the day they are born most at home and uncounted. Each year in Sub Saharan Africa, 30 million women become pregnant, and 18 million give birth at home without skilled care and therefore each day in Africa; 3,100 newborns die, and another 2,400 are stillborn, 9,600 children die after their first month of life and before their fifth birthday and1 in every 4 child deaths (under five years) in Africa is a newborn baby. Nigeria has the world highest new born mortality rate at 66 deaths per 1000 birth. Half of African's 1.16 newborn deaths occur in just 5 countries, Nigeria, Democratic Republic of Congo, Ethiopia, United Republic of Tanzania and Uganda. The report found two third (2/3) up to 800000 of new born death in Sub Saharan Africa in a year could be saved if 90% of women and babies received feasible low cost health intervention like immunization, providing a skilled attendant at birth, etc which would have needed only 1.39USD per capital(10).

The number of new born dying in Sub Saharan Africa barely changed to 41 per 1000 in recent years from 42 per 1000 in 1995. The number of newborn deaths for the Sub Saharan rose due to poor performances in some of the populous countries notably Nigeria. Five countries account for almost 600,000 deaths, over half the total newborn deaths in Africa. The major causes of newborn deaths are infections, premature delivery, problem of breathing during and soon after birth (7). A baby born in Africa faces a narrowing struggle to survive even a day due to lack of basic ante natal care. Studies have shown infant mortality rate was 114 per 1000 and 91 per 1000 in Malawi and Gambia respectively. In South Africa NMR is 21death per 1000 birth which is about half the average for Sub Saharan Africa, however there is no progress in reducing that

NMR in the last 10 years which is the barrier to meeting child survival targets especially for the MDG4. LBW is one of adverse neonatal outcome which is almost out of hand in Sub Saharan Africa. About 4 million newborn are low LBW together with other neonatal complication may live but not reach their full potential(10).

Tanzania has about total population of 37,627,000 with annual births 1,403,000 of which annual NMR 32 per 1,000 live births , annual under 5 mortality rate per 1,000 live births is 112 ,NMR as percentage of U5MR 29% , Preterm 27% , LBW rate 13%(10). In a study done in Dar es Salaam showed incidence of LBW was 7.8% and 9.4%. The rates of prematurity were 16.9% and 16.7% and the rates of fetal death were 4.3% and 5.0%, in women given multivitamin and placebo respectively. Another study showed the prevalence of LBW, preterm delivery, and SGA birth were 11.1%, 23.5%, and 11.5%, respectively in HIV positive women. A study which was conducted at Mwanza Tanzania showed at delivery,1536 women 12% of live births were preterm and 8% were LBW(11). The study by Habib et al found 15,255 births in north east Tanzanian hospital birth found overall neonatal mortality rate was 43.9 per 1000 births (95%CI 40.7-47.2). Neonatal mortality rates among twins and singletons were 91.0 and 41.1 per 1000 babies respectively, corresponding to a RR of 2.2 (95%CI 1.7-2.8). Twins had a generally lower birth weight and small birth weights as compared to singletons(12). These are Tanzania's estimates which are urban oriented. This study is going to be done at Mtwara Regional Hospital a remote, southern part of Tanzania where prevalence is probably high.

1.2.3. Adverse neonatal outcome and its association with HIV infection among postnatal women

Worldwide congenital HIV infection is now taken as the major cause of infant and childhood morbidity and mortality with an estimated 4 million deaths occurring since the start of the pandemic(3). In Kenya and Malawi it was found IPD was associated with HIV infection by five times more likely non infected. Poor obstetrical outcome was strongly associated with HIV infection(13). Infants born to HIV-1 positive mothers were much more likely to die during the first year of life than those born to HIV-1 negative mothers (235/1000 vs.144/1000 live births; P= 0.001) (14). In Kagera Tanzania the study was done to establish the association of HIV infection and adverse birth outcomes. Women tested for HIV status 314 deliveries, 29(0.1%) were IUFD and 33(0.11%) infants died before 15 months including 11 AIDS related deaths. Another study in the same region found the risk of adverse neonatal outcomes among HIV-uninfected women and those among HIV-infected women. HIV-infected women were about two times more likely to have severe immature infants (<34 weeks) than HIV-uninfected women. There was about two times more likely risk of low birth weight and prematurity among symptomatic HIV-infected women when compared with HIV-uninfected women. It was concluded that HIV-infected women, particularly those who are symptomatic, are at a higher risk of adverse neonatal outcomes (15).

1.2.4. Other factors associated with adverse neonatal outcome among post natal women

It has been shown that there are many factors which potentially attributed to the occurrence of the adverse neonatal outcomes. Several clinical conditions like diabetes mellitus, hypertension, chronic renal failure, etc often have been found to complicate pregnancy for both fetus and

mothers. There is increase risk by 2.5 fold in patient with diabetes mellitus to get fetal death(16). The women with children of less than 1.5kg and 1.5-2.5kg had increased risk of being hypertensive with renal disease by 17 and 2.5 respectively(17)**.** Infections like malaria, STDs, other viruses are also having significant risk for the fetus. It was found when examining the stillbirths in Zimbabwe among the 104 stillbirths 17-33% of specimens had bacteria growth and in Sweden 50-70% adults had parovirus B19 and in that population pregnancy was associated with adverse neonatal outcome(18). Prepregnancy BMI has impact on pregnancy in terms of neonatal outcomes. The study of poor pregnancy outcome versus BMI had found pregnant women with BMI of >25 had 4 times risk of late fetal death(19). Another study in Dar es salaam found weight loss, low weight gain during pregnancy and low maternal height were significantly related to increased about two fold risk of fetal death, preterm delivery. LBW was about three times more after adjusting for height, primiparity, baseline weight, malaria, CD4 cell count, HIV disease stage, and intestinal parasitoses. The association with fetal death was stronger for weight loss during the 2nd trimester, whereas increased risks of preterm delivery and LBW were higher for weight loss during the 3rd. Weaker associations were found with low weight gain during pregnancy (20). Maternal age has found to cause adverse neonatal outcome. In Muhimbili Hospital studies showed teenagers were at about one and half increased risk for LBW. Elderly mothers had one and half higher risk for LBW (21). Various studies have shown many other factors to be implicated with adverse prenatal outcomes. These are social status, life style, attendance to antenatal clinic, spacing where both short and long interpregnancy intervals(22).

In 54.7% of the cases of stillbirth. Increased maternal BMI was associated with IUFD rate (P<001), as was increased maternal age (P = .0012). There was no association between stillbirth rate and maternal ethnic group, maternal smoking, maternal Rhesus status, or fetal sex(23).

Preterm Premature Rupture of membranes which leads to LBW and preterm delivery was seen to be common among patients who were young (15-25 years), with low socioeconomic status, and with an educational status of primary to middle. The study in Ayub Teaching Hospital found the risk of PPROM was highest among patients giving birth to their first child. Perinatal mortality rate was 129.9/1000 (13%) of total births(24). Eugene et al found in Cameroon, adverse fetal outcome was about two fold in adolescent pregnancies as compared to others (25).

2.0. CHAPTER TWO

2.1. Problem Statement

In Tanzania adverse neonatal outcome is still challenging situation in health services. It is estimated that annual neonatal mortality is 44900 (NMR is 32 per 1000) and the stillbirth rate is 29 per 1000 (annual number of stillbirths is 42500). Tanzania is not achieving MDG4 although Government Development Vision under its health policy one of its strategies is reducing burden of infant mortality and morbidity by three third and increase life expectance through the improvement of health services to all people. This is due to poverty, lack of expertise, poor infrastructure, infections including HIV/AIDs. Tanzania has reduced NMR by 29% however the Nation is still among 5 Sub Saharan countries making half of African's 1.16million new born death(10)

Over 2.2 million persons are estimated to be living with HIV/AIDS and close to 800,000 cumulative AIDS cases in Tanzania. Prevalence among pregnant women in Tanzania varies from 4-32%(5). HIV-infected pregnant women are at increased risk of delivering LBW infants, of preterm delivery, and of IUFD. Tanzania being a resource limited country the overwhelming number of patients with adverse neonatal outcome adds burden to the already overburdened health system. If more effective measures are not going to be taken, adverse neonatal outcomes will continue to worsen the burden in health system and on economy growth of the country.

Many adverse neonatal outcomes are preventable with existing low-cost interventions, but to make the best use of limited resources. Planners and policy makers require the estimate number

and reliable cause of adverse neonatal outcome information such as HIV infection in women; hence without substantial information to reduce NMR and other severe morbidities, MDG-4 will not be achieved.

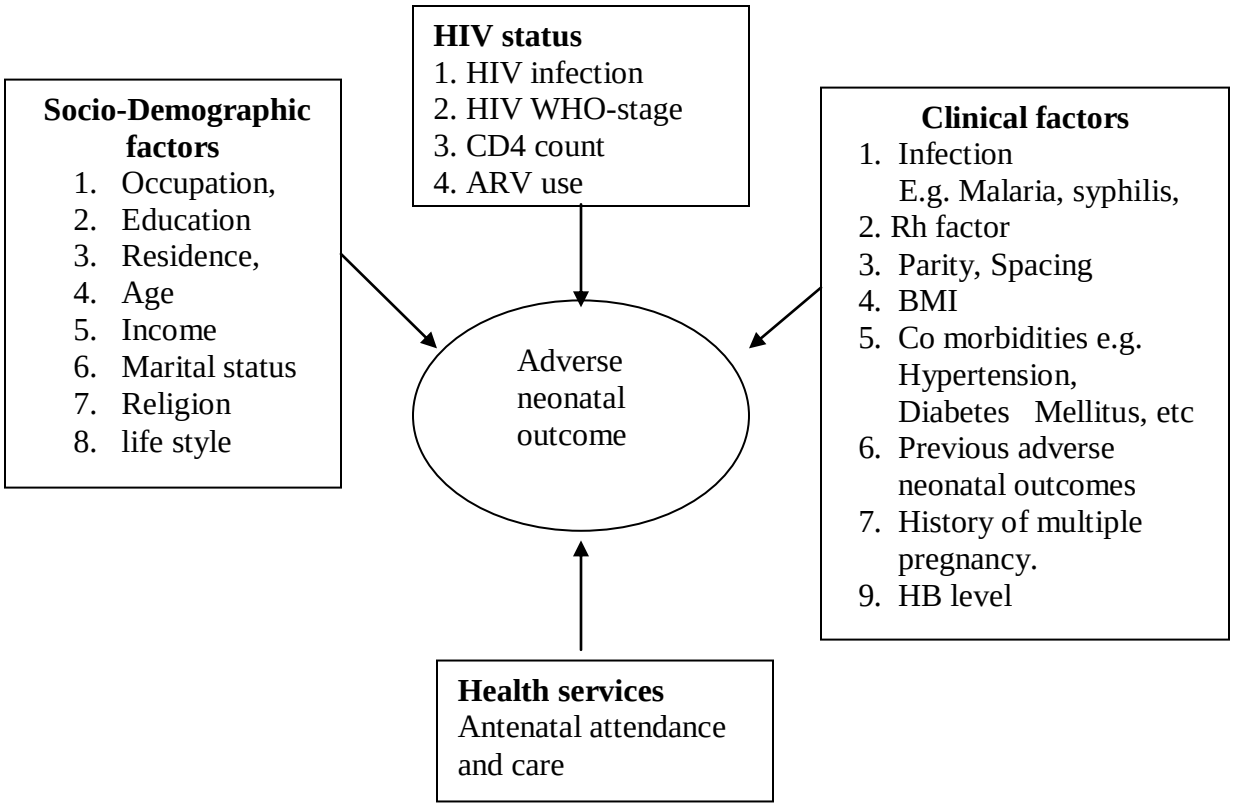
2.2. Significance

The fourth Millennium Development Goal (MDG-4) aspires to reduce under-5 years old child mortality and morbidity to by two thirds of present number by the year 2015. Tanzania through Government Development Vision links up with this MDG 4. Its strategy is to reduce the burden of infant mortality rates and morbidity by three thirds and increase life expectance through the improvement of health services to all people (26).

Although guidelines and policies on adverse neonatal outcomes and their association to HIV do exist in Ministry of Health of Tanzania, there is a gap in terms of implementation. We also do not know the extent of the burden of adverse neonatal outcome and its association with HIV infection among postnatal women at Mtwara Regional Hospital. Therefore there is a need to determine the prevalence of adverse neonatal outcome and its association with HIV infection among postnatal women in Mtwara Regional Hospital in Tanzania.

The findings from this study may be useful to reinforce the existing guidelines, complement the existing body of knowledge and may be used to generate the mechanism of implementing the policy that can cater for reduction of adverse neonatal outcomes particularly in HIV infected pregnant women so as to improve care. The information also can be used as a stepping stone for further studies.

2.3. FIGURE 1: CONCEPTUAL FRAMEWORK.



The scope of the study is to explore the prevalence of adverse neonatal outcome as the outcome variable and their association with HIV in postnatal women as the predictor variable by taking into consideration other factors. Other factors which are going to be considered are; demographic, social, health services and clinical factors however the study will focus on outcome of interest and on clinical factors.

2.4. Research Questions

2.4.1. Questions

1. What is the prevalence of adverse neonatal outcome among postnatal women in Mtwara Regional Hospital?
2. Is there an association between adverse neonatal outcome and HIV infection among postnatal women in Mtwara Regional Hospital?

2.4.2. Objectives of the study

2.4.2.1. General objective

The aim of the study was to establish the prevalence of adverse neonatal outcome and their association with HIV infection among postnatal women in Mtwara Regional Hospital

2.4.2.2. Specific objectives

1. To determine the prevalence of adverse neonatal outcome among postnatal women in Mtwara Regional Hospital
2. To establish the association between adverse neonatal outcome and HIV infection among postnatal women in Mtwara Regional Hospital.

2.4.3. Hypothesis

2.4.3.1. Null hypothesis

There is no association between adverse neonatal outcome and HIV infection among postnatal women in Mtwara Regional Hospital.

2.4.3.2. Alternative Hypothesis

There is association between adverse neonatal outcome and HIV infection among postnatal women among postnatal women in Mtwara Regional Hospital.

3.0. CHAPTER THREE

3.1. Methods

3.2. Study design

This was both descriptive and analytical cross sectional study on postnatal women that will be conducted at Mtwara Regional Hospital from January to March 2009/.

3.3. Study Setting

The study was conducted at Mtwara Regional Hospital Tanzania which it is located in remote southern part of Tanzania about 500km from Dar es salaam. Mtwara Region has five (5) districts and the hospital is responsible for all districts of Mtwara Region as the main referral hospital however it also responsible as the primary hospital for people living at Mtwara town. According to health system of Tanzania this Hospital was supposed to handle specialist services but due to limited resources no specialist services are being done. This hospital has generally limited standard of acre to the patients. It has bed capacity of 350 with 300 staffs. The obstetric unit serves about 20 deliveries per day. In this Hospital there is VCT service where all pregnant women attending the antenatal clinic are getting this service free of charge.

3.4. Population

3.4.1. Target Population

All postnatal women in catchment population of Mtwara Regional Hospital

3.4.2. Accessible population

All postnatal women period who attended at Mtwara Regional Hospital from 1st January to 31st March 2009.

3.4.3. Study Population

All postnatal women who attended at Mtwara Regional Hospital from 1st January to 31st March 2009 and meet selection criteria.

3.5. Selection Criteria

3.5.1. Inclusion

1. HIV tested postnatal women who attended at Mtwara Regional Hospital from 1st January to 31st March 2009 and provide informed consent to participate in the study.
2. Postnatal women who provided informed consent to check their HIV status if it was not tested before.

3.5.2. Exclusion Criteria

All post natal women who attended at Mtwara Regional Hospital with critical condition (terminally ill patients) such that they wont be able to communicate and participate the study.

3.6. Sampling Procedure

A consecutive sampling procedure was used for all post natal women who met selection criteria. All postnatal women who delivered in February were mobilized and encouraged to come back after 28 days when they were supposed to come for immunization. This was applied even to

those whose neonates died at home within the period. The assessment of the mother and the child was done on 28th day of life so as capture the whole neonatal period if any adverse neonatal outcome especially mortality has occurred. This gave a period prevalence of adverse neonatal outcome.

3.7. Sample size Estimation

For the prevalence of adverse neonatal outcomes

Using Kish and Leslie formula for sample size estimation

$$n = \frac{Z^2 \alpha / 2 \times P(1-P)}{D^2}$$

Where Zα/2 is the standard normal value at the 95% CI level = 1.96,

n is the sample size, D is the precision of 5%

P is the proportion of reported adverse neonatal outcome. Using 22.27% found in Tanzania by Deborah et al 2007.

Substituting in the formula above we get 266 subjects.

When using sample size for analytical studies:

Estimated sample size for two-sample comparison of proportions

Prevalence of adverse neonatal outcomes in HIV women is 10.7(13)

Prevalence of adverse neonatal outcomes in non HIV women is 3.2(13) Substituting in the formula:

n=[{z1-α*(p(1-p)(1/q2+1/q2)^½ + zβ*((1-p1)(1/q1)+p2(1-p2)(1/q2)^½}]^2/(p1-p2)^2

p1 = 0.1070, p2 = 0.0320, where

p1&p2=proportion of subjects expected to have the outcome in group 1&2 respectively

q1:q2 = 1:2 where q1=proportion of subjects in group 1, q2=proportion in group 2

Estimated required sample sizes: n1 = 160, n2 = 320

Assumptions: Z1-α/2 is the standard normal value at the 95%CI is 1.96 and Zβ is the standard normal value corresponding to (1-power) is (–0.84) at the 95% CI level

n is the sample size per group

We get 480 for both groups. Thus we are going to use that of analytical component formula for sample size estimation.

3.8. Measurements

3.8.1. Predictor Variables

HIV status (ELISA positive/capillus positive)

3.8.2. Potential Confounders

3.8.2.1. Social demographic factors of the mother :

Age, marital status, residence, Education level, income, Religion

3.8.2.2. social factors:

Life style (Smoking, Alcohol, drug abuse),

3.8.2.3. Health service factors

ANC attendance and care,

3.8.2.4. Clinical factors:

Any other infection e.g. Malaria, syphilis, Rh factor, CD4, HIV stage, Parity, Spacing, BMI, Co morbidities e.g. Hypertension, Diabetes Mellitus, etc. Previous adverse birth outcome history,

History of multiple pregnance(s), On ARV, used prophylaxis to protect the child during delivery if HIV positive, HB level during pregnancy.

3.8.2.5. Outcome variable

Adverse neonatal outcome (death, LBW, preterm delivery).

3.9. Data Collection, Management and Analysis

3.9.1. Data collection

In February the principal investigator (PI) and the research assistants (two doctors) enrolled postnatal women who met the selection criteria at antenatal wards. The postnatal women were asked for the informed consent and she with her child were assessed. The adverse neonatal outcome which could be picked at that time were noted. These were LBW, preterm delivery, mortality. The postnatal women were asked to come back after 28 days post delivery especially those whom their children died within the period as per MOH guideline. They were asked that so as to trace other adverse neonatal outcome which might have occurred during the whole neonatal period especially mortality. This gave period prevalence of adverse neonatal outcome. According to Ministry of Health of Tanzania schedule that day they are supposed to come for immunization. In March both the PI and research assistants assessed again both postnatal women and children for adverse neonatal outcome. Some of the children with mothers with HIV were not followed due to time limit. Data were collected by the PI and research assistants using the semi structured questionnaires. The questions were designed in English, translated in Swahili and back translation was done

3.9.2. Data Management

Data were checked daily for completeness, cleared, edited, coded and double entered in EPIDATA and then were exported to SPSS version12 for analysis. Backup of the data were done. Filled questionnaires were stored in a safe place.

3.9.3. Data Analysis

3.9.3.1. Univariate Analysis

Means, median, range and standard deviation were calculated for continuous variables. Histograms or pie chart were used to display the data. Frequencies and percentages were calculated for categorical variables. Prevalence of adverse neonatal outcome was obtained by computing percentage of adverse neonatal outcome among the entire sampled birth outcome.

3.9.3.2. Bivariate analysis

This was done to determine association between the HIV status as the main predictor and other various independent variables as the potential confounder and the outcome variable(adverse neonatal outcome). The categorical variables were analyzed using Chi square test or Fischer's exact test. $P < 0.05$ was considered significant. Odds ratios (OR) was the measure of association and confidence intervals (95% CI) were reported.

3.9.3.3. Multivariate Analysis

This was done to assess for interaction, confounding of the independent variables with respect to the main predictor. A difference of at least 10% between the adjusted odds ratio and the crude odds ratio was considered confounding. Factors with p-value 0.2 or less at bivariate analysis were selected for further multivariate analysis where by they were entered into logistic regression model for analysis using enter method method to determine the model that is best

explaining association between adverse neonatal outcome and HIV infection in post natal women.

3.9.3.4. Quality Control

1. Research assistants were trained.
2. Pre-testing the questionnaires and checking for their completeness was done daily.
3. Translation and back translation of questionnaires was done.
4. Back up of the data and filled questionnaires were stored in a safe place under lock and Key.
5. Meetings with research assistants were done to sort out data collection problems.

3.9.3.5. Ethical Consideration

1. Permission to conduct the study was sought from clinical epidemiology and biostatistics (CEU), Makerere University research and ethics committee (MUREC), National Institute for Medical Research Tanzania (NIMR), Health Research Ethics committee of Tanzania and Office of the Medical Officer in charge of Mtwara Regional Hospital.
2. Confidentiality of study subjects was ensured through the use of ID codes to conceal their identity.
3. Informed consent from subjects was sought and to the post natal women below 15 years l asked for special permission so as they are treated as emancipated minors so as they consent themselves
4. Informed consent for HIV testing was sought

4.0 CHAPTER FOUR

RESULTS

DESCRIPTION OF THE STUDY PARTICIPANTS

This study was conducted between February and March 2009 at Mtwara Regional Hospital southern part of Tanzania. This hospital serves as regional referral hospital. A total of 480 postnatal women were recruited into the study in order to assess for the prevalence of adverse neonatal outcome and establish its association with HIV infection in postnatal women. The semi structured questionnaires were used to collect the information. Of the 480 postnatal women 160 (33.3%) were those with HIV infection and the rest (66.6%) were those whose HIV results were negative. The 33.3% is not the expected prevalence of HIV. This happened because consecutive sampling procedure starting at birth and following the children to 28 days was not possible for a few mothers with HIV whom we sampled from the VCT clinics to ensure the number we wanted is achieved. This also gave unreal picture of prevalence of HIV in postnatal women.

SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS

The income of the postnatal women was skewed with a median of 2000 (range=38900) Tsh.

The participants were aged between 14 and 45 years. Their ages were normally distributed with a mean of 27.2 (SD=7.3) years as shown in Figure 2 below.

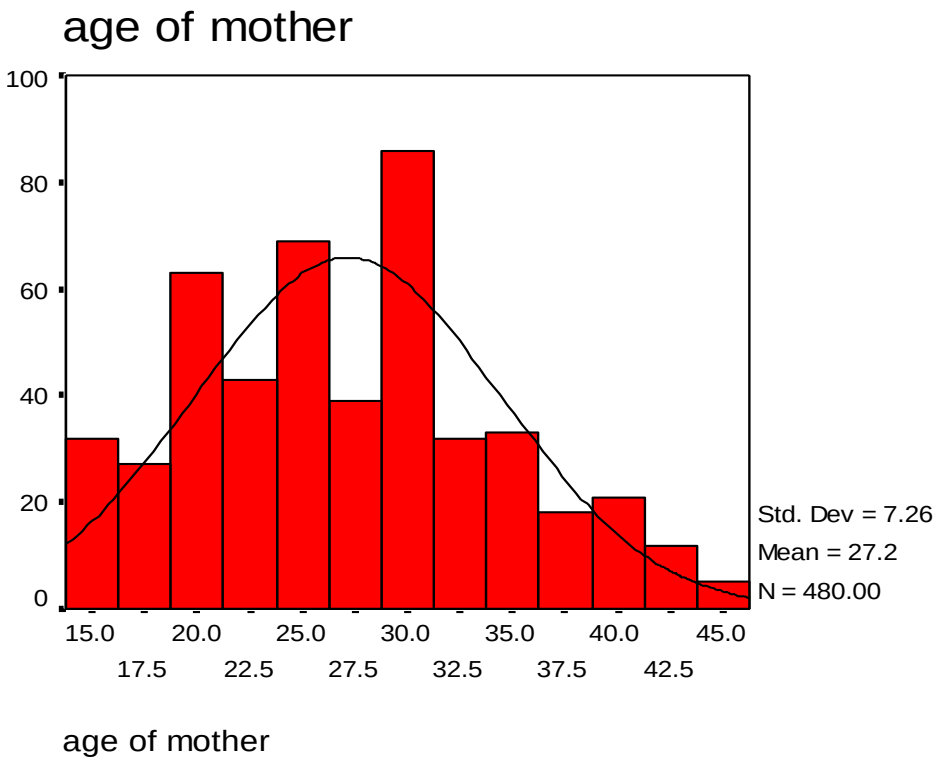


Figure 2: Age distribution of 480 postnatal women

Table.1. Baseline characteristics of the postnatal women (N=480)

Variable	Total (N=480)	Percent (%)
Marital status		
Married	324	67.5
Single	124	25.8
Separated	32	6.6
Residence		
Rural	147	30.6
Urban	333	69.4
Religion		
Christian	146	30.4
Muslim	334	69.5
Occupation of mother		
House wife	227	47.2
Business person	99	20.6
Salaried employee	53	11.04
Others	101	21.04
Education of the mother		
None	78	16.2
Primary	281	58.5
Secondary	96	20.0
Tertiary	25	5.2
Smoking		
Yes	23	4.7
No	457	95.3
Drinking alcohol		
Yes	129	26.9
No	351	73.1
Drug abuse		
No	480	100

The majority of respondents were married comprising (67.5%, n=324) of the participants. Out of a total of 480 participants, (66.6%, n=333) were living in urban areas and (30.6%, n=147) were living in rural areas. Of the 480 participants recruited into the study, (69.5%, n=334) were Muslims and the remaining (30.4%, n=146) were Christians. The majority of the participants (47.2%, n=227) were house wives. Many of the postnatal women had primary education (58.5%, n=281). A few of them smoked before, during and after pregnancy period were (4.7%, n=23) while majority (95.3%, n=457) did not. Postnatal women who drank alcohol before, during and

after pregnancy period were (26.9%, n=129). None of them took drug of abuse. Details on socio-demographic characteristics are shown in Table 1 above.

Table.2. Socio demographic characteristics comparison of postnatal women with HIV positive (n=160)and HIV negative(n=320)

Characteristics	HIV-positive n(%)	HIV-negative n(%)	p value
marrital status			
Married	117(36.1)	207(63.9)	
Single	30(24.2)	94(75.8)	0.001
Separated	13(40.6)	19(59.4)	
Age			
<19	18(23.7)	58(76.3)	
19-35	121(35.6)	219(64.4)	0.001
36+	21(32.8)	43(67.2)	
Religion			
Christian	52(35.6)	94(64.4)	0.001
Muslim	108(32.3)	226(67.7)	
Residence			
Rural	49(33.3)	98(66.7)	0.001
Urban	111(33.3)	222(66.7)	
Occupation mother			
House wife	88(38.8)	139(61.2)	
Business person	33(33.3)	66(66.7)	0.001
Salaried employee	14(26.4)	39(73.6)	
Others	25(24.8)	76(75.2)	
Education mother			
None	22(28.2)	56(71.8)	
Primary	101(35.9)	180(64.1)	0.001
Secondary	27(28.4)	68(71.6)	
Tertiary	10(38.5)	16(61.5)	
Income			
≥1usd	45(27.8)	117(72.2)	0.001
<1usd	115(36.2)	203(63.83)	
Smoking			
Yes	7(30.4)	16(69.6)	0.001
No	153(33.6)	304(66.5)	
Drinking alcohol			
Yes	55(42.3)	75(57.7)	0.001
No	105(30)	245(70)	

Socio demographic characteristics comparison of postnatal women with HIV positive and HIV negative

It was noted that there was general significant difference with p- value < 0.001 among the socio demographic characteristics of those postnatal women with HIV infection and those who were not HIV infected. The details of those differences are shown in the table 2 above.

Description of HIV status of the postnatal women

In this study we had (33.3 %, n=160) HIV infected postnatal women of whom (50%, n=80) were in WHO-stage 1 and the rest were in other three stages. The majority of the postnatal women used prophylaxis during delivery (59.4%, n=95), (18.8%, n=30) were using ARVs drugs and the rest didn't use any medicine. Of the 160 postnatal women (95%, n=152) had CD4 count more than 300 counts. Table 3 below has the detail.

Table 3. Description of HIV status of the postnatal women (n=160)

	HIV status	Total (n)	percent(%)
HIV results	HIV positive	160	33.3
	HIV negative	320	66.6
WHO stage of HIV	I	80	50
	Ii	58	36.3
	Iii	19	11.9
	Iv	3	1.8
Use ARVs drugs	Prophylaxis	95	59.4
	on usual ARVs	30	18.8
	Non	35	21.8
CD4 counts	300	8	5.0
	301+	152	95.0

PREVALENCE OF ADVERSE NEONATAL OUTCOME

The prevalence of adverse neonatal outcome was determined by considering the three levels of neonatal outcome that is neonatal death, low birth weight and preterm delivery. Most of the neonatal outcome were due to neonatal death (taking together intrauterine, intrapartum and post delivery death) 15% (74/480), low birth weight and preterm delivery was 13% (60/480) and 7% (35/480) respectively. The overall prevalence of adverse neonatal outcome (neonatal death, low birth weight and preterm delivery) was 28% (132/480) with 95% CI= (24.0-32.0). Details are as shown in Figure 4 below.

Table 4. Prevalence (descriptive) of adverse neonatal outcome

Adverse neonatal outcome	Frequency	Prevalence	95% CI
Overall	132	0.28	0.24-0.32
Still birth	24	0.05	0.03-0.07
Died during birth	15	0.03	0.01-0.05
Died after birth	35	0.07	0.06-0.12
Preterm	43	0.09	0.05-0.09
Low birth weight	60	0.13	0.10-0.16

Contribution of various levels to the general adverse neonatal outcome prevalence

Death was the leading adverse neonatal outcome with 56%, (74/132) followed by low birth weight 45%, (60/132). The least was preterm delivery with 32.5%, (43/132). The detail is indicated on table 5 below.

Table 5. Contribution of various levels to the general adverse neonatal outcome

Contribution of various levels to the overall adverse neonatal outcome		
Various levels	Frequency(n)	Percentage %
Died after birth	35	26.5
Died during birth	15	11.3
Still birth	24	18.1
Preterm	43	32.5
Low birth weight	60	45.4
Overall adverse neonatal Outcome	132	100

Table 6: Prevalence of adverse neonatal outcome at various demographic characteristics

Characteristic	Frequencies (n)	Prevalence	95% CI
Occupation of mother			
House wife	65	13.5%	10.4-16.6
Husiness person	25	5.2%	3.2-7.2
Salaried employee	13	2.7%	1.3-4.2
Others	29	6.0%	3.9-8.1
Residence			
Rural	51	10.6%	7.8-13.4
Urban	81	16.9%	13.5-20.3
Age			
< 19	22	4.6%	2.7-6.5
19-35	79	16.5%	13.2-19.8
36+	31	6.5%	3.2-9.8
Education			
Non	29	6.0%	3.9-8.1
Primary	69	14.4%	11.3-17.5
Secondary	30	6.3%	4.1-8.5
Tertiary	4	0.8%	0.4-1.2
marital status			
Married	87	18.1%	14.7-21.5
Single	34	7.1%	4.8-9.4
Separated	11	2.3%	1.6-3.0
Religion			
Christian	48	10.0%	7.3-12.7
Muslim	84	17.5%	14.1-20.9

Prevalence of adverse neonatal outcome among house wives was high 13.5% (65/480) compared with other postnatal women having different occupation. Those who lived in urban area had high

prevalence 16.9% (81/480) than those of rural area. The prevalence was higher in group 19-35 of age 16.5% (79) than in other age groups whereas those who were married had higher prevalence 18.1% (87) than single. The detail is as shown in figure 6 above

ASSOCIATION BETWEEN INDEPENDENT VARIABLE(S) AND ADVERSE NEONATAL OUTCOME

Bivariate analysis was done to determine association between the HIV status as the main predictor and other various independent variables as the potential confounders with respect to the outcome variable (adverse neonatal outcome). Adverse neonatal outcome was considered as the neonatal death including intrauterine, low birth weight and preterm delivery.

Bivariate analysis of HIV infection and adverse neonatal outcome

Those postnatal women with HIV infection (OR=3.09, CI 0.21-4.7) were more likely to get adverse neonatal outcome compared to non HIV infected. The risk of getting adverse neonatal outcome in HIV positive postnatal women in various levels were higher (OR=1.74, CI 0.7-3.9) stillbirth, (OR=2.35, CI 0.8-6.6) intrapurtum death,(OR=2.01, CI 1.01-4.1)died after delivery, (OR=2.82, CI 1.4-5.3)preterm delivery and (OR=3.92, CI 2.2-6.9) than in HIV negative postnatal women . Results for association between HIV infection in postnatal women and adverse neonatal outcome is indicated in Table 7 below

Table 7. Bivariate analysis of HIV infection and adverse neonatal outcome (N=480)

HIV-status	Adverse neonatal outcome No n(%)	Yes n(%)	OR	CI	p-value
	Overall				
HIV positive	91(56.87)	69(43.12)	3.09	2.1-4.7	0.001
HIV negative	257(80.31)	63(19.68)	1		
	Still birth				
HIV positive	149(93.10)	11(6.90)	1.74	0.7-3.9	0.187
HIV negative	307(95.90)	13(4.10)	1		
	Died during birth				
HIV positive	152(95.00)	8(5.00)	2.35	0.8-6.6	0.105
HIV negative	313(97.80)	7(2.20)	1		
	Died after birth				
HIV positive	142(89.30)	17(10.70)	2.02	1.01-4.1	0.045
HIV negative	302(94.40)	18(5.60)	1		
	Preterm				
HIV positive	135(84.90)	24(15.10)	2.82	1.4-5.3	0.001
HIV negative	301(94.10)	19(5.90)	1		
	Low birth weight				
HIV positive	122(76.70)	37(23.30)	3.92	2.2-6.9	0.001
HIV negative	277(92.80)	23(7.20)	1		

Description of the relation of HIV infected postnatal women and adverse neonatal outcome (N=160)

Those who were in WHO stage ii, iii and iv were (OR=2.87, CI 1.4-5.8), (OR=3.21, CI1.1-8.9) and (OR=4.71, CI 0.4-5.9) respectively more likely to get adverse neonatal outcome than those of stage i. Those who used usual ARVs drugs and who didn't use any drug were (OR=2.35, CI 1.02-5.4) and (OR=1.05, CI 0.4-2.3) more likely to get adverse neonatal outcome respectively than those who used prophylaxis during delivery. Postnatal women who had CD4 count less than300 counts were (OR=1.34, 0.3-5.6) more likely to get neonates with adverse outcome than those with CD4 counts above 300 counts. These results are displayed on the table 8 below.

Table 8: Description of the relation of HIV infected postnatal women and adverse neonatal outcome (n=160)

	Adverse neonatal outcome				
Variable	**No n(%)**	**Yes n(%)**	**OR**	**CI**	**P value**
WHO stage					
I	56(70.00)	24(30.00)	1		
Ii	26(44.82)	32(55.17)	2.87	1.4-5.8	0.003
iii	8(42.1)	11(57.89)	3.21	1.1-8.9	0.026
Iv	1(33.33)	2(66.66)	4.71	0.4-5.9	0.217
use ARVs drugs					
Prophylaxis	58(61.05)	37(38.94)	1		
on usual ARVs	12(40)	18(60)	2.35	1.02-5.4	0.046
Non	21(60)	14(40)	1.05	0.4-2.3	0.913
cd4 counts					
≤300	4(50.0)	4(50.0)	1.34	0.3-5.6	0.688
301+	87(57.24)	65(42.76)	1		

Bivariate analysis of sociodemographics and adverse neonatal outcome

Postnatal women who lived at rural areas were (OR=1.65, CI 1.1-2.5) more likely to get a neonates with adverse outcome than those who lived in urban. Those who drank alcohol were (OR=1.85, CI 1.2-2.9) more likely to get neonates with adverse neonatal outcome than those who did not. Both of the above were statistically significant.

Those with no education, primary and secondary levels were (OR=3.1, CI 0.9-9.9) , (OR=1.7 CI 0.5-5.1) and (OR=2.3, 0.7-7.5) respectively more likely to have adverse neonatal outcome compared to who had tertiary level of education. However the relation was not statistically significant. Other sociodemographic characteristics which were not significantly associated with adverse neonatal outcome were age (post natal women aged 18-35 years were OR=0.54, CI 0.2-1.04 less likely to get neonates with adverse outcome than postnatal women of <19 and ≥36 years), low income (those who had spent below a dollar a day) were (OR=1.36, CI 0.8-2.1) than

those who had above a dollar, marital status (being single and separated OR=1.03, CI 0.6-1.6 and OR=1.43, CI 0.6-3.1 versus being married respectively), religion (being Muslim OR=0.69 CI 0.4,1.04 versus Christian), smokers were (OR=1.75, CI 0.7-4.1) than non smokers, postnatal women who were doing business, employed and others were (OR=0.84, CI 0.4-1.4), (OR=0.89, CI0.4-1.7) and (OR=0.95, CI 0.5-1.6) respectively than housewives. Details of sociodemographic characteristics are also present in the table 9 bellow

Table 9. Bivariate analysis of sociodemographics and adverse neonatal outcome (N=480)

Variable	Adverse neonatal outcome No n(%)	Yes n(%)	OR	CI	P value
Education of mother					
Non	49(62.82)	29(37.18)	3.10	0.9-9.9	0.050
Primary	212(75.44)	69(24.56)	1.70	0.5-5.1	0.300
Secondary	66(68.75)	30(31.25)	2.30	0.7-7.5	0.100
Tertiary	21(84)	4(16.00)	1		
Occupation of mother					
House wife	162(71.40)	65(28.60)	1		
Husiness person	74(74.70)	25(25.30)	0.84	0.4-1.4	0.530
Salaried employee	39(73.60)	14(26.40)	0.89	0.4-1.7	0.750
Others	73(72.30)	28(27.70)	0.95	0.5-1.6	0.860
Age					
<18	29(64.40)	16(35.60)	1		
18-35	286(71.10)	85(22.90)	0.54	0.4-1.3	0.065
≥36	33(51.60)	31(48.40)	1.70	1.1,1.6	0.183
Marital status					
Married	237(73.15)	87(26.85)	1		
Single	90(72.58)	34(27.42)	1.03	0.6-1.6	0.904
Separated	21(65.63)	11(34.38)	1.43	0.6-3.1	0.365
Residence					
Rural	96(65.30)	51(34.70)	1.65	1.1-2.5	0.020
Urban	252(75.70)	81(24.30)	1		
Religion					
Christian	98(67.12)	48(32.88)	1		
Muslim	250(74.85)	84(25.15)	0.69	0.4-1.04	0.080
Income					
≥1usd	124(76.54)	38(23.45)	1		
<1usd	224(70.44)	94(29.55)	1.36	0.8-2.1	0.158
Smoking					
Yes	14(60.86)	9(39.13)	1.75	0.7-4.1	0.206
No	334(73.08)	123(26.91)	1		
drinking alcohol					
Yes	82(63.07)	48(36.92)	1.85	1.2-2.9	0.005
No	266(76.00)	84(24.00)	1		

Association between the clinical conditions, hospital services and adverse neonatal outcome

Postnatal women who had experienced diseases like malaria during pregnance were (OR=2.11, CI1.3-3.3) more likely to get adverse neonatal outcome than those who did not. Those who had history of multiple pregnancy were (OR=2.71, CI 1.3-5.4) more likely to get adverse neonatal

outcome than their counterpart. It was found those who had prior history of adverse neonatal outcome were (OR=3.17, CI 1.9-5.1) more likely to get adverse neonatal outcome than those who had not. All the above association were statistically significant.

Postnatal women with high blood sugar were (OR=2.7, 0.9-8.6) were not significantly associated with adverse neonatal outcome. Those who had history of STI (OR=1.61, CI 0.5-4.5), rhesus factor positive (OR=1.01, CI 0.2-3.8) and those who had more than three pregnancy (OR=1.6, CI 1.3-5.1) were all not significantly associated with adverse neonatal outcome. This information is shown in table 10 (a) below.

Table 10 a: Association between the clinical conditions, hospital services and adverse neonatal outcome (N=480)

clinical condition	Adverse neonatal outcome No n(%)	Yes n(%)	OR	CI	P value
blood sugar					
Normal	342(73.07)	126(26.92)	1		
High blood sugar	6(50)	6(50)	2.71	0.9-8.6	0.089
rhesus factor					
Negative	340(72.4)	129(27.50)	1		
Positive	8(72.7)	3(27.27)	1.01	0.2,3.8	0.986
STI					
Yes	10(62.5)	6(37.5)	1.61	0.5-4.5	0.366
No	338(72.8)	126(27.2)	1		
Malaria & other infections during pregnancy.					
Yes	63(60)	42(40)	2.11	1.3-3.3	0.001
No	285(76)	90(24)	1		
pregnancy number					
<4	284(74.5)	97(25.4)	1		
≥4	64(64.6)	35(35.3)	1.6	0.9,2.6	0.051
history of multiple pregnancy					
Yes	18(51.4)	17(48.5)	2.71	1.3-5.4	0.005
No	330(74.1)	115(25.8)	1		
history of prior adverse neonatal outcome					
Yes	46(13.2)	43(32.5)	3.17	1.9-5.1	0.001
No	302(86.7)	89(67.4)	1		

Association between the clinical conditions, hospital services and adverse neonatal outcome continue (N=480) continue

Postnatal women with high blood pressure (OR=2.58, 1.1-5.8) were more likely to get adverse neonatal outcome than those with normal blood pressure with statistical significant. Postnatal women with BMI more than twenty five were (OR=1.07, CI 0.7-1.6) more likely to have the adverse neonatal outcome. Those who didn't attend at ANC during pregnancy (OR=2.14, CI 0.5-8.1), were not significantly associated with adverse neonatal outcome. Those who had HB less than 8.5 were (OR=1.43, CI 0.9-2.1), not significantly associated with adverse neonatal outcome. Postnatal women who spaced pregnancies less than 3 years were (OR=0.7, CI 0.5-1.2) less likely to get adverse neonatal outcome than those who spaced below 3 and (OR=1.2, CI 0.6-2.3) more likely to get adverse neonatal outcome than those who spaced below 3. Table 10 (b) below has more information.

Table 10 b: Association between the clinical conditions, hospital services and adverse neonatal outcome continue (N=480)

	Adverse neonatal outcome				
variable	**NO n(%)**	**Yes n(%)**	**OR**	**95%CI**	**P value**
attending antenatal clinics					
Yes	343(72.82)	128(27.17)	1		
No	5(55.55)	4(44.44)	2.14	0.5-8.1	0.267
Spacing					
<3	130(70.6)	54(29.4)	1		
3_5	145(75.1)	48(24.9)	0.7	0.5-1.2	0.305
>5	72(70.6)	30(29.4)	1.2	0.6-2.3	0.575
BMI					
<25	249(71.8)	98(28.2)	1		
≥25	70(72.9)	26(27.1)	1.07	0.7-1.6	0.751
BP					
<140/90	335(73.6)	120(26.4)	1		
≥140/90	13(52)	12(48)	2.58	1.1-5.8	0.023
Hb					
</=8.5	147(68.7)	67(31.3)	1.43	0.9-2.1	0.080
>8.5	201(76.6)	65(24.4)	1		

RESULTS FROM THE MULTIVARIATE ANALYSIS

Variables considered for multivariate were those with a p-value <0.2 at bivariate analysis and these included age, education, residence, religion, alcohol drinking, blood sugar, other diseases, pregnancy number, history of adverse neonatal outcome, income, Blood Pressure, history of multiple pregnancy and Haemoglobin level

The final multivariate analysis was performed taking into account the biological knowledge about independent variables and how they relate with the adverse neonatal outcome. Under multivariate analysis it was found postnatal women who were HIV positive were more likely to get neonates with adverse outcome (OR 3.6, 95% CI=2.2-5.7). HIV infection was independently associated with neonatal adverse outcome after testing for interaction and controlling for confounders. Other factors which independently associated with adverse neonatal outcome were History of adverse neonatal outcome in prior pregnancy (OR=2.64, CI 1.5-4.5), history of other diseases during pregnancy e.g. malaria (OR=2.64 CI, 1.6-4.5) and residence in rural area (OR=1.75, 1.05-2.9).

The factors which were confounders of HIV infection were drinking alcohol (OR=1.69, CI 1.01-2.9), non education (OR=4.68, CI 1.2-17.8), and high blood pressure (OR=2.29, CI 0.9-5.9). The information is summarised in table 12 below

Table 11: Multivariate Logistic regression for adverse neonatal outcome

Variables	OR	95.0% CI OR	P value
HIV status			
HIV positive	3.6	2.2-5.7	0.001
HIV negative	1		
Alcohol drinking			
Yes	1.69	1.01-2.9	0.046
No	1		
Residence			
Rural	1.75	1.05-2.9	0.032
Urban	1		
Education			
Non	4.68	1.2-17.9	0.025
Primary	2.5	0.7-8.6	0.146
Secondary	3.4	0.9-11.9	0.060
Tertiary	1		
Hypertension			
≥ 140/90	2.29	0.7-5.9	0.374
< 140/90	1		
History of prior adverse neonatal outcome			
Yes	2.64	1.6-4.8	0.001
No	1		
Malaria & other infections during pregnancy.			
Yes	2.64	1.5-4.4	0.001
No	1		

5.0 CHAPTER FIVE

DISCUSSION

This is the first cross sectional study carried out at Mtwara Regional Hospital Tanzania on prevalence of adverse neonatal outcome and association with HIV infection in postnatal women. Tanzania is among the African countries constituting 50% of Africans' newborn death and neonatal morbidities being high (10). This study gives data on prevalence of adverse neonatal outcome and association with adverse neonatal outcome at Mtwara Regional Hospital Tanzania. The results show the prevalence is high and HIV infection is significantly associated with adverse neonatal outcome even after adjusting for potential confounders.

PREVALENCE OF ADVERSE NEONATAL OUTCOME

In every hundred postnatal women in Mtwara Regional Hospital about thirty four were HIV postive. The 33.3% is not the expected prevalence of HIV in this area. This happened because consecutive sampling procedure starting at birth and following the children to 28 days was not possible for a few mothers with HIV whom we sampled from the VCT clinics to ensure the number we wanted is achieved. This gave unreal picture of prevalence of HIV in postnatal women.

The overall prevalence of adverse neonatal outcome is high among postnatal women of Mtwara regional hospital as in every ten postnatal women at least 3 is having one or more adverse neonatal outcome. If we consider it in levels we found fifteen new born out of hundred died

including the IUFD, nine out of hundred were preterm delivery and thirteen out of hundred were LBW.

These findings happened to be lower than that found by Joy Lawn et al. They found there was Newborn deaths occurring in the first 28 days of life account for 38 percent of all child deaths under age 5 years and it was estimated that each year 4 million children die in the neonatal period—a global average of 30 neonatal deaths per 1000 live births(2, 7).

The prevalence of adverse neonatal outcome in this study is also lower compared to that which was carried out at King Fahad and showed the perinatal mortality rate was 34.9% (65/186)(8). Another study from Guatemala found among 671 infants born in 4 rural ladino villages,15.2% had low birth weights . The mean birth weight in the famous longitudinal study on the children of Santa María Cauqué by Mata was 2549 ± 383 g, with a prevalence of LBW of 41.3% among 415 live, singleton births [(9)].

This variability between findings can be explained by the differences in the study settings. For example the study which was carried out at the latino villages (in the community) got the real picture compared to this study which was conducted at the hospital setting where majority of women are not using the health facilities.

Probably majority or all women in the setting of King Fahad Hospital were delivering in the hospital as opposed to ours where by majority of women still deliver at home hence you can't capture the entire neonatal adverse outcome.

The variability might also be brought by difference in study designs. Joy E did meta analysis from several multi centres (these multi centres used cohort and case control studies) to get the global average of neonatal mortality. In this study we used cross sectional study in a single hospital centre.

This prevalence is likely to be an underestimate as the hospital and other infrastructures around the region where we got our sample is not as equipped as hospitals where other studies were conducted. In our hospital for example roads, means of transport and people themselves are too poor for them to get access to the available hospital services and at times when they go to the hospital no services available. This led majority to decide delivering at home limiting the true picture of adverse neonatal outcome. We also used a very short time to get our small sample size compared to others. This might as well lead to getting underestimate prevalence. On the other hand the prevalence of adverse neonatal outcome in Mtwara Regional Hospital might be overestimated. The over estimation might be due to the fact that the study was conducted at a large tertiary care centre were the hospital is getting complicated cases which are referred from lower centres.

Some studies took a range of levels to represent adverse neonatal outcome, others took only one. In this study we have used three levels. This can also explain the disparity.

The consecutive sampling procedure starting at birth and following the children to 28 days was not possible for a few mothers with HIV whom we sampled from the VCT clinics to ensure the

number we wanted is achieved. This also gave unreal picture of prevalence of adverse neonatal outcome.

In spite of all these set backs, our results are valid and hold as research assistants were trained on how to capture the information regarding the adverse neonatal outcome, No postnatal women in critical condition was met and so there was no exclusion of some HIV positive women, who may potentially have had adverse neonatal outcome. Hence these results can be generalised to the target population.

ASSOCIATION BETWEEN HIV INFECTION AND ADVERSE NEONATAL OUTCOME

The magnitude at which HIV infection increases the risk of adverse neonatal outcome is alarming. Tanzania is having an epidemic of HIV which is increasing in spite of the government's struggle to decelerate it. The prevalence of adverse neonatal outcome on the other hand continues to increase as well.

Bloland et al showed the association between HIV and adverse neonatal outcome does exist in their research findings(14). Brent et al also have shown maternal HIV status affects new born survival by causing an increased risk of morbidity and mortality in uterus or in the neonatal period. The interaction of HIV with other infections and the indirect effects of HIV such as poverty and maternal illness, malnutrition, also contribute to adverse neonatal outcome.

HIV infection in the pregnant mother may also result in being transmitted to the foetus and cause mortality and severe morbidity and even among those babies who do not become positive may

be affected by the same way due to the fact that that their mothers are affected and cant provide the necessary nutrition and other supplements to the foetus(3).

This study is in keeping with those past results of studies done in other places in Africa and the rest of the world. In this study it was found postnatal women with HIV infection had a higher (about four times) risk of getting the neonate with adverse neonatal outcome than among postnatal women of no HIV infection. Other studies have found the association to be almost the same as this, for instance in Kenya and Malawi where it was found IPD was associated with HIV infection five times more(OR = 5.1 p = .0002), than those who were HIV negative (13).

On the other hand our study found the risk to be higher than what was found in the study conducted at Kagera Region in Northern Tanzania by Coley I et al. They had found the risk of adverse neonatal outcome among HIV-infected women were about two more likely to have severe immature infants (<34 weeks) than HIV-uninfected women. There was a significantly higher risk also about two times more of getting neonates with low birth weight (RR 2.29, P = 0.03) and prematurity (<37 weeks) (RR 1.93, P = 0.0003) among symptomatic HIV-infected women when compared with HIV-uninfected women(15).

The explanation of these disparities can be because those studies were carried out long time ago when the prevalence of HIV were not at the same rate as of now due to lack of drugs which prolong life in HIV patients. The current pregnancy women Prevalence in HIV in Tanzania is 4-32(5). This might explain the risk we have got to be more than other studies.

The disparity may also be because of the different setting. This study was conducted in the hospital with resource limited where there is poor antenatal, intrapaturm, and postnatal care rendering increased adverse neonatal outcome especially in HIV infected patients. The other studies were conducted in the hospital with low adverse neonatal outcome even in HIV infected women. This may be as a result of the good services offered by the hospital explains the low risk in their findings.

Difference in the target population might have led to disparity as well. Our study looked at all the infected postnatal women while the study by Coley I et al looked at HIV infected women with symptoms. Those having symptoms are less likely to be pregnant and this might be the reason of their small risk between HIV infection and adverse neonatal outcome.

The disparity can also be brought about by the different ways we used in measuring our outcome of interest. In our study we based on clinical findings as opposed to some studies where they used high technology to assess their outcome like ultrasound to assess IUFD, echocardiogram to assess cardiac anomalies, etc. Some studies took a range of levels to represent adverse neonatal outcome, others took only one. In this study we had used three levels. These might bring differences affecting our results in terms of precision and validity.

Some variables also were found to independently associated with adverse neonatal outcome. Postnatal women who lived rural areas were more likely to get neonates with adverse outcome and the association was statistically significant, (OR=1.68, 95% CI=1.01-2.8), the statistical significance might be explained by the fact that those living in rural area lack some health services. They are having poor health seeking behaviour and they do a lot of vigorous work during pregnancy. They may fall sick and they neither treat it completely nor do they delay to

treat it. This relationship can explain the relationship of living in rural areas and adverse neonatal outcome.

Postnatal women with history of other diseases like malaria were (OR=2.52, CI 1.4-4.3) more likely to get adverse neonatal outcome than those who did not. During pregnancy several diseases do compromise the development of newly developing foetus as the immunity of the mother and the child is low. Eduardo Villamor et al found malaria in HIV pregnancy women increases the risk of neonatal adverse outcome by about two to three folds(20).

Postnatal women with history of previous history of adverse neonatal outcome were (OR=2.64, CI 1.5-4.5) more likely to get adverse neonatal outcome than those who had not. This is probably the factor which caused the previous adverse neonatal outcome still persists. This can be any cause of adverse neonatal outcome like HIV, malaria, high blood pressure etc.

Other variables were found to be confounders to the main predictor HIV infection. We found a significant association between education and neonatal adverse outcome. Non education as compared with tertiary education (OR 4.68, 95% CI=1.2-17.9) had increased risk of getting neonates with adverse outcome. This can be explained by their lack of knowledge of health behaviour living and difficult for them to follow the instructions of medical personnel. Like those who live in the rural area, non educated people also tend to have poor health seeking behaviour even those with HIV infection leading to increased adverse neonatal outcome.

Postnatal women with high blood pressure were more likely (OR=2.29, CI 0.7-5.9) to get the neonate with adverse outcome. In our findings high blood pressure was not statistically significant. This can be explained by the small proportion of those with high blood pressure. Biologically it is known and other studies have showed it. Lucy C found women with high blood pressure has three times more risk of getting neonates with adverse neonatal outcome than those with normal blood pressure(27)

Alcohol drinking has been found to be associated with adverse neonatal adverse outcome in this study as a confounder. Studies elsewhere have found alcohol is a risk factor to getting adverse neonatal outcome. Those who drink alcohol are prone to be infected with HIV, malnourished, neglecting health instructions, etc and hence increase the adverse neonatal outcome.

The interacting variables and the confounders were controlled in the modelling of data in the logistic regression. Hence in spite of these limitations which we encountered in this study our findings hold and valid to be generalised to the target population.

LIMITATIONS OF THE STUDY

Selection of Regional hospital as study site could have affected the prevalence of adverse neonatal outcome and by underestimating the risk as it would be, if the study was done in lower levels of health care delivery system such as in the district hospitals, health centres and dispensaries where the number and level of staffing are basically low and where many pregnant mothers are getting service in Tanzania.

Selection bias could have affected the accuracy of the data collected as the participants were sampled from hospital. This might have lead to underestimation of the prevalence of adverse neonatal outcome as majority of mothers are serviced in lower levels of health delivery and indeed many deliver at home. Improved data collection with use of knowledgeable trained research assistants (Medical officers) and rigorous follow up of research assistants through regular meetings, and supervision may have helped on the validity of reporting of risk of adverse neonatal outcome.

Limited fund and time of study hindered doing a big and strong study like cohort design with big sample size hence power of the study probably was not enough to give the realistic results as we had three levels of the outcome.

Despite of these limitations, our findings are valid to be generalised to the target population.

6.0 CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- This study has found postnatal women in Mtwara regional hospital are at high risk of getting newborns with adverse outcome. Three in every ten postnatal women have a risk of getting a newborn with at least one adverse outcome in a year.

- Postnatal women of Mtwara Regional Hospital with HIV infection are at four times more risk of getting newborn with adverse outcome as compared to non infected ones.

RECOMMENDATIONS

Ministry of Health and Social Welfare of Tanzania, Hospital managements, Local governments and other stakeholders of Mtwara Region should:

- Strengthen and implement all the policies and guidelines on mother and child health care so as to reduce adverse neonatal outcome
- Mothers with HIV infection should be given a special care. They should all deliver at hospital and take their prophylaxis in front of the medical personnel
- We recommend further studies to explore on extent of adverse neonatal outcome knowledge, experience, perception and attitude of postnatal women towards the health workers and health facilities and other unexplored variables pertaining to adverse neonatal outcome.

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8.0. APPENDIX I QUESTIONNAIRES

Participant ID No. ……. Date of interview ……

Name of the interviewer ……...

MOTHER

1. Demographic characteristic factors

a. Age of the mother…… (years)

b. Marital states

i) Single ii) Married iii) Separated

c. Religion

i) Christian ii) Moslem iii) others specify …….

d. Residence

i) Rural ii) urban iii) other areas. Specify…….

e. Level of Education of the mother

i) None ii) Primary iii) Secondary iv) Tertiary

f. Level of education of the /spouse/partner

i) None ii) Primary iii) Secondary iv) Tertiary

g. Occupation of the mother

i) House wife ii) Business person iii) Peasant farmer

iv) Salaried Employee v) Student iv) Others (specify)

h Occupation of the spouse/partner

i) Business person ii) Peasant farmer

iii) Salaried Employee iv) Student v) Others (specify)

i. What is your average income per day in Tsh?. ……

2. Heath habitats (life style) factors

a. Do you smoke? i) Yes ii) No

b. If yes, how many sticks a day? ……....

c. Do you drink alcohol? i) Yes ii) No

d. What type of alcohol?.....

e. How frequent? ……..

f. Ever used drug of abuse during pregnancy? i)yes ii) No

g. How frequent?.....

h. Have you been attending antenatal clinics? i) Yes ii) No

i. Did you attend all the appointments? i). Yes ii) No

j. if no, how many times……

k. What was mode of delivery?

i. normal vertex delivery ii. C/S

iii. vacuum delivery iv. Other (specify)……

l. if hospital, which one? i.District hospital ii.Reginal Hospital

3. HIV test result

i) Reactive ii) Non reactive iii) Non – specific

4. Clinical factors

a. cd4 count level if HIV test is reactive……

b. If HIV reactive, do you use(d) ARV drugs

i) prophylaxis ii) on usual ARVs iii) non

c. What is the WHO stage of HIV? i. I ii. II iii. III iv. IV

d Weight of the mother……

e Height of the mother……

f. BMI…….

g. Blood group of the mother i) A ii) B iii) O iv) AB

h. Rhesus factor i) positive ii) Negative

i. average HB level during pregnancy…….

j. Blood pressure…….

k. Blood Sugar results……..

l. Other co morbidities. Specify…….

m. Have you ever had an STI? i.) Yes ii) No

n. if yes which disease

i) gonorrhea ii) syphilis iii) others specify……

o. Ever been experienced fever during pregnancy? i) Yes ii) No

p if yes did you use any medicine? I) yes ii) no

q. had you ever been admitted during antenatal period? i) Yes ii) No

r If yes what was cause of admission

i) Malaria ii) others mention……

s did you loose weight during antenatal period? i)yes ii) no

t. How many times have you been pregnant ?.....

u. if more than one pregnancy, what is the time between them?.....

v. Ever used family planning? i) Yes ii) No

w Any history of multiple pregnancy? i. Yes ii. No

x If yes how many times?.....

y Any history of previous adverse perinatal outcome? i. yes ii. No

z If yes how many times?.....

CHILD

a. What is/was the condition of the baby?

i. apparently normal ii. not normal

b. If not normal what's his/her problem

i. stillbirth ii. died during birth iii. died after birth iv. Preterm v. low birth weight

c. what is the age of the baby(if died what was the age before death)? i) ……

d. what is/was the gender of the baby? i) Male ii) female

e. what is/was the weight of the baby? i) <2500g ii) ≥ 2500g

f if died during birth what happened?

i. bleeding ii. Fetal distress iii. Birth trauma iv prolonged labour

g. if died after delivery, what was wrong? .

i. Fetal distress ii. Birth trauma iii prolonged labor iv. fever v other ……

h. If cause of death was fever, what was the cause of it

i. malaria ii. Respiratory disease iii others (specify) ……..

DODOSO

1. Numba ya mshiriki……Tahere ya mahojiano……
2. jina la muulizaji……

MAMA

1. a) umri wa mama……

   b) hali ya unyumba

      i)nimeoa ii)sijaoa iii) tumetengana

   c) dini yako

      i)mkristu ii)mwisilamu iii)nyingine –taja……..

   d) makazi yako

      i)kijijini ii)mjini iii)maeneo mengine. Taja…….

   e) Elimu ya mama

      i)sijasoma ii)S/msingi iii)sekondari iv)elimu ya juu

   f Elimu ya baba

      i)sijasoma ii)S/msingi iii)sekondari iv)elimu ya juu

   g) kazi ya mama

      i)mama wa nyumbani ii)mfanya biashara iii)mkulima mdogo

      iv)mfanyakazi wa mshahara vi)mwanafunzi vi)kazi nyingine.taja…...

   h) kazi ya baba

      i)mfanya biashara ii)mkulima mdogo

      iii)mfanyakazi wa mshahara iv)mwanafunzi vi)kazi nyingine.taja…...

   i) Wastani wa kipato chako kwa siku.....

2. Tabia za kiafya

   a. Je,unavuta Sigara au Tumbaku? I) ndiyo ii) Hapana

   b. Kama ndiyo,unavuta ngapi kwa siku?

      i) 1-5 sigara/siku ii) 6-10 Sigara/siku iii) ≥11 sigara /siku

   c. Je, unakunywa pombel? i) ndiyo ii) hapana

   d. Kama ndiyo,unkunywa kiasi gain kwa siku?

      i) Vyupa vya bia 1-4 ii) Vyupa vya bia 5-9 iii) Vyupa 10 na zaidi

e. Je umetumia madawa ya kulevya wakati wa ujauzito? i)ndiyo ii) hapana

f. Kiasi gain kwa siku kwa siku?.....

g. Je ulikuwa unahudhuria clinic ya akina mama wajawazito? i) ndiyo ii) hapana

h. Kama ndiyo ulihudhuri clinic zote? i). ndiyo ii) hapana

i. kama hapana,ulihudhuria mara ngapi?……

j. Ulijifungulia wapi? i. dispensary ii.kituo cha Afya iii. Hospitali

k, Kama ni Hospitali ni ipi? i.ya wilaya ii. Ya mkoa

3. majibu ya HIV

1.)majibu ya kipimo cha UKIMWI i) ameathirika ii) haja athirika iii)hamna uhakika

4. Sababu za kitabibu

a) kiasi cha cd4 kama ameathirika……..

b) stage ya upungufu wa kinga mwilini? i. I ii. II iii. III iv. IV

c) unatumia/ulitumia dawa za kupunguza nguvu /kasi ya virus vya UKIMWI

i) kinga kwa motto ii)dawa zako za kawaida iii) hapana

d) Uzito wa mama…….

e) Urefu wa mama…….

f) BMI…….

g) shinikizo la damu…….

h) kiasi cha sukari kwenye damu……

i) group lako la damu i) A ii) B iii) O iv) AB

j) Rhesus factor i) positive ii) Negative

k) Wastani wa kiasi cha damu wakati wa ujauzito……

l) Magonjwa mengine. Yataje……..

m) uliugua ugonjwa wa zinaa wakati wa ujauzito? i)ndiyo ii)hapana

n) kama ndiyo ni ugonjwa gani?

i)kisonono ii)kaswende iii)mengine. Taja ……..

o)ulisha wahi kuugua magonjwa mengine wakati wa ujauzito

i)ndiyo ii)hapana

p)Kama ndiyo ulitumia dawa yoyote i)ndiyo ii)hapana

q) Je ,ulishawahi kulazwa wakati waujauzito? i) ndiyo ii) hapana

r) Kama ndiyo ,ulilazwa kwa ugonjwa gani?

i) malaria ii) mengine Taja…….

s) je, ulipungua uzito wakati wa ujauzito i) ndiyo ii) hapana

t) huu ni ujauzito wako wa ngapi?.....

u) kama ni zaidi ya mara moja,kati ya mamba kuna muda gani?.....

v) ushatumia uzazi wa mpango? i) ndiyo ii)hapana

w) Umewahi kuzaa mapacha?.i) ndiyo ii) hapana

x) Kama ndiyo ni mara ngapi?.....

y) Umewahi kuzaa mototo asiye wa kawaida (mfu,uzito mdogo) i) ndiyo ii) hapana

z) Kama ndiyo ni mara ngapi? …….

MTOTO

a. Mtoto ana hali gani?

i) hana tatizo ii) ana tatizo

b. kama ana tatizo,ni lipi?

i.alifia tumboni ii) alikufa wakati wa kujifungua iii) alikufa baada ya kuzaliwa iv.alizaliwa kabla ya muda v. anauzito mdogo

c. umri wa mototo kabla hajafa……

d. jinsia ya motto. I) mvulana ii) msichana

e. mototo ana uzito gani?

f. kama alifariki wakati wa kujifungua nini kilisababisha ?

i. kuvuja damu nyingi? ii. mtoto kuchoka

iii mtoto kuumia wakati wa kujifungua iv kupata uchungu kwa muda mrefu

v sabau nyingine . taja……

g. Kama alikufa baada ya kujifungua nini kilisababisha? .

i. mototo alizaliwa akiwa amechoka ii. mototo aliumia wakati wa kujifungua

iii motto alikuwa na homa iv.sababu nyingine. Taja……..

h. kama alikuwa na homa,ugonjwa gani ulisababisha?

i. malaria ii. magonjwa ya kifua

iii low APGAR score <4 iv) sababu njingine.Taja…..

9.0. APPENDIX II: PARTICIPANT CONSENT/ASSENT FORM

Principal Investigator
Joseph Christopher Hokororo
Tel: No. +255784743064

9.1. Study Purpose

To study the prevalence of adverse neonatal birth outcomes and their association with HIV infection among postnatal women at Mtwara Regional Hospital – Tanzania

9.2. Study Procedures

Every participant will be explained the purpose and important details of the study before she decides whether to or not to participate. She needs to understand its purpose how it may help her, any risk to her and any risks to her and member of her household, and what is expected of her if she decides to participate in the study. They will be asked to complete an interview if they agree to participate in the study. The answers will be recorded in a confidential manner. They will be asked some questions about their life and the recent pregnancy. As part of this study an HIV test will be done if they have never tested. All those information will be kept confidential.

9.3. Benefits

There may be no direct benefit from the study however the results obtained about adverse neonatal outcomes will be used to improve care, those who will be found to have HIV as the first time will be directed to the proper channel for the proper management and there will not be payment for participating in the study.

9.4. Risks

There may be discomfort to discuss issues of HIV status, mortality and other morbidities of the new born

9.5. Rights to refusal or withdrawal

Participation is entirely voluntary and free to take part or withdrawal at any time, you may choose to answer some or all questions posed.

9.6. Confidentiality

The results of this study will be kept strictly confidential and used only for research purposes. Your identity will be concealed in as far as the law allows. Your name will not appear anywhere on the coded forms with the information. Paper and computer records will be kept under lock and key and security codes respectively. The interviewer will discuss this information with you and offered to answer the questions. For further questions, I may contact either;

1. Director of National Institute for Medical Research Tanzania (NIMR)
   Dr.Andrew Kitua 2552223121400

2. Mwenyekiti wa kitengo cha maadili Taifa
   Dr Joyce Ikingura 0782-661064

9.7. Statement of Consent

……. has described to me what is going to be done, the risks, the benefits involved and my right regarding this study. In the use of information, my identity will be concealed. I am aware that I may withdraw anytime. I understand that by signing this form. I don't wave any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate.

Signature of participant / Thumb print …… Age …… Date …….

Signature of interviewer…….. ……Date……..

FOMU YA MAKUBALIANO YA KUSHIRIKI KATIKA UTAFITI (PARTICIPANT CONSENT FORM)

Mtafiti Mkuu.

Dr. HOKORORO JOSEPH CHRISTOPHER,MD (Dar)

Nambari ya simu +255784743064

Dhumuni la utafiti: Kuangalia kiwango cha matukio mabaya ya mtoto toka anapozaliwa hadi mwezi mmoja pia uhusiano wake na VVU (HIV)

Utaratibu wa utafiti:

Utangulizi

Mimi ni.....ninafanya utakifiti wa kuangalia kiwango cha matukio mabaya ya mtoto to anapozaliwa hadi mwezi mmoja pia na uhusiano wake na VVU (HIV). Ninakuomba unipe ushirikiano katika kufanikisha suala hili. Ukikubali kushiriki katika utafiti utaombwa kufanya mahojiano na mtafiti mkuu au msaidizi. Majibu yatahifadhiwa kwa siri. Naomba uelewe kwamba mahojiano yatahusu matukio mabaya ya mtoto wakati anapozaliwa pia na uhusiano wake na VVU (HIV). Ukikubali kushiriki katika utafiti, habari zote zitzhifadhiwa kwa usiri.

Faida ya ushiriki: hautapata faida ya moja kwa moja katika utafiti huu ila upata habari juu ya matukio mabaya ya mtoto toka wakati anapozaliwa hadi mwezi mmoja pia na uhusiano wake na VVU (HIV).Watakaogundulika kuwa na VVU wataelezwa kwenye mwelekeo muafaka kwaajili ya matibabu. Sitapata wala kutoa malipo yoyote kwa kushiriki katika utafiti huu.

Madhara: Utapata huzuni kuongelea habari za VVU (HIV) na matokeo mabaya ya mtoto toka azaliwapo hadi mwezi mmoja

Siri: Matokeo ya utafiti huu yatatunzwa kwa usiri na yatatumika kwa shughuli za utafiti tu. Utambulisho wako hautawekwa bayana kwa mujibu wa sheria. Jina lako halitaonekana mahala popote katika dodoso, kumbukumbu zote zitahifadhiwa kwa siri. Mdodosaji atajadili nawe juu ya utafiti huu kama ukiridhia kujibu maswali.

Kama kuna swali au tatizo lolote kuhusu utafiti huu tafadhali wasiliana na;

1. Mwenyekiti wa kitengo cha utifiti wa Taifa (Tanzania).
   Dr Joyce Ikingura
   Number ya simu 0782-661064

2. Mwenyekiti wa kitengo cha maadili Taifa
   Dr.Andrew Kitua 2552223121400

KIAPO CHA MAKUBALIANO

.....amenieleza juu ya nini kitafanyika, faida, hatari, na haki zangu katika utafiti. Katika matumizi ya habari za utafiti utambulisho wangu hautajitokeza.Natambua kuwa naweza kujiondoa muda wowote.Natambua kuwa kwa kusaini katika fomu hii hakuniondelei haki yangu ya kimsingi, bali ni kuonyesha kuwa naufahamu juu ya utafiti ambapo nakubali kushiriki kwa hiari.

Sahihiyamshiriki/Dolegumba.....Umri.....Tarehe.....

Sahihi ya mdodosaji.....Tarehe.....

10.0. APPENDIX III: HIV TESTING CONSENT/ASSENT FORM

Principal Investigator
Joseph Christopher Hokororo
Tel: No. +255784743064

10.1. Study Purpose

To study the prevalence of adverse neonatal outcomes and their association with HIV infection among postnatal women at Mtwara Regional Hospital – Tanzania

10.2. Study Procedures

Every participant will be explained the purpose and important details of the study including need to check HIV status before she decides whether to or not to participate. They will be counseled if they agree to check their HIV status and participate in the study. The HIV results will be recorded in a confidential manner.

10.3. Benefits

There may be no direct benefit from the study however the results obtained about adverse neonatal outcomes will be used to improve care, those who will be found to have HIV as the first time will be directed to the proper channel for the proper management and there will not be payment for participating in the study

10.4. Risks

There may be discomfort to discuss issues of HIV status.

10.5. Rights to refusal or withdrawal

The participation is entirely voluntary and they are free to take part or withdrawal at any time, they may choose to check for their HIV status or not.

10.6. Confidentiality

The results of HIV test will be kept strictly confidential and used only for research purposes. Your HIV status will be concealed in as far as the law allows. Your name will not appear

anywhere on the coded forms with the information. Paper and computer records will be kept under lock and key and security codes respectively.

1. Director of National Institute for Medical Research Tanzania (NIMR)
   Dr Andrew Kitua-2552223121400

2. Chairperson of IRB (NIMR)
   Dr. Joyce Ikingura 0782-661064

10.7 Statement of Consent

……. has described to me what is going to be done, the risks, the benefits involved and my right regarding this HIV testing. In the use of information, my identity will be concealed. I am aware that I may withdraw anytime. I understand that by signing this form. I don't wave any of legal rights but merely indicate that I have been informed about the HIV testing and research study in which I am voluntarily agreeing to participate.

Signature of participant / Thumb print …… Age …… Date …….

Signature of interviewer …….. ……..Date……..

FOMU YA MAKUBALIANO YA KUSHIRIKI KUPIMA VVU (HIV TESTING CONSENT/ASSENT FORM**)**

Mtafiti Mkuu.

Dr. HOKORORO JOSEPH CHRISTOPHER,MD (Dar)

Nambari ya simu +255784743064

Dhumuni la utafiti: Kuangalia kiwango cha matukio mabaya ya mtoto toka wakati anapozaliwa hadi mwezi mmoja pia uhusiano wake na VVU (HIV)

Utaratibu wa utafiti:

Utangulizi

Mimi ni.....ninafanya utakifiti wa kuangalia kiwango cha matukio mabaya ya mtoto toka wakati anapozaliwa hadi mwezi mmoja pia na uhusiano wake na VVU (HIV). Ninakuomba unipe ushirikiano katika kufanikisha suala hili. Ukikubali kushiriki katika utafiti utaombwa kupima HIV. Majibu yatahifadhiwa usiri.

Faida ya ushiriki: hautapata faida ya moja kwa moja katika utafiti huu ila upata habari juu ya matukio mabaya ya mtoto toka wakati anapozaliwa hadi mwezi mmoja pia na uhusiano wake na VVU (HIV).Watakaogundulika kuwa na VVU wataelezwa kwenye mwelekeo muafaka kwaajili ya matibabu. Sitapata wala kutoa malipo yoyote kwa kushiriki katika utafiti huu.

Madhara: Utapata huzuni kuongelea habari za VVU (HIV) na matokeo mabaya ya mtoto toka azaliwapo hadi mwezi mmoja

Siri: Matokeo ya utafiti huu yatatunzwa kwa usiri na yatatumika kwa shughuli za utafiti tu. Utambulisho wangu hautawekwa bayana kwa mjibu wa sheria. Jina langu halitaonekana mahala popote katika dodoso, kumbukumbu zote zitahifadhiwa kwa siri.

Kama kuna swali au tatizo lolote kuhusu utafiti huu tafadhali wasiliana na;

1. Mwenyekiti wa utifiti wa Taifa (Tanzania).
   Dr Andrew Kitua
   255-22-23121400

2. Mweyekiti wa Kitengo cha maadili Taifa
   Dr.Joyce Ikingura
   Number ya simu 0782-661064

KIAPO CHA MAKUBALIANO

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Sahihi ya mshiriki/ Dole gumba .....Umri.....Tarehe.....

Sahihi ya mdodosaji.....Tarehe.....