PREVALENCE OF BACTERIAL VAGINOSIS AND ASSOCIATED FACTORS AMONG WOMEN WITH PRETERM LABOUR AT MUHIMBILI NATIONAL HOSPITAL

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By

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CERTIFICATION

The undersigned certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **Prevalence of Bacterial Vaginosis and Associated factors among Women with Preterm labor at Muhimbili National Hospital** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Obstetrics and Gynecology) of Muhimbili University of Health and Allied Sciences.

_____

Dr. E. Ngwalle

(Supervisor)

Date: _____

DECLARATION

AND

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I, **Palapala Juventus Makene** 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.

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Above all, thanks to the Almighty God for keeping me alive and deriving me to whatever success in my life.

DEDICATION

This dissertation is dedicated to my family, in particular to my wife Respica. Thanks for your unconditional patience, love and devotion to me and the whole family. May wax and honey flow into your steps successfully

ABSTRACT

Bacterial vaginosis (BV), is a clinical syndrome resulting from replacement of the normal Hydrogen-peroxide (H2O2) producing Lactobacillus species with a higher concentration of anaerobic bacteria like *Prevotella* and *Mobilincus sp*, *Gadnerella vaginalis* and *mycoplasma hominis*. It is characterized by an increase of vaginal discharge with no obvious inflammation of the vagina. It represents about 40% to 60% of all cases of vaginitis, and it is thought to be more common than either Vulvovaginal candidiasis or Trichomoniasis.

BV is being associated with some serious obstetric risks like premature labor, low birth-weight, chorioamnionitis, and infection of the uterus post delivery. A wide range of prevalence has been reported in studies done in various parts of the world ranging from 6.8% to 28.5%, in pregnant women and 32.8% to 62.9% in non pregnant women.

This study was aimed at documenting the magnitude of BV among women with premature labor at the gestation age of least seven months pregnancy up to 36 weeks admitted at MNH labor ward and highlight the factors associated with it. A total of 206 patients were enrolled and the diagnosis of BV was done according to the clinical Amstel's criteria.

The prevalence of BV in this study was found to be 39.2%. Women with history of abnormal vaginal discharge were fifteen times more likely to have BV as compared to those without abnormal vaginal discharge (OR 15, 95% CI 6.7-37, P= <0.001), while women who had no more than primary school education or housewives were over twice as likely to have BV (OR 2.07, 95% CI 1.18-3.66, P=0.012). HIV positive women had also a twofold increased risk of getting BV when compared to HIV negative women. (OR 2.76, 95%CI 1.02-7.46, P=0.046)
There was a weak or no association between BV and such factors like low socio-economic status (being in the lowermost three wealth quintiles), history of recent antibiotics use,

primigravidity, being in a polygamous marriage or being married or a history of previous miscarriage.

In conclusion, BV appears to occur in a great magnitude in patients with premature delivery in our setting. The study therefore recommends that medical practitioners develop a high suspicion index for pregnant women with abnormal vaginal discharges. Besides, policy makers should probably include screening and treatment for BV in the future policy of Antenatal care package.

LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal clinic
BV	Bacterial vaginosis
HIV	Human immunodeficiency virus
IPPM	Intramural Private practice Muhimbili
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
PD	Preterm delivery
PIH	Pregnancy Induced hypertension.
PID	Pelvic Inflammatory Diseases.
PL	Preterm labor
PMTCT	Prevention of mother to child transmission
STD's	Sexually Transmitted Diseases
TAH	Total Abdominal Hysterectomy

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1.1 INTRODUCTION

Bacterial vaginosis (BV), is a clinical syndrome resulting from replacement of the normal Hydrogen-peroxide (H2O2) producing Lactobacillus species with a higher concentration of anaerobic bacteria like *Prevotella sp, Mobilincus sp, Gadnerella vaginalis* and *mycoplasma hominis[1]*. Hydrogen-peroxide producing micro-organisms like *Lactobacillus crispatus* and *Lactobacillus jensenii* appear to help preventing other vaginal microorganisms from multiplying to a level where they can cause symptoms[2].

Bacterial vaginosis represents about 40% to 60% of all cases of vaginitis, and it's thought to be more common than either Vulvovaginal candidiasis or Trichomoniasis[3].

In the past, the condition was called non- specific vaginitis or Gadnerella vaginalis named after the bacterium that was thought to cause the condition. However this new name BV reflects the fact that, there are a number of species of bacteria that naturally live in the vagina and may grow to an excess[4]. When these multiple species of bacteria become imbalanced, a woman can have vaginal discharge with a foul odor. Change in vaginal pH is one of the identified factors affecting the desired levels of bacteria inside the female reproductive tract and thus leading to the development of BV[2].

The exact cause of BV is not known, but certain factors have been identified to be associated with an increased chance of developing bacterial vaginosis. These include multiple or new sexual partners, intra-uterine contraceptive devices for contraception (IUCD), recent antibiotics use, vaginal douching, and even cigarette smoking [2, 4, 5]. However the role of sexual activity in the development of BV, is not fully understood as BV can still develop in women who have never had sexual intercourse[2].

A study done by Hans V and associates in Belgium 2005 depicted that subclinical iron deficiency or overt anemia, presumably resulting from preconception iron supplies is strongly associated with the development of BV in early pregnancy[6]

Increased psychosocial stress is also associated with greater BV prevalence and incidence, independent of other risk factors.[7]. Women do not get BV from toilet seats, bedding, swimming pools, or from touching objects around them [2].

About 85%, of those women affected with BV actually have no symptoms [8]. When symptoms occur, the main primary symptoms are increased vaginal discharge with a fishy odor, the discharge increasing especially after sexual intercourse. The alkalinity of semen may cause a release of volatile amines from the vaginal discharge and cause a fishy odor. It's characterized by an increase of vaginal discharge with no obvious inflammation of the vagina [1, 2, 4, 8]. Secondary symptoms of BV include vaginal itching, swollen vagina, and pain during intercourse, painful urination, burning feeling inside the vagina and vaginal irritation.[4]

Prevention of BV thus includes, limiting the number of sexual partners, using the medication to their completeness even if symptoms go away earlier in the course of treatment and to generally avoid douching[2].

Bacterial vaginosis (BV) can cause both adverse pregnancy outcomes and gynecological effects. Several studies have documented that, both subclinical and overt infections are associated with preterm delivery especially those occurring before 30 to 32 weeks gestation [9-11]. Adverse pregnancy outcomes associated with BV includes premature labor and birth, low birth-weights, chorioamnionitis and infection of the uterus post delivery (endometritis) [1, 4, 12].

The precise mechanism by which BV precipitates preterm labor is not precisely known, but the mechanism is similar to that proposed for amniotic fluid infection[1]. Additionally, it has been observed in some studies that most of the micro-organisms isolated from the amniotic fluid and the placenta of patients with preterm delivery, appear to come from the vagina, especially in patients with BV [13].

Gynecological risks of BV include, an increased susceptibility to HIV infection[14], increased risk of post surgical infection like TAH and abortion, and increased susceptibility to other STD's such as herpes simplex virus, Chlamydia and gonorrhea which may cause PID leading to infertility and ectopic pregnancies[2]

Treatment of BV includes the use of antibiotics like Metronidazole taken orally or as a vaginal gel and clindamycin. Both Metronidazole vaginal gel and Clindamycin vaginal gel has been shown to have similar effectiveness to treat BV, though with different transient effects on Lactobacillus species [3]. All women with bacterial vaginosis need treatment but their male partners do not need treatment[15].

While some studies reports that treatment of BV during pregnancy may not improve preterm birth and thus discouraging screening and treatment of asymptomatic pregnant women except for providing treatment for symptomatic relief[16, 17], a systematic review and meta-analysis study carried out in Belgium in 2011 in which five trials that comprised a total of 2346 women, concluded that, Clindamycin administered in early pregnancy at <22weeks gestation in patients with BV, significantly reduces the risk of spontaneous preterm birth at <37 weeks of gestation and late miscarriage[18]. Another study by John C Hauth and associates also established that treatment with Metronidazole and Erythromycin reduces the incidences of premature delivery in patients with BV.[19].

Recurrence of BV even after successful treatment has been reported by some studies to be more than 50% within 12 months and that in such circumstances a second course of extended

antibiotics is generally prescribed [20]. Additionally however, it has also been concluded that isolated antibiotic treatment is not very effective on the prevention of recurrences and that the use of probiotics like local estrogen application to complement antibiotic treatment has showed some effectiveness [21]. Although it's unclear why so many recurrent infections develop, a study in Cape town-south Africa revealed that HIV infection may be a contributing factor[14].

The diagnosis of BV in the clinical settings is usually done by using the Amstel's or Nugent criteria. There is no robust evidence to suggest any difference in the accuracy of any of the two tests in diagnosing BV in women with preterm labour[22]. Basing on this fact, the study used the Amstel's clinical criteria to diagnose BV because it is simple to use even in clinical settings and less expensive as compared to the Nugent score.

Amsel's clinical criteria has the following four components;

1. Thin, white, yellow, homogeneous discharge coating the vagina.
2. Clue cells on microscopy.
3. pH of vaginal fluid >4.5.
4. Release of a fishy odor on adding alkali—10% potassium hydroxide (KOH) solution. (the whiff test)

At least three of the four criteria should be present for a confirmed diagnosis.

The Nugent Score is a Gram stain scoring system for pap tests to diagnose bacterial vaginosis. It was first described in 1991 by R.P Nugent for whom it is named. It is done by assessing the presence of three parameters:

1. Large Gram-positive rods(Lactobacillus morphotypes scored as 0 to 4),
2. Small Gram-variable rods (Gardnerella vaginalis morphotypes; scored as 0 to 4)
3. Curved Gram-variable rods (Mobiluncus spp. morphotypes; scored as 0 to 2).

A score of 7 to 10 is consistent with bacterial vaginosis.

1.2 LITERATURE REVIEW

A wide range of prevalence of BV and its association with some adverse pregnancy outcomes have been reported in various studies done in various parts of the world. In pregnant women, it's reported to ranges from 6.8% to 28.5%, while in non pregnant women it's reported to range from 32.8% to 62.9%. The most documented adverse pregnancy outcomes include preterm labor and delivery, low birth weights and chorioamnionitis. Some of the indentified risk factors towards the acquisition of BV include multiple or new sexual partners, intra-uterine contraceptive devices for contraception (IUCD), recent antibiotics use, vaginal douching, cigarette smoking, HIV infection, subclinical iron deficiency and increased psychosocial stress.

In the U.S.A, a prospective cohort study was conducted for five years from five U.S. cities in pregnant women with the purpose of evaluating the association between the incidence of premature birth of low-birth-weight infants and bacterial vaginosis by Hillier S et al from 1985 to 1989. Women were enrolled during their routine prenatal visits after completing their 23 to 36 weeks gestation and meeting the exclusion criteria of the study. Bacterial vaginosis was diagnosed in 16% of women and, women with BV diagnosed during the second trimester of pregnancy were 40% more likely to give birth to a premature, low-birth-weight infant than women without bacterial vaginosis. The relation between bacterial vaginosis and such births remained unchanged after adjustment for confounding variables, which suggests that bacterial vaginosis is an independent risk factor for preterm delivery of an infant with low birth weight regardless of other recognized risk factors[12]

In 2003, a meta-analysis study was conducted at the University of Vienna to evaluate BV as a risk factor for Preterm delivery. The study involved eighteen studies published in English language and fulfilling the following three criteria. 1. Women at <37 weeks of gestation with intact amniotic membranes. 2. Method of screening for bacterial vaginosis was either Amstel's

clinical criteria or Nugent score. 3. Outcomes were preterm delivery, spontaneous abortion, maternal or neonatal infection and perinatal death. Results for 20,232 patients were available. The analysis found that BV increased the risk of preterm delivery by >2-fold and significantly increased the risk of spontaneous abortion and maternal infection[23]

In another study conducted in Denmark, in a cohort of Danish pregnant women involving 3540 clients aged 18years and more in the second trimester before 20weeks of gestation age, the prevalence of BV was found to be 16% and the rate of preterm delivery (<37weeks) was 5.2%. Infants of women with BV had significantly lower mean birth weight than infants of women without BV. Multivariate analysis after adjusting for various factors concluded that the presence of BV before 20weeks of gestation was an independent risk factor for delivery of an infant with low birth weight, preterm delivery and clinical chorioamnionitis[24]

In Paris a prospective blinded study was conducted for 19months at Port-Royal Maternity (a tertiary referral centre in Paris) among women hospitalized for preterm labor (PL) with intact membranes between 24 and 34 weeks of gestation. The study enrolled 354 women with the intention of assessing the prevalence of BV and its predictive values for premature delivery and neonatal infections. The prevalence of BV was found to be 6.8% and was not associated with age, nationality, level of education or smoking. It was however associated with a history of miscarriage after 14weeks and preterm delivery. The predictive values of BV for preterm birth before 33 weeks had a sensitivity of 12.8%, and a positive predictive value 35.3%. It was concluded therefore that BV is associated with the risk of very premature delivery, but its predictive value was not adequate [25].

The association between BV and the adverse fetomaternal outcomes was reported in a prospective cohort study by Laxmi, et al, 2012 in New Delhi India. In this study, BV was screened by using Amstel's criteria and Nugent score. It included Women with spontaneous preterm labor with gestation age between 28 and 35 weeks. The prevalence of BV was 24.34%. It also found that babies born to mothers with BV had a significant increase in the

incidence of respiratory distress, requirement of positive pressure ventilation (IPPV), admission in neonatal intensive care unit (NICU), and duration of NICU stay more > 2days. There was no significant difference found in mean birth weight, Apgar score, incidence of neonatal sepsis, perinatal mortality and postpartum fever between the two groups [26].

In south Yorkshire, United Kingdom, the prevalence of BV and that of Candida albicans in asymptomatic pregnant women attending ANC at Barnsley district General Hospital was found to be 3.54% for BV with almost 90% being in the age group of 21-30years and a prevalence of 12.5% years for Candida albicans with almost 65.7% being in the age group of 21-30[27].

With regard to Africa and in particular the East-African setting, there are no many published studies on the magnitude of BV and its associated fetal- martenal outcomes. On the other hand a number of published studies on BV in non pregnant women with various health issues and social characteristics are available.

In Bugando Medical Centre, Mwanza, Tanzania, a cross-sectional study was conducted to determine the prevalence of BV and associated factors among women admitted for delivery in the labor ward. A total of 284 women were enrolled for a period of a month and Nugent score was used to assess the presence of BV. A prevalence of 28.5% was established and there was no association with such factors as education, urban residence, intravaginal practices or HIV infection[28].

In Kenya, a cross-sectional study was conducted by Hassan W.M 2007, to determine the association between intra-vaginal practices and BV, in HIV-1 seronegative Kenyan female sex workers without symptoms of vaginal infection. A total of 237 women were enrolled, and 206 (87%) reported vaginal washing using either a finger or a cloth. It was found that increased frequency of vaginal washing or vaginal lubrication with petroleum jelly was associated with a high likelihood of BV [29].

A study done by Baisley et al, 2009 to determine the prevalence and the risk factors for BV among Herpes Simplex Virus 2 (HSV2) seropositive women working in bars, guesthouses and similar facilities (female facility workers) in North-Western Tanzania revealed a prevalence of BV to be 62.9%. The independent risk factors for BV were work facility type, fewer dependants, increasing alcohol consumption, sex in the last week, using clothes or cotton wool for menstrual hygiene, HIV and Trichomonas vaginalis infection [5].

With regard to the magnitude of BV among non pregnant women in different parts of the world, a study by .Bhalla, et al 2007 in Delhi, India compared the prevalence of BV among women in urban and rural communities. Its prevalence was 32.8% with the highest prevalence seen in urban slums, followed by rural and urban middle class community. Asymptomatic BV was found to be 31.2%. All women with vaginal trichomoniasis were found to have BV, while 50% of subjects with syphilis had BV[30]

1.3 PROBLEM STATEMENT

The literature search made so far above had been able to provide data on the prevalence of BV its association with obstetric complications in the general population of pregnant women at large and in non pregnant women in different parts of the world.

Not widely established so far was how common was BV in the subgroup of women who presents with premature labour and delivery. This paucity of data cut across the globe, but more so in the African settings, Tanzania being included.

On the other hand, the fact that the prevalence of BV in gynaecolgical patients was reported to be high (62.9% by Baisley, 2009). Coupled with fact that, recurrence of BV post successful treatments is more than 50% after 12months of successful treatment [20], may mean that many pregnant women with preterm labor conceives with a pre existing BV.

1.4 RATIONALE

The study intended to document the magnitude of BV among women with premature labor with intact fetal membranes and to highlight factors associated with it among these women. There was paucity of data on this subject matter in Tanzania and thus the need for this study. It is expected that, results from this study results may be a reason for more research on BV and provide the basis for dialogue for policy changes so that BV screening is included in the basic ANC package provided to women in hospitals. Additionally, available data from the hospital database (MNH) indicated that a total of 12098 obstetric admissions occurred in 2011 and of these, 624(5.2%) had premature labour. Further indicated that premature infants of birth weight of <1.5kg stayed in the hospital for about 2weeks, while those with birth weight of 1.5 – 2.5kg stayed for about a week. It's thus plausible to expect that decreasing the incidence of premature deliveries in our setting will reduce the economic costs spent by the institute to take care of the premature babies and reduce the social economic impacts of caring for mental handicaps, a risk which premature infants are prone to succumb.

1.5 RESEARCH QUESTION

How common was BV among women with Preterm labour admitted at maternity block-MNH?

1.6 OBJECTIVES

1.6.1 Broad Objective.

To determine the magnitude of BV and associated factors among women with preterm labor with intact fetal membranes admitted at MNH- labor wards using clinical Amstel's criteria.

1.6.2 Specific Objectives.

1. To determine the magnitude of BV among women with premature labor at 28 to 36 weeks gestation age admitted at MNH-labor wards using Amstel's clinical criteria.
2. To document the socio- demographic factors associated with BV among women with Preterm labor admitted at MNH-labor wards.

2.0 METHODOLOGY

4.1 Study design.

The study was a descriptive cross-sectional analytical study.

4.2 Study area and population.

The study was conducted at MNH- labor wards. MNH is the national referral hospital for Tanzania located in Dar es Salaam city. It also serves as the national teaching Hospital for Muhimbili University of Health and Allied Sciences (MUHAS). It has two labor wards, one serving for the public patients while the second labor ward serves the fast-track or IPPM patients. The labor wards were linked to the neonatal ward where premature babies are cared for. With over 600 premature deliveries a year, the hospital provided an ideal setting to complete the planned study timely.

The study population was pregnant women admitted in the labor ward with the diagnosis of premature labor with intact fetal membranes, defined as labor onset in woman of at least seven months pregnancy but before 37 completed weeks. Women with chronic illness such as diabetes mellitus, TB, Asthma, and HIV/AIDS as indicated by their PMTCT status were also included in the study if they consent to participate.

Women were excluded from the study if they had ruptured fetal membranes before the samples were taken, active vaginal bleeding, PIH, multifetal gestation or if they declined to participate. Patients with ruptured membranes or active vaginal bleeding were excluded the presence of amniotic fluid or blood would have affected the pH and the smell of the vaginal discharge and thus difficult to interpret the Whiff test. PIH and multifetal gestation were also excluded because these are by themselves risk factors for premature labour and delivery.

4.3 Data collection procedure

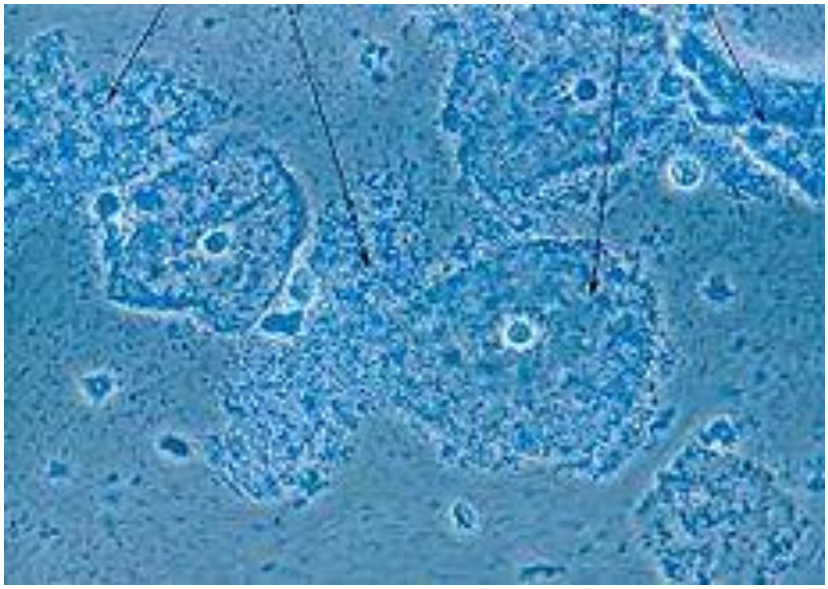
Information on the presence of the study was made available by the principal investigator in both the public and the IPPM labor wards with the exception of the eclampsia ward. One research assistant nurse was recruited from each labor ward. The main responsibility of the research assistants was to interview the patient and fill the questionnaires and to call the principal investigator for performing the Amstel's clinical criteria. They were not performing the procedure by themselves. Besides these two research assistants, other nurses in various shifts of everyday were encouraged to notify the principle investigator over the phone every time a patient with desirable characteristics was being admitted in the labor ward. To keep reminding them, an announcement about the study with the phone number of the principal investigator was pinned on the notice boards of each labor ward. Nevertheless the principal investigator was also available in the labor wards most of their time to look for patients with the desired diagnosis.

Patients with the diagnosis of preterm labor without the exclusion criteria stated above, were identified and requested to participate. Consenting patients were interviewed using a pre-tested questionnaire to get baseline information on socio-demographic characteristics, presence of chronic illnesses like diabetes, Asthma, TB and HIV, past obstetric and gynecological history and history of the index pregnancy. As the number of patients admitted in the labor wards with this problem on a day was so erratic, consecutive sampling was done till when the sample size was reached. Stated in other words, every patient admitted with the characteristics of interest for the study and consenting to participate was recruited.

Patients were then taken the vaginal swab for assessment by the principal investigator with the patient in a lithotomy position. Vaginal swabs were taken from the posterior fornix by using a sterile cotton tipped swab with a non lubricated Cusco's (bivalvular) speculum, after swabbing the perineum. The procedure of speculum examination was done in aseptic technique to avoid introducing infection and minimize vaginal discomfort to the minimum possible level.

The diagnosis of BV was done according to the clinical Amstel's criteria as follows.

1. Presence of homogenous, white, non-inflammatory discharge that smoothly coats the vaginal wall.
2. A characteristic fishy odor on the wet mounts before or after adding 10% KOH, to a microscope slide containing the vaginal discharge. (The Whiff test.)
3. Loss of vaginal fluid acidity done by putting a swab on the litmus paper, or placing a litmus paper in the vagina. The normal pH is 3.8 – 4.2. A pH of 4.5 or was taken as a sign of BV.
4. Presence of "clue" cells on the wet mount done by placing a drop of sodium chloride solution on a slide containing vaginal discharge, and visualize under the microscope. Clue cells are epithelial cells that are coated with bacteria. They are called so because they give a clue to the reason behind the discharge.



Clue cells picture

5. To make the diagnosis of BV, two positive results in addition to the abnormal discharge were taken as diagnostic, while in the absence of the discharge, then all the three criteria has to be present.

Amstel's criteria numbers 1 to 3 were done at the bedside immediately after examining the patient and taking the vaginal swab. Besides the principal investigator, the presence or absence of the malodorous smell (Whiff test) was also decided in corroboration with a group of intern or resident doctors or nurses available at the time of the test.

Criteria number 4 (identification of Clue cells) was done in the laboratory by one microbiologist, Dr. Mabula Kasubi, in collaboration with one laboratory technician Mr. James Kalabashanga. The principal investigator with the research assistants ensured that the samples for clue cells were delivered in the laboratory within a day for processing. Data collection was done for a period of 5months, from November 2012 to March 2013.

4.4 Sample size estimation

The sample size was calculated using the formula

$n=Z^2xp\ (1-p)/e^2$

Where

n= required sample size

Z= confidence level at 95% confidence level ~1.96

P=estimated prevalence of BV by Hillier et al, 1995 (taken as 0.16).

E= required size of standard error at 5% significance level (taken as 0.05)

The sample size was calculated to be 206.

4.5 Ethical consideration (issues)

The principal investigator was introducing himself to the clients in Kiswahili to get their informed consent.

Participants were made aware that the procedure used in vaginal examination is not harmful and that it does not contribute in any way to make their premature labor worse than before. They were also told that participation was voluntary and that declining from the study would not affect their rights to the available care. Patients who were found to have BV were given a prescription for treatment as per available institutional practice and national guidelines.

4.6 Ethical clearance

Ethical review and approval was sought from the department of Obstetrics and Gynaecology MNH, the MUHAS ethical committee and finally the Director of Hospital Services Muhimbili National Hospital.

4.7 Source of bias and potential confounder

Some social-demographic characteristics such as wealth quintile and level of education may affect the health care seeking behaviour, disease symptoms recognition and seeking appropriate care or even treatment adherence.

4.8 Expected outcomes and outcome indicators

The primary outcome was the prevalence of BV expressed as a percentage of the women with a positive Amstel's test over the total number of women tested.

The possible association of BV with various socio-demographic characteristics was dealt with in the analysis.

4.9 Data management

4.9.1 Data handling

The data were first entered in Microsoft Excel data sheet and then transferred into STATA statistical package in Windows version 12 (STATACorp LP College Station, Texas, USA) for cleaning and data analysis.

4.9.2 Data analysis

The primary objective was to document the prevalence of BV in women with premature labor in the study setting. Frequency distribution of participants with BV was calculated as a percentage of total women to provide the prevalence of BV. The wealth index and quintiles were calculated using the principal component analysis (PCA) of the STATA program. Household possessions were entered into a PCA model to calculate the Kaiser-Meyer-Olkin (KMO) which is the measure of sampling adequacy in STATA. All had a value of at least 0.5

and thus they were all entered in a subsequent model to calculate the worth quintiles divided into five groups of lowermost, 2nd lowermost, 3rd lowermost, 4th lowermost and highest.(KMO attaches weight in each household possession to explain the significance of each particular property on wealth.)

The association of BV with various factors such as, level of education, marital status gestation age in weeks and others was done by using bivariate logistic regression model in STATA. All the variables were assessed as binary variables recorded as zero (0) if absent and one (1) if present. Results were recorded in odds ratio with the respective 95% confidence intervals as well as p-values.

3.0 RESULTS

A: Baseline characteristics of the study participants.

As can be seen in table 1, a total of 206 pregnant women with premature labor were recruited in this study.

Most participants (81.1%) were aged between 20-34 years and a total of 31 (15.0%) participants were aged more than 35 years. Only 3.9% were aged less than 20years.

The mean age was 28.7±5.7 years with a range of 14 – 43years and the median age was 29 years (not shown in the table). Participants with primary school education comprised of 48.1% while 50.5% of them had at least secondary school education. On the other hand, 1.8% had no formal education.

The majority (88.3%) were married and of these 173 (95%) were in a monogamous relationship. Just over a quarter of the participants (27.7%) were employed while 44.7% were housewives. On the other hand, only 43(20.8%) were in the highest wealth quintile while as few as 29(14.1%) were in the lowermost quintile. Overall 86 (41.8%) belonged to the uppermost two quintiles.

About 87.4% were HIV negative, 8.8% were HIV positive and 3.9% had their HIV status unknown.

Primigravida contributed about 32.5% while there was 4.4% Grand-multipara participants. The mean gravidity of all 206 participants was 2.5±1.6 with a range of 1-9 and a median of 2 (not shown in the table). The overall gestation age of all participants ranged from 28-36 weeks with a mean of 34.5±1.6 and a median of 36 (not shown in the table).

Participants who had ever delivered at least once were 61.2% with the mean parity of 1.1±1.2 and a range of 1-6.

A history of previous preterm delivery was obtained in 28 participants (13.6%), while that of previous abortion was found in 47 participants (22.8%)

Presence of abnormal vaginal discharge was reported by 124 (60.2%) among all 206 participants, with the whitish colored discharge being the most common (78.2%). Participants who reported to have used various types of antibiotics within one week of testing were 28.3%.

Table 1: Baseline characteristics of the study participants (N=206)

Characteristic	No (%)	Mean±SD	Range
Age (n=206)			
<20	8 (3.9)		
20-24	50 (24.3)		
25-29	53 (25.7)	28.7±5.7	14-43
30-34	64 (31.1)		
≥35	31(15.0)		
Education level (n=206)			
No formal education	3 (1.5)		
1˚ School complete	89 (43.2)		
1˚School incomplete	10 (4.9)		
2˚School	67 (32.5)		
Post 2˚ School	37 (18.0)		
Marital status (n=206)			
Single	24 (11.7)		
Married	182 (88.3)		
Type of marriage (n=182)			
Monogamy	173 (95.0)		
Polygamy	9 (5.0)		
Occupation status (n=206)			
House wife	92(44.7)		
Petty trade	57 (27.7)		
Employed	57 (27.7)		
Household possessions			
Refrigerator	147 (71.4)		
Motorcycle	47 (22.8)		
Car	35 (17.0)		
Electricity	177 (85.9)		
House	66 (32.0)		
Wealth quintiles (n=206)			
Lowermost	29 (14.1)		
2nd lowermost	31 (15.1)		
3rd lowermost	60 (29.1)		
4th lowermost	43 (20.9)		
Highest	43 (20.9)		

HIV serostatus (n=206)			
Negative	180 (87.4)		
Positive	18 (8.8)		
Unknown	8 (3.9)		
Gravidity (n=206)			
Primigravida	67 (32.5)		
Gravida 2-3	90 (43.7)	2.5±1.6	1-9
Gravida 4-5	40 (19.4)		
Gravida >5	9 (4.4)		
GA in weeks		34.5±2.3	28-36
Ever Delivered (parity)	126(61.2)	1.1±1.2	1-6
H/o previous preterm delivery	28(13.6)		
H/o previous abortion	47 (22.8)		
H/o abnormal vaginal discharge (n=206)	124(60.2)		
Described colour of discharge (n=124)			
Whitish	97 (78.2)		
Yellowish	27(21.8)		
H/o antibiotics use within 1week of testing (n=206)	64(28.3)		

Note: Number in brackets denotes percentages (%)

Mean (μ) and Range, calculated only for numerical variables

B: Prevalence of Bacterial Vaginosis and the associated socio-demographic factors

It's shown in table 2 that, the presence of BV was found in 81 participants, making a prevalence of BV among pregnant women with premature labour at MNH to be 39.2%. Factors that were found to have an association with BV (p-value <0.05) in this study includes, a low level of education of at most primary school, being a house wife, being HIV positive and having an abnormal vaginal discharge.

Table 2a: Factors associated with bacterial vaginosis among women with preterm labor delivering at Muhimbili National Hospital, Dar es Salaam Tanzania

Characteristic	Positive BV results	p-value
Bacterial vaginosis	81(39.2)	
Education.		
At most primary school (n=92)	45 (48.9)	
Above primary school (n=114)	36 (31.6)	0.011 (Pearson)
Marital status		
Married (n=182)	68 (37.4)	
Others (24)	13 (54.2)	0.072 (Pearson)
Marriage type*		
Monogamy (n=173)	66 (38.2)	
Polygamy (n=9)	2 (22.2)	0.487 (**Fischer exact)
Occupation status		
House wife (n=92)	45 (48.9)	
Others (n=114)	36 (31.6)	0.011 (Pearson)
Wealth quintiles		
Lowermost 3 (n=120)	53 (44.2)	
Uppermost 2 (n=86)	28 (32.3)	0.093 (Pearson)
Gravidity		
Prim (n=67)	25 (37.3)	
Others (n=139)	56 (40.3)	0.682 (Pearson)
HIV status***		
Positive (n=18)	11 (61.1)	0.039 (Pearson)
Negative (n=180)	65 (36.1)	
Previous miscarriage (arbotion)		
Yes (n=47)	19 (40.4)	
No (n=159)	62 (38.9)	0.860 (Pearson)
Antibiotic use		
Yes (n=63)	27 (44.9)	
No (n=142)	53 (37.3)	0.454 (Pearson)
Vaginal discharge		
Yes (n=124)	74 (59.7)	
No (n=82)	7 (8.5)	<0.001(Pearson)

*24 participants were single. ** Fischer exact test used because entries were <5

***8participants had their HIV serostatus unknown.

Further analysis on the association between BV and various factors was conducted using regression analysis model to highlight the strengths of associations (table 2b).

A history of abnormal vaginal discharge, being a house wife, being HIV positive and having no more than primary school completed education, were significantly associated with BV. Specifically, women with history of abnormal vaginal discharge were over fifteen (15) fold likely to have BV than those without abnormal vaginal discharge (OR 15, 95% CI 6.7-37, P= <0.001). Likewise, women who had no more than primary school education or housewives were over twice as likely to have BV compared to those with higher education or those employed in other various sectors. (OR 2.07, 95% CI 1.18-3.66, P=0.012). HIV positive women have also a twofold increased risk of getting BV than the counterpart HIV negative women. (OR 2.76, 95%CI 1.02-7.46, P=0.046)

Table 2b: Factors associated with bacterial vaginosis among women delivering at Muhimbili National Hospital, Dar es Salaam Tanzania: Regression analysis

Factor	Number (%)	Odds ratio	95% CI	p-value
Positive for BV	**81 (39.2)**			
Antibiotic therapy in the past one week n= 206				
No therapy	142 (69.3)	1		
Had therapy	64 (30.7)	1.26	0.6885409-2.303674	0.454
Abnormal vaginal discharge n= 206				
No history	82 (39.8)	1		
Had history	124 (60.2)	15.88	6.7528-37.23625	<0.001
Previous miscarriage n=206				
No history	159 (77.2)	1		
Had history	47 (22.8)	1.06	0.5464999-2.062344	0.860
HIV serostatus n=197				
Negative	179 (90.9)	1		
Positive	18 (9.1)	2.76	1.018578-7.457241	0.046
Wealth quintile n=206				
Uppermost two	94 (41.6)	1		
Lowermost three	120 (58.2)	1.64	0.9199519-2.918616	0.094
Education n=206				
At least primary education	92 (44.7)	1		
No or less primary education	114 (55.3)	2.07	1.175067-3.662275	0.012
Marriage status n=206				
Not currently married	24 (11.7)	1		
Married	182 (88.3)	0.47	0.2000074-1.085115	0.077
Occupation n=206				
Housewives	114 (55.3)	1		
Others	92 (44.7)	2.07	1.175067-3.662275	0.012

Number of children ever had n=206				
Primigravida	67 (32.5)	1		
Others	139 (67.5)	0.88	0.4841763-1.607527	0.682
Marriage relationship n=182				
Polygamous	9 (5.0)	1		
Monogamous	173 (95.0)	2.16	0.4353782-10.70508	0.346

Factors that were weakly associated with BV included, being in the lowermost three wealth quintiles (OR 1.64, 95%CI 0.92 2.92,P=0.094), the use of antibiotics in the preceding one week (OR 1.26, 95%CI 0.69-2.30, P=0.454), being in polygamy marriage (OR 2.16, 95%CI 0.44-10.71, P=0.346) and a history of previous miscarriage (OR 1.06, 95%CI 0.55-2.06, P=0.86). There was no evidence to suggest an association between BV with primigravidity (OR 0.88, 95%CI 0.48-1.61, P=0.682) or being married (OR 0.47, 95% CI 0.20-1.09, P=0.077).

5.0 DISCUSSION

The prevalence of BV in this study was found to be 39.2%. It was found to be significantly associated with the presence of abnormal vaginal discharge, low education status of at most primary school level, HIV infection and being housewife. There was a weak association with a low socio-economic status (being in the lowermost three wealth quintiles), recent use of antibiotics, being in a polygamous marriage and a history of previous miscarriage. There was no evidence to suggest an association between BV with primigravidity or being married.

There is a wide variation of the prevalence of BV all across the globe reported in various studies. In pregnant women, it ranges from 6.8% to 28.5% [12, 24, 28, 31], while in non pregnant women it's reported to range from 32.8% to 62.9% [5, 30]. The high prevalence of BV found in this study may be explained by the fact that most of the above studies used pregnant women at large and not the most at risk subgroup like in this study. The high prevalence in this subgroup of pregnant women is being supported by the fact that BV by itself is a risk factor for premature deliveries[1, 12] as well as chorioamnionitis and postpartum endometritis[1].

While BV is well known cause of premature deliveries, several other risk factors for premature labor has been documented in various studies. They include, incompetent cervix or cervical length of less than 15mm, other lower genital tract infection, periodontal disease (periodontitis) and elevated levels of maternal salivary oestriol[1, 32]. The high prevalence of BV (39.2%) found in this study may imply that BV accounts for about 39% of all the above risk factors for premature delivery.

On the other hand, the fact that the prevalence of BV in non pregnant women is high[5] coupled with the finding that recurrence rate post successful treatment is also high[20], make it arguable that the high prevalence (39.2%) obtained in this study implies that many pregnant women conceives with a preexisting BV.

With regard to the risk factors for BV, the study has been able to document that pregnant women with the abnormal vaginal discharge has a fifteen fold risk of getting BV. This is consistent with the findings from other studies that abnormal vaginal discharge is the commonest symptom in BV[1, 2, 8]. This finding, coupled with the fact that BV is more common than either vaginal Candidiasis or Trichomoniasis[3], makes the study to be of the opinion that testing for BV in patients with abnormal vaginal discharges is never to be forgotten in the clinical setting.

Furthermore, the study has been able to document a strong association between BV and such risk factors like low level of education of no more than primary school education, being a house wife and being HIV positive. This is also consistent with other several studies.[2, 5, 14, 30]. On the other hand BV increases susceptibility to HIV infection.[14].

Even though the study has found a weak or no association between BV and such factors like low socio-economic status (being in the lowermost three wealth quintiles), history of recent antibiotics use, primigravidity, being in a polygamous marriage or being married or a history of previous miscarriage, they are well documented risk factors in several other studies [12, 30]. This may be due to the fact that by virtue of its small sample size, the study was not powered enough to find these associations.

Other factors that have been documented by various studies to be risk factors for developing BV include, cigarette smoking, multiple or new sexual partners, intrauterine contraceptives (IUCD), vaginal douching or increased frequency of vaginal washing and increased psychosocial stress [2, 4, 7, 29]. Nevertheless these factors were not part of this study for reasons that, there were only very few candidates who smoked cigarette or used IUCDs in the pilot studies. Inclusion of these rare factors would have thus affected the analysis of the study.
The most important single limitation of this study was the use of only a single method, Amstel's clinical criteria to diagnose BV. Ideally, both Nugent score and Amstel's criteria would have been employed for more plausible results even though a study done at Birmigham

women hospital in UK, concluded that there is no difference between the two methods.[22]. The use of only Amstel's clinical criteria made the study incapable of including patients with ruptured fetal membranes because of the effect of amniotic fluid on the pH of the vaginal fluid.

6.0 CONCLUSION AND RECOMMENDATIONS

In conclusion, BV appears to occur in a great magnitude in patients with premature delivery in our setting as implicated by its high prevalence rate, (39.2%). Specifically, women with abnormal PV discharge have a fifteen fold risk of having BV than women without abnormal PV discharge, as well as those with low level of education of at most primary school level, being a housewife and having HIV infection.

The study therefore recommends that medical practitioners develop a high suspicion index of BV in pregnant women with abnormal vaginal discharge in our clinical setting. Besides, policy makers should probably include screening and treatment for BV in the future policy of Antenatal care package.

REFERENCES

1. Gary F.C, k.J.L., Steven L.B, John C.H, Larry C.G, katharine D.W, ed. *Preterm birth, Sexually transmitted infections: Williams Obstetrics*. 22nd ed. 2005, McGraw-Hill Companies: Dallas-Texas. 862-863.
2. Hillier S, S.P., Mardh P. *Bacterial vaginosis- CDC Fact sheet*. 2006; Available from: http://www.cdc.govt/std/bv/std-fact.
3. Nyirjesy, P., et al., *The effects of intravaginal clindamycin and metronidazole therapy on vaginal lactobacilli in patients with bacterial vaginosis.* Am J Obstet Gynecol, 2006. **194**(5): p. 1277-82.
4. Stoppler M.C. *Bacterial vaginosis*. 2012 March 22, 2012; Available from: http://www.medicinenet.com.
5. Baisley, K., et al., *Bacterial vaginosis in female facility workers in north-western Tanzania: prevalence and risk factors.* Sex Transm Infect, 2009. **85**(5): p. 370-5.
6. Hans V, J.D., Kristien R, Stijn B, Geert C, Marleen T., *subclinical iron deficiency is a strong predictor of bacterial vaginosis in early pregnancy.* BMC Infect Dis, 2005. **55**(5): p. 1497-2334.
7. Nansel, T.R., et al., *The association of psychosocial stress and bacterial vaginosis in a longitudinal cohort.* Am J Obstet Gynecol, 2006. **194**(2): p. 381-6.
8. Curran S.M, *Bacterial vaginosis clinical presentation.* 2012.
9. Goldenberg, R.L., J.C. Hauth, and W.W. Andrews, *Intrauterine infection and preterm delivery.* N Engl J Med, 2000. **342**(20): p. 1500-7.
10. Gomez, R., et al., *Premature labor and intra-amniotic infection. Clinical aspects and role of the cytokines in diagnosis and pathophysiology.* Clin Perinatol, 1995. **22**(2): p. 281-342.
11. Gibbs, R.S., et al., *A review of premature birth and subclinical infection.* Am J Obstet Gynecol, 1992. **166**(5): p. 1515-28.

12. Hillier, S.L., et al., *Association between bacterial vaginosis and preterm delivery of a low-birth-weight infant. The Vaginal Infections and Prematurity Study Group.* N Engl J Med, 1995. **333**(26): p. 1737-42.
13. Gravett, M.G., et al., *Preterm labor associated with subclinical amniotic fluid infection and with bacterial vaginosis.* Obstet Gynecol, 1986. **67**(2): p. 229-37.
14. Myer, L., et al., *Recurrence of symptomatic bacterial vaginosis 12 months after oral metronidazole therapy in HIV-positive and -negative women.* J Infect Dis, 2006. **194**(12): p. 1797-9.
15. Potter, J., *Should sexual partners of women with bacterial vaginosis receive treatment?* Br J Gen Pract, 1999. **49**(448): p. 913-8.
16. Manns-James, L., *Bacterial vaginosis and preterm birth.* J Midwifery Womens Health, 2011. **56**(6): p. 575-83.
17. Carey, J.C., et al., *Metronidazole to prevent preterm delivery in pregnant women with asymptomatic bacterial vaginosis. National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units.* N Engl J Med, 2000. **342**(8): p. 534-40.
18. Lamont, R.F., et al., *Treatment of abnormal vaginal flora in early pregnancy with clindamycin for the prevention of spontaneous preterm birth: a systematic review and metaanalysis.* Am J Obstet Gynecol, 2011. **205**(3): p. 177-90.
19. John C. H, W.W.A., Mary B.D, Rachel L.C *Reduced incidence of preterm delivery with Metronidazole and Erythromycin in women with Bcterial vaginosis.* N Engl J Med, 1995. **333**: p. 1732-1736.
20. Bradshaw, C.S., et al., *High recurrence rates of bacterial vaginosis over the course of 12 months after oral metronidazole therapy and factors associated with recurrence.* J Infect Dis, 2006. **193**(11): p. 1478-86.
21. Bohbot, J.M. and J.P. Lepargneur, *[Bacterial vaginosis in 2011: a lot of questions remain].* Gynecol Obstet Fertil, 2012. **40**(1): p. 31-6.
22. Honest, H., et al., *The accuracy of various tests for bacterial vaginosis in predicting preterm birth: a systematic review.* BJOG, 2004. **111**(5): p. 409-22.

23. Leitich, H., et al., *Bacterial vaginosis as a risk factor for preterm delivery: a meta-analysis.* Am J Obstet Gynecol, 2003. **189**(1): p. 139-47.
24. Svare, J.A., et al., *Bacterial vaginosis in a cohort of Danish pregnant women: prevalence and relationship with preterm delivery, low birthweight and perinatal infections.* BJOG, 2006. **113**(12): p. 1419-25.
25. Goffinet, F., et al., *Bacterial vaginosis: prevalence and predictive value for premature delivery and neonatal infection in women with preterm labour and intact membranes.* Eur J Obstet Gynecol Reprod Biol, 2003. **108**(2): p. 146-51.
26. Laxmi, U., et al., *Association of bacterial vaginosis with adverse fetomaternal outcome in women with spontaneous preterm labor: a prospective cohort study.* J Matern Fetal Neonatal Med, 2012. **25**(1): p. 64-7.
27. Akinbiyi, A.A., R. Watson, and P. Feyi-Waboso, *Prevalence of Candida albicans and bacterial vaginosis in asymptomatic pregnant women in South Yorkshire, United Kingdom. Outcome of a prospective study.* Arch Gynecol Obstet, 2008. **278**(5): p. 463-6.
28. Shayo A.P, K.A., Masinde A.N, Rumanyika R.N, Ngwalide N, Gumodoka B, Kidola J, Magoma M, *Prevalence of Bacterial vaginosis and associted factors among pregnant women attending at Bugando Medical centre, Mwanza, Tanzania.* Tanzania J Med Res, 2012.
29. Hassan, W.M., et al., *Associations between intravaginal practices and bacterial vaginosis in Kenyan female sex workers without symptoms of vaginal infections.* Sex Transm Dis, 2007. **34**(6): p. 384-8.
30. Bhalla, P., et al., *Prevalence of bacterial vaginosis among women in Delhi, India.* Indian J Med Res, 2007. **125**(2): p. 167-72.
31. Goffinet F, M.F., Mihoubi N, Kayem G, Papiernick E,, *Bacterial vaginosis: Prevalence and predictive values for premature delivery and neonatal infection in women with preterm labour and intact membranes.* Eur J Obstet Gynecol Reprod Biol, 2003. **108**(2): p. 146-151.

32. Hassan, S.S., et al., *Patients with an ultrasonographic cervical length < or =15 mm have nearly a 50% risk of early spontaneous preterm delivery.* Am J Obstet Gynecol, 2000. **182**(6): p. 1458-67.

APPENDICES

Appendix I: Questionnaire. (English version)

PART A. Socio-demographic Questions

1. **Name**.....
2. **Age**.....
3. **Residence** ……..
4. **Contact phone number……..**
5. **Education level**
    1. No formal education
    2. Primary school complete.
    3. Primary school incomplete
    4. Secondary school
    5. Post secondary school
6. **Marital status**
    1. Not married(single)
    2. Married.
    3. Divorced.
    4. Widowed
    5. Cohabiting
7. If married, is your marriage a monogamy or polygamy one?
8. When did you have had sex the last time?
9. **Occupation status**
    1. Housewife
    2. Petty trader.
    3. Employed.
    4. Others. (specify)……

10. Do you have the following items at your house?
    1. Refregirator
    2. Motorcycle.
    3. Car
    4. Eletricity.
11. Is a house you live in your own house or a rent one?

12. Are you suffering from any of the following chronic conditions?
    1. Tuberculosis
    2. Diabetes
    3. Asthma.
    4. HIV/ AIDS. (Confirm with the ANC card.)

PART B: Obstetric and Gynaecological Questions.

13. **How many times have you ever been pregnant? (Gravidity**).....

14. **Dou you have any history of previous preterm delivery**…….
    1. **Yes.**
    2. **No.**
15. **Dou you have any history of previous miscarriage?.....**
    1. Yes.
    2. No.

16. **What is your gestation age**?.....(in weeks)

17. **What is your parity**?……..

18. **Do you have any abnormal vaginal discharge**?

    1. Yes
    2. No

19. **If yes, when did it start**?.....

20. What is the colour of the discharge?

21. **Does the discharge have any offensive smell**?

    1. Yes
    2. No

22. Have you used any antibiotics in the past one week?

    1. Yes
    2. No

23. If yes what kind of antibiotics have you used?

PART C. Amstel's criteria chart.

Name of the patient……

Registration Number……..

Age of the patient……..

Address of the patient……..

Patient phone number…….

CRITERIA	POSITIVE	NEGATIVE
Vaginal discharge with non-inflammatory discharge coating the vaginal wall		
Fishy odor before or after adding 10% KOH		
Vaginal acidity with litmus paper.	≥4.5	<4.5
Clue cells on adding a drop of Nacl solution.		

Results. Positive criteria----------

Negative criteria----------

Conclusion. (1) Positive for BV …….( )

(2) Negative for BV…….( )

Appendix II: Questionnaire (Kiswahili Version)

PART A. Socio-demographic Questions

8. **Jina**.....
9. **Umri**.....
10. **Unakaa wapi?** ……..
11. **Namba yako ya simu……..**
12. **Kiwango chako cha juu cha elimu ni kipi?**
    1. Sijasoma
    2. Nimemaliza elimu ya msingi.
    3. Sijamaliza elimu ya msingi
    4. Elimu ya sekondari
    5. Elimu zaidi ya sekondari.
13. **Hali yako ya ndoa ya sasa ikoje?**
    1. Sijaolewa
    2. Nimeolewa
    3. Nimetalikiwa
    4. Mjane
    5. Ninakaa na bwana
14. Kama umeolewa, ndoa yako ni ya mke mmoja au wake wengi?
15. Umefanya tendo la ndoa mara ya mwisho lini?
16. **Kazi yako kwa sasa ni nini?**
    1. Mama wa nyumbani
    2. Biashara ndogondogo
    3. Muajiriwa
    4. Nyinginezo,taja…….

17. Je nyumbani kwenu kuna kipi kati ya vifuatavyo?
    1. Jokofu
    2. Pikipiki.
    3. Gari.
    4. Umeme.

18. Je nyumba mnayoishi ni ya kwenu wenyewe au ni ya kupangisha?

19. Je una magonjwa yoyote sugu kati ya yafuatayo?
    1. Kifua kikuu.
    2. Kisukari.
    3. Pumu.
    4. VVU/ Ukimwi. (Thibitisha kwenye kadi lake la kiliniki.)

PART B: Obstetric and Gynaecological Questions.

20. **Hii ni mimba yako ya ngapi**.....

21. **Je umewahi kuzaa mtoto njiti** …….
    3. **Ndiyo.**
    4. **Hapana**

22. **Je umewahi kuharibikiwa mimba kabla ya kufikisha miezi saba?.....**
    3. Ndiyo
    4. Hapana

23. **Je,mimba yako kwa sasa ina umri gani?.....(andika wiki)**

24. Je,unajua tarehe yako ya makadirio ya kujifungua?

1. Ndiyo, ni lini ..... (Thibitisha kwa kutumia kadi ya kliniki)
2. Hapana

25. **Je,umeshazaa mara ngapi**?……..

26. **Je kuna uchafu wowote usio wa kawaida unaokutoka kwenye sehemu zako za siri**?

3. Ndiyo
4. Hapana

27. **Kama ndiyo, una rangi gani**?.....

28. Je uchafu huo una rangi gani?

29. **Je uchafu huo una harufu mbaya** ?

3. Ndiyo
4. Hapana

30. Je umetumia dawa za antibiotiki ndani ya wiki 1 iliyopita?

3. Ndiyo
4. Hapana

31. Kama ndiyo, je ni dawa gani hizo?

PART C. Amstel's criteria chart.

Name of the patient……

Registration Number…….

Age of the patient……..

Address of the patient……..

Patient phone number……..

CRITERIA	POSITIVE	NEGATIVE
Vaginal discharge with non-inflammatory discharge coating the vaginal wall		
Fishy odor before or after adding 10% KOH		
Vaginal acidity with litmus paper.	≥4.5	<4.5
Clue cells on adding a drop of Nacl solution.		

Results. Positive criteria……..

Negative criteria…….

Conclusion. (1) Positive for BV ……( )

(2) Negative for BV…….( )

Appendix III: Consent Form (English Version)

My name is Dr Palapala J. M from Muhimbili University of Health and allied sciences.
I am conducting a study on prevalence of Bacterial vaginosis and the associated factors among women with preterm labour at Muhimbili National Hospital. The information obtained will provide the descriptive information necessary in understanding the possible association Bacterial vaginosis and preterm labour and thus provide probable ways of preventing the problem.

There is no risk to you if you agree to participate in the study neither will the procedure make your problem worse. Your participation is absolutely voluntary and there is no penalty for refusing to participate. You are free to ask any question and you may stop to participate in this assessment any time if you find it inconvenient.

Do you have any question?

Would you like to participate? (1) Yes [ ] (2) No [ ]

Signature of the participant ……

Date ……

Appendix IV: CONSENT FORM (Kiswahili Version)

Mimi naitwa Dr. Palapala J.M kutoka chuo kiuu cha sayansi za tiba Muhimbili.
Ninafanya utafiti juu ya " uwezekano wa uwepo wa wadudu wa aina ya Bacteria katika sehemu za siri kwa wanawake wanao pata uchungu kabla ya wakati.
Matokeo ya utafiti huu yataweza kusaidia kupanua uelewa juu ya tatizo hilo na yamkini kutoa namna ya kukabiliana nalo.

Hakuna madhara yoyote yatakayo tokana na kushiriki kwenye utafiti huu. Taarifa za ushiriki wako zitakuwa ni siri kati yangu mimi na wewe.
Hakutakuwa na adhabu yoyote ile kwa kutoshiriki kwenye utafiti huu, na utaendelea kupata huduma kama kawaida. Unaweza kujiondoa kwenye utafiti mda wowote ikiwa utapata shida au udhia wowote.
Je una maswali yoyote?

Na je ungependa kushiriki? (1) Ndiyo [ ] (2) Hpana. [ ]

Saini ya mshiriki …….

Tarehe …….