

AFRICA UNIVERSITY

(A United Methodist-Related Institution)

**PAP SMEAR VS GRAM STAINED HIGH VAGINAL SMEARS TO
DETECT BACTERIAL VAGINOSIS IN WOMEN BETWEEN (21-65)
YEARS AT OMNIPATH MEDICAL LABORATORIES, HARARE: A
RETROSPECTIVE STUDY (OCTOBER 2023 TO SEPTEMBER 2024)**

By

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A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE
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Abstract

Disagreement between Gram's stain and Pap smear diagnostic tests leaves doctors uncertain on which test to trust for clinical decision-making. This study compares the effectiveness of Pap smear method against Gram stain method to detect bacterial vaginosis thereby determining the reliability of Pap smear as a diagnostic tool. Bacterial vaginosis (BV) is a common vaginal condition resulting from an imbalance in the normal bacterial flora. It is characterized by an overgrowth of certain bacteria and can lead to various health complications, including pelvic inflammatory disease and increased susceptibility to sexually transmitted infections. There are often discrepancies in the results obtained from Pap smear cytology reports and Gram's stain diagnostic methods, leading to challenges in confirming the diagnosis. Bacterial vaginosis has been recorded as the second leading cause of newborn mortality and it costs \$4.8 billion to treat annually. A retrospective cross-sectional study was done from December 2024 to January 2025 at Omnipath Medical Laboratories involving 200 women aged between 21 and 65 years with suspected cases of bacterial vaginosis. Exclusion criteria included women below 21 years and those above 65 years. Systematic random sampling was used as choice of sampling method. Data collected was analyzed and presented in tables and graphs. Statistical methods including Cohen's Kappa, specificity, sensitivity, negative and positive predictive values were used to analyze and summarize the data. The most participants were from the age group 21-35 years. From the 200 participants there were 300 samples provided, 173 were High Vaginal Smears (HVS) and 127 were Pap Smears. Hundred patients had provided both swabs and pap smear; 64 of the test results from Pap smear were negative and 36 were positive whereas results from Gram's stain showed 86 positives and 14 negatives indicating a lack of agreement between two methods. The study highlighted that Pap smear had a low sensitivity when compared against Gram's staining. The Cohen's Kappa shows that there is no agreement between the two tests. Gram's stain had a higher turn-around time compared to Pap smear. The study showed Gram's staining is a simple procedure that can be done in various settings whereas pap smear is more complex due to the need for proper fixation and processing methods. Based on the observations made from this study, it is recommended that clinicians prioritize gram staining over pap smear in detecting bacterial vaginosis. It is also recommended to have training programs to enhance laboratory personnel skills in reporting HVS and Pap smear based on these findings.

DECLARATION

I, Lynn Mutunzi, student number 210597 do declare that this project work has never been submitted, nor will it ever be submitted to another university for the award of a Bachelor of Science degree.

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Acronyms and Abbreviations

AUREC..... Africa University Research Ethics Committee

BV.....Bacterial Vaginosis

WHO.....World Health Organisation

Definition of key terms

- Bacterial Vaginosis- a vaginal condition where there is an imbalance in the normal bacterial flora of the vagina.
- Pap Smear- screening test for cancer and precancerous changes in cervical cells.
- Gram stain- staining technique used to classify bacteria into gram-positive or gram-negative bacteria based on their cell wall composition.
- High vaginal Swab- a sample collected from the upper vagina for laboratory testing.
- Sampling- It is a process of selecting a group of individuals from a larger population that will be representative of the larger population.
- Systematic Random sampling- It is a sampling technique where individuals are selected from a population at regular intervals after a random starting point.
- Study Design- It is the overall plan that outlines the approach and methods used to conduct a research study.

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Chapter 1 Introduction

1.1 Introduction

This research aims to fill in a gap in the understanding of the comparative effectiveness of pap smears and gram stained smears, contributing valuable insights to the field of women's health. The gram stain method is recognized as the gold standard for diagnosing bacterial vaginosis hence this research will compare the effectiveness of the Pap smear method against the gram stain method to detect bacterial vaginosis. In this chapter, the background, the problem statement, research objectives, research questions, hypothesis, justification of study and study delimitations will be discussed.

1.2 Background of Study

World Health Organisation (WHO) defines Bacterial vaginosis (BV) as a common vaginal condition resulting from an imbalance in the normal bacterial flora (WHO, 2023). Normal flora refers to microorganisms that naturally inhabit various parts of the human body, that includes the skin, mouth, gut and other mucosal surfaces (Davis,1996). According to WHO, bacterial vaginosis is the most common cause of vaginal discharge and is predominant in women of reproductive age (WHO, 2023). It is characterized by an overgrowth of certain bacteria and can lead to various health complications, including pelvic inflammatory disease and increased susceptibility to sexually transmitted infections (Floch et al., 2017). Pap smear and Gram staining are tests used to detect bacterial vaginosis in women (Anand, 2020). Gram stain is a laboratory technique that is used to help identify bacteria species according to their cell wall composition. It groups them into either gram-positive species that can retain the primary colour during staining or gram-negative

bacteria that lose the primary color and pick up the counterstain (Cheesbrough, 2006). Gram staining of HVS is considered a standard diagnostic method for BV, as it can detect the presence of a high Nugent score, which indicates a shift in the normal vaginal flora (Santos et al., 2023). A high vaginal swab is taken from the vaginal canal for gram staining to help diagnose BV. Research has highlighted that presence of bacterial vaginosis is shown by abundance of gram-positive and gram-negative cocci, along with a decrease in lactobacilli causing shift in normal flora (WHO, 2023). Pap Smear is a screening procedure mainly used to detect cervical cancer or precancerous changes in cervical cells, but it can also be used to detect BV because of the presence of clue cells which are an indicator of BV (Santos et al., 2023). Pap smear cytology, a routine screening test for cervical cancer, can potentially provide clues about the presence of BV, such as the observation of clue cells and a shift in the vaginal flora. Despite the potential utility of both techniques, there are often discrepancies in the results obtained from these methods. For instance, a Gram-stained HVS may show a high Nugent score and the presence of clue cells, indicating the presence of BV, while the corresponding Pap smear cytology report may suggest no evidence of pathogens and a normal vaginal flora. In as much as both tests can be used to diagnose BV, there are often differences in results obtained which can make it difficult to diagnose bacterial vaginosis. Results can differ due to diagnostic criteria, staining limitations and areas where the sample is collected (Santos et al., 2023). The diagnosis of BV primarily relies on clinical assessment and laboratory tests, notably Gram staining of high vaginal smears and Pap smear cytology (Money, 2005). This study aims to compare the effectiveness of the pap smear against the Gram stain in detecting BV in women aged 21-65 years at Omnipath Medical Laboratories.

1.3 Statement of Problem

Bacterial vaginosis (BV) is a common vaginal infection characterized by an imbalance in the normal vaginal flora, with an overgrowth of anaerobic bacteria. Accurate and timely diagnosis of BV is crucial for appropriate treatment and management of the condition. However, there are often discrepancies in the results obtained from different diagnostic methods, leading to challenges in confirming the diagnosis. One such challenge arises in the comparison of Pap smear cytology reports and Gram-stained high vaginal swabs (HVS) for the detection of BV. Bacterial vaginosis (BV) is a common polymicrobial disorder of the vaginal microbiota characterized by loss of lactobacilli and increasing numbers of anaerobes and Gram-negative rods. According to WHO (2023), BV affects about 30% of women of reproductive age and it costs around \$4.8 billion to treat annually. Not only does BV increase risk of getting sexually transmitted infections but it has been recorded as the second leading cause of newborn mortality (WHO, 2023). WHO has noted that BV prevalence varies across countries and population groups and globally it affects 23-29% women of reproductive age. In Europe and central Asia, BV has been recorded to be 23%, East Asia and Pacific 24%, Middle East and North Africa 25%, Sub-Saharan Africa 25% and South Asia 29% (Morressier, 2017). Prevalence of BV in South Africa is about 50%, BV incidence and recurrence was associated with the younger age (Asare,2023). A study conducted in Zimbabwe showed 24.7% of the women had BV (Chirenje et al.,2018).

In clinical practice, doctors frequently receive conflicting reports on BV for the same patient. One report comes from a Gram-stained high vaginal smear (HVS), the recognized gold standard for BV diagnosis, while another comes from a Pap smear cytology report, where BV is noted as secondary result. These two reports can yield different results, leaving doctors uncertain about which test to trust for clinical decision-making. Furthermore, there is no clear protocol on which

diagnostic method to prioritize for clinical decision making and this often complicates patient management, potentially leading to misdiagnosis, delays in treatment, or unnecessary interventions.

This study thus aimed to address this diagnostic uncertainty by determining the prevalence of BV among women aged 21–65 years using both HVS Gram stains and Pap smear cytology. It compared the sensitivity, specificity, and overall diagnostic accuracy of Pap smear cytology against the Gram stain method to establish the more reliable test. Additionally, the study evaluated the operational characteristics of both methods, including turnaround time, sample requirements, and expertise needed. While existing literature suggests that the Gram stain method is superior, this study sought to provide local evidence to guide clinical practice and establish a standardized protocol for BV diagnosis. By clarifying the diagnostic reliability of these methods, the study aimed to improve patient outcomes and enhance the accuracy of BV detection in healthcare settings.

1.4 Justification

Conducting a research comparing the diagnostic reliability of gram stain and pap smear in detecting BV is of public health importance. Studies show BV recurrence rates are high, about 80% three months after treatment (Coudray & Madhivanan, 2020). The research added valuable data to the existing body of research in BV diagnosis hence improving diagnostic tests for better patient outcome. There is a significant difference in the diagnostic accuracy (sensitivity and specificity) between Pap smear cytology and Gram-stained high vaginal smears (HVS) in detecting bacterial vaginosis among women aged 21 to 65 years. Specifically, Gram-stained HVS demonstrated higher sensitivity in identifying bacterial vaginosis compared to Pap smear cytology.

1.5 Research Objectives

1.5.1 Broad Objectives

To compare pap smear cytology reports against gram stained high vaginal smears amongst women aged between 21 to 65 years to detect bacterial vaginosis.

1.5.2 Specific Objectives

1. To determine prevalence of bacterial vaginosis in high vaginal swabs (HVS) and pap smears amongst women aged between 21-65years
2. To compare the diagnostic accuracy (Specificity, Sensitivity) of Pap smear cytology reports against Gram-stained high vaginal smears (HVS) in the detection of bacterial vaginosis
3. To compare the operational characteristics (Turn-around time, Sample requirements, Expertise required) for the Gram Stained HVS and Pap smear cytology test.

1.6 Research Questions

1. What is prevalence of bacterial vaginosis using gram stained high vaginal swabs (HVS) and pap smears amongst women aged between 21-65years?
2. How do the diagnostic accuracies of pap smear cytology reports and gram stained HVS's compare in detecting bacterial vaginosis?
3. How do the sensitivity and specificity of gram stain and pap smear contribute to discrepancies observed between Pap smear cytology and Gram-stained high vaginal swabs in detecting bacterial vaginosis?

4. How do the operational characteristics of both tests compare?

1.7 Study Limitations

This study is a retrospective study that analyzed records at Omnipath Medical Laboratories. Some patients included in the study may not represent the broader population, existing records may be incomplete, missing or poorly documented. The interpretation of the results may vary based on the scientist's experience and criteria of diagnosis, affecting the reliability of the comparative analysis.

1.8 Delimitation

The study was conducted in Harare using data from Omnipath Medical Laboratories. The research looked for data captured from women aged between 21 and 65 years who have suffered from bacterial vaginosis. It focused on comparing the diagnostic tests; pap smear and gram-stained HVS's in detecting bacterial vaginosis. Considering that Omnipath Medical Laboratory mainly focuses on microbiology and doing gram stains of HVS made it ideal to conduct a research in this area. The results are limited to Omnipath Medical Laboratory.

1.8 Summary

This chapter introduced the study, highlighting the challenge of conflicting BV diagnostic results from Pap smear cytology and Gram-stained high vaginal smears (HVS). It outlined the study's aim to compare the diagnostic accuracy and operational characteristics of both methods to establish the more reliable test. The chapter also covered the background, problem statement, research objectives, research questions, justification, limitations, and delimitations of the study.

Chapter 2: Literature review

2.1 Introduction

Bacterial Vaginosis is a condition prevalent amongst women of reproductive age. In this chapter, relevant literature on causes of BV and the diagnostic methods used including Pap Smear and gram-stained high vaginal smears will be reviewed.

2.2 Conceptual Framework

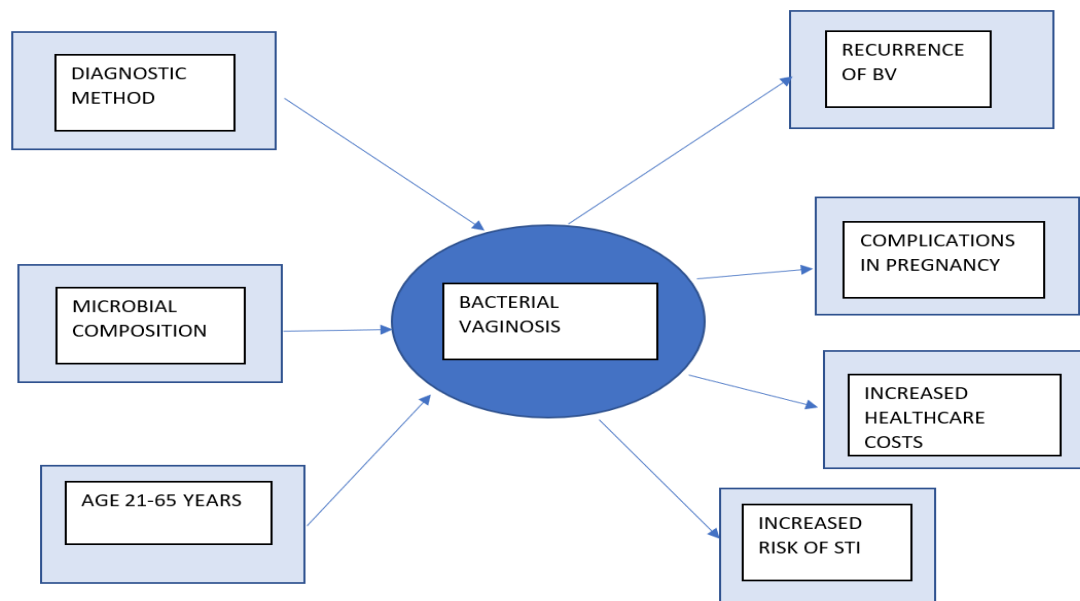


Figure 2.1 : Conceptual framework for diagnostic discrepancies for BV diagnosis

This study's conceptual framework examines the relationship between Pap smear cytology and Gram-stained high vaginal smear (HVS) for diagnosing bacterial vaginosis (BV), emphasizing diagnostic accuracy, concordance, and operational feasibility. Key variables include sensitivity,

specificity, and practical factors like turnaround time, technical expertise, and sample requirements. Moderating variables, such as patient demographics (age, sexual behavior) and clinical factors (vaginal microbiota composition), potentially influence BV prevalence and diagnostic discrepancies between methods. Diagnostic outcomes focus on accuracy metrics (e.g., Positive Predictive Value, Negative Predictive Value) and agreement, aimed to clarify each method's diagnostic reliability and the factors affecting concordance, ultimately guiding improved BV detection and management. Poor diagnosis and diagnostic methods can lead to increased chances of STI, complications in pregnancy and ultimately poor prognosis and increased healthcare costs.

2.3 Literature Review

2.3.1 Prevalence of Bacterial Vaginosis

Bacterial vaginosis (BV) is one of the most common vaginal infections, with prevalence rates varying significantly by age, geographic region, and sexual behavior. The reproductive age significantly influences the detection of BV. There is higher prevalence of nearly 29.2% in younger women particularly aged 21-25 years because of their higher sexual activity levels and risk is increased if they have multiple sexual partners (Kamga et al., 2019). The highest prevalence of about 58.8% is amongst women aged 25-34 years due to their lifestyles and possibly sexual behaviors (Abdullateef et al., 2018). Ages above 35 years seem to have a lower rate of BV, maybe due to increased stability in relationships or improved knowledge about vaginal hygiene (Kamga et al., 2019). These findings underscore the importance of effective diagnostic methods across age groups, particularly in those with higher prevalence, to ensure early detection and management.

2.3.2 Microbial composition of Vaginal Flora

A healthy vaginal environment is dominated by *Lactobacillus* species, which maintain an acidic pH that inhibits pathogen overgrowth. BV is characterized by a shift in the vaginal microbiota, often with a decline in *Lactobacillus spp.* and an overgrowth of anaerobes. Key microbial players include *Lactobacillus spp.*, *Gardnerella vaginalis* and anaerobic gram-negative rods (Vardar et al., 2002). Balance between *Lactobacillus spp.* and anaerobic bacteria is important in diagnosing BV. pH changes affect the environment of normal flora, an alkaline environment causes a decline in *Lactobacillus* causing shift in normal flora leading to BV (Muzny,2019). *Gardnerella vaginalis* adheres to vaginal epithelial cells and outcompete *Lactobacilli* for nutrients leading to microbial dysbiosis (Mondal,2023). *Gardnerella vaginalis* can form biofilms on the vaginal epithelium which are difficult to treat because they are resistant to most antibiotics (Lamont, 2020).

2.3.3 Diagnosis of Bacterial Vaginosis

According to Colonna and Steelman (2023), the gold standard for BV diagnosis is using the Nugent scoring system whereby specific bacterial morphotypes identified in vaginal swab sample are categorized then provide a quantitative score. The smears are examined for *Lactobacillus*, *Gardnerella* and curved gram rods. Based on the number of bacteria counted, each bacteria is given a score which is then summed up to give a total score that is used to confirm presence of BV (Colonna and Steelman, 2023).

Diagnosis of BV can also be done using a Pap Smear. This is a test that involves collecting cells from the cervix and examining them microscopically. A pap smear is taken by using a brush or

spatula then spread sample on a glass slide, stain using Papanicolaou. If the cells viewed appear to be covered by bacteria they are identified as clue cells which is an indicator of BV showing an imbalance in the vaginal flora (Tokyol et al.,2004). Studies have shown that pap smears can detect BV but its sensitivity for diagnosing BV is limited (Anand,2020). The pap smear does not specifically target the bacterial composition of the vaginal flora, which is essential for diagnosing BV (Redelinghuys et al., 2020).

A gram stain can also be used. Gram staining is a direct assessment of the vaginal microbial flora. It uses the Nugent score, where a score of 7 or higher indicates BV. Gram staining involves spreading sample on glass slide and staining it uses Gram's technique then viewing it under a microscope (Cheesbrough, 2006). The Nugent score system quantifies different bacterial morphotypes that includes *Lactobacillus spp.*, *Gardnerella vaginalis* and anaerobic gram-negative rods and *Mobiluncus spp.* (Colonna & Steelman, 2023). Normal flora is shown by an abundance of *Lactobacillus spp.* whereas abundance of anaerobic gram negative rods and *mobiluncus spp.* indicate BV (Spiegel et al., 1983). This method has shown to have higher sensitivity and specificity for BV diagnosis to Pap smears, making it more reliable option to use in clinical settings (Mondal et al., 2023).

Bacterial vaginosis can be detected using molecular testing like real time PCR(RT-PCR). This technique can detect specific bacterial DNA associated with BV such as that of *Gardnerella vaginalis* and *atopobium vaginae* In the sample (Savicheva,2023). Although using RT-PCR to detect bacterial vaginosis is reliable, it is very expensive to use compared to other methods such as gram stain and may not provide a cost benefit.

Vaginal pH testing measures the acidity of vaginal fluid. A pH greater than 4.5 is an indicator of BV. This test on its own is not reliable hence it need to be used with other tests to support the diagnosis (Savicheva, 2023).

Whiff test is done by mixing vaginal discharge sample with potassium hydroxide to observe a fishy odor which is a characteristic of BV (Money D.,2005).

2.3.4 Diagnostic Accuracy of Pap smear vs Gram Stained HVS

Studies have shown that while Pap smears can detect BV, their sensitivity is generally lower compared to other methods like Gram staining. For instance, one study reported a sensitivity of approximately 70.9% for Pap smears in diagnosing BV, indicating that while they can be effective, they may miss some cases. The specificity was noted to be around 56.8%, suggesting that false positives can occur (Verhelst et al.,2005). Due to its limitations in sensitivity, pap smear results are often used together with gram stain results to yield best diagnostic outcomes. In a situation where the results do not agree, we have to rely on gram stain results since they are more sensitive and specific. Misdiagnosis can lead to poor treatment and management. Literature suggests that while pap smears can provide some insight into the vaginal flora, gram stained HVS are superior in diagnosing bacterial vaginosis (Anand,2020).

2.3.5 Operational Characteristics: Turnaround Time, Technical Expertise, and Sample Requirements

Operational aspects such as turnaround time, technical expertise, and sample requirements are crucial in selecting diagnostic methods for BV. Pap smear cytology, typically performed in conjunction with routine cervical screening, may have a longer turnaround time as slides require staining, examination, and pathologist review, which can delay BV diagnosis (Sobel, 2018). Gram-stained HVS, however, allows for faster processing and results, often within hours if resources are available, facilitating timely diagnosis and treatment (Schwebke et al., 2020). Furthermore, the expertise required for each test differs; Gram-stained HVS requires familiarity with Nugent scoring, while Pap smears necessitate cytology skills for cellular assessment, which can impact accessibility and consistency across laboratories (Schwebke et al., 2020). Sample requirements also vary, as Pap smears use cervical cells collected during a pelvic exam, whereas Gram-stained HVS involves a high vaginal swab that can be collected in a broader range of clinical settings. These operational differences highlight that while Gram-stained HVS may provide faster and potentially more accurate results, its utility and accessibility may depend on available expertise and laboratory infrastructure.

2.4 Summary

Addressing the diagnostic differences is essential in selecting appropriate diagnostic tools in clinical practice thereby making informed decisions that enhance patient outcomes. Implementing these evidence-based recommendations can help reduce the burden of BV among women.

Chapter 3: Methodology

3:1 Introduction

This chapter is about the methodology of how this research was conducted. It highlights the research design, study site, people involved in the study, sample size, how the population of study was selected, data collection instruments, how the data was collected, data presentation and ethical consideration

3.2 The Research Design

A retrospective cross-sectional study design was employed in this study, as it allowed for the analysis of existing records to compare the diagnostic accuracy of Pap smear cytology and Gram-stained high vaginal smears (HVS) for bacterial vaginosis (BV) among women aged 21–65 at Omnipath Medical Laboratories over a one-year period. This design enabled a comparative assessment of diagnostic performance metrics, including sensitivity, specificity, positive predictive value, and negative predictive value, without the need for patient follow-up. All relevant patient records within the study timeframe was reviewed, focusing on diagnostic results and any pertinent demographic data like patient age. The cross-sectional approach was both cost-effective and appropriate for analyzing historical data, making it suitable for determining which diagnostic method provides greater reliability for BV detection in this setting.

3.3 Study Population

Study was done at Omnipath Medical Laboratories found in Harare, Zimbabwe. The laboratory receives an average of 230 patients a day, with about 23 patients requesting for pap smear and high

vaginal swab tests, it has 20 staff members including 3 Scientists. Omnipath Medical Laboratory receives samples across Harare province and other samples are referred to the laboratory from provinces outside Harare, this gives it a greater probability of finding samples from women of reproductive age with bacterial vaginosis.



Figure 3.1: Map of Zimbabwe showing location of Harare.

3.4 Inclusion Criteria

The study focused on women between the age of 21 to 65 years with suspected cases of bacterial vaginosis, from the period October 2023 to September 2024. This age group is commonly diagnosed with bacterial vaginosis and at this age vaginal microbiome is affected by hormonal fluctuations. Samples were taken from the vaginal area.

3.5 Exclusion Criteria

Study excluded samples from women under 21 years and above 65 years. In young women below 21 years there may not yet be sexually active, or they would have just begun sexual activity.

Women above 65 years often would have reached menopause which can alter the vaginal microbiome due to decreased estrogen levels.

3.6 Sampling

Formulae used to calculate sample size is;

$$SS = \frac{Z^2 \times (p) \times (1-p)}{C^2}$$

Where;

SS= Sample size

Z= the Z value (e.g. 1.96 for 95% confidence level)

P= percentage of population picking a choice (expressed as a decimal)

C= Confidence interval (expressed as a percentage)

Therefore; SS = 200

A sample size of 200 patient records was used for the study. Of that sample size, 100 patient records were used for comparing diagnostic tests Pap smear against Gram's staining technique to detect BV and the other 100 of this sample size was used as a validation study to evaluate and confirm which diagnostic test is accurate, reliable and consistent in detecting BV.

3.7 Sampling Procedure

Sampling Procedure used is systematic random sampling. This method allowed for the selection participants from a larger population, ensuring a representative sample of women who may have bacterial vaginosis. This reduced bias and increased representativeness of the whole population.

3.8 Pilot Study

A preliminary study of 15 samples was conducted at Omnipath Medical Laboratory using data from October 2023 to evaluate the feasibility, duration and cost of the study. The pre-testing procedure involved looking at 15 records of patients diagnosed with BV.

3.9 Study setting

Study was conducted at Omnipath Medical laboratories. Data was collected from laboratory reports, forms and clinical data of desired patients. Permission was sort from authorities at Omnipath Medical Laboratories.

3.10 Data Collection Instruments

Secondary data was used. Laboratory reports and forms were used to collect data including medical records and forms with information on bacterial vaginosis. Omnipath Medical Laboratories is not only a medical facility but also an educational institute that allows students or researchers to use their data for research purposes hence their data collection process is transparent and well documented increasing its reliability as a source of secondary data.

3.11 Analysis And Organisation of Data

Data collected was reviewed for completeness, accuracy and checked for anomalies that may affect analysis. Key variables were described, and statistical methods were applied in the analysis including negative predictive value, positive predictive value, Cohen's Kappa specificity and sensitivity. Cohen's Kappa is a statistical measure of agreement between two measurement methods or diagnostic tests in-order to evaluate the methods agree beyond what would be expected by chance. This helped compare the two diagnostic tests used to detect bacterial vaginosis. Descriptive statistics were used to summarize the characteristics of the study population and prevalence of bacterial vaginosis. Data was presented in tables, graphs and frequency distribution to help in understanding.

3.12 Ethical Consideration

The study was done keeping in mind the ethical considerations. Approval was sought from the Africa University Research Ethics Committee and Omnipath Medical Laboratories. All information was collected following the guide from the ethics committee. Ethical approval number is AUREC 3531/24.

3.13 Summary

The study was done at Omnipath Medical Laboratories using cross sectional study design. Data was collected from the Laboratory and ethical considerations were observed. Participants were randomly selected using systematic random sampling. Data was analyzed and organized.

Chapter 4: Data Presentation, Analysis and Interpretation

4.1 Introduction

This chapter contains the results obtained from the study. The study aims to determine prevalence of BV, compare the diagnostic accuracy between pap smears against gram stained high vaginal smears and compare operational characteristics of the two tests. The results will outline the demographic characteristics of the study population followed by a detailed comparison of the diagnostic outcomes from pap smears and gram-stained high vaginal smears.

4.2 Results

4.2.1 Demographics

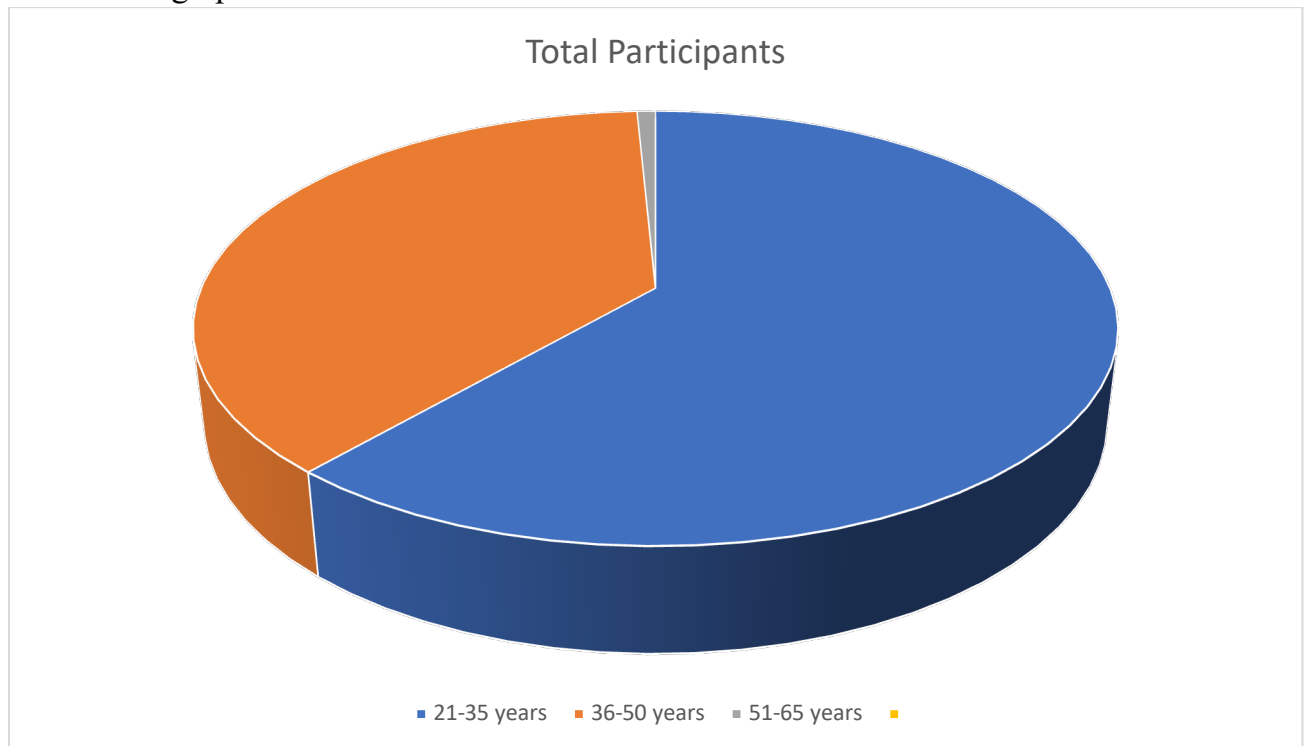


Figure 4.1: Distribution of participants by age

The data in Figure 4.1 shows the distribution of participants across different age ranges. The largest group of participants falls within the 21-35 years age range, representing 56% of the total. The 36-50 years age range accounts for 34.5% of the participants, while the smallest group is the 51-65

years age range, making up 9.5% of the total. This indicates that the majority of participants are younger, with participation decreasing as age increases. The 21-35 years group is the most represented, highlighting a higher prevalence in this age group compared to the older age groups.

4.2.2 Distribution of Testing methods based on age

Table 1: Demographic distribution of the study population

Patient Age Range	High vaginal smear	PAP Smear	Both HVS and PAP smear	Total
21-35 years	30	6	76	112
36-50 years	37	17	15	69
51-65years	6	4	9	19
Total	73	27	100	200

A total of 200 patient records were observed with age ranging from 21 years to 65 years. 100 of the patients had provided either a Pap smear or HVS for processing as shown in table 1. The other 100 had provided both Pap smear and HVS for processing as shown in table 1. The total number of procedures done was 300. The majority of patients who underwent these procedures were in the 21-35 age range, accounting for 62.7% of the total samples. The number of procedures decreased with increasing age, with the 36-50 years and 51-65 years groups representing 28% and 9.3%, respectively. The total number of Pap Smears was lower than High Vaginal Smears, suggesting a preference or higher demand for HVS in this population. The findings indicate a trend toward younger women undergoing these screenings more frequently. The patients provided either vaginal swabs or pap smear, in some cases both to be processed for the detection of bacterial vaginosis.

4.2.2 Prevalence of Bacterial vaginosis

Table 2: Results of Bacterial Vaginosis from samples

Bacterial Vaginosis	High Vaginal Smear	PAP Smear	Total
Positive Patients	146	45	191
Negative Patients	27	82	109
Total	173	127	300

Out of 300 samples provided by 200 patients, 173 were high vaginal swabs and 127 were Pap Smear. 191 were positive for bacterial vaginosis. As a percentage the prevalence of BV was 63.7%. On the other, the samples negative for BV were 109. As a percentage 36.3% were negative for bacterial vaginosis.

4.2.3 Overall Prevalence Based on both testing methods

100 patients had provided both swabs and Pap smear. There was lack of agreement between the Pap smear results and gram staining results. 64 of the test results from pap smear were negative and 36 were positive whereas gram staining effectively identified presence of clue cells and assessed the vaginal flora's composition resulting in 86 positives and 14 negatives.

This is represented in the table below.

Table 3: Patients that provided both a swab and Pap smear

Testing Method	Positive Results	Negative Results	Total Samples
High Vaginal Smear(Gram Staining)	86	14	100
PAP Smear	36	64	100

The analysis of 100 patients who underwent both High Vaginal Smear (Gram Staining) and PAP Smear testing revealed a significant discrepancy in results. While Gram Staining identified 86 samples as positive for clue cells and assessed vaginal flora, the PAP Smear reported only 36 positive and 64 negative results. This indicates a lack of agreement between the two methods, suggesting that Gram Staining may be more effective in detecting vaginal abnormalities in this subset of patients.

Determining Prevalence of BV among the Patients

With the above data, the total prevalence of BV using both methods for the sample given can be calculated as such

$$\begin{aligned}\text{Prevalence} &= \text{Total unique patients tested} / \text{Total unique positive cases} \times 100 \\ &= 155 / 200 \times 100 = 77.5\%\end{aligned}$$

Using both testing methods, the overall prevalence of BV amongst this sample is therefore 77.5%

Prevalence amongst different age groups has been graphically represented. There is higher prevalence of BV in the younger age group than the older ages.

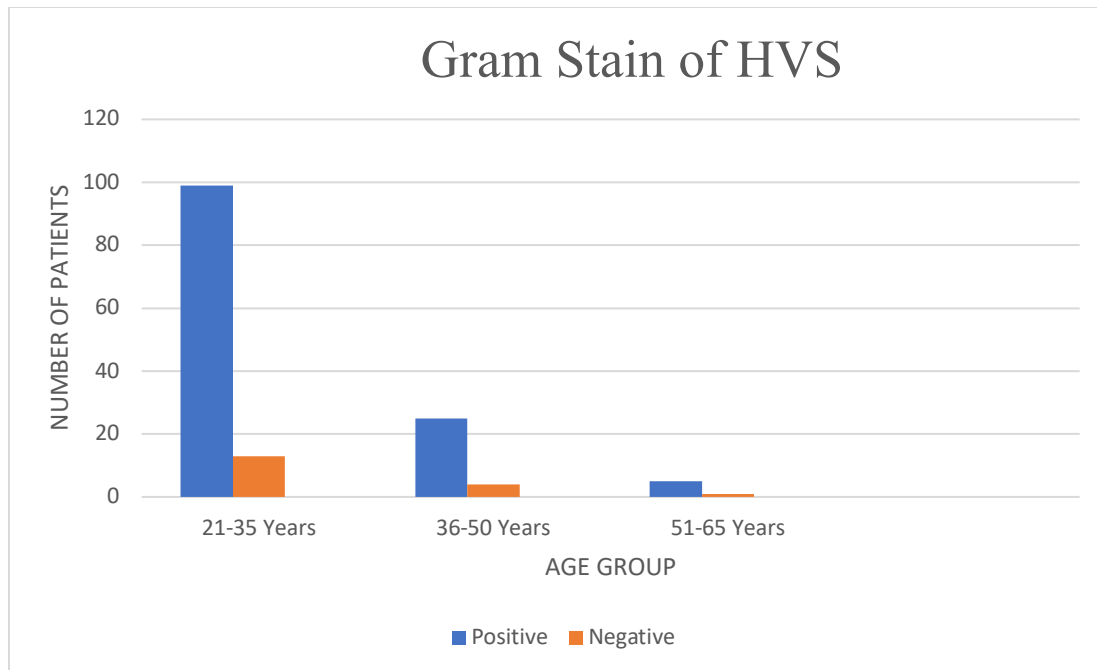


Figure 4.2: Prevalence of bacterial vaginosis in different age groups using Gram's stain

With Gram staining, Age group of 21-35 Years had 99 positive patients and 13 negative patients, age group of 36-50 Years had 25 positive patients and 4 negative patients, then age group of 51-65 Years had 5 positive patients and 1 negative patient.

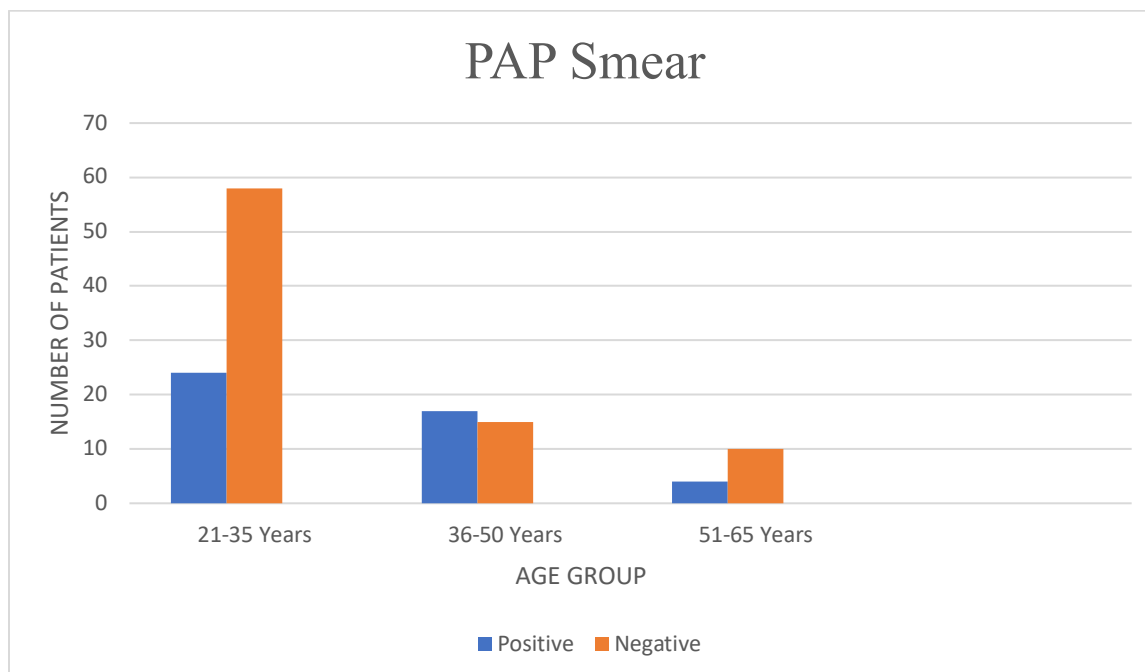


Figure 4.3: Prevalence of bacterial vaginosis in different age groups using Pap smear

With PAP Smear, Age group of 21-35 Years had 24 positive patients and 58 negative patients, age group of 36-50 Years had 17 positive patients and 15 negative patients, then age group of 51-65 Years had 4 positive patients and 9 negative patients.

4.2.3 Diagnostic accuracy of pap smear cytology reports against gram -stained HVS in detection of BV

To compare the diagnostic accuracies of PAP smear cytology reports against gram-stained high vaginal swabs in detecting bacterial vaginosis, sensitivity and specificity was calculated based on the data collected. Sensitivity is the ability of a test to correctly identify those with the disease whereas specificity is the ability of a test to correctly identify those without the disease. Out of the 64 pap smear results that tested negative, about 50 of the results were false negatives. These 50 patients had requested for both gram staining and pap smear to be done and there was no agreement between the results. This has been presented in a contingency table below with Gram staining as the gold standard.

Table 4: Contingency table for diagnostic accuracy of Pap smear against Gram stain

	Pap Smear	HVS Gram Stain(Gold Standard)	Total
Positive	36(True positives)	0(False Positives)	36
Negative	50(False Negatives)	0(True Negatives)	50
Total	86	0	86

Table 5: Diagnostic accuracy of Pap Smear against Gram staining

Metric	Formula	Calculation	Value
Sensitivity	$TP / (TP + FN)$	$36 / (36 + 50)$	42%
Specificity	$TN / (TN + FP)$	$14 / (14 + 0)$	100%
PPV	$TP / (TP + FP)$	$36 / (36 + 0)$	100%
NPV	$TN / (TN + FN)$	$0 / (0 + 50)$	0%
Accuracy	$(TP + TN) / (TP + TN + FP + FN)$	$(36 + 0) / (36 + 0 + 0 + 50)$	42%
Cohen's Kappa*	$(Po - Pe) / (1 - Pe)$	$(0.42 - 0.42) / (1 - 0.42)$	0

The study results highlight that Pap smear had a low sensitivity (42%), detecting only 42% of true BV cases, and an undefined specificity due to the absence of true negatives. However, the positive predictive value (PPV) was 100%, indicating all positive Pap smear results were true positives, but the negative predictive value (NPV) was 0%, meaning it failed to rule out BV in negative cases. Overall accuracy was 42%, reflecting its limited reliability as a standalone diagnostic tool. These findings highlight the need to prioritize Gram staining for BV diagnosis, as Pap smear alone may lead to underdiagnosis.

The Cohen's Kappa shows that there is no agreement in the test methods by any chance, highlighting the fact that the two methods cannot be used interchangeably.

4.2.4 Operational characteristics (Turn-around time, Sample requirements, Expertise required) for the Gram Stained HVS and Pap smear cytology test.

4.2.4.1 Turn-around time for processing

Turn-around time differs depending on workload and laboratory protocols but for swabs processing takes about 2 to 3 days whereas for PAP smear it takes about 5 to 10 working days upon receipt of specimen. Ideally two endocervical swabs are recommended for gram staining, one for culture and the other for staining and wet preparation. The graph below shows average turn- around times for each month from October 2023 to September 2024 for both diagnostic tests.

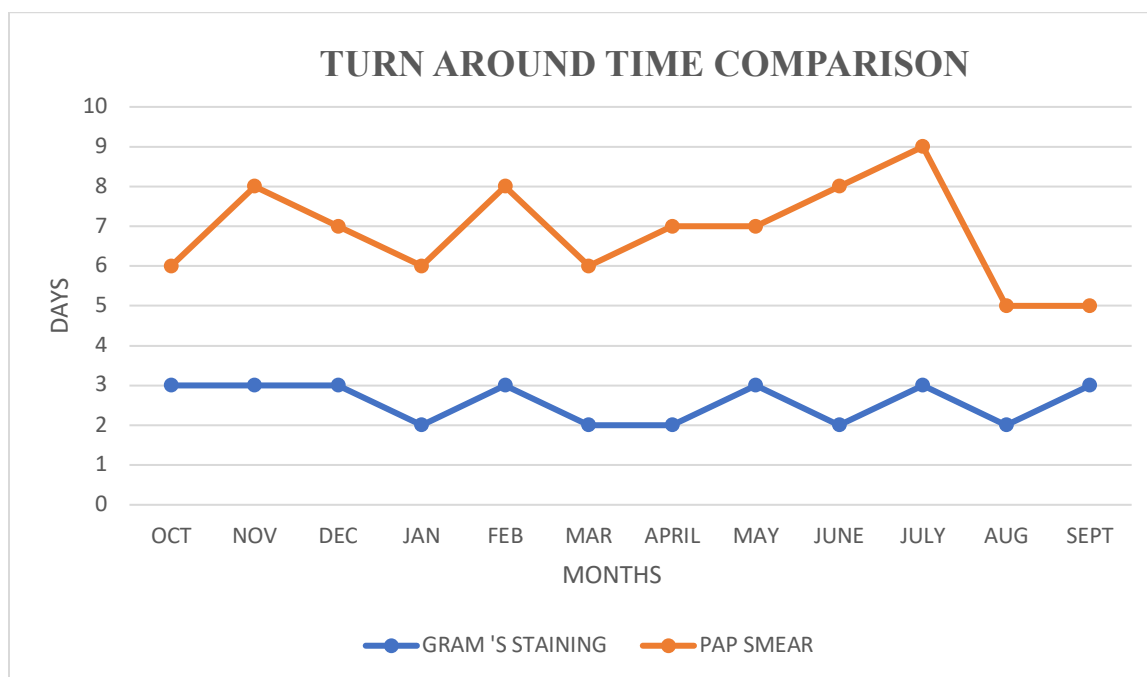


Figure 4.4 :Turn-around time for pap smear and gram's stain

4.2.4.2 Sample requirements

For PAP smear a single slide with brushings from the uterine cervix or endocervical canal is needed. For performing gram staining, personnel that understands microbiological techniques is needed whereas for pap smear cytology the personnel must be skilled in both cell collection and immediate wet fixation to ensure sample integrity and have knowledge on cytological evaluation.

Table 6: Sample requirements

HVS Gram's Stain	Pap Smear
Needs a sterile swab as sample collection tool	Needs a cervical brush/ spatula
Sample collected from posterior fornix of vagina	Sample collected from Cervix and transformation zone
No fixatives	Needs immediate fixation

4.2.4.3 Technical requirements and Expertise

From the SOPs these are the technical requirements and expertise needed.

Table 7: Technical requirements and expertise

Aspect	Pap Smear	HVS Gram's Stain
<i>Sample collection</i>	-requires knowledge of proper cervical sampling techniques using a spatula -needs anatomical understanding to ensure accurate collection from cervix	-involves collecting vaginal secretions -requires skill in avoiding contamination of sample

<i>Staining Technique</i>	Needs knowledge on the Papanicolaou staining method and fixation	Needs knowledge on gram's staining method
<i>Interpretation of results</i>	Requires ability to identify coccobacilli patterns that indicate BV	Requires understanding of the Nugent score
<i>Diagnostic Accuracy</i>	Needs knowledge of when to use Pap results as an adjunct rather than a standalone diagnostic tool for BV	Needs understanding on how results correlate with clinical symptoms and other diagnostic methods.
<i>Clinical context</i>	Needs understanding of implications of abnormal Pap results, including potential links to cervical cancer and HPV	Requires knowledge of bacterial infections beyond BV such as STIs that may present similarly

Gram's staining is a simple procedure that can be done in various settings whereas pap smear is more complex due to the need for proper fixation and processing methods. Pap smears need trained cytologists whereas gram staining can be done by lab scientists as well as lab technicians.

Generally, gram staining is quicker than pap smear. Pap smear takes longer due to the need for cytological evaluation and interpretation. These findings can be used to update diagnostic protocols for BV in microbiology practice, inform global health guidelines on BV screening and inform medical education and training for laboratory technicians, scientists and cytologists.

Chapter 5: Summary of findings, conclusion and recommendations

5.1 Introduction

This chapter provides summary of findings and interpretations from analyzing data collected. It also includes conclusions drawn from the study and provides recommendations for future research and clinical practice.

5.2 Discussion

Many of the participants in this study were from the younger age group of 21-35 years, representing 56% of the total population. This indicates that BV is more likely to come from this age group. The study shows there is a higher prevalence of BV in the younger age group compared to the older age groups indicating that BV is prevalent in young women of reproductive age. Overall, using both diagnostic tests, about 93.8% of the younger age group of 21-35 years had BV. One study highlighted that the highest rates of BV were observed among women of age group 26-30 years in Nigeria and it might be due to the age being the most reproductively active age group and high sexual exposure at this age (Al-Mamari, 2020). The findings of this study indicate that BV is most prevalent in the age group 21 to 30 years. The older age group of 51-65 years had the least prevalence of BV.

Using Gram staining, 93.4% of the age group 21-35 years had BV, 73.1% of the age group 36-50 years had BV and 60% of the age group 51-65% had BV. Using Pap smear, 29.3% of the age group 21-35 years had BV, about 53.1% of the age group 36-50 years had BV and 30.8% of the age group 51-65% had BV. The difference in the prevalence between the two diagnostic tests is mainly due to the sensitivity and specificity of each method. The sensitivity of PAP smear is about 42% and the specificity is about 100% whereas the sensitivity of gram staining is about 100% whereas

the specificity is about 100%. Specificity and sensitive for gram staining is 100% assuming that there were no false negatives or false positives using the diagnostic test. Both tests prove to be useful to detect BV, but gram staining shows a higher sensitivity and specificity. There are factors that make one diagnostic test better than the other that include the turn-around time and expertise required to carry out the test. The study shows that carrying out PAP smear needs an expert and it takes longer than the gram staining to produce the result.

Prevalence of BV

The current study revealed a prevalence rate of 77.5% for bacterial vaginosis (BV) among the 200 samples tested. This figure represents a notably high prevalence, especially when compared to other reported studies. However, it is consistent with the growing body of research suggesting that BV is most prevalent among young women of reproductive age. Prevalence rates in other studies have varied widely, with figures ranging from 17.8% to 48.6% in women of reproductive age.

For instance, a study conducted in Rwanda found an overall prevalence of 17.8%, with the highest rate of 52.8% observed in women aged 21-30 years (Muvunyi & Hernandez, 2009). Other studies have reported even higher rates, such as a 38% prevalence among women aged 20-29 years, which also highlighted the influence of factors like marital status and education on the likelihood of BV (Achondou et al., 2016). In Ethiopia, Bitew et al. (2017) found a prevalence of 48.6%, emphasizing the impact of personal hygiene practices on the occurrence of BV. Globally, the World Health Organization (WHO, 2024) estimates that BV affects 23-29% of women of reproductive age, with regional variations. In Southern Africa, for example, a study indicated a prevalence as high as 52.4% among pregnant women (Nyemba et al., 2021).

In Zimbabwe, Turner et al. (2016) reported a prevalence of 31% among women of reproductive age, which is relatively lower compared to our findings but still significant. These varying figures across different studies underscore the importance of considering local factors and diagnostic methods when interpreting prevalence data. The choice of diagnostic method, such as clinical examination or laboratory-based testing, can significantly influence the prevalence rates reported, thus highlighting the need for standardized diagnostic approaches in clinical settings to accurately detect BV.

Diagnostic Accuracy of Gram Stained HVS against Pap Smear Cytology

Analysis from this study revealed that the sensitivity of Pap Smear in detecting BV was 42%, which means it identified only 42% of the true positive cases as confirmed by Gram Staining. This low sensitivity is in line with existing literature, where the sensitivity of Pap Smears for BV diagnosis ranges from 26.8% to 70.9%, depending on the population studied (Iqbal et al., 2018; Santos et al., 2023). In contrast, Gram Staining (HVS) consistently shows a higher sensitivity, typically around 77.8% to 93.69% (Iqbal et al., 2018; Mondal et al., 2023). This stark difference emphasizes that Gram Staining is more reliable than Pap Smears for detecting BV, as it misses fewer true positive cases. In our study, Gram Staining correctly identified all 25 positive cases, while Pap Smear missed 17 of these, underlining its limited sensitivity. This could have been confirmed by culture to determine viable organisms or PCR for more sensitive diagnosis.

While the sensitivity of Pap Smear is lower, it excels in its specificity. The results from this study showed a high specificity which is supported by literature consistently reporting that Pap Smears have high specificity, ranging from 93.6% to 97.7% (Anand et al., 2019; Mondal et al., 2023). This means that when the Pap Smear result is negative, it is a strong indicator that the patient does not

have BV. A high specificity also contributes to a high Positive Predictive Value (PPV), which was observed in our analysis as 100%. This suggests that all positive Pap Smear results were indeed true positives, further supporting the utility of Pap Smears in confirming the absence of BV when the results are negative.

The results showed a Cohen's Kappa of 0, indicating no agreement beyond chance between Pap Smear and Gram Staining. This lack of agreement is consistent with previous studies, which report only moderate agreement between the two diagnostic methods (Santos et al., 2023). The poor agreement underscores that while both methods have high specificity, they are not interchangeable, and their combined use could lead to diagnostic inconsistencies.

Furthermore, despite its low sensitivity, Pap Smear has a role as an auxiliary diagnostic tool due to its high specificity. As noted in the literature, Pap Smears are particularly useful for confirming the absence of BV, especially in settings where Gram Staining may not be readily available or when quick results are needed (Anand et al., 2019; Puran et al., 2014). The high specificity of Pap Smears makes them valuable for ruling out BV, although they cannot replace Gram Staining as the primary diagnostic method due to the HVS gram staining's superior sensitivity in detecting true positive cases.

Therefore, findings from this study, when compared with the broader literature, strongly support the conclusion that Gram Staining is the superior method for BV diagnosis due to its higher sensitivity and reliability. Pap Smear, while useful for confirming the absence of BV in negative cases, is not a reliable standalone diagnostic tool for detecting BV, especially given its low sensitivity. Therefore, Gram Staining should remain the primary diagnostic method for BV, with Pap Smear serving as an auxiliary method in clinical practice.

Looking at the trend of the data obtained, the data is skewed towards the young age group therefore the observed frequencies of BV are also higher giving the impression that they are many. The difference observed in the BV prevalence across age groups may be due to random variation rather than a real relationship.

To dispell the confusion on which result to use, clinicians should prioritize Gram Staining for diagnosing BV due to its higher sensitivity. However, in resource-limited settings or where rapid results are needed, Pap Smear can be used as an additional screening tool, particularly to confirm the absence of BV. Further research with larger and more diverse populations is necessary to refine the diagnostic roles of both methods and explore ways to enhance the sensitivity of Pap Smears, possibly through improved techniques or combined diagnostic approaches.

When we juxtapose our analysis with findings from other studies, it is evident that Gram Staining remains the more reliable method for BV diagnosis, while Pap Smear plays a limited but important role in confirming negative results.

Operational characteristics(turn-around time and expertise)

When comparing the two diagnostic tests for detecting bacterial vaginosis (BV), several factors influence their effectiveness, including turnaround time and expertise required. The findings from laboratory operations indicate that Gram staining has a significantly faster turnaround time of approximately 2 to 3 days, while Pap smear processing requires 5 to 10 working days upon receipt of the specimen. These differences are largely due to the technical complexity and evaluation processes involved in each method.

Gram staining is a relatively simple and rapid technique that requires trained personnel to interpret the microscopic findings accurately. It is widely accessible in clinical settings and provides results within hours in some cases (Vasundhara et al., 2019). The procedure involves collecting two endocervical swabs, one for culture and the other for staining and wet preparation. This ensures a comprehensive microbiological evaluation. Additionally, studies highlight that Gram staining, particularly when interpreted using the Nugent scoring system, offers high sensitivity and remains a gold standard for BV diagnosis (Ahmed et al., 2022). The ability to perform Gram staining efficiently in routine laboratory settings makes it a preferred method for rapid BV screening.

In contrast, Pap smear cytology requires a more complex workflow, including sample fixation, staining, and microscopic evaluation by trained cytologists. A single slide with brushings from the uterine cervix or endocervical canal is needed, and immediate wet fixation is crucial to maintaining sample integrity. Due to the processing demands, Pap smear is primarily used for cervical cancer screening rather than for BV diagnosis (Girerd, 2024). Research conducted in Sudan further supports this, demonstrating that Gram staining produces results within hours, whereas Pap smear requires extended processing time due to the need for cytological evaluation (E. Siddig et al., 2017). Karani et al. (2007) also emphasize that Pap smear interpretation necessitates expertise in cellular morphology, making it more resource-intensive than Gram staining.

The turnaround time trends observed in laboratory data (October 2023 – September 2024) align with these findings, as Gram staining consistently demonstrates a shorter processing time compared to Pap smear. The operational delays associated with Pap smear highlight the need for efficient diagnostic strategies in settings where rapid detection of BV is critical.

In summary, Gram's stain has a higher sensitivity and specificity compared to pap smear. Pap smear has a lower sensitivity for BV detection due to its primary focus on cellular abnormalities rather than microbial composition. Pap smear has a high rate of false negatives because it relies on cytological features "clue cells" which are not always present or correctly identified by cytologists. The study noted that unlike Gram's staining which has the Nugent's scoring system, Pap smear interpretation for BV lacks a universally accepted quantitative grading system leading to observer variability. The study also noted that despite the Pap smear having a high specificity meaning that it can detect a true negative in the absence of a disease, it was not able to identify all negative samples for BV and reasons for lack of expertise and poor sample processing contributed to such results.

Limitations

It is important to acknowledge the limitations of this study. The analysis was limited to a specific population and variations in the rate could be related to geographical distribution or systematic differences in the various population samples or educational level.

5.3 Conclusion

In conclusion, gram staining generally offers a higher sensitivity and specificity and produces the results faster with less technical difficulty compared to PAP smear making it a more effective method for diagnosing BV. However, Pap smears maintain their utility due to their high Positive Predictive value and additional benefits in screening for cervical cancer.

5.4 Recommendations

Based on the observations made from this study, the following recommendations were made;

1. Since results are not interchangeable, clinicians should prioritize HVS for BV management if discrepancies arise between tests if the tests are run 2 different laboratories. Training programs should enhance laboratory personnel's skills in reporting HVS and Pap smear results (Report on one and not both).
2. Gram Staining should be the primary method for BV diagnosis due to its higher sensitivity, faster turn-around time, and lower technical complexity.
3. PAP Smear can be used as an auxiliary tool to confirm the absence of BV, particularly in settings where Gram Staining is unavailable.
4. More studies are needed to explore the epidemiological overview of BV in Zimbabwe and to evaluate the diagnostic performance of both methods in diverse populations.

5.5 Results dissemination

A soft copy of results will be submitted to Omnipath Medical Laboratories. These findings can be presented at medical conferences for scientists and microbiologists.

5.6 Suggestions for further study

Further studies for investigating bacterial vaginosis are required especially for evaluating the association of socio-demographic risk factors and hygiene related variables in women.

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Appendices

Appendix I: Grant chart

Activities/Months	SEPT 2024	OCT 2024	NOV 2024	DEC 2025	JAN 2025	FEB 2025	MAR 2025
Developing proposal							
Seek Permission from the laboratory							
Submit proposal to AUREC							
Data collection							
Data Analysis							
Results and recommendations							
Submission of Project							

APPENDIX II: Budget

STATIONARY	\$15
TRANSPORT	\$20
PRINTING SERVICES	\$5
INTERNET	\$13
AIRTIME	\$5
TOTAL	\$58

APPENDIX III: Gram's staining and PAP smear test results

200 patients provided 300 samples. Out of the 200 patients, 100 provided both a swab and a pap smear for analysis, the other 100 provided either a swab or a Pap smear for analysis.

100 patients with either test

HVS

Age group (years)	Positive	Negative	TOTAL
21-35	26	4	30
36-50	29	8	37
51-65	5	1	6
TOTAL	60	13	73

PAP Smear

Age group (years)	Positive	Negative	TOTAL
21-35	6	0	6
36-50	3	14	17
51-65	0	4	4
TOTAL	9	18	27

100 patients with both tests

100 HVS

Age group (years)	Positive	Negative	TOTAL
21-35	73	3	76
36-50	9	6	15
51-65	4	5	9
TOTAL	86	14	100

100 PAP Smear

Age group (years)	Positive	Negative	TOTAL
21-35	18	58	76
36-50	14	1	15
51-65	4	5	9
TOTAL	36	64	100

155 out of 200 patients were positive for bacterial vaginosis. Out of 100 patients who provided both pap and swab samples, 64 pap smear were negative and 50 were false negatives.

APPENDIX IV: Letter requesting for permission

Africa University

Department of Biomedical Sciences

To the chief scientist

Omnipath Medical Laboratories

Harare

Zimbabwe

03 November 2024

Dear Sir/Madam

RE: REQUEST FOR DATA ON PAP SMEAR AND GRAM STAIN HIGH VAGINAL SMEARS IN FEMALE'S OF REPRODUCTIVE AGE VISITING YOUR LABORATORY

My name is Mutunzi Lynn. I am a student at Africa University doing biomedical sciences and I am proposing to carry out a research project titled “**A comparative study between pap smear and gram stain high vaginal smears to detect bacterial vaginosis.**” I am kindly requesting data on pap smear and gram stain high vaginal smears from female patients of reproductive age visiting your laboratory for the period November 2023 to November 2024. The information will not be shared by any other stakeholders beyond the academic purpose. I would like to start collecting data in January 2025.

Yours sincerely

Mutunzi Lynn

APPENDIX V: Site approval letter

Omnipath Medical Laboratory
11 Herbert Chitepo
Harare, Zimbabwe

Africa University
Department of Biomedical Sciences

08 November 2024

Dear: Mutunzi Lynn

RE: REQUEST FOR HISTORICAL DATA ON PAP SMEAR AND GRAM STAIN HIGH VAGINAL SMEARS IN FEMALES OF REPRODUCTIVE AGE VISITING OMNIPATH MEDICAL LABOARATORY (NOVEMBER 2023 TO NOVEMBER 2024)

I write to acknowledge your letter dated 03 November 2024 with the above-mentioned reference. Your request is granted without any restriction, and should you need any other information kindly inform in time so that you are helped timeously. As Omnipath medical laboratory we wish you the very best.

Warm regards

MR W N MBIRI



APPENDIX VI: Supervisor's letter



"Investing in Africa's Future"

DEPARTMENT OF BIOMEDICAL AND LABORATORY SCIENCES
COLLEGE OF HEALTH, AGRICULTURE AND NATURAL RESOURCES

04 November 2024

The Director

OmniPath Clinical Laboratories

Dear Sir/ Madam

RE: APPLICATION FOR SUBMISSION OF PROJECT PROPOSAL FOR LYNN MTUNZI

This letter serves to confirm that I am supervising the above-mentioned student in her final year dissertation. She has satisfied the requirements of the college in developing his research proposal and it is ready for ethical review.

Your facilitation for the review of the proposal is greatly appreciated.

Thank you

Mr Z Chiwodza

Research Supervisor

zchiwodza@afriau.edu

APPENDIX VII: AUREC letter



AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

P.O. Box 1320 Mutare, Zimbabwe, Off Nyanga Road, Old Mutare-Tel (+263-20) 60075/60026/61611 Fax: (+263 20) 61785 Website: www.africau.edu

Ref: AU 3531/24

28 November 2024

Mutunzi Lynn
C/O Africa University
Box 1320
MUTARE

RE: **A COMPARATIVE STUDY OF PAP SMEAR CYTOLOGY REPORTS AND GRAM STAINED HIGH VAGINAL SMEARS TO DETECT BACTERIAL VAGINOSIS AMONG WOMEN BETWEEN THE AGE OF 21-65 YEARS AT OMNIPATH MEDICAL LABORATORIES, HARARE: A RETROSPECTIVE STUDY (OCTOBER 2023 TO SEPTEMBER 2024)**

Thank you for the above-titled proposal you submitted to the Africa University Research Ethics Committee for review. Please be advised that AUREC has reviewed and approved your application to conduct the above research.

The approval is based on the following.

a) Research proposal

- **APPROVAL NUMBER** AUREC 3531/24
This number should be used on all correspondences, consent forms, and appropriate document
- **AUREC MEETING DATE** NA
- **APPROVAL DATE** November 28, 2024
- **EXPIRATION DATE** November 28, 2025
- **TYPE OF MEETING:** Expedited
After the expiration date, this research may only continue upon renewal. A progress report on a standard AUREC form should be submitted a month before the expiration date for renewal purposes.
- **SERIOUS ADVERSE EVENTS** All serious problems concerning subject safety must be reported to AUREC within 3 working days on the standard AUREC form.
- **MODIFICATIONS** Prior AUREC approval is required before implementing any changes in the proposal (including changes in the consent documents)
- **TERMINATION OF STUDY** Upon termination of the study a report has to be submitted to AUREC.



Yours Faithfully

MARY CHINZOU
ASSISTANT RESEARCH OFFICER: FOR CHAIRPERSON
AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE

