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HELICOBACTER PYLORI INFECTION RATE AMONG PATIENTS PRESENTING WITH DIFFERENT GASTROINTESTINAL SYMPTOMS AT LANCET CLINICAL LABORATORIES FROM JANUARY 2024 TO DECEMBER 2024

BY

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF BACHELOR OF MEDICAL LABORATORY SCIENCE HONOURS IN THE DEPARTMENT OF BIOMEDICAL AND LABORATORY SCIENCES

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Abstract

Infection with *Helicobacter pylori* occurs everywhere across the world with the highest burden recorded on the African continent with a prevalence of 70.1%. *H. pylori* infection manifests itself with different gastrointestinal symptoms (GIT). There is limited research on the burden of *H. pylori* infection among patients presenting with different GIT symptoms in Zimbabwe specifically, as only one study was conducted focusing on the general asymptomatic population. Therefore, this study sought to address this gap in the current knowledge by determining *H. pylori* infection rate among patients presenting with different GIT symptoms. The study was a retrospective cross sectional quantitative study conducted at Lancet Clinical Laboratories, Harare main branch. One hundred and eighty (180) *H. pylori* stool Ag test results from patients who were naïve to treatment were included in the study. A data extraction form was used to compile the relevant patient data. The data was analysed using the Chi-square test of association or Fisher's exact test in IBM SPSS version 27. A p value cut off of $p \leq 0.05$ was considered statistically significant for all the statistical tests conducted. The results of the study revealed a prevalence of 31.1%. Older adults aged 51 years and above were the most infected group, with a prevalence of 44.6%. A statistically significant association was found between loss of appetite, abdominal pain and *H. pylori* infection with p values 0.028 and 0.001, respectively. There was a higher frequency of abdominal pain in patients with positive *H. pylori* Ag in stool (28.5%) while there was a lower frequency in those with negative *H. pylori, ($X^2(1) = 10.484$, p value = 0.001, $p \leq 0.05$)*. There was no statistically significant association for *H. pylori* Ag in stool regarding the following GIT symptoms heartburn, nausea, bloating, blood in stool, indigestion and vomiting. A statistically significant association between iron deficiency anaemia and *H. pylori* infection was found (*$X^2(1) = 3.974$, p value = 0.046, $p \leq 0.05$)*. There was no statistically significant association for *H. pylori* Ag in stool regarding the following comorbid diseases Hypertension, Hyperthyroidism, Peripheral neuropathy, Arthritis, Gout and Cardiac disease. The study concluded that *H. pylori* infection rate was relatively high among patients presenting with GIT symptoms with abdominal pain being the most common GIT presentation. The study recommended that incorporating *H. pylori* standard diagnostic tests in symptomatic older adults who are at risk would go a long way reducing the occurrence of severe *H. pylori* related diseases or cancers.

Keywords: *Helicobacter pylori* antigen, Gastrointestinal symptoms

Declaration

I declare that this dissertation is my original work except where sources have been cited and acknowledged. The work has never been submitted, nor will it be ever submitted to another university for the award of a degree.

Tinotenda Mapuranga	 (14/04/25)
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Dedication

I dedicate this dissertation to my parents Mr and Mrs Mapuranga and my siblings, I would not have been able to complete this dissertation without their guidance, support and prayers.

List of Acronyms and Abbreviations

AUREC	Africa University Research Ethics Council
H. pylori	*Helicobacter pylori*
HPI	*Helicobacter pylori* infection
GIT	Gastrointestinal
Ag	Antigen
IDA	Iron Deficiency Anemia
LIS	Laboratory Information System
W.H.O	World Health Organization
MoHCC	Ministry of Health and Child Care
SPSS	Statistical Package for the Social Sciences

Definition of Key Terms

Helicobacter pylori – a bacteria that infects the stomach (Smith et al., 2022).

Gastrointestinal symptom – signs and sensations related to the digestive system (Namyalo et al., 2021).

Dyspeptic symptoms – collection of digestive issues of discomfort associated with indigestion (Oraijah et al., 2022).

Comorbid disease – presence of one or more additional diseases at the same time (Yang et al., 2023).

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CHAPTER 1 INTRODUCTION

1.1 Introduction

Helicobacter pylori infection (HPI) is a widespread bacterial infection which occurs everywhere across the world with an estimate of 50% of the world's population being infected, with Africa having the highest burden as it has reported, prevalence of 70.1% (Smith et al., 2022). HPI is associated with certain gastrointestinal (GIT) symptoms which include abdominal pain, nausea, vomiting, bloating and loss of appetite (Mestrovic et al., 2021). It is strongly related to various GIT pathological outcomes which include peptic ulcers, gastritis and gastric adenocarcinoma (Alexander et al., 2021).

Previous studies, particularly in Zimbabwe have investigated the HPI rate in diverse populations and healthcare settings (Mungazi et al., 2018a). However, there remains a gap in existing literature regarding the specific rate of HPI among patients presenting with GIT symptoms particularly in Zimbabwe. Therefore, this study aimed to cover this gap in order for healthcare professionals to tailor their approach to diagnosis, treatment and prevention of *H. pylori* related gastrointestinal conditions within the local patient population.

1.2 Background to the study

1.2.1 Overview of *Helicobacter pylori* – Structure and Pathophysiology

Helicobacter pylori is a gram-negative spiral shaped bacteria which belongs to the family *Helicobacteraceae* which was first characterized by Barry Marshall and Robin Warren in 1983 (Dawood & Mamdooh, 2021). *H. pylori* is either transmitted through oral-oral or faecal-oral route (Duan et al., 2023). Normally, its primary reservoir is the stomach specifically in the gastric mucosa. *H. pylori* bacteria consist of two to six

sheathed flagella which grant mobility and penetrability into the gastric mucosa. It is a microaerophilic bacteria which survives in lower oxygen levels, thus making the gastric mucosa its favourable niche (Alexander et al., 2021).

It is responsible for a majority of gastrointestinal illnesses due to its pathophysiology which involves several key mechanisms which include adhesion, motility, urease production and its evasion of the host immune system (Denic et al., 2020). Entry of the bacteria into the viscous mucus layer of the stomach is driven by its sheathed flagella and it is also essential for maintaining a swimming reservoir in the mucus (Dawood & Mamdooh, 2021). The sheathed flagella also evade the activation of the host innate immune system through various mechanisms such as inhibition of phagocytosis by host immune cells and regulation of cytokine production (Martinelli et al., 2023). *H. pylori* has the ability to survive in acidic environments of the stomach through its ability to produce urease which hydrolyses urea to ammonia and carbon dioxide which then creates a local increase in the stomach pH, thus neutralizing the acidic environment in the stomach (Nguyen et al.,2023).

1.2.2 Global, Regional and Local distribution of *H. pylori* infection

H. pylori infection is the most common infection occurring in 4,4 billion people worldwide thus representing over 50% of the world's total population (Smith et al., 2022). WHO has considered it as Class 1 carcinogenic which leads to peptic ulcer diseases and gastric adenocarcinoma (Bashir & Khan, 2023). It has been noted that its infection rate is 30-50% in developed countries and 85-95% in developing countries in which it is typically acquired in childhood (Kuntoji et al., 2020). Certain factors such as age, poor hygiene, drinking untreated water and having a low socioeconomic status have been identified as factors contributing to the differences in the prevalence of *H. pylori* infection (Borka Balas et al., 2022). The *H. pylori* infection rate is 30% in

Western countries; 20%-30% in North America, 25% in Africa, 30% in Asian and 34% in South America (Chen et al., 2024). An overall, prevalence of *H. pylori* infection rate has been noted to be 70,1% in Africa (Jaka & Smith, 2024).

The map below clearly shows the different prevalence rates of *H. pylori* infection among asymptomatic patients, across various countries in Africa:

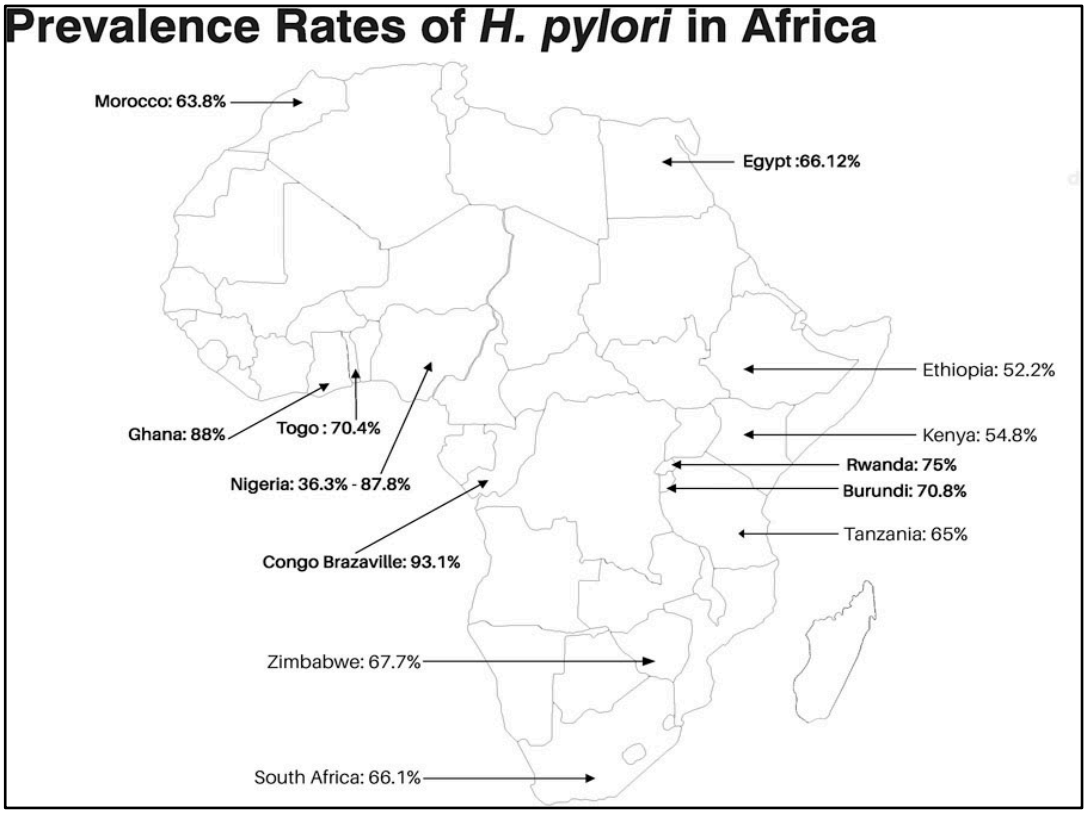

Figure 1.1: *Prevalence of H. pylori among asymptomatic patients, across different African countries (Jaka & Smith, 2024)*

According to a study done in Zimbabwe focusing only on asymptomatic patients at a surgical outpatient department in Harare hospitals, a prevalence rate of 67,7% was reported (Mungazi et al.,2018).

1.2.3 Laboratory detection methods of *H. pylori*

H. pylori detection tests are part of the many tests performed at Lancet Clinical Laboratories, Harare Branch. The main tests include immunochromatographic assays

and histology tests. Two immunochromatographic assays are done on either blood serum or stool samples. Tests using serum detect antibodies against *H. pylori* which can either be past or present infection (Godbole et al., 2020). Stool samples can be tested in the microbiology department using the linear *H. pylori* Ag cassette which is a lateral flow chromatographic immunoassay for qualitative detection of the *H. pylori* antigen in human faecal specimens. Gastric mucosa tissue specimens are tested in the histology department using Giemsa stain.

1.3 Problem Statement

Helicobacter pylori is the major causative agent of gastric adenocarcinoma, gastritis, peptic ulcers and gastric mucosa-associated lymphoid tissue lymphoma. During the time spent on attachment in the Microbiology department at Lancet Clinical Laboratories, high volumes of stool samples were submitted for *H. pylori* antigen test. According to the Microbiology Laboratory Information System (LIS), a total of 185 stool samples were submitted during a four-month period from January to April 2024. During the same period in 2023, a total of 137 stool samples were submitted indicating a possible increase in the number of stool samples being processed for *H. pylori* antigen this year. Literature reveals that in Zimbabwe, a study was conducted focusing only on the asymptomatic population indicating a prevalence of 67.7% (Mungazi et al., 2018). As a result, there is limited knowledge with regards to the prevalence of *H. pylori* infection among symptomatic patients who already experience the various types of GIT symptoms.

1.4 Research Objectives

1.4.1 Broad Objective

The main aim of this study was to determine *H. pylori* infection rate among patients

presenting with different GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024.

1.4.2 Specific Objectives

1. To determine the prevalence of *H. pylori* infection among patients presenting with various GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024.
2. To determine the age group most commonly infected with *H. pylori* among patients presenting with various GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024.
3. To determine the GIT symptom commonly associated with *H pylori* infection among patients attending Lancet Clinical Laboratories from January 2024 to December 2024.
4. To determine the association between *H. pylori* infection and patient comorbid disease among those attending Lancet Clinical Laboratories from January 2024 to December 2024.

1.5 Research Questions

1. What was the prevalence of *H. pylori* infection among patients presenting with various GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024?
2. Which age group was commonly infected with *H. pylori* among patients presenting with different GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024?
3. Which GIT symptom was commonly associated with *H. pylori* infection among patients attending Lancet Clinical Laboratories from January 2024 to December 2024?

4. Which patient comorbid disease was associated with *H. pylori* infection among those patients attending Lancet Clinical Laboratories from January 2024 to December 2024?

1.6 Study Justification

While past studies on the prevalence of *H. pylori* infection among asymptomatic individuals provide valuable baseline information, it is equally important to assess the infection rate in the symptomatic patients particularly in Zimbabwe where the information is inaccessible. This will cover the gap in existing literature where there is need to understand the specific prevalence of *H. pylori* infection among the symptomatic population as opposed to the general population. Therefore, this study aimed to fill the gap by providing a more precise understanding of the true burden of *H. pylori* infection among individuals who present with different GIT symptoms, to help develop more effective strategies for prevention and management of *H. pylori* associated GIT conditions within the local community.

1.7 Study Limitation

The researcher had limited time and resources to fully conduct the research. Since the research was a retrospective study, the researcher solely relied on others for accurate record keeping in the LIS.

1.8 Study Delimitation

The research on *H. pylori* infection rate among patients presenting with different GIT symptoms focused only on symptomatic patients who were diagnosed for *H. pylori* at Lancet Clinical Laboratories, Head Quarters, Harare branch from January 2024 to December 2024. The study was limited to one laboratory, potentially affecting generalizability.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter reviewed literature related to *H. pylori* infection among patients presenting with various GIT symptoms. It examined and summarised numerous selected literatures on what others came up with and what had already been said concerning the prevalence of *H. pylori* infection, most common age, most common GIT symptom and other patient comorbid diseases associated with *H. pylori* infection. Literature review was conducted in relation to the researcher's objectives.

2.2 Conceptual framework

A conceptual framework is a structured system of ideas and concepts that researchers' employ to most effectively describe and outline the key variables and their relationships within a particular research study (Moschis, 2024). It provides a clear visual presentation of how the independent variable are expected to relate to the dependent variable, aligning to the researchers' objectives. Therefore, in this chapter, results of the literature review are primarily given in accordance with the conceptual framework that supports this study. The diagram below illustrates the conceptual framework of the research under study.

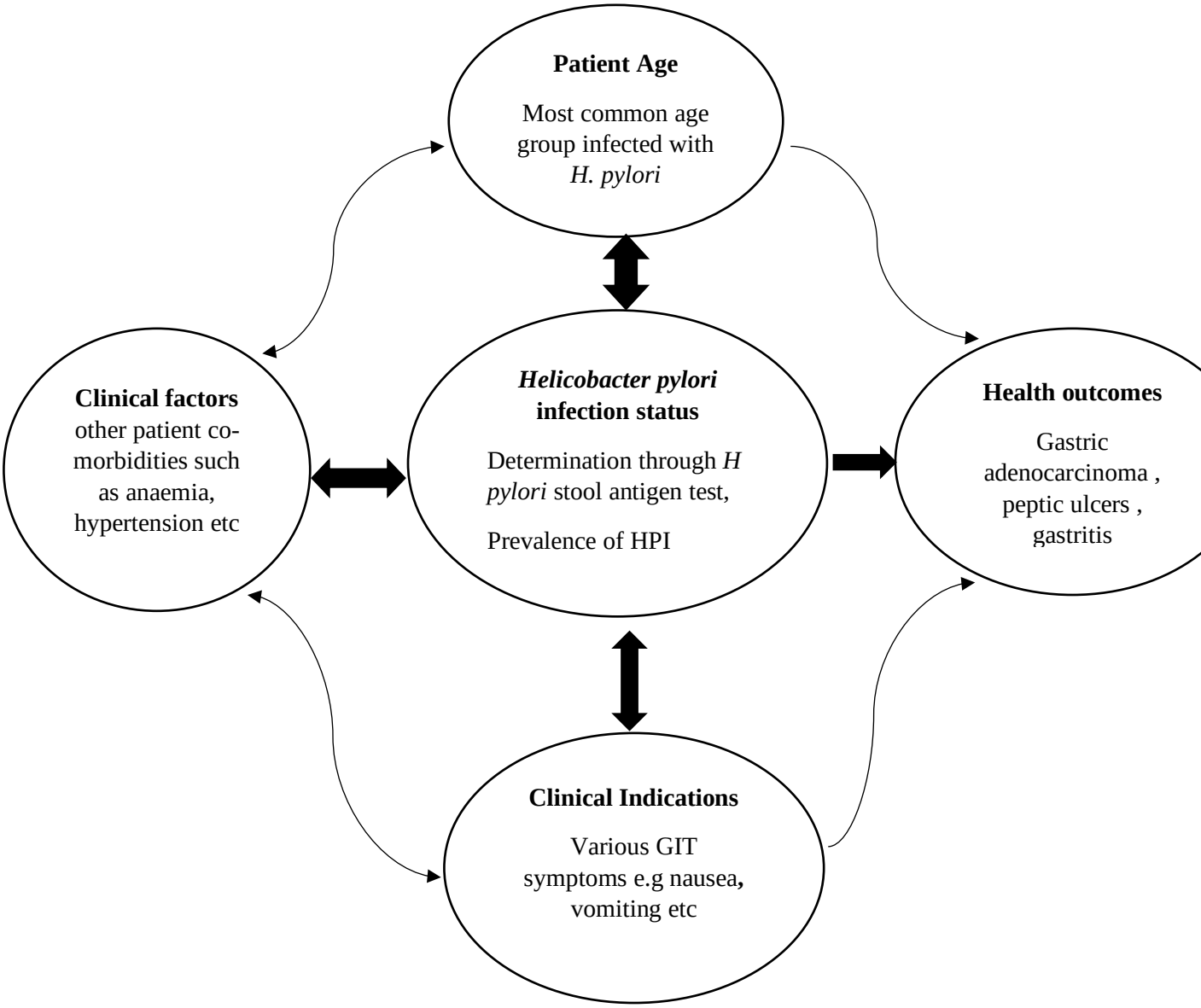

Figure 2.1*: Conceptual Framework for H. pylori infection among patients presenting with different GIT symptoms*

The conceptual framework provided above illustrates the relationship between the independent variable and the dependent variables of the research under study. The dependent variable in this research is *H. pylori* infection rate as it is the outcome that the researcher is trying to predict and explain among patients presenting with different GIT symptoms. The dependent variable is influenced by certain independent variables as indicated in the diagram above. Such independent variables include patient age,

clinical factors and certain clinical indications. Positive *H. pylori* infection leads to certain health outcomes such as gastric adenocarcinoma, peptic ulcers and gastritis.

The prevalence and *H. pylori* infection status varies with age across different populations. Literature review shows that age influences the susceptibility of *H. pylori* infection. Some researchers have stated that the prevalence of *H. pylori* infection is directly proportional to age, which means the prevalence of *H. pylori* infection increases as age increases (Le et al., 2024). Older adults exhibit higher infection rates due to cumulative exposure over time, as the infection is often acquired in childhood but can persist for years if left untreated. Patient comorbidities such as hypertension that varies with age also influences an individual's infection status with *H. pylori* (Fang et al., 2022).

A significant interlinkage between age and health outcomes is also shown. As age increases, there is increased risk of experiencing severe health outcomes arising from *H. pylori* infection. This is due to on-going exposure and potentially weakened immune responses (Lipatova et al., 2023). Older patients often suffer from multiple comorbidities that can also complicate the management of *H. pylori* infection, leading to more complicated health outcomes.

Clinical factors such as hypertension, iron deficiency anemia and cardiovascular disease may be a key indication of a positive *H. pylori* infection. Iron deficiency anemia has been indicated as closely related to a positive *H. pylori* infection in an individual (Eyoum Bille & Kouitcheu Mabeku, 2022). Some comorbid diseases may be an indication of *H. pylori* infection and vice versa. Patients suffering from other diseases may present with clinical indications similar to that of an *H. pylori* infected individual.

GIT symptoms such as nausea, epigastric pain and abdominal pains are good predictors of *H. pylori* infection (Mwangi et al., 2020). Patients infected with *H. pylori* infection present with various GIT symptoms. This relationship is indicated by the interlinkage between *H. pylori* infection status and clinical indications. Acute or chronic GIT symptoms indicate the presence of certain health outcomes that are related to *H. pylori* infection.

2.3 Literature Review in relation to objectives

2.3.1 Prevalence of *H. pylori* infection among patients presenting with different GIT symptoms

In Bagalkot, Karnataka, India, a cross sectional prospective study was done and it aimed at establishing the proportion of *H. pylori* infection in patients presenting with dyspeptic symptoms. A total of 105 patients were studied out of which 44 patients were positive for the *H. pylori* infection resulting in a prevalence rate of 41,9% (Kuntoji et al., 2020). In this study the investigators concluded that the burden of *H. pylori* infection was high among patients that presented with dyspeptic symptoms. These findings concur with the results that were obtained in a similar prospective study that was conducted in Kenya, also focusing on the prevalence of endoscopic findings of *H. pylori* infection among dyspeptic patients. In the study a total of 487 dyspeptic patients were enrolled at Aga Khan Hospital in Kenya, 199 patients out of 487 enrolled patients were positive for *H. pylori* infection indicating a prevalence of 40,86% among the dyspeptic patients (Mwangi et al., 2020).

In contrast, a retrospective cohort study on the prevalence of *H. pylori* infection that included 680 patients in Taif city, Saudi Arabia reported a prevalence of 30,1 % among patients with dyspepsia compared to 34,5% among those without dyspepsia (Oraijah et al., 2022). The study indicated a relatively lower prevalence of *H. pylori* infection

among the dyspeptic patients than that reported by Kuntoji in India and Mwangi in Kenya. The author suggested that there was a decrease in the rate of infection in the region, probably due to improved hygiene and widespread antibiotic use among the patients.

In Kampala, Uganda a 5-year retrospective study was conducted at three Africa Air Rescue (AAR) clinics on the prevalence of *H. pylori* infection among patients showing clinical indications of GIT symptoms from 2015 to 2019. The results obtained in the study highlighted an overall 5-year *H. pylori* infection prevalence of 35,7% in the three clinics selected. As highlighted by the study, despite the fluctuations over time, the trends for *H. pylori* infection were rising. In 2015, the prevalence was 21.4% (49/229); in 2016, it rose to 34.0% (170/500); in 2017, it fell to 28.2% (168/596); in 2018, it rose to 43.4% (355/818); and in 2019, it ultimately dropped to 37.3% (556/1491), (Namyalo et al., 2021). This is in contrast to the findings that were obtained in a similar 5-year retrospective analysis of patient records that was done at Wum District Hospital, a primary care hospital in Wum town, Cameroon. The study highlighted a decline in the seroprevalence of *H. pylori* infection among patients presenting with dyspepsia from 82,1% in 2012; 80,6% in 2013; 43,8% in 2014; 47,5% in 2015 to 45,5% in 2016 (Aminde et al., 2019). The seroprevalence in the study decreased at an average of 6,8% annually.

2.3.2 Age group most commonly infected with *H. pylori* among patients presenting with GIT symptoms

Several infections are associated with age and their prevalence differs significantly based on factors such demographic factors. In a cross sectional study conducted between January 2024 and May 2024 by Le et al., (2024) among 246 children who presented with GIT symptoms at Thai Binh Pediatric Hospital in Vietnam, a total of

200 children out of 246 children (81,3%) tested positive for *H. pylori* infection. In their study, children aged 11 and older were four times more likely to be infected with *H. pylori* compared to children under the age of 5 with an odds ratio of 3.50. This was a noteworthy and alarming statistical report. It indicated that an increase in age would mean an increase in the rate of *H. pylori* infection.

In Bunir district, Pakistan, a cross-sectional study was conducted at Bilal Medical Trust Hospital from February 2018 to 30 November 2019 among patients presenting with different GIT symptoms. The study reported a high prevalence of *H. pylori* infection in the age group of 20 to 30 years (43,67%) and a low prevalence in the age group lower than 20 years (8,55%) and more than 40 years (17, 81%), (Muhammad et al., 2020). These findings relate to what the previous study indicated that the prevalence of *H. pylori* infection increases with an increase in age.

Similarly, in Lithuania, a study conducted by Lipatova et al., (2023) also identified a significant impact of age on the prevalence of *H. pylori* infection. There was a significant increase of *H. pylori* infection with an increase in age. The highest prevalence rate of 33,7% was noted among patients aged between 40 and 59 years. This might be due to the difference in the immune-system behaviour during childhood and adulthood where the immune system is very effective during childhood.

2.3.3 GIT symptom commonly associated with *H. pylori* infection

Research by Yu et al., (2020) conducted in China with 234 children enrolled in the study indicated that abdominal pains were the most common GIT symptom presented. It accounted for a prevalence rate of 47,95% followed by acid reflux 32,88%; epigastric pain 15,07%; nausea and vomiting had a combined prevalence rate of 2,74%, which was noted to be the lowest. Similarly, in Portugal, a retrospective observational study was conducted on 461 symptomatic children and 37,3% of the

cases were positive for *H. pylori* infection. Its findings indicated that the most common clinical indication of *H. pylori* infection among children was abdominal pains as this was noted in almost 50% of the children who were positive for *H. pylori* (Antunes et al., 2023). The author identifies abdominal pain as a good predictor of *H. pylori* infection.

Mwangi et al., (2020) identify heartburn as the sole clinical indicator of *H. pylori* infection among dyspeptic patients. In their study 199 out of 487 dyspeptic patients were positive for *H. pylori* infection. 25,2% of the patients that were positive for *H. pylori* presented with heartburn, 14,8% vomited, 14,4% experienced nausea, 10,2% had constipation and belching was the least experienced symptom with 1,2%. *H. pylori* infected dyspeptic patients had a higher rate of presenting with heartburn as the sole clinical indication. According to this study it implies that heartburn is highly suggestive of *H. pylori* infection.

2.3.4 Patient co-morbid disease associated with *H. pylori* infection

A cross sectional study was done in two hospitals in Douala, Cameroon, an area that has a higher prevalence of *H. pylori* infection. The study aimed to assess the association between *H. pylori* infection and anaemia. In the study 842 patients were enrolled. Findings from the study indicated that *H. pylori* infection seemed to be associated with iron deficiency anaemia as the prevalence of anaemia was high in *H. pylori* positive patients (82,3%) than in the negative patients (17,70%), (Eyoum Bille & Kouitcheu Mabeku, 2022).

A systematic review and meta-analysis of the association of hypertension with *H. pylori* infection was conducted in a total of 6 eligible studies with 11 317 hypertensive patients and 12 765 controls included in the analysis (Fang et al., 2022). In the analysis, 3 studies were cross sectional studies and the others were case control studies. The

investigators observed an association of *H. pylori* infection with hypertension in three studies with an odds ratio ranging from 1.42 to 3.06. The results of the systematic review and meta-analysis indicated that people with *H. pylori* infection had a 13,4% increased risk of suffering from hypertension.

A cross sectional study conducted by (Yang et al., 2023) from January to December 2020 among people who went for medical examinations at the Second Affiliated Hospital of Baotou Medical College of Inner Mongolia University, reports an association between *H. pylori* infection with hypertension. Participants in the study were grouped into two groups, the hypertensive group and the non-hypertensive group. The investigators reported that the prevalence of *H. pylori* infection was high in the hypertensive group with a prevalence rate of 29,16% and low in the non-hypertensive group with a prevalence rate of 25,44%.

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Introduction

The following chapter provides an overview of how the research was done. It outlines the research methodology which was used to determine *H. pylori* infection rate among patients presenting with different GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024. The researcher looked at the following: research design; study population; inclusion criteria; exclusion criteria; sample size; sampling procedure; pilot study; study setting; data collection procedure; data analyses and lastly ethical considerations.

3.2 Research Design

A retrospective cross sectional quantitative study was adopted. This research design allowed the researcher to analyse existing patient data from Lancet Clinical Laboratories LIS (MedTech) records at a single point in time at a specified period of time. The research was quantitative, it focused on collecting and analyzing numerical data. This research design was appropriate as it was cost and time effective.

3.3 Study Population

The study participants for this research were patients that attended Lancet Clinical Laboratories, Harare branch presenting with different GIT symptoms and had their stool samples tested for *H. pylori* antigen, from January 2024 to December 2024.

3.4 Inclusion Criteria

All test results recorded in the Microbiology department LIS for patients that presented with one or more GIT symptoms and had their stool samples tested for *H. pylori* antigen within the specified time period, 1 January, 2024 to December 31, 2024 were included in the study.

3.5 Exclusion Criteria

The research excluded all patients that had a recorded previous history of treatment for *H. pylori* infection. Asymptomatic patients were excluded in the study. Any test results recorded in the LIS that did not fall within the specified time frame were excluded.

3.6 Sample size

No sample size calculation method was used. *H. pylori stool* Ag test results from patients with GIT symptoms recorded in LIS at Lancet Clinical Laboratories from January 2024 to December 2024 were analysed.

3.7 Sampling procedure

Purposive sampling technique was used. It involves selecting participants based on specific characteristics or criteria relevant to the research (Douglas, 2022). It allowed the researcher to focus solely on the *H. pylori* stool Ag test results obtained from patients that specifically exhibited different GIT symptoms within the study time frame.

3.8 Pilot Study

A pilot study is a small scale preliminary study conducted before a larger, more comprehensive study inorder to test and evaluate the feasibility, time and cost of a full scale study (Dźwigoł, 2020). A pilot study was conducted to test the data collection procedure and data sources used to ensure validity and reliability of the full-scale study results. A small sample size of 10 test results available in LIS were selected. Relevant data obtained was recorded on the designed Microsoft Excel spreadsheet as shown in Appendix 3 to confirm its appropriateness in gathering the relevant data. The selected test results used in the pilot study were not included in the full-scale study. This improved the quality and efficiency of the final research study.

3.9 Study setting

The study setting for this research was Lancet Clinical Laboratories, Harare main branch, Microbiology laboratory. Lancet Clinical Laboratories are one of the main clinical laboratories in Zimbabwe providing accurate, reliable and timely diagnostic tests to various people across the country. The Harare branch is the main branch and most Microbiology tests are performed therefore, this allowed for a comprehensive analysis of *H.pylori* infection rates across different demographics and symptom presentations.

3.10 Data Collection Procedure

Permission to collect data from LIS used in the Microbiology laboratory was requested from respective authorities at Lancet Clinical Laboratories. Symptomatic patient results obtained during the specified period of interest were selected. Purposive sampling technique was used to obtain data from patients that experienced certain GIT symptoms only. Data retrieved from the LIS was recorded on a data spreadsheet created using Microsoft Excel as shown in Appendix 3. The data spreadsheet displayed the specimen number, patient age, GIT symptom experienced, patient co-morbid disease and the *H. pylori* stool antigen test result. Patient names were not used in the research, instead identification numbers were generated inorder to maintain confidentiality. This spreadsheet was used to analyse the obtained data.

3.11 Data Analysis

Data was collected using a Microsoft Excel spreadsheet shown in Appendix 3. After data cleaning, the excel spreadsheet was imported into a statistical package called IBM SPSS version 27 for statistical data analysis. Descriptive statistical analysis was requested to provide a clear summary of the age-group of the patients through numerical measures like mean, median and standard deviation. Tables were used for

the visualization of data. Categorical data analysis methods such as Chi-square test of independency and Fisher's exact test were employed to determine the statistical significance of association between categorical variables.

Chi-square test of independency was used where the expected frequency in any cell of the contingency table was 5 or greater while Fisher's exact test was used where the expected frequency in any cell of the contingency table was less than 5. In both the tests a p-value ≤ 0.05 indicated a significant association, suggesting a meaningful association between two categorical variables. A high p-value (>0.05) was considered not statistically significant, meaning there was no association between two categorical variables.

3.12 Ethical Considerations

Ethical clearance and permission to conduct the study was obtained from AUREC. The research was conducted under protocols approved by AUREC. Permission to conduct the study and review patient records from LIS was requested from and granted by respective authorities at Lancet Clinical Laboratories. Patient information obtained was stored in an Excel spreadsheet that was secured with an encrypted password to protect data from access by other persons. Confidentiality was maintained throughout the research process and after the research. Patient personal information such as names were not included in the research. Laboratory reference numbers were used instead of patient names during and after the course of the research.

3.13 Summary

This study was a retrospective cross sectional quantitative study of *H. pylori* infection rate among patients presenting with different GIT symptoms at Lancet Clinical Laboratories from January 2024 to December 2024. Permission to conduct the research was sought from AUREC and permission to collect data was requested from respective

authorities at Lancet Clinical Laboratories. Purposive sampling technique was used to obtain data from patients that solely exhibited different GIT symptoms and were recorded in LIS. Relevant data obtained was recorded on Microsoft Excel data spreadsheet. Confidentiality of patient information was exercised by using laboratory reference numbers to represent patient identity. Recorded data was analysed using IBM SPSS version 27.

CHAPTER 4 DATA PRESENTATION, ANALYSIS AND INTERPRETATION

4.1 Introduction

This chapter presents a detailed analysis and interpretation of data obtained from 180 patients who presented with different GIT symptoms at Lancet Clinical Laboratories, Harare, between 1 January and 31 December 2024 and had their stool samples tested for *H. pylori* stool antigen. The findings are categorized according to demographic characteristics of the study population, prevalence of *Helicobacter pylori* infection, common age group infected with *H. pylori*, common GIT symptom experienced and the association between *H. pylori* infection and other patient comorbid diseases. A p-value cut-off of $\mathbf{p \leq 0.05}$ was considered statistically significant for all statistical tests conducted.

4.2 Demographic characteristics of the study participants

Descriptive statistical analysis of the study participant's age group was performed on IBM SPSS version 27 as shown in **Table 4.1**. Age range of the patients was 4 years to 88 years. The minimum age of the study participants was 4 years and the maximum age was 88 years. The mean age was 43.74 and the standard deviation was ± 19.65. Among the 180 patients, 105 (58,3%) were females while 75 (41,7%) were males as shown in **Figure 4.1**.

***Table 4. 1**: Descriptive statistics of age*

Descriptive Statistics of Age						
	n	R	Mini	Maxi	Mean	Std. Deviation
Age	180	84	4	88	43.74	19.651
Valid N (listwise)	180					

R: Range; Mini: Minimum age; Maxi: Maximum age; Std: Standard Deviation

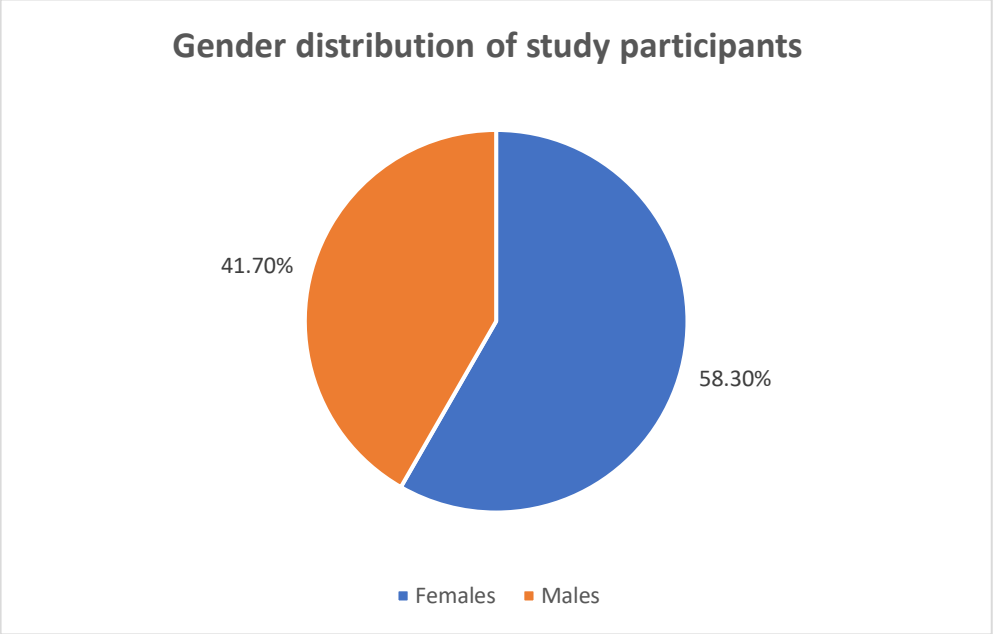

***Figure 3.1**: Gender distribution of study participants*

4.3 Prevalence of *Helicobacter pylori* infection among patients with different GIT symptoms

A total of 56 out of 180 patients tested positive for *H. pylori*, resulting in a prevalence rate of **31.1%.**

Table 4. 2*: Prevalence of H. pylori infection among patients with different GIT symptoms*

H. pylori **stool Ag test result**	**Frequency (n = 180)**	**Percentage n = (%)**
Positive	56	31.1
Negative	124	68.9

H. pylori: *Helicobacter pylori,* Ag: Antigen.

4.4 *Helicobacter pylori* Infection by Age Group

Table 4.3 shows the distribution of *H. pylori* infection positive cases across different age groups. The highest prevalence of positive cases was observed in the age group 51 years and above (44.6%) while the lowest prevalence was observed among 4 to 30 years (10.7%). A prevalence of 19.6% was observed between 31 and 40 years and 25.0% was obtained between 41 and 50 years.

Table 4. 3: *Age distribution of H. pylori positive cases*

Age Group (Years)	**Positive cases (n=56)**	**Percentage n (%)**
4 – 30	6	10.7
31– 40	11	19.6
41–50	14	25.0
51 and above	25	44.6

4.5 GIT symptom associated with *H. pylori* Infection

Table 4.4 shows the frequency of the GIT symptoms among the positive and negative patients. Among the GIT symptoms, abdominal pain was the most frequently reported symptom among the *H. pylori* positive patients, contributing 28.5% of the cases. A chi-square test of independence revealed a highly significant association between abdominal pain and *H. pylori* infection ($p \leq 0.001$). Although loss of appetite was also significantly associated with the infection ($p = 0.028$), its effect size was smaller

compared to abdominal pain. Therefore, it can be suggested that *H. pylori* positive individuals are significantly more likely to have abdominal pain than those without the infection.

Statistically non-significant associations, such heartburn (p = 0.687); nausea (p = 0.182); Bloating (p = 0.883); blood in stool (p = 0.555); indigestion (p = 0.909) and vomiting (p = 0.128) were observed and are important to discuss to avoid bias. The lack of the significant association may be due to their non-specific nature, which can result from various other gastrointestinal conditions unrelated to *H. pylori* infection.

Table 4. 4: *GIT symptoms associated with H. pylori infection*

Gastrointestinal symptom	***H.pylori* Ag in stool**				**Chi-square value**	**P-value**
	Positive		Negative			
	n=56	n(%)	n=124	n(%)		
Heartburn	9	16.1	23	18.5	0.162	0.687
Nausea	11	19.6	15	12.1	1.778	0.182
Bloating	3	5.4	6	4.8	0.022	0.883
Loss of Appetite	5	8.9	28	22.6	4.802	0.028*
Blood in stool	2	3.6	7	5.6	0.349	0.555
Indigestion	6	10.7	14	11.3	0.013	0.909
Abdominal pain	16	28.5	12	9.7	10.484	≤0.001**
Vomiting	4	7.1	19	15.3	2.316	0.128

Using X^2 (1): Chi-square test of independency or Fisher's exact test, when appropriate p-value> 0.05 is insignificant, *p-value< 0.05 is significant and **p-value≤0.001 is highly significant. **Ag**: Antigen

4.6 Association between *H. pylori* Infection and patient comorbid disease

Among the 180 study participants, only 34 patients had comorbid diseases recorded on their clinical data. Among the 34 patients, 28 patients tested positive for *H. pylori* and 6 patients were negative. **Table 4.5** illustrate the frequencies of different patient comorbid diseases among *H. pylori* positive and negative patients. Out of the 34

patients with recorded comorbid diseases, IDA was the most common comorbidity associated with *H. pylori* infection (21.4%). A statistically significant association was observed between IDA and *H. pylori* infection (p = 0.046). This means that *H. pylori* positive individuals are significantly more likely to be suffering from iron deficiency anemia than those without the infection.

Non-significant associations, such as Hypertension (p = 0.395); Hyperthyroidism (p = 0.455); Peripheral neuropathy (p = 0.638); Arthritis (p = 0.945); Gout (p = 0.176); CAD (0.559) were observed. The lack of significant association between *H. pylori* infection with the stated comorbid diseases suggest that *H. pylori* infection does not influence the development or worsening of these diseases.

Table 4. 5*: H. pylori infection association with patient comorbid disease*

Comorbid Disease	***H. pylori* Ag in stool**				**Chi-square value**	**P-value**
	Positive		Negative			
	n	n(%)	n	n(%)		
IDA	12	21.4	0	0	3.974	0.046*
Hypertension	5	8.9	2	1.6	0.724	0.395
Hyperthyroidism	2	3.6	1	0.8	0.557	0.455
PN	1	1.8	0	0	0.221	0.638
Arthritis	5	8.9	1	0.8	0.005	0.945
Gout	0	0	1	0.8	4.808	0.176
CAD	3	5.4	1	0.8	0.169	0.559

Using X^2 (1): Chi-square test of independency or Fisher's exact test, when appropriate P-value> 0.05 is insignificant and *P-value< 0.05 is significant. **Ag:** Antigen, **IDA**: Iron deficiency anaemia, **PN**: Peripheral Neuropathy, **CAD**: Cardiac Disease

4.7 Chapter summary

The chapter presented the demographic characteristics, prevalence, age distribution, common GIT symptoms and comorbid diseases associated with *H. pylori* infection.

Statistical analyses were conducted to determine the significance of associations with chi-square test and Fisher's exact tests applied where appropriate. The statistical tests were conducted with a significance level of $p \leq 0.05$. Non-significant associations were also discussed to provide a balanced interpretation of the data. The findings indicated a high prevalence of *H. pylori* infection among older adults (51 years and above) and a significant association between abdominal pain and infection status. Additionally, IDA was identified as the most common comorbid disease significantly associated with *H. pylori* infection.

The retrospective nature of the study may introduce selection bias and the findings may not be generalizable due to the limited geographic scope of data collection from only one laboratory branch. The next chapter will discuss these findings in the context of existing literature and provide conclusions and recommendations.

CHAPTER 5 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter focuses on the summary, conclusions and recommendations. It also provides suggestions for future research. The summary is based on the objectives stated in Chapter 1 and results analysed and presented in Chapter 4. Results obtained are summarized and discussed in comparison to what was obtained in literature. The chapter ends with recommendations for future research, highlighting areas that require further understanding.

5.2 Discussion

This section provides the main conclusions of the major findings of the study on *H. pylori* infection in patients exhibiting with different GIT symptoms at Lancet Clinical Laboratories along with a comparison of the results obtained with the relevant literature to determine whether they are similar or different.

5.2.1 Prevalence of *H. pylori* infection in patients with GIT symptoms

The study revealed a 31.1% prevalence of *H. pylori* infection among patients presenting with various GIT symptoms, a relatively high prevalence similar to what was obtained in other developing countries. Oraijah et al., 2022 obtained a similar prevalence that concurs to the prevalence obtained in this study in which the prevalence rate was 30,1% among dyspeptic patients. A study conducted in Zimbabwe mainly focusing on the asymptomatic population by Mungazi et al., 2018b highlighted a prevalence rate of 67,7%. Therefore, a prevalence rate of 31,1% among symptomatic patients would suggest that a large proportion of individuals may carry the *H. pylori* infection without exhibiting symptoms. However, there is need to conduct this research among symptomatic patients in the greater population in different health facilities.

5.2.2 *H. pylori* infection by age group

The current study found that older adults (51 years and above) are the most infected group, accounting for 44,6% of the total positive cases. This trend is consistent with other global studies linking increased age to higher infection rates due to prolonged exposure, declining immunity and age-related changes in the gastric physiology (Nguyen et al., 2023). These findings concur with the results obtained in studies conducted by Muhammad et al., (2020), Lipatova et al., (2023) and Le et al., (2024). Furthermore, the low prevalence in younger age groups (10,7% in 4-30 years) reflects lower cumulative exposure to risk factors like poor hygiene, untreated water and a more effective immune system during childhood (Lipatova et al., 2023). Older adults are disproportionately affected by *H. pylori* infection, emphasizing the need for age-specific diagnostic and treatment strategies.

5.2.3 GIT symptom associated with *H. pylori* infection

This study identified abdominal pain as the most common GIT symptom associated significantly with *H. pylori* infection. A chi-square test of independence was conducted to determine the statistical significance of association of each GIT symptom presented by the patients and *H.pylori* infection status. A high statistically significant association was found between abdominal pain and *H. pylori* infection (X^2 (1) = 10,484, p value = 0.001; $p < 0.005$).

The results indicate that presence of abdominal pain as a GIT symptom and *H. pylori* positive infection have a significant association among the patients that attended Lancet Clinical Laboratories. The findings of this study suggested that *H. pylori* positive individuals are significantly more likely to have abdominal pain that those without the infection. Findings of the current study are in line with the suggestions of Yu et al., (2020) and Antunes et al., (2023) who identify abdominal pain as a good predictor of *H. pylori* positive infection. However, the findings are not in line with the findings of (Mwangi et al., 2020)) who

suggests heartburn as the sole clinical indicator of *H. pylori* infection among symptomatic patients.

5.2.4 Association between *H. pylori* infection and patient comorbid disease

IDA was the most common comorbid disease. Findings of this study highlighted a higher prevalence of IDA in *H. pylori* positive patients (21.4%) than in negative patients (0%). A statistically significant association between IDA and *H. pylori* was found to be (X^2 (1) = 3.974; p value = 0.046; $p < 0.05$). These findings indicated IDA as the most significant comorbid disease associated with *H. pylori* positive infection. Therefore, patients with IDA are significantly more likely to be infected with *H. pylori*. Findings obtained by Eyoum Bille & Kouitcheu Mabeku, (2022) concur with the findings of this study as they identified a higher prevalence of IDA in *H. pylori* positive patients (82.3%) than in negative patients (17.7%). This association can be explained by the biological impact of *H. pylori* on iron absorption. The bacterium colonizes the gastric mucosa causing chronic gastritis which can damage the gastric epithelium thereby decreasing the production of gastric acid and intrinsic factors which are essential for proper digestion and absorption of nutrients including iron.

However, the findings of this current study do not agree with what (Fang et al., 2022)) and (Yang et al., 2023) obtained in their researches. In their studies, they identified hypertension as the most common comorbid disease in *H. pylori* positive patients.

5.3 Conclusions

Prevalence of *H. pylori* infection among patients presenting with GIT symptoms at Lancet clinical Laboratories from January 2024 to December 2024 was 31,1%. The study arrived at a conclusion that patients presenting with GIT symptoms particularly abdominal pain are more likely to be infected with *H. pylori.* The rate of *H. pylori* infection increases with age, thus, older adults are at risk of being infected with the bacteria. There is a notable association

between *H. pylori* infection and patient comorbid disease particularly iron deficiency anaemia.

5.4 Implications of the findings

The key areas emerging from this study are that older adults are the most infected group and abdominal pain is the most common GIT symptom associated with *H. pylori* infection. Another key element highlighted by this study is that IDA is significantly associated with *H. pylori* positive infection. Given the following information the Ministry of Health and Child Care of (MoHCC) Zimbabwe and other health care facilities can tailor their approach to diagnosis, treatment and prevention of *H. pylori* infection related GIT conditions within the local community. The findings of this research highlight the need to assess the risk factors associated with a high prevalence of *H. pylori* infection in older adults especially in Zimbabwe. There is also need for the MoHCC to allocate resources in raising public awareness about the GIT symptoms associated with *H. pylori* infection so that members of the communities can seek treatment early and avoid the occurrence of gastric carcinomas and peptic ulcers.

5.5 Recommendations

The study made the following recommendations:

5.5.1 For Clinical Practice

H. pylori diagnostic tests should be incorporated into standard protocols for symptomatic patients. There should be age-specific interventions with particular focus on older adults who are at a higher risk of *H. pylori* infection.

5.5.2 For Public Health

Communities should be educated on the symptoms and risks of *H. pylori* infection through awareness campaigns. There should be sanitary improvements through advocating for better

water quality and hygiene practices to reduce transmission. Diagnostic and treatment options should be made available in underserved areas where most of the older adults live.

5.6 Suggestions for further research

This study mainly focused on *H. pylori* infection among patients presenting with various GIT symptoms who were diagnosed at Lancet Clinical Laboratories, Harare branch, Zimbabwe only. Therefore, if resources permit studies on larger sample sizes should be conducted to determine the nationwide prevalence of *H. pylori* infection among symptomatic patients. Research on genetic and environmental risk factors resulting in increased rate of *H. pylori* infection in older adults in Zimbabwe should be conducted. Future research should also study the efficacy of locally available diagnostic and treatment options to avoid recurrent *H. pylori* infection.

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APPENDICES

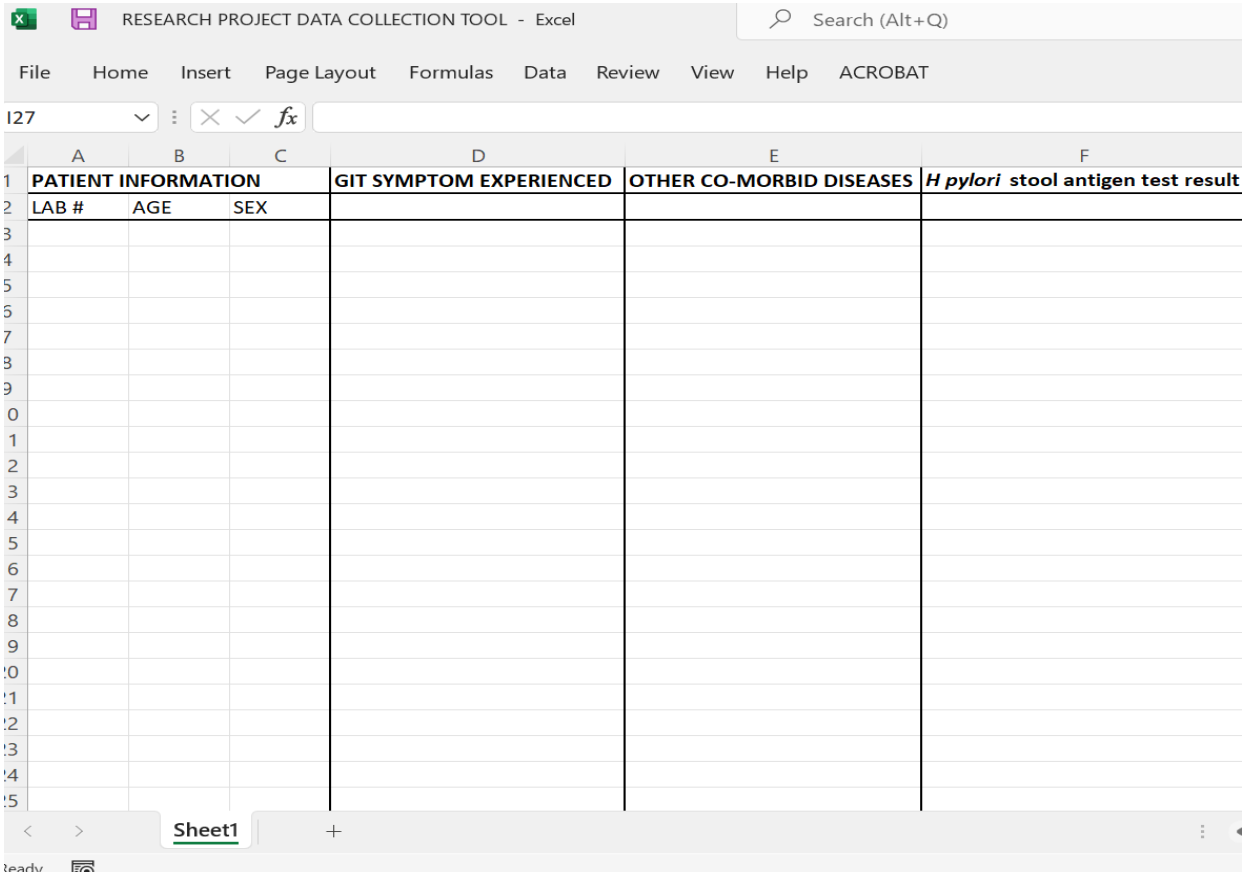
Appendix 1: Time frame

	Month	**August 2024**				**September 2024**				**October 2024**				**November 2024**				**December 2024**			
	Week	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Activity																					
Preparation and submission of proposal to AUREC																					
Pretesting																					
Data collection																					
Data processing and analysis																					
Final project writing																					
Project submission to Africa University																					

Appendix 2: Budget

ITEM	UNIT COST $	MULTIPLYING FACTOR	TOTAL COST (US $)
Stationery (Pens & Pencils)	0.50	2	1.00
Note book	2.00	1	2.00
Bond paper	5.00	1	5.00
Printing and binding services	-	-	10.00
Total	-	-	18.00

Appendix 3: Research Project Data Collection Tool



Appendix 4: Application to conduct study and approval from study site

Africa University

P.O. Box 1320

Mutare

Zimbabwe

30 September 2024

Lancet Clinical Laboratories

22 Fife Avenue Corner Blakiston Street

Harare

Zimbabwe

LANCET
CLINICAL LABORATORIES
22 FIFE AVE / Cnr BLAKISTONE ST.
P.O. BOX BW260
BORROWDALE, HARARE

Ranger Approved
01/10/24

Dear Mr Magaisa (Laboratory Manager)

REF: APPLICATION TO CONDUCT RESEARCH AT LANCET CLINICAL LABORATORIES, HARARE, MAIN BRANCH

I am a final year student at Africa University, pursuing a Bachelor's degree in Medical Laboratory Sciences Honours. I am writing to request permission to conduct research on the following topic:

Helicobacter pylori infection rate among patients presenting with various gastrointestinal (GIT) symptoms from January 2024 to December 2024.

This study is part of the requirements needed by my university for the attainment of a degree in Medical Laboratory Sciences.

I aim to analyze data from the Microbiology Laboratory Information System (LIS). Patient confidentiality will be maintained during and after course of the research. Patient names will not be used throughout the research.

Please find attached a copy of my research proposal.

Thank you for considering my request. I look forward to your favourable response.

Yours Sincerely

Tinotenda Mapuranga

Appendix 5: Approval Letter from AUREC

"Investing in Africa's future"

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 3529/24 28 November 2024

TINOTENDA MAPURANGA
C/O Africa University
Box 1320
MUTARE

RE: ***HELICOBACTER PYLORI*** INFECTION RATE AMONG PATIENTS PRESENTING WITH DIFFERENT GASTROINTESTINAL SYMPTOMS AT LANCET CLINICAL LABORATORIES FROM JANUARY 2024 TO DECEMBER 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 3529/24
  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