

Original Research

Establishing a Consensus Algorithm for H. Pylori Screening, Diagnosis, Initial Management, and Referral Protocols for Primary Care Physicians.

Sarah Abere¹, Ozuomba Sixtus², Ngozi Koko-James³.

¹Gastroenterology Unit, Department of Internal Medicine, Rivers State University Teaching Hospital, Nigeria

²Department of Family Medicine Physician, General Hospital Lagos and Chairman, Society of Family Physicians of Nigeria, Lagos chapter, Nigeria, ³New Mile One Hospital, Port-Harcourt, Nigeria.

Abstract

Background: Helicobacter pylori (H. pylori) infection is a significant public health concern, contributing to various gastrointestinal disorders, including peptic ulcers and gastric cancer. The infection is highly prevalent in Africa, but still diagnostic and treatment challenges persist in primary care settings. Effective treatment regimens are therefore crucial for eradicating this infection and preventing complications. This study aimed to develop a consensus-based algorithm for H. pylori management optimized for Primary care settings utilizing data from primary care physicians, patient screening, and treatments.

Methodology: A cross-sectional study was conducted among forty-four primary care physicians involved in diagnosing and treating H. pylori infection. They were provided with a data Collection Form (DCF) and an H. pylori rapid antibody test kit. All the questionnaire responses and the result of rapid antibody test were recorded and analyzed. A panel of experts involving senior family medicine doctors, and a gastroenterologist via a modified Delphi process of discussions on the DCF responses, and test results from the 44 physicians arrived at a consensus-based treatment algorithm developed to guide clinical decision-making for H. pylori management.

Results: This study comprised 245 patients with a female preponderance and mean age of 35.0±11.5 years. The most common symptoms from the DCF were epigastric pain, nausea/vomiting and bloating in 74.5%, 52.7% and 35% respectively while the mean duration of symptoms was 3weeks. Constipation and irritability were the least common symptoms with heartburn reported less frequently in the H. Pylori positive cases. 79.9% of the 245 patients were H. Pylori treatment naïve with a higher likelihood (57.1%) of having a positive antibody test. It was recommended that both treatment experienced and naïve patients with epigastric or abdominal pain, nausea vomiting and/or bloating with symptom duration > 2weeks be tested and eradicated while those with alarm symptoms be referred to the specialist.

Conclusion: The proposed algorithm provides a comprehensive guide for Physicians at the primary and secondary care level in selecting the most effective treatment regimen for H. pylori infection. H. Pylori antibody testing is a primary screening tool for patients with persistent symptoms or those lasting greater than 2weeks and where positive confirmatory test is recommended.

Keywords: Consensus; Algorithm; H. Pylori; Clinical Guide; Primary Care.

***Correspondence:** Sarah Abere. Department of Internal Medicine, Rivers State University Teaching Hospital, Nigeria.

Email: sarah.abere@ust.edu.ng

How to cite: Abere S, Sixtus O, Ngozi KJ. Establishing a consensus algorithm for H. pylori screening, diagnosis, initial management, and referral protocols for primary care physicians. Niger Med J 2025; 66 (4):1374-1385. <https://doi.org/10.71480/nmj.v66i4.789>.

Quick Response Code:



Introduction

Helicobacter pylori (*H. pylori*) is a spiral Gram-negative bacterium that inhabits the stomach lining, causes chronic gastritis and peptic ulcers, and is linked to gastric cancers such as adenocarcinoma and mucosal associated lymphoid tumor (MALT) lymphoma. Since its discovery in 1982 by Marshall and Warren, *H. pylori* is recognized as a major public health concern, with a global prevalence estimated to affect 50% of the population- an infection that is typically acquired during childhood and persists lifelong if untreated, leading to significant morbidity and mortality.^[1,2,3]

The prevalence of *Helicobacter pylori* infection in Nigeria varies across regions, with the Northern and Southwest regions having the highest rates.^[4,5] Studies report prevalence rates ranging from 5.5% to 96% in different populations.^[3] In Northern Nigeria, the prevalence is especially high, with some studies reporting over 50%, and risk factors like age, gender, alcohol consumption, poor socio-economic status, unhygienic practices and overcrowding are associated with the infection.^[3,5] In Southern Nigeria, the prevalence varies, with lower rates of 19.6% observed in areas like Port Harcourt and higher rates in Lagos of up to 80%, particularly among duodenal ulcer patients.^[3,6]

Across regions, low socioeconomic status, poor hygiene, lack of access to clean water, and crowded living conditions contribute to the spread of *H. pylori*. Addressing these factors could help curb infection rates.^[3]

The management of *H. pylori* infection poses a substantial challenge in clinical practice due to the bacterium's increasing resistance to antibiotics, variations in treatment response among different populations, and the complexity of achieving successful eradication.^[2] The standard first-line therapy for *H. pylori* includes a combination of a proton pump inhibitor (PPI) and two antibiotics, usually clarithromycin and amoxicillin or metronidazole. However, the growing prevalence of antibiotic-resistant *H. pylori* strains, particularly against clarithromycin, has led to a decline in eradication rates, prompting the need for alternative treatment strategies.^[2,3]

In response to these challenges, several studies^[7,8] have explored various treatment regimens, including sequential therapy, concomitant therapy, and the use of novel antibiotics or adjunctive therapies. Despite these efforts, the optimal treatment regimen remains a subject of debate, and there is a need for a standardized approach to improve treatment outcomes.^[9]

According to the African *Helicobacter* and Microbiota study group,^[10] “There are several international and national diagnostic and therapeutic algorithms, but these are based on studies from developed countries and maybe applicable to a limited extent in poor resource countries.” This maybe because of multiple factors including challenges with screening for *H. pylori*, poor funding for *H. pylori* research and the specific challenges of healthcare systems in low-medium income countries like Nigeria.^[10-12]

This study aims to utilize the outcome of primary care physician screening and treatment data for *H. pylori* infection in developing an evidence-based treatment algorithm that can be implemented in clinical practice at the Primary and secondary care levels particularly for family medicine practitioners especially in low to medium income countries. This study seeks to provide a comprehensive guide for these subsets of clinicians in selecting the most effective treatment strategies for their patients, thereby improving eradication rates, and reducing the burden of *H. pylori*-related diseases.

Methods

Study Design: Development of the Treatment Algorithm:

The study design was a Modified Delphi consensus study with a cross-sectional observational component to develop a region-specific treatment algorithm for *H. pylori* management. *H. pylori* antibody test Data Collection Form (DCF) and a rapid antibody test kit were distributed to physicians involved in diagnosing and treating *H. pylori* infection across various healthcare facilities, who further carried out the rapid diagnostic serology tests on patients.

Forty-four physicians were purposively selected based on their clinical experience in diagnosing and managing *Helicobacter pylori* infections, including senior Family Medicine practitioners and a gastroenterologist from diverse healthcare settings. Each physician recruited approximately five consecutive patients presenting with symptoms suggestive of *H. pylori* infection between May and August 2022, resulting in a total of 245 patients. The sample size was considered adequate to inform consensus development rather than for inferential statistical

analysis. Eligible patients were adults (≥ 18 years) with upper gastrointestinal symptoms who provided consent, while those recently treated for *H. pylori* infection or on antibiotics, proton pump inhibitors, or bismuth compounds within two weeks were excluded.

The DCF was designed to capture essential patient information, including demographic data, clinical symptoms, risk factors, and previous treatment history. It was developed by the expert panel based on their clinical insights and a review of previously published literature. While not previously validated, it was reviewed by the expert group to ensure content relevance and clarity.

The rapid antibody test kit provided an immediate, point-of-care diagnostic tool, allowing for real-time assessment of *H. pylori* status. The *H. pylori* Antibody Rapid Test (Immunochromatography) from Qingdao Hightop Biotech Co, Ltd, China was used.

Data from the forms was entered into Microsoft Excel (version 2021; Microsoft Inc., USA) and analysed using the same software. The categorical data were presented with numeric frequency and proportions. Continuous data were presented with mean and standard deviation (SD). The chi-square test was applied to assess statistical differences in categorical variables, with a p-value below 0.05 considered significant.

Firstly, the assessment of patients by the 44 doctors was conducted using the DCF and rapid antibody test. Secondly, the consensus process for algorithm development was carried out based on the collected data and expert deliberations.

A consensus meeting was convened with three experts (two senior Family Medicine physicians and one gastroenterologist) to review the collected data and rapid antibody test results. They were purposively selected based on their clinical experience and active role in managing *H. pylori* infections. Using the modified Delphi technique, the panel discussed clinical applicability, shared iterative feedback, and reached agreement to finalize a region-specific treatment algorithm.

The consensus process was guided by principles of evidence-based medicine, multidisciplinary participation, transparency, contextual relevance, and iterative validation. Recommendations were derived from a systematic review of regional antimicrobial resistance patterns and global *H. pylori* treatment guidelines,^{10,13} followed by structured discussions among the panel members. The resulting algorithm emphasizes feasibility in Nigerian primary healthcare practice while aligning with international standards. Periodic review of the recommendations was agreed upon to incorporate emerging local data and evolving evidence.

Patient Initial: Age: years
 Gender: Male Female Duration of symptoms: weeks / months / years
H. pylori treatment naive patients: Yes No

Please mention your response or select (tick) appropriate option

1. Which symptoms are observed that is indicative of *H. pylori* infection?
 Bloating Abdominal pain Ongoing indigestion Not feeling hungry
 Unplanned weight loss Anemia Bloody vomit/stool
 Other _____

2. What is result of *H. pylori* Antibody Rapid Test?
 Positive Negative

3. Have recommended confirmatory *H. pylori* diagnosis test?
 Yes No

4. If answer to above question is yes, which confirmatory test is recommended?

5. Have you prescribed Omeshal Plus Kit for this patient?
 Yes No

6. If answer for above question is yes, for how many days?
 7 days 14 days other duration _____ days

7. What is line of follow-up?

Figure 1: *H. pylori* antibody test Data Collection Form (DCF)

Validation of the Algorithm:

The developed algorithm was reviewed by a panel of clinical experts specializing in gastroenterology and family medicine. The panel provided feedback on its clinical relevance, feasibility, and potential impact on patient outcomes. Additionally, a pilot implementation of the algorithm was conducted in a selected clinical setting to assess its practicality and effectiveness in guiding treatment decisions.

Results:

Demographics of the Respondents

From the forty-four participating doctors, a total of 245 patient responses were collected and analysed. Of these, 204 patients (163 treatment-naïve and 41 treatment-experienced) were included in the final analysis. There were more female patients (59%) than male patients (41%). The mean age of the patients was 35.0 ± 11.5 years. The median duration of symptoms was 3 weeks; 37.7% of patients reported symptoms lasting less than 2 weeks, while 45.5% had symptoms persisting for more than 2 weeks (Figure 2).

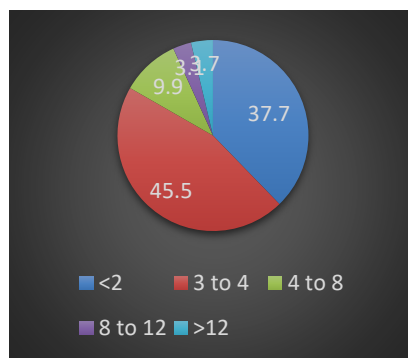


Figure 2: Duration of symptoms (No of patients= 191)

DCF Responses (Symptoms and Treatment History)

The most reported symptoms of *H. pylori* infection were abdominal/epigastric pain, nausea, bloating, and loss of appetite. Heartburn, a typical symptom of GERD, was reported less frequently among *H. pylori*-positive patients. This symptom pattern may assist primary care providers in differentiating *H. pylori* infection from GERD (Figure 3).

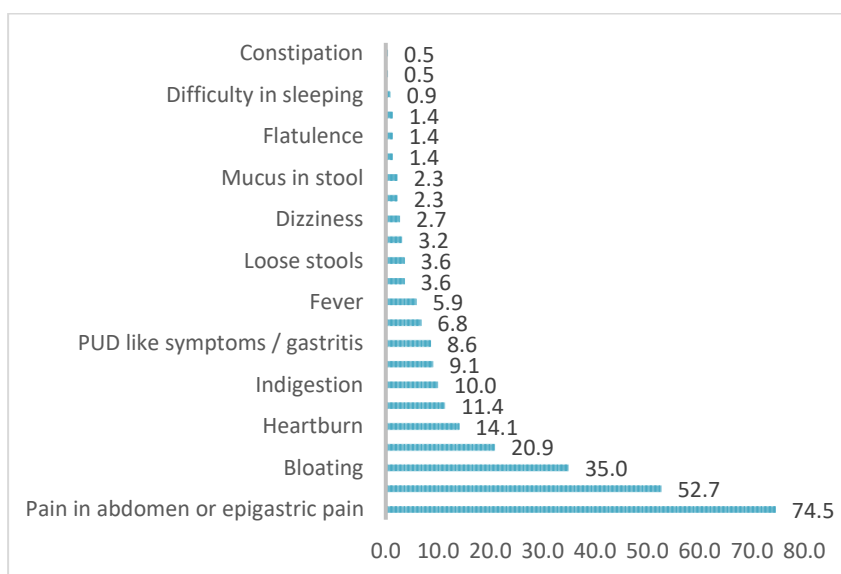


Figure 3: Clinical symptoms of *H. pylori* infection reported from DCF responses

Most patients (79.9%) were treatment-naïve for *H. pylori*, while approximately 20% were treatment-experienced (Figure 4).

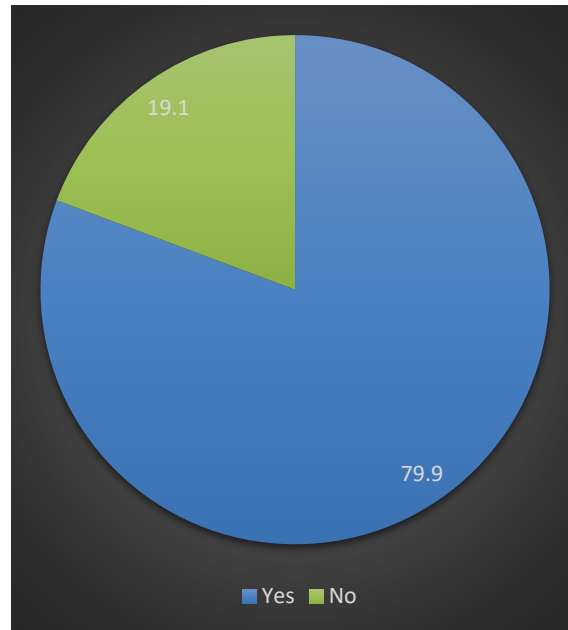


Figure 4: *H. Pylori* treatment naïve patient (N=204)

Rapid Antibody Test Outcomes

Among the 204 patients tested, 55% were positive on the rapid antibody test (Figure 5).

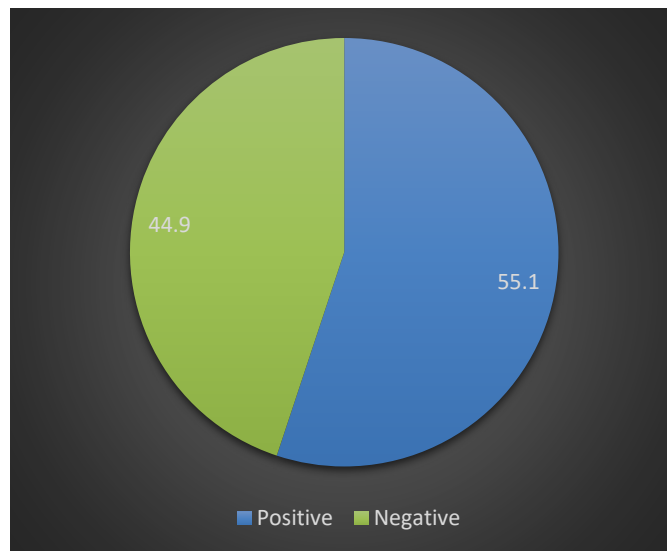


Figure 5: *H. pylori* Rapid Antibody Test (N=204)

Treatment-naïve patients had a significantly higher likelihood of testing positive compared to treatment-experienced patients (57.1% vs. 39%, $p=0.039$) (Table 1).

H pylori antibody test	H. pylori treatment-experienced		P value
	Naïve (n=163)	Received treatment in past (n=41)	
Positive	93 (57.1)	16 (39.0)	0.039
Negative	70 (42.9)	25 (61.0)	

Table 1: Cross tabulation: Antibody test / H pylori treatment status

Confirmatory Test Outcomes

Of the 245 patients assessed, 65% (158/245) were advised to undergo a confirmatory test. Among these, 57% had positive rapid antibody test results, while 43% were negative. This difference was not statistically significant (p=0.547), indicating that the rapid antibody test may not reliably predict the need for further diagnostic testing (Figures 6&7).

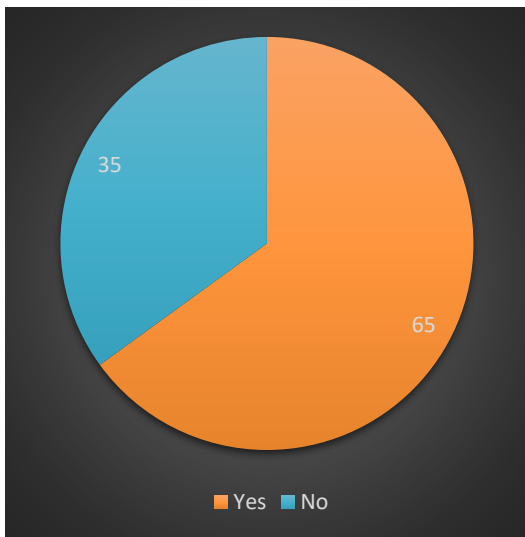


Figure 6: Confirmatory test rate

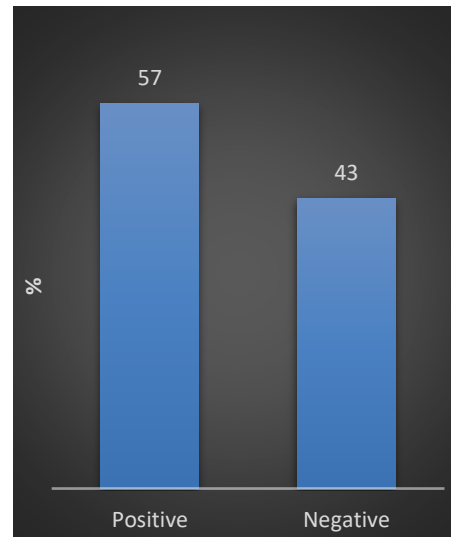


Figure7: Rapid antibody test correlation

The most preferred confirmatory test was the urea breath test, followed by stool antigen and serum antigen tests (Figure 8).

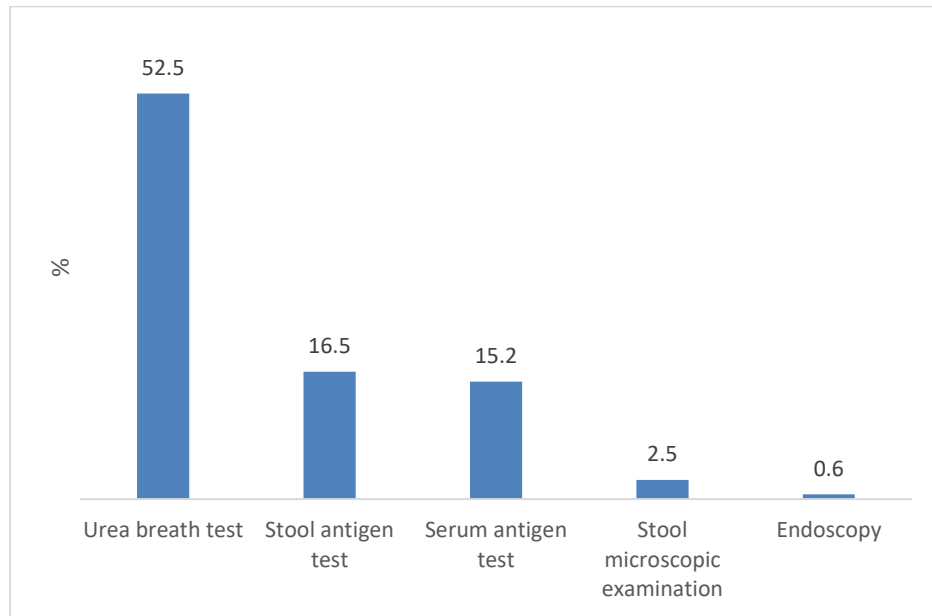


Figure 8: Confirmatory Test Advised

Treatment Prescriptions

Among the 245 cases, a triple therapy combination kit (Omeprazole 20 mg, Clarithromycin 250 mg, Tinidazole 500 mg) was prescribed in 125 patients (51.2%) (Figure 9).

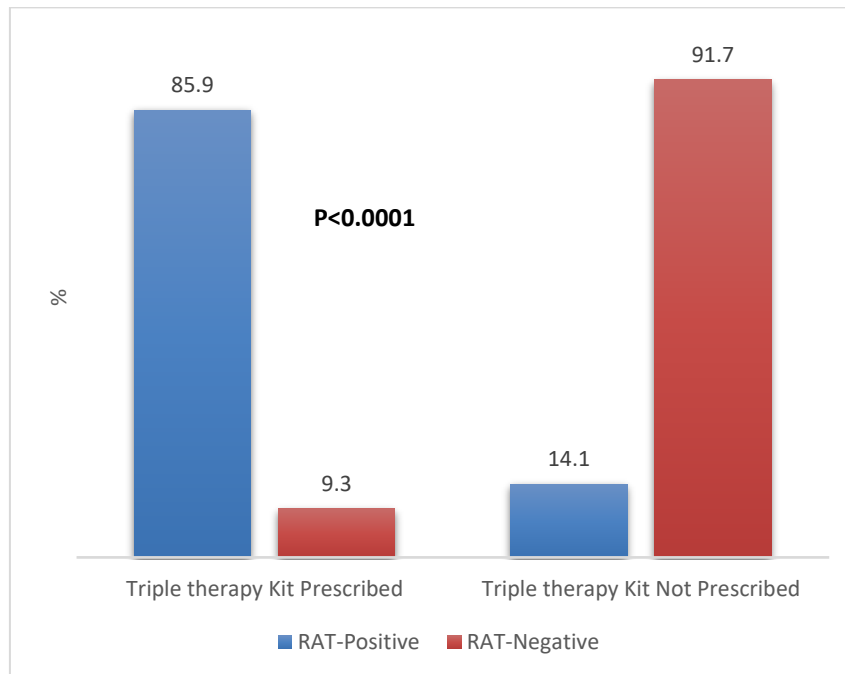


Figure 9: Prescription of Triple therapy kit by Rapid Antibody Test results

Most patients (85.9%) with rapid antibody test positives were prescribed triple therapy, while 14% were not, despite being antibody positive.

In treatment-naïve patients with positive rapid antibody test results, 90.3% received triple therapy. Notably, 11.4% of patients with negative antibody tests also received therapy (Table 2).

H. Pylori treatment naïve cases (n=163)

Triple therapy kit	RAT-positive (n=93)	RAT negative (n=70)	P value
Prescribed	84 (90.3)	8 (11.4)	<0.0001

Table 2: Triple therapy kit prescribed to *H. pylori* treatment naïve patients

Triple therapy was prescribed for 14 days in 60.5% of cases, and for 7 days in 39.5% of cases.

Consensus Process and Algorithm

The consensus formed during the expert panel meeting integrated the DCF responses, rapid antibody test results, and expert clinical judgment. The resulting algorithm addresses:

Screening: Initial assessment of patients with epigastric/abdominal pain, nausea, vomiting, and/or bloating. Differentiation is based on symptom duration (<2 weeks vs. ≥2 weeks).

Diagnosis: Use of the rapid antibody test as a primary screening tool, followed by confirmatory testing (urea breath test, stool antigen, serum antigen) before treatment initiation.

Initial Empirical Treatment: Triple therapy is recommended for confirmed cases, with clear guidance on treatment duration (7 vs. 14 days).

Referral Criteria: The algorithm highlights warning signs that warrant immediate referral, including persistent symptoms, family history of gastric cancer, unintended weight loss, and gastrointestinal bleeding.

A detailed screening, diagnosis, and treatment algorithm (figure 10) was developed as a practical tool for primary care physicians, particularly in resource-limited settings.

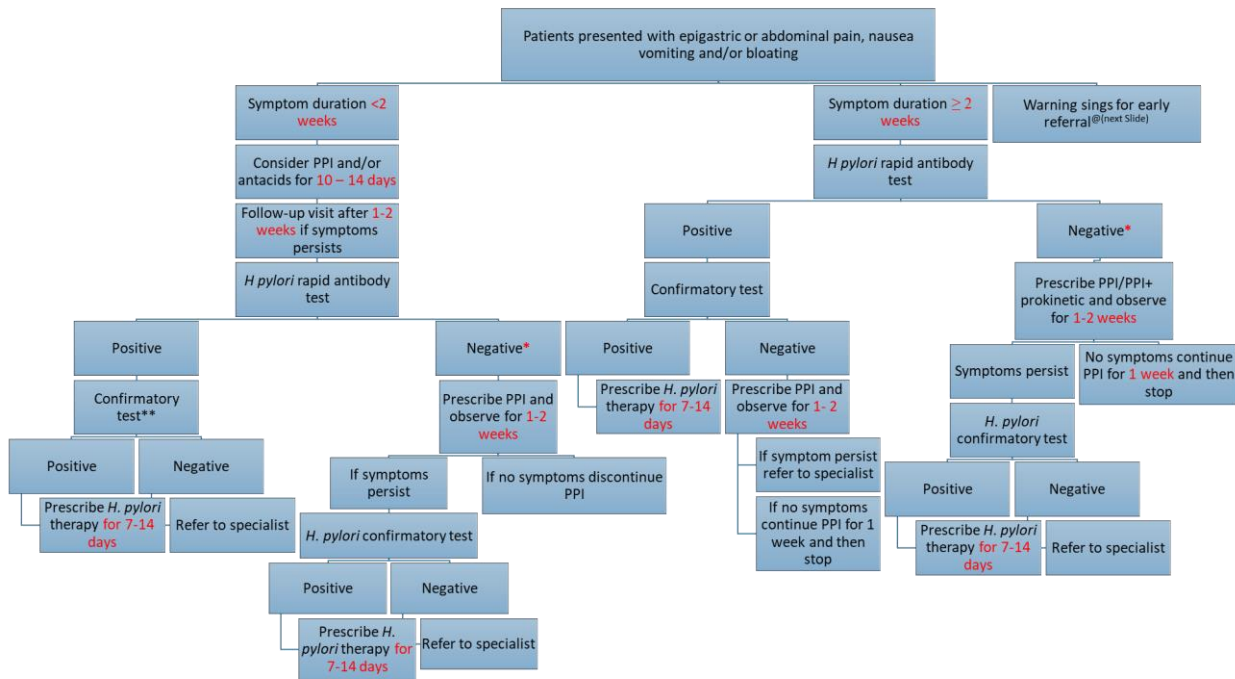


Figure 10: H. Pylori screening, diagnosis and treatment algorithm

**confirmatory test: Urea breathe test, stool antigen tests

PPI: proton pump inhibitors; NUD: Non-ulcer dyspepsia; ZES: Zollinger-Ellison syndrome; GERD: gastro esophageal reflux disease; IBD: Inflammatory bowel disease

*In patients with negative rapid antibody tests, please consider other causes e.g. Use of NSAIDs, NUD or functional dyspepsia, Crohn’s disease, ZES, GERD, IBD, Gastritis, Esophagitis and consider taking detailed patient history [4]

The algorithm begins with patients presenting with epigastric or abdominal pain, nausea, vomiting, and/or bloating. It differentiates between symptoms lasting less than 2 weeks and those persisting for 2 weeks or more. For symptoms lasting less than 2 weeks, the algorithm recommends considering proton pump inhibitors (PPIs) and/or antacids for 10 to 14 days, with a follow-up visit if symptoms persist. The algorithm incorporates the use of the *H. pylori* rapid antibody test as a primary screening tool for patients with persistent symptoms or those lasting 2 weeks or more. In cases of positive rapid antibody tests, the algorithm recommends confirmatory testing to ensure accurate diagnosis before initiating treatment. The algorithm provides clear guidance on when to prescribe *H. pylori* therapy based on test results and symptom persistence. The algorithm includes specific criteria for follow-up care and referral to specialists, ensuring appropriate management of complex or persistent cases. For patients with negative test results, the algorithm suggests considering alternative diagnoses and provides guidance on further management. The algorithm highlights specific warning signs that warrant immediate referral to a specialist, including dyspepsia symptoms with a family history of gastric cancer, persistent symptoms, unintended weight loss, and signs of gastrointestinal bleeding.

Discussion

Addressing *H. pylori* infection is a critical global public health priority, as it is a preventable cause of gastric cancer- one of the leading causes of cancer-related deaths worldwide. There have been three previous well known consensus reports prepared over time for the management of *H. pylori* infection when treatment become challenging: the European Helicobacter and Microbiota Study Group (Maastricht

V/ Florence report), the American College of Gastroenterology (ACG), and the Canadian Association of Gastroenterology/ Canadian Helicobacter Study Group (Toronto Consensus).^[11,14-15] One consensus report was prepared in 2016 by Maastricht V/Florence which recommended strongly the use of the triple therapy as first line empirical treatment for *H. pylori* infection where there is low resistance of Clarithromycin, and this triple therapy can be extended up to 14 days.^[12]

Developing countries face a high and regionally variable *H. pylori* burden, rising and heterogeneous antibiotic resistance, and uneven diagnostic capacity. In Africa however, there is a single well-known study performed on the pooled prevalence of antibiotic resistance which was conducted in three countries, Cameroon, Congo, Senegal. The overall pooled prevalence of antibiotic resistance for clarithromycin was only about 15% only for *H. pylori* infection treatment.^[16]

The definition of “who to test” according to the consensus is based on the most common symptoms at presentation- epigastric/upper abdominal pain, bloating and/or nausea or vomiting and the duration of symptoms. This conforms to the principle of ‘test and treat’ recommended globally and the symptomatology of the disease as reported by other researchers.^[15,17]

The test-and-treat approach was ranked as the most effective strategy for managing uninvestigated dyspepsia, especially in younger patients without alarming symptoms and for patients positive for *H. pylori* ^[18] thus the consensus recommendation of primarily utilizing the *H. pylori* antibody test as a screening tool followed by a confirmatory test (If antibody positive) for all symptomatic patients. Antibody testing is often recommended as a pragmatic screening tool in poor-resource centers because it is cheap, widely available, simple to run, stable for transport, and has acceptable positive predictive value in high-prevalence populations though it cannot distinguish active from past infection and is therefore unsuitable for test-of-cure. ^[19,20]

It was also stipulated that in confirmed *H. pylori* infected patients, eradication therapy for *H. pylori* using the triple regimen should be initiated and the recommended duration is 7-14 days while *H. pylori* negative patients should receive symptomatic therapy with PPIs and /or antacids. This is like recommendations by other study groups. ^[21,22]

Importantly, the consensus advised that Patients presenting with warning signs or alarm features such as unintentional weight loss, progressive dysphagia/odynophagia, persistent vomiting, gastrointestinal bleeding or iron-deficiency anemia, palpable abdominal mass, or new-onset symptoms in an older patient should be referred promptly for specialist assessment and upper gastrointestinal endoscopic investigation. This approach is supported by major guideline bodies and systematic evidence reviews ^[23-25] as alarm features markedly raise the likelihood of clinically important structural disease

Conclusion:

The algorithm which we developed as a guide to *H. pylori* care in primary and secondary care setting follows a stepwise approach, starting with symptom assessment, progressing through diagnostic tests and treatments. It aims to streamline the identification and treatment of *H. pylori* infection as a potential cause of the gastrointestinal symptoms experienced by our study participants.

The algorithm's strength lies in its comprehensive approach, addressing the entire spectrum of *H. pylori* management from initial presentation to specialist referral. Its development through a rigorous process involving data collection, rapid testing, and expert consensus ensures its relevance and applicability in real-world clinical settings.

This consensus algorithm represents a valuable tool in the fight against *H. pylori* infection in resource-limited settings. Its widespread adoption and continued refinement have the potential to significantly improve the management of *H. pylori* infection and reduce its associated health burden in Africa and beyond.

Disclosure: The authors declare no conflict of interest.

Acknowledgement: The authors acknowledge with gratitude the input of all participating physicians, centers as well as the faculty at Shalina Pharmaceuticals for their support.

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