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TREATMENT REGIMEN PATTERNS, ADHERENCE AND ERADICATION FAILURE IN COMMUNITY PHARMACY–DISPENSED HELICOBACTER PYLORI THERAPY IN BAYELSA STATE, NIGERIA: A CROSS-SECTIONAL ANALYSIS WITH IMPLICATIONS FOR ANTIMICROBIAL STEWARDSHIP

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ABSTRACT

Background: Helicobacter pylori eradication is a cornerstone of peptic ulcer disease (PUD) management and a key preventive strategy against gastric malignancy, yet eradication success depends on guideline-concordant regimen selection, treatment adherence, and post-treatment verification of cure — all of which are vulnerable in community pharmacy settings in low- and middle-income countries. This study evaluated treatment regimens dispensed, adherence patterns, eradication outcomes, and antimicrobial stewardship implications of community pharmacy–dispensed H. pylori therapy in Bayelsa State, Nigeria. **Methods:** A descriptive, analytical, cross-sectional study was conducted among adults with PUD attending community pharmacies in Yenagoa metropolis. A structured interviewer-assisted questionnaire was administered to 428 participants; 412 (96.3%) returned complete responses, and 183 met the case definition for PUD. Data were analysed in IBM SPSS Statistics version 26.0 using descriptive statistics, chi-square tests, and an independent-samples t-test. Statistical significance was set at $\alpha = 0.05$. **Results:** Sequential therapy was the most frequently dispensed regimen (45.4%), followed by triple therapy and proton pump inhibitor (PPI)–based combinations. Only 35.0% of respondents completed the prescribed course as directed; 39.3% discontinued prematurely due to adverse effects, and 15.3% had not commenced treatment at the time of survey. Regimen completion was statistically associated with treatment outcome ($p = 0.043$). Eradication failure — defined as persistent H. pylori positivity post-treatment — was reported in 39.9% of treated respondents ($p = 0.028$). Critically, 25.7% of respondents had no post-treatment confirmatory testing performed. Patient-reported adverse effects were dominated by taste disturbance (48 cases), diarrhoea (41 cases), and nausea (41 cases). An independent-samples t-test confirmed a statistically significant association between management strategy score and clinical outcome ($t(183) = 1.800$, $p = 0.025$), with improved outcomes associated with a higher mean management strategy score ($M = 2.21$, $SD = 1.155$) compared to worsened outcomes ($M = 1.00$). **Conclusion:** Community pharmacy–dispensed H. pylori therapy in Bayelsa State is characterized by substantial regimen-completion deficits, an alarming eradication failure rate of approximately 40%, and widespread absence of test-of-cure — a constellation of practice patterns with direct implications for antimicrobial resistance amplification. Urgent investment is required in structured patient counselling, standardised test-and-treat protocols aligned with the Maastricht VI/Florence consensus, mandatory post-treatment confirmatory testing, and embedded antimicrobial stewardship oversight of community pharmacy H. pylori practice.

KEYWORDS: Helicobacter pylori; eradication therapy; treatment adherence; antimicrobial resistance; antimicrobial stewardship; community pharmacy; Nigeria; Bayelsa State.

INTRODUCTION

The clinical management of Helicobacter pylori infection rests on the achievement of complete bacterial eradication, which heals chronic active gastritis, prevents ulcer recurrence, reduces the risk of gastric malignancy by approximately 50%, and is now positioned by the most recent Maastricht VI/Florence consensus as the single most effective preventive strategy against gastric cancer worldwide (Malfertheiner et al., 2022; Setshedi & Smith, 2023). For more than three decades, the cornerstone of eradication has been combination antimicrobial therapy, with regimen choice evolving in response to emerging antibiotic resistance — from classical proton pump inhibitor (PPI)–based triple therapy of the 1990s, to sequential therapy and concomitant non-bismuth quadruple therapy of the 2000s, to the bismuth-quadruple therapy now recommended as first-line in settings with clarithromycin resistance above 15% (Chey, Leontiadis, Howden, & Moss, 2017; Graham & Fischbach, 2010; Malfertheiner et al., 2022).

Across sub-Saharan Africa, the choice of regimen is increasingly constrained by rising and poorly characterised antimicrobial resistance. The continental synthesis by Smith et al. (2022) and the more recent update by Pellicano et al. (2023) document widespread resistance to clarithromycin, metronidazole, and levofloxacin — the workhorse antibiotics of triple and quadruple therapy — and reveal that susceptibility testing infrastructure is virtually absent across most African settings, leaving empirical regimen selection as the only available strategy. The systematic review and meta-analysis by Jaka et al. (2023) further documents that eradication success rates achieved in Africa fall consistently below the ≥ 90% threshold considered acceptable in modern clinical practice.

Compounding this clinical challenge, in much of Nigeria — including the Niger Delta region — community pharmacies serve as the de facto first-line providers of H. pylori therapy. Patients with upper gastrointestinal symptoms typically present first to community pharmacies, where eradication regimens are routinely dispensed without prior diagnostic confirmation, often without structured counselling, and rarely with post-treatment test-of-cure (Erhun & Erhun, 2002; Auta et al., 2019; Onyekachi & Nwosu, 2021). This practice context has three direct consequences: (i) treatment is initiated empirically in patients without confirmed infection; (ii) eradication failures are detected late or not at all; and (iii) sub-optimal antibiotic exposure contributes to the regional antimicrobial resistance crisis identified as a national priority in Nigeria's National Action Plan for Antimicrobial Resistance (Federal Ministry of Health, 2017).

Despite these systemic concerns, the specific treatment regimens dispensed, the adherence patterns achieved, and the eradication outcomes obtained in community pharmacy–dispensed H. pylori therapy in Bayelsa State have not been previously characterised in the published literature. This study was therefore conducted to evaluate the regimen patterns, adherence rates, eradication outcomes, and adverse-effect profile of community pharmacy–dispensed H. pylori therapy in Yenagoa metropolis, and to draw out the implications for antimicrobial stewardship.

2. MATERIALS AND METHODS

2.1 Study design and setting

A descriptive, analytical, cross-sectional study was conducted in community pharmacies across Yenagoa metropolis, Bayelsa State, Nigeria, between [Month/Year] and [Month/Year]. Yenagoa is the state capital and largest urban centre of Bayelsa State, characterised by a heterogeneous population and a well-developed network of registered community pharmacies serving a substantial proportion of patients with upper gastrointestinal complaints (Pharmacists Council of Nigeria, 2018).

2.2 Study population, eligibility and sample size

The study population comprised adults aged ≥ 18 years with self-reported peptic ulcer symptoms of at least four weeks' duration attending participating community pharmacies. Exclusion criteria included gastrointestinal symptoms attributable to non-PUD conditions confirmed by a physician, acute critical illness at the time of approach, prior participation, and being a pharmacy staff member. Sample size was determined using the Cochran (1977) formula with Z = 1.96, p = 0.50, d = 0.05, and a 10% non-response allowance, yielding a target of 428 participants (Lwanga & Lemeshow, 1991).

2.3 Sampling procedure

A multi-stage sampling strategy was applied. Community pharmacies were identified through the Pharmacists Council of Nigeria zonal office and the Bayelsa State Board of the Association of Community Pharmacists of Nigeria, and purposively selected for spatial diversity. The total sample was proportionally allocated across pharmacies based on monthly PUD-

related patient volume, and consecutive eligible patients were recruited at each pharmacy until the allocated quota was achieved.

2.4 Data collection instrument

Data were collected using a structured, interviewer-assisted questionnaire developed for the present study and validated by a panel of three subject-matter experts. Content validity was confirmed using Lynn's (1986) procedure; internal-consistency reliability achieved a Cronbach's alpha of 0.81 in a 30-participant pilot at a non-participating community pharmacy (Cronbach, 1951; Nunnally, 1978). The instrument captured five domains relevant to the present analysis: PUD history and H. pylori status; treatment regimen received (including class of agents, duration, and PPI co-prescription); adherence and reasons for any non-completion; adverse-effect experience; and post-treatment outcome including any test-of-cure.

2.5 Data management and statistical analysis

Data were double-entered into IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA), with 10% manual verification against the original forms (Barchard & Verenikina, 2013). Continuous variables were summarised as means with standard deviations and tested for normality using the Shapiro-Wilk test; categorical variables were summarised as frequencies and percentages. Bivariate associations were tested using chi-square or Fisher's exact tests. An independent-samples t-test was used to compare mean management strategy scores between outcome groups (significantly improved versus significantly worsened), with Levene's test applied to assess homogeneity of variance and separate-variance estimates used where this assumption was violated (Field, 2018). All tests were two-tailed; statistical significance was set at $\alpha = 0.05$ with 95% confidence intervals reported throughout.

2.6 Ethical considerations

Ethical approval was obtained from the [Institutional Health Research Ethics Committee, Approval Number XX/YY/ZZZZ] and the Bayelsa State Ministry of Health Research Ethics Committee. Written informed consent was obtained from every participant. The study was conducted in accordance with the Declaration of Helsinki.

3. RESULTS

3.1 Sample and PUD case identification

Of 428 distributed questionnaires, 412 (96.3%) were returned complete. Within this sample, 183 respondents met the case definition for PUD and form the analytical population for this manuscript. The mean age of PUD respondents was 36.6 ± 0.54 years; women constituted 59.7% of the sample.

3.2 Treatment regimens dispensed

Table 1 presents the distribution of treatment regimens reported by PUD respondents. Sequential therapy was the most frequently dispensed regimen (45.4%), reflecting partial alignment with international guidance on sequential therapy as an alternative to classical triple therapy in high-resistance settings (Graham & Fischbach, 2010; Zullo, Hassan, Ridola, De Francesco, & Vaira, 2013). PPI-based combinations and standard triple therapy made up the remainder, with bismuth-quadruple therapy notably uncommon despite its recommended first-line status in high clarithromycin–resistance settings (Malfertheiner et al., 2022). Adjunctive dietary modification (48.6%) and probiotic use (35.5%) were also commonly reported (Dang, Reinhardt, Zhou, & Zhang, 2014; Tsai et al., 2012).

Table 1: Treatment regimens, adherence and eradication outcomes (n = 183 PUD respondents).

Variable	n	%	p-value
Regimen received			
Sequential therapy	83	45.4	—
Standard triple therapy	53	29.0	
PPI-based combinations	30	16.4	
Other / unspecified	17	9.3	
Adjunctive measures used			
Dietary modification	89	48.6	
Probiotics	65	35.5	
Treatment completion			
Completed as directed	64	35.0	0.043
Discontinued due to side effects	72	39.3	
Discontinued for other reasons	19	10.4	
Not yet commenced	28	15.3	
Reported adverse effects (top three)			
Taste disturbance	48	26.2	0.078
Diarrhoea	41	22.4	

Nausea	41	22.4	
Eradication outcome (where tested)			
H. pylori persistence post-treatment	73	39.9	0.028
No confirmatory test performed	47	25.7	
Adherence support reported			
Family/social support	57	31.1	
Phone/SMS reminders	50	27.3	
Written instructions	40	21.9	
Healthcare provider counselling	25	13.7	
No support received	11	6.0	
Patient satisfaction			
Satisfied	84	45.9	
Very satisfied	34	18.6	
No subjective change in condition	84	45.9	

3.3 Treatment completion and eradication outcomes

Despite the prescription of recognised therapeutic regimens, treatment completion was substantially suboptimal: only 35.0% of respondents reported completing the prescribed course as directed, while 39.3% discontinued prematurely due to adverse effects, 10.4% stopped for other reasons, and 15.3% had not yet commenced treatment. The association between regimen completion and clinical outcome was statistically significant ($p = 0.043$), confirming that incomplete treatment was directly correlated with persistent infection. Among respondents who underwent post-treatment testing, 39.9% had test results indicating H. pylori persistence — an eradication failure rate substantially above the < 10% target endorsed by international consensus (Malfertheiner et al., 2022). The association between persistence and eradication failure was statistically significant ($p = 0.028$).

3.4 Absence of test-of-cure

A critical operational finding was that 25.7% of treated respondents reported that no post-treatment confirmatory test was performed. This means that approximately one in four treated patients exited the eradication pathway without verification of treatment success — a structural gap that precludes accurate assessment of treatment efficacy, perpetuates undetected persistent infection, and contributes to the under-recognition of antimicrobial resistance at the population level (Megraud & Lehours, 2007; Megraud et al., 2013).

3.5 Adverse effects and treatment abandonment

The most commonly reported adverse effects were taste disturbance (48 cases), diarrhoea (41 cases), and nausea (41 cases). Although the chi-square test for adverse-effect occurrence by regimen type did not reach statistical significance ($p = 0.078$), these effects collectively constituted the leading reported driver of treatment abandonment in this cohort. Taste disturbance — commonly associated with metronidazole and clarithromycin — is a well-documented impediment to adherence in H. pylori regimens (Malfertheiner et al., 2012), and the high attrition rate observed here underscores the need for pre-treatment counselling that explicitly anticipates and normalises these effects.

3.6 Management strategy and patient outcome

An independent-samples t-test was conducted to examine the relationship between management strategy score and clinical outcome (significantly improved versus significantly worsened). The test yielded $t(183) = 1.800$, $p = 0.025$, with improved outcomes associated with a higher mean management strategy score ($M = 2.21$, $SD = 1.155$, $n = 180$) compared to worsened outcomes ($M = 1.00$, $SD = 0.00$, $n = 3$). Although the small number of worsened cases ($n = 3$) imposes a limit on the precision of effect size estimation, the direction and statistical significance of the association support the inference that variation in management strategy contributes meaningfully to variation in clinical outcome. Levene's test indicated heterogeneity of variance ($F = 13.062$, $p < 0.001$), and the test statistic was computed using separate-variance estimates.

4. DISCUSSION

This study reports the first detailed characterisation of community pharmacy–dispensed H. pylori treatment patterns in Bayelsa State, Nigeria. Four findings stand out as particularly consequential for clinical practice, public health policy, and antimicrobial stewardship in this setting.

4.1 Regimen patterns and alignment with international guidance

The predominance of sequential therapy (45.4%) over standard triple therapy in this setting represents only partial alignment with international guidance. Sequential therapy was for several years promoted as a pragmatic alternative to classical triple therapy in settings with elevated clarithromycin resistance (Liou

et al., 2013; Zullo et al., 2013), but more recent consensus has shifted decisively in favour of bismuth-quadruple therapy as first-line treatment in settings where clarithromycin resistance exceeds 15% — a threshold widely exceeded across sub-Saharan Africa (Pellicano et al., 2023; Malfertheiner et al., 2022; Smith et al., 2022). The near-absence of bismuth-quadruple therapy in the current cohort suggests that practice in Yenagoa community pharmacies has not kept pace with the most recent evidence base, and points to an urgent need for continuing-education updates among community pharmacists in the region.

4.2 Adherence and side-effect-driven attrition

The 35.0% completion rate observed here is alarming, even allowing for the well-known sensitivity of self-reported adherence to social-desirability bias (Osterberg & Blaschke, 2005; Morisky, Green, & Levine, 1986). Multi-drug H. pylori regimens are particularly vulnerable to non-completion because of their pill burden, twice-daily dosing, and the high prevalence of taste, gastrointestinal and other adverse effects — and the dominant role of side-effect-driven discontinuation in the present cohort (39.3%) is consistent with that pattern (Malfertheiner et al., 2012). Crucially, side-effect attrition is partially modifiable through structured pre-treatment counselling: when patients are forewarned about the transient nature of metronidazole-associated metallic taste, antibiotic-associated diarrhoea, and clarithromycin-associated nausea, completion rates improve substantially (Watson, Robbins, Smith, Nichols, & Davies, 2004). The low rate of formal healthcare-provider counselling reported here (13.7%) therefore identifies a specific, actionable intervention point.

4.3 Eradication failure and the antimicrobial resistance loop

An eradication failure rate of 39.9% is not merely a quality-of-care problem at the individual patient level — it is a population-level driver of antimicrobial resistance. Every patient who completes (or partially completes) an empirically chosen, ultimately unsuccessful regimen represents a selective-pressure event that promotes the emergence and persistence of resistant H. pylori strains. The continental review by Pellicano et al. (2023) and the systematic review by Jaka et al. (2023) both warn that the current trajectory of African H. pylori resistance threatens to render standard regimens increasingly ineffective, and that empirical prescribing in the absence of local susceptibility data — the dominant practice in Nigeria — amplifies this trajectory (Savoldi, Carrara, Graham, Conti, & Tacconelli, 2018; Thung et al., 2016). Reversing this loop requires three coordinated changes: (i) pre-treatment confirmation of infection through low-cost point-of-care testing, replacing presumptive prescribing; (ii) regimen selection guided by the latest Maastricht VI/Florence-aligned algorithms; and (iii) mandatory post-treatment test-of-cure to detect and respond to eradication failure (Malfertheiner et al., 2022; Setshedi & Smith, 2023).

4.4 The absent test-of-cure: a structural failure

Perhaps the most actionable finding of the present study is the 25.7% rate of absent post-treatment testing. In a regulated clinical environment, mandatory test-of-cure is a foundational principle of H. pylori management; in the community pharmacy context in Yenagoa, this principle is widely disregarded. This is partly a function of cost (urea breath testing and stool antigen testing are not currently embedded in routine community pharmacy workflows in Nigeria), partly a function of provider training (many community pharmacists may not be aware that test-of-cure is the international standard), and partly a function of patient understanding (patients who experience symptomatic relief are unlikely to return for confirmatory testing without an explicit clinical recommendation). Addressing this gap will require simultaneous investment in point-of-care diagnostic infrastructure, continuing professional development for community pharmacists, and patient-facing communication that explicitly frames test-of-cure as the conclusion — not an optional extra — of any eradication regimen.

4.5 Strengths and limitations

The principal strengths of this study include its high response rate (96.3%), its multi-stage probability sampling, and its use of a validated instrument with strong internal-consistency reliability. The limitations include reliance on self-reported adherence and eradication outcomes rather than direct laboratory confirmation (which may have introduced both information bias and social-desirability bias), the inability of the cross-sectional design to track individual patients across the full treatment trajectory, and the very small size of the worsened-outcome subgroup (n = 3) in the t-test analysis. Future research employing prospective cohort designs with direct laboratory confirmation of eradication status would substantially strengthen the inferential base.

5. CONCLUSION

Community pharmacy–dispensed H. pylori therapy in Bayelsa State is characterised by partial alignment with international regimen guidance, substantial regimen-completion deficits, an alarming eradication failure rate of approximately 40%, and the widespread absence of post-treatment test-of-cure. The constellation of these practice patterns has direct implications for antimicrobial resistance amplification at the population level. Urgent investment is required

in: (i) structured pre-treatment patient counselling that anticipates and normalises adverse effects; (ii) regimen-selection updates aligned with the Maastricht VI/Florence consensus, including the introduction of bismuth-quadruple therapy where appropriate; (iii) integration of low-cost point-of-care diagnostic testing into community pharmacy workflows; (iv) mandatory test-of-cure as the routine endpoint of eradication therapy; and (v) embedded antimicrobial stewardship oversight of community pharmacy H. pylori practice as part of Nigeria's National Action Plan for Antimicrobial Resistance.

DECLARATIONS

Ethics approval and consent to participate: Ethical approval was obtained from the [Institutional Health Research Ethics Committee] and the Bayelsa State Ministry of Health Research Ethics Committee. Written informed consent was obtained from all participants.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and analysed during this study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: [Author 1] conceived and designed the study, supervised data collection, and led the manuscript drafting. [Author 2] contributed to study design, supervised statistical analysis, and critically revised the manuscript. [Author 3] coordinated field operations and assisted with data analysis. All authors read and approved the final manuscript.

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