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Clinical and environmental factors associated with *Helicobacter pylori* infection among patients presenting with *Karuho* syndrome in Bunia, Democratic Republic of the Congo

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ABSTRACT

Introduction
Karuho syndrome is a culturally recognised condition in eastern Democratic Republic of the Congo (DRC), commonly perceived as a form of poisoning and frequently managed in tradimodern healthcare settings. Its clinical characteristics and underlying aetiology remain poorly understood.

Purpose
To investigate the association between *Karuho* syndrome and *Helicobacter pylori* infection by describing the sociodemographic profile of affected patients, identifying associated clinical manifestations, and examining environmental, behavioural, and comorbidity-related factors.

Methods
A cross-sectional analytical study was conducted between 5 May 2024 and 2 January 2025 among 345 consecutive patients presenting with *Karuho* syndrome at four tradimodern treatment centres in Bunia, Ituri Province, Democratic Republic of the Congo. Participants underwent stool antigen testing for *H. pylori*. Sociodemographic, clinical, environmental, behavioural, and biological variables were analysed using bivariate logistic regression. Associations were reported as odds ratios (ORs) with 95% confidence intervals (CIs), and statistical significance was set at $p < .05$.

Results
Of the 345 participants, 267 (77.4%) tested positive for *H. pylori* infection. The most affected age group was 20–29 years (OR = 10.7, p = .004), while secondary education was the strongest sociodemographic correlate (OR = 12.8, p = .004). Consumption of food prepared outside the home (OR = 20.78, $p < .001$) and self-medication (OR = 17.81, p = .012) were the strongest environmental and behavioural factors associated with infection. Clinically, chest pain (OR = 15.16), cough (OR = 11.70), epigastric pain (OR = 10.93), and vomiting (OR = 10.21) showed the strongest associations with *H. pylori* positivity. Diabetes mellitus (OR = 8.94), malaria (OR = 5.42), and typhoid fever (OR = 6.22) were significantly associated with infection.

Conclusion
Karuho syndrome demonstrated substantial overlap with the clinical manifestations associated with *H. pylori* infection. The findings suggest that many symptoms attributed to *Karuho* may be associated with *H. pylori* infection and related environmental exposures. However, the cross-sectional design does not permit causal inference. Further microbiological, endoscopic, and longitudinal studies are required to clarify the relationship between *Karuho* syndrome and *H. pylori* infection.

INTRODUCTION

Karuho is a term used in the Kivu provinces (South Kivu, North Kivu, and Maniema) of the Democratic Republic of the Congo (DRC) to describe a toxic substance or poison. A review of the literature reveals divergent perspectives regarding its nature. Some authors consider *Karuho* a common illness, whereas others describe it as a form of poisoning or a sociocultural disease (Kyolo et al., 2018, 2019; Nassenstein, 2019). The most widespread perception is that *Karuho* is a toxic substance deliberately manufactured and administered to endanger the lives of targeted individuals (Kyolo et al., 2019; Nassenstein, 2019). Consequently, affected individuals are frequently referred to traditional healers for non-conventional treatment.

Although reliable morbidity and mortality statistics related to *Karuho* are unavailable, the increasing number of tradimodern health facilities dedicated to *Karuho* treatment in Bunia indicates the growing importance of this phenomenon. A tradimodern health facility is defined as a healthcare establishment that integrates both traditional and modern medical practices. In this study, the term "site" refers either to an individual tradimodern facility or collectively to all participating facilities. In the DRC, both traditional and modern healthcare facilities are officially recognised and authorised to operate by health authorities.

However, concerns have been raised regarding the limitations of traditional medicine, particularly the lack of adequate diagnostic equipment and infrastructure, which may compromise the quality of care provided (Marcellini et al., 2000). Previous studies conducted in the DRC, particularly in Bunia, have reported that *Karuho* is predominantly managed within traditional treatment settings (Mwabi et al., 2020). Diagnostic practices commonly include asking patients to spit into a glass of water, drink their own urine, spit onto duplicating paper, or sprinkle sulphur over collected urine samples. Such practices do not constitute scientifically validated toxicological tests and raise questions regarding the actual existence of the alleged poison.

At the same time, diagnostic challenges within conventional healthcare facilities remain substantial. These challenges include inadequate laboratory infrastructure, shortages of qualified personnel, insufficient professional training, and weaknesses in governance and supervision systems. Such deficiencies contribute to diagnostic errors, inappropriate treatment, and increased healthcare costs (Linsuke et al., 2020).

Given the uncertainty surrounding the aetiology of *Karuho* and the absence of robust scientific evidence supporting its interpretation as poisoning, it is important to investigate alternative explanations, including infectious causes such as *Helicobacter pylori* infection. Clarifying the relationship between *Karuho* and *H. pylori* infection may contribute to improving diagnostic accuracy and informing evidence-based treatment strategies.

Objectives

This study sought to:

1. Determine the sociodemographic profile of patients presenting with clinical manifestations attributed to *Karuho* syndrome, including age, sex, and educational level.
2. Identify the clinical manifestations most significantly associated with positive *H. pylori* infection, including chest pain, epigastric pain, vomiting, and related symptoms.
3. Analyse environmental and behavioural risk factors associated with bacterial transmission, including consumption of food prepared outside the home and self-medication practices.
4. Evaluate the impact of comorbidities, including diabetes mellitus, malaria, and typhoid fever, on the likelihood of *H. pylori* positivity and on the severity of clinical manifestations.
5. Explore the sociocultural interpretation of *Karuho* syndrome by examining its statistical association with *Helicobacter pylori* infection.

Hypotheses

1. Null Hypothesis (H_0): There is no statistically significant association between *Karuho* syndrome and *Helicobacter pylori* infection.
2. Alternative Hypothesis (H_1): There is a statistically significant association between *Karuho* syndrome and *Helicobacter pylori* infection.

METHODS

Study Design

A cross-sectional analytical study with prospective data collection was conducted from 5 May 2024 to 2 January 2025.

Study Population

The target population consisted of all patients admitted for *Karuho* treatment at four participating tradimodern treatment centres during the study period.

For study purposes, a *Karuho* case was defined as any patient diagnosed with *Karuho* by a practitioner at a participating tradimodern treatment centre using the facility's routine diagnostic procedures.

Inclusion Criteria

Participants eligible for inclusion were:

i. Male and female patients of all ages;
ii. Individuals diagnosed with *Karuho* according to the diagnostic procedures used at participating treatment centres;
iii. Patients who voluntarily agreed to participate in the study prior to receiving traditional treatment.

Exclusion Criteria

The following individuals were excluded:

i. Patients unwilling to participate;
ii. Pregnant women;
iii. Individuals who voluntarily withdrew from enrolment;
iv. Participants lost during data collection;
v. Individuals with suspected or confirmed suicide attempts;
vi. Individuals not identified as *Karuho* cases by the participating treatment centres;
vii. Patients who had already undergone *Karuho* treatment before recruitment.

Study Variables

Dependent Variable

The primary outcome variable was the result of the *H. pylori* stool antigen test (Hp-Ag).

Independent Variables

Sociodemographic variables included:

a. Age;
b. Sex;
c. Marital status;
d. Religion;
e. Educational level;
f. Employment status;
g. Income level.

Clinical variables included:

i. Presenting complaints;
ii. Medical history;
iii. Physical examination findings.

Environmental and behavioural variables included:

A. Consumption of food prepared at home versus outside the home;
B. Use of medications with or without medical prescription.

Additional biological variables included:

a) Malaria rapid diagnostic test (PfHRP-II);
b) Salmonella Typhi antigen and antibody tests;
c) HIV screening;
d) Syphilis screening;
e) Fasting blood glucose levels.

Sampling Procedure

A consecutive non-probability sampling approach was employed. All eligible patients presenting to participating tradimodern treatment centres during the study period and meeting the traditional diagnostic criteria for *Karuho* were recruited.

Sample Size Determination

The sample size was estimated using the formula proposed by Charan and Biswas (2013):

$$n = Z^2P(1 - P)/d^2$$

where:

- ✧ n = required sample size;
- ✧ Z = standard normal deviate corresponding to a 95% confidence level (1.96);
- ✧ P = estimated prevalence (25%);
- ✧ d = margin of error (5%).

The estimated prevalence was derived from a previous study conducted in Goma, DRC, which reported that 25% of patients sought care from physician-led healthcare facilities (Mbeva et al., 2021).

Substituting the values into the formula:

$n = (1.96^2 \times 0.25 \times 0.75) / (0.05^2)$

$n = 288.12$

After adding a 20% allowance for potential non-response: Final sample size = 345 participants.

Data Collection Procedures

Data were collected using a structured interviewer-administered questionnaire. Information was obtained by trained research assistants who recorded participant responses directly.

Laboratory Investigations

The following rapid diagnostic tests (RDTs) were performed:

Table 1:
Laboratory Diagnostic Tests, Specimen Types, and Reported Performance Characteristics Used in the Study

Test	Specimen	Reported Performance
H. pylori Antigen Diagnostic Kit (Fluorocare)	Stool sample	Manufacturer specifications
Salmonella Typhi Antigen Rapid Test	Venous blood	Sensitivity 98.7%; Specificity 98.1%
Determine HIV-1/2 Abbott	Venous blood	Sensitivity 100%; Specificity 100%
ADV Malaria Pf (HRP-II)	Venous blood	Sensitivity 96.3–96.9%; Specificity 98.2%
Syphilis Rapid Test Strip	Venous blood	Sensitivity 99.7%; Specificity 99.6%

Fasting blood glucose was measured using the Seamaty Blood Gas and Electrolyte Analyser from fasting venous blood samples.

Data Quality Assurance

Prior to data collection, the questionnaire was reviewed and standardised by a team comprising four general practitioners and two experienced medical laboratory scientists.

Research personnel received training on:

I. Study procedures;
II. Research ethics;
III. Data collection tools;
IV. Sample collection and transportation procedures.

The principal investigator conducted daily supervision of field and laboratory activities to ensure protocol compliance and data accuracy. Weekly monitoring meetings were held to review progress and address any identified errors.

Data Management and Statistical Analysis

Completed questionnaires were entered into the Statistical Package for the Social Sciences (SPSS), Version 20.

Descriptive statistics were used to summarise sociodemographic, clinical, and biological characteristics using frequencies and percentages.

Associations between *H. pylori* infection and explanatory variables were assessed using bivariate logistic regression analysis.

Results were reported as odds ratios (ORs) with corresponding 95% confidence intervals (95% CIs). Statistical significance was defined as $p < .05$.

The *H. pylori* stool antigen test result served as the dependent variable in all regression analyses.

Ethical Considerations

The study adhered to the principles of voluntary participation, informed consent, confidentiality, anonymity, and data protection.

Written informed consent was obtained from all participants prior to enrolment. For participants unable to provide consent independently, consent was obtained from a parent, guardian, or legally authorised representative.

Participants were informed that participation was entirely voluntary and that they could withdraw at any stage without consequences. Any data collected from participants who withdrew from the study were destroyed.

Participant confidentiality was maintained through the use of unique identification codes instead of personal identifiers. All study personnel were bound by professional confidentiality obligations and were

prohibited from disclosing information obtained during the conduct of the study without prior authorisation.

This study received ethical approval from the Research Ethics Committee of the Doctoral School of the University of Goma, Democratic Republic of the Congo (Approval No. UNIGOM/CEM/010/2023). All procedures were conducted in accordance with the principles of the Declaration of Helsinki.

Study data were securely stored by the investigators for the duration required by the research programme and were scheduled for destruction following completion of the study

RESULTS

Sociodemographic Characteristics According to Helicobacter pylori Status

Of the 345 participants enrolled, 267 (77.4%) tested positive for H. pylori infection, while 78 (22.6%) tested negative.

Table 2:
Sociodemographic Characteristics of Participants According to *H. pylori* Test Results (N = 345)

Characteristic	*H. pylori* Positive n (%) (n = 267)	*H. pylori* Negative n (%) (n = 78)	Crude OR	p-value
Age 20–29 years	93 (34.8)	15 (19.2)	10.7	.004
Secondary education	112 (41.9)	25 (32.1)	12.8	.004
Male sex	158 (59.2)	45 (57.7)	1.06	.068

The age group most affected by *H. pylori* infection was 20–29 years, which demonstrated a strong positive association with infection (OR = 10.7, p = .004).

Participants with a secondary level of education exhibited the strongest sociodemographic association with *H. pylori* positivity (OR = 12.8, p = .004).

Although males accounted for a greater proportion of positive cases, the association between sex and *H. pylori* infection was not statistically significant (OR = 1.06, p = .068).

Clinical, Environmental, and Comorbidity Factors Associated with H. pylori Infection

Table 3:
Clinical Manifestations, Environmental Factors, and Comorbidities Associated with *H. pylori* Infection

Variable	Crude OR	95% CI	p-value
Anorexia	7.89	1.76–9.63	.025
Asthenia	4.33	0.84–5.99	.001
Weight loss	4.12	1.03–5.47	.013
Fever	8.19	1.72–9.81	<.001
Headache	7.67	1.18–8.77	.010
Generalised weakness	9.30	2.10–10.33	.038
Somnolence	4.82	0.54–6.15	.004
Nausea	5.99	1.39–7.26	.021
Vomiting	10.21	2.82–14.09	.014
Constipation	6.73	1.44–8.28	.041
Generalised abdominal pain	6.91	1.12–9.60	.002
Epigastric pain	10.93	2.47–12.03	.002
Cough	11.70	1.55–15.98	.009
Chest pain	15.16	1.28–20.13	<.001
Self-medication (without prescription)	17.81	2.57–21.95	.012
Consumption of food prepared outside the home	20.78	3.03–25.76	<.001
Malaria	5.42	1.34–6.43	.033
Typhoid fever	6.22	1.21–7.65	.041
Diabetes mellitus	8.94	2.05–9.92	.001

The findings indicate that *H. pylori* infection was strongly associated with several clinical manifestations commonly attributed to *Karuho* syndrome.

The strongest associations were observed for chest pain (OR = 15.16), cough (OR = 11.70), epigastric pain (OR = 10.93), vomiting (OR = 10.21), generalised weakness (OR = 9.30), fever (OR = 8.19), and anorexia (OR = 7.89). All associations reached statistical significance (p < .05).

From an epidemiological perspective, consumption of food prepared outside the home emerged as the strongest environmental risk factor (OR = 20.78, p < .001), followed by self-medication without medical prescription (OR = 17.81, p = .012).

Regarding comorbid conditions, diabetes mellitus showed the strongest association with *H. pylori* positivity (OR = 8.94, p = .001), while malaria and typhoid fever were also significantly associated with infection.

Conceptual Overlap Between Karuho Syndrome and Helicobacter pylori Infection

Table 4:
Conceptual Comparison Between Clinical Features of *Karuho* Syndrome and Manifestations Reported in the Literature on *Helicobacter pylori* Infection

Observed *Karuho* Manifestation	Clinical Manifestation Reported in *H. pylori* Literature	Nature of Association
Epigastric pain (OR = 10.93)	Dyspepsia, gastritis, epigastric discomfort	Direct gastric association
Nausea and vomiting (OR = 10.21)	Common manifestations of dyspeptic syndromes	Direct gastrointestinal association
Chest pain (OR = 15.16)	Gastro-oesophageal reflux-related symptoms	Possible indirect association
Generalised weakness and headache (OR = 9.30)	Systemic inflammatory manifestations	Possible systemic association
Consumption of food prepared outside the home (OR = 20.78)	Oro-faecal transmission pathway	Epidemiological association

The comparison presented in **Table 4** highlights important similarities between the symptom complex traditionally described as *Karuho* syndrome and clinical manifestations frequently reported among patients infected with *H. pylori*. These findings suggest a potential overlap between the two conditions and warrant further investigation through analytical studies capable of establishing causal relationships.

DISCUSSION

Principal Findings

This study investigated the association between *Karuho* syndrome and *Helicobacter pylori* infection among patients attending tradimodern treatment centres in Bunia, Democratic Republic of the Congo. A high proportion of participants (77.4%) tested positive for *H. pylori*, and several clinical manifestations traditionally attributed to *Karuho* syndrome showed strong statistical associations with infection. The strongest associations were observed for chest pain, epigastric pain, vomiting, cough, and generalised weakness. Environmental and behavioural factors, particularly the consumption of food prepared outside the home and self-medication, were also strongly associated with *H. pylori* positivity. In addition, diabetes mellitus, malaria, and typhoid fever were significantly associated with infection.

Sociodemographic Factors Associated with H. pylori Infection

The age group most affected by *H. pylori* infection was 20–29 years. This finding may reflect increased mobility, greater social interaction, and a higher frequency of consuming food prepared outside the home among young adults. Similar observations have been reported in urban populations where exposure to communal eating environments and informal food vendors increases the risk of gastrointestinal infections.

Although males accounted for a larger proportion of infected participants, sex was not significantly associated with infection in this study. This finding suggests that both males and females may experience similar levels of exposure to the risk factors that facilitate transmission of *H. pylori*.

An unexpected finding was the strong association observed among participants with secondary-level education. While higher educational attainment is generally associated with lower infection rates, this result may reflect lifestyle factors specific to the urban context of Bunia, including frequent reliance on school cafeterias, street-food vendors, and informal restaurants.

Clinical Manifestations and Their Relationship to Karuho Syndrome

Several symptoms commonly attributed to *Karuho* syndrome were strongly associated with *H. pylori* infection. Epigastric pain and vomiting, which demonstrated some of the strongest associations, are well-recognised manifestations of gastritis and dyspeptic disorders caused by *H. pylori*. Evidence from systematic reviews indicates that eradication of *H. pylori* can significantly improve dyspeptic symptoms, supporting the biological plausibility of these findings (Franceschi et al., 2015; Gravina et al., 2020; Mazzoleni, 2011; Yadav et al., 2024).

Chest pain and cough, although traditionally considered extra-gastric manifestations, may be explained by gastro-oesophageal reflux disease (GERD), which can occur in the presence of gastric inflammation. Reflux-related oesophageal irritation may produce symptoms that patients interpret as chest disease, poisoning, or severe systemic illness. Previous studies have reported associations between upper gastrointestinal disorders and

chronic cough through vagally mediated reflex mechanisms (Bouchentouf, 2012; Gravina et al., 2020).

The strong association between *H. pylori* infection and symptoms traditionally attributed to *Karuho* suggests substantial overlap between the two conditions. However, because the present study employed a cross-sectional design, these findings should be interpreted as associations rather than evidence of causality.

Environmental and Behavioural Risk Factors

Consumption of food prepared outside the home emerged as the strongest environmental risk factor identified in this study. This finding is consistent with established transmission pathways of *H. pylori*, which include oral–oral, oro-faecal, and gastro-oral routes (Camilo Santana Silva, 2021; Gravina et al., 2020; He et al., 2020).

In many low-resource urban settings, inadequate access to safe water, poor sanitation, and suboptimal food-handling practices may facilitate bacterial transmission. These conditions may contribute substantially to the high prevalence of infection observed among study participants.

Self-medication also demonstrated a strong association with infection. The unsupervised use of medications, particularly non-steroidal anti-inflammatory drugs (NSAIDs), may compromise gastric mucosal integrity and aggravate gastrointestinal symptoms. In addition, inappropriate treatment practices may delay diagnosis and appropriate management of *H. pylori*-associated disease.

These findings highlight the importance of public health interventions aimed at improving food safety, sanitation, health education, and rational drug use.

Comorbidities and Co-Infections

An important finding of this study was the association between *H. pylori* infection and several co-existing health conditions, including diabetes mellitus, malaria, and typhoid fever.

Diabetes mellitus demonstrated the strongest association among the identified comorbidities. This finding is biologically plausible because diabetes may impair immune function and alter gastric motility, potentially favouring persistent bacterial colonisation and prolonged gastric inflammation (Baryshnikova et al., 2024; Fakhry et al., 2023; He et al., 2020).

Malaria and typhoid fever, which are endemic in the study area, were also significantly associated with infection. These diseases may contribute to a heightened inflammatory burden and may complicate clinical diagnosis because symptoms such as fever, headache, weakness, and anorexia are common to all three conditions.

Importantly, these comorbidities and co-infections should not be interpreted as causes of *Karuho* syndrome. Rather, they may act as modifiers of disease severity by creating a biological environment that favours more severe clinical manifestations.

Implications for Understanding Karuho Syndrome

Karuho is widely perceived in parts of eastern Democratic Republic of the Congo as a form of poisoning or externally inflicted illness. The present findings suggest that many symptoms attributed to *Karuho* overlap substantially with recognised manifestations of *H. pylori* infection.

This observation does not imply that all cases of *Karuho* are attributable to *H. pylori*. However, it raises the possibility that some presentations culturally interpreted as poisoning may in fact reflect undiagnosed gastrointestinal infection and its associated systemic manifestations.

Understanding this overlap may contribute to improved communication between biomedical and traditional healthcare systems and may facilitate earlier diagnosis and treatment of affected individuals.

Public Health Implications

The high prevalence of *H. pylori* infection observed in this study underscores its importance as a public health concern in Bunia. The strong associations identified with food consumption practices, self-medication, and common comorbid conditions suggest several opportunities for intervention.

Public health strategies should prioritise improved access to safe drinking water, strengthened food hygiene regulations, health education campaigns, and wider

availability of affordable diagnostic testing and evidence-based treatment for *H. pylori* infection.

In addition, collaboration between conventional healthcare providers and tradimodern treatment centres may improve recognition of infection-related symptoms and facilitate timely referral for appropriate medical management.

Strengths of the Study

This study is among the first to investigate the relationship between *Karuho* syndrome and *H. pylori* infection in eastern Democratic Republic of the Congo. The inclusion of laboratory testing for *H. pylori* provided objective microbiological evidence, while recruitment from multiple tradimodern treatment centres enabled the study of a culturally significant health condition that has received limited scientific attention. The findings contribute valuable evidence to the understanding of *Karuho* syndrome and provide a foundation for future clinical and epidemiological investigations.

Limitations

Several limitations should be considered when interpreting these findings.

First, the cross-sectional design permits the identification of associations but does not establish temporal or causal relationships between *Helicobacter pylori* infection and *Karuho* syndrome.

Second, information on dietary habits, medication use, and other behavioural factors was self-reported and may therefore be subject to recall bias and reporting inaccuracies.

Third, stool antigen rapid diagnostic testing, although practical and widely used in field settings, may be less accurate than endoscopic biopsy-based methods, histopathological examination, or urea breath testing, which are considered reference diagnostic approaches.

Fourth, the study relied primarily on bivariate analyses and did not adjust for potential confounding variables through multivariable modelling. Consequently, some observed associations may have been influenced by unmeasured or uncontrolled factors.

Fifth, participants were recruited exclusively from tradimodern treatment centres. As a result, the study population may not be representative of the general population of Bunia or the Democratic Republic of the Congo, thereby limiting the generalisability of the findings.

Finally, *Karuho* syndrome was defined according to routine diagnostic practices employed at participating tradimodern treatment centres. Because no standardised biomedical diagnostic criteria currently exist for *Karuho*, some degree of diagnostic variability between centres cannot be excluded.

CONCLUSION

This study identified significant associations between *Helicobacter pylori* infection and the principal symptoms traditionally attributed to *Karuho* syndrome, particularly chest pain, epigastric pain, vomiting, cough, and generalised weakness.

The findings support rejection of the null hypothesis and demonstrate a significant statistical association between *Karuho* syndrome and *H. pylori* infection among patients attending tradimodern treatment centres in Bunia.

Environmental and behavioural factors, particularly the consumption of food prepared outside the home and self-medication, were strongly associated with infection. In addition, diabetes mellitus, malaria, and typhoid fever were associated with more severe clinical presentations and may act as important modifiers of disease expression.

Taken together, these findings suggest that many manifestations attributed to *Karuho* syndrome overlap substantially with recognised clinical manifestations of *H. pylori* infection. While the results do not establish causality, they support the hypothesis that *H. pylori* infection may contribute to the symptom complex culturally recognised as *Karuho*.

These findings have important implications for clinical practice and public health. Strengthening food hygiene, improving access to safe drinking water, promoting rational medication use, expanding access to accurate diagnostic testing, and encouraging collaboration between conventional and tradimodern healthcare systems may

contribute to reducing the burden of *H. pylori*-associated disease in Bunia and similar settings.

Further longitudinal, microbiological, molecular, and endoscopic studies are required to clarify the causal pathways involved, identify locally circulating *H. pylori* strains, and better understand the relationship between *H. pylori* infection and *Karuho* syndrome.

Data Availability: The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Author Contributions: **Conceptualisation:** Roger Lonema Vajeru. **Methodology**: Roger Lonema Vajeru, Zacharie Tsongo Kibendelwa. **Data Collection:** Roger Lonema Vajeru. **Formal Analysis:** Roger Lonema Vajeru. **Supervision:** Zacharie Tsongo Kibendelwa, Stanislas Wembonyama Okitotsho. **Manuscript Preparation:** All authors. **Approval of Final Version:** All authors

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Informed Consent: Written informed consent was obtained from all participants or their legally authorised representatives prior to enrolment.

Conflicts of Interest: None declared.

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