

**HELICOBACTER PYLORI ANTIGEN IN THE MOTHERS
STOOL AND THAT OF THEIR CHILDREN IN
KAKAMEGA COUNTY HOSPITALS**

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BY

DR.BENARD WANYAMA WAMBULWA

**INSTITUTE OF TROPICAL AND INFECTIOUS DISEASES
UNIVERSITY OF NAIROBI**

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DECLARATION

I declare that this dissertation is my original work and has not been published elsewhere or presented to any other University for the award of any degree.

Signed-----date-----

Dr Wambulwa W. Benard (B.pharm.UoN

Admission Number: W64/81064/2015

This dissertation has been submitted to the University of Nairobi for examination with our approval as University supervisors.

Signed-----date-----

Prof. Ezekiel Masibo Wafula

Professor of Paediatrics, University of Nairobi

MBChB, M.Med (paed), Dip clinical epidemiology

Signed-----date-----

Ms .Winnie Chepkurui Mutai

Lecturer Department of Medical Microbiology

Bsc, Msc -Microbiology

DEDICATION

This work is dedicated to my wife Maureen Munyasia for her support.

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List of Abbreviations, Acronyms and definitions

GDP:	Gross Domestic Product
CAG A:	Cytotoxin Associated Gene A
CAGPAI:	Cytotoxin Associated Gene Pathogenicity Island
VAC A:	VacuolatingCytotoxin A
SAT:	Stool Antigen Test
UBT:	Urea Breath Test
ESPGHAN:	European Society for Paediatric Gastroenterology Hepatology, and Nutrition
NASPGHAN:	North American Society for paediatric Gastroenterology, Hepatology and Nutrition
MALT:	Mucosa Associated Lymphoid Tissue
PPI:	Proton Pump Inhibitors
ERC:	Ethics and Research Committee
NSAID:	Non-Steroidal Anti-Inflammatory Drugs
NF_ B:	Nuclear Factor-kappa B.
CGH:	County General Hospital-Kakamega
SPSS:	Statistical Package for the Social Sciences
MCH:	Maternal-Child Health centre
SES	Socioeconomic status
PFGE	Pulsed Field Gel Electrophoresis
RFLP	Restriction Fragment Length Polymorphism
RAPD	Random Amplified Polymorphic DNA
MLST	Multi-Locus Sequence Typing

<u>Gene</u>	<u>Role or Function</u>
CagA (Cytotoxin associated gene A)	Injected into host epithelial cells and modulates host signalling.
VacA (Secreted toxin)	Removes epithelial barriers
BabA (Blood group antigen binding adhesin)	Binds to fucosylated epithelial cells
FlaA (Flagellin polymer)	Motility. Evokes low level response from TLR5
ABO blood antigens	Targets on epithelial cells for binding
TLR5 (Toll-like receptor 5)	Binds to flagella to activate host innate immune response
Il1B (Interleukin 1 β -subunit)	Host inflammatory cytokine. Activates TH1 cells
Il-8 (Interleukin 8)	Host pro-inflammatory cytokine expression polymorphisms

ABSTRACT

Background: *Helicobacter pylori* prevalence in children may be affected by the infection status of the mother as speculated by recent studies and the family socio-economic status. Studies done in Kenya have not tried to establish an association between the mothers' infection status and that of their children. In families where the mother spends most of her time with the child, it is thought that she plays a major role in transmission.

Main Objective: To establish the association between presence of *H.Pylori* antigen in mothers stool and that of their children in Kakamega County.

Design: Cross sectional study

Methodology: A total of 492 Mothers and children who met the inclusion criteria were recruited by consecutive sampling through mother-child pairing; but 430 were tested and included in the final analysis. Their *H. pylori* infection status was determined by testing for *H. pylori* antigens in their stool samples using the lateral flow chromatographic immunoassay method and was documented as negative or positive. The family socioeconomic status (SES) was assessed using the modified Hollingshead four factor indexes for SES assessment.

Results: The prevalence of *H. pylori* stool antigen in children was 21.8% and 18.7% in of mothers while study population prevalence was 20 %. There was a statistically significant association between mothers *H. pylori* Stool Antigen Test (SAT) results and that of their children's (value<0.001). The proportion of mother-child- positive (37%) was 2.7 times that of mother-negative-child positive (13.7%). Children with *H. pylori* SAT positive results were 5 times more likely to have a mother with a positive *H. pylori* SAT result compared to those with negative result which was statistically significant (p-value <0.001). Only the association between mother's *H. pylori* SAT results and economic status of the family was statistically significant (p value<0.05).

Conclusion: The study strengthens previous evidence that there's an association between the *H. pylori* infection status of the mother and their children. The prevalence in children has reduced compared to similar studies conducted in Kenya. The effect of the family social economic status on infection status of the children was not clearly demonstrated in this study.

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CHAPTER ONE-INTRODUCTION

1.1.0 Background of the study

Helicobacter Pylori bacterium causes infection that is associated with chronic inflammation which may lead to gastritis, gastric or peptic ulcers and gastric cancer. The bacterium is also implicated in extra-gastrointestinal conditions like unexplained iron deficiency anaemia and idiopathic thrombocytopenic purpura. The bacterium is acquired in early childhood and the peak infection period is the first 5 years of life and transmission is mainly intra-familial. Infection or colonization with *H. pylori* is considered lifelong unless eradication therapy is given and the micro-organism confirmed to have been eradicated after successful treatment.

It is postulated that *H. pylori* prevalence in children is affected by the infection status of their parents especially the mother and that this prevalence is high in families with low socio-economic status. Epidemiological studies have shown that, while *H. pylori* clearly increases the risk of peptic ulcers and gastric cancer in some populations, it is also associated with lower risk of oesophageal cancer, allergic conditions and several other important pathologies. (Lee et al. 2013). Therefore, the interaction of *H. pylori* and man can either be mutualistic or pathogenic. Studies done in Kenya have not tried to establish an association between the mothers' infection status and the prevalence in children and mostly focussed on children less than five years unlike in other developed countries. For instance, in a study in Japan mother-to-child transmission of *H. pylori* was shown to occur in four out of five families, whilst transmission from

father-to-child and sibling-to-sibling in two families and one family, respectively (Osaki et al. 2016).

Most studies designed to examine intra-familial transmission have concluded that *H. pylori* transmission occurs mainly within the family from parents to children especially mother to child and that transmission outside the family and sibling to sibling is rare (Schwarz et al. 2008). The main risk factors for acquiring the infection include low socioeconomic status, increasing number of siblings and having an infected parent—especially an infected mother. *H. pylori* studies in Kenyan children have reported prevalence rates ranging from 40% to as high as 80%. Nabwera et al. 2000 et al in a cross-sectional study in Trans Nzoia District found 80.7% prevalence of *H. pylori* infection in school children aged 3-15 years; and concluded that most acquisition occurs before 3 years of age. Children who normally shared a plate with other family members during meals in the home had a higher prevalence of infection (Nabwera 2000). The bacterium is sometimes spontaneously cleared by use of antibiotics for treatment of other bacterial conditions. Kenya has been recently ranked as a middle income country due to improved GDP as well as living standard (see appendix 10). Therefore, with improvement in socioeconomic determinants of *H. pylori* transmission it is expected that prevalence in children has declined. Additionally, there's insufficient published local data on the prevalence of *H. pylori* in children less than 14 years of age in Kakamega County and no data on important risk factors of *H. pylori* infection in this setting. This study seeks to obtain such information.

1.1.1 Research questions

1. Is the positivity rate of *H. pylori* in children whose mothers test positive for *H. pylori* antigens higher than in those who test negative?
2. What has been the impact of recent improvements in standards of living on the prevalence of *H. pylori* in Kenyan children?

1.1.2 Main objective

To establish the association between presence of *H. pylori* antigens in mothers stool and that of their children in Kakamega County

1.1.3 Specific objectives

1. To determine the positivity rates of *H. pylori* in children less than 14 years of age and their mothers.
2. To establish an association between mothers *H. pylori* positivity and that of their children.
3. To examine the effect of recent improvements in standards of living on the prevalence of *H. pylori* in Kenyan children.

1.1.4 Problem statement

H. pylori prevalence in children may be affected by the infection status of their parents especially the mother and family socio-economic status. Studies done in Kenya have not tried to establish an association between the mothers' infection status and the prevalence in children and mostly focussed on children less than five years. In addition most studies in Kenya have been conducted in an urban setting and not in a rural- urban region like Kakamega County and

also the prevalence pattern in the age category of 5-14 years is not well established. The transmission mode for *H. pylori* is person to person mainly from parents to children as there is no known animal reservoir. The mother spends most of her time with the child and is thought to be the main source of infection. This prevalence is known to increase with age and positivity rates are highest in older children. *H. pylori* global prevalence shows a declining prevalence with age and most studies have shown two peaks where prevalence is highest –age 3-5 years and 6-9 years. It is important to note that current paediatric guidelines do not recommend eradication therapy in children unless there are gastrointestinal symptoms. A recurrent abdominal pain of childhood is not an indication for a test-and-treat strategy; children who have a positive family history of peptic ulcer and gastric cancer are recommended for *H. pylori* testing after exclusion of other causes. However, ‘test and treat’ strategy may be more beneficial in a high prevalence region and in places where gastro duodenal disease burden is high.

1.1.5 Study Justification

Helicobacter pylori bacterial infection is acquired in early childhood and prevalence is high in less developed countries. It causes persistent chronic inflammation throughout the stomach leading to gastritis, peptic ulcers and gastric tumours later on in life.

The World Health Organisation classifies *H. pylori* as a class 1 pathogen based on data showing that patients with the infection were found to have a 2-fold to 6-fold greater risk of developing non-cardial gastric cancer. The products of the

Cytotoxin Associated Gene A (**cag-A**) gene alters the phosphorylation status of host genes especially the anti-oncogenic gene p53. Children with a mother or father with gastric cancer are considered to be at a very high risk owing to the shared genetic characteristics, environmental factors and features of infecting strain of *H. pylori*. Population based screening for *H. pylori* in children less than 14 years if employed may help in identifying those at risk and initiation of treatment as a cancer prevention strategy.

Knowledge of the prevalence of *H. pylori* in children less than 14 years will help our understanding of how early this infection is acquired in our setting. It has been shown that children who acquire cag-A positive *H. pylori* infection very early in childhood almost always develop serious manifestations of the infection. The knowledge will also alert health workers to the possibility of *H. pylori* infection when faced with young children with dyspeptic symptoms. These children may then be evaluated further for *H. pylori* with the background knowledge of the prevalence in this geographical region. This will help in choosing the management strategies such as ‘test and treat’ or ‘test and refer’. It will also help in making available the diagnostic tests used to identify *H. pylori* at the County referral facilities and also providing *H. pylori* eradication therapy when recommended. Public health measures can also be instituted to prevent the transmission of *H. pylori* once the associated risk factors are known and hence reduce the disease burden.

Kenya is currently ranked as a middle income country due to improved GDP as well as living standard (see appendix 10). Therefore, with improvement in general sanitation and hygiene conditions and considering the birth cohort phenomenon associated with *H. pylori* it is expected that *H. pylori* prevalence in children has declined. Therefore, this study seeks to show how sensitive *H. pylori* acquisition is to improvement in standards of living. Additionally, there's limited information on prevalence of *H. pylori* in children less than 14 years of age in Kakamega County and there is no data on main risk fact.

CHAPTER TWO-LITERATURE REVIEW

2.1.0 Properties and Pathogenesis of *H. pylori*

Helicobacter pylori is a Gram negative bacterium, spiral shaped, flagellated, urease positive bacilli inhabits the human stomach. It is microaerophilic; meaning can survive low oxygen tension. The organisms are also tolerant to the acidic environment of the stomach through production of ureases, an enzyme that catalyzes a chemical reaction producing ammonia. The ammonia produced neutralizes the acid environment around the bacterium, allowing it to survive within the stomach.

H. pylori were first described by Warren and Marshall in 1980s. The bacterium was called *Campylobacter pyloridis* but later differentiated from *Campylobacter* by among other properties the presence of multiple flagella thus the new Genus *Helicobacter* was officially advised in 1983. After several years it became clear that the bacterium is also involved in gastritis and peptic ulcers in children (Gold et al. 2014).

Epidemiology of *H. pylori*-*Helicobacter pylori* infection is acquired in early childhood. The peak infection period is between 1-5 years. The gastrointestinal manifestations are rarely present at this age group of 1-5 years because of low inflammatory and immunological response to *H. pylori* antigens in children (Koletzko et al. 2011). *H. pylori* is found in half of the population in the world- a global prevalence of 50% (Eusebi et al. 2014). However, the prevalence is variable in relation to ethnicity, geography, age and socio-economic factors- high prevalence in developing countries and low in developed world. It is

important to note that there has been a decrease in the prevalence of *H. pylori* in many parts of the world in recent years attributed to improved living standards. In a longitudinal cohort study in Dutch children *H. pylori* prevalence decreased from 19% in 1978 to 9% in 1993 and in a follow-up study again in Dutch children the prevalence was much lower thought to be due to improved housing and hygiene conditions. A study in China looking at the prevalence of *H. pylori* in different birth cohorts found out that there was a striking decrease in prevalence in younger generation as compared to older generation (Gold et al. 2014). A 10 year follow-up study in Russia showed that *H. pylori* is very sensitive to improvements in living conditions such that transmission rates decreased significantly from 44% to 13% due improved sanitation and hygiene conditions. They also observed that age –specific prevalence increases with age. This was supported by other studies; birth cohort effect and economic growth may have accounted for the observed decrease (Tkachenko et al. 2007). DNA typing and phylogenetic analyses by nucleotide sequencing in Japan have shown *H. pylori* clustering in families and that the same strain of the bacteria with otherwise high genetic diversity is often found in the same family (Osaki et al. 2016; Taneike et al. 2001).

2.1.1 Transmission of *H. pylori*

The routes of *H. pylori* transmission remains controversial, person to person transmission remains to be the obvious means because there is no known animal reservoir for *H. pylori*. The bacterium has been cultured from saliva, dental plaques and faecal specimens supporting person to person transmission.

The root canals may serve as reservoirs for the bacterium and therefore playing a role in oral-oral transmission. The probable transmission routes include; oral-oral, fecal-oral and gastro-oral. The oral –oral route is the most favoured one based on transmission risks factors. Apart from intra-familial spread, the infection may also be transmitted through contaminated water supplies particularly in developing countries but studies have shown that this mode of transmission is rare (Osaki et al. 2016). Therefore, for the general population, it appears that the most likely mode of transmission is direct contact, by either the oral-oral route (through vomitus and saliva) or perhaps the fecal-oral route (rarely).

Role of Mother –Child Transmission- It appears that in developing countries, overcrowded conditions that create closer contacts between mothers and children and between siblings sharing the same bed might be the main reason for the high infection rates. In addition, in these countries working fathers have little contact with their children and that is why transmission of *H. pylori* is mostly linked to the mother. The risk factors or risky practices contributing to intrafamilial transmission include: Sharing spoons, plate sharing, Bed sharing, overcrowding in the household (more than 8 occupants), three generation household, poor housing, bottle feeding in children, chewing and testing food for children, kissing, poor personal hygiene, Poor disposal of fecal matter and household wastes, family history of peptic ulcer disease and gastric cancer. The main risk factors for acquiring the infection are thought to be low socioeconomic status, increasing number of siblings and having an infected

parent—especially an infected mother. A prevalence study in both rural and urban Benin children found prevalence of 72% and 75% respectively. It was also noted in the study that overcrowding and poor sanitation were the main risk factors for transmission (Aguemon et al. 2005). A study in Swedish school children between 10-12 years found out that intra-familial transmission is far more important than child-child transmission outside the family. Therefore, high *H. pylori* prevalence especially of parents who spend most time with the children is a risk for contracting the infection (Tindberg et al. 2001). In a population based survey carried in Italy in 416 families, children belonging to families in which both parents were infected had *H. pylori* prevalence of 44% while those from families whose parents were not infected had 21% prevalence. Therefore, person –person transmission played a major role in *H. pylori* transmission (Dominici et al. 1999). In a study in Japan mother-to-child transmission of *H. pylori* was demonstrated in four out of five families, whilst transmission from father-to-child and sibling-to-sibling were demonstrated in two families and one family, respectively. Most studies designed to examine intra-familial transmission have concluded that *H. pylori* transmission occurs mainly within the family from parents to children especially mother to child and that transmission outside the family and sibling to sibling is rare(Osaki et al. 2016;Schwarz et al. 2008). These studies therefore, support the hypothesis of a major role of mother- to -child transmission and spouse-to-spouse transmission of *H. pylori* infection and that continuous contact is required for the establishment of such infection-close contact for longer periods may be a prerequisite for transmission). (Nabwera et al. 2000)in a cross –sectional study

in Trans Nzoia District found 80.7% prevalence of *H. pylori* infection in school children aged 3-15 years; suggesting that most acquisition occurs before age 3 years. Children who normally shared a plate with other family members during meals in the home had a higher prevalence of infection, suggesting that oral-oral transmission may be important in this population(Nabwera et al. 2000).

2.1.3 Pathogenesis and Immunity

H. pylori colonises the surface of the gastric epithelium; it targets more neutral microenvironment of the mucus layer lining and the surfaces of the epithelial cells. The ammonia produced by the enzyme urease, protects it from the stomach acid.

2.1.4 Attachment in the Stomach and immune response

There are a number of adhesion molecules that the bacterium uses for attachment onto the mucosa and the type of molecule used is linked to the level of inflammation caused.

An adhesion protein called Sialic-acid binding adhesion A (SabA) has been associated with inflammation and the Lewis B antigen binding adhesin (BabA) is for attachment to the inflamed cells. The bacterial antigens cause increased production of pro-inflammatory cytokines and chemokines. The initial innate immunity response encompasses Toll-like receptor 2 (TLR2) and 5 (TLR5) which recognize *H. pylori* and initiate signalling pathways that result in enhanced activation of NF_κB. then IL-8 is secreted by the host cells to attract components of the innate and adaptive immune systems at infection sites (Cristina et al. 2014). Therefore, local immune response to *H. pylori* is

characterized by the recruitment of neutrophils, T and B lymphocytes, plasma cells, macrophages and dendritic cells (DCs), together with epithelial cell damage. The immune and inflammatory response to clear the microorganism are ineffective, allowing lifelong bacterial persistence however, most infections do not cause any pathologies; the factors that determine whether disease develops or not are host genetics, environmental and biological characteristics of the infecting strain (Ihan & Gubina 2014).

2.1.5 Persistence of *H. pylori* in the Stomach and evasion of immune system

The expression of adhesion molecules by *H. pylori* is depended on the growth phase of the bacteria such that it is bound to gastric mucosa in certain phases and not in other phases. This interchangeable binding prevents *H. pylori* from being removed completely from the stomach together with the superficial epithelial cells that are shed into the lumen.

Therefore, attached and un-attached bacterium exists in the stomach all the time. While the attached bacteria are shed together with the stomach epithelia, the free ones are able to infect new yet uninfected epithelial lining. This is the mechanisms that enable *H. pylori* to persist in the stomach (Cristina et al. 2014). An effective CD4⁺T-cell response is essential to clear *H. pylori*, however the bacteria inhibits CD4⁺T-cell proliferation and arresting IL-2 cell-cycle progression resulting in avoidance of clearance thereby staging an infection thus, the response mounted by the immune system cannot completely

eliminate the bacteria, and unless antibiotic treatment is used, the infection is chronic (Ihan & Gubina 2014).

Role of *H. pylori* in Gastric Cancer-The cytotoxin-associated gene-pathogenicity island (Cag PAI) is a virulence factor implicated in carcinogenesis. Cag A is thus an onco-protein due to its intracellular activities that lead to dysregulation of cell division(Lee et al. 2014). Cag A increases the motility of gastric epithelial cells; hence has potential for metastatic role. Cag A also induces over-expression of micro RNAs, leading to increased NF-kB and Erk1/2 signalling, targeting, and inducing epithelial mesenchymal transition and intestinal metaplasia of gastric epithelial cells (Pachathundikandi et al. 2015). The other oncoprotein is the Vacuolating Cytotoxin A (VacA), which is responsible for damaging host cells by forming pores in host cell membranes, disrupting membrane trafficking and inducing apoptosis. Mechanisms associated with apoptosis include VacA-induced inhibition of Stat3 and Bcl-2 cell survival proteins (Zhu et al. 2012).

2.1.6 The Impact of *H. pylori* Infection in children

H. pylori eradication reduces the prevalence of pre-cancerous gastric lesions and gastric cancer incidences. The Asian, European and Australian paediatric gastroenterology guidelines recommend diagnostic testing for children with primary relative who has stomach cancer and starting eradication therapy in confirmed patients (Chey et al. 2017;Maurizio et al. 2015).These strategies have helped reduce the incidences of gastric cancer in China and Japan in places where disease burden is high. Studies in Columbia, Japan and Alaska

have shown that children infected with *H. pylori* grew more slowly than non-infected children and that majority of these children have iron deficiency and iron deficiency anaemia. It was noted that once the infection was cleared the iron deficiency resolved(Gómez et al. 2015).

***H. pylori* and risk of Obesity**

Recent studies involving adults and children have shown existence of a negative association between *H. pylori* infection and obesity. There's strong evidence pointing to the fact that *H. pylori* infection is linked to decreased likelihood of obesity (Gómez et al. 2015). In a retrospective study, Vo et al. compared the prevalence of *H. pylori* infection between obese and healthy weight children. 10% of the obese children were *H. pylori* positive compared to 21% of the healthy weight children. Conversely, 39% of non-infected children, but only 21% of the infected children, were obese. They noted that when doing a multivariate analysis ,individuals infected with *H. pylori* had a 50% reduction in the odds of being obese (Roma & Miele 2015).

2.1.7 *H. pylori* prevalence studies in Kenya

Andrew Nyerere et al. conducted a *H. pylori* prevalence study in dyspeptic patients who had been referred for endoscopy at Aga Khan Hospital. The study involved 696 patients and found prevalence of 73% in children and 54% in adults. In the study diagnostic endoscopy, histology and Rapid urease test were used for *H. pylori* diagnosis. It was concluded that despite the high prevalence

the associated pathology was low and did not parallel the prevalence in the population (Nyerere et al. 2010).

Langat et al in 2005 conducted a prevalence study using the Helicobacter Pylori Stool Antigen (*H. pylori* SAT) test in children less than 3 years in Nairobi health facilities and found a prevalence of 45% and noted that poor socioeconomic status was a major risk factor for infection (langat et al.2005).

Nabwera et al in the year 2000 conducted a prevalence study in Kenya school children aged 3-15 years in Trans-Nzoia district using urea breath test and found a prevalence of 80%.

2.1.8 Diagnosis of *H. pylori*

The diagnosis of *H. pylori* gastritis, gastric and duodenal ulcers can be made through many laboratory tests. The techniques are divided into two groups the invasive and non-invasive tests. All invasive test methods are based on endoscopic examination during which biopsy specimens are obtained for direct (histological analysis, isolation) or indirect (urease test) diagnosis of *H. pylori* infection (Fallone et al. 2016). The gold standard for diagnosis involves endoscopy where a biopsy specimen is obtained and subjected to rapid urease test or culture on some special media. Non- invasive methods reveal the presence of *H. pylori* by measuring the activity of urease and by confirming the presence of antibodies in the serum. Other non-invasive tests include the detection of *H. pylori* antigens in stool and presence of *H. pylori* in the saliva. Various factors are considered when determining the choice of a diagnostic method. These factors include: availability and cost, a distinction between tests

used to establish a diagnosis of the infection and those used to confirm eradication, clinical situation, population prevalence of infection, test performance, use of proton pump inhibitors and antibiotics. Therefore, the doctor will determine which test to perform based on clinical presentation, history and physical examination.

Urea Breath Test- UBT-¹³C/¹⁴C (UBT) is the recommended diagnosis for *H. pylori* before treatment and for confirming eradication. The test has a sensitivity and specificity exceeding 95% and may reach 100% after the completion eradication therapy of *H. pylori* in children. Therefore, guidelines such as the ESPGHAN and NASPGHAN for *H. pylori* management in children recommend UBT as the most reliable non-invasive method for confirming the eradication of *H. pylori* in children over six years of age (Peng et al. 2005).

H. pylori Stool Antigen Test-Fecal antigen testing identifies *H. pylori* antigen in stool through immunologic techniques using a polyclonal or monoclonal antibody directed against the bacteria. This test detects active infection; therefore it can be used as a screening test as well as for confirming eradication. Most studies comparing *H. pylori* SAT with the gold standard have shown sensitivity of 87-100% and specificity of 82-100% in both adults and children. A study suggested that the test is comparable to the Urea Breath Test (Sensitivity of 94.7% and specificity of 95.7%) in the initial detection of *H. pylori* infection (Koletzko et al. 2011). Thus *H. pylori* SAT is suitable non – invasive tool for detection of the bacterial antigen in stool. As a non-invasive

test, the *H. pylori* SAT could be used in all age groups and hence was chosen as the most suitable test method in our study.

H. pylori Antibody Tests: IgM antibodies may rise during the early stages of *H. pylori* infection. Therefore, demonstration of a rising titre may indicate an active infection.

2.1.9 Relationship between *H. pylori* Gastritis, Gastric and Duodenal Ulcers

Researchers' have shown that 10% to 20% of *H. pylori*-positive patients will have a lifetime risk of developing ulcer disease and a 1%to 2% risk of developing distal gastric cancer.

H. pylori infection may be associated with dyspepsia symptoms but treating *H. pylori* doesn't always improve dyspepsia symptoms. If symptoms persist despite successful cure of infection these patients may benefit from ongoing acid suppressive therapy. Aspirin and NSAIDS are common causes of peptic ulcer disease. The risk of peptic ulcers is highest if both *H. pylori* infections are present and NSAIDS or aspirin are used (Fallone et al. 2016).

Recently it was demonstrated that iron deficiency accelerates *H. pylori*-induced gastric carcinogenesis by enhancing deployment and function of the pilus component of the *cag* PAI type 4 secretion system, as well as up-regulating proteins involved in survival and persistence of the bacterium. It thus would be important also to consider eradication of *H. pylori* in those infected children without anaemia, but with decreased serum ferritin (Queiroz et al. 2017).

2.1.10 Treatment of *H. pylori*

Indications for treatment of infection in *H. pylori*-positive patients include the following: Past or present duodenal and/or gastric ulcer, with or without complications, following resection of gastric cancer, atrophic gastritis, gastric mucosa-associated lymphoid tissue lymphoma, dyspepsia (un-investigated and functional dyspepsia), patients with first-degree relatives with gastric cancer, patient's wishes in consultation with the gastroenterologist, patients initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID) should be tested for *H. pylori* infection and treated if positive and unexplained iron deficiency in children. *H. pylori*. Triple therapy eradication regimen consists of at least two antibiotics (amoxicillin, Clarithromycin or metronidazole) plus a PPI (Proton pump inhibitor like omeprazole, esomeprazole, lansoprazole and pantoprazole) or a quadruple therapy with Bismuth based salts added. The treatment is given for a period of 14 days. A salvage regimen containing levofloxacin can replace clarithromycin in case of confirmed resistance. A Population-based study was conducted in Matsu Island located between Taiwan and main land China; where Cag-A strains of *H. pylori* are highly prevalent. It was noted that eradication of *H. pylori* reduced the incidence of infection, gastric atrophy and peptic ulcer disease; but there was an increase in cases of oesophagitis. The interventions did not reduce the incidence of intestinal metaplasia the 'point-of-no-return' theory. Thus the need for early initiation of eradication therapy before extensive inflammation and cellular transformation takes place (Lee et al. 2013).

CHAPTER THREE-METHODOLOGY

3.1.0 Design:

This was a hospital based analytical cross sectional study.

3.1.1 Sampling and sample size

Data available from studies conducted in many African countries reported prevalence ranges of 20% to 60% in children. Langat et al in 2005 conducted a prevalence study using the *H. pylori* SAT test in children less than 3 years in Nairobi health facilities and found a prevalence of 45%. A similar study in children aged 0-12 years in Uganda found a prevalence of 44%. However, the global prevalence is estimated to be 50% and has been decreasing with improved living standard and socioeconomic status. Therefore, 20% was used as the estimate of the expected prevalence. Using the formula below for calculating sample size for prevalence studies, then 246 children will be recruited and an equivalent 246 mothers-Total of 492 participants.

The formula is $n = \frac{1.96^2 p(1-p)(DEFF)}{d^2}$ where,

p=Estimate of the expected prevalence -which will be set at 20 %(0.2)

d=Desired level of precision –which will be set at 5% (+0.05 or -0.05)

Deff=Estimated design effect =1

Therefore= $\frac{1.96 \times 1.96 \times 0.2 (1-0.2) \times 1}{0.05 \times 0.05}$

0.05×0.05

$=\frac{3.8416 \times 0.16 \times 1}{0.0025}$

0.0025

=246 (246 children and 246 mothers)

3.1.2 Inclusion criteria

1. Children aged 0-13 years and their parents (the parents were not be subjected to any other inclusion criteria independently)
2. Willingness to provide stool samples
3. Informed consent by the mothers for their children (less than 8 years) and assent for children aged 8-13 years
4. Informed and signed consent by the mother on her behalf.

3.1.3 Exclusion criteria

1. Refusal to participate or sign the consent form by the parents.
2. Patient attendants who are not parents of the sick child.
3. Patients who are on *H. pylori* eradication therapy.

3.1.4 Sampling method

Children and their mothers in the 4 health facilities who met the eligibility criteria were recruited by consecutive sampling technique. Therefore, selection was based on mother-child pairing however, for mothers having more than one child only two children were randomly selected.

3.1.5 Study population

Children aged 0 < 14 years and their mothers seeking services at the 4 health facilities both inpatient and outpatient.

3.1.6 Study Area

This study was carried out in Lurambi Sub-County selected health facilities but the main study facility was Kakamega County General Hospital which serves a large catchment area. The Report of the 2009 census shows that the total population in the County was 1,660,651 consisting of 797,112 males and

863,539 females. Children aged 0-5 years constituted 21% while 0-14 years constituted 47% of the total population. This is a level five referral facility located within Kakamega town in Lurambi Sub-county and constituency. The hospital has a bed capacity of 448 and two paediatric wards-general paediatric and surgical wards. The hospital serves a large catchment area –Kakamega County and neighbouring counties of Vihiga, Bungoma, Busia and Nandi.

3.1.8 Variables

Dependent variable: Infection or colonization of children by *Helicobacter pylori* (child *H. pylori* SAT status)

Independent variables include; mothers *H. pylori* infection status (mother's *H. pylori* SAT status), family's socio-economic status, housing conditions, age of the children and the number of children per household.

3.1.9 Data collection

Children and their mothers *H. pylori* infection status was determined by testing for presence of antigens in their stool samples. The family Social Economic Status (SES) was assessed using the modified Hollingshead Four-Factor Index of SES that measures the following parameters: household income, occupational prestige, level of education attained and marital status. The grading of education and occupation are explained as shown in the appendix 4 and in the questionnaire. The parents were given information on the study and informed consent obtained. Structured questionnaires were administered to parents by the researcher to obtain demographic data, socio-economic and environmental risk factors that may play a role in transmission. The stool

samples were collected in plastic polypot containers provided to the parents and their children. The polypots were carried in a specimen carrier box and transported to the laboratory where they were tested immediately.

Participants who were unable to provide the stool specimen at the site were allowed to go home with the polypot and asked to bring the specimen early morning the following day so long as the specimen was collected within 24 hours (the antigens are viable for 24 hours).

3.1.10 Laboratory Diagnosis

Stool samples were tested for presence of *H. pylori* antigens using the lateral flow chromatographic immunoassay kits manufactured by Laborex Milan, Italy supplied by Laborex Kenya. The test kit has sensitivity of 97% and specificity of 96% as per the manufacturer.

The cap on the specimen collection bottle was removed and the specimen collection applicator was randomly stabbed at 3 different sites to collect approximately 50mg of faeces. The applicator was placed into the dilution buffer and shaken vigorously then allowed to settle for 2 minutes; by holding the sample collection device upright, the tip of the device was carefully broken off and then 2 drops of the sample solution were added to the sample well of the cassette. The test results were read in 10 minutes in an area with clear background.

Results interpretation

Negative test result: Only one pink coloured band (control line-C) appeared across the white central area of the reaction strip. *H. pylori* antigens were absent or below the level of detection.

Positive test result: In addition to the pink band, a distinguishable Pink-Red band (test-line) also appeared across the white central zone of the reaction strip.

A positive line indicated that there were detectable *H. pylori* antigens in the specimen.

Invalid test result: The pink band (control line) was absent, with or without a visually detectable pink-red band (test line-T).

Quality control

A coloured line in the control region (C) is an internal procedural control. It confirmed that sufficient specimen volume; adequate membrane wicking and correct procedural technique was followed. It is a standard practice at the CGH laboratory that internal quality control checks are performed on newly purchased kits, by using known positive and negative as controls to assess performance characteristics of the new *H. pylori* SAT kit.

3.1.11 Ethical considerations

Written approvals from KNH-UON ERC and Kakamega Hospital ERC were obtained before commencing the study (see approval letters in the appendices). Clearance was sought and obtained from the management of Lupe medical Centre before recruitment of study participants. Signed informed consents and assent for children and mothers after full disclosure of study protocol were also

obtained. In addition, all information and results obtained remained confidential as participants were assigned unique numbers and were treated professionally. Stool specimens were handled and disposed as potential biohazards as they may contain infectious agents (gloves were worn when handling them and were disposed with other immunology laboratory infectious waste). Infection prevention and control practices were strictly adhered followed. For mothers and children who were *H. pylori* SAT positive and presented with signs and symptoms suggestive of peptic ulcer disease or gastritis they were offered triple therapy at Pharmacy department at CGH. The children who had no gastrointestinal manifestations of *H. pylori*, the parents were advised to be watchful such that if they develop chronic or recurrent abdominal pain in future they should immediately seek medical services. This is because the current paediatric *H. pylori* eradication guidelines do not advocate for the test and treat strategy in children who have no manifestations of the effects of the bacteria. The natural history of *H. pylori* was also explained to the parents.

3.1.12 Data analysis and presentation

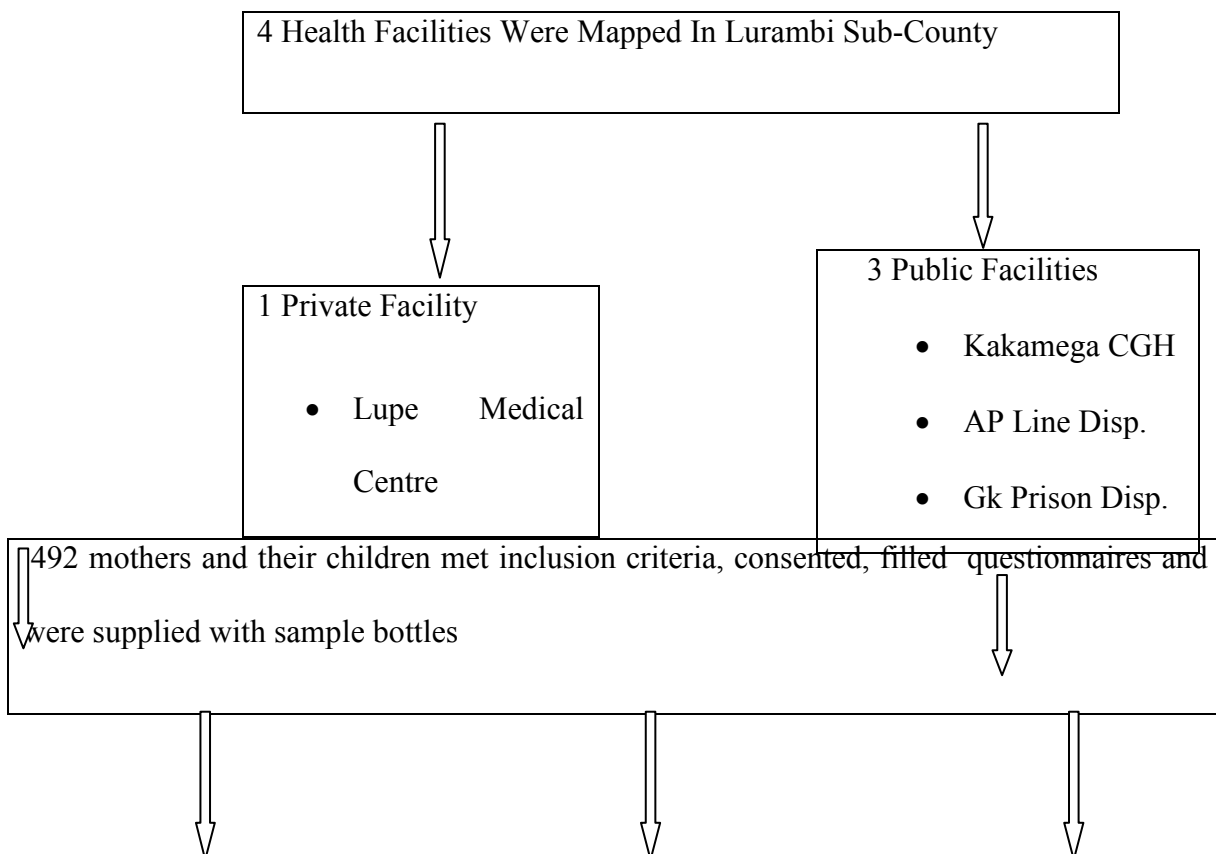
Data collected from the study was entered in the computer database for management. It was analysed using SPSS software version 22 .The data was summarised into frequency tables with numbers and percentages. The measures of dispersion were also calculated. Positivity rates were calculated in different age categories in children and mothers. Descriptive statistics for demographic characteristics was also done. Associations of *H. pylori* were evaluated by a comparison of proportions of children with and without infection in relation to their mother's *H. pylori* infection status using Chi-square and Fischer's exact test as appropriate. Multivariate logistic regression modelling was done as well.

CHAPTER FOUR –RESULTS

4.1.0 Description of Study and Study Population

A total of 492 mothers and their children were recruited after consenting to participate in the study and were supplied with stool bottles for specimen collection (which was to be produced on the same day or following day). A total of 428(214 pairs) subjects returned bottles with suitable samples for analysis, 2 returned non-paired samples but suitable for analysis and 62 recruits (31pairs) did not submit the samples-no feedback was obtained or submitted unsuitable samples. Therefore, 430 samples for mothers and their children were analyzed in the study. See figure the illustration in figure 4.1 below.

Fig 4.1.Study Profile



428 paired samples (214 pairs)-tested	2 non-paired samples –tested	62 subjects did not give samples (31pairs) or gave unsuitable samples and were not tested
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430 samples suitable and used in final analysis

4.1.1 Demographic Characteristics of the Study Population

Table 4.0 Descriptive Statistics for Age of Children and Mothers

<u>Variable</u>	<u>N</u>	<u>Min</u>	<u>Max</u>	<u>Mean</u>	<u>Sdv</u>	<u>IQR</u>
Age of Child	216	1	13	6.5	3.7	3, 9.8
Age of Mother	214	16	56	32.7	7.9	27, 38
Valid N	430					

The minimum age for children was 1.0 year and maximum was 13.0 years with a mean age of 6.5 (Std deviation 3.69).The minimum age for mothers was 16 and maximum 56 years respectively with a mean

age of 32.7 (Std deviation 7.9).The Interquartile Range (IQR) for children's' age was 6.8 while for the mother' age was 11. In addition 56% of participants reside in the village while 44% in an urban setting; 39% of them stay in permanent houses while 61% in semi-permanent ones. The minimum number of people living in one house was 2 and maximum 11 with a mean of 4.67.

4.1.2 Prevalence of *H. pylori* in Comparison With Different Demographics

Table 4.1:Study Population Prevalence of *H. pylori*

Age	Number (N)	<i>H.pylori</i> SAT(+)	<i>H. pylori</i> Positive %
children<14yrs	216	47	21.8
Mothers	214	40	18.7
Total	430	87	20.2

The *H. pylori* SAT positivity rates in children were 21.8% and 18.7% in mothers while the positivity rates in both mothers and their children were 20%.

Table 4.2: Prevalence of *H. pylori* as Per Age Categories in Children

Age	Total	SAT (+)	% (+ ve)	SAT(-ve)	% (-ve)	Prevalence
1<3 yrs	39	7	14.89	32	18.93	17.95
3<6yrs	69	18	38.30	51	30.18	26.09
6<9yrs	37	7	14.89	30	17.75	18.92
9<12yrs	46	12	25.53	34	20.12	26.09
12<14yr	25	3	6.38	22	13.02	12.00
Total	216	47	100	169	100	21.76

The prevalence in children < 3 years was 18% while those aged 9<12 and 3<6 was 26% the lowest prevalence was observed in age range 12<14 years.

Table 4.3: Relationship between *H. pylori* infection and child's gender

Gender (child)	Number(N)	<i>H. pylori</i> SAT (+) No. (%)	<i>H. pylori</i> SAT (-) No. (%)	P Value
Female	137	31(66.0)	106(62.7)	0.684
Male	79	16(34)	63(37.3)	
Total	216	47	169	

In terms of sex of the child among those who were positive (47), 66% were female and 34% were male. The positivity rate among male children was 7.4% while in female was 14.3%. The difference in positivity in terms of sex was not statistically significant (P- value >0.05).

Table 4.4: Positivity Rates In Children Over and Under Five Years

Age category	Total tested	<i>H. pylori</i> SAT (+) No. (%)	<i>H. pylori</i> SAT (-) No. (%)	P-value
< 5yrs	88	22(25)	66(75)	0.339
≥5yrs	128	25(19.5)	103(80.5)	
Total	216	47(21.6)	169(78.4)	

The positivity rates in children aged > 5 and < 5 was 19.5% and 25% respectively.

Table 4.5: Relationship between Mother's Marital Status and *H. pylori* Infection

Marital status	Number (N)	<i>H. pylori</i> SAT (+) No. (%)	<i>H. pylori</i> SAT (-) No. (%)	P Value
Married	194	46(21.5)	148(69.6)	0.123*
Single	19	1(0.5)	18(8.4)	
Total	213	47	166	

Majority of the mothers were married and there was no statistically significant difference in prevalence between married status and single mothers.

Table 4.6: Association between child *H. pylori* SAT and Household Characteristics

Household	Categories	<i>H.</i>	<i>H.</i>	Total	P-
Characteristics		<i>pylori</i>	<i>pylori</i>		value
		SAT (+)	SAT (-)		
		No. (%)	No. (%)		
Residence	Urban	16	79	95	0.121
	Village	31	90	121	
House type	Permanent	14	70	84	0.148
	Semi-Permanent	33	99	132	
Mother and child	Own Bed	24	98	122	0.397
	Shared Bed	23	71	94	
Number of rooms	>2	28	91	119	0.485
	≤2	19	78	97	
Family size	2 to <5	27	94	121	0.824
	≥5	20	75	95	
Family history of	No	29	93	122	0.414
	Ulcer	18	76	18	
fecal disposal	Toilet Inside	5	20	25	0.521
	Toilet Outside	9	45	54	
	Pit Latrine	33	104	137	

In the above table, none of the household characteristics was statistically associated with *H. pylori* SAT results of the child ($p>0.05$).

Table 4.7: Association between *H. pylori* and Socioeconomic Status (SES)

Variable	Socioeconomic Status (SES)	<i>H. pylori</i> SAT (+) No. (%)	<i>H. pylori</i> SAT (-) No. (%)	TOTAL	p-value
Mother HPSA	Low	18	118	136	0.022*
	Medium	17	43	60	
	High	5	13	18	
	Total	40	174	214	
Child HPSA	Low	30	107	137	0.873*
	Medium	14	46	60	
	High	3	16	19	
	Total	47	169	216	

Association between mother *H. pylori* SAT results and economic status of the family was statistically significant ($p<0.05$). However, the child's *H. pylori* SAT results was not statistically associated with socio-economic status of the family ($P>0.05$).

Table 4.8: Association between *H. pylori* Status of Children and their Mothers

Mother's results	Child's results		Total	P Value
	<i>H. pylori</i> SAT(+)	<i>H. pylori</i> SAT(-)		
	No. (%)	No. (%)		
<i>H. pylori</i> SAT(+)	17(37)	23(13.7)	40	<0.001
<i>H. pylori</i> SAT(-)	29(63)	145(86.3)	174	
Total	46(100)	168(100)	214	

There was a statistically significant association between mothers *H. pylori* SAT results and their children's (p<0.001,95% CI 2.16-11.69); proportional comparison shows that 37% of children who were positive had also mothers positive for *H. pylori* SAT while 13.7% of children with positive *H. pylori* SAT had their mother's *H. pylori* SAT negative results. The proportion of mother-child- positive (37%) is 2.7 times that of mother-negative-child positive (13.7%)

Table 4.9: Multivariate Analysis for Different Variables and Children's Infection Status

		Child <i>H. pylori</i> SAT 0= -ve 1= +ve		
Variable	Categories	Adj. (OR)	95% CI	p-value
Child's gender	Female	1		
	Male	0.82	0.38, 1.74	0.611
Mother- <i>H. pylori</i> SAT	<i>H. pylori</i> SAT(-)	1		
	<i>H.Pylori</i> SAT(+)	5.03	2.16, 11.69	<0.001
Family SES	Low	1		
	Medium	1.15	0.47, 2.84	0.748
	High	0.33	0.05, 2.00	0.231
Residence	Village	1		
	Urban	0.50	0.21, 1.16	0.110
House type	Permanent	1		
	Semi-Permanent	1.93	0.78, 4.71	0.153
Mother share	Yes	1		
Bed with child	No	0.64	0.30, 1.37	0.258
Family size	2 to <5	1		
	≥5	0.84	0.40, 1.76	0.649
fecal disposal	Toilet Inside	1		

	Toilet Outside	0.35	0.08, 1.49	0.158
	Pit Latrine	0.51	0.13, 1.93	0.323
Family history	No	1		
Of ulcer	Yes	0.67	0.32, 1.39	0.289

Adjusting for child's gender, family SES, residence, house type, bed sharing, family size, fecal disposal and history of ulcer, children with *H. pylori* SAT positive results were 5 times more likely to have a mother with a positive *H. pylori* SAT result compared to those with negative *H. pylori* SAT and it was statistically significant (P-value <0.001, OR 5.03, 95% CI-2.16-11.69)

4.1.1 Discussion

This study revealed a *H. pylori* stool antigen prevalence of 21.8% in children which was low compared to similar studies conducted in Kenya and East African region. Langat et al carried out a similar study in 2005 in Nairobi health facilities with a sample size of 195 children less than 3 years and found a prevalence of 45% (Langat 2005). Similarly in 2010, Hestviketal conducted prevalence study in Kampala in 427 healthy children aged 0-12 years using the *H. pylori* SAT test and found a prevalence of 44% (Hestvik et al. 2010). **In 2010**, Nyerereetal conducted a *H. pylori* prevalence study in 696 dyspeptic patients and found a prevalence of 73% in children and 54% in adults (Nyerereet al. 2010). The study by Nabwera et al in children aged 3-15 years in Trans-Nzoia district found very high *H. pylori* prevalence of 80%. These variations in *H. pylori* prevalence in Kenyan children cannot be clearly explained and therefore we cannot point to specific factors or variables that may be playing a role. However, our findings are comparable to other findings in some African and European countries. Koffi et al in a study of intrafamilial*H. pylori* transmission between mothers and their children (6 months to 5 years) in the Ivory Coast found a prevalence of 24.8% in children and 40 % in mothers and concluded that the major risk factor was having a mother infected with *H. pylori*. Therefore, the study had comparable findings especially the prevalence in children and the emphasis that there as an association between *H. pylori* status of mothers and their children. *H. pylori* infection is very sensitive to improvements in the living conditions and hygiene standards. A study in China looking at the prevalence of *H. pylori* in different

birth cohorts found out that there was a striking decrease in prevalence in younger generation as compared to older generation (Gold et al. 2014). A ten year follow-up study in Russia showed that *H. pylori* is very sensitive to improvements in living conditions such that transmission rates decreased significantly from 44% to 13% due improved sanitation and hygiene conditions. They also observed that age –specific prevalence increases with age. The birth cohort effect and economic growth may have accounted for the observed decrease (Tkachenko et al. 2007). Therefore, the observed prevalence in our study may also be because of improvement in living conditions and hygiene standards in Kenya. Our study revealed a statistically significant association between mothers *H. pylori* SAT results and their children's ($p < 0.001$, 95% CI 2.16-11.69); proportional comparison shows that 37% of children who were positive had also mothers positive for *H. pylori* SAT while 13.7% of children with positive *H. pylori* SAT had their mother's *H. pylori* SAT negative results. The proportion of mother-child- positive (37%) is 2.7 times that of mother-negative-child positive (13.7%).

Adjusting for child's gender, family SES, residence, house type, bed sharing, family size, faecal disposal and history of ulcer; children with *H. pylori* SAT positive results were 5 times more likely to have a mother with a positive *H. pylori* SAT result compared to those with negative result and it was statistically significant (P-value < 0.001). Only the association between mother's *H. pylori* SAT results and economic status of the family was statistically significant ($p < 0.05$). None of the household characteristics was statistically associated

with *H. pylori* SAT results of the child ($p > 0.05$). The findings of existence of association between the mother and the child's *H. pylori* infection status is in agreement with many studies that have tried to explain intrafamilial transmission of *H. pylori* especially Mother to child spread. Mamishi et al investigated intrafamilial spread of *H. pylori* in Iranian families by genotyping of fecal specimens using RAPD-PCR in children and their parents and found 33% of children had *H. pylori* genotypes related to their mother's while 6.7% related to the father. They conclude that mother to child spread of *H. pylori* was the main route of transmission. Konno et al tried to establish mother-child *H. pylori* transmission in Japan by performing random amplified polymorphic DNA fingerprinting analyses in Japanese families; it was noted that 69% of the analyses of the *H. pylori* infected children were identical to those of their mothers and they concluded that mother to child spread was the main mode of transmission. Tsami et al investigated the possible presence of *H. pylori* in sub- gingival plaques in children and their parents. The presence of *H. pylori* in the dental plaques was associated with its presence in the gastric mucosa. Children who had *H. pylori* in their dental were from families with members who had *H. pylori* in the dental plaques and cavities. Therefore the dental plaques could be the main source of re-infection and oral-oral spread of *H. pylori*. Konno et al in a five year follow-up study of mother –child *H. pylori* spread using RAPD method found out that most children acquired the bacteria between ages 1-4 years and confirmed that the strains of the 5 children exhibited DNA fingerprinting patterns identical to those of their mother. They also concluded that mother to child spread was the most probable cause of

intrafamilial transmission (Konno et al. 2005). A study in Swedish school children between 10-12 years found out that intra-familial transmission was more prominent than child-child transmission outside the family. They conclude that high *H. pylori* prevalence especially of parents who spend most time with the children is a risk for contracting the infection (Tindberg et al. 2001). In a population based survey carried in Italy in 416 families, children belonging to families in which both parents were infected had *H. pylori* prevalence of 44% while those from families whose parents were not infected had 21% prevalence. Our study strengthens the postulation that an infected mother plays a major role in transmitting *H. pylori* to her children-(close contact for longer periods may be a prerequisite for transmission). The routes of *H. pylori* transmission remains controversial, person to person transmission remains to be the obvious means because there is no known animal reservoir for *H. pylori*; the bacterium has been cultured from saliva, dental plaques and faecal specimens supporting person to person transmission. No associations were found between the prevalence of *H. pylori* and any of the following factors: Family size, family income, gender, water treatment practices, and disposal of faecal matter, house type, and place of residence, family history of stomach cancer and ulcers and number of people in a household.

4.1.2 Conclusion

This study strengthens previous evidence that there's an association between the *H. pylori* infection status of the mother and their children- the mother could be playing a role in transmission of *H. pylori* to the child. The infected mother is most likely the main source of *H. pylori* infection. The prevalence of 21.8% of *H. pylori* in children shows that prevalence has reduced compared to similar studies conducted in Kenya; this could be attributed to improved living conditions as well as sanitation and hygiene standards. The effect of the family SES on infection status of the children was not clearly demonstrated in this study. In addition, the variations in level of prevalence in children could not be explained in relation to factors that affect transmission in comparison with similar studies conducted in Kenya.

4.1.3 Recommendations

There's need to do a prospective cohort study using molecular typing techniques such as PFGE, RFLP, RAPD and MLST to determine mother to child transmission and clearly demonstrate the role of the mother and other family members in transmission of *H. pylori* in our setting. Lastly, when treating parents for gastro- duodenal conditions due to *H. pylori*; it is important to also test or screen their children for *H. pylori* as a cancer and peptic ulcer prevention strategy (test -and -treat strategy).

4.1.4 Study limitations

It was not possible to establish the *H. pylori* infection status of the father, caretakers and other siblings in the family; this could have a correlation with observed positivity rates. A prospective cohort study would be useful to establish intra-familial transmission of *H. pylori* and thus determine existence of a causal relationship between infection of parents and their children or sibling-sibling transmission. Multi-Locus Sequence Typing and phylogenetic analyses may be appropriate to show intra-familial transmission. We did not also determine the effect of the 62 mothers and children who did not submit back stool samples for laboratory analysis which may have had an impact on this study.

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6.1.0 APPENDICES

6.1.1 Appendix 1-Questionnaire

Note: *This questionnaire would be administered to the respondents by the researcher and the research assistants in a simple and easy to understand*

format in form of an interview. The services of a translator would be sought if necessary.

Title: Helicobacter Pylori Antigen in the Mothers Stool and that of their Children in Kakamega County Hospitals

The following statements and questions can be answered by ticking or by writing in the spaces provided. (To be filled by the researcher and his assistants)

A) Socio-Demographic Data

Unique number for the child and mother.....

Date...../...../2017

Age of child (years) months

Age of mother (years)

Sex: Male **Female**

Sex: Male **Female** (Tick appropriately)

Marital status; single **married** **other**

Physical address.....

B) Household Characteristics

Place of residence. Village **urban** **slum**

Type of house; permanent **semi-permanent**

Number of rooms in the house excluding kitchen, toilet and bathroom

Number of people living in one house

Sharing of bed by siblings shared bed

Each with own bed

Sharing of bed with parents: mother shares bed with the child

Child has own bed

Where fecal matter or baby's excreta is disposed

Toilet inside the house

Toilet outside the house

Pit latrine

Other (open field, trench....)

Household Water treatment practices;

Chlorination

Boiling	<input type="text"/>
Filtration	<input type="text"/>
Sedimentation	<input type="text"/>
None	<input type="text"/>

Combined family income and household	family size (people in a
<input type="text"/>	<input type="text"/>
KSH >50,000	<input type="text"/>
<input type="text"/>	<input type="text"/>
KSH 30,000-50,000	<input type="text"/>
KSH 20,000-30,000	<input type="text"/>
<input type="text"/>	<input type="text"/>
KSH 10,000-20,000	<input type="text"/>
<input type="text"/>	<input type="text"/>
KSH <10,000	<input type="text"/>

C) Education and Occupation

Level of education of the father and mother of the child (fill for mother and father separately)

<u>Score</u>	<u>education attained</u>	<input type="checkbox"/>
	<u>tick here</u>	<input type="checkbox"/>
7=	university graduate-degree or masters	<input type="checkbox"/>
6=	technical institute	<input type="checkbox"/>
5=	partial college (at least 1 yr of specialised technical training)	<input type="checkbox"/>
4=	secondary school graduate	<input type="checkbox"/>
3=	partial secondary school (did not finish)	<input type="checkbox"/>
2=	completed primary school	<input type="checkbox"/>
1=	did not complete primary school	<input type="checkbox"/>
0=	unknown	<input type="checkbox"/>

The occupation of the father and mother of the child (fill for mother and father separately)

<u>Score</u>	<u>current occupation</u>	
	<u>tick</u>	<input type="checkbox"/>
9=	major professional, proprietor of large business	<input type="checkbox"/>
8=	administrators, managers, proprietor of medium business	<input type="checkbox"/>
7=	small business owners, large farm owners, minor professionals	
6=	skilled technicians, semi-professionals, smaller business owners	<input type="checkbox"/>
5=	clerical/sales workers, small farm or business owners	<input type="checkbox"/>
4=	peasant/tenant farmers, skilled manual labourers, small business owners	<input type="checkbox"/>
3=	machine operators, bodabodas, semi-skilled workers	<input type="checkbox"/>
2=	unskilled workers	<input type="checkbox"/>
1=	farm labourers, students, housewives	<input type="checkbox"/>

0= unknown

Each parent would be scored separately and the total score for occupation and education would be obtained for the mother and father. The following key would be used to rank the family SES. A total of:

1. <14=LOW SOCIO-ECONOMIC STATUS
2. 14-24 =MEDIUM SOCIO-ECONOMIC STATUS
3. >24 (24-32) = HIGH SOCIO-ECONOMIC STATUS-SES

D) CLINICAL DATA

- | | | | |
|---|----------|--------------------------|--------------------------|
| 1. Stool <i>H. Pylori</i> SAT test for the child; | positive | <input type="checkbox"/> | <input type="checkbox"/> |
| | negative | | <input type="checkbox"/> |
| 2. Mothers <i>H. Pylori</i> SAT test for mother; | positive | <input type="checkbox"/> | <input type="checkbox"/> |
| | negative | | <input type="checkbox"/> |
| 3. Family history of stomach cancer; | Yes | <input type="checkbox"/> | No |
| | | | <input type="checkbox"/> |
| 4. Family history of stomach ulcers; | Yes | <input type="checkbox"/> | No |
| | | | <input type="checkbox"/> |

6.1.2 APPENDIX 2-Consent Form for the mother

Study Title:Helicobacter Pylori Antigen in the Mothers Stool and that of their Children in Kakamega County Hospitals

Study number: KAK/W64/81064/2015

Principal Investigator: Wambulwa Benard Wanyama

Contact Information: Phone: 0726708735- Senior Pharmacist County General Hospital Kakamega, postgraduate student -University of Nairobi Institute of Tropical and Infectious Diseases -UNITID

Supervisors:

1. Prof Ezekiel Masibo Wafula

Contact information: 0722366077, Department of Paediatrics University of Nairobi

2. Ms Winnie Chepkurui Mutai

Contact information: 0724886584, Department of Medical Microbiology, College of Health Sciences University of Nairobi

INTRODUCTION

We are kindly requesting you to participate in a research study. The aim of this consent form is to provide you with information you need to help make an informed decision whether or not to participate in the study. There will be approximately 246 mothers and 246 children participating in this study who will be randomly chosen.

You are free to ask questions about what we will do, your rights, any risks benefits or anything else that may not be clear to your. When all your questions

have been answered, you can then decide to participate or not. This process is called 'informed consent'. Once you understand and agree to participate in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for withdrawal iii) Refusal to participate in the research will not affect the services you and your child are entitled to in this health facility or other facilities.

May I continue? YES / NO

Background of the Study

H. pylori is a bacterium that has been implicated in stomach cancer and ulcers. It is acquired in early childhood and if not eradicated it persists in the stomach establishing a chronic inflammatory process that may lead to gastro duodenal diseases. The purpose of this study is to investigate *H. pylori* infection among children and their mothers and establish an association between the mothers' infection status and that of the children. We will also investigate the socio-economic risk factors that play a role in transmission. The recommendations from the study may help in future planning of interventions to prevent or minimise transmission to children.

Procedure

I will get some stool from you and your child with your help for the detection of *Helicobacter Pylori* antigens.

Risks of participating in the study

There is no risk for those who participate in the study. You and your child shall undergo no discomfort at all.

Benefits of participating in the study

If you and/or your child are found to have any symptoms of peptic ulcer disease or dyspepsia you shall be offered free consultation and advice on treatment or referred to a specialist if necessary. This information is a major contribution to science and will help in understanding H .pylori transmission in our setting

Voluntary participation

Your participation in this study is voluntary. You are free to decline consent or withdraw from the study at any time without any adverse effects. Participation in this study entails no financial benefit.

Confidentiality

All of the information obtained will be held in the strictest confidence and no information of any kind by which you or your child may be identified will be released or published. We will use a code number to identify you and your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out you participated in this study.

What If You Have Questions in Future?

For further questions or concerns about you participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your child's rights as a

research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

Ethical Consideration-This study has been approved by the Ethical Review Committee of the Kenyatta National Hospital and the University of Nairobi as well as the ethics review committee and the management of the County General Hospital of Kakamega.

Do you have any questions? Do you agree to participate?

Signature

Name

Date

Principal Investigator
.....

The study described above has been explained to me. I agree to participate and also allow my child to provide stool sample and participate in the study. I have had a chance to ask questions. I have been told that if I have any further questions about the research or about my rights as a subject I can ask the investigator listed above. I understand that I am free to withdraw from the study at any time.

	Signature	Name	Date
Mother
Witness	
		

6.1.3 Appendix 3- Child Assent Form

Note: This Assent Form Is For Children Aged 8 -13 Years Only

Study Title: Helicobacter Pylori Antigen in the Mothers Stool and that of their Children in Kakamega County Hospitals

Study number: KAK/W64/81064/2015

Principal Investigator: Wambulwa Benard Wanyama

Contact Information: Phone: 0726708735- Senior Pharmacist County General Hospital Kakamega, postgraduate student -University of Nairobi Institute of Tropical and Infectious Diseases -UNITID

Supervisors:

1. Prof Ezekiel Masibo Wafula

Contact information: 0722366077, Department of Paediatrics University of Nairobi

2. Ms Winnie Chepkurui Mutai

Contact information: 0724886584, Department of Medical Microbiology, College of Health Sciences University of Nairobi

INTRODUCTION

We are kindly requesting you to participate in a research study. The aim of this consent form is to provide you with information you need to help make an informed decision whether or not to participate in the study. There will be approximately 246 mothers and 246 children participating in this study who will be randomly chosen.

You are free to ask questions about what we will do, your rights, any risks benefits or anything else that may not be clear to you. When all your questions have been answered, you can then decide to participate or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities

May I continue? YES / NO

Background of the Study

H. pylori is a bacterium that has been implicated in stomach cancer and ulcers. It is acquired in early childhood and if not eradicated it persists in the stomach establishing a chronic inflammatory process that may lead to gastro duodenal diseases.

The purpose of this study is to investigate *H. PYLORI* infection among children and their mothers and establish an association between the mothers' infection status and that of the children. We will also investigate the socio-economic risk factors that play a role in transmission. The recommendations from the study may help in future planning of interventions to prevent or minimise transmission to children.

Procedure

I will get some stool from you to help for the detection of Helicobacter Pylori antigens.

Risks of participating in the study

There is no risk for those who participate in the study. You shall undergo no discomfort at all.

Benefits of participating in the study

If you found to have any symptoms of peptic ulcer disease or dyspepsia you shall be offered free consultation and advice on treatment or referred to a specialist if necessary. Also the information you provide will help us better understand how early this infection is acquired in childhood and may guide future testing and treatment guidelines. This information is a major contribution to science and will help in understanding H .pylori transmission in our setting.

Voluntary participation

Your participation in this study is voluntary. You are free to decline consent or withdraw from the study at any time without any adverse effects. Participation in this study entails no financial benefit. Your mother knows about the study too.

Confidentiality

All of the information obtained will be held in the strictest confidence and no information of any kind by which you may be identified will be released or

published. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out that you were in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

For further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

Ethical Consideration

This study has been approved by the Ethical Review Committee of the Kenyatta National Hospital and the University of Nairobi as well as the ethics review committee and the management of the County General Hospital of Kakamega.

Do you have any questions? Do you agree to participate?

If you agree you want to be in this study, please sign your name.

I, _____, want to be in this research study.

(Signature/Thumb stamp)

(Date)

6.1.4 Appendix 4- Parental Consent for Children Less Than Ten (8)

Study Title: Helicobacter Pylori Antigen in the Mothers Stool and that of their Children in Kakamega County Hospitals

Study Number: KAK/W64/81064/2015

Principal Investigator: Wambulwa Benard Wanyama

Contact Information: Phone: 0726708735- Pharmacist at County Hospital Kakamega and postgraduate student -University of Nairobi Institute of Tropical and Infectious Diseases -UNITID

Supervisors:

1. Prof Ezekiel Masibo Wafula

Contact information: 0722366077, Department of Paediatrics University of Nairobi

2. Ms Winnie Chepkurui Mutai

Contact information: 0724886584, Department of Medical Microbiology, College of Health Sciences University of Nairobi

INTRODUCTION

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. There will be approximately 246 mothers and 246 children participating in this study who will be randomly chosen.

When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO

Background of the Study

H .pylori is a bacterium that has been implicated in stomach cancer and ulcers. It is acquired in early childhood and if not eradicated it persists in the stomach establishing a chronic inflammatory process that may lead to gastro duodenal diseases.

The purpose of this study is to investigate *H. PYLORI* infection among children and their mothers and establish an association between the mothers' infection status and that of the children. We will also investigate the socio-economic risk factors that play a role in transmission. The recommendations from the study may help in future planning of interventions to prevent or minimise transmission to children.

Procedure

I will get some stool from your child with your help for the detection of *Helicobacter Pylori* antigens.

Risks of participating in the study

There is no risk for those who participate in the study. You and your child shall undergo no discomfort at all.

Benefits of participating in the study

Your child may benefit by receiving free *helicobacter pylori* testing. We will refer your child to a hospital for care and support if necessary. Also the information you provide will help us better understand how early this infection is acquired in childhood and may guide future testing and treatment guidelines. This information is a major contribution to science and will help in understanding *H .pylori* transmission in our setting.

Voluntary participation

Your child's participation in this study is voluntary and is free to decline consent or withdraw from the study at any time without any adverse effects. Participation in this study entails no financial benefit.

Confidentiality

All of the information obtained will be held in the strictest confidence and no information of any kind by which you or your child may be identified will be released or published. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out your child was in this study and could find out information about your child.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

For further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

Ethical Consideration-This study has been approved by the Ethical Review Committee of the Kenyatta National Hospital and the University of Nairobi as

well as the ethics review committee and the management of the County General Hospital of Kakamega.

What Will Happen If You Decide You Want Your Child To Be in This Research Study?

If you agree for your child to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 30 minutes. The interview will cover topics such as: household characteristics, socioeconomic status, family income, your occupation and that of your husband and education level. You will be informed about the results. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: giving feedback report and when there's need for the child to receive any form of treatment or further investigations. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have and your child to provide stool sample. We will do everything we can to ensure that this is done in privacy. Stool bottles and wrapped in non transparent parcels/bags will be provided to your.

Parent/Guardian Statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw at any time.

I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my child's participation in this research study: Yes/ No

I agree to have my child undergo *H. pylori* testing: Yes /No

I agree to provide contact information for follow-up: Yes/ No

Parent signature/Thumb stamp: _____ Date

Parent printed name: _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____ **Date:**

Signature: _____

Role in the study: _____

Witness Printed Name _____

Signature: _____ **Date:**

6.1.5 Appendix 5.Occupation and Education Level Scoring

The child parent's education will be rated on a 7-point scale that lists highest grade completed, in which 7=graduate/professional training, 6= standard college or technical institute, 5=partial college, at least one year of specialized training, 4= high school graduate, 3=partial secondary school, 2= completed primary school, 1= did not complete primary school, 0=not applicable or unknown.

The child parent's occupational code will be rated on a 9-point scale: 9=higher executive, proprietor of large businesses, major professional,

8=administrators, lesser professionals, proprietor of medium-sized business,
7=smaller business owners, farm owners, managers, minor professionals,
6=technicians, semi-professionals, small business owners, 5=clerical and sales
workers, small farm and business owners, 4=smaller business owners, skilled
manual labourers, craftsmen, tenant farmers, 3=machine operators and semi-
skilled workers, 2=unskilled workers, 1=farm labourers, menial service
workers, students, housewives, (dependent on welfare, no regular occupation),
0=not applicable or unknown.

Each parent will be scored separately and the total score for occupation and education shall be obtained for the mother and father; the following key shall be used to rank the family SES based on totals obtained.

- 1. <14=low socio-economic status**
- 2. 14-24 =medium socio-economic status**
- 3. >24 (24-32) = high socio-economic status**

6.1.7 Kiambatisho 7-Fomu YaKibaliKwaWatotoChiniYaMiakaNane

Kichwa cha Utafiti: Uwiano kati ya Uwepo wa Helicobacter Pylori Antijeni
kati ya kina Mama na Watoto Wao: Utafiti wa Msingi wa Hospitali

Nambari ya Utafiti: KAK / W64 / 81064/2015

Mtafiti Mkuu: Wambulwa Benard Wanyama

Maelezo ya Mawasiliano: Simu: 0726708735-Daktari katika Hospitali ya
Kakamega na Mwanafunzi wa Chuo Kikuu - Taasisi ya chuo cha Nairobi.

Wasimamizi:

1. Professa Ezekiel Masibo Wafula

Maelezo ya Mawasiliano: simu -0722366077, Chuo Kikuu cha Nairobi

2. Winnie Chepkurui Mutai

Maelezo ya mawasiliano: simu-0724886584, Idara ya Microbiolojia, Chuo
Kikuu cha Nairobi.

UTANGULIZI

Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti waliotajwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji ili kukusaidia kuamua ikiwa mtoto wako atashiriki katika utafiti huu. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea kwa mtoto wako anayeshiriki katika utafiti, hatari na faida iwezekanavyo, haki za mtoto wako , na chochote kingine kuhusu utafiti huu au kwenye fomu hii ambayo sio

Wazi. Kutakuwa na kina mama karibu na 246 na watoto 246 wanaoshiriki katika utafiti huu ambao watachaguliwa kwa urahisi.

Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kama unataka mtoto wako awe katika utafiti huu au la. Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubaliana kuwa mtoto wako awe katika utafiti, nitawaomba usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa mtoto wa kushiriki ni kikamilifu kwa hiari ii) Mtoto anaweza kujiondoa kwenye utafiti wakati wowote bila kutoa sababu ya kuondolewa kwake iii) Kukataa kushiriki katika utafiti hauathiri huduma ambazo mtoto wako ana haki katika kituo hiki cha afya au vifaa vingine.

Naweza kuendelea? NDIO LA

MAMBO MUHIMU YA KUJIFUNZA

H .pylori ni bakteria ambayo imehusishwa na kansa ya tumbo na vidonda. Inapatikana katika utoto wa mapema na ikiwa haijaangamizwa inakaa ndani ya tumbo kuanzisha mchakato wa uchochezi unaoweza kusababisha ugonjwa wa vidonda vya tumbo na kansa.

Kusudi la utafiti huu ni kuchunguza maambukizo ya bakteria hii kati ya watoto na mama zao na kutafuta kuwepo kwa ushirikiano kati ya hali ya maambukizi ya mama na ya watoto wake. Tutafuatilia pia mambo ya hatari ya kijamii na kiuchumi ambayo yana jukumu la kuambukiza. Mapendekezo kutoka kwa

utafiti yanaweza kusaidia katika mipango ya baadaye ya hatua za kuzuia au kupunguza maambukizi kwa watoto.

Utaratibu

Nitapata choo kutoka kwa mtoto wako kwa msaada wako kwa kutambua kuwepo kwa bakteria ya *Helicobacter Pylori*.

Hatari za kushiriki katika utafiti

Hakuna hatari kwa wale wanaoshiriki katika utafiti huu. Wewe na mtoto wako hamtakuwa na wasiwasi wakati wote.

Faida ya kushiriki katika utafiti huu

Mtoto wako anaweza kufaidika kwa kupimwa bure kuwepo kwa *H. pylori*. Tutaelekeza mtoto wako kwa hospitali kwa ajili ya huduma na msaada ikiwa ni lazima. Pia maelezo unayoyatoa yatakusaidia kuelewa vizuri jinsi mapema maambukizi haya yanapatikana wakati wa utoto na inaweza kuongoza miongozo ya upimaji na matibabu ya baadaye. Taarifa hii ni mchango mkubwa kwa sayansi na itasaidia kuelewa *H. pylori* na maambukizi yake katika mazingira yetu.

Ushiriki wa hiari

Kushiriki kwa mtoto wako katika utafiti huu ni kwa hiari na ni huru kupungua kibali au kujiondoa kwenye utafiti wakati wowote bila madhara yoyote. Kushiriki katika utafiti huu hakuhusishi faida yoyote ya kifedha.

Usiri

Taarifa zote zilizopatikana zitafanyika kwa ujasiri thabiti na hakuna habari yoyote ya aina ambayo wewe au mtoto wako anaweza kutambuliwa itatolewa au kuchapishwa. Tutatumia namba ya kisiri ili kutambua mtoto wako katika databana la kompyuta iliyohifadhiwa na nenosiri na kuweka kumbukumbu zote za karatasi kwenye sanduku lililofungwa. Hata hivyo, hakuna mfumo wa kulinda siri unaweza kuwa salama kabisa na bado inawezekana kwamba mtu anaweza kumtambua mtoto wako katika utafiti huu na anaweza kupata habari kuhusu mtoto wako.

Iwapo utakuwa na maswali baada ya utafiti kukamilika

Kwa maswali zaidi au wasiwasi juu ya mtoto wako anayeshiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyakazi wa kujifunza kwa nambari iliyotolewa chini ya ukurasa huu. Kwa habari zaidi kuhusu haki za mtoto wako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Kenyatta National Hospital-Chuo Kikuu cha Nairobi Maadili na Utafiti Kamati Namba 2726300 - 44102 barua pepe uonknh_erc@uonbi.ac.ke.

Wafanyakazi wa kujifunza watawalipa malipo yako kwa idadi hizi ikiwa wito ni kwa ajili ya mawasiliano inayohusiana na utafiti.

Kuzingatia Maadili

Utafiti huu umekubaliwa na Kamati ya Ukaguzi wa Maadili ya Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi pamoja na kamati ya ukaguzi wa maadili na usimamizi wa Hospitali ya Kakamega

Ni nini kitafanyika iwapo utakubali mtoto wako kushiriki kwa utafiti huu?

Ikiwa unakubaliana na mtoto wako kushiriki katika utafiti huu, mambo yafuatayo yataokea:

Utashughulikiwa na mhojiwaji mwenye mafunzo katika eneo la kibinafsi ambako unajisikia kujibu maswali. Mahojiano itaendelea kwa muda wa dakika 30. Mahojiano yatashughulikia mada kama vile: usafi wa nyumbani, hali ya kijamii, mapato ya familia, kazi yako na ya mume wako na ngazi ya elimu. Utaelezwa kuhusu matokeo. Tutaomba nambari ya simu ambapo tunaweza kuwasiliana na wewe ikiwa ni lazima. Ikiwa unakubaliana kutoa maelezo yako ya mawasiliano, itatumiwa tu na watu wanaofanya kazi kwa ajili ya utafiti huu na kamwe hawatashirikiwa na wengine. Sababu ambazo tunaweza kuwasiliana na wewe ni pamoja na: kutoa ripoti ya maoni na wakati kuna haja ya mtoto kupokea aina yoyote ya matibabu au uchunguzi zaidi. Pia, kujibu maswali katika mahojiano inaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote unayokataa kujibu, unaweza kuyaepuka. Una haki ya kukataa mahojiano au maswali yoyote yaliyoulizwa wakati wa mahojiano.

Inaweza kuwa aibu kwa wewe na mtoto wako kutoa sampuli ya kinyesi. Tutafanya kila kitu tunaweza kuhakikisha kuwa hii imefanywa kwa faragha.

Chupa na vifurushi visivyowazi ama mifuko yatatolewa kwako kuweka sampuli ya kinyesi.

Taarifa ya Mzazi

Nimeisoma fomu hii ya idhini au nimesomewa maelezo. Nimekuwa na fursa ya kujadili utafiti huu na mshauri wa utafiti. Nimekuwa na maswali yangu akajibu naye kwa lugha ambayo ninaelewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kwamba nitapewa nakala ya fomu hii ya idhini baada ya kuisaini. Ninaelewa kuwa ushiriki wangu na wa mtoto wangu katika utafiti huu ni hiari na kwamba nipate kuchagua wakati wowote.

Ninaelewa kuwa jitihada zote zitafanywa kuweka habari kuhusu mimi na siri ya utambulisho wa mtoto wangu.

Kwa kusaini fomu hii ya kibali, sijaacha haki za kisheria za mtoto wangu kama mshiriki katika utafiti huu wa kisayansi.

Mimi kwa hiari kukubali ushiriki wa mtoto wangu katika utafiti huu :

Ndio / Hapana

Nakubali kuwa mtoto wangu apate kupima *H. pylori*: Ndio / Hapana

Nakubali kutoa taarifa ya mawasiliano kwa kufuatilia: Ndio / Hapana

Sahihi ya mzazi: _____ Tarehe _____

Jina la mzazi lililochapishwa:

Taarifa ya Mtafiti

Mimi, mshirikiwaji, nimeelezea kikamilifu maelezo muhimu ya utafiti huu wa utafiti kwa mshiriki aliyechaguliwa hapo juu na kuamini kuwa mshiriki ameelewa na amekiri idhini yake.

Jina la kuchapishwa: _____

Tarehe: _____ Sahihi: _____

Jukumu katika utafiti: _____

Jina la kuchapishwa kwa shahidi _____

Saini: _____

Tarehe;

6.1.8 Kiambatisho 8-Fomu Ya Kukubaliana Kwa Watoto

Kumbuka: Fomu hii ya Usaidizi ni kwa Watoto wa miaka 8-13 pekee

Kichwa cha Utafiti: Uwiano kati ya Uwepo wa Helicobacter Pylori Antijeni kati ya kina Mama na Watoto Wao: Utafiti wa Msingi wa Hospitali

Nambari ya Utafiti: KAK / W64 / 81064/2015

Mtafiti Mkuu: Wambulwa Benard Wanyama

Maelezo ya Mawasiliano: Simu: 0726708735-Daktari katika Hospitali ya Kakamega na Mwanafunzi wa Chuo Kikuu - Taasisi ya chuo cha Nairobi.

Wasimamizi:

1. Professa Ezekiel Masibo Wafula

Maelezo ya Mawasiliano: simu -0722366077, Chuo Kikuu cha Nairobi

2. Winnie Chepkurui Mutai

Maelezo ya mawasiliano: simu-0724886584, Idara ya Microbiolojia, Chuo Kikuu cha Nairobi.

UTANGULIZI

Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti waliotajwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji ili kukusaidia kuamua ikiwa mtoto wako atashiriki katika utafiti huu. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea kwako katika utafiti, hatari na faida iwezekanavyo, haki za kujitolea, na chochote kingine kuhusu utafiti huu au kwenye fomu hii ambayo sio Wazi. Kutakuwa na kina mama karibu na 246 na watoto 246 wanaoshiriki katika utafiti huu ambao watachaguliwa kwa urahisi.

Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kama unataka uwe katika utafiti huu au la. Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubaliana uwe katika utafiti, nitawaomba usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kikamilifu kwa hiari ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila kutoa sababu ya kujiondoa iii) Kukataa kushiriki katika utafiti hauathiri huduma ambazo utapata ana haki katika kituo hiki cha afya au vifaa vingine. Naweza kuendelea? NDIO /LA

MAMBO MUHIMU YA KUJIFUNZA

H .pylori ni bakteria ambayo imehusishwa na kansa ya tumbo na vidonda. Inapatikana katika utoto wa mapema na ikiwa haijaangamizwa inakaa ndani ya tumbo kuanzisha mchakato wa uchochezi unaoweza kusababisha ugonjwa wa vidonda vya tumbo na kansa.

Kusudi la utafiti huu ni kuchunguza maambukizo ya bakteria hii kati ya watoto na mama zao na kutafuta kuwepo kwa ushirikiano kati ya hali ya maambukizi ya mama na ya watoto wake. Tutafuatilia pia mambo ya hatari ya kijamii na kiuchumi ambayo yana jukumu la kuambukiza. Mapendekezo kutoka kwa utafiti yanaweza kusaidia katika mipango ya baadaye ya hatua za kuzuia au kupunguza maambukizi kwa watoto.

Utaratibu

Nitapata sampuli ya kinyesi kutoka kwako ili kusaidia kutambua antijeni ya *Helicobacter Pylori*.

Hatari za kushiriki katika utafiti

Hakuna hatari kwa wale wanaoshiriki katika utafiti huu. Hutakuwa na wasiwasi wakati wowote.

Faida ya kushiriki katika utafiti

Ikiwa umegundua kuwa na dalili yoyote ya ugonjwa wa kidonda cha tumbo utapewa ushauri bure na ushauri juu ya matibabu au utapelekwa kwa mtaalamu ikiwa ni lazima. Pia maelezo unayoyotoa yatatusaidia kuelewa vizuri jinsi mapema maambukizi haya yanapatikana wakati wa utoto na inaweza kuongoza miongozo ya upimaji na matibabu ya baadaye. Taarifa hii ni mchango mkubwa kwa sayansi na itasaidia kuelewa *H. pylori* na maambukizi yake katika mazingira yetu.

Ushiriki wa hiari

Kushiriki kwako katika utafiti huu ni kwa hiari. Wewe ni huru kupinga kibali au kujiondoa kwenye utafiti wakati wowote bila madhara yoyote mabaya. Kushiriki katika utafiti huu hakuhusisha faida yoyote ya kifedha. Mama yako anajua kuhusu utafiti pia.

Usiri

Taarifa zote zilizopatikana zitafanyika kwa ujasiri thabiti na hakuna taarifa yoyote ya aina ambayo unaweza kutambuliwa itatolewa au kuchapishwa. Tutatumia nambari ya siri kukutambua kwenye databana la kompyuta iliyohifadhiwa na nenosiri na tutahifadhi rekodi zote za karatasi kwenyesandukui lililofungwa. Hata hivyo, hakuna mfumo wa kulinda siri

unaweza kuwa salama kabisa na bado inawezekana kwamba mtu anaweza kujua kwamba ulikuwa katika utafiti huu.

Iwapo utakuwa na maswali baada ya utafiti kukamilika

Kwa maswali zaidi au wasiwasi wowote katika utafiti huu, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyakazi wa kujifunza kwa nambari iliyotolewa chini ya ukurasa huu. Kwa habari zaidi kuhusu haki za watoto kushiriki utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Kenyatta National Hospital-Chuo Kikuu cha Nairobi Maadili na Utafiti Kamati Namba 2726300 - 44102 barua pepe uonknh_erc@uonbi.ac.ke.

Wafanyakazi wa kujifunza watawalipa malipo yako kwa nambari hizi ikiwa wito ni kwa ajili ya mawasiliano inayohusiana na utafiti.

Kuzingatia Maadili

Utafiti huu umekubaliwa na Kamati ya Ukaguzi wa Maadili ya Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi pamoja na kamati ya ukaguzi wa maadili na usimamizi wa Hospitali ya Kakamega

Una maswali yoyote? Je! Unakubali kushiriki?

Utafiti ulioelezwa hapo juu umeelezewa kwangu. Nakubali kushiriki na kutoa sampuli ya kinyesi . Nimekuwa na nafasi ya kuuliza maswali. Nimeambiwa kuwa ikiwa nina maswali zaidi juu ya utafiti au kuhusu haki zangu kama mshiriki mimi ninaweza kumuuliza kwa nambari aliyeorodheshwa hapo juu.

Ninaelewa kuwa niko huru kujiondoa kwenye utafiti wakati wowote.

Sahihi : _____ Tarehe _____

Jina la kijana lililochapishwa: _____

Taarifa ya Mtafiti: Mimi, mshirikiwaji, nimeelezea kikamilifu maelezo muhimu ya utafiti huu wa kisayansi kwa mshiriki aliyechaguliwa hapo juu na kuamini kuwa mshiriki ameelewa na amekiri idhini yake.

Jina _____ la _____ kuchapishwa:

_____ Tarehe: _____ Sahihi: _____

Jukumu katika utafiti: _____

Jina la kuchapishwa kwa shahidi _____

Sahihi: _____ Tarehe; _____

6.1.9 Kiambatisho 9-Fomu YaKibali Cha KushirikiUtafitiKwa Mama Mzazi

Kichwa cha Utafiti: Uwiano kati ya Uwepo wa Helicobacter Pylori Antijeni kati ya kina Mama na Watoto Wao: Utafiti wa Msingi wa Hospitali

Nambari ya Utafiti: KAK / W64 / 81064/2015

Mtafiti Mkuu: Wambulwa Benard Wanyama

Maelezo ya Mawasiliano: Simu: 0726708735-Daktari katika Hospitali ya Kakamega na Mwanafunzi wa Chuo Kikuu - Taasisi ya chuo cha Nairobi.

Wasimamizi:

1. Professa Ezekiel Masibo Wafula

Maelezo ya Mawasiliano: simu -0722366077, Chuo Kikuu cha Nairobi

2. Winnie Chepkurui Mutai

Maelezo ya mawasiliano: simu-0724886584, Idara ya Microbiolojia,Chuo Kikuu cha Nairobi.

UTANGULIZI

Tunakuomba kwa usaidizi kushiriki katika utafiti wa kisayansi. Lengo la fomu hii ya idhini ni kukupa taarifa unayohitaji ili kusaidia kufanya uamuzi sahihi ikiwa ni kushiriki kwa utafiti huo. Kutakuwa na kina mama karibu na 246 na watoto 246 wanaoshiriki katika utafiti huu ambao watachaguliwa kwa urahisi.

Wewe ni huru kuuliza maswali kuhusu tutafanya nini, haki zako, faida yoyote , hatari au kitu kingine chochote ambacho hakiwezi kuwa wazi kwako. Wakati maswali yako yote yamejibuwa, unaweza kisha kuamua kushiriki au la.

Utaratibu huu unaitwa 'kibali cha habari'. Mara baada ya kuelewa na kukubali kushiriki katika utafiti huo, nitawaomba usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kikamilifu kwa hiari ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu ya uondoaji iii) Kukataa kushiriki katika Utafiti haiwezi hauathiri huduma wewe na mtoto wako una haki katika kituo hiki cha afya au vifaa vingine.

Naweza kuendelea? **NDIO / LA**

MAMBO MUHIMU YA KUJIFUNZA

H .pylori ni bakteria ambayo imehusishwa na kansa ya tumbo na vidonda. Inapatikana katika utoto wa mapema na ikiwa haijaangamizwa inakaa ndani ya tumbo kuanzisha mchakato wa uchochezi unaoweza kusababisha ugonjwa wa vidonda vya tumbo na kansa.

Kusudi la utafiti huu ni kuchunguza maambukizo ya bakteria hii kati ya watoto na mama zao na kutafuta kuwepo kwa ushirikiano kati ya hali ya maambukizi ya mama na ya watoto wake. Tutafuatilia pia mambo ya hatari ya kijamii na kiuchumi ambayo yana jukumu la kuambukiza. Mapendekezo kutoka kwa utafiti yanaweza kusaidia katika mipango ya baadaye ya hatua za kuzuia au kupunguza maambukizi kwa watoto.

Utaratibu

Nitapata choo kutoka kwako na mtoto wako kwa msaada wako kwa kutambua antijeni ya *Helicobacter Pylori*.

Hatari za kushiriki katika utafiti

Hakuna hatari kwa wale wanaoshiriki katika utafiti huu. Wewe na mtoto wako hamtakuwa na wasiwasi wakati wote.

Faida ya kushiriki katika utafiti

Ikiwa wewe au mtoto wako anaonekana kuwa na dalili za ugonjwa wa kidonda cha tumbo utapewa ushauri wa bure na ushauri juu ya matibabu au upelekwe kwa mtaalamu ikiwa ni lazima. Taarifa hii ni mchango mkubwa kwa sayansi na itasaidia kuelewa H .pylori na yake maambukizi katika mazingira yetu

Ushiriki wa hiari

Kushiriki kwako katika utafiti huu ni kwa hiari. Wewe ni huru kupungua kibali au kujiondoa kwenye utafiti wakati wowote bila madhara yoyote mabaya. Kushiriki katika utafiti huu hakuhusishi faida yoyote ya kifedha.

Usiri

Taarifa zote zilizopatikana zitafanyika kwa ujasiri thabiti na hakuna habari yoyote ya aina ambayo wewe au mtoto wako anaweza kutambuliwa itatolewa au kuchapishwa. Tutatumia nambari ya kisiri ili kukutambua wewe na mtoto wako katika databana la kompyuta iliyohifadhiwa na nenosiri na utaweka rekodi zote za karatasi kwa sanduku lililofungwa. Hata hivyo, hakuna mfumo wa kulinda siri unaweza kuwa salama kabisa na bado inawezekana kwamba mtu atambue wewe umeshiriki katika utafiti huu.

Iwapo utakuwa na maswali baada ya utafiti kukamilika

Kwa maswali zaidi au wasiwasi juu ya mtoto wako anayeshiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyakazi wa kujifunza kwa nambari iliyotolewa chini ya ukurasa huu. Kwa habari zaidi

kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Kenyatta National Hospital-Chuo Kikuu cha Nairobi Maadili na Utafiti Kamati Namba 2726300 - 44102 barua pepe uonknh_erc@uonbi.ac.ke. Wafanyakazi wa kujifunza watawalipa malipo yako kwa idadi hizi ikiwa wito ni kwa ajili ya mawasiliano inayohusiana na utafiti.

Kuzingatia Maadili

Utafiti huu umekubaliwa na Kamati ya Ukaguzi wa Maadili ya Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi pamoja na kamati ya ukaguzi wa maadili na usimamizi wa Hospitali ya Kakamega

Una maswali yoyote? Je! Unakubali kushiriki?

Utafiti ulioelezwa hapo juu umeelezewa kwangu. Nakubali kushiriki na pia kuruhusu mtoto wangu kutoa sampuli ya kinyesi na kushiriki katika utafiti. Nimekuwa na nafasi ya kuuliza maswali. Nimeambiwa kuwa ikiwa nina maswali zaidi juu ya utafiti au kuhusu haki zangu kama somo mimi ninaweza kumuuliza uchunguzi aliyeorodheshwa hapo juu. Ninaelewa kuwa niko huru kujiondoa kwenye utafiti wakati wowote.

Sahihi ya mama mzazi: _____ Tarehe _____

Jina la mama mzazi lililochapishwa:

Taarifa ya Mtafiti

Mimi, mshirikiwaji, nimeelezea kikamilifu maelezo muhimu ya utafiti huu wa kisayansi kwa mshiriki aliyechaguliwa hapo juu na kuamini kuwa mshiriki ameelewa na amekiri idhini yake.

Jina la kuchapishwa: _____

Tarehe: _____ Sahihi: _____

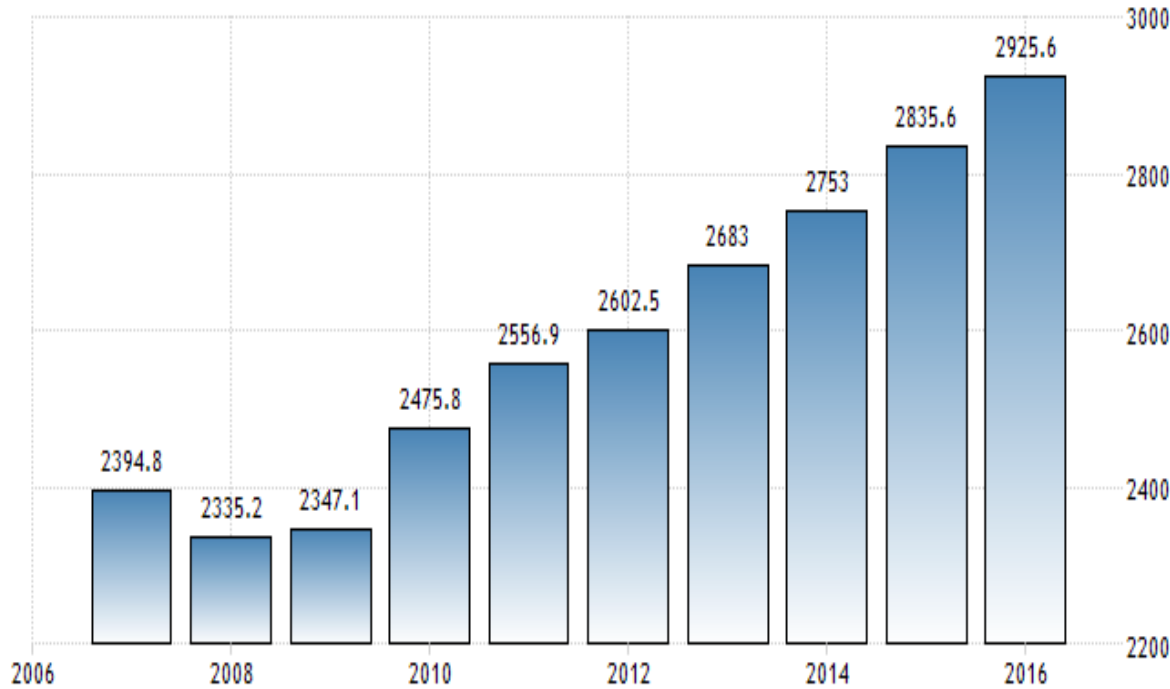
Jukumu katika utafiti: _____

Jina la kuchapishwa kwa shahidi _____

Saini: _____

Tarehe;

KENYA GDP PER CAPITA PPP



SOURCE: TRADINGECONOMICS.COM | WORLD

6.1.10 Appendix 10- Graph Of Ten Year Trend Kenyan GDP

The table shows a 10 year trend in the Kenyan GDP Per Capita Purchasing Power Parity.



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P.O. BOX 19676 Code 00202
Tel: 254-201 272300 Ext. 4133
Tel: 254-201 272300 Ext. 4133

15 SEP 2017

KNH-UoN ERC
Email: ethics.erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/ethics.erc>
Twitter: @UONBIERC



KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723 Code 00202
Tel: 7222559
Fax: 725023
Telegrams: YEDUP, KENYA

Ref: KNH-ERC/A/260

8th September, 2017

Dr. Bernard Wanyama Wambui
Reg. No. W6431034-2015
Institute of Tropical and Infectious Diseases (UoN ID)
College of Health Sciences
University of Nairobi

Dear Dr. Wanyama

RESEARCH PROPOSAL – HELICOBACTER PYLORI ANTIGEN IN THE MOTHERS STOOL AND THAT OF THEIR CHILDREN IN KAKAMEGA COUNTY HOSPITAL (P2905/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 5th September, 2017 – 4th September, 2018.

This approval is subject to compliance with the following requirements.

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events, whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others involved; the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 30 days prior to expiry of the approved period. *March 2018 a comprehensive progress report is required (see annex)*
- Submission of an *executive summary report* within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Protect to discover

6.1.12: Kakamega ERC approval letter

REPUBLIC OF KENYA
COUNTY GOVERNMENT OF KAKAMEGA



Telegram: "CGKUN MEEP", Kakamega
E-mail: cggh15@yahoo.co.ke
Telephone: Kakamega 056-300501/2
When replying, please quote:
REF:ERC/CGH/GEN/05

COUNTY GENERAL HOSPITAL
P.O. Box 13-ELP 10-02000
KAKAMEGA
DATE: 23/09/17

MINISTRY OF HEALTH

Dr. Bernard Wanyama Wambuiwa,
BOX 39,
KAKAMEGA,

Dear Sir,

REF: RESEARCH PROPOSAL APPROVAL (001/09/2017)

This is to inform you that the Ethics and Research Committee has reviewed and approved your work titled "HELICOBACTER PYLORI ANTIGEN IN THE MOTHERS STOOL AND THAT OF THEIR CHILDREN IN KAKAMEGA COUNTY HOSPITALS".

The approval is valid for 1 year from the above date and any continuation thereafter will necessitate a request for renewal.

Note that this approval is only for the work that you have submitted to us. The committee must be notified of any changes or amendments and serious or unexpected outcomes related to the study. You will be expected to submit a final report at the end of the study and may be requested to do a presentation of the same to the hospital.

This information will form part of the database that will be consulted in future when processing related research studies so as to minimize chances of study duplication.

Thank you for your interest in research in our institutions.

 
Dr. AUSTIN S. AJEVI
CHAIRMAN
ETHICS AND RESEARCH COMMITTEE
CC: Medical Superintendent
CGH KAKAMEGA