

**ECONOMIC BURDEN OF ACUTE GASTROENTERITIS AND
ASSOCIATED COST VARIABILITY IN PATIENTS ATTENDING
HEALTH FACILITIES IN BUSIA COUNTY, KENYA**

BY

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DEGREE OF MASTER OF SCIENCE IN FIELD EPIDEMIOLOGY MOI
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DECLARATION

Declaration by Candidate

This thesis is my original work and has not been presented for a degree in any other university.

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DEDICATION

I dedicate this thesis to my wife Winnie for being my source of inspiration, encouragement and her support in conducting this study.

ABSTRACT

Background: Infectious diarrhoea was the third leading cause of death in Kenya across all age groups in 2019 and a leading cause of hospitalisation in Busia County. More than 70% of acute gastroenteritis cases result from contaminated food & water. Busia County had low sanitation coverage with estimated open defecation rate of 74% in rural areas. The approximated economic burden in Kenya in 2009 due to a single cause of infectious diarrhoea was US\$10.9 million. Missing paid employment due to illness in low income communities can have negative economic impacts.

Objectives: The study aimed to estimate the total cost of acute gastroenteritis from a household perspective for patients attending health facilities in Busia County and assess factors influencing the cost as a pre-requisite for understanding the economic burden of acute gastroenteritis at county level.

Methods: A cross sectional cost-of-illness study was conducted among gastroenteritis patients in Busia County between September & October 2020. Patients were sampled from facilities proportionate to number of diarrheal cases in the previous year. Interviews were conducted using structured questionnaires. Data on demographic, socio-economic, clinical & costs incurred were collected. We calculated median and interquartile range for direct medical costs (e.g. medications, diagnostics), non-medical direct costs (e.g. transport, food) and indirect costs (e.g. lost income). Linear regression was applied to identify factors associated with variation in cost of illness and p-value of less than 0.05 and 95% confidence interval were considered significant.

Results: We enrolled 249 acute gastroenteritis patients; Median age was 8 years (IQR) 2–21), 143(57.4%) were female, 134(54%) visited public facilities, 241 (99.2%) had diarrhoea and 104 (46.2%) had medical insurance. The average duration of illness was 3.3 days (SD 1.2).

The average total cost for patients visiting Public health care facilities was KES 1374.62; SD 502.21 (US\$12.5), Private KES 1461.11; SD 637.35 (US\$13.28) and Faith-based KES 1506.06; SD 477.45 (US\$13.69). The average total cost of seeking care for acute gastroenteritis patients in Busia was KES 1,497.8; SD 578.5 (US\$13.6). Self-medication significantly influenced total cost, $p=0.0001$. Total cost was 27% higher for those with prior treatment compared to those without. Having insurance also significantly influenced the total cost, $p=0.02$. Total cost was 15% higher for those paying cash compared to those with medical insurance.

Conclusion: The cost of seeking health care for an episode of acute gastroenteritis was high relative to household incomes. This study observed low utilization of medical insurance especially in public health care facilities. Lost wages due to illness represented a substantial proportion of the costs due to acute gastroenteritis.

Recommendation: To reduce out of pocket costs to their residents, the county government should promote enrollment in the publically available insurance coverage that is offered by the state through the national hospital insurance fund (NHIF). With high number of acute gastroenteritis cases in the country, the economic burden on citizens becomes considerable indicating the need to strengthen existing strategies for prevention & control

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LIST OF ACRONYMS AND ABBREVIATIONS

AGE	Acute gastroenteritis
CDC	Centers for Disease Control and Prevention
DALY	Disability adjusted life year
DHIS2	District Health Information System 2
FBD	Food borne disease
IID	Infectious intestinal disease
ILRI	International Livestock Research Institute
IREC	Institutional Research and Ethics Committee
KDHS	Kenya Demographic and Health Survey
KES	Kenya shillings
IQR	Interquartile range
NACOSTI	National Commission for Science Technology and Innovation
NGO	Non-Governmental Organisation
OOP	Out of pocket costs
SD	Standard deviation
UHC	Universal Health Coverage
USA	United States of America
USD	United States Dollars
WHO	World Health Organisation
ZooLink	Zoonoses in Livestock in Kenya Project

DEFINITION OF TERMS

Acute gastroenteritis refers to an inflammation of the mucous membranes of the stomach and the intestinal tract

Catastrophic health expenditure refers to out of pocket costs exceeding 40% of the household income net of subsistence needs

Diarrhoea is defined as the passage of three or more loose or liquid stools per day (or more frequent passage than is normal for the individual)

Health facility refers to hospitals or primary health-care centres

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Worldwide, diarrheal diseases are a leading cause of morbidity and mortality (Keusch et al., 2006a). Acute gastroenteritis is commonly defined as diarrhoea (three or more loose stools) or vomiting in the past 24 hours (Rivière et al., 2017). Acute gastroenteritis (AG) is frequently caused by infectious intestinal diseases (IID) including food- and waterborne pathogens of public health importance (Bless et al., 2016a). Every year, gastroenteritis affects 3 to 5 billion children worldwide and accounts for 1.5 to 2.5 million fatalities or 12% of all fatalities among children under the age of 5 (M Chow et al., 2010). Studies have shown that the burden of gastro-enteritis on the African continent remains particularly high in poverty stricken areas (Fletcher et al., 2011a). The highest mortality from diarrheal diseases are from Africa and South Asia (Dadonaite et al., 2018a). In Kenya, the Global health index ranked diarrheal diseases as the leading cause of death in the country (*CDC Global Health - Kenya*, 2018). A 2009 study in Kenya estimated the economic burden on the health care system from a single cause of infectious diarrhoea at US\$ 10.8 million (Tate et al., 2009). A significant proportion of diarrhoeal disease can be prevented through safe drinking-water and adequate sanitation and hygiene (Keusch et al., 2006a). Food- and waterborne pathogens such as *Campylobacter* spp. and *Salmonella* spp., are of particular public health concern as they can lead to disease outbreaks in addition to causing sporadic cases. Introduction of the rotavirus vaccine is also considered key in reducing incidence of diarrheal diseases. However, vaccine coverage is still quite low with only 35% of children below one year of age being vaccinated in 2018 (Dadonaite et al., 2018b). The feasibility of controlling or eliminating diarrheal episodes differs depending on the

causal pathogen. Weak surveillance systems and inadequate health sector financing remain a big challenge especially in developing countries. In many low- and middle-income countries where diarrheal disease is common, health care costs can represent a significant proportion of household expenditures (Zimmermann et al., 2019). Gastroenteritis affects rich and poor, old and young, with high morbidity in developed and higher morbidity and mortality in developing countries. A strong relationship however exists between being resource poor, low sanitation standards, and the number and severity of diarrheal episodes, especially for children under five (Sarker et al., 2018a). Hospitalizations for diarrhoea among children <5 years of age and represents a substantial economic burden in both developing and developed countries (Tate et al., 2009). Illness creates a burden upon households in many ways. The cost of illness is determined by several factors, including causative agent, severity of complications, the demographic characteristics of the study population, access to medical care, and the quality of care sought. Household costs for gastroenteritis treatment include direct costs such as consultation fees, diagnostic tests and medication including previous treatment costs as well as non-medical direct costs such as transportation, lodging, food items and informal payments for helping the patients during treatment. Also included are productivity losses that consider foregone economic activities due to the illness. The estimated frequency of diarrheal episodes in children <5 is up to 3 episodes per year especially in high burden low-income countries (WHO). The perceived and actual financial costs of seeking health care is known to influence health seeking behaviour as these costs can be economically catastrophic for low-income households. A fundamental objective of universal health coverage is financial protection through reduction of out of pocket payments and equitable access to good-quality health services according to one's healthcare needs (Mbau et al., 2020). This study aims to

estimate the economic burden of acute gastro-enteritis and the associated cost variability for patients attending health care facilities in Busia County, Kenya. An estimate of the economic burden of acute gastroenteritis can be used in raising awareness, by demonstrating the economic burden of the disease so that politicians, community leaders and health administrators can become convinced of the problem and be encouraged to engage in prevention (*WHO_IVB_05.10.Pdf*, n.d.).

1.2 Problem Statement

Gastroenteritis presents an economic burden to health care systems and households (Burke et al., 2014a). Strategies for controlling diarrheal diseases have remained substantially unchanged for several decades and yet the burden in developing countries remains significantly high (Fletcher et al., 2011b). Gastroenteritis is rarely fatal, however, morbidity and economic costs are substantial due to its high incidence (Pijnacker et al., 2019). Due to the self-limiting nature of diarrheal diseases, most patient never visit a health care facility and as a result such cases are not captured by local and national surveillance systems resulting in a significant underestimation of the true burden of the disease compared to other morbidities. The consequence of this is a failure to allocate adequate resources for control and prevention measures due to the perceived lower burden of disease. More than 70% of acute gastroenteritis cases result from contaminated food and water (Montgomery & Elimelech, 2007). A recent study by the International Livestock Research Institute (ILRI) identified several enteric pathogens circulating in human and livestock populations in Busia and other Western Kenya counties. Busia County had a low sanitation coverage with estimated open defecation rates of 74.9% in rural areas and 40% in urban areas (*Kenya*, 2015). It is generally agreed that countries cannot manage what they cannot measure, thus, the need for policy makers to track resources for health (WHO, 2018).

1.3 Study justification

Diarrhoea was the third leading cause of patients presenting at health care facilities in Busia in 2018 (DHIS2, 2019). The high global economic burden coupled with high morbidity and mortality necessitate greater effort in implementing prevention strategies. Under estimation of the true burden of acute gastroenteritis results in a missed opportunity for its control and prevention due to inadequate resource allocation. Cost of illness studies from a household perspective provides an opportunity for estimation of the true burden as they provide valuable information on cost per patient per episode. A fundamental objective of universal health coverage is protection for all and particularly the resource poor from catastrophic health expenditure (Puteh & Almuallm, 2017). Busia has a mixed subsistence-based economy in which households rely on a combination of wage labour and the subsistence outputs of fishing. Missing both paid employment and subsistence activities due to illness can have negative individual and household-level economic impacts. As primary health services have been devolved to the County level, there is need for locally appropriate estimates of disease burden which are currently lacking.

1.4 Research question

What is the economic burden of acute gastroenteritis and what factors influence the cost of illness in patients attending health care facilities in Busia County?

1.5 Objectives

1.5.1 General objective:

- To estimate the economic burden of acute gastro-enteritis and associated cost variability in patients attending health care facilities in Busia County, Kenya.

1.5.2 Specific Objectives

1. To estimate the total cost of seeking treatment for acute gastroenteritis patients attending health facilities in Busia County
2. To assess the factors that influence the cost of illness due to acute gastroenteritis in patients attending health facilities in Busia County, Kenya

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Global burden of gastroenteritis

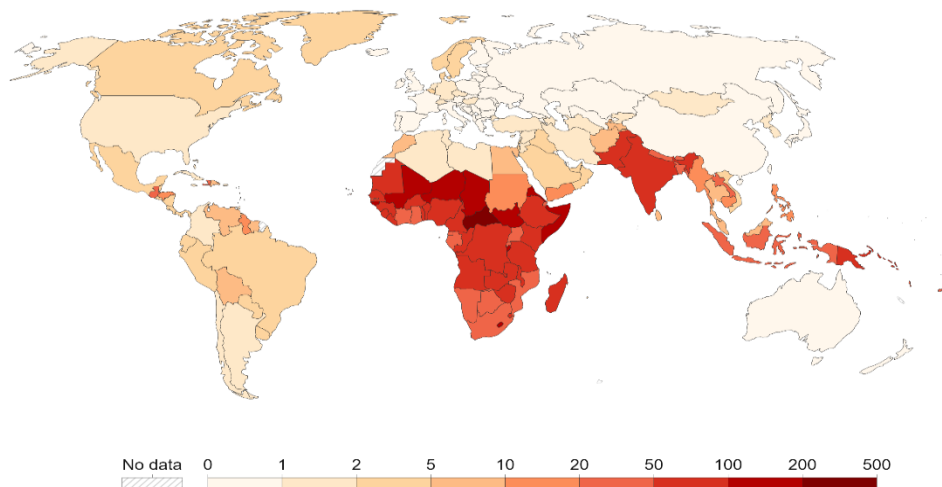
Acute gastroenteritis is a serious public health concern causing significant morbidity and mortality in developing and significant economic burden in developed countries (Chow et al., 2010). Worldwide, gastroenteritis causes 3 – 5 billion cases in children under 5 years with illness accounting for 10% of hospitalizations and 19% of deaths in children under 5 years (Oppong et al., 2020). Diarrheal diseases account for approximately 20% of deaths globally.

In Africa, there were an estimated 30 million cases of severe diarrhea in the year 2015 with approximately 78% of deaths globally due to diarrheal diseases occurring in Africa and South East Asia where sanitation and access to medical care are limited (*Variation in Childhood Diarrheal Morbidity and Mortality in Africa, 2000–2015*, 2018).

In Kenya, diarrheal diseases were the leading cause of death among all ages in the country (CDC, 2018). The age adjusted death rate was 127.36 per 100,000 of population and Kenya ranked 5th in the world. Figure 2.1 shows the geographical distribution of deaths due diarrheal diseases by country in the year 2019.

Death rate from diarrheal diseases, 2019

The annual number of deaths from diarrheal diseases per 100,000 people



Source: IHME, Global Burden of Disease (2019)

Note: To allow comparisons between countries and over time this metric is age-standardized.

OurWorldInData.org/diarrheal-diseases • CC BY

Figure 1: Death rate from diarrheal diseases in 2019

2.2: Definition of acute gastroenteritis

Acute gastroenteritis (AGE) is an infectious disease that causes inflammation of the gastrointestinal tract presenting with symptoms and signs, such as nausea, vomiting, fever or abdominal pain). Acute gastroenteritis (AG) is commonly defined as diarrhoea (three or more loose stools) or vomiting in the past 24 hours (Rivière et al., 2017). Acute gastroenteritis is characterised by diarrhoea, vomiting, abdominal pain and cramps, nausea and dehydration that occur in different combinations and with varying degrees of severity (Bless et al., 2016). Gastroenteritis is one of the most common cause of patients presenting to a physician and among the commonest cause of outbreaks of infectious diseases.

2.3 Classification of acute gastroenteritis

There are three clinical classifications for acute gastroenteritis:

- Acute watery diarrhoea lasting several hours or days
- Acute bloody diarrhoea commonly referred to as dysentery
- Persistent diarrhoea lasting 14 days or longer

The most severe threat posed by diarrhoea is dehydration. During a diarrhoeal episode, water and electrolytes (sodium, chloride, potassium and bicarbonate) are lost through liquid stools, vomit, sweat, urine and breathing. Dehydration occurs when these losses are not replaced (WHO).

2.4 Causes of acute gastroenteritis

Infection: Gastroenteritis results from infections caused by a host of bacterial, viral and parasitic organisms, most of which are spread by water contaminated with faeces. Infection is more common when there is poor or inadequate sanitation and safe water for drinking cooking and cleaning is lacking. Rotavirus and *Escherichia coli*, are the two most common etiological agents of moderate-to-severe diarrhoea in low-income countries. Other pathogens such as *cryptosporidium* and *shigella* species may also be important (WHO).

Malnutrition: Children who die from diarrhoea often suffer from underlying malnutrition, which makes them more vulnerable to diarrhoea. Each diarrhoeal episode, in turn, makes their malnutrition even worse. Diarrhoea is a leading cause of malnutrition in children under five years old (WHO).

Source: Water contaminated with human faeces, for example, from sewage, septic tanks and latrines, is of particular concern. Animal faeces also contain microorganisms that can cause diarrhea (WHO).

Other causes: Diarrhoeal disease can also spread from person-to-person and is often made worse by poor personal hygiene. Food is another major cause of diarrhoea when it is prepared or stored in unhygienic conditions. Unsafe domestic water storage and handling is also an important risk factor. Fish and seafood from polluted water may also contribute to the disease (WHO).

2.5 Pathogens that cause gastroenteritis

Acute gastroenteritis causes illness across all age groups worldwide but is usually more severe in children (*Diarrhoeal Disease*, 2016). A higher burden is expected in lower income countries where access to sanitation and health care is limited. More than 70% of gastroenteritis cases have been associated with ingestion of contaminated food and water (Montgomery & Elimelech, 2007).

2.5.1 Viral aetiology of gastroenteritis

Rotaviruses are the most common cause of acute gastroenteritis in children and accounts for between 30% and 72% of all the hospitalizations and between 4% and 24% of acute gastroenteritis at the community level. Majority of children will get infected by rotavirus by the age of 3 years with peak age of infection ranging between 6 months and 2 years (M Chow et al., 2010). Studies have shown that rotavirus infection occurs throughout the year in tropical countries but has a seasonal pattern of occurrence in temperate climates (Patel et al., 2013). In addition to diarrhoea, rotavirus infection can induce vomiting, malaise and fever.

Rotavirus is shed in large quantities in stools during episodes of rotavirus-associated diarrhoea. The virus is primarily transferred through the faecal–oral route, mainly through close person-to-person contact (Crawford et. al, 2017). A reduction in the burden of rotavirus disease has however been observed in many countries following the introduction of rotavirus vaccines. Despite extensive use of the vaccine in developed countries, rotavirus continues to be the leading cause of childhood diarrhoea worldwide (Stuempfig & Seroy, 2019).

Norovirus, an RNA virus is a human enteric pathogen that causes substantial morbidity across both health care and community settings. Norovirus frequently causes outbreaks in closed groups such as nursing homes, colleges and cruise ships (Stuempfig & Seroy,

2019). The incubation period is relatively brief in most infected individuals who develop symptoms. Fecal excretion of norovirus infection in asymptomatic individuals is common, especially in children. The dominant symptoms of norovirus infection are vomiting and diarrhoea and are generally of a relatively short duration. Diarrhoea is non-bloody and can consist of multiple bowel movements per day. The illness is self-limiting, and most patients recover within 72 hours without complications (Shane et al., 2017). Treatment of norovirus gastroenteritis is supportive, involving primarily the reversal of dehydration and electrolyte abnormalities. Antiemetics and antimotility agents may play a role in some patients (Robilotti et.al, 2015). The virus can withstand freezing, heating, and common disinfectant products containing alcohol or chlorine

2.5.2 Bacterial aetiology of gastroenteritis

The most common bacterial causes of gastroenteritis are *Salmonella* species, *Campylobacter* species, *Shigella* species and pathogenic *E.coli* species.

Salmonella species specifically non typhoidal species are a leading bacterial cause of acute gastroenteritis (Majowicz et al., 2010). Nontyphoidal salmonellae are gram-negative bacteria that primarily cause gastroenteritis, bacteremia, and focal infections. Most non-typhoidal *Salmonella* infections are caused by *S. enterica* subspecies *enterica* serotype Enteritidis, *S. Typhimurium*. The non typhoidal *Salmonella* species are freely present in the environment and reside in the gastrointestinal tracts of animals. Salmonellosis in humans is generally contracted through the consumption of contaminated food of animal origin, mainly eggs, meat, poultry, and milk, although other foods, including green vegetables contaminated by manure, have been implicated in its transmission. Person-to-person transmission can also occur through the faecal-oral route (WHO, 2018). The onset of disease symptoms occurs 6–72 hours (usually 12–36 hours) after ingestion of *Salmonella*, and illness lasts

2–7 days. Non-typhoidal salmonellae mainly cause a self-limiting enterocolitis in immune-competent individuals, however, bacteraemia without associated diarrhoea, occurs in at risk groups such as patients who are immunosuppressed because of HIV infection, steroid use, malignancy, chronic renal or liver disease, diabetes, or sickle-cell disease, the elderly and new-born patients (Feasey et al, 2012).

Campylobacter species are Gram-negative spiral, rod-shaped, or curved bacteria. *Campylobacter jejuni* infection is one of the most widespread causes of bacterial gastroenteritis causing disease worldwide (Kaakoush et al, 2015). *Campylobacter* species are widely distributed in warm-blooded animals and are prevalent in food animals such as poultry, cattle, pigs and sheep as well as in pets such as cats and dogs (WHO, 2018). The main route of transmission is generally believed to be foodborne, through undercooked meat and meat products, as well as raw or contaminated milk. Onset of symptoms occurs within 2 to 5 days after infection with the bacteria, but can range from 1 to 10 days. Most common clinical symptoms of *Campylobacter* infections include diarrhoea frequently bloody, abdominal pain, fever, headache, nausea, and or vomiting.

E.coli are gram-negative, facultative aerobic, rod-shaped, coliform bacterium of the genus *Escherichia*. They are considered to be part of the normal flora of the intestinal tract of humans and other warm-blooded animals. Most *E.coli* strains in the intestinal tract of humans and animals are harmless commensals. A few strains however, are pathogenic and cause gastroenteritis (CDC, 2018).

The *E. coli* that are responsible for reports of contaminated foods and beverages are those that produce Shiga toxin with the most notorious being *E. coli* O157:H7 (Clark, 2018). Six pathotypes are associated with diarrhoea and collectively are referred to as diarrheagenic *E. coli*. The four main categories include enteropathogenic *E. coli*

(EPEC), enteroinvasive *E. coli* (EIEC), enterotoxigenic *E. coli* (ETEC), and enterohemorrhagic *E. coli* (EHEC) (CDC, 2018). The main route of transmission is foodborne through contaminated food. A 2003 Study demonstrated that *E. coli* O157:H7 could be isolated from beef cattle, dairy cattle, pigs, sheep, and goats (Clark, 2018). Incubation period ranges from 3 to 9 days and duration of illness ranges from 2 to 9 days. Symptoms include sudden onset of abdominal cramps, followed within 24 hours by watery diarrhoea which later becomes grossly bloody. Vomiting may occur with or without fever (CDC, 2018).

Staphylococcus are gram-positive cocci appearing in clusters and are facultative anaerobes capable of both aerobic and anaerobic growth. Staphylococci are commonly found in a wide variety of mammals and birds, and transfer of *S. aureus* to food has two main sources: human carriage during food processing and dairy animals in case of mastitis (Hennekinne et al, 2012). Staphylococcus gastroenteritis is commonly a result of food poisoning due to eating foods contaminated with toxins produced by the bacterium *Staphylococcus aureus* bacteria (CDC, 2018).

Staphylococcus gastroenteritis is usually characterized by a sudden onset of nausea, vomiting, and stomach cramps and most people will also have diarrhea. Symptoms usually develop within 30 minutes to 8 hours after eating or drinking an item containing Staph toxin and usually last for one day. Severe illness is rare and the illness cannot be passed from one person to another (CDC, 2018).

2.5.3 Parasitic etiology of gastroenteritis

Parasitic infections causing gastroenteritis are common; for example, giardia is detected in about 5% to 30% of infectious gastroenteritis in low-income countries and is thought to be associated with poverty. Giardia lamblia was most detected in cases (400/662). Parasitic infections can be prevented by improving sanitation (Oppong et al., n.d.).

Table 1: Distribution of pathogens and the total number of detections in diarrhoeal cases from a meta-analysis of 23 studies covering West African Region, East African Region, Middle African Region and South African Region (Oppong et al., 2020)

Pathogen	Total number of cases	Percentage
Viruses		
Rotavirus	1599	29.2
Norovirus	361	6.6
Astrovirus	197	3.6
Adenovirus	592	10.8
Total	2749	50.2
Bacteria		
E. coli	854	15.6
Salmonella species	248	4.5
Shigella	526	9.6
Campylobacter	442	8.1
Total	2070	37.8
Parasites		
Giardia lamblia	400	7.3
E. histolytica	100	1.8
T. intestinalis	162	3.0
Total	662	12.1
Total	5481	100

2.6 Who is at risk

Diarrheal diseases affect the high income and low income, those in developed and developing countries alike. A strong relationship has however been demonstrated between being resource poor and the number and severity of diarrheal episodes

especially for children under five (Keusch et al., 2006b). Burden of diarrheal diseases is higher in children compared to adults with an estimated 1.3 billion diarrheal cases globally (WHO, 2017). This could be due to their weaker immune systems and greater exposure to risk factors. The majority of cases of diarrhoea in people aged 70 and over are caused by bacterial pathogens. The pathogen responsible for most deaths from diarrhea in this age group is shigella (Dadonaite et al., 2018b). Some of the identified risk factors for diarrhoea from previous studies include younger age, male gender and low maternal education (George et al., 2014).

Residing in urban areas has also been associated with higher incidence of diarrheal diseases compared to residents of rural areas and this was attributed to the effects of crowded living conditions and poor waste disposal especially in middle and low income countries (Kattula et al., 2015).

2.7 Control and Prevention

Management of acute gastroenteritis can either be clinical or involve a public health aspect depending on the aetiology and scope of the infection. Many enteric pathogens are transmitted through similar exposures routes, hence community based multi-stage prevention measures will control several at the same time (Fletcher et al., 2011b). According to the Health Protection Surveillance Centre of Ireland, the importance of gastroenteritis lies in its potential to cause clinically severe disease coupled with the fact that most pathogens that cause gastroenteritis are contagious and a single case can infect many people.

2.7.1 Preventive strategies

Strategies for controlling diarrheal diseases are well established and were strengthened by the breakthrough in development of vaccines in recent years. “Existing interventions to prevent or treat diarrheal diseases have proven their efficacy in reducing mortality,

but a major challenge going into the future will be to scale up these interventions to achieve universal utilization coverage” (Keusch et al., 2006a). The key strategies currently recommended include:

Promotion of personal and domestic hygiene through improved water hygiene and sanitation through appropriate waste disposal. Human faeces are the primary source of diarrheal pathogens. Poor sanitation, lack of access to clean water, and inadequate personal hygiene are responsible for an estimated 90 percent of childhood diarrhea (WHO 1997). Washing hands after defecating or handling children's feces and before handling food is recommended.

Exclusive breast feeding which means no other food or drink, not even water, is permitted, except for supplements of vitamins and minerals or necessary medicines for the first six months of life is another recommended preventive strategy. Exclusive breastfeeding protects young infants from diarrheal disease in two ways: first, breast milk contains both immune (specific) and non-immune (nonspecific) antimicrobial factors; second, exclusive breastfeeding eliminates the intake of potentially contaminated food and water (Keusch et al., 2006a).

Rotavirus vaccination is another key preventive strategy. Almost all infants acquire rotavirus diarrhea early in life with rotavirus accounting for at least one-third of severe and potentially fatal watery diarrhea episodes, primarily in developing countries. An effective rotavirus vaccine has been in use for several years and would have a major effect in reducing the burden and mortality due to diarrhoea in developing countries.

2.7.2 Case management

Majority of cases of gastroenteritis are mild causing self-limiting illness hence are uncomplicated and can be managed successfully through fluid therapy in primary care as they do not require specific treatment. However, gastroenteritis can be severe and

complicated depending on the cause and who is affected requiring hospitalisation and specific treatment with antibiotics. Most cases of uncomplicated, acute gastroenteritis in immune-competent individuals tend to have a duration of less than 14 days irrespective of the cause. Some of the current recommendation for case management includes:

Oral Rehydration Solutions refers to a formulation of glucose-based ORS considered optimal for cholera, irrespective of cause or age group affected has proven effective and without significant adverse effects (WHO).

Zinc Supplementation given during an episode of acute diarrhea reduces both duration and severity. WHO and UNICEF now recommend that all children with acute diarrhea be given zinc in some form for 10 to 14 days during and after diarrhoea.

Recommended management of bloody diarrhoea predominantly caused by shigellosis is antimicrobials.

2.8 Associated costs

World Health Organization (WHO) proposed guidelines for estimating the economic burden of diarrheal diseases (*WHO_IVB_05.10.Pdf*, n.d.). A micro-costing approach may be used to generate the cost of illness per episode per patient where all relevant cost components are identified and valued at the most detailed level. To capture the household economic cost of illness both direct and indirect costs should be captured.

2.8.1 Out of pocket costs

Refers to direct medical costs paid for by patients and/or caregivers and non-medical costs, such as transportation to and from health care facilities and household costs to accommodate the needs of the patient (WHO, 2005). Costs associated with diarrhoea include; consultation, diagnostic tests and medication including previous treatment

costs as well as non-medical direct costs including transportation, lodging, food items and informal payments for helping the patients during treatment.

2.8.2 Productivity losses

Refers to the value of the time lost by patients and caregivers from other productive activities during the illness episode. This takes into account income loss as well as productivity loss because of travel to the health centre and costs due to absence from work because of illness related to the diarrheal disease. Economic impact of time lost varies with age and occupation of affected person whether patient or caregiver. Productivity losses are difficult to estimate as it may be possible for affected persons to make up for time lost or their duties taken up by other workers. It is also common for participants to give an upward biased figure and therefore it is recommended to give overall results with and without the inclusion of productivity losses (WHO, 2005).

2.8.3 Total costs

Total cost of illness per episode of gastroenteritis is a summation of direct medical costs, direct non-medical costs and indirect costs. The summation of unit costs generates patient specific unit cost estimate which varies from patient to patient.

2.9 Economic burden

The economic burden of diarrhoea in a country is estimated by combining the frequency of each type of event with information on the mean costs associated with each event. The estimated frequency of gastroenteritis is 3 cases per person per year especially in children under 5 years. Economic burden can be presented according to the targeted focus or perspective of the study. Where the focus is the household, economic burden is presented as cost of illness relative to household income. Catastrophic health expenditure is a term used to represent out-of-pocket (OOP) payments for health care

that exceeds a specified threshold of household's income or household's capacity to pay (Liu et al., 2019). Health care expenditure can be considered catastrophic when out of pocket costs exceed 40% of the household income net of subsistence needs. In situations where mechanisms for health financing that protect households against the financial risks associated with ill health are unavailable or deficient, even modest healthcare bills could lead to CHE (Buigut et al., 2015). A WHO study on household catastrophic health expenditure observed that poor households can be protected from catastrophic health expenditures by reducing the health system's reliance on out-of-pocket payments and providing more financial risk protection.

2.10 Healthcare administration and financing in Kenya

The universal declaration of human rights recognized health as a right that all humans are entitled to enjoy (*Kenya-Health-Financing-Strategy_-Final.Pdf*, n.d.). Health systems especially in low income countries have struggled with stagnant or declining budgets, system inefficiencies, persistently poor service quality and lack of equity. The health sector in Kenya relies on several sources of funding: public (government), private firms, households and donors (including faith based organizations and NGOs) as well as health insurance schemes. Kenya has prioritized the attainment of universal health coverage (UHC) through the expansion of health insurance coverage by the National Hospital Insurance Fund (NHIF). A fundamental objective of UHC is financial protection through reduction of out of pocket payments and equitable access to good-quality health services according to one's healthcare needs (Mbau et al., 2020). Catastrophic health expenditure is a term used to represent out-of-pocket (OOP) payments for health care that exceeds a specified threshold of household's income or household's capacity to pay (Liu et al., 2019). Health care expenditure can be considered catastrophic when out of pocket costs exceed 10% of monthly income

(Burke et al., 2014a). In situations where mechanisms for health financing that protect households against the financial risks associated with ill health are unavailable or deficient, even modest healthcare bills could lead to CHE (Buigut et al., 2015). A WHO study on household catastrophic health expenditure observed that poor households can be protected from catastrophic health expenditures by reducing the health system's reliance on out-of-pocket payments and providing more financial risk protection.

2.11 Opportunities for gastroenteritis control and prevention in Busia County

The rotavirus vaccine was introduced in the routine infant immunization program in Kenya in July 2014. The Ministry of Health delivers free immunization through the Division of Vaccines and Immunization. In the former Western province of Kenya, vaccination coverage has been traditionally high with most Sub-Counties performing at above 80% fully vaccinated child coverage. Most children initiate their vaccinations at the facility but completion of the required vaccinations is very low compared to national and county rates (Emmanuel et al., 2015). Clusters of low immunization completion rates have been identified as a major cause of vaccine preventable disease outbreaks in areas with otherwise high immunization coverage. There is opportunity to achieve 100% coverage by promoting vaccine completion.

Busia County was among the counties with the lowest (42%) sanitation coverage compared to National level of 49% (Masinde, 2017). The Busia Water & Sewerage Services Company (BUWASSCo) currently only serves just over one-quarter of its population of 784,000 with clean, safe drinking water. A lot of opportunity lies in water, sanitation and sewerage infrastructure development towards enhancing accessibility to safe water for residents.

2.12 Conceptual Framework

The study framework (Figure 2.2) demonstrates known factors that may influence the household cost of illness for patients seeking treatment in health care facilities. Patient

variables such as age, sex and residence determine predisposition to illness and by extension the direct and indirect costs, health facility factors such as facility type determine direct medical costs and economic factors determine access to health care. All factors considered together influence the total household cost of illness due to acute gastroenteritis.

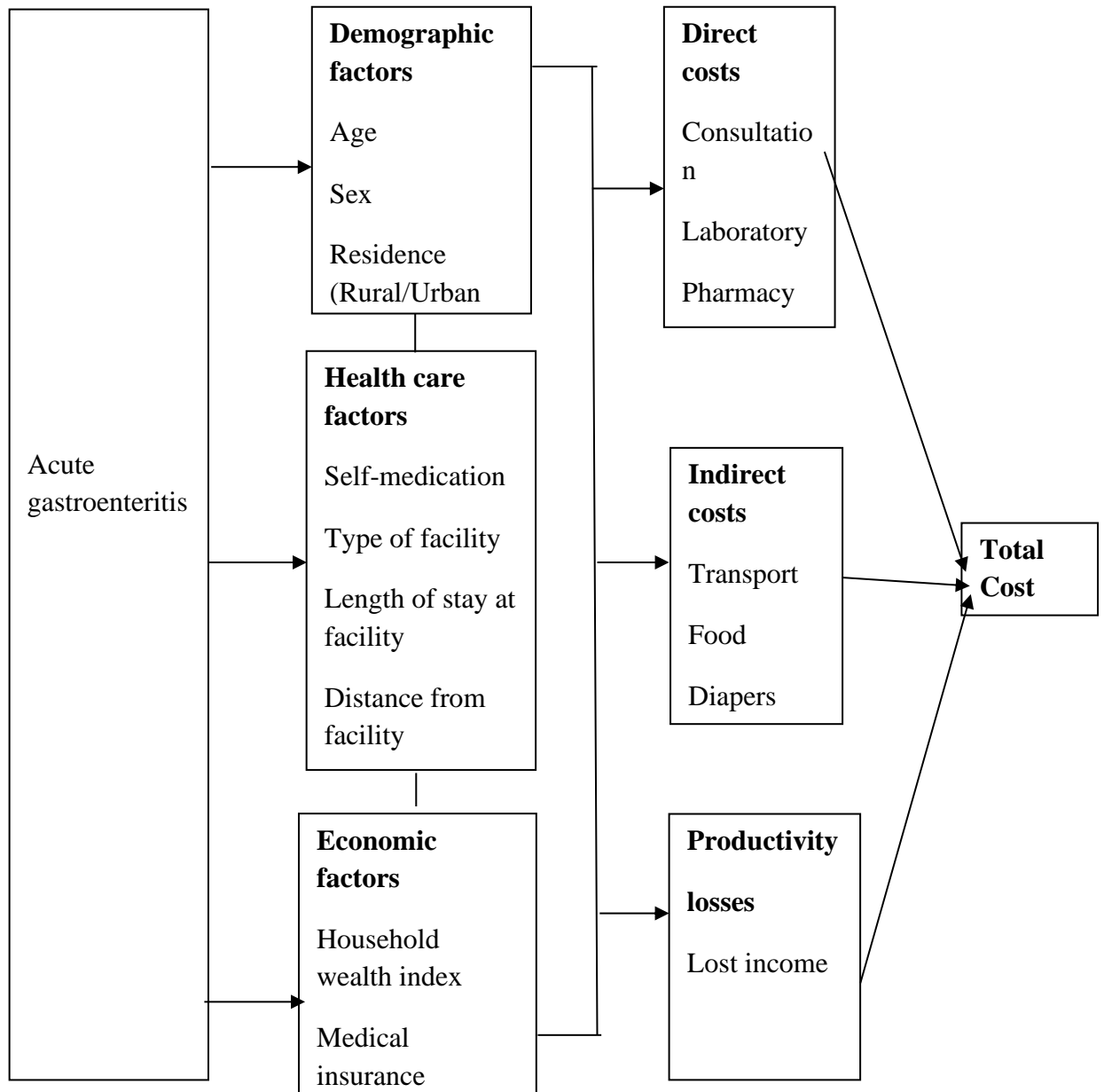


Figure 2: Conceptual framework adapted from (WHO_IVB_08.14_eng.Pdf, n.d.)

CHAPTER THREE

3.0 MATERIALS AND METHODOLOGY

3.1 Study area

Busia is a County in the former Western Province of Kenya. The County is divided into six sub-counties namely: Busia, Funyula, Nambale, Butula, Teso North & Teso South. The county covers an area of 1,628.4 square kilometres (Appendix III shows map of study area). The 2017 projected population for Busia was estimated at a total of 953,337(456,356 males and 496,981 females). Busia County has 62 public health facilities, 14 Faith based/NGO facilities and 8 private health facilities. Most reported diseases in year 2017 were malaria, respiratory diseases and diarrheal diseases (DHIS2, 2018). The dominant community in Busia are the Luhya who mainly earn their living as small scale farmers, producing maize, beans, groundnuts, cassava, sorghum, vegetables and fruits. The Teso engage in subsistence farming and trade in agricultural produce. On the other hand, the Luo - who mainly live in fishing villages near the shores of Lake Victoria, are fish farmers and traders. The Kenya population census of 2009 estimated 91.4% of Busia as being rural. Sanitation coverage in Busia County is also poor with estimated open defecation rate of 78.9% in rural areas and 40.3% in urban areas (KDHS 2014). Previous studies in western Kenya have indicated the presence of multiple zoonoses and foodborne diseases and in response the Zoonoses in Livestock in Kenya (ZooLinK) project was established in Busia, Bungoma and Kakamega Counties with the goal to support Kenya in the development of an effective surveillance programme for infectious diseases acquired through contact with animals or their products (Falzon et al., 2019). Four of the pathogens *Salmonella* spp., *E. coli*, *Campylobacter* spp. and *Staphylococcus* spp. are known aetiologies for gastroenteritis. Understanding the economic performance of the proposed surveillance system was a

key objective of the ZooLinK project. The current study was therefore designed as cost-of-illness for gastroenteritis was a key variable for calculating the cost-benefit of improved surveillance. This was a cross sectional study from a household perspective conducted in Busia County in 4 selected health care facilities. A Tertiary public health care facility (Busia County Referral Hospital located in Busia Township); A public primary health care facility (Burumba Dispensary located in Butula); a faith based health care facility (Holy Family Nangina Hospital located in Funyula) and a private health care facility (Tanaka Nursing Home located in Busia Township). The selected health care facilities attended to high numbers of diarrhoeal cases in the previous year 2019 in their respective categories in Busia County (DHIS2).

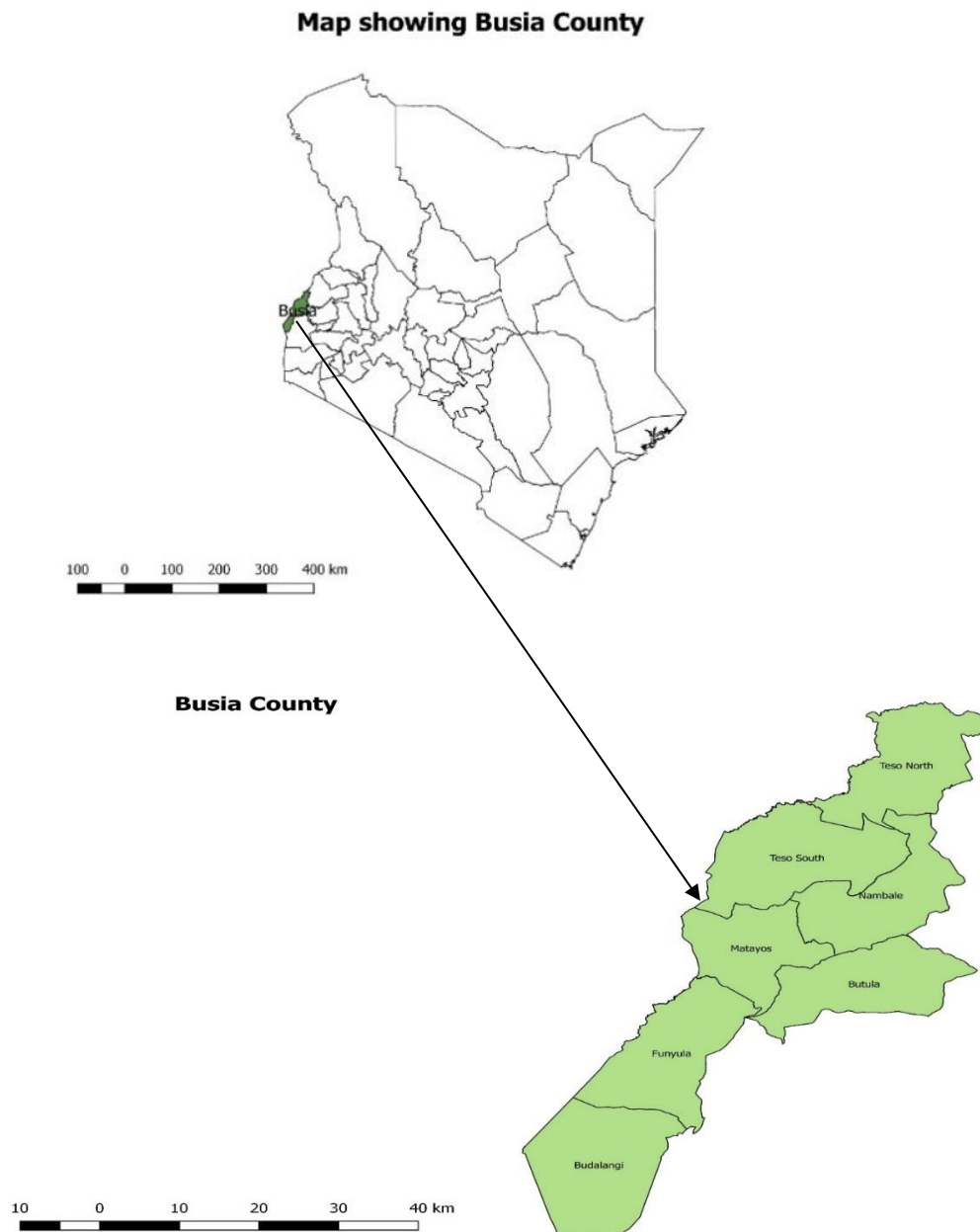


Figure 3: Map of study area

3.2 Study Design:

This was a cross sectional study from the perspective of the individual patient and their household to estimate costs due to one episode of acute gastroenteritis presenting at a health care facility.

3.3 Study Population:

The study population comprised of all eligible patients (or their parent/guardian in the case of children). An eligible participant was defined as follows: Any person above 6 months of age presenting with 3 or more episodes of diarrhoea in participating health facilities in Busia County. A case was defined as any individual with 3 or more loose stools or any vomiting in 24 hours residing in Busia County (MAJOWICZ et al., 2008).

3.4 Eligibility Criteria

3.4.1 Inclusion criteria

- Patients >6 months of age
- Recent onset of vomiting and/or diarrhoea, with or without fever or abdominal pain, not due to chronic disease

3.4.2 Exclusion criteria

- Patients with chronic diarrhea >14 days

3.5 Sample Size Determination

Sample size determination was arrived at using WHO guidelines for estimating economic burden of diarrheal diseases that bases the sample size on the number of cases in the previous year and the desired level of precision. The sample size calculation formula was as follows: $n = [(precision^2 / (CV^2 \times Z^2)) + (1/N_0)^{-1}]$, where Precision is 10%, CV is coefficient of variation = 0.5, Z is 1.96 for level of significance at $p = 0.05$ and N_0 is expected # of cases. For example, the selected public health care facilities had a combined total of 2734 cases in the past year, and a 10% level of precision is chosen, the sample size would be 92 patients.

$$[(0.1^2 / (0.5^2 \times 1.96^2)) + (1/2734)^{-1}] = 92.5.$$

This sample size was proportionately divided between the two health facilities based on the number of cases attended at each facility in the previous year.

WHO recommended that *table 3.1* be used to determine sample size for cost of illness studies on diarrheal diseases.

Table 2: WHO table for determining sample size of patients per facility (WHO_IVB_05.10.Pdf, n.d.).

Precision	10%					
Total number of cases in prior year	Coefficient of variation					
	0.25	0.5	0.75	1	1.5	2
100	20	49	69	80	90	94
200	22	65	104	132	163	177
500	23	81	151	218	317	378
1000	24	88	178	278	464	606
2000	24	92	196	323	604	869

With a total number of cases of 5,056 across the selected facilities, to achieve a 10% precision and 0.5 co-efficient of variation per facility, a sample size of 265 participants was recommended as shown in *table 3.2*.

Table 3: Sample size by facility type for economic burden of acute gastroenteritis in Busia County

Category	Facility	Diarrheal cases previous year (Total)	Recommended sample	Facility sample
Public	Busia County	1962	92	66
	Referral Hospital	772		26
		2734		

	Burumba Dispensary			
Faith based	Holy Family Nangina Hospital	421	81	81
Private	Tanaka Nursing Home	1901	92	92
Total				265

3.6 Sampling procedure

WHO guidelines on cost of illness calculation for diarrheal diseases recommended a sample of all categories of health facilities be included for any analysis that is from a societal perspective using the criteria shown in *Table 3.3*. Health care facilities per category with the highest number of diarrheal cases in the previous year were selected for the study. The recommended sample for each category of facilities was proportionately distributed based on total number of cases per facility in the previous year to get the sample size per facility.

Table 4: Health care facility selection by category of services offered

	Public	Mission/NGO	Private
Hospital based cases			
Tertiary Hospital Inpatient department	Busia County Referral	-	Tanaka Nursing Home

Secondary Hospital Inpatient department	-	Holy Family Nangina Hospital	-
Outpatient care			
Tertiary Hospital outpatient department	Busia County Referral	-	-
Secondary Hospital outpatient department	-	-	-
Primary health care providers	Burumba Dispensary	-	-

3.6.1 Participants recruitment

This was an incidence based cross-sectional study. Participants were selected using inclusion and exclusion criteria (Setia, 2016). All eligible patients meeting the case definition were referred by the physician on duty to the principal investigator. On meeting the patient, the aims and objectives of the study were explained and informed consent obtained. Parents or caretakers of children were asked to give consent for participation in the study. Those who consented were entered into the study. Recruitment continued consecutively until the sample size for each facility was attained.

3.7 Data Collection:

During the time the study was conducted, all health care facilities were fully operational and there were no restrictions on movement within counties. Four trained interviewers each stationed at one health care facility used smart phones to collect demographic and cost information from eligible patients or their caregivers. The questionnaires were translated into kiswahili language which the participants were most comfortable and

recorded in English. Patients, or in the case of minors their caregivers, were recruited at the health facilities. Data was collected using structured questionnaires. Data collection took place from 10th September, 2020 to 30th October, 2020. The questionnaires were used to collect information on the socio demographic characteristics of the respondents such as sex, age, education level, residence and information on current illness such as symptoms and duration of illness. Proxy measures of household wealth were collected and indicators used in this study were: household assets, housing conditions, household head education level and occupation. Household assets ownership was considered using an index of currently owned household and productive assets such as refrigerator and television. Household conditions included in the survey were access to electricity, source of household water, type of toilet facility, fuel used for cooking, floor and wall material of the main dwelling unit in the household.

Patients were also asked to provide cost information for their current visit to the health care facility as well as any previous expenditures for the current illness. The costs included direct and indirect costs. Direct costs consisted of healthcare costs and non-healthcare costs. Direct medical costs were defined as the medical care expenditures for diagnosis, treatment, and rehabilitation for hospitalised patients. Direct non-health care costs included costs like transportation, food, lodging and informal care of any kind while seeking treatment. Indirect costs referred to productivity losses due to the illness.

3.8 Quality assurance of study results

To ensure data quality, 10 % (26) questionnaires were pre-tested at Uguu Pole Clinic in Busia. This ensured that the questions were well understood and corrected any

ambiguous questions before using them in the main study. Data was collected by qualified and trained research assistants.

3.9 Patient illness characteristics

All eligible patients meeting the case definition were referred by the physician on duty to the data collectors. Patients were asked for details about clinical symptoms such as the appearance and frequency of stools and the occurrence of vomiting, fever and abdominal pain. Where the patient was referred to the laboratory, data on specimen collected and laboratory test done were recorded.

3.10 Cost estimation

To estimate the economic burden of acute gastroenteritis, patients were requested to provide information on costs related to managing the current episode of illness. The information sought included; costs for medical consultation, medicine, Laboratory and transportation.

Indirect costs were estimated using the human capital approach. Productive time lost for patients and accompanying caregivers was estimated as the reported duration of illness and time spent seeking treatment. For adults older than 18 years, the average daily wage rate for general laborers was used (Hailu et al., 2017). At the time of data collection, schools had been closed due to Corona virus pandemic. Therefore, in the case of minors below the minimum age of employment in Kenya (≤ 18 years old), only productivity losses for their accompanying caregivers were considered. Busia County has a high level of self or informal employment hence the basic daily minimum consolidated wages (KES 367) for unskilled employees prescribed by the Labour Institutions Act (Amendment order, 2018) of the laws of Kenya was used to convert the workdays lost into monetary value. We assumed an average workday of 8 hours per day and 22 working days per month (Oyando et al., 2019). We estimated the minimum

wage rate per month for general unskilled workers in Busia to be approximately KES 8,074 (US\$ 73.4). This study was from a household perspective and therefore the cost of illness generated represented the cost of illness per patient per episode of acute gastroenteritis.

3.11 Construction of wealth index and wealth tertile

Principal components analysis was used to calculate indicator weights and index values. The process involves standardization of indicator variables and calculation of factor coefficient score (factor loadings) for each household. The indicator values are then multiplied by the loadings and summed up to produce the household's index value (Karigi, 2014). Factor one of principal component analysis was used to represent the wealth index. The principal component yields a wealth index that assigns a larger weight to assets that vary the most across households so that an asset found in all households is given a weight of zero.

3.12 Wealth scores index

A wealth index was derived using principal component analysis using Ms Excel 2013 (add in XLSTAT 2020). Patient households were sorted by the asset index and cut off values for percentiles of the population were established. Households were then assigned to a group on the basis of their value of the index. The households were divided into a tertile comprising; Poor 40%, Middle 40% and Rich 20% (Filmer & Pritchett, 1998).

Table 5: Socio-economic score by tertile for acute gastroenteritis patients in Busia County, September 2020

Socio-economic status	n	Proportion (%)	Index range
Poor	89	40	-4.452 to -0.659
Middle	89	40	-0.618 to 1.858
Rich	45	20	1.888 to 3.779

The complete wealth scores (index) for the 223 households is shown in appendix iv.

3.13 Data analysis

All statistical analysis were performed using Microsoft Excel 2013 (Seattle, Washington).

Demographic and illness data was analyzed by calculating frequencies and proportions for categorical variables, and means, standard deviations, medians and interquartile range accordingly for continuous variables. Student's *t* Test was used to compare costs between individual independent variables. Household wealth index was calculated from household characteristics and asset data using principal component analysis. Households were divided into household wealth tertile (poor, middle and rich) according to their wealth index score. Total household costs associated with the current illness episode resulting in hospital management was obtained by summing total direct and indirect costs for the current health care facility visit.

To deal with skewed cost data, we used log transformation to obtain a more symmetrical distribution. Linear regression models were fitted to identify factors associated with variability of Logs of direct, indirect and total cost of acute gastroenteritis and p-values of less than 0.05 and 95% confidence intervals were considered significant. The outcome variable was total cost per episode of acute gastroenteritis and the independent

variables were patient sex, age, household wealth tertile, type of facility, mode of payment, whether the patient sought care prior to coming to the facility and whether patient was accompanied to facility. The results were presented in tables and figures.

Cost results are presented in KES and US Dollars (US\$) to allow for comparison with other studies. Cost in KES was converted to US\$ using the following exchange rate: US\$ 1 = KES 110 (average exchange rate, September- October 2020).

3.14 Ethical Consideration

Research license was granted by National Commission for Science Technology & Innovation (NACOSTI). Ethical approval for the study was obtained from Moi University IREC (Ref: IREC/2019/206) and from the County Department of Health in Busia. Facility managers were informed about the study and granted permission to access clinics and patients. Written consent was obtained from each participant. Parents, next of kin, or guardians responded on behalf of children. Data collected was used in confidence for the sole purpose of this study.

CHAPTER FOUR

4.0 RESULTS

4.1 Characteristics of study participants

A total of 249 participants enrolled in the study. Patients were aged between 1 to 85 years with a median age of 8 years, interquartile range (IQR) 2–21). Children under 5 years were 106 (42.6%) with 143 (57.4%) of patients being 5 years and older. More than half 143 (57.4%) of acute gastroenteritis patients were female and the majority 172 (69.9%) lived in Matayos Sub-County. More than half 168 (67.5%) of the households' heads had secondary and higher level of education but only 37 (14.9%) had attended tertiary level of education. Approximately half 130 (52.4%) of the patients came from households where the occupation of the household head was owned business. The mean household size was 4.9, standard deviation (SD) ± 2.1 .

Table 6: Characteristics of patients who provided information about household costs for management of acute gastroenteritis episodes in Busia County health facilities, September 2020

	n	Frequency	Percentage
Age (Years)	249		
<5		106	42.6
≥5		143	57.4
Sex	249		
Male		106	42.6
Female		143	57.4
Residence	246		
Matayos			
Samia		172	69.9
Teso South		30	12.2
Bunyala		20	8.1
Teso North		9	3.7
Butula		6	2.4
Nambale		5	2
		4	1.6
Education household head	249		
None		22	8.8
Primary		59	23.7
Secondary		131	52.6
Tertiary		37	14.9
Occupation	249		
Unemployed		75	30.2
Business		130	52.2
Salaried		44	17.7
Wealth index	223		
Poor		89	40
Middle		89	40
Rich		45	20

4.2 Illness characteristics of acute gastroenteritis patients

Out of the 249 participants, 134 (54%) were recruited at public facilities, 79 (32%) at private and 36 (14%) at Faith based health care facilities. Majority of the patients 224 (90%) were treated as outpatients and patients reported being ill for a median of 2 days (IQR 2–3) prior to seeking treatment at a health facility and a total of 69 (28%) of patients had sought treatment elsewhere prior to visiting the health care facility. All 104 patients with medical insurance visited private and faith based health care facilities. We excluded 6 patients with gastroenteritis because they suffered from co-infections. Of the 243 persons with acute gastroenteritis, 135 (55.6%) had diarrhea and vomiting, 106 (43.6%) had diarrhea without vomiting, and 2 (0.8%) had vomiting without diarrhea. The most frequently reported additional symptoms were fever 93(38.3%), abdominal cramps 72 (29.6%) and nausea 44 (18.1%). The average duration of illness was 3.3 days (SD 1.2).

Table 7: Illness characteristics of acute gastroenteritis patients treated at health care facilities in Busia County, Kenya, September 2020

	n	Frequency	Percentage
Health facility type	249		
Public		134	53.8
Private		79	31.7
Faith based		36	14.5
Admission type	249		
Outpatient		224	90
Inpatient		25	10
Signs/symptoms	243		
Diarrhoea		241	99.2
Vomiting		137	56.4
Abdominal cramps		72	29.6
Fever		93	38.3
Nausea		44	18.1
Mode of payment	225		
Cash		74	32.9
Medical insurance		104	46.2
Free primary health		47	20.9
Sought care prior to facility visit	249		
Yes		69	27.7
No		180	72.3

4.3 Costs incurred by patients in seeking health care

4.3.1 Out of pocket costs

The median out of pocket cost incurred by patients admitted for acute gastroenteritis episodes was KES 140; (IQR 100–250). Patients who had sought prior care for their present acute gastroenteritis episode had significantly higher out of pocket costs (median KES 150; IQR KES 130–300) compared to patients who had not sought prior

care (median of KES50, IQR 50-100) ($p = 0.0002$). Out of pocket costs varied significantly for children under 5 years (median 50; IQR 50-150) compared to patients over 5 years mean (median KES100; IQR 50-310) $p=0.0000$.

There was no significant difference in out of pocket costs for patients attending private hospitals (median KES150; IQR 100-200) compared to those attending public hospitals (median KES100; IQR 100-260) $p=0.18$. There was however a significant difference in costs for patients attending private (median KES150; IQR 100-200) compared to faith based (median KES225; IQR 100-845) $p= 0.0004$ as well as for patients attending public (median KES100; IQR 50-192.5) compared to faith based health care facilities (median KES225; IQR 100-845) $p= 0.002$.

There was no significant difference in out of pocket cost for patients paying cash (median KES100; IQR 100-360) compared to those with medical insurance (median KES140; IQR 100-200), $p=0.05$. There was no difference in out of pocket costs among the three socio-economic classes of poor, middle and rich.

Table 8: Out of pocket costs for acute gastroenteritis costs patients (KES) at Busia health facilities, September 2020

	n	Mean	Median	p-value
Facility ownership				
Public	112	218.7	100	
Private	75	183.5	150	0.18
Faith based	36	447.1	225	0.002
Cost by age				
<5	97	144.6	100	0.0000
≥5	120	320	200	
Sex				
Male	89	241.5	100	0.46
Female	133	246.3	140	
Payment				
Cash	122	274.9	100	0.05
Insurance	101	206	140	
Wealth tertile				
Poor	89	244.1	100	
Middle	89	248.1	140	0.47
Rich	45	241.8	150	0.48
Sought care prior				
Yes	69	396.7	250	0.0002
No	166	205.9	100	

4.3.2 Indirect costs

The average total indirect cost of one episode of acute gastroenteritis for patients visiting health care facilities in Busia was KES1,254.1; SD 462.3 (US\$11.4) The average indirect cost for patients was KES1,235.4; SD 456.9 (US\$11.2) while that for caregivers was KES1,195.8; SD 429 (US\$10.9).

4.3.3 Total incurred cost

This was calculated as a summation of total direct cost (out of pocket costs) and total indirect costs. The average total cost for patients visiting Public health care facilities was KES 1374.62; SD 502.21, Private KES 1461.11; SD 637.35 and Faith-based KES 1506.06; SD 477.45. The average total cost of seeking care for acute gastroenteritis patients in Busia was KES 1,497.8; SD 578.5 (US\$13.6).

4.4 Economic burden

Busia County has a high level of self or informal employment. Using the basic minimum consolidated wages of KES 367 (US\$3.3) for unskilled employees prescribed by the Labour Institutions Act (Amendment order, 2018) of the laws of Kenya, the minimum wage rate per month for general unskilled workers in Busia was estimated to be approximately KES 8,074 (US\$ 73.4).

The average out of pocket cost for patients was KES 243.6 (US\$2.2). This represents approximately 3% of monthly income and does not amount to catastrophic expenditure.

4.5 Factors that influence cost of illness

Prior treatment before seeking care significantly influenced both out of pocket ($p=0.0001$) and total costs, $p=0.0003$. Out of pocket costs for those who sought alternative care was 49% higher than OOP cost for those who did not seek alternative care while total cost was 27% higher for those who sought prior care compared to those who did not.

Being under 5 years old ($p = 0.02$) and being accompanied ($p = 0.03$) significantly influenced indirect costs. Indirect cost for under years were 10.97% higher than that for 5 years and above, while indirect costs for patients who were accompanied were 13.4% lower than that for patients who were not accompanied.

Paying cash as opposed to use of medical insurance significantly influenced the total cost, $p=0.03$. Total costs for patients paying cash was 15% higher than that for patients paying via medical insurance. Table 4.4 presents the multiple regression coefficients with 95% confidence interval for different factors associated with variability in cost of seeking treatment for acute gastroenteritis.

Table 9: Multiple linear regression of factors associated with cost variability and logs of direct, indirect and total cost of acute gastroenteritis, patients attending health facilities in Busia County, Kenya, 2020

LNOut of pocket Cost (n = 209, pseudo $r^2 = 0.1134$)

	<i>Coefficien</i>	<i>Standar</i>			<i>Lower</i>	<i>Upper</i>
	<i>ts</i>	<i>d Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>95%</i>	<i>95%</i>
			21.4340	1.04E-	4.43894	5.33844
Intercept	4.888693	0.22808	8	53	2	4
		0.11287	-	0.70635	-	0.17999
Sex	-0.04259	7	0.37729	6	0.26517	4
		0.11471	0.91753	0.35996	-	0.33146
Age<5	0.105257	7	7	7	0.12095	8
		0.12442	1.16168	0.24674	-	
Facility Public	0.144545	6	9	6	0.10081	0.3899
Facility		0.17535	-	0.21634	-	0.12830
Mission	-0.21748	6	1.24023	2	0.56327	2
		0.12398		0.00010	0.24536	0.73432
Prior Rx	0.489847	2	3.95096	8	8	6
			0.49747	0.61939	-	0.11302
Duration ill	0.022769	0.04577	9	8	0.06748	2
		0.14541	-	0.69183	-	0.22901
Accompanied	-0.05772	2	0.39694	4	0.34446	7
		0.11650	-	0.94954	-	0.22235
Payment Cash	-0.00738	4	0.06336	5	0.23711	2

LNIndirect Cost (n = 208, pseudo r² = 0.1049)

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
			67.4333		6.83026	
Intercept	7.036015	0.10434	5	5E-139	1	7.24177
		0.04780		0.34478	-	0.04899
Sex	-0.04527	6	-0.947	5	0.13954	9
		0.04719	2.32395	0.02113	0.01661	0.20274
Age<5	0.109679	5	3	7	3	6
			1.62107	0.10658	-	0.19208
Facility Public	0.086662	0.05346	2	6	0.01876	2
Facility		0.07324	-	0.16463	-	0.04227
Mission	-0.10216	4	1.39478	8	0.24659	5
		0.05246	0.60536	0.54562	-	0.13521
Prior Rx	0.031759	2	4	7	0.07169	2
		0.01958	0.76232	0.44676		0.05356
Duration ill	0.014934	9	9	6	-0.0237	3
		0.06235	-	0.03233	-	-
Accompanied	-0.13439	4	2.15532	8	0.25735	0.01143
		0.04973	1.54539	0.12383	-	0.17493
Payment Cash	0.07686	5	8	9	0.02121	6

LNTotal Cost (n = 209, pseudo r² = 0.1007)

	<i>Coefficien</i>	<i>Standar</i>			<i>Lower</i>	<i>Upper</i>
	<i>ts</i>	<i>d Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>95%</i>	<i>95%</i>
		0.13657	49.5843	2.5E-	6.50250	7.04111
Intercept	6.771808	1	9	114	4	3
		0.06758	-	0.74445	-	0.11121
Sex	-0.02206	9	0.32641	9	0.15534	8
		0.06869	0.12679	0.89922	-	0.14416
Age<5	0.00871	1	8	8	0.12674	2
		0.07450		0.89393	-	0.13696
Facility Public	-0.00995	5	-0.1335	2	0.15686	9
Facility		0.10500	-	0.39822	-	0.11815
Mission	-0.0889	1	0.84662	1	0.29595	5
		0.07423	3.66376	0.00031	0.12560	0.41838
Prior Rx	0.271993	9	8	8	2	4
		0.02740	0.46085	0.64540	-	0.06667
Duration ill	0.01263	6	3	5	0.04141	3
		0.08707	1.27460	0.20392	-	0.28267
Accompanied	0.110981	1	4	8	0.06071	5
		0.06976		0.02937	0.01550	0.29062
Payment Cash	0.153066	1	2.19415	7	5	7

Female reference category for sex

>5 years reference category for age

Private facility reference category for facility ownership dummy variables

Medical insurance reference category for mode of payment

CHAPTER FIVE

5.0 DISCUSSION

5.1 Characteristics of study participants

Acute gastroenteritis is a major cause of morbidity and mortality in children under five years and, therefore most previous studies targeted children. This study examined cases of acute gastroenteritis in patients of all ages. Nearly half of the patients consisted of children under 5 years of age which is consistent with findings of past studies (Dadonaite et al., 2018b). Patients in the age category of 5 years and above made up slightly more than half of persons seeking treatment. A study by Halim & Haider, 2017 in Bangladesh found an equally high frequency of diarrheal illness among older patients. Another study conducted in Netherlands reported a frequency of 14.8% in young adults (Doorduyn et al., 2012).

Females made up a slight majority of patients seeking treatment. This may be attributed to health seeking behavior among females. This was consistent with past studies that found near equal frequency in sex of patients seeking treatment (Sinmegn Mihrete et al., 2014). Another study in Bangladesh however found higher frequency in males than in females (Halim & Haider, 2017).

Busia is a predominantly rural county with approximately 10% of the population residing in urban areas (*Busia-Final-2017-.Pdf*, n.d.). This made it difficult to classify residences into urban and rural. Past studies have found higher frequency of acute gastroenteritis in patients residing in urban areas (Ecollan et al., 2020). The high frequency in urban areas could be due to effects of overcrowding (Thiam et al., 2017).

5.2 Illness characteristics of patients

Majority of patients seeking treatment visited public health care facilities followed by private and faith based facilities. Charges at public health care facilities were lower

compared to that in private and faith based facilities. In addition, children under the age of 5 years were treated for free in public health care facilities. A similar observation was made by Burke et al., 2014 in a study on economic burden of paediatric gastroenteritis in Bolivia.

Of the acute gastroenteritis cases in this study, 55.6% reported diarrhea and vomiting, 43.6% had diarrhea without vomiting and 0.8% had vomiting without diarrhea. This was in variance to a 2019 study in Netherlands where 13% had diarrhea and vomiting, 47% had diarrhea without vomiting, and 40% had vomiting without diarrhea (Pijnacker et al., 2019).

5.3 Costs of seeking treatment

Out of pocket costs for one episode of illness (excluding lost income) exceeded daily household income in 14.7% of cases treated. Out of pocket costs accounted for a small fraction of incurred costs (16%) and was consistent with literature from previous studies (Burke et al., 2014b).

In this study, productive time lost was used to estimate indirect costs due to illness. Lost wages were a substantial burden on families representing an average of 83% of incurred costs for outpatients. Past studies on household costs of diarrhoea also found that lost earnings represented a substantial proportion of the cost (Zimmermann et al., 2019). Another study estimated indirect costs at 89% of total incurred costs (Rheingans et al., 2012). Assumptions employed to convert the workdays lost into monetary value did not account for individual-level variations in actual or potential earning which varies with age. The same value of labour (i.e the average wage rate for agricultural workers) was considered for patients of legal working age in Kenya which is 18 years old and above. This could have potentially overestimated indirect costs among patients who were

unemployed prior to their illness or underestimated indirect costs among those who were employed.

The average total cost of illness per episode of acute gastroenteritis of KES 1,497.8 (US\$ 13.6). Past studies estimated the cost of primary care at a hospital in Kenya at US\$ 19.74 (Tate et al., 2009). Severe cases requiring inpatient admission would result in much higher costs and an even bigger strain on households.

5.4 Cost burden

The cost burden of acute gastroenteritis was described as a percentage of the monthly earnings of the households. Health care expenditure is considered catastrophic when out of pocket costs exceed 40% of household expenditure net of subsistence needs. The average out of pocket cost for acute gastroenteritis patients was approximately 3% of monthly income and did not amount to catastrophic expenditure. This was consistent with a study on economic impacts of diarrheal illness in three African countries (Rheingans et al., 2012). Other studies however found out of pocket costs exceeding 10% of household monthly income for hospitalized patients resulting in catastrophic health expenditure (Sarker et al., 2018b).

5.5 Factors that influence cost

Significant predictors of cost of illness identified were seeking prior care before visiting a facility and mode of payment whether cash or insurance.

Out of pocket and total costs for patients who sought prior care was significantly higher than costs incurred by patients who did not seek prior alternative care. Households incur costs for self-medication which if unsuccessful has the implication of worsening of an illness due to delayed treatment and possibly prolonging the recovery time. The findings concur with those of 2014 study in Bolivia that identified previous treatment as a predictor of cost (Burke et al., 2014b).

Being under 5 years and being accompanied significantly influenced indirect costs. Where an adult patient is accompanied to a health care facility, indirect costs would be incurred by both raising the cost of productivity losses. A similar observation was made in a 2016 cost of illness study in Bangladesh (Pavel et al., 2016).

Total costs were significantly higher for uninsured patients compared to insured patients. This was consistent with findings of a study in the USA and Canada which found that having medical insurance significantly influenced the cost of illness to the patient (Blackwell et al., 2009). This however differed with findings of a study in Germany where having medical insurance did not significantly affect the cost of illness to the patient (Heider et al., 2014). This was attributed to Germany's universal healthcare system where most direct costs of treatment are paid for by the state.

5.6 Limitations and mitigations

Assumptions employed to convert the workdays lost into monetary value did not account for individual-level variations in actual or potential earning which varies with age. The same value of labour (i.e the average wage rate for agricultural workers KES 367) was considered for patients of legal working age in Kenya which is 18 years old and above (Labour Institutions Act 2018 Amendment). This could have potentially overestimated indirect costs among patients who were unemployed prior to their illness or underestimated indirect costs among those who were employed.

As a mitigation measure, two different regression models were generated using two different outcome variables: Out of pocket costs which excludes productivity losses and Total Cost which includes productivity losses, to allow for comparison of predictors of cost variability taking into consideration the challenge of estimating indirect costs.

CHAPTER SIX

6.0 CONCLUSION & RECOMMENDATION

6.1 Conclusion

The average cost incurred for a single episode of acute gastroenteritis in Busia County was KES 1,497.8 (US\$13.6) which was high relatively high compared to household incomes. Lost wages due to illness represented a substantial proportion of the costs due to acute gastroenteritis. All patients with medical insurance visited either Faith based or Private health care facilities. The factors that influenced the total cost were self-medication before visiting a health care facility and whether or not the patients had medical insurance.

6.2 Recommendation

Busia County should encourage more residents to enrol in affordable health coverage plans targeting both formally employed and those in the informal sector, which is critical in reducing out of pocket costs and lessens the likelihood of catastrophic medical expenditure.

A larger majority of acute gastroenteritis cases are associated with contaminated food and water making them preventable through improvements in hygiene and sanitation. The County should utilise data from burden of illness studies in health planning and resource allocation towards mitigating the economic burden of illness for its residents. We recommend future studies on the possible benefits that might have been realised in reducing burden of diarrheal diseases as a result of Covid 19 mitigation measures in particular improved hand hygiene.

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APPENDICES

APPENDIX I

Table A. 1: Index for variables included in principle component analysis

Variable	index
Home ownership	
Homestead	1
Rented	2
Owned	3
Occupation	
Unemployed	1
Business	2
Salaried	3
Household head Education	
None	0
Primary complete	1
Secondary complete	2
Tertiary	3
Mode of payment	
Cash	1
Medical insurance	2
Source of Household water	
Spring	1
Borehole	2
Public tap	3
Piped into home	4
Toilet type	
Latrine	1
Flushed to septic/sewer/latrine	2
Wall material	
Mud	1
Timber	2
Brick	3

Stone	4
Floor material	
Earth	1
Dung	2
Cement	3
Ceramic tiles	4

APPENDIX II

Table A. 2: Factor scores for household wealth indicator variables in principal component analysis for acute gastroenteritis patients in Busia County, September 2020

Factor loadings:					
	F1	F2	F3	F4	F5
FacilityNumber	0.703	-0.409	0.408	-0.150	0.252
ResidenceNumber	-0.014	0.274	0.047	-0.116	0.082
EducationNumber	0.505	0.378	-0.107	0.071	-0.255
OccupationNumber	0.566	0.283	-0.188	0.205	-0.159
PaymentNumber	0.694	-0.386	0.373	-0.060	0.237
WaterNumber	0.007	0.002	0.610	0.237	-0.231
ToiletNumber	-0.129	0.229	0.601	0.233	0.062
WallNumber	-0.384	0.448	0.522	0.083	-0.236
FloorNumber	-0.341	0.369	0.581	0.101	-0.177
LandNumber	0.353	-0.475	-0.060	0.482	-0.379
LivestockNumber	0.388	-0.431	0.016	0.549	-0.336
ElectricityNumber	0.589	0.397	-0.106	-0.197	-0.242
Refrigerate	0.234	0.552	-0.095	0.438	0.316
Internet	0.673	0.150	0.022	0.128	0.186
CookElectricity	0.203	0.266	0.141	0.281	0.663
CookCharcoal	0.288	0.339	0.057	-0.423	-0.245
CookGas	0.550	0.393	-0.165	0.181	-0.058
CookKerosine	0.496	-0.355	0.390	-0.469	-0.058
CookFirewood	-0.491	-0.437	-0.048	0.346	0.120

APPENDIX III

Table A. 3: Factor loadings for individual acute gastroenteritis patient households' in Busia County, September 2020

Households unique identifier	Factor loading (weights)	Socio Economic Status
4	-4.452	Poor
77	-4.251	Poor
186	-3.917	Poor
50	-3.839	Poor
162	-3.828	Poor
159	-3.461	Poor
180	-3.425	Poor
137	-3.392	Poor
1	-3.344	Poor
26	-3.291	Poor
47	-3.280	Poor
90	-3.269	Poor
160	-3.186	Poor
46	-3.165	Poor
76	-3.126	Poor
152	-3.089	Poor
43	-3.065	Poor
70	-2.968	Poor
128	-2.884	Poor
45	-2.859	Poor
223	-2.836	Poor
164	-2.766	Poor
169	-2.745	Poor
27	-2.725	Poor
106	-2.717	Poor
60	-2.661	Poor
33	-2.634	Poor

2	-2.630	Poor
25	-2.587	Poor
136	-2.574	Poor
217	-2.562	Poor
105	-2.516	Poor
122	-2.440	Poor
23	-2.397	Poor
124	-2.394	Poor
41	-2.320	Poor
207	-2.218	Poor
61	-2.210	Poor
37	-2.175	Poor
38	-2.175	Poor
134	-2.164	Poor
168	-2.157	Poor
101	-2.148	Poor
195	-1.956	Poor
219	-1.922	Poor
3	-1.868	Poor
127	-1.854	Poor
135	-1.744	Poor
44	-1.642	Poor
118	-1.625	Poor
51	-1.611	Poor
149	-1.607	Poor
151	-1.502	Poor
126	-1.438	Poor
52	-1.421	Poor
68	-1.401	Poor
13	-1.388	Poor
15	-1.308	Poor
21	-1.250	Poor

154	-1.249	Poor
113	-1.232	Poor
39	-1.197	Poor
34	-1.194	Poor
37	-1.181	Poor
179	-1.170	Poor
67	-1.101	Poor
187	-1.067	Poor
96	-1.062	Poor
40	-1.057	Poor
119	-1.016	Poor
112	-0.987	Poor
6	-0.944	Poor
48	-0.941	Poor
58	-0.912	Poor
197	-0.909	Poor
8	-0.906	Poor
183	-0.898	Poor
103	-0.895	Poor
57	-0.868	Poor
95	-0.856	Poor
12	-0.771	Poor
10	-0.761	Poor
104	-0.761	Poor
42	-0.723	Poor
94	-0.705	Poor
36	-0.704	Poor
172	-0.696	Poor
89	-0.683	Poor
171	-0.678	Poor
102	-0.659	Poor
116	-0.618	Middle

117	-0.607	Middle
53	-0.604	Middle
36	-0.578	Middle
14	-0.560	Middle
121	-0.542	Middle
216	-0.522	Middle
91	-0.505	Middle
69	-0.482	Middle
64	-0.448	Middle
129	-0.447	Middle
49	-0.381	Middle
35	-0.365	Middle
150	-0.333	Middle
56	-0.263	Middle
16	-0.201	Middle
185	-0.155	Middle
147	-0.137	Middle
203	-0.103	Middle
167	-0.099	Middle
7	-0.031	Middle
200	0.070	Middle
115	0.138	Middle
17	0.153	Middle
18	0.159	Middle
161	0.164	Middle
199	0.173	Middle
173	0.184	Middle
9	0.263	Middle
92	0.305	Middle
65	0.311	Middle
83	0.404	Middle
93	0.404	Middle

22	0.413	Middle
59	0.435	Middle
222	0.506	Middle
114	0.519	Middle
211	0.526	Middle
125	0.577	Middle
163	0.584	Middle
86	0.640	Middle
108	0.647	Middle
181	0.730	Middle
142	0.764	Middle
178	0.769	Middle
62	0.792	Middle
170	0.851	Middle
81	0.885	Middle
184	0.894	Middle
88	0.901	Middle
218	0.912	Middle
205	0.931	Middle
107	0.994	Middle
63	0.995	Middle
109	1.005	Middle
208	1.005	Middle
97	1.014	Middle
30	1.118	Middle
54	1.118	Middle
153	1.124	Middle
182	1.261	Middle
82	1.304	Middle
131	1.304	Middle
72	1.307	Middle
212	1.318	Middle

174	1.320	Middle
100	1.352	Middle
141	1.367	Middle
111	1.381	Middle
157	1.394	Middle
66	1.419	Middle
35	1.438	Middle
78	1.453	Middle
79	1.484	Middle
80	1.484	Middle
29	1.532	Middle
202	1.635	Middle
130	1.659	Middle
32	1.678	Middle
196	1.729	Middle
192	1.761	Middle
220	1.770	Middle
198	1.813	Middle
98	1.819	Middle
143	1.858	Middle
73	1.888	Rich
120	1.919	Rich
31	1.926	Rich
85	1.961	Rich
194	1.980	Rich
156	1.989	Rich
206	2.053	Rich
175	2.074	Rich
99	2.096	Rich
55	2.187	Rich
213	2.192	Rich
133	2.210	Rich

190	2.218	Rich
84	2.261	Rich
210	2.269	Rich
214	2.270	Rich
144	2.280	Rich
74	2.319	Rich
148	2.322	Rich
39	2.381	Rich
87	2.418	Rich
215	2.457	Rich
221	2.460	Rich
110	2.625	Rich
146	2.631	Rich
138	2.634	Rich
140	2.634	Rich
191	2.634	Rich
176	2.635	Rich
165	2.638	Rich
20	2.707	Rich
193	2.760	Rich
209	2.769	Rich
201	2.828	Rich
188	2.854	Rich
38	2.934	Rich
139	2.958	Rich
158	2.965	Rich
166	3.047	Rich
123	3.057	Rich
132	3.060	Rich
75	3.063	Rich
145	3.408	Rich
177	3.408	Rich

189	3.414	Rich
204	3.580	Rich
155	3.771	Rich
71	3.779	Rich

**APPENDIX IV: CONSENT FORM
INFORMED CONSENT FORM**

Principal Investigator;

Gerald Munai, Kenya Field Epidemiology and Laboratory Training Program,
geraldmunai@gmail.com

Co-investigators:

Dr Lian Thomas, Institute of Infection and Global Health, University of Liverpool, UK
and ILRI, lian.thomas@liverpool.ac.uk

Name of Organization: Kenya Field Epidemiology and Laboratory Training Program
(FELTP) and ILRI (Zoo-link Project)

Name of Sponsor: Kenya Field Epidemiology and Laboratory Training Program
Name of Project and Version: Economic burden of acute gastroenteritis and associated
cost variability in patients attending health facilities in Busia County, Kenya

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form Economic burden of
acute gastroenteritis consent form

Part I: Information Sheet**Introduction**

I am Gerald Munai from the Kenya Field Epidemiology and Laboratory Training Program (FELTP) and a graduate fellow at ILRI. I am conducting a study on economic burden of acute gastroenteritis and associated cost variability in patients attending selected health facilities in Busia County, Kenya

Purpose of the research

I wish to estimate costs associated with seeking treatment for illness due to acute gastroenteritis and to identify the factors that influence these costs to provide specific recommendations to the Government on where to prioritize interventions towards reducing the cost of seeking healthcare for residents of the County. Specifically, I will seek to identify and quantify direct and indirect costs associated with seeking treatment for acute gastroenteritis in Busia County, Kenya

The results will be of use to policy makers and providers of health care in identifying gaps and areas that need improvement.

Type of study intervention

This study will involve your participation in one approximately 30 minute interview.

Participant Selection

You are being invited to take part in this study because we feel that your experience as a resident of the county affected by this illness and seeking health care in the County can contribute much to our understanding of the cost of seeking health care for this illness in the County.

Voluntary Participation

Your participation in this study is entirely voluntary. If you choose not to participate all the services you receive at the health facility will continue and nothing will change. The choice that you make will have no bearing on the kind of services you receive. You may change your mind later and stop participating even if you agreed earlier

Procedures

If you accept to participate, you will be asked to answer questions in the questionnaire

For interviews; you will participate in an interview with me.

If it is better for you, the interview can take place at the health facility or a public place.

If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there.

For questionnaire; the questionnaire will be filled on an electronic device. If you do not wish to answer any of the questions included in the questionnaire, you may ask us to skip them and move on to the next question.

Risks

There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable. You do not have to give us any reason for not responding to any question or for refusing to take part in the interview"

Benefits

There will be no direct benefit to you, but your participation is likely to help us understand the cost of seeking health care due to acute gastroenteritis. The results of the evaluation will be of use to policy makers and providers of health care in identifying gaps and areas that need improvement

Reimbursements

You will not be provided any incentive to take part in the research.

Confidentiality

For questionnaires and interviews;

We will not be sharing information about you or the information you give us with anyone outside of the evaluation team. Any information about you will have a number

on it instead of your name. Only the researchers will know what your number is and it will be kept in a secure location

Sharing the Results; the knowledge that we get from this exercise will be shared with you and other stakeholders before it is made widely available to the public. There will also be dissemination meetings at the national and county levels and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the exercise.

Right to Refuse or Withdraw;

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. We will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Principal Investigator;

Gerald Munai, Field Epidemiology and Laboratory Training Program,
geraldmunai@gmail.com

Co-investigator:

Dr Lian Thomas, Institute of Infection and Global Health, University of Liverpool, UK
and ILRI, lian.thomas@liverpool.ac.uk

**Dr. Elvis Oyugi, Kenya Field Epidemiology and Laboratory Training Program,
eoyugi@feltp.or.ke**

This proposal has been reviewed and approved by Moi University IREC, which is a committee whose task it is to make sure that research participants are protected from

harm. If you wish to find out more about the Moi University IREC, contact irecmtrh@gmail.com.

You can ask me any more questions about any part of the evaluation exercise, if you wish to. Do you have any questions?

Part II: Certificate of Consent

I have been invited to participate in a study on Economic burden of acute gastroenteritis and associated cost variability in patients attending selected health facilities in Busia County, Kenya

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the evaluator/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

—

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

ASSENT FORM**Principal Investigator;**

**Gerald Munai, Kenya Field Epidemiology and Laboratory Training Program,
geraldmunai@gmail.com**

Co-investigators:

**Dr Lian Thomas, Institute of Infection and Global Health, University of Liverpool,
UK and ILRI, lian.thomas@liverpool.ac.uk**

**Dr. Elvis Oyugi, Kenya Field Epidemiology and Laboratory Training Program,
eoyugi@feltp.or.ke**

**Name of Organization: Kenya Field Epidemiology and Laboratory Training
Program (FELTP) and International Livestock Research Institute (ILRI)**

**Economic burden of acute gastroenteritis and associated cost variability in
patients attending health facilities in Busia County, Kenya**

Part I: Information Sheet**Introduction**

I am Gerald Munai from the Kenya Field Epidemiology and Laboratory Training Program (FELTP) and a graduate fellow at ILRI. I am conducting a study on economic burden of acute gastroenteritis and associated cost variability in patients attending selected health facilities in Busia County, Kenya.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain.

Purpose:

I wish to estimate costs associated with seeking treatment for illness due to acute gastroenteritis and to identify the factors that influence these costs to provide specific recommendations to the Government on where to prioritize interventions towards reducing the cost of seeking healthcare for residents of the County.

Participation is voluntary:

You don't have to be in this study if you don't want to be. It is up to you. If you decide not to be in the study, it is okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it is still okay.

Procedures:

If you accept to participate, you will be asked to answer questions in the questionnaire. This study will involve your participation in one 30 minute interview.

Risks:

There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

Benefits

There will be no direct benefit to you, but your participation is likely to help us understand the cost of seeking health care due to acute gastroenteritis. The results of the evaluation will be of use to policy makers and providers of health care in identifying gaps and areas that need improvement

Reimbursements

You will not be provided any incentive to take part in the research.

Confidentiality

For questionnaires and interviews;

We will not be sharing information about you or the information you give us with anyone outside of the study team.

Right to Refuse or Withdraw;

You do not have to take part in this study if you do not wish to do so, and choosing to participate will not affect you in any way. You may stop participating in the [discussion/interview] any time you wish without being affected. We will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact

You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.

Principal Investigator;

Gerald Munai, Field Epidemiology and Laboratory Training Program,
geraldmunai@gmail.com

Co-investigator:

Dr Lian Thomas, Institute of Infection and Global Health, University of Liverpool, UK
and ILRI, lian.thomas@liverpool.ac.uk

PART 2: Certificate of Assent

I have read this information (or heard the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the study.

OR

I do not wish to take part in the research and I have not signed the assent below. _____ (initialled by child/minor)

Only if child assents:

Print name of child _____

Signature of child: _____

Date: _____

day/month/year

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

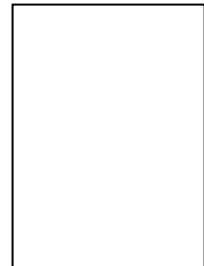
I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent)_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year



APPENDIX V: Questionnaire for Acute gastroenteritis patients at recruitment**Patient information questionnaire****Questionnaire information**

1. Questionnaire number: _____
2. Date of interview: _____
3. Interviewer: _____
4. Health facility name: _____
5. Health facility type
 - a) Public (Tertiary, Secondary, Primary)
 - b) Mission/ NGO
 - c) Private

Patient information

6. Patient unique I.D : _____
7. Phone contact: _____
8. Date of admission: _____
9. Date of discharge: _____
10. Admission type
 - a) Outpatient
 - b) Inpatient
11. Patient age/ Date of birth: _____
12. Patient sex
 - a) Male
 - b) Female
13. Patient Sub-county of residence: Teso North, Teso South, Matayos, Nambale, Butula, Bunyala, Samia
14. Patient area of residence
 - a) Urban
 - b) Rural
15. Level of education of head of household
 - a) None
 - b) Primary complete
 - c) Secondary complete

- d) Tertiary complete
- 16. Occupation of head of household
 - a) Salaried employment
 - b) Wage employment
 - c) Business person
 - d) Unemployed

Patient diagnostic history

- 17. Number of days of illness before seeking healthcare

- 18. What symptoms are you currently experiencing
 - a) Diarrhoea
 - b) Vomiting
 - c) Abdominal pain
 - d) Nausea
 - e) Fever
- 19. What was the admission diagnosis

- 20. What is the final diagnosis _____
- 21. Did you have any co-infections (verify from patient treatment records)
 - a) Yes
 - b) No
- 22. Specify co-morbidity _____
- 23. Length of stay at facility in hours

- 24. Were any samples collected for laboratory
 - a) Yes
 - b) No
- 25. Which samples
 - a) Stool
 - b) Blood
 - c) Other specify
- 26. Which diagnostic tests were used (verify from treatment records)
 - a) No test

- b) Stool culture
 - c) Blood count
 - d) Blood culture
 - e) Other specify
27. Was any medicine prescribed
- a) Yes
 - b) No
28. What medicines were prescribed

Name of drug	Route	Dose	Treatment duration

29. Was the medicine dispensed at the facility
- a) Yes
 - b) No
30. How much did you pay for treatment at the facility (Obtain from billing records/ receipt)
- a) Registration _____
 - b) Consultation _____
 - c) Laboratory _____
 - d) Medicine _____

Thank you

APPENDIX VI: QUESTIONNAIRE FOR OUT OF POCKET COSTS**Out of pocket costs questionnaire****Facility information**

1. Facility name:

2. Type of facility

a) Public (Tertiary, Secondary, Primary)

b) Mission/ NGO

c) Private

Patient information

3. Patient unique ID:

4. Sex

a) Male

b) Female

5. Age/ Date of birth:

6. Informed consent date:

Care giver information

7. Was patient accompanied to the health facility

a) Yes

b) No

8. If yes, by who (Relationship to patient)

a) Parent

b) Sibling

c) Grandparent

d) Other relative

e) Friend

f) Other specify:

Travel information

9. How far is your home from the facility? (Approximate distance in Kilometres one way) _____
10. How much time did it take you to travel from home to facility? (Approximate time in minutes) _____
11. What kind of transportation did you use to come to the facility?
- a) Personal car
 - b) Public bus transport
 - c) Taxi
 - d) Motor cycle
 - e) Bicycle
 - f) By foot
 - g) Boat
 - h) Ambulance
12. If you paid for transport to the health facility, how much did you pay? (KES) _____ (Put zero (0) if no payment was made)
13. How many trips did you or any other relative make to the health facility due to this illness? _____
14. What was the duration of illness in days?

Treatment costs

15. Before visiting the health facility, did you seek any other treatment?
- a) Yes
 - b) No
16. If yes, where from?
- a) Pharmacy
 - b) Private clinic
 - c) Shop
 - d) Traditional healer
 - e) Friend
 - f) Other specify _____

17. If you incurred any cost, how much? (If none put zero)

18. Did you lose some income as a result of being at the facility due to the illness?

a) Yes

b) No

19. If you were not at the health facility, what would you have been doing?

a) Salaried work

b) Daily wage work

c) Business

d) Housework

e) School

f) Nothing

g) Other specify _____

20. If you were accompanied, what would the person who accompanied you have been doing had they not come to the facility

a) Salaried work

b) Daily wage work

c) Business

d) Housework

e) School

f) Nothing

g) Other

specify

21. Mode of payment

a) Cash

b) Credit card

c) Medical insurance

22. What is the total number of people in your household

a) Children _____

b) Adults _____

23. Has the household had to resort to coping strategies to compensate for the direct and indirect costs due to the illness?

a) Yes

b) No

24. If yes, which ones?
- a) Borrowing
 - b) Skipping meals
 - c) Selling household assets
 - d) Doing manual work

Household Economic information

25. What is the source of drinking water for your household
- a) Piped into home
 - b) Public tap
 - c) Borehole/ Tube well
 - d) Protected well
 - e) Spring Protected or unprotected
 - f) Rain water
 - g) Tanker truck
 - h) Bottled water
26. Type of toilet facility in household
- a) Flushed to sewer
 - b) Flushed to septic
 - c) Flush to Pit latrine
 - d) Pit latrine with slab or without
 - e) Bucket toilet
 - f) Public facility
 - g) No facility
27. Do you have electricity?
- a) Yes
 - b) No
28. Do you have access to any of the following?
- a) T.V
 - b) Radio
 - c) Microwave
 - d) DVD player
 - e) Mobile phone
29. Do you refrigerate your food?

a) Yes

b) No

30. What type of fuel do you use to cook?

a) Electricity

b) Gas

c) Biogas

d) Kerosine

e) Charcoal

f) Firewood

31. What type of floor does your home have?

a) Earth

b) Dung

c) Wood planks

d) Cement

e) Ceramic tiles

f) Polished wood

g) Carpet

32. What type of walls does your home have?

a) Stone

b) Bricks

c) Cement blocks

d) Wood

e) Iron sheet

f) Dung/ Mud

33. How many members of your household per sleeping room?

34. Do you own livestock?

35. What species?

36. Main form of transportation?

a) Walking

b) Bicycle

c) Motorcycle owned

d) Bodaboda

e) Matatu

f) Taxi

APPENDIX VII: CONSENT FORM IN KISWAHILI

Sehemu ya I: Karatasi ya Taarifa

Utangulizi

Mimi ni Gerald Munai kutoka Kenya Field Epidemiology and Laboratory Training Program (FELTP) na mhitimu mwenzake katika ILRI. Ninafanya utafiti kuhusu mzigo wa kiuchumi wa ugonjwa wa gastroenteritis kali na kutofautiana kwa gharama zinazohusiana na wagonjwa wanaohudhuria vituo vya afya vilivyochaguliwa katika Kaunti ya Busia, Kenya.

Madhumuni ya utafiti

Natamani kukadiria gharama zinazohusiana na kutafuta matibabu ya ugonjwa unaosababishwa na ugonjwa wa gastroenteritis kali na kubainisha mambo yanayoathiri gharama hizi ili kutoa mapendekezo mahususi kwa Serikali kuhusu mahali pa kuweka kipaumbele katika kupunguza gharama ya kutafuta huduma za afya kwa wakazi wa Kaunti hiyo. Hasa, nitatafuta kutambua na kuhesabu gharama za moja kwa moja na zisizo za moja kwa moja zinazohusiana na kutafuta matibabu ya ugonjwa wa tumbo katika Kaunti ya Busia, Kenya.

Matokeo yatatumika kwa watunga sera na watoa huduma za afya katika kutambua mapungufu na maeneo yanayohitaji kuboreshwa.

Aina ya uingiliaji wa masomo

Utafiti huu utahusisha ushiriki wako katika mahojiano ya takribani dakika 30.

Uteuzi wa Mshiriki

Unaalikwa kushiriki katika utafiti huu kwa sababu tunahisi kwamba uzoefu wako kama mkazi wa kaunti iliyoathiriwa na ugonjwa huu na kutafuta huduma za afya katika Kaunti hii unaweza kuchangia sana uelewa wetu wa gharama ya kutafuta huduma za afya kwa ugonjwa huu katika kata.

Kushiriki kwa Hiari

Ushiriki wako katika utafiti huu ni wa hiari kabisa. Ukiamua kutoshiriki huduma zote unazopokea kwenye kituo cha afya zitaendelea na hakuna kitakachobadilika. Chaguo

utakalofanya halitakuwa na athari kwa aina ya huduma utakazopokea. Unaweza kubadilisha mawazo yako baadaye na kuacha kushiriki hata kama ulikubali mapema

Taratibu

Ukikubali kushiriki, utaulizwa kujibu maswali kwenye dodoso

Kwa mahojiano;utashiriki katika mahojiano nami.

Ikiwa ni bora kwako, mahojiano yanaweza kufanyika katika kituo cha afya, nyumbani kwako au mahali pa umma. Ikiwa hutaki kujibu lolote kati ya maswali wakati wa mahojiano, unaweza kusema hivyo na mhojiwa ataendelea na swali linalofuata. Hakuna mtu mwingine ila mhojiwa atakuwepo isipokuwa ungependa mtu mwingine awepo.

Kwa dodoso;dodoso litajazwa kwenye kifaa cha kielektroniki.Ikiwa hutaki kujibu swali lolote kati ya maswali yaliyojumuishwa kwenye dodoso, unaweza kutuuliza tuyaruke na kuendelea na swali linalofuata.

Hatari;

Kuna hatari kwamba unaweza kushiriki baadhi ya taarifa za kibinafsi au za siri kwa bahati mbaya, au kwamba unaweza kujisikia wasiwasi kuzungumza kuhusu baadhi ya mada. Hata hivyo, hatutaki hili litokee. Sio lazima kujibu swali lolote au kushiriki katika majadiliano/mahojiano/utafiti ikiwa unahisi kuwa swali/maswali ni ya kibinafsi sana au ikiwa kuyazungumza kunakufanya ukose raha. Sio lazima utupe sababu yoyote ya kutojibu swali lolote au kukataa kushiriki katika mahojiano"

Faida

Hakutakuwa na manufaa ya moja kwa moja kwako, lakini ushiriki wako unaweza kutusaidia kuelewa gharama ya kutafuta huduma ya afya kutokana na ugonjwa wa gastroenteritis kali. Matokeo ya tathmini yatatumika kwa watunga sera na watoa huduma za afya katika kubaini mapungufu na maeneo yanayohitaji kuboreshwa.

Marejesho

Hutapewa motisha yoyote ya kushiriki katika utafiti.

Usiri

Kwa dodoso na mahojiano;

Hatutakuwa tunashiriki maelezo kukuhusu au maelezo unayotupa na mtu yeyote nje ya timu ya kutathmini. Taarifa yoyote kukuhusu itakuwa na nambari badala ya jina lako. Watafiti pekee ndio watakaojua nambari yako ni ipi na itawekwa mahali salama

Kushiriki Matokeo; Maarifa tunayoyapata kutokana na zoezi hili yatashirikishwa na wewe na wadau wengine kabla ya kuwekwa wazi kwa umma. Pia kutakuwa na mikutano ya uenezaji katika ngazi ya kitaifa na kaunti na hii itatangazwa. Kufuatia mikutano, tutachapisha matokeo ili watu wengine wanaopendezwa wajifunze kutokana na zoezi hilo.

Haki ya kukataa au kujitoa;

Si lazima ushiriki katika utafiti huu ikiwa hutaki kufanya hivyo, na kuchagua kushiriki hakutaathiri kazi yako au tathmini zinazohusiana na kazi kwa njia yoyote ile. Unaweza kuacha kushiriki katika [majadiliano/mahojiano] wakati wowote unaotaka bila kazi yako kuathiriwa. Tutakupa fursa mwishoni mwa mahojiano/majadiliano ya kukagua maoni yako, na unaweza kuomba kurekebisha au kuondoa sehemu hizo, ikiwa hukubaliani na madokezo yangu au kama sikukuelewa ipasavyo.)

Nani wa Kuwasiliana

Ikiwa una maswali yoyote, unaweza kuwauliza sasa au baadaye. Ikiwa ungependa kuuliza maswali baadaye, unaweza kuwasiliana na yoyote kati ya yafuatayo:

Mpelelezi Mkuu;

Gerald Munai, Mpango wa Mafunzo ya Epidemiology na Maabara,
geraldmunai@gmail.com

Mchunguzi mwenz:

Dk Lian Thomas, Taasisi ya Maambukizi na Afya Ulimwenguni, Chuo Kikuu cha Liverpool, Uingereza na ILRI, lian.thomas@liverpool.ac.uk

Dkt. Elvis Oyugi, Mpango wa Mafunzo ya Maabara na Maabara ya Kenya, Dk. Elvis Oyugi,
eoyugi@feltp.or.ke

Pendekezo hili limepitiwa na kupitishwa na Chuo Kikuu cha Moi IREC, ambayo ni kamati ambayo kazi yake ni kuhakikisha kuwa washiriki wa utafiti wanalindwa dhidi

ya madhara. Ikiwa ungependa kujua zaidi kuhusu IREC ya Chuo Kikuu cha Moi, wasilianairecmtrh@gmail.com.

Unaweza kuniuliza maswali yoyote zaidi kuhusu sehemu yoyote ya zoezi la tathmini, ukipenda. Je, una maswali yoyote?

Sehemu ya II: Cheti cha Idhini

Nimealikwa kushiriki katika utafiti kuhusu mzigo wa Kiuchumi wa ugonjwa wa tumbo kali na kutofautiana kwa gharama zinazohusiana na wagonjwa wanaohudhuria vituo vya afya vilivyochaguliwa katika Kaunti ya Busia, Kenya.

Nimesoma habari iliyotangulia, au imesomwa kwangu. Nimepata fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyouliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kuwa mshiriki katika utafiti huu.

Chapisha Jina la Mshiriki _____

Sahihi ya Mshiriki _____

Tarehe _____

Siku/mwezi/mwaka

Taarifa ya mtathmini/mtu anayekubali

Nimesoma karatasi ya habari kwa usahihi kwa mshiriki anayetarajiwa, na kwa kadiri ya uwezo wangu nilihakikisha kwamba mshiriki anaelewa kuwa yafuatayo yatafanyika:

Ninathibitisha kwamba mshiriki alipewa fursa ya kuuliza maswali kuhusu utafiti, na maswali yote yaliyoulizwa na mshiriki yamejibiwa kwa usahihi na kwa uwezo wangu wote. Ninathibitisha kuwa mtu huyo hajalazimishwa kutoa idhini, na idhini imetolewa kwa hiari na kwa hiari.

Nakala ya Fomu hii ya Idhini iliyoarifiwa imetolewa kwa mshiriki.

Chapisha Jina la Mtafiti/mtu anayepokea kibali _____

Sahihi ya Mtafiti/mtu anayechukua ridhaa

Tarehe _____

Siku/mwezi/mwaka

FOMU YA KURIDHIA**Mpelelezi Mkuu;****Gerald Munai, Mpango wa Mafunzo ya Epidemiolojia na Maabara ya Kenya,
geraldmunai@gmail.com****Wachunguzi-wenza:****Dk Lian Thomas, Taasisi ya Maambukizi na Afya Ulimwenguni, Chuo Kikuu cha
Liverpool, Uingereza na ILRI, lian.thomas@liverpool.ac.uk****Dkt. Elvis Oyugi, Mpango wa Mafunzo ya Maabara na Maabara ya Kenya, Dk.
Elvis Oyugi, eoyugi@feltp.or.ke****Jina la Shirika: Kenya Field Epidemiology and Laboratory Training Program
(FELTP) na Taasisi ya Kimataifa ya Utafiti wa Mifugo (ILRI)****Mzigo wa kiuchumi wa gastroenteritis ya papo hapo na kutofautiana kwa
gharama zinazohusiana na wagonjwa wanaohudhuria vituo vya afya katika
Kaunti ya Busia, Kenya**

Sehemu ya I: Karatasi ya Taarifa

Utangulizi

Mimi ni Gerald Munai kutoka Kenya Field Epidemiology and Laboratory Training Program (FELTP) na mhitimu mwenzake katika ILRI. Ninafanya utafiti kuhusu mzigo wa kiuchumi wa ugonjwa wa gastroenteritis kali na kutofautiana kwa gharama zinazohusiana na wagonjwa wanaohudhuria vituo vya afya vilivyochaguliwa katika Kaunti ya Busia, Kenya.

Nitakupa taarifa na kukualika kuwa sehemu ya utafiti wa utafiti. Unaweza kuchagua kama unataka kushiriki au la. Tumejadili utafiti huu na mzazi/mlezi wako na wanajua kwamba tunakuomba pia makubaliano yako. Ikiwa utashiriki katika utafiti, mzazi/mlezi wako pia atalazimika kukubaliana. Lakini ikiwa hutaki kushiriki katika utafiti, si lazima, hata kama wazazi wako wamekubali.

Unaweza kujadili jambo lolote katika fomu hii na wazazi wako au marafiki au mtu mwingine yeyote unayejisikia vizuri kuzungumza naye. Unaweza kuamua kushiriki au kutoshiriki baada ya kulizungumza. Huna budi kuamua mara moja.

Huenda kuna baadhi ya maneno huelewi au mambo ambayo unataka nieleze zaidi kwa sababu una nia au wasiwasi. Tafadhali naomba nisimame wakati wowote na nitachukua muda kueleza.

Kusudi:

natamanikukadiria gharama zinazohusiana na kutafuta matibabu ya ugonjwa unaosababishwa na ugonjwa wa gastroenteritis kali na kubainisha mambo yanayoathiri gharama hizi ili kutoa mapendekezo mahususi kwa Serikali kuhusu mahali pa kuweka kipaumbele katika kupunguza gharama ya kutafuta huduma za afya kwa wakazi wa Kaunti hiyo.

Kushiriki ni kwa hiari:

Si lazima uwe katika utafiti huu ikiwa hutaki kuwa. Ni juu yako. Ukiamua kutokuwepo kwenye utafiti, ni sawa na hakuna kinachobadilika. Hii bado ni kliniki yako, kila kitu kinakaa sawa na hapo awali. Hata ukisema "ndiyo" sasa, unaweza kubadilisha mawazo yako baadaye na bado ni sawa.

Taratibu:

Ukikubali kushiriki, utaulizwa kujibu maswali kwenye dodoso.

Utafiti huu utahusisha ushiriki wako katika mahojiano moja ya dakika 30.

Hatari:

Kuna hatari kwamba unaweza kushiriki baadhi ya taarifa za kibinafsi au za siri kwa bahati mbaya, au kwamba unaweza kujisikia wasiwasi kuzungumza kuhusu baadhi ya mada. Hata hivyo, hatutaki hili litokee. Sio lazima kujibu swali lolote au kushiriki katika majadiliano/mahojiano/utafiti ikiwa unahisi kuwa swali/maswali ni ya kibinafsi sana au ikiwa kuyazungumza kunakufanya ukose raha.

Faida

Hakutakuwa na manufaa ya moja kwa moja kwako, lakini ushiriki wako unaweza kutusaidia kuelewa gharama ya kutafuta huduma ya afya kutokana na ugonjwa wa gastroenteritis kali. Matokeo ya tathmini yatatumika kwa watunga sera na watoa huduma za afya katika kubaini mapungufu na maeneo yanayohitaji kuboreshwa.

Marejesho

Hutapewa motisha yoyote ya kushiriki katika utafiti.

Usiri

Kwa dodoso na mahojiano;

Hatutashiriki maelezo kukuhusu au taarifa utakayotupa na mtu yeyote nje ya timu ya utafiti.

Haki ya kukataa au kujitoa;

Si lazima ushiriki katika utafiti huu ikiwa hutaki kufanya hivyo, na kuchagua kushiriki hakutakuathiri kwa njia yoyote ile. Unaweza kuacha kushiriki katika [majadiliano/mahojiano] wakati wowote unapotaka bila kuathiriwa. Tutakupa fursa mwishoni mwa mahojiano/majadiliano ya kukagua maoni yako, na unaweza kuomba kurekebisha au kuondoa sehemu hizo, ikiwa hukubaliani na madokezo yangu au kama sikukuelewa ipasavyo.)

Nani wa Kuwasiliana

Unaweza kuniuliza maswali sasa au baadaye. Unaweza kumuuliza muuguzi maswali. Nimekuandikia nambari na anwani ambapo unaweza kutufikia au, ikiwa uko karibu, unaweza kuja kutuona. Ikiwa unataka kuzungumza na mtu mwingine unayemjua kama mwalimu wako au daktari au shangazi yako, hiyo ni sawa pia.

Mpelelezi Mkuu;

Gerald Munai, Mpango wa Mafunzo ya Epidemiology na Maabara,
geraldmunai@gmail.com

Mchunguzi mwenza:

Dk Lian Thomas, Taasisi ya Maambukizi na Afya Ulimwenguni, Chuo Kikuu cha
Liverpool, Uingereza na ILRI, lian.thomas@liverpool.ac.uk

SEHEMU YA 2: Cheti cha Idhini

Nimesoma habari hii (au nimesikia habari nikisomwa) nimejibiwa maswali yangu na ninajua kuwa ninaweza kuuliza maswali baadaye ikiwa ninayo.

Ninakubali kushiriki katika utafiti.

AU

Sitaki kushiriki katika utafiti na sijatia saina kibali kilicho hapa chini._____ (iliyoanzishwa na mtoto/mtoto)

Ikiwa tu mtoto atakubali:

Chapisha jina la mtoto _____

Sahihi ya mtoto: _____

Tarehe: _____

siku/mwezi/mwaka

Kama hawajui kusoma na kuandika:

Shahidi anayejua kusoma na kuandika lazima atie sahihi (ikiwezekana, mtu huyu anapaswa kuchaguliwa na mshiriki, asiwe mzazi, na asiwe na uhusiano na timu ya utafiti). Washiriki ambao hawajui kusoma na kuandika wanapaswa kujumuisha alama za vidole gumba pia.

Nimeshuhudia usomaji sahihi wa fomu ya idhini kwa mtoto, na mtu binafsi amepata fursa ya kuuliza maswali. Ninathibitisha kuwa mtu huyo ametoa kibali kwa uhuru.

Chapisha jina la shahidi (sio mzazi) _____ NA Alama ya kidole gumba cha mshiriki

Saini ya shahidi _____

Tarehe _____

Siku/mwezi/mwaka



APPENDIX VIII: STUDY QUESTIONNAIRE IN KISWAHILI**Taarifa za dodoso**

1. Nambari ya dodoso: _____
2. Tarehe ya mahojiano: _____
3. Mhoji: _____
4. Jina la kituo cha afya: _____
5. Aina ya kituo cha afya
 - d) Umma (Chuo cha Juu, Sekondari, Msingi)
 - e) Mission/NGO
 - f) Privat

Taarifa za mgonjwa

6. Kitambulisho cha kipekee cha mgonjwa: _____
7. Mawasiliano ya simu: _____
8. Tarehe ya kuingia: _____
9. Tarehe ya kutolewa: _____
10. Aina ya kiingilio
 - c) Mgonjwa wa nje
 - d) Mgonjwa wa kulazwa
11. Umri wa mgonjwa/ Tarehe ya kuzaliwa: _____
12. Ngono ya mgonjwa
 - c) Mwanaume
 - d) Mwanamke
13. Kaunti ndogo ya makazi ya Mgonjwa: Teso Kaskazini, Teso Kusini, Matayos, Nambale, Butula, Bunyala, Samia
14. Eneo la makazi ya mgonjwa
 - c) Mjini
 - d) Vijijini
15. Kiwango cha elimu ya mkuu wa kaya
 - e) Hakuna
 - f) Msingi umekamilika

- g) Sekondari imekamilika
 - h) Elimu ya juu imekamilika
16. Kazi ya mkuu wa kaya
- e) Ajira ya kulipwa
 - f) Ajira ya mshahara
 - g) Mtu wa biashara
 - h) Wasio na kazi

Historia ya uchunguzi wa mgonjwa

17. Idadi ya siku za ugonjwa kabla ya kutafuta huduma ya afya

18. Ni dalili gani unazo nazo kwa sasa

- f) Kuhara
- g) Kutapika
- h) Maumivu ya tumbo
- i) Kichefuchefu
- j) Homa

19. Utambuzi wa uandikishaji ulikuwa nini

20. Utambuzi wa mwisho ni nini _____

21. Je, ulikuwa na maambukizo mengine yoyote (thibitisha kutoka kwa rekodi za matibabu ya mgonjwa)

- c) Ndiyo
- d) Hapana

22. Bainisha magonjwa yanayoambatana

23. Muda wa kukaa kwenye kituo kwa saa

24. Je, sampuli zozote zilikusanywa kwa ajili ya maabara

- c) Ndiyo
- d) Hapana

25. Sampuli zipi

- d) Kinyesi
- e) Damu

f) Nyingine bayana

26. Ni vipimo vipi vya uchunguzi vilitumika (thibitisha kutoka kwa rekodi za matibabu)

f) Hakuna mtihani

g) Utamaduni wa kinyesi

h) Hesabu ya damu

i) Utamaduni wa damu

j) Nyingine bayana

27. Dawa yoyote iliwekwa

c) Ndiyo

d) Hapana

28. Ni dawa gani zilizowekwa

Jina la dawa	Njia	Dozi	Muda wa matibabu

29. Je, dawa ilitolewa kwenye kituo hicho

c) Ndiyo

d) Hapana

30. Ulilipa kiasi gani kwa matibabu kwenye kituo (Pata kutoka kwa rekodi za bili/risiti)

e) Usajili _____

f) Ushauri _____

g) Maabara _____

h) Dawa _____

Asante

APPENDIX IX: DODOSO KWA GHARAMA ZA NJE YA MFUKO**Dodoso la gharama za nje ya mfuko****Taarifa za kituo**

37. Jina _____ la _____ kituo:

38. Aina ya kituo

d) Umma (Chuo cha Juu, Sekondari, Msingi)

e) Mission/NGO

f) Privat

Taarifa za mgonjwa

39. Kitambulisho _____ cha _____ kipekee _____ cha _____ mgonjwa:

40. Ngono

c) Mwanaume

d) Mwanamke

41. Umri/ _____ Tarehe _____ ya _____ kuzaliwa:

42. Tarehe _____ ya _____ idhini _____ iliyoarifiwa:

Taarifa za mlezi

43. Mgonjwa aliongozana na kituo cha afya

c) Ndiyo

d) Hapana

44. Ikiwa ndio, na nani (Uhusiano na mgonjwa)

g) Mzazi

h) Ndugu

i) Babu na babu

j) Jamaa mwingine

k) Rafiki

l) Maelezo _____ mengine:

Taarifa za usafiri

45. Nyumba yako iko umbali gani kutoka kwa kituo? (Takriban umbali katika Kilomita kwa njia moja) _____

46. Imekuchukua muda gani kusafiri kutoka nyumbani hadi kituo? (Takriban muda katika dakika) _____

47. Ulitumia usafiri wa aina gani kufika kituoni?

i) Gari la kibinafsi

j) Usafiri wa basi la umma

k) Teksi

l) Mzunguko wa pikipiki

m) Baiskeli

n) Kwa miguu

o) Mashua

p) Ambulance

48. Ikiwa ulilipia usafiri hadi kituo cha afya, ulilipa kiasi gani? (KES) _____ (Weka sifuri (0) ikiwa hakuna malipo yaliyofanywa)

49. Je, wewe au jamaa mwingine mlifanya safari ngapi kwenye kituo cha afya kutokana na ugonjwa huu? _____

50. Je! ni muda gani wa ugonjwa kwa siku? _____

Gharama za matibabu

51. Kabla ya kutembelea kituo cha afya, ulitafuta matibabu mengine?

c) Ndiyo

d) Hapana

52. Ikiwa ndio, kutoka wapi?

g) Apoteket

h) Kliniki ya kibinafsi

i) Duka

j) Mganga wa kienyeji

- k) Rafiki
- l) Nyingine taja _____
53. Ikiwa ulitumia gharama yoyote, ni kiasi gani? (Kama hakuna weka sifuri)
- _____
54. Je, ulipoteza kipato kwa sababu ya kuwa kwenye kituo hicho kutokana na ugonjwa huo?
- c) Ndiyo
- d) Hapana
55. Kama haungekuwa kwenye kituo cha afya, ungekuwa unafanya nini?
- h) Kazi ya kulipwa
- i) Kazi ya mshahara wa kila siku
- j) Biashara
- k) Kazi za nyumbani
- l) Shule
- m) Hakuna kitu
- n) Nyingine taja _____
56. Ikiwa ulikuwa unaongozana, mtu aliyeongozana naye angekuwa anafanya nini ikiwa hangefika kituoni
- h) Kazi ya kulipwa
- i) Kazi ya mshahara wa kila siku
- j) Biashara
- k) Kazi za nyumbani
- l) Shule
- m) Hakuna kitu
- n) Nyingine taja _____
57. Njia ya malipo
- d) Fedha taslimu
- e) Kadi ya mkopo
- f) Bima ya matibabu
58. Ni idadi gani ya jumla ya watu katika kaya yako
- c) Watoto _____
- d) Watu wazima _____

59. Je, kaya imelazimika kutumia mikakati ya kukabiliana na hali hiyo ili kufidia gharama za moja kwa moja na zisizo za moja kwa moja kutokana na ugonjwa huo?
- c) Ndiyo
 - d) Hapana
60. Ikiwa ndio, zipi?
- e) Kukopa
 - f) Kuruka milo
 - g) Kuuza mali za kaya
 - h) Kufanya kazi za mikono

Taarifa za Uchumi wa Kaya

61. Nini chanzo cha maji ya kunywa kwa kaya yako
- i) Bomba ndani ya nyumba
 - j) Gongu hadharani
 - k) Borehole/ Kisima cha bomba
 - l) Imelindwa vizuri
 - m) Spring Imelindwa au haijalindwa
 - n) Maji ya mvua
 - o) Lori la tanki
 - p) Maji ya chupa
62. Aina ya vyoo katika kaya
- h) Iliyosafishwa kwa maji taka
 - i) Imesafishwa hadi septic
 - j) Suuza hadi kwenye choo cha Shimo
 - k) Shimo la choo chenye slab au bila
 - l) Choo cha ndoo
 - m) Kituo cha umma
 - n) Hakuna kituo
63. Je, una umeme?
- c) Ndiyo
 - d) Hapana
64. Je, unaweza kufikia mojawapo ya yafuatayo?
- f) TV

- g) Redio
 - h) Microwave
 - i) Kicheza DVD
 - j) Simu ya rununu
65. Je, unaweka chakula chako kwenye friji?
- c) Ndiyo
 - d) Hapana
66. Je, unatumia mafuta ya aina gani kupika?
- g) Umeme
 - h) Gesi
 - i) Biogesi
 - j) Mafuta ya taa
 - k) Mkaa
 - l) Kuni
67. Nyumba yako ina sakafu ya aina gani?
- h) Dunia
 - i) Kinyesi
 - j) Mbao za mbao
 - k) Saruji
 - l) Matofali ya kauri
 - m) Mbao iliyosafishwa
 - n) Zulia
68. Nyumba yako ina kuta za aina gani?
- g) Jiwe
 - h) Matofali
 - i) Vitalu vya saruji
 - j) Mbao
 - k) Karatasi ya chuma
 - l) Kinyesi/ Matope
69. Je! ni watu wangapi wa kaya yako kwa kila chumba cha kulala?
70. Je, unamiliki mifugo?
71. Aina gani?
72. Njia kuu ya usafiri?
- g) Kutembea

- h) Baiskeli
- i) Inamilikiwa na pikipiki
- j) Bodaboda
- k) Matatu
- l) Teksi

APPENDIX X: RESEARCH ETHICS CERTIFICATE



FHI 360

certifies that

Gerald Munai Okaalo

has completed the

RESEARCH ETHICS TRAINING CURRICULUM

July 27, 2018

APPENDIX XI: ETHICAL APPROVAL



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

Reference: IREC/2019/206
Approval Number: 0003510

Mr. Gerald Munia Okaalo,
Moi University,
School of Public Health,
P.O Box 4606-30100,
ELDORET-KENYA.



MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3
19th December, 2019



Dear Mr. Okaalo,

ECONOMIC BURDEN OF ACUTE GASTROENTERITIS AND ASSOCIATED COST VARIABILITY IN PATIENTS ATTENDING HEALTH FACILITIES IN BUSIA COUNTY, KENYA

This is to inform you that **MU/MTRH-IREC** has reviewed and approved your above research proposal. Your application approval number is **FAN: 0003510**. The approval period is **19th December, 2019 – 18th December, 2020**.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by **MU/MTRH-IREC**.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **MU/MTRH-IREC** within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **MU/MTRH-IREC** within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to **MU/MTRH-IREC**.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <https://oris.nacosti.go.ke> and also obtain other clearances needed.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

APPENDIX XII: MINISTRY OF HEALTH APPROVAL

**MINISTRY OF HEALTH
DIRECTORATE OF PUBLIC HEALTH
FIELD EPIDEMIOLOGY AND LABORATORY TRAINING PROGRAM**

Telephone: Nairobi 2724951/ Fax 2724951
When replying please quote:

KENYATTA HOSPITAL GROUNDS
P. O. BOX 22313-00100 NAIROBI

Ref: MOH/DPH/FELTP/REG/024/VOL. 3

21st January, 2020

TO WHOM IT MAY CONCERN

RE: GERALD MUNAI OKAALO

The Kenya Field Epidemiology and Laboratory Training Program (KFELTP) is a competency based training program anchored within the Ministry of Health and training in Field Epidemiology in collaboration with Moi University where graduates are awarded MSC in Field Epidemiology.

This is to confirm that the above named officer is a trainee of FELTP and a registered Moi University student (SPH/PGH/FE/05/2017) currently in his second year and undertaking a study on "*Economic burden of acute gastroenteritis and associated cost variability in patients attending health facilities in Busia County, Kenya*".

Any assistance accorded to him will be highly appreciated.

Sincerely,

Dr. Josephine Githaiga
Head, Field Epidemiology and Laboratory Training Program



ISO 9001:2015
Certified

APPENDIX XIII: BUSIA COUNTY APPROVAL

COUNTY GOVERNMENT BUSIA
 County Health Director
 Health & Sanitation Department
 P.O. BOX 1040 – 50400
 BUSIA, KENYA



CG/BSA/H/ADM/1/56/VOL.II/8

3rd March, 2020

TO WHOM IT MAY CONCERN

Dear Sir/Madam,

GERALD MUNAI OKAALO

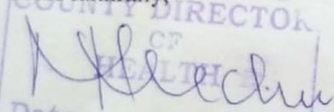
This is to confirm that the above named officer who is a trainee of FELTP and a registered Moi University Student (SPH/PGH/FE/05/2017) has been approved by this office to conduct a study entitled: **“Economic Burden Of Acute Gastroenteritis And Associated Cost Variability In Patients Attending Health Facilities In Busia County,”** In partial fulfilment of his MSC in field epidemiology at Moi University.

The IREC approval from Moi University is attached.

Kindly accord him the necessary assistance.

Thank you.

Yours faithfully,


 Date:
 Dr. Melsa Lutomia,
 County Director (P&P Services),
 Department of Health and Sanitation,
BUSIA COUNTY.

C.C. C.E.C.M. - Department of Health and Sanitation


Chief Officer - Department of Health and Sanitation

APPENDIX XIV: RESEARCH LICENSE


REPUBLIC OF KENYA

Ref No: 244936

RESEARCH LICENSE




This is to Certify that Dr.. Gerald Munai Okaalo of Moi University, has been licensed to conduct research in Busia on the topic: Economic burden of acute gastroenteritis and associated cost variability in patients attending health facilities in Busia County, Kenya for the period ending : 10/February/2021.

License No: NACOSTI/P/20/3621

244936
Applicant Identification Number


Director General
NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code



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NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

Date of Issue: 10/February/2020