

**COST EFFECTIVENESS ANALYSIS OF THE ORAL CHOLERA VACCINE IN  
KENYA: THE CASE OF NAKURU COUNTY**

**BY  
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**A RESEARCH PROJECT REPORT SUBMITTED IN PARTIAL FULFILLMENT FOR THE  
REQUIREMENTS OF THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN  
HEALTH ECONOMICS AND POLICY OF  
THE UNIVERSITY OF NAIROBI**

**NOVEMBER 2015**

## DECLARATION

This research project report is my original work and has not been presented to any other university for the award of a degree.

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## **DEDICATION**

I dedicate this project report to my daughters Leticia and Karsha and my wife Irene for the inspiration I draw from them.

## **ACKNOWLEDGEMENTS**

I wish to convey my sincere gratitude to Dr. Martine Oleche for his tireless effort in providing guidance for the entire period of this work. I also thank the University of Nairobi for the opportunity to study, all those who supported me in the course of this work, notably, my lecturers and the entire staff of the School of Economics for taking me through the course work. I also extend my sincere gratitude to all my classmates with whom we held group discussions together.

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## ABBREVIATIONS AND ACRONYMS

<b>CFR</b>	Case Fatality Rate
<b>CHOICE</b>	Choosing Interventions that are Cost Effective
<b>COI</b>	Cost of illness
<b>DALY</b>	Disability Adjusted Life Year
<b>GDP</b>	Gross Domestic Product
<b>ICER</b>	Incremental Cost Effectiveness Ratio
<b>IP</b>	Inpatient Number
<b>MoH</b>	Ministry of Health
<b>OCV</b>	Oral Cholera Vaccine
<b>TWG</b>	Technical Working Group
<b>VICE</b>	Vaccine Introduction Cost Effectiveness
<b>WHO</b>	World Health Organization

## DEFINITIONS OF SIGNIFICANT TERMS

The definition of parameters below is as suggested in the VICE model instruction manual (Troeger *et al.*, 2015)

**People Fully Vaccinated:** The number of people in the scenario receiving vaccine. The VICE model does not consider vaccine coverage or wastage.

**Vaccine Purchasing Cost:** The total cost of purchasing all required doses.

**Vaccine Delivery Cost:** The total cost of delivery for all required doses.

**Duration of Immunity:** How long vaccinated individuals are protected from illness.

**Cost of Illness:** The total cost per disease infection. Whether this is the cost to the private sector, public sector, or both depends on from where the funds for the vaccine intervention come. Private costs of illness may include treatment, transportation, and lost income or production while public costs of illness include outpatient or hospitalization treatment at a public hospital.

**Gross Domestic Product per Capita:** National level values available for this estimate from the World Bank.

**Population Distribution:** The percentage of the people fully vaccinated that exists in each Group.

**Incidence:** The disease incidence is the number of people infected per 1,000 per year.

**Case Fatality Ratio:** The percentage of infections that are fatal.

**Vaccine Efficacy:** The percentage reduction in the risk of infection for individuals receiving the vaccine.

**Life Expectancy at Age of Vaccination:** The number of years of additional life expected, on average, at age of vaccination.

**Annual Discount Rate:** Future health and economic outcomes are discounted at an annual rate, recommended at 3% per year. DALYs Averted in Year 2 will be 3% less than Year 1.

**Illness Duration:** The length of time, on average, that an illness lasts, in days.

**Disability Weight:** A feature of DALYs that quantifies how disabling a disease or condition is on a scale from 0 to 1. Zero represents no disability and 1 represents death. Moderate to Severe diarrhea has a Disability Weight of 0.202, according to the 2010 Global Burden of Disease Study.

## ABSTRACT

Cholera is caused by exposure to a bacterium *Vibrio cholerae* and may result in acute dehydration or even death in severe cases. It has affected many people in Kenya in recent months and therefore warrants attention. Between December 2014 and July 2015 sixteen counties had experienced a cholera outbreak with varying case fatalities. A total of 4,938 case and 97 deaths were reported. Nakuru County alone had 281 cases out of which 17 people died. This research work sought to establish if using the oral cholera vaccine is cost effective for vulnerable populations by taking a case study of Nakuru County. The cost of treating a cholera incidence was determined from the patient's perspective and included direct medical costs, direct non medical costs and indirect productivity losses. The results indicate that of the direct medical costs, the medicines used accounted for the largest cost burden. The Vaccine Introduction Cost Effectiveness Model was then used to determine the cost effectiveness of the intervention. It was found that giving the oral cholera vaccine to 100,000 vulnerable people would cost USD 78,000 and this would avert 1120 cases and 67.98 deaths. The number vaccinated per death averted would be 1471 and per case averted would be 89. The cost to save one life was found to be USD 7526.55 and the total cost per Disability Adjusted Life Year would be 337.21. The GDP per capita for Kenya as at 2014 after rebasing the economy was USD 1246. It was concluded that using the oral cholera vaccine as a preventive measure is very cost effective and is highly recommended since the cost per DALY averted is less than the GDP per capita for Kenya.

# CHAPTER ONE

## INTRODUCTION

### 1.1 Background to the study

Cholera, an infectious disease, is caused by exposure a bacterium *Vibrio cholera* subtypes 01 or 0139. It results in acute dehydration and in severe cases may lead to death. As reported by WHO in 2006, there were more than 236,000 cases globally of which 6311 deaths occurred. It is thought that these estimates are low mainly due to under reporting (Jeuland *et al.*, 2006). This disease presents a great health burden on poor nations of the world. Cholera is endemic in Africa and other parts of the world like Asia, South America, and Central America. The exact magnitude the problem is unclear for reasons of insufficient surveillance systems and failure to report cholera to WHO as would be desired ( Zuckerman, 2007).

The reemergence of cholera in Kenya in 2014 re-awakened concern over vulnerability to this disease of poor populations residing in slum urban areas and poor rural regions. This has raised interest in the potential of an oral cholera vaccine for reducing such risks. Clement *et al.*, (1986) showed the protective effect of oral cholera vaccines in 63 498 children aged 2-15 years and women aged over 15 years in their study in Bangladesh.

Health experts advocate for preventive measures such as improved sanitation and hygiene as the best method for avoiding cholera. However, such proposals have not been very easy to achieve in some of Kenya's informal settlements. If cholera is promptly diagnosed, it is easily treatable with intravenous rehydration therapy. This is only possible if there is easy access to health facilities which is a challenge in informal settlements due to various access barriers (Loharikar *et al.*, 2013)

Naidoo *et al.*, (2002) note that in situations with inadequate healthcare, an outbreak can have a case fatality rate of up to 20% or higher. Another approach to dealing with cholera is to amalgamate prevention and preparedness activities. This will require widespread use of the oral cholera vaccine. Data from recent Bangladesh trials demonstrate that using the oral

cholera vaccine gives appreciable herd protection by reducing the risk of infection among those not vaccinated and enhances protection of those vaccinated and who reside in vulnerable neighborhoods (Ali *et al.*, 2005). Cholera is a disease with a predilection to the poor and therefore vaccination initiatives should be directed to these populations.

In Kenya, as late as July 2015, 19 counties reported cholera outbreaks. The central government, through the Ministry of Health indicated it would spend Ksh500 Million in combating the outbreak sighting the county governments for failure to contain the outbreaks. In Migori County alone, 31 people had died between January and July 2015 (MoH, 2015).

The increasing availability of and demand for an oral cholera vaccine (OCV) suggests that an integrated strategy that incorporates OCV is a desirable option for reducing the burden of disease in many endemic and epidemic settings (Rouzier *et al.*, 2013). As cholera primarily affects the developing world where economic resources are limited, there is often a dilemma of how to allocate these vaccines in the most cost effective manner (Ivers *et al.*, 2013). Cost effectiveness analysis is often useful in guiding policy decisions regarding the most efficient use of resources in healthcare. It may play a key role in assisting governments on how best to allocate limited resources by assessing the value of commodities like the oral cholera vaccine.

## **1.2 Problem statement**

In Kenya, 16 counties were affected by the cholera outbreak between December 2014 and July 2015. As at June 2015, 4,938 cases and 97 deaths had been reported countrywide as shown in the table below.

**Table 1: Incidence of Cholera Cases in Kenya 2015**

County	No. of Cases	No. of Deaths
Nairobi	1090	24
Migori	915	12
Homabay( 1 <sup>st</sup> wave)	377	5
Homabay ( 2 <sup>nd</sup> wave)	111	1
Bomet	272	2
Mombasa	226	10
Muranga	633	5
Nakuru	281	17
Baringo	58	1
Kirinyaga	417	2
Kiambu	136	7
Embu	201	2
Machakos	80	5
Narok	20	0
Kilifi	54	1
Turkana	46	0

Source: MoH, 2015

While the introduction of an oral cholera vaccine to these vulnerable populations may be effective in reducing the deaths occasioned by cholera, no study has been conducted to date to demonstrate if the OCV as a preventive strategy is cost effective in Kenya. Similar studies carried out globally and within the region have been centered on stable refugee populations and areas served by relief agencies in which medical care is readily accessible (Nacify *et al.*, (1993): Murray *et al.*, (2006): Ilaria *et al.*, (2014). This is unlike the Kenyan vulnerable populations who mostly lack access to reliable, accessible and affordable medical care. The studies also lack a clear sensitivity analysis to show how cost effectiveness would be affected by slight changes in the cost of the vaccine as well as other epidemiological parameters. This study in Kenya will seek to fill in this gap. The study will establish whether

the oral cholera vaccine is cost effective by applying a newly developed model named Vaccine Introduction Cost Effectiveness model.

### **1.3 Research questions**

- i. What is the cost of the oral cholera vaccine per dose in Kenya?
- ii. What is the cost per dose to deliver the vaccine to the people?
- iii. What is the cost of treating a cholera case from the patient's perspective?
- iv. Is the cholera vaccine cost effective in this setting

### **1.4 Research objectives**

This study's overall aim was to establish whether introducing the oral cholera vaccine as a strategy for prevention of cholera epidemics in susceptible populations is cost effective in the Kenyan setting. The specific objectives of this study are:

- i. To establish the cost of the oral cholera vaccine per dose in Kenya
- ii. To determine the cost per dose to deliver the vaccine to the people
- iii. To estimate the cost of treating a cholera case from the patient's perspective
- iv. To ascertain whether the cholera vaccine is cost effective in this setting.

### **1.5 Justification**

The cholera problem persisted in Kenya between December 2014 and July 2015 despite public health measures to combat it, implying that a more effective method or combination of methods is needed if better health outcomes are to be achieved. One of the methods suggested in the literature is to include an oral cholera vaccine to augment the sanitation measures already being used. However, the oral cholera vaccine is new in Kenya and no study is available to show if this vaccine is cost effective. This study seeks to fill in this gap and contribute to policy formulation on vaccines for vulnerable populations.



## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 Introduction

This chapter dwells on the perspective of research works carried out on the cholera situation and the cost effectiveness of the oral cholera vaccine globally and within the region for the purpose of comparing trends. In Kenya, despite the reemergence of cholera over the last few years, there is no data on the cost effectiveness of this new vaccine.

#### 2.2 The cholera situation in the world

The real global burden of this disease is unknown. In cholera endemic regions, it is estimated that 1.4 billion people risk infection every year and 2.8 million cholera cases and 91 000 cholera deaths occur annually. Another 87 000 cases and 2500 deaths are expected in non-endemic countries annually (Ali *et al.*, 2012). Slow progress in providing access to safe water and sanitation to underserved populations, limitations of systems of surveillance for detection of cholera outbreaks, and lack of access to timely and appropriate healthcare have contributed to this burden of disease. Other factors contributing to make cholera a public health priority include the emergence of new strains of the bacterium more virulent and resulting in more severe clinical outcomes, the increased antimicrobial resistance, climate change and rapid and unplanned urbanization ( Siddique *et al.*, 2010). Children under five years are at the greatest risk of cholera and contribute half of the reported cholera deaths (Deen *et al.*, 2008).

In May 2011, the World Health Assembly adopted Resolution 64.15 which calls for implementation of an overall approach to cholera control that includes the use of oral cholera vaccines (OCV) “where appropriate, in conjunction with other recommended prevention and control methods and not as a substitute for such methods.” In September 2011, the World Health Organization (WHO) Secretariat organized a technical consultation that proposed the creation of an OCV stockpile for controlling outbreaks (WHO, 2012).

### **2.3 Cholera in the African Region**

In a study to assess the use of new cholera control methods such as vaccines, a database was compiled for cholera reports from 1995 to 2005. Of the 632 reviewed, 66% were from Sub-Saharan Africa and 16.8% from Southeast Asia. The outbreaks in Africa were comparatively larger in size. It was identified that the main risk factors were contaminated water, heavy rains that led to flooding, and population movements (David *et al.*, 2005).

Industrialized countries have minimized cholera infections through water and sewage treatment but the disease still is significant cause of morbidity and mortality in Africa. The continent still reports many cholera cases and outbreaks across its countries (Gaffga *et al.*, 2007). The deaths from cholera cases are highest in Africa than elsewhere in the world, showing inadequate access to basic health since cholera is simply treatable by rehydration therapy (WHO, 2011).

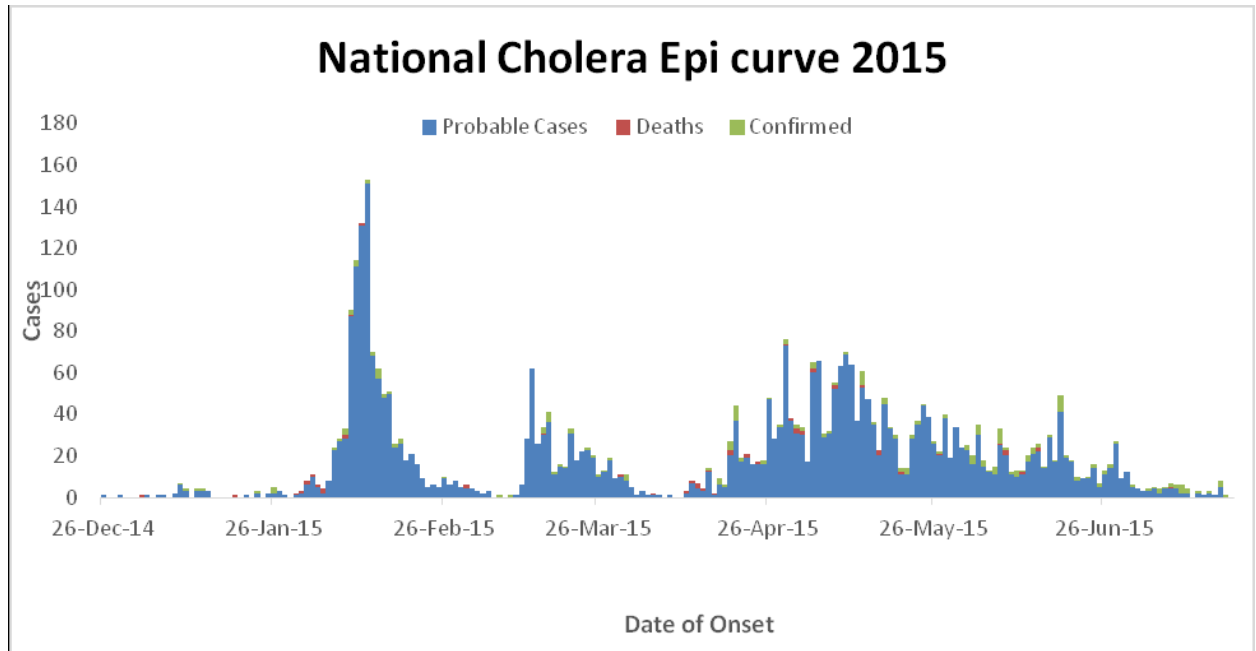
Since November 2013, Namibia suffered a cholera outbreak in four northern regions, including Kunene, Omusati, Oshana and Ohangwena. In 2014, they 504 cases and 16 deaths recorded (UN, 2014).

### **2.4 Cholera in Kenya**

Cholera outbreaks were reported in Kenya from early 1970's with the two largest epidemics in the country occurring in 1997, where about 33,000 cases were recorded, and in 2009 that listed 11,769 cases according to Kenya's Department of Public Health. The Ministry of health reports that 17 counties suffered Cholera outbreaks that began in December 2014. This report reveals that most counties are at risk of cholera and there is need for better preparedness. Loharikar *et al.*, (2013), in their study on Cholera Epidemics with high case fatalities reveal that the high number of deaths in Kenya are related to healthcare access differences, that also affects the availability of rehydration needs in averting such deaths.

The figure below shows the national cholera epidemiological curve as at 2015.

**Figure 2.1: National Cholera Epidemiological Curve as at 2015**

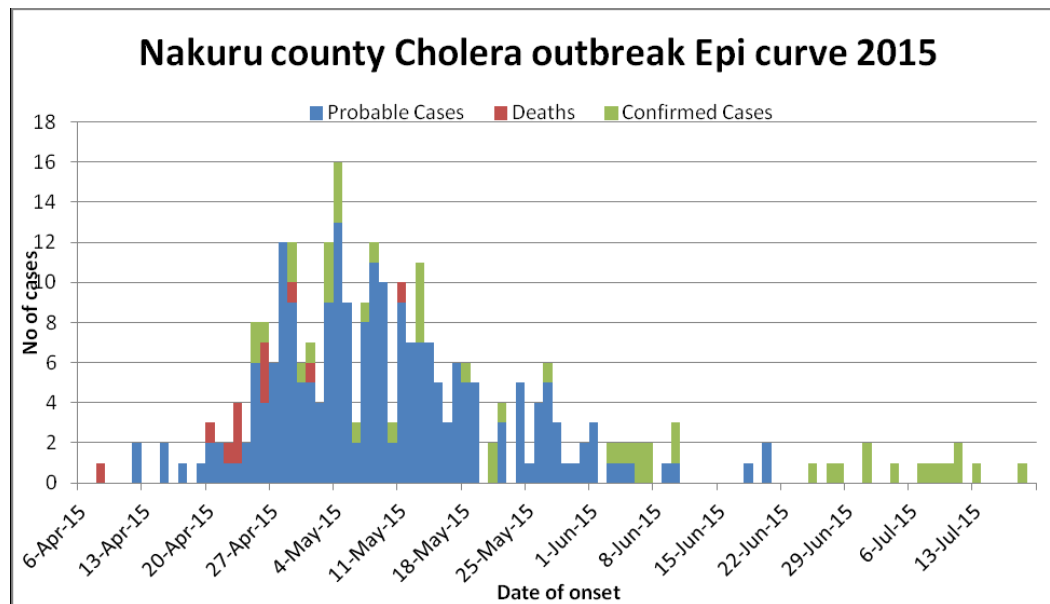


Source: MoH, 2015

#### **2.4.1 Cholera in Nakuru County**

Nakuru County has borne the burden of cholera recently from April 2015. By June 2015, the Ministry of Health reported that Nakuru County had experienced 281 cases and lost 17 people to this disease. The figure below details the number of cases reported in the period under review.

**Figure 2.2: Nakuru County Cholera Outbreak Epi Curve 2015**



Source: MoH, 2015

### 2.5 Cost effectiveness of the oral cholera vaccine

Nacify *et al.*, (1993), conducted a study to elucidate the cost-effectiveness of different interventions that also included vaccination, to contain cholera outbreaks in refugee camps in Africa. They used epidemiologic data from refugee settings in Malawi spanning 1987 to 1993. Costs data were got from facilities that provide medical care in refugee camps. The results showed that where there is no rehydration therapy for the managing severe cholera, using preemptive strategies costs less but is more effective than reactive treatment. Adding the OCV to preventive schemes was more expensive. They concluded that preemptive schemes were the most cost effective option.

In a study to evaluate the cost effectiveness of the cholera vaccine in Bangladesh, Troeger *et al.*, developed and applied the VICE model. They concluded that vaccinating the entire population was not cost-effective in that analysis as it would cost \$3,113 per DALY averted, and interventions needed to cost less than \$2,250 per DALY averted to be considered cost-effective in that setting. They found that non-selective mass vaccination in high risk

districts would be cost-effective, costing \$2,156 per DALY averted, \$825 per cholera case averted, and \$54,980 per death averted. Vaccinating children from 1 to 4 years of age in the high-risk districts cost less than \$500 per DALY averted and was very cost-effective when vaccine efficacy was 65%. The costs per DALY averted was higher in school-aged children (5–14 years of age), but it was still cost-effective to vaccinate these age groups (\$1,678/DALY). Vaccinating adults (15 years and older) was not cost effective. It was also found that targeting a spatial hotspot with a very high incidence of cholera (10/1,000/year) can be very cost-effective even in an endemic setting with a low CFR. The cost per DALY averted in the hotspot was \$592, the cost per case averted was \$226, and the cost per death averted was \$15,094.

Murray *et al.*, (2006) studied the cost-effectiveness of the oral cholera vaccine among refugees residing in cholera endemic areas. Their outcome showed that the net costs per DALY averted higher where incidence was low. They found that the most cost-effective combination of interventions was to provide water and sanitation plus treatment. They concluded that the OCV should not be used as routine vaccine in countries where cholera is non endemic.

Jeuland *et al.*, (2009) conducted a cost effectiveness study of new-generation oral cholera vaccines at multiple sites. They studied the cost-effectiveness of an OCV used in Vietnam, having collected data from four countries where cholera was deemed endemic. They took into account the herd protective effects of the OCV. They concluded that omitting the herd effects of the OCV underestimates of the cost-effectiveness of the strategy.

A modeling study conducted by Levin *et al.*, (2012) on the effectiveness of various strategies employing the OCV in Bangladesh found that vaccinating all eligible children, needed the least number of vaccinations to avert a case as compared to vaccinating preschool children or the whole population.

## **2.6 Cost of Illness due to Cholera**

Abdur *et al.*, (2013) conducted a study to gauge the economic cost of cholera treatment in households in Bangladesh. They employed both prospective and retrospective methods to

elicit direct medical costs, direct non-medical cost and indirect cost of affected persons as well as their caretakers. They found out that the average cost of illness during an attack of cholera was estimated to cost 30.4 US\$ per household per episode. Direct and indirect costs made up 24.4% and 75.6% respectively. Direct costs were similar for males and females although the indirect costs were higher for the males. Drugs were seen as the largest cost driver. They also concluded that by preventing cholera, production loss by individuals could be lessened.

Schaetti *et al.*, (2012) in a study on the costs of cholera illness in Zanzibar, found that their 2009 mass vaccination campaign was not cost effective. This was blamed on the high OCV buying price and a low incidence in the general population. However, they suggested that using the OCV in mass campaigns in Zanzibar to control cholera may be cost-effectiveness in high-incidence regions and where OCV prices fall to below USD 1.3 per dose.

Poulos *et al.*, (2011) studied the costs of endemic cholera from a public, provider, and patient costs perspective. The public costs were obtained at health facilities by utilizing a bottom -up methodology. The study reveals the cost of severe cholera was USD 32 in Matlab and USD 47 and Beira. Communitywide studies were in North Jakarta and Kolkata and showed that cholera cost from USD 28 to USD 206, depending on the period of hospitalization.

In a study on the cost of OCV program in endemic urban population in Bangladesh, Khan *et al.*, (2013) noted the two doses of vaccine cost US\$3.93, where about US\$1.63 was used to deliver the vaccine. Sarker *et al.*, (2013) studied the cost of illness due to cholera in Bangladesh. Their study suggested that by preventing a cholera case, they could save about US\$30.40 for every household. For them also, drugs were identified as the biggest cost contributor.

## **2.7 Feasibility of introducing the oral cholera vaccine**

In Guinea, Ciglencecki *et al.*, (2013) showed the possibility of using OCV campaigns before suspected epidemics and concluded that OCVs may help control cholera epidemics and can

prevent morbidity and mortality mainly in areas with limited access to health care and where sanitation measures are difficult to achieve.

In a feasibility study of the OCV in South Sudan, Ilaria *et al.*, (2014) found that vaccinating a large population during an emergency is feasible. They found it to be a possible way forward in minimizing cholera deaths.

Maskery *et al.*, (2013) reviewed the feasibility of mass use of the OCV in a study in Haiti and Zimbabwe. They were convinced that keeping a stockpile of the OCV could improve the efforts to contain future outbreaks by ensuring the availability of the OCV. Chao *et al.*, (2011) recommended a stockpile of OCV that covers 30% of a population at risk of exposure to *Vibrio Cholerae*. Khatib *et al.*, (2012) suggested that mass OCV campaigns can provide protection for both vaccinated individuals and the unvaccinated ones. DeRoeck *et al.*, (2005) conducted a study on the policymakers' views of the OCV in Asia and found that among other factors, local disease burden data was the most crucial in influencing decisions to introduce the OCV.

## CHAPTER THREE

### RESEARCH METHODOLOGY

#### 3.1 Introduction

This chapter covers the conceptual framework, research design, study area and target population, sampling method, data collection, data validity and reliability as well as data analysis.

#### 3.2 Conceptual Framework

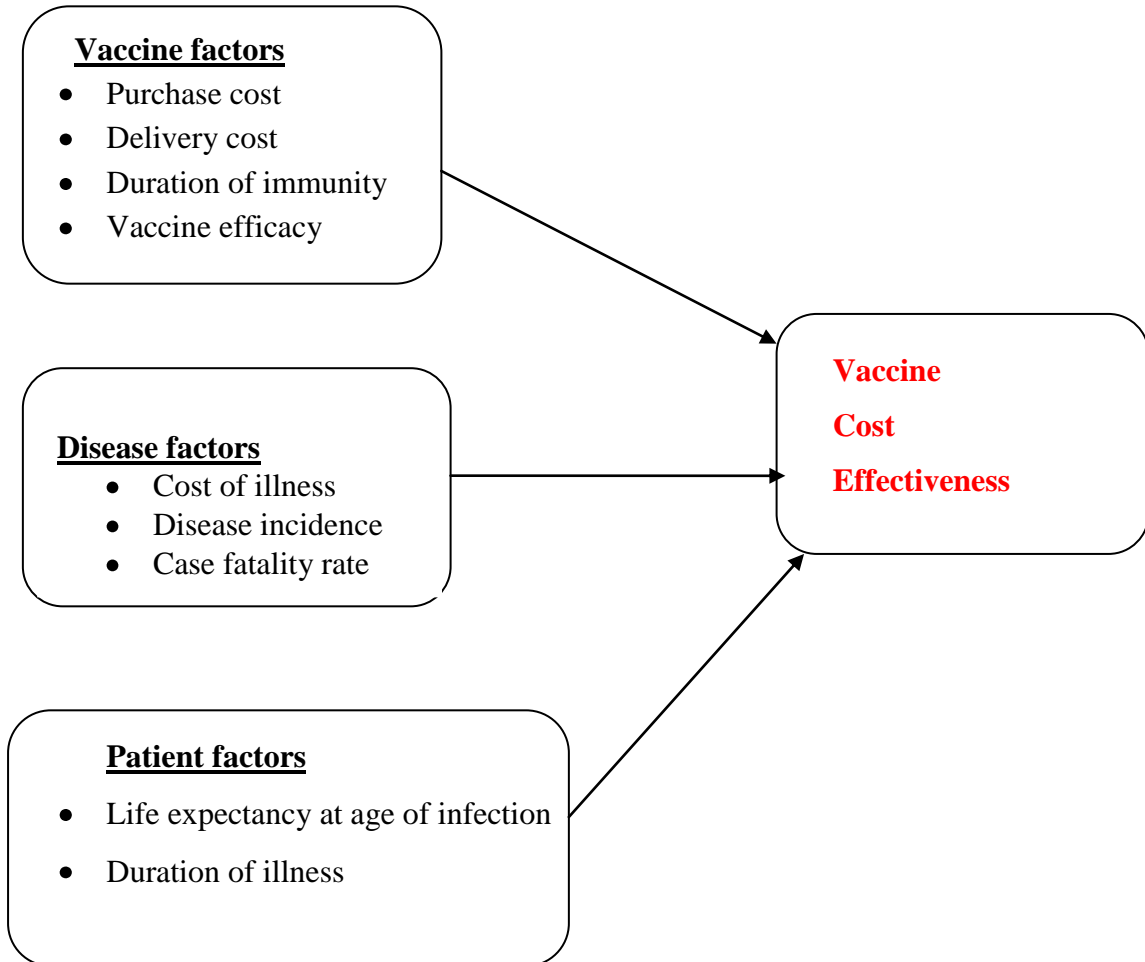


Figure 3.1: Conceptual framework



### **3.3 Research design**

The study adopted the Vaccine Introduction Cost-Effectiveness (VICE) model developed by Christopher Troeger and others at John Hopkins Bloomberg School of Public Health, Baltimore, Maryland. The model provides a calculator that computes cost-effectiveness outcomes. The VICE calculator is implemented as a spreadsheet in Microsoft Excel (Microsoft Corporation, Redmond, WA, 2011) and is available for download from <http://stopcholera.org>. It allows for full control over parameters to describe the epidemiology of a population, vaccine characteristics, and economic values (Christopher *et al.*, 2014). Economic analyses of health interventions compare current practices and prospective new interventions (Tan-Torres *et al.*, 2003). In this study the current practice was “do nothing” which implies not using the oral cholera vaccine while the new intervention was vaccination using the oral cholera vaccine.

#### **3.3.1 The VICE model**

The Vaccine Introduction Cost-Effectiveness (VICE) calculator is an Excel-based model used to evaluate the cost-effectiveness of vaccine projects. Currently it is calibrated for oral cholera vaccine but is applicable to any disease intervention. The VICE model is fully flexible for a variety of user-specified parameters for disease epidemiology, population demographics, and intervention characteristics. It can be stratified into up to 4 subpopulations that may vary in demographic and epidemiological characteristics to compare different scenarios. In addition to calculating estimated health and economic quantitative outcomes, VICE automatically generates a series of graphs to visualize vaccination interventions and health and economic outcomes, including sensitivity analyses (Christopher *et al.*, 2014).

#### **3.3.2 Cost Effectiveness**

The Cost-Effectiveness of a health intervention is the ratio of Intervention cost to health benefits. The Intervention Cost is the Total Intervention Cost less the Incremental Cost Averted: how much an intervention costs minus how much that intervention saves in medical costs and/or lost time and wages. The Health Benefit is measured by DALYs (Disability Adjusted Life Years). DALYs Averted is the Baseline DALYs less the DALYs

Averted by the Intervention. DALYs are a widely used metric for the burden of disease and is a sum of Years of Life Lost (YLL) and Years Lost to Disability (YLD). This is as per the WHO, Global Burden of Disease Study of 2010.

In this study, Cost-effectiveness was examined based on the WHO criteria that defines an intervention as ‘cost-effective’ if the ICER is less than three times per capita gross domestic product (GDP) per DALY averted and as ‘highly cost-effective’ if the ICER is less than per capita GDP per DALY averted (WHO, 2001). The Vaccine Introduction Cost-Effectiveness calculator is a useful tool for vaccine introduction decision making. VICE is suitable for both homogeneous and heterogeneous populations

### 3.3.3 Calculating DALYs

This research used disability-adjusted life years (DALYs) to be consistent with the prevalent literature in developing countries and cholera vaccine contexts and the WHO CHOICE program.

(i) **Years Lost to Disability (YLD) Averted** $_{i,t} =$

$$[(1 - \text{CaseFatalityRatio}_i) \cdot \text{VaccineEfficacy}_t \cdot \text{Incidence}_i \cdot \text{Length of Illness} \cdot \text{DALY Weight}]$$

(ii) **Years of Life Lost (YLL) Averted** $_{i,t} =$

$$([\text{CaseFatalityRatio}_i \cdot \text{VaccineEfficacy}_t \cdot \text{Incidence}_i] / \text{Discount}) \cdot [1 - \exp(-\text{Discount} \cdot \text{Life Expectancy}_i)]$$

(iii) **DALYs Averted** $_{i,t} = \text{Years Lost to Disability}_{i,t} + \text{Years of Life Lost}_i$

(iv) **Total DALYs Averted** $_i = (t=0, \text{Duration of Immunity}) \sum (\text{DALYs}_{i,t}) / (1 + \text{Discount})$

(v) **Cost Effectiveness Ratio** = *Net Cost / DALYs Averted*

Where **t** = time in years and **i** = subgroup i

**DALYs** are the sum of the present value of future years of lifetime lost through premature mortality( **YLL**), and the present value of years of future lifetime adjusted for the average severity (frequency and intensity) of any mental or physical disability caused by a disease or injury( **YLD**).

**Case Fatality Ratio (CFR)** is the percentage of infections that are fatal

**Vaccine Efficacy** is the percentage reduction in the risk of infection for individuals receiving the vaccine.

**Incidence** The disease incidence is the number of people infected per 1,000 per year.

**Length of illness** is the length of time, on average, that an illness lasts, in days.

**DALY Weight** is feature of DALYs that quantifies how disabling a disease or condition is on a scale from 0 to 1. Zero represents no disability and 1 represents death. Moderate to Severe diarrhea has a Disability Weight of 0.202, according to the 2010 Global Burden of Disease Study.

**Annual Discount Rate:** Future health and economic outcomes are discounted at an annual rate, recommended at 3% per year. DALYs Averted in Year 2 will be 3% less than Year 1.

**Life Expectancy at Age of Vaccination** is the number of years of additional life expected, on average, at age of vaccination.

**Duration of Immunity** refers to how long vaccinated individuals are protected from illness.

**Cost Effectiveness Ratio** refers to the amount of money spent to avert one DALY. WHO criteria defines an intervention as ‘cost-effective’ if the ICER is less than three times per capita gross domestic product (GDP) per DALY averted and as ‘highly cost-effective’ if the ICER is less than per capita GDP per DALY averted (WHO, 2001)

### **3.4 Study area and target population**

The study was conducted in Nakuru County, chosen because it has been greatly affected by the recent cholera outbreak. As at June 2015 the Ministry of Health reported Nakuru County as having recorded 281 cholera cases and 17 deaths from this disease.

The target population included all the people affected by the cholera outbreak in the last one year in Nakuru County. This population resided in both the rural and urban settings.

### **3.5 Sample size and Sampling procedure**

To estimate the cost of treating cholera from the patient's perspective, persons from families affected by cholera in the last one year were interviewed. Records from the Public Health Department were used to get the contacts for these persons. The researcher followed up and contacted the affected families for interviews. The ones who accepted to participate were included in the study.

### **3.6 Data collection**

The VICE model requires certain data to be entered into the VICE calculator. These data include the cost of the vaccine per dose which was obtained from the distributors of the vaccine in Kenya. The number of doses given per patient is known to be two currently. The cost per dose to deliver the vaccine to the people was obtained through an interview with key informants, notably the distributors and the public health officials involved in other vaccine initiatives in the County. The cost of treating a case of cholera from a patient's perspective was revealed from questionnaires issued to affected families. As the cost varied across families, an average figure was used.

The study surveyed both the rural and urban areas and all age groups were included. The hospital-based studies were in the Provincial General Hospital, Nakuru that handled the cholera cases during the outbreak. The community-based studies were directed by data from the Hospital but comprised of the slum neighborhoods that had residents who presented with cholera during the recent outbreak and others from the neighboring rural regions.

To collect data on patient costs of illness due to cholera, an interview was conducted at the patient's home. Patient costs included the out-of-pocket costs borne by the patient including payments for medical care, drugs, transportation cost, and imputed expenses, such as lost work time. For adult cases, the patients were interviewed and for children an adult familiar with the cholera episode and the household finances.

Standardized questionnaires were made to ensure that identical data was collected in the various households. The questionnaires measured direct costs and indirect costs.

### **3.7 Validity of instruments**

Validity refers to how well a test measures what it is purported to measure. The questionnaires were pre-tested on non participating respondents over a period of three days, one week before the actual study. After pre testing, the data collection instruments were adjusted appropriately in order to enhance the validity of the data collected. This was done by removing troublesome words in the tool as well as removing ambiguous statements. Colleagues were also requested to re-examine the questionnaire and critique it. To ensure confidentiality, all the respondents were asked not to write their names on any questionnaire that they filled.

Caution was exercised to ensure the confidence of the respondents through full introduction by the investigator and ensuring the questions were framed in a manner that was non-judgemental and non intrusive into their personal life. The purpose of the study was also fully explained to the respondents so that they do not withhold vital information. Data was collected and analysed by the investigator to minimize errors caused by different investigators. Completed questionnaires remained in the custody of the investigator. The personal computer and laptops used to store and analyse data were password protected. Flash discs and hard copies of all documents were safely stored by the investigator.

### **3.8 Data analysis**

The information collected was entered into the statistical package for social sciences (SPSS) version 21.0 and the parameters required by the VICE model computed. Data was entered into the VICE calculator which is implemented as a spreadsheet in Microsoft Excel (Microsoft Corporation, Redmond, WA, 2011). In addition to calculating estimated health and economic quantitative outcomes, VICE automatically generated a series of graphs to visualize vaccination interventions and health and economic outcomes, including sensitivity analyses.

### **3.9 Ethical Review**

The research proposal document and the data collection tools for both health facility and patient costs were presented for approval by the relevant Hospital and County ethical review committees. After explaining the purpose of the study, voluntary consent was obtained from each respondent in the patient COI study prior to the start of the interview.

### **3.10 Basic assumptions of the study**

This study assumed that the vaccine was administered in two doses, although studies are ongoing to test how well a single dose works. The study also assumed the vaccine offers protection for five years as revealed in the study in Kolkata, India (Poulos *et al.*, 2005). This period may be more or less in Kenya. Medical costs may varied from patient to patient but this study assumed the value of three days in hospital. The GDP per capita in Kenya was the prevailing figure from World Bank sources at the time of the study. The population to be covered by the vaccine was assumed to be homogenous for the purpose of simplicity.

## CHAPTER FOUR

### DATA ANALYSIS, PRESENTATION AND INTERPRETATION

#### 4.1 Introduction

This chapter presents the data analysis, presentation and interpretation of the research findings. The data obtained was arranged into categories and interpreted on the basis of each research objective. The costs were collected in Kenya shillings but converted into US Dollars since this is the currency used by the VICE Model calculator. The currency exchange rate used was Ksh 102 to the USD as at 2014.

#### 4.2 Vaccine Characteristics

The brand of the oral cholera vaccine available in the Kenya is Shanchol®. The cost of a single dose of this OCV is USD 1.92 and would require a further USD 0.97 to deliver to those who need it. Normally, two doses are given to complete the vaccination. The documented efficacy according to local experts is about 70% if all precautions are adhered and it would provide protection for four years after vaccination. The average life expectancy after vaccination is forty years, although it would be more for children and less for adults.

**Table 4.1 Vaccine Characteristics**

S. No.	Item	Value
1	Vaccine brand name	Shanchol®
2	Cost of a single dose	USD 1.92
3	Cost to deliver vaccine in the field	USD 0.97
4	Number of doses given	2
5	Documented efficiency	70%
6	Years of protection offered by the OCV	4
7	Average life expectancy after vaccination	40

Source: Author generated

### 4.3 Disease Characteristics

The incidence of cholera in the areas recently affected by cholera in Nakuru County is 4 people per one thousand people per year. The case fatality rate as per the last epidemic was 6.07% and the average number of days the patients spent in hospital was three days. This is summarized in the table 4.2 below.

**Table 4.2: Disease Characteristics**

S. No	Item	Value
1	Cholera incidence in Nakuru	4
2	Case fatality rate	6.07%
3	Number of days admission was required	3 days

Source: Author generated

### 4.4 Direct Medical Costs

This was the cost of resources that went directly into the provision of healthcare. The average admission fee was Ksh 100 which also catered for the consultation. It was the cost of buying a hospital card. The average laboratory cost was Ksh 200. This was mainly a stool test to confirm suspected cholera cases. Bed charges per hospital day were Ksh 300. Drugs accounted for the largest share of this category consuming Ksh 600 on average but higher for patients who spent more than 3 days in hospital. Non drug items varied from patient to patient and cost an average of Ksh 350.

**Table 4.3: Direct Medical Costs**

S/No.	Item	Cost (USD)
1	Admission fees/card fees	0.98
2	Consultation fees	-
3	Laboratory tests fees	1.96
4	Bed charges per hospital day	2.94
5	Drug charges	5.88
6	Non-drug items e.g. gloves etc	3.43

Source: Author generated



#### 4.5 Direct Non Medical Costs

These were the costs of resources that are related to provision of healthcare but don't go directly into the provision of healthcare. Transport costs to and from hospital varied according to the mode of transport used. The average cost was Ksh 400. Special diet for these patients was also varied depending on the age of the patient and on average it cost Ksh 470. Other non medical items mainly included sandals, towels, mosquito nets and on their costs is as listed in table 4.4 below.

**Table 4.4 Direct Non-medical Costs**

S.No	ITEM		COST(USD)
1	Transport to and from hospital		3.92
2	Special diet		4.60
3	Non medical items	Pair of slippers	0.98
		Basin	1.96
		Mosquito net	4.90
		Towel	3.92

Source: Author generated

#### 4.6 Indirect costs

This is the estimated costs of lost productivity by the patient while in hospital as well as the costs spent on caretakers both in hospital and at home. The average costs for these.

**Table 4.5 Indirect Costs**

S.No	ITEM	COST(USD)
1	Income lost due to absence from work	16.38
2	Money spent on caretaker in hospital	2.94
3	Money spent on caretaker at home while you were admitted	4.41

Source: Author generated

#### 4.7 Cost effectiveness outcomes

Using the VICE calculator the parameters of interest were realized as shown in table 4.6 below. The vaccination initiative was estimated to cover 100,000 people.

**Table 4.6: Cost Effectiveness outcomes**

<b>Parameter</b>	<b>Value</b>
Total cost	USD 78,000
Cost averted	USD 66,315
Net Costs	USD 511,684
Non fatal cases averted	1052
Deaths averted	67.98
Total cases averted	1120
Number Vaccinated per death averted	1471
Number vaccinated per case averted	89
DALYs averted	1517.1
Cost per case averted	USD 456.86
Cost per life saved	USD 7,526.55
Total cost per DALY averted	337.21

Source: Author generated

The table shows that the total cost of the new vaccination initiative is USD 78,000 and it would avert a cost of USD 66,315. This would prevent about 67 deaths out of the 100,000 vaccinated individuals. The vaccine would also prevent 1,120 cases from occurring and avert 1517 DALYs. It would cost USD 456.86 to avert a case and USD 7526.55 to save a life. The total cost per DALY saved would be USD 337.21

#### 4.8 Cost Effectiveness Thresholds

Table 4.7 below shows the cost effectiveness thresholds for this vaccination initiative.

**Table 4.8 Cost Effectiveness Thresholds**

<b>TOTAL VACCINE COST OF PURCHASE AND DELIVERY (\$)</b>	
Cost effective	\$57.38
Very cost effective	\$19.50
<b>VACCINE EFFICIENCY (%)</b>	
Cost effective	7.1%
Very cost effective	20.7%
<b>INCIDENCE (PER 1000/YEAR)</b>	
Cost effective	0.4
Very cost effective	1.18
<b>CASE FATALITY RATIO %</b>	
Cost effective	0.55%
Very cost effective	1.64%

Source: Author generated

For the vaccine to be cost effective, the maximum cost to purchase and deliver the vaccine is USD 57.38. It would be very cost effective at USD 19.59. The vaccine efficacy needs to be 7.1% and 20.7% for the initiative to be cost effective and very cost effective respectively. A cholera incidence of 0.4 per 1000 people per year would render the OCV cost effective and at 1.18 it would be very cost effective. With respect to the case fatality ratio, at 0.55% the OCV would be cost effective and very cost effective at 1.64%.

## **CHAPTER FIVE**

### **SUMMARY OF FINDINGS, DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS**

#### **5.1 Introduction**

This chapter gives the summary of key findings, discussion, conclusions and recommendations of the research on the cost effectiveness of the oral cholera vaccine in Nakuru County.

#### **5.2 Summary of the findings**

The study found that while there are two brands for the oral cholera vaccine, the brand most known and available was Shanchol<sup>®</sup>. The cost of a single dose of this vaccine was USD 1.92 in Nairobi city. To deliver this vaccine to the people who need it, it would cost USD 0.97 per dose assuming ease of delivery within the affected areas. The cost of treating an incidence of cholera from a patient's perspective was estimated at USD 59.21 from a patient's perspective. This cost was the sum of direct medical costs, direct non medical costs and indirect costs. It may vary widely depending upon the non medical costs and the indirect costs. In determining whether the oral cholera vaccine is cost effective, the study found that it would cost USD 7526.55 to save one life. Similarly, it costs USD 337.21 to avert one DALY.

#### **5.3 Discussion of key findings**

The key findings are as discussed below in congruence with the objectives of the study.

##### **5.3.1 The cost of the oral cholera vaccine per dose in Kenya**

The study established that there are two brands of the oral cholera vaccine namely Shanchol<sup>®</sup> and Dukoral<sup>®</sup>. The former brand is more readily available in Kenya. The Shanchol<sup>®</sup> brand is estimated to cost USD 1.92 per dose and therefore USD 3.84 for the full dose per vaccinee. For a population of 100,000 vulnerable people in a County like Nakuru, it would cost USD 384,000 to vaccinate. The cost could be lower if the groups requiring

vaccination can be pooled in a common area as occurs for school going children. This cost may be higher in slum areas that are difficult to access.

### **5.3.2 The cost per dose to deliver the vaccine to the people**

In this study, it was realized that the average cost to deliver the vaccine to the people would be USD 0.97 per dose and thus USD 1.94 for the full dose. Depending on the ease of access of these populations, this cost may be higher or lower. While it may be cheaper to issue the vaccine in the hospital, this strategy may congest the facilities and some of the intended beneficiaries may not make it to the health facilities due to transport challenges that are normally associated with these populations.

### **5.3.3 The cost of treating a cholera case from the patient's perspective**

On average, the cost of treating a cholera episode was found to be about USD 59.21. This was divided into direct medical costs, direct non medical costs and indirect costs. Among the direct costs, drug charges were highest costing an average of USD 5.88. However, it is worth noting that even this cost has a subsidy from the government and the cost could be higher in a private hospital. Poulos *et al*, 2005 found that hospital-based costs of severe cholera were USD 32 and 47 in Matlab and Beira. Community-based studies in North Jakarta found that cholera cases cost USD 28. These figures show that the cost of treatment in Kenya is almost double that in North Jakarta. This may be due to the cost of drugs which is much less in Asia than in Kenya

### **5.3.4 The cost effectiveness of the oral cholera vaccine in Nakuru County**

The oral cholera vaccine initiative would cost USD 7526.55 to save a life and USD 337.21 to avert a DALY. The WHO criteria defines an intervention as 'cost-effective' if the ICER is less than three times per capita gross domestic product (GDP) per DALY averted and as 'highly cost-effective' if the ICER is less than per capita GDP per DALY averted (WHO, 2001). In this case the GDP per capita for Kenya after rebasing the economy was USD 1246 according to the 2014 World Bank figures. The USD 337.21 is much less than the GDP per capita of 1246 making the intervention of using an oral cholera vaccine very cost effective. Christian *et al*, 2012 using empirical and site-specific cost and effectiveness data from

Zanzibar, in a 2009 mass vaccination campaign found that it was cost-ineffective mainly due to the relatively high OCV purchase price and a relatively low incidence. A high incidence and a low cost of the OCV below USD 1.3 were necessary for cost effectiveness. Mass vaccination may not be cost effective because the incidence of cholera in the general population is generally low. Targeting specific vulnerable groups may be more preferred.

#### **5.4 Conclusions**

The following conclusions were made from this study;

1. The cost of the available brand of the oral cholera vaccine is slightly less than USD 2.0 in Nairobi but may be slightly higher in other towns out of the city due to transport and cold chain costs. However, as long as the cost to purchase and deliver the vaccine does not exceed USD 57.35, the intervention remains very cost effective.
2. The cost to deliver the vaccine stands at USD 0.97 but will differ depending upon ease of access to the population in need. It may be necessary to compare the costs of delivery to a pooled site like a school or a church and that of inviting beneficiaries to a health facility. Another option worth considering is door to door visit although it may be more expensive than the first two options. A commonly used option is to combine all the methods if funds allow. This may be necessary especially in cases of an outbreak in order to cover as large a population as possible in the least time.
3. From a patient's perspective, the cost of treating a cholera case is about USD 59.21. While the medical costs component is large, the non medical costs are also a considerable contributor. This is because in some hospitals, some basic requirements like mosquito nets, basins and sandals may not be provided and patients have to cater for these costs.

The oral cholera vaccine is very cost effective and costs USD 337.21 per DALY averted which is much less than the GDP per capita in Kenya which stands at USD 1246 after rebasing the economy.

## **5.5 Recommendations**

The following recommendations were made from this study;

1. County Governments can negotiate with vaccine manufacturers to produce the vaccine on a large scale as this will reduce the cost of production per dose. With an assured market the manufacturers may be very willing to enter into such a partnership.
2. Mapping out cholera hotspots may be crucial. In areas commonly affected by flooding during the rainy season, stations can be established where a cold chain store is provided for such that in case of an outbreak, vaccines can be stored there and distributed as required. This will lower the cost of delivery of the vaccine by a certain margin
3. The cost of treating cholera cases is still high and can be brought down by further subsidies to the medical input. Cholera is a disease of the poor who may not afford costly medicines. The government could consider treating the cases for free to avert the deaths occasioned by cholera. This will also give the government an impetus to offer the vaccine in order to spend less on treatment
4. The oral cholera vaccine is cost effective and should be considered for stockpiling especially in areas inhabited by vulnerable groups like slums areas and poor rural communities.

## **5.6 Suggestions for further studies**

This study suggests that further research be carried out in order to establish the cost effectiveness of the oral cholera vaccine on a nationwide basis. The studies should also endeavor to account for herd protection effects which were omitted in this study.

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7. How much did you pay to travel to hospital?

Less than Ksh 50..... Between 50 and 100...Between 100 to 500.....

Between 500 to 1000..... More than 1000.....

8. In Hospital, how much money did you spend on the following items?

Admission fee/ buying the card-----

Lab tests-----

Bed charges-----

Medicines-----

IV fluids-----

Special diet-----

Others ( specify)-----

9. How many days did you spend in hospital?

2 days..... 3 days.....

4 days..... More than 4 days ( specify).....

10. After being discharged, how did you travel back home?

Walking.....Bicycle.....Motorbike.....Matatu.....

Taxi..... Private car.....

11. How much did you pay to travel back home?

Less than ksh 50.....Between 50 to 100.....Between 100 and 500.....

500 to 1000..... More than 1000.....

12. How much money did you spend on buying the following non medical items while in hospital?

Slippers..... Basins..... mosquito net.....

food and drinks.....others ( specify).....

13. How much did you spend on tips to ensure promptness of service?

-----

14. Did you go to hospital with a person to assist you?

Yes-----

No-----

15. How much did you pay the assistant for this purpose?

-----

16. Back at home, how much money did you spend on medicines?

-----

**DIRECT NON MEDICAL and INDIRECT COSTS**

17. How many are you in the family?

1 to 3..... 3to 6.....3 to 9.....more than 9.....

18. What are your educational qualifications?

Primary school... secondary school.....college and above.....

19. Occupation:

Casual worker.....self employed.....permanent employment.....

Jobless.....

20. Monthly income

5000 and less..... 5000 to 10,000.....10,000 to 20,000... 20,000 to 50,000

50,000 and above.....

21. How much money did you lose as a result of absence from work due to hospitalization?

-----

22. What form of medical insurance do you have?

None.....NHIF.....Private insurance.....NHIF and private insurance.....

23. What is the combined monthly income for your family?

-----

24. While you were admitted in hospital who took care of your family?

-----

**25. How much did you pay this person for that period?**

---

26. What is his/ her occupation? -----

27. What is her/his monthly income?-----

28. Did she experience any loss of income and how much?-----

## **APPENDIX 2: SAMPLE HOSPITAL DATA COLLECTION TOOL**

### **Introduction**

My name is Samuel Kabara, a research student undertaking a Master of Science degree in Health Economics and Policy in the University of Nairobi. I am conducting a survey to assess the costs associated with the cholera disease and whether a cholera vaccine can be cost effective in preventing this disease.

Kindly provide the information requested below:

### **Cost of illness due to Cholera data collection**

Patient IP No.....

Ward No.....

Patient's Phone No.....

What is the incidence of cholera in this area.....

### **Direct Medical Costs**

**Please indicate the cost of the following items used in managing cholera patients**

1. Admission fees/ card fees.....
2. Consultation fees.....
3. Lab tests fees.....
4. Bed charges per hospital day.....
5. Drug charges.....
6. Non drug items e.g. gloves etc.....
7. Any other items (specify).....
8. How many days on average does a cholera patient spend in hospital.....
9. What is the case fatality rate for the patients who get cholera.....

**APPENDIX 3: SAMPLE KEY INFORMANT DATA COLLECTION TOOL**

**Introduction**

My name is Samuel Kabara, a research student undertaking a Master of Science degree in Health Economics and Policy in the University of Nairobi. I am conducting a survey to assess the costs associated with the cholera disease and whether a cholera vaccine can be cost effective in preventing this disease.

Kindly provide the information requested below:

**Information associated with the cholera vaccine**

Cholera vaccination site.....

Cholera vaccine brand name.....

What is the cost of administering a single dose of the OCV in the clinic.....

What would be the cost per dose of delivering the vaccine in the field.....

How many doses of the OCV are usually given.....

What is the documented efficacy of the OCV brand that you offer.....

How many years of protection does the vaccine offer.....

What is the average life expectancy after vaccination with the OCV.....