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(UNITID)

A CASE STUDY ON THE PREVALANCE AND CLINICAL PRESENTATION OF ROTAVIRUS DIARRHOEA IN CHILDREN LESS THAN FIVE YEARS ADMITTED IN THE PAEDIATRIC WARD IN EMBU PROVINCIAL HOSPITAL

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A PROJECT SUBMITTED IN PARTIAL FULFILMENT FOR THE AWARD OF MASTERS OF SCIENCE DEGREE IN MEDICAL STATISTICS AT THE INSTITUTE OF TROPICAL AND INFECTIOUS DISEASES.

DECLARATION:

This is my original project report and has not been submitted for a degree in any other university

JULIA WANJIRU MUTHUA

Signature……. Date…….

This work has been submitted with my approval as a university supervisor

MRS ANNE WANGOMBE

Signature…….. Date……

DEDICATION:

This work is dedicated to my parents Mr. and Mrs. MuthuaMwangi and to my brothers Samuel Mwangi, Alex Gathui and James Njuguna and to my grandparents Mary Njeri and Abraham Mwangifor their love, support and encouragement throughout this study. These would not have been possible without all of you. And to the girls Peninah and Nimo thank you for all your support and love.

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ABSTRACT:

In Kenya diarrhoeal diseases is one of the leading causes of mortality in children less than 5 years and accounted for 21% of the cases (MoPHS, 2010).Diarrhoeal prevalence has remained unchanged as seen in the KDHS reports of 2003 where the prevalence reported was 16% while in 2008/9 KDHS report the prevalence was 17% in the households surveyed. Rotavirus infection is a major cause of dehydrating diarrhoea globally and leads to high hospitalization of children less than 5 years. The aim of this study was to determine the prevalence and the associated clinical presentation of rotavirus infection in children less than 5 years hospitalized at Embu Provincial Hospital with diarrhoea. A descriptive-cohort prospective study was conducted at Embu PGH a level 5 facility in Eastern province, as from January 2009-December 2011. 555 children were enrolled into the study, their stool specimens were collected and analyzed using commercial rotavirus antigen detection-enzyme immune assay kit. The prevalence of rotavirus infection was found to be 26.7% these finding was compared to the 30% prevalenceset on the WHO Generic Protocol on Rotavirus Surveillance for Developing Countries. The one sample proportion test done showed that the two prevalence rates as being similar, there was no significant statistical difference between the two prevalence. The study found that a child hospitalized at Embu PGH with diarrhoea was 1.99 times more likely to be RV Positive if he vomits compared to a child who does not vomit these was statistically significant with a P. value of 0.015. It was also found that the Children with rotavirus infection were 1.6 times more likely to be treated with intravenous fluids as compared to oral rehydration salt, these finding was statistically significant with a p. value of 0.037.RV gastroenteritis is an important aetiologic agent in causing dehydrating diarrhoea in children less than 5 years hospitalized in Embu PGH. To mitigate the effects of RV gastroenteritis and control the disease burden the introduction of RV vaccination nationally can impact on RV infection. The control measures that focus on improved hygiene and sanitation are able to deal and impact on diarrhoeal diseases brought about by bacterial and or parasitic agents and should therefore still be encouraged at all levels.

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ABBREVIATION:

1.	MDG4	Millennium Development Goals
2.	RV	Rotavirus
3.	EPI	Expanded Programme of Immunization
4.	PGH	Provincial General Hospital
5.	WHO	World Health Organization
6.	IMCI	Integrated Management of Childhood Illnesses
7.	DHIS	District Health Information System
8.	HCW	Health Care Worker
9.	MLE	Maximum Likelihood estimation
10.	CI	Confidence Interval
11.	KDHS	Kenya Demographic Health Survey
12.	MOPHS	Ministry of Public Health and Sanitation
13.	IVF	Intravenous fluid
14.	ORS	Oral rehydration salt
15.	TB	Tuberculosis
16.	LR	Logistic Regression
17.	SD	Standard Deviation

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CHAPTER ONE:

1. INTRODUCTION:

1.1 Background:

Diarrhoeal diseases are among the leading causes of high morbidity and mortality among children aged 5 years and below in the world. In a WHO factsheet report released in 2011, diarrhoeal disease was rated third among the top causes of childhood mortality and resulted to approximately 11% of mortality in this age group(WHO, september 2012).

In Kenya diarrhoeal diseases is also rated as the third leading cause of under 5 mortality and accounted for 21% of the deaths in 2010(MoPHS, 2010). The Kenya demographic health survey carried out in 2003 reported the prevalence of diarrhoea as 16% while that conducted in 2008-2009 the prevalence was 17% among the children in households surveyed. Not much improvement can be noticed between the two surveys in terms of reduction in prevalence of diarrhoea. In both surveys the prevalence increased with age peaking at 6-11 months (29% and 30% respectively) and later tapering off. The current morbidity out-patient work load for children less than five years in Embu PGH presenting with diarrhoea (minus dysentery) as per the DHIS report (MOH 705A) for the year 2011 was 1021, total attendance was 8380 thus diarrhoeal disease accounted for 12.2% of the morbidity cases.

There are various causes of dehydrating gastroenteritis(diarrhoea)in children under five years of age, and includes viral, bacterial and parasitic causative agent but viral infection is the leading cause of acute gastroenteritis both in the developed and developing countries. Among the viral agents causing acute gastroenteritis rotavirus (RV) is the leading causative agent and is experienced in both the developed and developing countries. The proportion of rotavirus detection rate is higher in developed countries but most mortalities related to RV is mostly experienced in developing countries and especially so in sub-Saharan Africa (Umesh D. Parashar, 2003; Jacqueline E Tate, 2011).

RV is a double stranded RNA virus that has several serotypes based on the G and P proteins found on the outermost shell of the virus. RV affects the small intestines where it has an incubation period of 18-36 hours, the virus later causes profuse watery diarrhoea without or blood or white cells, for a duration of 2-7 days. The virus is shed in stool and transmission is via the fecal oral route, RV can survive on hands for several hours and on the environment for days if not disinfected. A child with rotavirus infection will present with vomiting, low grade fever and profuse watery diarrhea. These results in symptoms of dehydration which if not managed early, via replacement of the lost fluids may result in increased morbidity and/or mortality of the child. The 1st infection of RV usually can be severe, repeated infection by rotavirus is

possible, though immunity is usually acquired later thus subsequent infections are less severe.(Tsion Bizuneh, 2004; Jyoti Malik., 2008; William W Hay, 2003).

The Government has made great efforts to promote breastfeeding, oral rehydration treatment, water purification, hand washing and improved handling of human waste and also through the introduction of IMCI strategy in the management of childhood illnesses(Anne wamae, 2009; MoPHS, 2010).These efforts have the capacity to manage and reduce the burden of diarrhoea secondary to bacterial and parasitic infection but has minimal effect on diarrhoea caused by RV.(Anne wamae, 2009; Jane S Nakawesi, 2010; Jacqueline E Tate, 2011).

Due to the above, the current recommendation by WHO in the management and control of RV infection is through vaccination of children under one year. The inclusion of RV vaccine in the schedule of immunizable diseases of childhood will go a long way in decreasing the burden of infection caused by the virus and thus aid in achieving MDG 4.(Kathleen M. Neuzil, 2010; Jacqueline E Tate, 2011).

Kenya is one of the countries forming the African Rotavirus Surveillance Network and therefore several studies regarding RV infection have been carried out both in urban and rural areas. Currently most of the studies being carried out are hospital based in either or both the outpatient and inpatient pediatrics departments (Nicholas M. Kiulia, 2008; J. M. MWENDA, 2003). As per the WHO Generic Protocol 2002 for hospital based surveillance, RV prevalence for Developing countries was set at approximately 30%. A review done on RV studies that had been carried out in various hospitals in Kenya, found that the prevalence rate of RV hospitalization stood between 6% to 56% (Nicholas M. Kiulia, 2008).

In many cases clinical studies focus on outcome measure that usually takes a dichotomous or binary format that is presence or absence of disease or exposure like is the case in this study (Rotavirus positive or Rotavirus negative), and the interest is to see how the outcome is related to e.g. sex, age etc (the predictor variables). Since the dependent/outcome variable is binary, the OLS (ordinary least squares) analysis is unsuitable to deal with dichotomous outcomes due to their strict statistical assumptions of linearity and normality. Therefore the model of choice in these situations is logistic regression which can handle binary outcomes.

Logistic Regression is used to model relationship between categorical outcome and a set of predictor variables. The goal is to check whether the probability of getting a particular value of the outcome variable is associated with the predictor variable and also to predict the probability of getting a particular value of the outcome variable given the predictor variable.

This is a sub-study within a major hospital based surveillance to estimate the burden of rotavirus gastroenteritis in children under five years of age in a rural setting (Embu, Eastern part) of Kenya. This study therefore aims at finding the prevalence of RV infection in children

less than 5 years admitted to Embu PGH and through the use of logistic regression model find out the clinical presentation of diarrhoea that are closely associated to R.V infection in children less than five years admitted to Embu PGH.

1.2 Justification:

In Kenya diarrhoea is the third leading cause of mortality and morbidity in children less than 5 years of age. The mortality secondary to diarrhoea stood at 21%(MoPHS, 2010). In Embu PGH diarrhoeal diseases accounted for 12.2% of the outpatient morbidity cases in the 2011 and it's among the leading top ten causes of morbidity among children less than five years reported in the hospital (DHIS).Rotavirus infection has been noted as one of the leading causes of severe dehydrating diarrhoea in the world, and is found both in the developed and developing countries. Thus it's a major contributor to high hospitalization rate of children suffering from diarrhoea. The mortality rate secondary to RV infection has been noted to be higher in developing countries as compared to the developed countries (Umesh D. Parashar, 2003).Thisstudy therefore aimed at gathering information on the prevalence and burden of RV infection in hospitalized children aged less than five years in Embu PGH which is a facility based in rural Kenya and compare it with the prevalence set by WHO in the generic protocol for developing countries. The study also aimed at looking for the associated clinical presentation of diarrhoea in children confirmed to have RV infection using logistic regression as the statistical model.

1.3 Limitation:

This study did not include the social demographics of the parents or guardians of the children such as marital status, education level employment status this was because the main study did not include it as part of the RV surveillance data to be reported.

1.4Main Objective:

To find out the prevalence of Rotavirus infection and the associated symptoms among children less than 5 years presenting with diarrhea and admitted at Embu PGH.

1.4.1 Specific objective:

1. To find out the prevalence of rotavirus infection among children less than five years admitted at Embu PGH with Diarrhoea.
2. To find out the demographic factors and clinical presentation associated with RV diarrhoea among children less than five years admitted at Embu PGH using univariate logistic regression
3. To find out the demographic factors and the clinical presentation of diarrhoea that are able to predict RV diarrhoea among children less than five years admitted at the Embu PGH using multivariable logistic regression

1.4.2 Hypothesis:

Null: There is no difference between the prevalence of rotavirus infection in Embu PGH and the prevalence set by WHO in the Generic protocol for surveillance studies in developing countries.

Alternative: There is a difference in the prevalence rate of rotavirus infection in Embu PGH and the prevalence set by WHO in the Generic protocol for surveillance studies in developing countries.

$$H_0 : prev_{(EmbuPGH)} = 30\%$$

$$H_A : prev_{(EmbuPGH)} \neq 30\%$$

CHAPTER TWO:

2. LITERATURE REVIEW:

This chapter shall deal with studies done using Logistic Regression and also look at various literature reviews of studies done on prevalence and the associated clinical presentation of Rotavirus diarrhoea Globally, in Africa and in Kenya.

2.1 Logistic Regression:

In many clinical settings the research problems is usually in the form of patient disease status or exposure status. A patient's well being is measured in terms of presence or absence of disease,exposure or an outcome of interest (e.g. RV positive or RV negative diarrhoea, smoking or not smoking, dead or alive etc). The above outcome of interest are said to be in a binary or dichotomous format. In medical research the idea is determining or finding out the associated factors that may lead to the outcome of interest. These findings may help in preventing the development of disease outcome and also improve medical knowledge on various issues relating to health.

A Study carried out to predict high school student's cigarette smoking behavior by Adwere et al, 2010 used multiple logistic regression model. The outcome of interest was current cigarette use among the youth coded as yes/no and there were five predictor variables. The main aim was to find out which of the predictor variables could accurately predict current cigarette smoking among the youth. The logistic regression model fitted was;

$$\log it(cfcu) = \alpha + \beta_1(hispanics) + \beta_2(white) + \beta_3(icsa) + \beta_4(fsh) + \beta_5(fcu) + \beta_6 pib$$

The regression analysis for the above showed that the full model was statistically significant, χ^2 = 1700.966 with a p.value of < 0.001.The odds of a high school student smoking was related to all five predictor variables. But in the pack the strongest predictors were Race (white), cocaine use (fcu) and physically inactive behavior (pib). The model classified 93% of the cases and explained about 31% of the variance in current frequency cigarette use by students in high school.

Sharareh R et al, 2010 carried out a study in Iran using logistic regression to predict the risk of TB treatment failure. A retrospective analysis was carried out using data for 9672 TB patients. Failing to complete treatment was the dependant variable and there were 6 predictor variables. Descriptive analysis was performed in relation to the dependent variable. The LR model was developed and the wald test showed that all the predictor variable (sex, age, weight, Nationality, prison and case type) were significantly associated to the outcome of interest. The

validity of the model was checked using Train and test and also by Hosmer and Lemeshow goodness of fit.

2.2 Prevalence and Clinical Presentation of Rotavirus Diarrhoea:

Diarrhoea is a major cause of morbidity and mortality among children less than 5 years globally and especially so in developing countries. RV is among the major causes of severe form of diarrhoea and contributes to almost 22% of hospitalization in children under the age of 5 years. Globally RV causes approximately 2 million hospitalization and 25 million outpatient visits (Umesh D et al, 2006; Umesh D et al, 2003; Kumar et al, 1994).

In a study carried out in Basrah-Iraqby Abbas et al, 2000 RV was found in 43.3% 0f children admitted with acute watery diarrhoea in Busrah Maternity and Children Hospital and the frequency of RV was noted to be higher among children aged less than 2 years (7-12 months) these findings were similar to a study carried out in Indiaby Kumar et al, 1994. There was no significant association with a single clinical presentation which could differentiate RV infection from other causes of diarrhoea whether viral or non viral.

In Palestine a study carried out found that 28% of children aged less than five years who presented with acute diarrhoea were RV Positive. Most of the children infected with RV were less than 2 years and infectivity rate decreased with increase in age. Watery stool and metabolic acidosis were significantly associated with RV infection in this study and there were more males than females who had RV infection(Farid H et al, 2006).

A standardized RV surveillance was carried out in Indonesia by Yati et al, 2009 using the WHO generic protocol, found that RV prevalence was at 60% in children admitted with diarrhoea and 41% in children treated at the outpatient clinics with diarrhoea. Children aged between 6-11 months had the highest prevalence of 64%; more males were found to have rotavirus infection but wasnot significant. Vomiting and dehydration were the most prominent clinical presentation in children with RV infection. No seasonal variation was noted in all sites that took part in the study. Similar results on lack of seasonality variation was also found in a systematic review study carried out by (Mark A et al, 2010), the study looked at articles in 22 countries in the Eastern Mediterranean Region. The prevalence of RV in children less than five years hospitalized secondary to acute diarrhoea was found to range between 17% to 46% with a median of 40%, but the summary statistic estimate calculated using nonparametric statistic was 35% . In children treated at the outpatient department the prevalence range was 6% to 41% with a median of 23%, the summary estimate calculated using nonparametric statistic was still 23%.

Jacqueline et al, 2011 conducted a systematic review and meta-analysis to estimate worldwide RV associated mortality. In 2008 the RV associated deaths were approximately 453,000 in children less than five years. Most children detected to have RV infection were from developed countries but most deaths occurred in developing countries Africa and Asia and especially so in sub-Saharan Africa. There was a marked decrease of diarrhoeal related deaths between 2004 which stood at 527,000 (95% CI 475,000-580,000) compared to that of 2008, though the Confidence intervals overlapped. The decline noted was not evenly distributed to the various causes of diarrhoea, having non RV diarrhoeal causes decreasing by 32% and RV diarrhoea mortality declining by 14%. The introduction of Vaccination against RV infection and especially in developing countries may have an effect in mortality associated with RV diarrhoea in children less than five years. Currently the recommendation by WHO to all countries worldwideis the introduction of RV vaccine into their childhood immunization programs.

In Africa there are several studies that have been carried out by various researchers. Jason Mwenda et al, 2010 looked at surveillance data from 8 countries in the African Rotavirus Surveillance Network and Kenya was among these countries looked at. The prevalence of RV infection in countries that had data for 2years (Kenya, Uganda, Zambia and Ghana) was 41% ranging from 39% to 52% in hospitalized children less than five years with acute diarrhoea, while in countries that had data only for 1 year (Tanzania, Cameroon, Ethiopia and Zimbabwe) the prevalence was 35% ranging from 29% to 47%. The cumulative prevalence for the hospitalized children aged less than five years in all the study sites was 40% ranging from 29% to 52%. While the prevalence of RV infection in children treated at the outpatient department ranged from 10% to 20%, which was much lower than the inpatient prevalence. Children aged 3-18 months accounted for 90% of the RV infection across the board. RV infection was experienced all through the year though there was slightly more infections noted during the cool dry months. The strains observed routinely included G1 and G2 but also unusual strains such as G8 and G12 were also noted.

Na Cunliffe et al, 1998 conducted a review of studies done in Africa and found the prevalence of RV infection in children less than 5 years treated at the outpatient department was 23% ranging from 7% to 40%, while in the hospitalized children it was 24% ranging from 13% to 55%. The children hospitalized tended to be relatively younger having a median age of 6 months while those treated at the outpatient department the median age was 9 months. 81% of the children hospitalized were aged less than 1 year while in the outpatient department they comprised 61% of the children treated. Most countries had no seasonal variations and RV infection occurred throughout the year except for Ghana where seasonal peaks were more frequent during the dry seasons compared to the wet seasons. Both the G and P serotypes were found, G1 comprised 42% of theserotypes seen.

Jacqueline et al, 2009 carried out a study to estimate the burden of rotavirus among children less than 5 years in Bondo and Siaya Districts in Nyanza province. In the study area diarrheal diseases caused approximately 842 deaths /100,000, where 164 of the deaths were secondary to RV infection in children < 5 years annually and 19% of hospitalization secondary to diarrhoea is due to RV infection. Clinic visits secondary to diarrhoea was found to be 109,000/100,000 and rotavirus accounted for 16% of these visits. To get the RV estimates for Kenya extrapolation of the results found in Nyanza was carried out and the estimated deaths hospital and clinic visit were 68,132 and 21,800 per 100,000 respectively. The economical burden brought about due to treatment of RV infection both in the Outpatient and inpatient department is approximately $10.8 million/year or $8.14 per child per year. Estimated savings that may be attained secondary to introduction of RV vaccination at the national level is approximately $6.4million the bulk of these cost is due to clinic visits.

Nigel A et al, 2001 carried out a study in 3 countries, the site in Kenya was Gertrudes Garden children hospital and the study was carried out between January to March 2000. Stool specimens were collected from children less than 5 years who were admitted to the hospital with gastroenteritis. The prevalence of RV was found to be 41% while the predominant serotypes were G1 (12.6%) and G9 (10%).

CHAPTER THREE:

3. METHODOLOGY:

3.1 Study Design:

The main study is a descriptive cohort- prospective study that was Inco-operated and built on an already existing pneumococcal meningitis surveillance system at the Embu PGH. This sub study sought to ascertain the prevalence of RV infection in a hospital setup in rural Kenya (Embu County), using the WHO protocol for RV surveillance. The study also sorts to determine the associated clinical presentation of RV infection in this region.

3.2 Study Area and Population of Interest:

Embu PGH is one of the government owned level 5 health institution in the country and is situated in Eastern province, Embu County, in Embu west district. The hospital is approximately 120 kilometers northwest of Nairobi and serves as the referral centre in Eastern province. The paediatric ward has 117 beds and 657 cots, and caters for admissions of all children less than five years. As per the DHIS report Embu PGH attends to approximately 1000 cases of diarrhoea in children less than five years annually. Diarrhoea also forms part of the top ten causes of morbidity at the hospital in children less than 5 years.

The study targeted children aged less than five years who were admitted to the hospital for the treatment of diarrhoea as from January 2009 to December 2011.

3.2.1Sample Size:

As per the WHO Generic protocol, hospitals that are to be used as a surveillance site should at least attend to 250-500 children annually, with gastroenteritis. This is based on the conservative prevalence of 30% for Rotavirus infection set for developing countries. For this study the significance level is set at 0.05 and the margin of error is set at 5%. If the WHO conservative prevalence of 30% is used, the sample size calculated will be 323 using the formulation below:

Sample size calculation;

$$n = \frac{Z^2 pq}{d^2}$$

Where: n = calculated sample size (323)
z = level of significance (1.96)
p =prevalence of RV infection (0.3)
q = 1-p (0.7)

d = the margin of error(0.05)

3.3 Case Definitions, Inclusion and Exclusion criteria:

The case definition, inclusion and exclusion criteria used in these study was as per the WHO 2002 generic protocol for hospital based RV surveillance

Case Definition:

A Suspected case of RV diarrhoea is defined as a child aged less than 5 years presenting and admitted to the hospital secondary to diarrhoea

A Confirmed case of RV is a suspected case with demonstrated evidence of RV in the stool through laboratory confirmatory tests.

Diarrhoea (gastroenteritis) is the presentation of at least 3 loose or watery stools in 24 hours. The Acutepresentation of clinical symptoms is when they occur within less than 7 days of attendance by the HCW.

The inclusion criteria were as follows:

- Children aged below 5 years,
- Presenting with acute diarrhoea
- Admitted to the hospital for treatment primarily due to diarrhoea.
- Having had diarrhoea for less than 7 days on presentation to the hospital

Exclusion criteria were as follows:

- Children presenting with bloody diarrhoea
- Diarrhoea lasting more than 7 days before presentation to hospital
- Children aged more than 5 years
- Diarrhoea acquired during hospitalization for another disease (nosocomial RV infection).

3.4 Ethical Consideration,Data Collection and Laboratory Investigation:

Ethical Consideration:

This study was approved by the Kenyatta National Hospital ethics and Research Committee.Informed consent from parents / guardians of the eligible children was obtained before their enrollment into the study. The recruitment of children into the study followed the inclusion and exclusion criteria above and once the child was eligible the recruitment into the study was done serially.

Data Collection:

Patient log book and a case report forms were used to collect data. The case report form covered demographic data (i.e. age, gender and district of origin), clinical presentation (i.e. date of onset of symptoms and the duration, treatment and patient outcome) and laboratory information of the enrolled children. (Annex ii and Annex i respectively)

Laboratory Investigation:

Stool specimens of approximately 5mLwere collected from the suspected cases within 48 hours of admission, thus ensuring nosocomial infection is avoided. The samples were then analyzed with a commercial rotavirus antigen-detection enzyme immunoassay kit and the results posted to the diarrhoea case report form. All Elisa positive and 10% of the Elisa negative stools specimen were stored at the recommended temperature for QA/QC and further molecular analysis at the regional reference laboratory. The Enteric Research Group of the Institute of Primate Research was instrumental in providing laboratory technical support and management of the data during the study period.

3.5 Data Analysis:

This section shall deal with issues relating to data processing and preparation, data structure and the statistical model to be used in the analysis of the data in this study.

3.5.1 Data Processing and Preparation:

The computer case study form was used during the surveillance study which is based on Epi info data base structure. These ensured complete data entry and reduced error brought about by keying of information from a manual system to the computer data base system.

The data was later extracted and converted from the access base format into an excel format. Selection of variables needed for further analysis was done, together with the creation of new variables from the original ones and recoding of variables into more appropriate form.

3.5.2 Data Structure**:**

There are various methods used in statistical analysis of data, it is therefore prudent to look at the structure of the dependent and the predictor variables so as to pick the most appropriate model. The table below gives the description of the data generated from the study;

Table 1: Variable Description

Variable Name	Variable type	Variable Code (Categorical)
patient identification	Discrete	
Dependant variable		
Elisa test for rotavirus in stool	Binary	Positive-1 Negative-0
Predictor Variable		
Demographic variable		
district of origin	categorical	
age in months	continuous	
Age in categorical format	categorical	
gender	categorical	Female-1 Male-2
Clinical presentation variables		
lethargy/unconscious	categorical	1-yes 2-no
sunken eyes	categorical	1-yes 2-no
temperature	continuous	
Dehydration status	categorical	1-severe 2- some 3-shock 4-none
drinking poorly	categorical	1-yes 2-no
Number of vomiting episode in a day	Continuous	
vomiting status	categorical	1-yes 2-no
number of days vomited	continuous	
number of diarrheal episodes	Continuous	
diarrheal status	categorical	1-yes 2-no
Patient outcome on discharge	categorical	1-alive 2-dead 3-transferred 9- unknown
days patient had diarrhoea	continuous	
treatment offered	categorical	1-ors 2-ivf 3-ors&ivf 4-other
skin turgor impairment	categorical	1-yes 2-no

The dependent/outcome variable as shown in table 1 above, is Elisa test for rotavirus done on the stool specimen collected from the suspected cases enrolled into the study and the coding for the outcome variable result was; positive=1 and negative= 0.

Since the dependant variable is in a categorical form it will therefore be of essence to use a statistical model that will cater for these. The predictor variables were in two format continuous variables and categorical variable with some having more than two categories. Below is a table giving the various models that can be used when the dependant variable is in the categorical (binary) format like in this case;

Table 2: Statistical Models

Dependent variable	Predictor variable	Statistical model
Categorical (with 2 categories i.e. binary)	Categorical	Contigency tables Logistic Regression
	Continuous	Logistic Regression Probit Analysis
	Categorical and Continuous	Logistic Regression
Greater than 2 Categories	Nominal	Contigency Tables
	Categorical and Continuous	Nominal Logistic Regression

3.6 Logistic Regression:

Regression Analysis is a measure of association between the dependent variable and one or more predictor variables. This is usually achieved by use of mathematical equation/model that summarizes the relationship between the dependent variable and the predictor variable/s. The summary statistics generated from the model are used to describe how well the model fits the data, the amount of variation in the outcome accounted for by the model. Thus one is able to determine a combination of predictor variables that most satisfactorily predict the values of the outcome/dependent variable.

3.6.1 Model Description:

Logistic regression model utilizes and builds further on the linear regression analysis model. In logistic regression there is a transformation of the dependent variable to the log odds ratio and therefore can be used for analysis of binary dependent variable.

Simple Linear regression

Simple linear regression analysis with a single predictor variable is as shown below;

$$y = \alpha + \beta x \qquad (1)$$

Where:

Y Is the dependent/outcome continuous variable

α Is the intercept

β Is the predictor variable coefficient (e.g. Age in months)

The above linear probability model is not appropriate when dealing with a binary outcome since Proportions and Probabilities are different from continuous variables. In binary outcome the expected value of y is a probability that y=1 and therefore it lies between 0 to 1, while in equation (1) y which is a continuous variable takes values from $-\infty$ to $+\infty$ .Therefore to produce the same equation on the right hand side and maintain what is on the left aspect we let p(probability of an event occurring) = p(y=1) , and the ratio p/1-p takes on values between 0 and ∞, on transformation of the ratio through natural logarithm; ln (p/1-p) takes on values between $-\infty$ and $+\infty$ just as the right side of equation (1), therefore the equation can be

Written as;

$$\ln\left(\frac{p}{1-p}\right) = \alpha + \beta x \qquad (2)$$

The above is the logistic regression model and the transformed ratio i.e. ln (p/1-p) is the logit which is also the natural log of the odds of y.
From equation (2) we see that the logistic model actually forms a linear model for the log odds. The odds ratio measures how much greater or lesser the odds are for subjects possessing the risk factor to experience a particular outcome.

3.6.2 Assumptions in Logistic Regression:

- The dependent/outcome variable should be binary/ have 2 categories
- P(Y=1) is the probability of the event occurring, thus the dependent variable should be coded to reflect the same (In this case Rotavirus test positive = 1 while Rotavirus test negative = 0).
- The model should be fitted correctly only the meaningful variables should be included, this can be achieved by use of stepwise method to estimate the logistic regression.
- Independent error terms: Each observation needs to be independent, the data-points should not be from any dependent samples design, e.g., before-after measurements, or matched pairings. The model should have little or no multicollinearity (the independent variables should be independent from each other).
- Linearity of predictor variables and log odds i.e. the predictor variables are linearly related to the log odds.

- Large sample sizes: logistic regression uses maximum likelihood estimates which is less powerful than ordinary least squares

No assumptions are made on the following situations:

- Linearity- the dependent and predictor variable do not need to have a linear relationship since logistic regression has a non-linear log transformation to the predicted odds ratio.
- Normality- the predictor variables and error terms (the residuals) do not need to be multivariate normally distributed
- Homoscedasticity is not needed the variances can be heteroscedastic for each level of the independent variables
- Measurement level- logistic regression can handle ordinal and nominal predictor variables and they not need to be metric (interval or ratio scaled).

3.7 Univariate Logistic Regression Model:

The model usually has one predictor variable which could either be a categorical or continuous variable:

$$\ln\left(\frac{p}{1-p}\right) = \alpha + \beta x \quad (3)$$

or

$$\ln\left(\frac{p}{1-p}\right) = e^{\alpha+\beta x} \quad (4)$$

Equation (3) is in the form of β coefficient while equation (4) is in the form of odds.

Univariate logistic regression is used to look at the association between the dependent/outcome variable in this case Elisa test for rotavirus in stool (positive/negative) with one predictor variable example Age in months in terms of odds ratio or vomiting status (yes/no) also in terms of odds ratio (but each is looked at independently). The resultant logistic regression coefficient is subjected to parameter estimation (as explained below) to determine if the association between the dependent/outcome variable and the predictor variable in terms of odds ratio is significant or not.

3.8 Multivariable Logistic Regression Model:

In this model there is more than one predictor variable thus the simple logistic regression can be extended to accommodate more variables as follows;

$$\ln\left(\frac{p}{1-p}\right) = \alpha + \beta_1 x_1 + \beta_2 x_2 + ...\beta_k x_k$$

We get the adjusted odds when you run a multivariable logistic regression

The predictor variables can either be categorical or having both categorical and continuous variables. In this study the predictor variables were both in continuous and categorical variable format as shown on table 1 above. Since we have more than one predictor/Explanatory variable in the study, we therefore need to find the set of the predictor variables that well explains or models the relationship with the dependent/outcome variable in the best fit and in a biologically reasonable model (I.e. to get the predictor variables that can accurately predict a child with rotavirus infection).

3.9 Parameter Estimation:

The Parameters used in the logistic Regression Model include;

- The constant, α, and
- The logistic regression coefficients β

Both parameters are unknown and therefore must be estimated using the sample data.
In linear regression the estimation of parameters is based on the least square estimation principles, this method does not work well with logistic regression model thus the use of Maximum Likelihood Estimation (MLE) method invented by fisher 1922. The MLE is derived from the probability distribution of the dependent variable in the sample data. MLE method maximizes the probability of classifying the observed data into the appropriate category given the regression coefficients therefore a best fitting equation or function is formed
The general principle is getting the likelihood function which is the joint probability function of the random variables.
The likelihood function is given by;

$$p(y_1, y_2 ... y_n; \pi) = \prod_{i=1}^{n} \pi_i^{y_i} (1-\pi_i)^{(1-y_i)}$$

The estimation of α and β is achieved by the maximization of the log likelihood instead of the likelihood function and is denoted as follows;

$$L(\beta_0, \beta_1 .... \beta_p) = \sum_{i=1}^{n} Y_1(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + ... + \beta_p x_p) = \sum_{i=1}^{n} \ln\left\{1 + \exp(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + ... + \beta_p x_p)\right\}$$

The MLE can be used even when the unknown parameter has several components (i.e. $\beta_{o,}\beta_1.....\beta_p$).

3.10 Model Evaluation:

This section shall deal with the various inferential statistical tests carried out so as to determine how adequate the model fits the observed sample data; these shall be achieved through,

- Statistical testing of the individual predictors
- Overall model significance testing
- Goodness of fit statistics

During inferential testing the following are the assumption taken when using logistic regression model:

- Randomization occurred during sample data collection
- The dependant variable has a binomial distribution.

3.10.1 Statistical test of individual predictors:

The estimated parameters need to undergo significance testing so as to determine the importance of each regression coefficient in the logistic regression model, these is achieved by use of Wald chi-square test. The wald test is a ratio of the regression coefficient to its standard error and checks if the regression coefficient is significantly different from zero.

Hypothesis to be tested:

$$H_o : \beta x = 0$$
$$H_{\mathrm{A}} : \beta x \neq 0$$

The Wald's statistic:

$$\frac{\hat{\beta}}{\mathrm{var}(\hat{\beta})} \sqcup \chi^2$$

or

$$\mathrm{Z} = \frac{\hat{\beta}}{s.e(\hat{\beta})} \sqcup N(1,0)$$

Decision Formulation:
Compare computed χ^2 and the tabulated χ^2
Reject H_o if $\chi^2_{(comp)} \geq \chi^2_{\alpha,1}$ (χ^2 tabulated for a chosen value of α)

Confidence Interval:
The confidence Interval is derived by using the standard error of the log odds ratio

The 100(1-α) % C.I for β is;

$$\hat{\beta} \pm Z_{\frac{\alpha}{2}} se(\hat{\beta})$$

The 100(1-α) % C.I for $e^{\beta x}$ is;

$$\exp\left[\hat{\beta} \pm Z_{(\frac{\alpha}{2})} se(\hat{\beta})\right]$$

If the sample size of the data collected is small the likelihood ratio test would be a better test of coefficient significance.

3.10.2 Overall model parameter significance testing:

During the overall model testing of all parameters used in a model the procedure employed is usually to test if there is much improvement of the full model from the null model (i.e Intercept only model).The null model is used as a baseline since it has no predictors and should actually be nested in the full model these ensures comparison of the two models to be achievable.
The test employed to achieve this is called the likelihood ratio test and it usually compares the two models i.e. the null and the full model where it determines whether the other parameters in the full model equal zero. The likelihood ratio test is an analogue to F- test that is usually employed in linear regression.

Example:

$$M_0 \rightarrow \log it\left[\pi(x)\right] = \alpha + \beta_1 x_1$$

$$M_1 \rightarrow \log it\left[\pi(x)\right] = \alpha + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3$$

From the above we see that M_0 is formed from M_1 (i.e. M_0 is nested within M_1)

Hypothesis:

$H_0 : \beta_2 = \beta_3 = 0$

The MLE for the two models are;

$M_0 \rightarrow LogL_1$

$M_1 \rightarrow LogL_2$

The likelihood Ratio statistics:

$LR = 2*(L\log L_2 - LogL_1) \square \chi^2(d)$

$d \rightarrow$ Parameter difference of the two models.

3.10.3 Goodness of fit:

Goodness of fit involves the determination of how well the observed outcomes compares with the values fitted in the model. The test employed for these purpose is the Hosmer-Lemeshow $\hat{C}_g$ test which is a Pearson chi-square statistic.

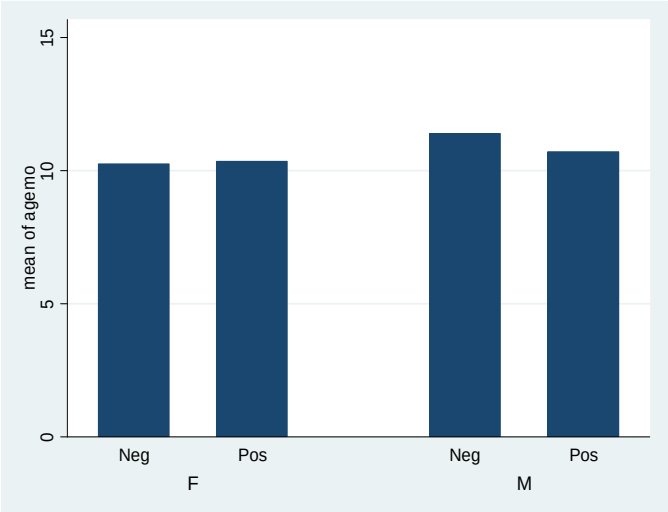
CHAPTER FOUR:

4. RESULTS:

4.1 Descriptive Statistics:

A total of 555 children aged less than five years with diarrhoea, were admitted at Embu PGH and the presence of rotavirus in stool investigated. Out of these 250 (45%) were females and 303(54.6%) were males and 2(0.4) gender data missing. Most of the children enrolled were from within Embu district 423 (76%), 87(15%) were from Mbeere district, and the rest were from the other districts.

Figure 1: Mean Age in Months vs Gender and RV test:



In figure one above and in table3 below; they both show that there were more males presenting to the facility with diarrhoea compared to the females. Rotavirus positivity was higher among the male children as compared to the female children. The difference between the two genders is not very huge.

Table 3: Gender Distribution

Gender	Rota Test				Total
	Positive	**(n%)**	**Negative**	**(n%)**	
females	63	(25.5)	184	(74.5)	247
males	82	(27.1)	215	(72.4)	297
Total	146	(26.7)	399	(73.4)	544

26.7% of the children were positive for rotavirus with majority of them being less than one year (67.8%).The mean age at admission of all the children was 10.8 months with a Standard

deviation of 6.7, those who were RV Positive the mean age of admission was 10.6 months (SD 6.6) while those who were RV negative was 10.9 months (SD 6.7). There were more males admitted with diarrhoea and testing positive for rotavirus compared to females these was replicated on all the age groups as shown on table4 below. The difference in incidence seen between the different age groups was not statistically significant both in gender and the numbers recorded. There were 11 Missing dataset information from the results above as shown on table3, thus giving a total of 544 instead of 555 children (reason: 3 females without RV test results while males were 6, 2 children tested but no gender recorded).

Table 4: Distribution of rotavirus by age

	Total Tested		Positive Rota Test	
Age in months	**Total**	**Pos (n%)**	**Males**	**females**
< 6	142	41 (28.1)	21	20
6--11	212	58 (39.7)	35	23
12--23	162	40 (27.4)	21	18
24--35	25	6 (4.1)	5	1
36--47	3	0(0.0)	0	0
48--59	2	1 (0.7)	0	1
Total	546	146 (100)	82	63

Among the 555 children admitted with diarrhoea the other clinical presentations were as follows;145 of the children presented with lethargy,300 with sunken eyes,125 with severe dehydration and 332with some dehydration,278 with impaired skin turgor,444 were vomiting.

Table 5: Clinical Presentation

Signs and Symptoms		Rota test	
	Level	Negative	Positive (n%)
Drinking poorly	Yes	175	73 (15)
	No	171	65 (13.4)
Vomiting	Yes	315	129 (23.7)
	No	83	17 (3.1)
Lethargy	Yes	98	47 (9.7)
	No	245	91 (18.9)
Sunken eyes	Yes	214	86 (17.5)
	No	138	53 (10.8)
Dehydration	Severe	89	36 (6.8)
	Some	241	91 (17.3)
	None	57	13 (2.5)

Skin Turgor	Yes No	202 143	76 (15.8) 60 (13)

The average temperature for children with RV infection was 37.9^0c, those who presented with vomiting had an average of 4.08 vomiting episode per day for an average of 2.8 days. The children who were RV negative had an average temperature of 38.1^0 c and an average of 3.7 episodes of vomiting per day for an average of 3.2 days .All children enrolled to the study had diarrhoea on presentation. The average diarrhoeal episode per day was 4.3 and lasted for an average of 3 days, the diarrhoeal finding was similar for both the RV positive group and RV negative group.

Table 6: Treatment and outcome

		Rota Test	
	Level	**Negative**	**Positive (n%)**
Treatment	Ors Ivf Ors&ivf	281 88 28	91 (16.8) 45 (8.3) 9 (1.66)
Outcome	Alive Dead	340 2	135 (28.2) 1 (0.21)

4.2 Rotavirus Prevalence:

The prevalence of rotavirus infection in children admitted at Embu PGH with Diarrhoea was 26.7% with a 95% C. Interval of 23.0% to 30.4%.

The WHO approximation on the prevalence of rotavirus infection for developing countries in the Generic Protocol for hospital based RV surveillance set at 30% was subjected to a One Sample Proportion Test. This was done to test the hypothesis;

$$H_0 = prev_{(EmbuPGH)} = 30\%$$

$$H_A = prev_{(EmbuPGH)} \neq 30\%$$

The One Sample Proportion Test performed showed that the prevalence of RV infection in Embu PGH of 26.7% was not statistically different from the set WHO prevalence of 30%, for developing countries in the Generic Protocol for hospital based RV surveillance, the p. value was 0.0964.

Table 7: One Sample Test of Proportion

Mean	Std Error	95% Conf. Interval		Z score	P value
0.2673993	0.189416	0.2302743	0.3045242	-1.6623	0.0964

4.3 Univariate Analysis:

Univariate analysis was carried out using logistic regression, the dependent variable was rotavirus Elisa test results obtained from the stool specimens (positive =1 and negative=0) ,the following were the results found from the model;

All the demographic variables were not significantly associated with rotavirus infection i.e. Age, sex and the district of origin. For gender the males were 1.11 more likely to be rotavirus positive compared to the females but these finding was non-significant. Among the 6 age categories shown on table 3, none had any significant association with rotavirus infection.

Among the clinical symptoms seen in children presenting with Gastroenteritis the following were the findings; the odds of children who were rotavirus positive vomiting, was 1.99 times more compared to the children who were not vomiting, these finding was significant with a chi square of 0.0107 and a p. value of 0.015. Drinking poorly, days experienced vomiting, vomiting episodes per day, number of diarrhoeal days and episodes per day were all non significant. The clinical symptoms lethargy, skin turgor impairment, sunken eyes, temperature and dehydration were all also not significantly associated with Rotavirus infection. The clinical outcome on discharge was also non significant. Treatment in general was also non significant but the odds of children who were rotavirus positive and treated, were 1.6 times more likely to be treated with IVF as compared to being treated using ORS and these finding was significant with a p. value of 0.037.

Table 8: Univariate Analysis

Characteristics	**Odds ratio**	**95% C. Interval**	**P. Value**
Demographics:			
Gender (males)	1.11	0.76 - 1.63	0.58
Age in months	0.99	0.97 - 1.02	0.68
Clinical Symptoms:			
Drinking Poorly	0.91	0.61 - 1.35	0.64
Vomit Status	1.99	1.14 - 3.5	0.015*
Vomit Days	0.91	0.82 - 1.03	0.136
Diarrhoeal Days	0.98	0.89 - 1.08	0.68
Vomiting Episodes	1.05	0.96 - 1.15	0.22
Diarrhoeal Episodes	0.99	0.91 - 1.09	0.96

Clinical Signs:			
Lethargic	0.77	0.51 - 1.18	0.24
Sunken Eyes	0.96	0.64 - 1.43	0.83
Dehydration	0.83	0.60 - 1.05	0.11
Skin Turgor	1.12	0.59 - 0.75	0.59
Temperature	0.87	0.74 - 1.03	0.98
Treatment	1.20	0.89 - 1.63	0.23
Outcome	1.26	0.11 - 14.0	0.85

4.4 Multivariable Analysis:

Vomiting Status was the only explanatory variable that was statistically significant as shown in the univariate analysis results.

Stepwise Logistic Regression was carried out in two steps and using a p. value cut off point of 0.25(p.e). In the 1st step all the explanatory variables were run independently. The variables added are shown on Table 8 below.

The 2nd step involved running the stepwise using vomiting status as the first covariate, the variables retained are as shown on the Table 8Below;

Table 9: Stepwise Logistic Regression

Step one		Step two Term 1: Vomiting Status	
Variable Added	P. value	Variable Added	P. value
Lethargy	0.24	Temperature	0.14
Temperature	0.09	Dehydration	0.17
Dehydration	0.11		
Vomit Episodes	0.22		
Vomiting status	0.02		
Vomiting duration	0.12		
Treatment	0.23		

Model 1:

Ln (odds) = -1.586+0.693vomit

Log likelihood =-313.16

LR χ^2 =6.51 with p. value =0.011

Model 2:

Ln(odds) = 3.974 +0.58 vomit -0.136dehy -0.149temp

Log likelihood = -298.23

LR χ^2 *=9.18 with p. value =0.03*

Goodness of fit using Hosmer and Lemeshow test:

Model 2 was tested for goodness of fit using H-L test and was determined that it was the best fit of the two models.

χ^2 *=7.56*

P.value =0.4774

Logistic Regression Model for RV infection

By use of the results on table10, the following is the fitted logistic regression model for RV infection in this study.

Ln(odds of RV) = 3.974 +0.58 vomit -0.136dehy -0.149temp

A child less than five years presenting with gastroenteritis and vomiting the odds of the child having RV infection was 1.8 times more than the child who was not vomiting; this finding was the only one in this model that was significant with a p. value of 0.045.

Table 10: Model with Fitted Predictors of RV Diarrhoea

Predictor	Odds Ratio	β	P. value	OR-95% CI	
Vomit status	1.785	0.580	0.045*	1.01	3.15
Temperature	0.873	-0.136	0.119	0.74	1.04
Dehydration	0.861	-0.149	0.214	0.68	1.09
Constant	53.175	3.973	0.235	0.76	373

*significant p<0.05

NB: the odds ratio reported above are the adjusted odds ratios.

CHAPTER FIVE:

5. Discussion, Conclusion and Recommendation:

5.1 Discussion:

One of the aims of the study was to find out the prevalence of RV infection in children aged less than 5 years admitted to Embu PGH with a history of diarrhoea and also perform a hypothesis test on the calculated prevalence so as to compare it with that set by the WHO Generic protocol for Hospital based surveillance in developing countries. The prevalence of rotavirus in children less than 5 years admitted to Embu PGH was at 26.7% with a 95% C. Interval of 23.0% to 30.4%. These results mirror findings of a study carried out in Jimma Hospital in Ethiopia (Tsion Bizuneh, 2004) that found the prevalence of RV infection in children less than 5 years hospitalized was 26.6%. The prevalence of RV infection in Embu PGH also fell within the prevalence bracket of 6%-56% (Nicholas M. Kiulia, 2008). A study carried out in Bondo and Siaya found a hospitalization prevalence of 19%, while the Gertrudes Garden Hospital study found a prevalence of 41% although the main aim of the study was not to get the prevalence but rather the serotypes of RV in circulation there sample size was smaller than the one advocated for by WHO in the Generic Protocol (Jacqueline E. Tate, 2009; Nigel A. Cunliffe, 2001).

The one sample proportion test carried out to determine if the set WHO generic protocol prevalence for developing countries is similar to the findings in these study, showed that there was no significant statistical difference between the two prevalence (i.e. 26.7% Embu PGH prevalence and 30% WHO set prevalence are similar).

The study enrolled 555 children out of these 250(45%) were females while 303(54%) were males. 146 children tested RV positive, there were more males testing positive for RV infection 82(56.6%) compared to females 63(43.5%) although these difference was not statistically significant. Similar results have been seen in study's carried out in Ethiopia at Jimma hospital and in Uganda at Mulago hospital (Tsion Bizuneh, 2004; Jane S Nakawesi, 2010). Although in a study carried out at Jos hospital in Nigeria the differences seen between the males (8.8%) and females (5%) was statistically significant with a p. value of 0.015(Surajudeen A Junaid et al, 2011).

The mean age of children admitted to Embu PGH with RV diarrhoea was 10.6 months while those testing rotavirus negative were aged 10.9 months, cumulatively the mean age of admission of all the children with diarrhoea was 10.8 months. In all the age groups there were

more males testing RV positive as compared to the females but the difference was not statistically significant. The study found that children aged between 6-11 months had the highest positivity rate (39.7%) and in total children aged less than 1 year were the majority testing positive for RV (67.8%). The difference noted in the various age groups was not statistically significant both in terms of numbers and sex difference.

A child less than 5 years admitted at Embu PGH with diarrhoea has odds of 1.99 to have RV infection if vomiting compared to those who are not vomiting, having a p. value of 0.015. The average temperature of children with RV infection was 37.9^0c which is regarded as a low grade fever. Treatment in general was also non significant but the odds of children who were rotavirus positive and treated, were 1.6 times more likely to be treated with IVF as compared to being treated using ORS and these finding was significant with a p. value of 0.037.The final model that was found in this study to be most able to predict the presence of RV infection included vomiting status, temperature and dehydration. Vomiting status was the only clinical presentation in the final model that was statistically significant. The three clinical presentation noted above in the final model are among the main symptoms associated with RV infection (William W Hay, 2003) but these symptoms/signs are not unique to gastroenteritis secondary to RV alone but other agents (non-rotavirus, bacterial and parasitic agents) can cause similar presentation thus at history taking point the clinician can only suspect that a child may be suffering from RV infection, the only way to confirm that a child has RV infection is through laboratory stool analysis.The introduction of RV vaccine into the government EPI schedule will be of importance in management of morbidity related to RV diarrhoeal diseases but more study's especially in rural areas need to be done and mainly in areas with high infant mortality rates in the country.

5.2 Conclusion:

RV gastroenteritis is an important aetiologic agent in causing dehydrating diarrhoea in children less than 5 years Hospitalized at Embu PGH.

RV infection is a major contributor of high morbidity and mortality in children less than 5 years. Therefore the reduction in RV gastroenteritis among children less than 5 years will have an impact on the reduction of mortality and morbidity among children aged less than 5 years. Prevention of diseases is a Public Health strategy and in children less than 5 years, one of the measures put in place is immunization against childhood illnesses. To mitigate the effects of RV gastroenteritis and control the disease burden the introduction of RV vaccination can be an important control measure. The other control measures that focus on improved hygiene and sanitation should still be emphasized since are able to deal and impact on the reduction of diarrhoeal diseases brought about by bacterial and or parasitic agents.

5.3 Recommendation:

It is important to know the prevalence of rotavirus disease at baseline not only in Embu PGH but in the country as a whole. The information gathered will give vital statistics to policy makers who can make informed decision especially on the usefulness or need to introduce RV vaccine in the EPI schedule in the country. The statistical data generated from the various surveillance studies can be used as a bench mark or baseline indicator when ascertaining the impact brought about by introduction of a Rota vaccine at the National Level as part of the EPI schedule.

The introduction of RV vaccine has a potential of having an impact in reduction of childhood mortality and morbidity in the country but if the immunization coverage is low the country may not realize these benefit. Thus timely vaccination of children less than 5 years is very important for any benefit to be achieved.

It is also important to create systems to assess and to conduct surveillance of rotavirus diarrhoea in the community and in hospitals both in the outpatient and inpatient departments. These will aid in monitoring any impact brought about by introduction of immunization and the data generated from the various health care facilities will provide a sensitive indicator for the same(Umesh D. Parashar, 1999).

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Annex 1

Rotavirus Diarrhea case report form

Information extracted from patient management file

Medical Record Number
Hospital/ Health Facility/City_____
Date of admission: ----/----/---- (day/month/year)
Treated at: ( ) Emergency Room, Duration in hours ( )
( ) admitted to Ward Duration in days ( )

Patient information

Patient ID number _____
Patient name: _____
City/village of residence: _____
Age (months): ____
Sex: M ( ) F ( )

Clinical information

Duration of symptoms: ____days
History of fever: Yes ( ) No ( )
Temperature at admission: _____°C (axillary)
Vomiting: _____ (Yes/No) No. of episodes/24 hr: _____ Duration (days): _____
Diarrhoea: _____ (Yes/No) No. of episodes/24 hr: _____ Duration (days): _____
Dehydration status (as defined in the notes): ( ) severe ( ) some ( ) none
Treatment ORT: ( )
IVF: ( )
Outcome (mark one): ( ) improved ( ) Died
( ) Transferred ( ) unknown
Date of discharge, transfer or death: __ __/__ __/__ __ (day/month/year)

Laboratory information

Stool collected: Yes ( ) No ( )
Date stool specimen collected: __/ __/ __ (day/month/year)
Patient ID Number __/__/__/__/__/__/__/__/__
Date of sending the specimen to laboratory__ __/__ __/__ __
Date of receiving Lab results: __ __/__ __/__ __(day/month/year)

Rotavirus EIA results_____

Person who completed the form:

Name: _____ Signature: _____

Date of report completed: __ __/__ __/__ __ (day/month/year)

Annex11

Patients' logbook (Line list of <5 years hospitaliseddiarrhoea cases)

Country---------- City---------- Health facility----------
Month…….

Serial	Folder number		Demographic data				Clinical data								Stool data				
							Date of onset (1)	Temp at admission (°C)	Vomiting		diarrhoea		Date of discharge (1)	Status at discharge (2)	Patient/ stool ID	Date stool taken (1)	Date sent to lab (1)	EIA Result (3)	Genotyping re
			Name	Address (village/ City)	Age (months)	Sex (M/F)			Duration (days)	Episodes/24h	Duration (days)	Episodes/24h							