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#### **Abstract**

**Introduction:** Rotavirus vaccines were included in routine immunization schedule in all public facilities in Kenya for free since July 2014. The purpose of our study was to establish behavioral factors associated with completion of rotavirus vaccine series.

**Methods:** The study population was children aged 11 weeks to 52 weeks attending the pediatric casualty. We define completion as receipt of the two doses of rotavirus vaccine doses by the 12<sup>th</sup> month of age. Health belief model (HBM) guided the study.

**Results:** Overall, 86.3% of the children had completed two doses of rotavirus vaccine within 12 months of birth. However, only 10% had completed within the recommended age range (10-12 weeks). There was a significant association between maternal age and knowledge of rotavirus with the completion of rotavirus vaccine series. Whereas perceived barriers were significantly associated with completion of rotavirus vaccine series, perceived threats (susceptibility, seriousness or severity of rotavirus disease) and perceived benefits of protection of the rotavirus vaccine were not. Binary regression analysis indicated that knowledge of rotavirus and perceived barriers best explained the completion of rotavirus vaccine series in children.

**Conclusion:** Among the HBM constructs, perceived barriers were most significant in determining completion of rotavirus vaccine series. These relationships are of interest to public health personnel because they elucidate barriers to vaccination and provide targets for health education intervention.

### INTRODUCTION

Rotavirus disease which is transmitted through the oral-fecal route is highly contagious and resilient. It is the leading cause of severe and fatal diarrhea in infants and young children worldwide. Rotavirus diarrhea accounts for an estimated five percent of all deaths in children less than five years and is responsible for millions of hospitalizations and clinic visits each year, (Black et al., 2010; Tate et al., 2012). While rotavirus deaths and hospitalizations vary by region, the majority (95 percent) of deaths in young children are found in low-income countries of Africa and Asia, (Seheri, Page, Mawela, Mphahlele, & Steele, 2012). A study carried out in four surveillance sentinel sites in Kenya, indicated that children admitted with

gastroenteritis, rotavirus accounted for 35% to 52% of infections, (KNH 52%, Embu 48% and 35% in Siaya). Over 40% of cases are admitted with acute gastroenteritis in children under five years of age, (Government of Kenya, 2015). Rotavirus infection causes 4,471 deaths, 8,781 hospitalizations, and 1,443,883 clinic visits among children with diarrhea aged five years and below annually in Kenya. Children between the ages 6–11 months are most affected, (Katz et al., 2014).

Incidence and severity of rotavirus infections have declined significantly in countries that have added rotavirus vaccine to their routine childhood immunization policies, (Jiang, Jiang, Tate, Parashar, & Patel, 2010). In Kenya, rotavirus vaccines were

introduced as part of a comprehensive approach to control diarrheal disease, along with other interventions including oral rehydration therapy, breastfeeding, zinc treatment, and improvements in water and sanitation in July 2014, (World Health Organization, 2013). The private market has both monovalent and pentavalent rotavirus vaccines. The National Vaccines and Immunization Program (NVIP) provides monovalent (Rotarix from Glaxo Smith and Kline) vaccines free of charge in all public health facilities. The vaccines are given in two doses at six weeks and ten weeks of age or to children below one year of age who were not vaccinated at the scheduled times. Since the introduction of the vaccine is relatively recent in Africa, studies conducted on completion of rotavirus vaccine series are few. Descriptive studies conducted in various parts of Africa show that many children aged less than one year do not complete two doses of rotavirus vaccine. The rate of completion ranges from 30% to 67%, (Etana & Deressa, 2012; Seheri et al., 2012). The few studies that have assessed factors associated with rotavirus uptake in Africa have focused on social demographic factors and knowledge as it related to immunization in general and are not specific to rotavirus. These studies show that as maternal age increases, vaccine uptake also increases, (Etana & Deressa, 2012; Nnenna TB, Davidson UN, 2013; Salmon et al., 2006). Other studies have indicated that likelihood of a child receiving full immunization rose with maternal educational attainment, (Brown & Oluwatosin, 2012; Kusuma, Kumari, Pandav, & Gupta, 2010; Wiysonge, Uthman, Ndumbe, & Hussey, 2012). Nonetheless, these African studies focused on social and demographic factors as they relate to uptake and virtually none were on behavioral aspects. A behavioral study conducted in Nigeria showed that only 27.5% of the respondents considered rotavirus a disease severe disease. The investigation further revealed that mothers reported a high likelihood of using a new vaccine, only 29% were likely to have their child vaccinated, (Brown & Oluwatosin, 2012).

Since this is a new vaccine, there are gaps in studies looking at behavioral factors related to rotavirus vaccine uptake in Africa. Our research was guided by the Health Belief Model which attempts to explain and predict health behaviors. We used the three original concepts of the Health belief model which

are, perceived threats (susceptibility, seriousness or severity of rotavirus disease), perceived benefits of the vaccine and barriers to the rotavirus vaccination. The perceived threat is based on medical information or knowledge, or from beliefs a person has about the difficulties a disease would create or the effects, it would have on his or her life, (Chepkemoi Ng'etich Mutulei, 2013). The greater the perceived risk, the greater the likelihood of engaging in new behaviors to decrease the risk, (Stretcher & Rosenstock, 1997). Perceived benefitsinvolvea person's opinion of the value or usefulness of new behavior in decreasing the risk of developing a disease. Perceived barriers are the individual's evaluation of the obstacles in the way of his or her adopting a new behavior. We did not study other constructs which were added later (cues to action, motivating factors, and self-efficacy). Results from a critical review of 29 HBM-related prospective studies and retrospective research published between 1974 and 1984 provide substantial empirical support for the HBM dimensions to be a part of health education programming. Findings from these studies showed that "Perceived barriers" were the most powerful of the HBM dimensions across the various study designs and behaviors. "Perceived susceptibility" was a stronger contributor to understanding preventivehealth behaviors, than sick-role behaviors (SRB), while "perceived benefits" was a stronger contributor to understanding the sick-role behaviors." "Perceived severity" produced the lowest overall significance ratios; and was weakly associated with preventivehealth behaviors, but strongly related to sick-role behaviors, (Janz & Becker, 1984). Our research question was whether the behavior is related to the completion of the rotavirus vaccine series which is a preventive-health behavior.

### **METHODOLOGY**

### **Study Design**

This study was conducted from July to September 2015. We used a cross-sectional study with an analytical aspect. An infant was categorized as having completed the vaccine if he/she had received two doses of RV1 (Rotarix) following the recommended schedule. Rotavirus vaccine series completion was the outcome variable. We obtained information on vaccination status from Mother Child Health Booklet (MCHB), and Road to Health (RTH) vaccination card.

The independent variables that explained the outcome were: threats (susceptibility, seriousness or severity of rotavirus disease), perceived benefits of the vaccine and barriers to the rotavirus vaccination. Social demographic factors were the intervening variables.

### The Study Site and Study Population

Mbagathi hospital in Nairobi County, Kenya was selected because it was the first public health facility to introduce rotavirus vaccine in May 2014. All routine immunizations are offered free. Children with missed vaccinations are referred to Maternal Child Health (MCH) clinic which provides vaccines.

The study population was children aged 11 to 52 weeks who had attended the pediatric casualty for therapeutic services and, screening for compliance and completion of immunization. The 11 to 52 weeks gave the buffer time after the six weeks for the first dose and ten-week recommendation for the second dose in case they were slightly late. The Kenya policy guideline states that the age for administration of Rotavirus is up to one year, thus the reason the study enrolled children up to one year. It was not prudent to go above one year as the vaccine was introduced only one year earlier. Our study population comprised of children listed in the computer records (which had 1807 children at the time of our study), and not identified from the immunization register. The children sampled from the registry were identified and interviewed when they reported to the causality department.

## Sample Size and Sampling Technique

Fisher et al. (1998) ( $n=Z^2pq/d^2$ ) formula which is applied to population  $\geq 10000$  was used to calculate the sample size, (Creswell, 2013). Where: n=1 the desired sample size; Z=normal standard deviation (usually set at 1.96 which corresponds to 95 percent confidence level); p=1 the proportion in the target population estimated to have characteristic being measured (rotavirus vaccine uptake); q=1 percentage of people without the characteristic, q=1 Level of statistical significance of 95% = (0.05). We chose a p of 0.5 which gave maximum sample size, of 384. Since our population was less than 10,000, the sample size was adjusted using the formula q=1 n/1+n/N. In this formula q=1 the desired sample size; q=1 the calculated sample size, and q=1 the estimated population size.

After adjustment, we arrived at a sample size of 317 children. A systematic random sampling technique was used to ensurean equal chance (probability) of selecting each child aged a year and below to participate in the study.

## **DATA COLLECTION METHODS**

We used quantitative methods to collect data. A structured questionnaire with closed-ended questions. The survey included: social demographic factors, knowledge, and mother's perception of the rotavirus disease and vaccination and barriers. Likert scale statements were used to obtain data on perception.

### **Measurement of Variables**

Our outcome variable was the completion of rotavirus vaccine series. Complete rotavirus vaccine uptake was defined as a child who has received the two recommended doses of rotavirus vaccine within 12 months of birth. Incomplete rotavirus vaccine uptake was considered when a child had not received any dose or received only one dose of rotavirus vaccine.

Knowledge was based on medical information or knowledge or beliefs the respondents had on the effects rotavirus has on the health of children. Eleven knowledge questions which required yes/no answers questions were based on transmission, prevention, and vaccine administration. Afive-point Likert scale was used to assess the importance of rotavirus vaccine. The statement used was, how important is rotavirus vaccine?' (Unimportant=1, little importance=2, moderately important=3, important=4 and very important=5). The total knowledge score was 16 points. Perceived benefits and perceived barriers were measured on a 5-point Likert scale each containing four statements giving a maximum of 20 points for each variable. Statements on the seriousness and severity of rotavirus included: rotavirus is a severe disease; rotavirus diarrhea is a leading killer of children, young, and children are more at risk or susceptible. Statements on benefits of the vaccination included; rotavirus vaccination reduces the severity of diarrhea, rotavirus vaccine reduces childhood illness, rotavirus vaccine reduce childhood deaths, rotavirus vaccine is effective against diarrhea. Statements on barriersincluded: distance to the health facility as a barrier, availability of vaccine as a barrier, accessibility of vaccine as a barrier and fear of side effects as a barrier.

Intervening variables included: maternal age, recorded in complete years, and maternal education categorized as none, primary level, secondary level or tertiary level using Kenyan system of education. The child's variables included child's age recorded in complete months and child's sexmarked as either male or female.

Ethical approval was obtained from Great Lakes University of Kisumu Institution Review Board and permission to conduct the study was obtained from Mbagathi Hospital. An explanation of the nature of the research, benefits or risks and ethical considerations were given to the mothers before the interview and informed consent obtained.

### RELIABILITY AND VALIDITY

Two health workers were trained to, fill the responses in the questionnaire, get the consent from the mothers and observing study ethics. Pre-testing and piloting of the data collection tool were carried out to minimize bias and strengthen the validity and reliability of the results. It included a check on whether the instrument gave consistent results, covered all the variables, the length of time the enumerators took to fill the questionnaire, appropriateness of the language used in the survey as well as determining the problematic items. A test and re-test were conducted on the randomly selected respondents. At the end of the pretesting, errors, challenging questions, sensitive questions were identified and corrected before the actual study was conducted. Necessary modifications of the tool were made to improve the level of instrument's reliability and validity.

#### **Approach to Data Analysis**

Data was entered in Ms-Excel 2007 windows and Statistical Package for the Social Science (SPSS) version 19 was used for analysis. Data cleaning included checking for errors in responses, omissions, inconsistencies, missing values, outliers, and biases. The dependent/outcome variable was a dichotomous variable (Complete or incomplete rotavirus vaccine). Complete rotavirus vaccine was defined as 1 if the child received both recommended doses and incomplete as 0 if a child had not received any dose or received one dose of Rotavirus Vaccine. The analysis explored the relationship between the dependent (completion of rotavirus vaccine series) and the

explanatory variables which were; maternal age, mother's level of education, mother's knowledge, the perception of threat, benefit and barriers. Mother's knowledge of rotavirus disease and vaccine questions required yes/no answers. A yes scored 1, and a no scored 0. A composite score of variables for knowledge, perceived benefit, perceived seriousness and perceived barriers were estimated by adding up the score each mother obtained for each of these variables. The maximum score for knowledge was 16, while the ratings for the perceived benefit, perceived seriousness, and perceived barriers was 20 points each. Using these scores, those mothers whose who scored less than 8/16 for knowledge were classified as having inadequate knowledge while those who scored more than 8/16 were classified as having adequate knowledge. Mothers who scored less than 10/20 for the perceived benefit and perceived seriousness were classified as having poor perception. A score of perceived barrier (<10) was classified as fewer reported barriers (<10), while those who scored more than 10/20 were classified more reported barriers (<10). Pearson chi-square statistic was used in categorical data to evaluate how likely it is that any observed difference between the sets arose by chance. The results were described using odds ratio (OR=1,>1, and <1). OR=1 indicates that exposure does not affect odds of the outcome, OR>1, exposure is associated with higher odds of outcome and OR<1 exposure is associated with lower odds of outcome). A P<0.05 was considered significant. Binary logistic regression was then used to establish which amongst the explanatory variables found significant from the chi-square test best explained the completion of rotavirus vaccine series.

### RESULTS

### **Social Demographic Factors**

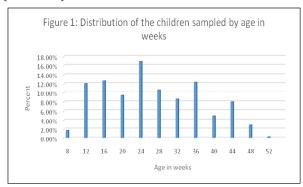
A description of the social demographic background of the mothers is given in (Table 1). Young and adolescent mothers ( $\leq$ 25 years) comprised 42.5% of total respondents. Close to  $2/3^{\rm rd}$  of the respondents had gone beyond the basic primary school level of education. Only 1.0% of the respondents reported having no formal education. About 3/4 (77%) of the respondents were married. Half of them were Protestants (50%). A majority (64.3%) of respondents had proximity to the health facility (< less than five kilometers).

**Table 1.** Social demographic Characteristics of the Mothers n=350

Baseline characteristics	Variable	Number	Percentage	
Maternal age in years	<=20	46	13.1	
	21-25	103	29.4	
	26-30	134	38.3	
	>30	67	19.2	
Mother's education	None	5	1.4	
	Primary	106	30.3	
	Secondary	155	44.3	
	Tertiary	84	24	
Marital status	Single	62	17.7	
	Married	267	76.3	
	Divorced/ widowed/ separated	21	6	
Mother's religion	None	9	2.6	
	Catholic	121	34.7	
	Protestants	173	49.6	
	Muslim	32	9.2	
	Indigenous	14	4.0	

The total number of children studied was 350. The proportion of males and females were almost the same (49.7%) and (50.3%) respectively. Most (97.4 %) of the mothers had Mother and Child Health Booklet (MCHB) or Child Welfare Card (CWC).

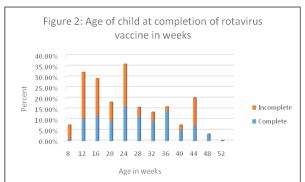
The distribution of children sampled by age in weeks is given in Figure 1. The age range was 8 to 52 weeks. About half (46%) of the children were below 24 weeks (6 months).



Completion of Rotavirus Vaccine Series in Children by Age in Weeks

Overall, 86.3% of the children had completed the two doses of rotavirus vaccine by 12 months. However,

only 10% of the children had completed the two doses of rotavirus vaccine at the recommended age range (10-12 weeks) as shown in Figure 2.



# FACTORS ASSOCIATED WITH THE COMPLETION OF ROTAVIRUS VACCINE SERIES

Table 2 presents the factors associated with completion of rotavirus vaccine series. There was no significant difference between completion of rotavirus vaccine series by the sex of the infant, (OR= 01.37, p-value = 0.32).

There was a significant association between maternal age and completion of rotavirus vaccine series, (OR = 2.3, p-value =0.009). Children of mothers who were

above 25 years were twice more likely to complete rotavirus vaccine series than those born to mothers below 25 years. Maternal education was significantly associated with completion of rotavirus vaccine series, (p-value =0.023).

Knowledge of rotavirus based on medical information was associated with completion of rotavirus vaccine series, (OR = 2.8, p-value =0.002). Children of mothers with adequate knowledge of the virus were about three times more likely to complete rotavirus vaccine series than those with inadequate knowledge.

Perceived barriers were significantly associated with the completion of rotavirus vaccine series, (OR = 2.1, p-value =0.022). Children of mothers who had a lower

score of a perceived barrier asobstacle were twice more likely to complete rotavirus vaccine series than those with a higher perception of barriers. There was no significant association between the mother's perceived threats (susceptibility, seriousness or severity of rotavirus disease, (p-value= .445), or benefits of protection of the rotavirus vaccine, (p value= .124) and completion of rotavirus vaccine series. The binary regression analysis conducted on all the variables which showed a positive association indicated that knowledge of rotavirus ( $\beta$ =2.514, p=.020), and perceived barriers, ( $\beta$ =2.650, p=.011) best explained the completion of rotavirus vaccine series in children.

**Table 2.** Factors associated with the completion of rotavirus vaccine series

Factor	Variable	Completion %	OR	95% CI	P value
Sex	Male	85.1	1.37	.32- 2.56	.322
	Female	88.6			
Age of the mother	< 25 years	80.2	2.27	1.21-4.25	.009
	>25 years	90.2			
Marital status	Married	87.6			.669
	Single	82.3			
	Widowed	85.7			
Education of the mother	None	80.0			.023
	Primary	80.0			
	High school	87.0			
	Tertiary	95.2			
Knowledge of rotavirus	Limited knowledge (< 8)	81.5	2.87	1.43-5.76	.002
	Adequate knowledge (>8)	92.7			
Perceived barriers	perception less barriers (<10)	89.1	2.14	1.11-4.13	.022
	perception higher barriers (>10)	79.3			
Perceived benefit	Poor perception(<10)	50.0	6.67	.41-108.48	.124
	Good perception (>10)	87.0			
Perceived seriousness of disease	Good perception(<10)	75.0	2.37	.24-23.43	.445
	Poor perception(>10)	87.7			

### **DISCUSSION**

The purpose of this study was to establish behavioral factors associated with the completion of rotavirus vaccine series in children attending a Pediatric casualty in a Public Hospital, Nairobi County, Kenya. Measurement of the outcome variable completion of rotavirus vaccine series was accurate as it depended on the card which was seen in 97.4% of observations.

Our sample was representative of children attending the health facility but not the general population.

Though most children had completed the vaccination series within 12 months, very few children were compliant with the timeliness of the vaccine which requires that a child receives their second dose of rotavirus vaccine at ten weeks.

Maternal knowledge of rotavirus and perceived barriers of the vaccination best explained the variation in the completion of rotavirus vaccine series. The mother's perceived threats of rotavirus disease or benefits of vaccine were not determinants of completion of rotavirus vaccine series.

Our results were consistent with those of other studies from Africa which found that children born to younger mothers (less than 25 years) were less likely to complete the rotavirus vaccine, (Etana & Deressa, 2012; Salmon et al., 2006). Our results are also consistent with those conducted in developing countries which indicated that education level of the mother was related to vaccination status of their children. (Brown & Oluwatosin, 2012; Etana & Deressa, 2012; Kusuma et al., 2010).

Our finding that among the constructs, perceived barriers are the most significant in determining completion of rotavirus vaccine series, is supported by HBM-related prospective and retrospective research which showed that "Perceived barriers" were the most powerful of the HBM constructs across the various study designs and behaviors, (Janz & Becker, 1984). Perceived barriers such distance to the health facility, fear of side effects were cited as the explanation for the low rate of uptake of rotavirus vaccine in a South African study, (Seheri et al., 2012).

Our findings are also consistent with the results of studies which showed that perceived "Perceived severity" and "Perceived benefits" were not strong contributors to preventive health behavior. A study done in Nigeria further indicated that few mothers considered the rotavirus disease severe disease, (Brown & Oluwatosin, 2012).

### STRENGTHS OF THE STUDY

Studies conducted in Africa on rotavirus were descriptive while analytical studies focused on immunization uptake in general and not specific to rotavirus. To best of our knowledge, this is the first study conducted on behavioral factors related to completion of rotavirus vaccine series in Kenya. The study forms a significant contribution to the rotavirus vaccine knowledge base for future research. Our study further used Health Belief Model (HBM) which attempted to explain rotavirus vaccine uptake behavior.

#### LIMITATIONS OF THE STUDY

The study was conducted in a health facility and on a study population that had easy access to a health facility. Thus, the completion of rotavirus vaccine seriesmight have been overestimated, and hence results cannot be generalized to the general population. Similar studies are needed at the household level and in a rural community. The study furthermore used a quantitative method and thus limited mother's answers to choices available and did not explore the 'whys' of the behavior. We also did not study other constructs which have been added such motivating factors, and self-efficacy.

#### CONCLUSIONS

Among the HBM constructs, perceived barriers (accessibility to a health facility, fear of side effects and availability of vaccine) were most significant in determining completion of rotavirus vaccine series. Perceived severity" and "Perceived benefits" were not strong contributors to completion of rotavirus vaccine series. These relationships are of interest to clinicians and public health practitioners because they elucidate barriers to vaccination and provide targets for educational intervention.

### **DECLARATIONS**

### **Ethics and Consent to Participate statement**

The Great Lakes University of Kisumu gave the certificate of Approval of Research Protocol, Research Ethics Committee (GREC). Consent statement to participate in the study was part of the questionnaire, and it included introduction and purpose of the study, the study procedure, the benefits and risks, confidentiality, voluntary participation/withdrawal from research and contact person.

### **Competing Interests**

The authors declare that they have no competing interests. They do not hold any stocks or shares in any organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future.

### **Authors' Contributions**

LWK conceptualized the study and was responsible for data acquisition, analysis, and interpretation of data; LWK and AMP participated in study design, data

analysis and facilitated the drafted the manuscript. All authors read and approved the final manuscript.

### **Availability of Data and Materials**

The data supporting our findings can be found in the Great Lakes Library repository or from the corresponding author.

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