KNOWLEDGE ON HUMAN PAPILLOMA VIRUS AND ACCEPTABILITY OF HUMAN PAPILLOMA VIRUS VACCINE AMONG MOTHERS SEEKING MATERNAL-CHILD HEALTH SERVICES AT MBAGATHI DISTRICT HOSPITAL, NAIROBI, KENYA ANN BOSIBORI MASESE MASTER OF SCIENCE (Public Health) JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY MASESE A.B. 2016

Knowledge on Human Papilloma Virus and Acceptability of Human Papilloma Virus Vaccine among Mothers Seeking Maternal-Child Health Services at Mbagathi District Hospital, Nairobi, kenya

Ann Bosibori Masese

A Thesis submitted in partial fulfillment for the Degree of Master of Science in Public Health in the Jomo Kenyatta University of Agriculture and Technology

DECLARATION

This thesis is university	my original work and has not	been presented for a degree in any other
Signature		Date
	Ann Bosibori Masese	
This thesis ha	s been submitted for examina	ation with our approval as the university
Signature		Date
	Prof. Zipporah Ng'ang'a JKUAT, Kenya	
Signature		. Date
	Prof. Mohammed Karama	ı
	KEMRI, Kenya	

DEDICATION

I dedicate this work to my dear husband Lawrence Gikundi Mbae, and my lovely children; Tara Kendi and Tamira Nyaboke for their unwavering love, support and encouragement throughout my study period. May God Bless you

ACKNOWLEDGEMENT

First and foremost, I thank the almighty God for granting me good health and the opportunity to complete my studies successfully. I extend my sincere gratitude to my supervisors; Prof. Zipporah Ng'ang'a of JKUAT and Prof. Mohamed Karama of KEMRI for their invaluable guidance, technical advice and constant encouragement throughout my study. I am forever indebted to my statistician, Dr. Carol Gitonga for her invaluable assistance during my analysis of the study results

I am grateful to the Mbagathi District Hospital management for granting me permission to use their facility for this study and all the staff at the Maternal and Child Health (MCH) clinic for their tremendous support during the data collection period.

Finally, I extend my gratitude to my family, all the women who participated in this study, the staff at the Institute of Tropical Medicine and Infectious Diseases (ITROMID), classmates and friends for their support and encouragement.

TABLE OF CONTENTS

DECLARATION	ii
DEDICATION	iii
ACKNOWLEDGEMENT	iv
TABLE OF CONTENTS	V
LIST OF TABLES	X
LIST OF FIGURES	xi
LIST OF APPENDIXES	xii
ABBREVIATIONS AND ACRONYMS	xiii
ABSTRACT	XV
CHAPTER ONE	1
INTRODUCTION	1
1.1 Background Information	1
1.2 Statement of the Problem	4
1.3 Justification	5
1.4 Research Questions	6
1.4 Research Questions	6

CHAPTER TWO	8
LITERATURE REVIEW	8
2.1 Human Papilloma virus infection	8
2.2 Risk factors for HPV infection	9
2.2.1 Number of sexual partners	9
2.2.2 Age at first sexual intercourse	10
2.2.3 Long-term use of oral contraceptives	10
2.2.4 Family History / Genetic Predisposition	11
2.3 Transmission of the Human Papilloma Virus	11
2.4 Symptoms of Human Papilloma Virus Infection	12
2.5 Diagnosis of Human Papilloma Virus infection	12
2.6 Human Papilloma Virus Vaccines	13
2.6.1 Efficacy of HPV vaccine	14
2.6.2 HPV vaccine safety	15
2.6.3 Duration of protection conferred by HPV vaccine	15
2.6.4 Age to Vaccinate for HPV	16
2.6.5 Vaccination of Males against HPV	17
2.7 Treatment of Human Papilloma Virus infection	18
2.7.1 HPV Treatment for Genital Warts	18
2.7.2 HPV Treatments for Tissue Changes	19
2.7.3 Immunization Schedule and Cost of the Vaccine	20

CHAPTER THREE2	1
MATERIALS AND METHODS2	1
3.1 Study Area	1
3.2 Study Design	1
3.3 Study Population	1
3.3.1 Inclusion criteria	1
3.3.2 Exclusion criteria	1
3.4 Sample Size Determination	2
3.5 Data Collection Tools	3
3.6 Data Analysis	4
3.7 Ethical Considerations	4
CHAPTER FOUR2	6
RESULTS2	6
4.1 Socio-Demographic Characteristics of Mothers	6
4.2 Mothers' knowledge on risk factors of cervical cancer and consequences of HPV	
infection	8
4.2.1Univariable analysis of factors associated with mothers' knowledge of cervical	al
cancer, associated risk factors and consequences of HPV infection2	9
4.2.2 Multivariable analysis of factors associated with mother's knowledge of	
cervical cancer, associated risk factors and consequences of HPV infection3	1

4.5 Knowledge of Human Papilloma Virus (HPV) infection, risk factors and the	
consequences among mothers	.33
4.4 Awareness of the HPV vaccine among the Mothers	.35
4.4.1 Univariable analysis of factors associated with awareness of HPV vaccine	.36
4.4.2 Multivariable analysis of factors associated with awareness of HPV vaccine	:38
4.5 Attitude towards safety and efficacy of the HPV vaccine among mothers	.40
4.6 Acceptability of the HPV vaccine among the mothers	.41
4.6.1 Factors associated with acceptability of HPV vaccine among mothers seeking	ng
maternal-child health services at Mbagathi District Hospital, Nairobi	.43
4.7 Qualitative Analysis	.45
4.7.1 Knowledge of STDs among mothers	.45
4.7.2 Knowledge of Human Papilloma Virus Infection among mothers	.45
4.7.3 Knowledge of Cervical Cancer among Mothers	.46
4.7.4 Knowledge of HPV vaccine and its acceptability among Mothers	.47
4.7.5 Factors Associated with Acceptability of the HPV vaccine	.48
CHAPTER FIVE	,49
DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS	,49
5.1 Discussions	.49
5.2 Conclusions	.59
5.2.1 Limitations of the Study	.60
5.3 Recommendations	.60

REFERENCES	61
APPENDIXES	78

LIST OF TABLES

Table 2.1: T	he common clinical conditions caused by HPV infections9
Table 4:1: Se	ocio-Demographic Characteristics of Mothers27
	Univariable analysis of factors associated with mother's knowledge of risk actors and consequences of HPV infection
	Iultivariate analysis of factors associated with knowledge of risk factors and onsequences of HPV infection, among mothers
	nowledge of Human Papilloma Virus (HPV) infection, risk factors, ymptoms and the consequences of HPV infection, among mothers34
Table 4.5: A	wareness of the HPV vaccine among the Mothers35
Table 4.6: U	nivariate analysis of factors associated with awareness HPV vaccine37
Table 4.7: M	Iultivariate analysis of factors associated with awareness of HPV vaccine 39
Table 4.8: A	ttitude towards safety and efficacy of the HPV vaccine among the mothers
Table 4.9: A	cceptability of the HPV vaccine among the mothers42
0	Univariate and multivariate analysis of factors associated with acceptability f HPV vaccine among mothers attending maternal and child health clinic at Abagathi hospital.

LIST OF FIGURES

Figure 4.1 Frequency distribution of correct responses to classify knowledge levels....29

LIST OF APPENDIXES

Appendix I: Consent form	78
Appendix II: Questionnaire	86
Appendix III: Focus group discussion guide	93
Appendix IV: Scientific Steering Committee Approval	94
Appendix V: National Ethical Review Committee Approval	95

ABBREVIATIONS AND ACRONYMS

AIDS Acquired Immunodeficiency Syndrome

CIN 2/3 Cervical Intraepithelial Neoplasia Grade 2/3

CPHR Centre for Public Health Research

DNA Deoxyribonucleic Acid

EPI Expanded Program on Immunization

FDA Food and Drug Administration

FGD Focus Group Discussion

GAVI The Vaccine Alliance

GLOBOCAN International Agency for Research in Cancer

GSK Glaxo Smith Kline

HIV Human Immunodeficiency Virus

HPV Human Papilloma Virus

KEMRI Kenya Medical Research Institute

LLETZ Large Loop Excision of the Transformation Zone

MDH Mbagathi District Hospital

PCR Polymerase Chain Reaction

STD Sexually Transmitted Disease

STI Sexually Transmitted Infection

SWOP Sex Workers Outreach Project

US United States of America

TV Television

VLPs Virus like particles

WHO World Health Organization

ABSTRACT

The Human Papilloma Virus (HPV) is one of the most common sexually transmitted viruses worldwide and is associated with cervical cancer. Through research, a prophylactic HPV vaccine has been developed and has proven effective in a number of clinical trials. For a HPV vaccination program to be successfully implemented, parental knowledge, preferences, perceptions and willingness to use the HPV vaccine are very important and need to be assessed correctly. The main objective of this study was to determine the knowledge on human papilloma virus and acceptability of the Human Papilloma Virus vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi. This was a cross-sectional descriptive hospitalbased study that utilized both qualitative and quantitative methods. The study was conducted among mothers seeking maternal and child health services in Mbagathi District Hospital. A total of 354 study subjects were selected using random sampling method. Quantitative data was obtained by use of structured questionnaires that were administered to the mothers while qualitative data was collected through focus group discussions. Quantitative data was analyzed using Stata version 11.0 (Stata Corporation, College Station, TX, USA), and NVIVO 9 software was used for thematic analysis of qualitative data. A total of 348 mothers were included in the study, six mothers were left out of the study due to missing values in their questionnaires. Of the respondents, 100% reported having a general knowledge of STDs. The mean knowledge score on risk factors and consequences of HPV infection was 12.5 with a range of between 0 and 18. A total of 218 women (62.6% (95% CI: 57.5 – 67.8%) reported having heard of the HPV vaccine. Overall, 67.8% women said they would vaccinate their adolescent children against HPV. Some of the factors reported to hinder utilization of the vaccine included cost, side effects and that the vaccine would lead to teenage promiscuity. In conclusion, these findings offered insight on understanding the beliefs about and identifying the barriers of HPV vaccine use; how it will influence the effectiveness of the vaccine and

its potential impact in reducing cervical cancer incidence in Kenya. The study recommends the need to educate the public on HPV, Cervical Cancer, and the HPV vaccine. The government should subsidize the cost of the vaccine and as much as possible to have it accessible to the entire population through the Kenya Expanded Program on Immunization. This study will significantly contribute to the formulation of the Ministry of Health policy guidelines on cancer prevention which have not factored in HPV.

CHAPTER ONE INTRODUCTION

1.1 Background Information

Cancer is a major health concern globally (WHO/ICO, 2012). Human papilloma virus (HPV) infection is a major risk factor for cervical cancer, the most common cancer among women of reproductive age and second largest cause of death after breast cancer (WHO/ICO, 2012). According to International Agency for Research on Cancer (GLOBOCAN) 2012 report, there were an estimated 527,624 new cases of cervical cancer and an estimated 265, 653 deaths from cervical cancer. The report further reports that 87% of cervical cancer deaths occur in the less developed regions of the world.

In Africa, about 24.9% of women in the general population are estimated to harbor cervical HPV infection at any given time (Ferlay *et al.*, 2004). Africa has a population of 331.4 million women aged 15 years and older who are at risk of developing cervical cancer (GLOBOCAN, 2012). Current estimates indicate that in Africa, 99,038 women are diagnosed with cervical cancer and 45,707 die from the disease every year (Bruni *et al.*, 2014). Eastern Africa is one of the high-risk regions with an estimated Age-Standardized incidence rate of 42.7 per 100,000 population; this is almost three times the global estimate of 15.7 (WHO/ICO, 2012).

It is estimated that more than 15% of the 10 million cancer cases that develop every year globally are attributed to infectious agents (Kumar *et al.*, 2007). Infection by human papilloma viruses (HPVs) accounts for approximately 30% of these cancers (~5% of all cancers). Cervical cancer has received more attention compared to the other cancers associated with HPV infection because it accounts for about 10% of all these cancer cases in women worldwide (Kumar *et al.*, 2007).

Cervical cancer accounts for about two-thirds of all cancer cases linked etiologically to HPV. There are about 15 different types of HPV that cause cancer, two types 16 and 18 are the major causes of cervical cancer contributing to about 15% and 20% respectively (Munoz *et al.*, 2003). Human Papilloma Virus types 16 and 18 also account for an even higher proportion of other genital and mucosal cancers attributable to HPV infection. Almost all cases of cervical cancer are associated with sexually transmitted HPV infection, while HPV infection contributes to a small proportion of the other tumors in which the virus has been associated etiologically (Walboomers *et al.*, 1999).

Most HPV infections do not show symptoms and clear on their own over a short period of time; about 70% of new HPV infections clear within 1 year and about 91% clear within 2 years (Ho *et al.*, 1998; Moscicki *et al.*, 1998). The high-risk types are more persistent than low risk types. Infection with HPV can persist for several years to even more than a decade; this may lead to grade 2 or 3 cervical intraepithelial neoplasia (CIN) and cervical cancer (Zimmerman, 2006).

Cervical cancer is not common in women below 25 years; the incidence increases gradually for women above 25 years and is highest in women over 40 years (Demay, 2007). This is because the interval between the time of HPV infection and the malignant procession takes more than 10 years. The process of transformation of normal cells to cancerous ones is slow and this explains why cancer occurs in people who have been infected with HPV over a long period of time; mostly more than ten years (Greenblatt, 2005).

There is a high-risk of developing cervical cancer in women who do not receive regular screening because the precancerous lesions will not be detected early enough. Consequently, appropriate follow-up care will not be provided (Wharton *et al.*, 2000)

The incidence and mortality rates due to cervical cancer in developed countries have significantly dropped in the last 50 years. In the United States for example, mortality from cancer has declined by approximately 70% during this period (Patrick *et al.*, 2011). On the contrary, in developing countries, cervical cancer continues to be a major health problem due to poor health care systems, inaccessibility to medical services and lack of effective screening programs (Lowy *et al.*, 2006).

The introduction of vaccines has been one of the most effective public health interventions for combating infectious diseases. For example, in 1974, the WHO established the Expanded Programme for Immunization (EPI) that saw the global eradication of smallpox and has greatly reduced the burden of other childhood illnesses like measles, poliomyelitis, diphtheria and tetanus in many parts of the world (Chauke-Moagi & Mumba., 2012)

Two prophylactic vaccines have been licensed by the FDA for use in the prevention of HPV types that cause 70% of cervical cancer and 90% of genital warts, these vaccines are Gardasil (quadrivalent and protects against HPV types 6, 11,16 and 18) produced by Merck and approved in 2006 and Cervarix (bivalent and protects against HPV types 16 and 18) produced by GlaxoSmithKline and approved in 2009 (Inglis et al., 2006). For vaccination to be effective, it must be given to children before they are exposed to sexual activity that is before sexual debut. Those who receive the vaccine are however advised to continue seeking Pap smear testing because the vaccines available do not protect them against all the HPV types that cause cervical cancer (Franco *et al.*, 2005). Acceptability of this vaccine by parents/guardians is critical because vaccination of a minor requires consent.

Although HPV vaccination is acceptable to most people; most of these knowledge and acceptability studies have been performed in the developed countries, and may thus not be applicable in Africa. Scanty HPV vaccine knowledge and acceptability data from

developing countries is a significant gap that may hinder global cervical cancer prevention (Brewer *et al.*, 2007).

Some of the studies conducted in Kenya show low levels of knowledge of the HPV vaccine. In a study of female primary school teachers in Kasarani division, only 14% (52) of the respondents had ever heard about the HPV vaccine (Ombech *et al.*, 2012). In another study conducted in Thika, the knowledge of the vaccine was 16.7% (83) among the respondents (Ngugi *et al.*, 2011). In a study conducted in western Kenya, none of the respondents had heard of the vaccine (Becker-Dreps et al., 2010), an indication of the low level of awareness of the cervical cancer vaccine in the region.

The findings of this study will provide knowledge that will influence policy formulation in the development of guidelines in the prevention of cervical cancer and strategies to be implemented to prevent cervical cancer.

1.2 Statement of the Problem

Cervical cancer continues to be a major global health problem, with an estimated 527,642 new cases and 265,653 deaths occurring in 2012 (WHO/ICO, 2012). Cervical cancer is the second most common cancer and the third leading cause of cancer deaths in women worldwide (GLOBOCAN, 2012). If current trends continue, by the year 2050, there will be more than one million new cases of invasive cervical cancer in the whole world annually (Parkin *et al.*, 2006).

In sub-Saharan Africa, cervical cancer rates are among the highest in the world, with an age-standardized incidence rate (ASR) of 27.6 per 100,000 women (GLOBOCAN, 2012). East Africa has among the highest age-standardized incident rate (42.7 per 100,000) and mortality rates in the world. In Kenya, 12.92 million Women are aged above 15 years and are at a risk of developing cervical cancer (Bruni *et,al*, 2014).

Kenyan women face a cervical cancer mortality rate that is approximately 14 times higher than that in the United States (35/100,000 women vs. 2.4/100,000 women annually) (Parkin, 2002).

According to Sankaranarayanan (2001) there are higher incidence and mortality rates in developing countries where approximately 80% of all cases of cervical cancer occur. This is due to lack of sufficient resources to support high-quality cervical cancer screening programs which will detect cervical abnormalities. Where the screening services are available, they are very expensive for majority of the women. Most women especially those in rural areas are not aware of such services or cannot access them.

1.3 Justification

Cervical cancer screening in developing countries has been very low due to lack of knowledge about screening, few diagnosis and treatment centers, and where these services are available; they are expensive for majority of the population, therefore resulting in physicians receiving cervical cancer patients when the disease is at a very advanced stage. Like any other medical procedure, for a HPV vaccine to be administered, consent is required. This will be provided by a parent or guardian since it is administered to minors; thus their knowledge and acceptability of the vaccine is paramount to increase uptake as a result reduce morbidity and mortality due to with cervical cancer.

This study intended to provide new knowledge and useful insight into potential barriers that hinder utilization of the HPV vaccine that offers promise and direction to future public health initiatives. The results will be used as a baseline in future studies to enable health care providers and policy makers to make informed decisions in formulating appropriate health care policies and will also improve the quality of health. For a HPV

vaccination program to be successfully implemented, mothers knowledge and willingness to use the HPV vaccine is paramount and needs to be assessed correctly.

Myths and misconceptions about side effects and adverse outcomes that may not be related to the vaccine need to be understood and addressed. If not well addressed they may negatively impact on public trust and adversely impact on the HPV immunization programming leading to collapse, or suspension of the program altogether as recently experienced in Japan (Gilmour *et al.*, 2013) and India (Larson et al., 2010).

1.4 Research Questions

- 1. What is the mothers' level of knowledge on HPV infection and risk factors associated with cervical cancer?
- 2. What is the mothers' level of awareness of HPV vaccine?
- 3. What factors are associated with acceptability of HPV vaccine among mothers?

1.5 Objectives

1.5.1 General Objective

To determine knowledge on Human Papilloma Virus and acceptability of Human Papilloma virus vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi.

1.5.2 Specific Objectives

1. To determine the level of knowledge on risk factors associated with HPV infection and cervical cancer among mothers seeking maternal – child health services at Mbagathi District Hospital, Nairobi

- 2. To assess the level of awareness of the HPV vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi
- 3. To determine the factors associated with acceptability of HPV vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi

CHAPTER TWO

LITERATURE REVIEW

2.1 Human Papilloma virus infection

HPV is an agent that causes cervical cancer as defined by the International Agency for Research on Cancer (IARC, 1995). In a few occasions it can also cause cancer of the vulvae, anal canal, penis and oropharynx. Infection with high-risk HPV is the most important risk factor for cervical cancer (Rajeevan *et al.*, 2005). HPV infection has been established as the cause of cervical cancer (Bosch *et al.*, 2002), and is now generally accepted with strong evidence that HPV is epidemiologically the primary aetiologic infectious agent for cervical cancer. (Brinton, 1992). There are more than 100 different types of HPV and about 40 of them are known to infect the genital tract of human beings (CDC, 2006).

Epidemiological studies suggest that at least 14 of these, called oncogenic or high-risk types, are significantly associated with progression to cervical cancer (Bosch *et al.*, 1995). The high-risk groups for cancer includes HPV 16, 18, 45 and 56, the intermediate groups are HPV 31, 33, 35, 52 and 58 and the low-risk groups are; 6, 11, 42, 43 and 44 (Stewart and Kleihues, 2003). HPV is passed from one person to another during skin-to-skin contact. HPV can be spread during sex, including vaginal intercourse, anal intercourse, and even during oral sex.

About 70% of all cervical cancer cases worldwide are caused by HPV 16 and 18 (WHO/ICO, 2010). About 38.8% of women in the general population are estimated to harbor cervical HPV infection at a given time, and 60.9% of invasive cervical cancers are attributed to HPVs 16 or 18 (WHO/ICO, 2010). Although HPV is the major cause of cervical cancer, it is not sufficient in itself to cause progression from HPV infection to cancer, there are other factors that contribute to this progression e.g. lifestyle and genetic predisposition (WHO/ICO, 2010).

The table below outlines the various clinical conditions caused by the HPV virus and the causative type of HPV.

Table 2.1: The common clinical conditions caused by HPV infections

CLINICAL CONDITION	CAUSATIVE HPV TYPE
Plantar warts	1,2,4
Common warts	1,2,4,26,27,29,41,57
Flat warts	3,10,27,28,41,49
Genital warts	6,11,30,40,45,51,54
Cervical cancer	16,18,31,33,35,39,45,51,52,56,58
(caused by high-risk HPV type)	
Precancerous changes	16,18,34,39,42,55
Laryngeal Papillomas	6,11,30

Adapted from Reichman, 1994

2.2 Risk factors for HPV infection

2.2.1 Number of sexual partners

Sexual activity has been confirmed as a major risk factor for contracting HPV infection by a number of studies (Burchell *et al.*, 2006; Winer *et al.*, 2006). There has been evidence from case-control studies that women with cervical cancer more frequently reported multiple sexual partners than controls. Moreover, the risk appears to increase directly with the reported number of sexual Partners (Brinton, 1992). Women who had more than ten partners had a threefold risk compared to those with one or fewer partners.

The effect of increasing lifetime number of sexual partners is found to be stronger for development of cervical cancer (Green *et al.*, 2003).

In addition, the role of the male in the causation of cervical cancer had also been examined by comparing the sexual characteristics of husbands of cervical cancer cases with husbands of women free of the disease. In most studies, the husbands of cases reported significantly more sexual partners than those of controls (Brinton, 1992).

2.2.2 Age at first sexual intercourse

Early sexual debut poses an increased risk to HPV infection just like other sexually transmitted diseases (Franco *et al.*, 2001) and thus a higher risk of developing cancer of the cervix compared to those who start sexual activity later on in life (Brinton, 1992; Thomas *et al.*, 2002; Green *et al.*, 2003).

2.2.3 Long-term use of oral contraceptives

Long-term use of oral contraceptives seems to be a significant co-factor in the development of cervical cancer (Adam *et al.*, 2000). A recent systematic study that compared results from 28 case-control and cohort studies showed that prolonged use of oral contraceptives for more than 5 years in women who had HPV infection had an increased risk of cervical cancer. The risk increased with an increase in the duration of oral contraceptive use (Moreno *et al.*, 2002; Smith *et al.*, 2003).

The odds ratio for use of oral contraceptive was 1.3 for 5-9 years of use, and 2.5 for 10 or more years of use (Smith *et al.*, 2003). However, the risk of cervical cancer may decrease after use of oral contraceptives has ceased (Smith *et al.*, 2003). A number of epidemiological studies that adjusted for HPV status also found an association between the use of oral contraceptives and cervical cancer. This further confirms that oral contraceptives are a cofactor in HPV causing cervical cancer (Castellsague and Munoz

2003; Smith *et al.*, 2003). Hormone-related mechanisms may influence the progression from pre-malignant to malignant cervical lesions by promoting integration of HPV DNA into the host genome (IARC, 1995).

2.2.4 Family History / Genetic Predisposition

Genetic predisposition has been found to be a major component in cervical cancer (Magnusson *et al.*, 2000). In comparison to the general population, the risk of getting cervical cancer is 74-80% higher in women with a first degree relative (mother, sister, daughter) with cervical cancer (Hussain *et al*, 2008).

Heredity affects a number of factors contributing to the progression of HPV infection to cervical cancer; it also affects how susceptible the HPV infection is, the ability of the body to clear the HPV infection and the period of time it takes for development of the disease (Magnusson *et al.*, 2000).

2.3 Transmission of the Human Papilloma Virus

Genital HPV is usually transmitted via vaginal (or anal) intercourse. Transmission by non-penetrative genital contact is rare, but infection has been reported in women who did not have a history of penetrative intercourse. Oral-genital and hand to genital transmission is possible with some HPV types, however, this needs to be further proven (Winer *et al.*, 2003). Vertical transmission from mother to child is not common, but it can lead to significant morbidity in the form of respiratory papillomatosis (Derkay *et al.*, 2006).

2.4 Symptoms of Human Papilloma Virus Infection

Most HPV infections are asymptomatic, meaning they may not be visible. The visible ones are genital warts usually caused by HPV types 6 and 11 and anogenital warts caused by HPV types 16, 18, 31, 33, and 35 which have also been strongly associated with cervical dysplasia. Genital warts can occur in many forms, they can be raised, flat, pink, or flesh-colored. They can even be shaped like cauliflower. Warts can be single or multiple. They can be small or large. They can be on the anus, cervix, scrotum, groin, thigh, or penis (Winer *et al.*, 2003).

2.5 Diagnosis of Human Papilloma Virus infection

Diagnosis of HPV is by use of type-specific HPV nucleic acid tests, (this is not necessary for routine diagnosis and management of genital warts that can be see). The diagnosis is done by molecular technologies that detect HPV DNA in cervical/vaginal samples. The molecular techniques can either be amplified e.g. polymerase chain reaction (PCR) or those not amplified e.g. nucleic acid probe tests. Diagnostic tests should not only detect HPV DNA, they should also be able to determing the type(s) of HPV present because different types cause different types of cancer while some do not have oncogenic potentioal (Nindl *et al.*, 1999).

Diagnosis of HPV can be made by a physical examination where the genital warts are visible or palpable. Biopsy is also done to confirm diagnosis of genital warts but this is rarely done except when; diagnosis is uncertain, lesions do not respond to standard therapy, disease worsens during therapy, patient is immunocompromised and warts are pigmented, indurated, fixed, and ulcerated.

2.6 Human Papilloma Virus Vaccines

The Human papillomavirus (HPV) vaccine prevents infection from certain species of human papillomavirus associated with the development of cervical cancer, genital warts (CDC, 2006) and some less common cancers. Two prophylactic HPV vaccines have been developed thus presenting an opportunity for global cervical cancer prevention. Both vaccines are based on the recombinant expression and self-assembly of the major capsid protein, L1, into virus-like particles (VLPs) that resemble the outer capsid of the whole virus. The HPV VLPs contain no DNA and are not live/attenuated viruses. Injection of the HPV VLP elicits a strong and sustained type-specific response (Pinto *et al.*, 2003).

Two virus-like-particle vaccines have been developed for primary HPV vaccination. Gardasil® (Merck and Co, Bluebell, PA, USA) and Cervarix® (GlaxoSmithKline, Rixensart, Belgium) (Inglis *et al.*, 2006). Gardasil (by Merck), protects against HPV types 6, 11, 16, and 18 (quadrivalent), and Cervarix (bivalent), protects against types 16 and 18. The aim of the vaccine is to prevent HPV related genital diseases. In addition, the quadrivalent vaccine will reduce laryngeal papillomatosis in children (Emeny *et al.*, 2002). However, Gardasil® and Cervarix® are preventative vaccines and do not treat HPV infection or cervical cancer and cross-protection against other HPV types is partial or non-existent (Mao *et al.*, 2006).

If mass vaccination is done on all women to confer long-term protection, cervical cancer related deaths in the world will reduce by two thirds. Vaccination will subsequently reduce the need to have invasive procedures and biopsies related to HPV infection thus reducing healthcare related costs and physical pain/trauma associated with the procedures (Steinbrook, 2006). General well-being will also be enhanced due to reduced anxiety of contracting cervical cancer and hence increased productivity. HPV vaccination is a more effective way of reducing the burden of cervical cancer especially

in developing countries which have challenges in screening and treatment programs (Wittet and Tsu, 2008).

Even after vaccination against HPV infection, women are advised to continue doing regular Pap smear screening because the vaccines do not confer protection against all HPV types that cause cancer (National cancer Institute, 2011). They only reduce the chances of getting cancer related to particular types of HPV (Cutts *et al.*, 2007). It is thus possible to get cervical cancer due to another type of HPV that is not covered by the vaccines.

2.6.1 Efficacy of HPV vaccine

Cervarix uses a new proprietary adjuvant intended to boost immunogenicity. Both vaccines have shown near perfect efficacy against HPV infection for up to 5 years in young women who have not been exposed to the HPV types covered by these vaccines (Future II study group, 2007; Joura *et al.*, 2007; Villa *et al.*, 2006; Paavonen *et al.*, 2007).

Several randomized placebo-controlled trials in the USA have shown that prophylactic vaccines for HPV types 16 and 18; and 6, 11, 16, and 18 prevented persistent HPV16 and HPV18 infections and HPV16- and HPV18-related CIN2/3 (Mao *et al.*, 2006). The enrollment criteria for the trials limited women with a history of cervical abnormalities and the lifetime number of sex partners. The results showed that the vaccines provided 100% efficacy in preventing persistent type specific HPV infections and CIN2/3 (Pinto *et al.*, 2003). Some study subjects were followed up for up to 4-5 years.

Gardasil also protected against HPV6-, HPV11-, HPV16-, and HPV18-related external genital lesions, including genital warts and vulval and vaginal neoplasia. Cervarix reduced the rate of abnormal cytology results associated with HPV 16 and 18 by 93% in

women who had normal pap tests and had no infection by any of the 14 carcinogenic HPV types within 90 days of enrollment into the study (Emeny *et al.*, 2002).

2.6.2 HPV vaccine safety

The HPV vaccine is safe and well-tolerated (Canavan *et al.*, 2000). Injection site adverse events for example; pain, redness and swelling, were reported more among those who received the vaccine compared to those who received the placebo (94% versus 88%). Systemic adverse events for example; headaches, fatigue, and gastrointestinal symptoms were reported by a similar proportion of vaccine and placebo recipients (86%). Most adverse events reported were mild to moderate in intensity. Overall, 16.6% of those who received the vaccine and 13.6% of those who received the placebo had a temperature of 37.5°C. Only 0.2% (n_1) of those who received the vaccine and none of those who received the placebo discontinued use of the vaccine due to serious adverse effects (Saslow *et al.*, 2007).

Pregnancy and congenital anomaly data for this vaccine have not yet been published (Harper *et al.*, 2006). In order to assess the safety and to identify rare adverse events including effects to pregnancy, surveillance studies will be required.

2.6.3 Duration of protection conferred by HPV vaccine

Protection against infection with oncogenic types HPV-16 and HPV-18 and associated precancerous lesions has been established in randomized clinical trials for both Gardasil and Cervarix. Protection has been established for at least 6.4 years post-vaccination for Cervarix (Harper *et al.*, 2008) and at least five years for Gardasil (Villa *et al.*, 2006).

Women are at risk of acquiring HPV infection so long as they are sexually active, thus the need for a vaccine that will induce long-term protective efficacy. Serum neutralizing antibodies are assumed to constitute the major basis of protection against HPV infection

for prophylactic vaccines. Induction of HPV-specific memory B-cells that can replenish the pool of antibody-secreting cells is important for long-term maintenance of vaccine-induced protection (Stanely *et al.*, 2006)

The currently available HPV vaccines do not protect against all carcinogenic HPV types; long-term surveillance will need to assess genital HPV type-specific infections in vaccine recipients to adequately measure the duration of vaccine efficacy against HPV types. These evaluations are critical in identifying potential diminishing immunity and evaluating any requirements for booster immunizations (Saslow *et al.*, 2007).

2.6.4 Age to Vaccinate for HPV

There are important factors that need to be taken into consideration when determining the appropriate age to provide the HPV vaccine; the duration that the vaccine will offer protection, the age that will provide maximum efficacy and the feasible distribution plans. The HPV vaccine is prophylactic and thus it is critical to provide vaccination to the women/girls before their sexual debut that is before they are exposed to HPV infection (Moscicki *et al.*, 2001). Efficacy studies conducted by Gardasil used the lower age limit of 16 years while Cervarix used 15 years.

At present, girls aged 11-12 years are being targeted in the USA, before entry into middle school (Schiffman *et al.*, 2007). Several jurisdictions in the developed countries are considering mandatory vaccination for 11-12 year old girls, but this is controversial, especially regarding cost-effectiveness analyses (Newall *et al.*, 2007). Therefore, the current HPV vaccines are most certain to yield the greatest public-health benefit in girls before most have begun sexual activity (Mao *et al.*, 2006). The value of universal vaccination in the upper age range, 19-26 years, is even more controversial (Markowitz *et al.*, 2007). New evidence has shown that so long as a woman has not been exposed to HPV infection, the vaccines can be effective for women up to 45 years of age (CDC,

2006). HPV related cervical disease is an important health issue for girls and women. Routine vaccination is critical in achieving the optimum effectiveness (Winer *et al.*, 2003).

There is currently insufficient evidence to recommend for or against universal vaccination of women aged 19 to 26 years in the general population. HPV is highly prevalent in the sexually active population, and the median number of lifetime sexual partners for women aged 19 to 26 years is 3- 4 (Santelli *et al.*, 1998), the likelihood of prior HPV exposure to at least one of the high-risk types is substantial. The potential population benefit of universal prophylactic HPV vaccination in women aged 19 to 26 years, therefore, is diminished. A woman in this age group who has been sexually active may choose whether to receive the vaccine based upon her personal sexual history; an understanding of the likely diminished benefit with increasing likelihood of previous HPV exposure; and her values, preferences, and health care needs (Winer *et al.*, 2003).

Data from the vaccine trial has not shown efficacy for women who have already been exposed to the HPV, safety has only been demonstrated on women who have not initiated sexual activity. HPV testing before initiating vaccination, however, is not recommended because there are no good measures of past exposure; current clinically available tests reflect only current viral shedding (Saslow *et al.*, 2007). Studies have not yet conclusively shown benefits for patients over 26, possibly due to the high prevalence of infection and the fact that the vaccine has no effect on current infections (Canavan *et al.*, 2000)

2.6.5 Vaccination of Males against HPV

Efficacy trials for young men are ongoing. If the results show that the vaccine prevents HPV infection in males, then vaccination may be recommended in the future for the purpose of preventing anogenital warts in males and, indirectly, infection and

anogenital neoplasia and warts in female and male partners; a subset of anal, penile, oral, and head and neck cancers; and juvenile respiratory papillomatosis in their children. However, mathematical modeling has shown that, vaccinating males when there is high vaccine coverage for females will not provide additional benefit in preventing HPV related cervical cancer (Barnabas *et al.*, 2006). Thus, a vaccination program targeting females only will provide herd immunity for the males. A setting with low vaccination coverage especially in low resource countries will benefit from vaccinating both males and females (Garnett, 2005).

2.7 Treatment of Human Papilloma Virus infection

There is no cure for HPV infection. The majority of HPV infections resolves spontaneously and do not cause symptoms or disease. However, infection with high-risk HPV types e.g. 16 and 18 may progress and lead to precancerous lesions which finally progress to cervical cancer if they are not managed in the early stages (WHO/ICO, 2010).

2.7.1 HPV Treatment for Genital Warts

Some HPV types e.g. 6 and 11 cause genital warts (table 2.1). After infection occurs, the genital warts grow for about six months and then stabilize. Sometimes, visible genital warts go away without treatment. Those requiring treatment are prescribed for topical treatments like imiquimod, podophyllin resin and trichloroacetic acid (Scheinfeld., 2006).

Podophyllin resin works by destroying the wart tissue; 45-90% of the warts clear in about four weeks however, they recur in about 30-60% of cases. Imiquimod works by boosting the immune system which then fights the virus. It clears 70-85% of the warts, however, 5-20% of the warts recur (Edwards *et al.*, 1998).

Other types of wart-removal treatments include: cryotherapy which is the freezing of the wart with liquid nitrogen, trichloracetic acid applied to the surface of the warts, surgical removal by cutting the cells out with a scalpel, electrocautery which is burning off warts using an electric current and laser vaporization or excision of the warts. (Scheinfeld., 2006)

Surgical removal of the warts by cutting the cells out with a scalpel is the most effective and can get rid of the warts completely without recurrence. The success rate of the other treatment techniques ranges from 80-90% and may require repeated treatment sessions. The problem should be re-evaluated if a particular treatment does not work after three treatments, or if the warts don't disappear after 6 treatments (Krogh *et al.*, 2000).

2.7.2 HPV Treatments for Tissue Changes

HPV infection causes abnormal cell changes that could lead to cervical cancer if it does not resolve on its own. The goal at this stage becomes to remove all abnormal cells with the HPV. There are four main treatment options: Sometimes the cell changes (cervical dysplasia) precancerous cell changes, or cervical intraepithelial neoplasia will heal on their own. Cryotherapy; this involves freezing the abnormal cells with liquid nitrogen. Conization (cone biopsy); this procedure, removes the abnormal areas, LLETZ (Large loop excision of the transformation zone) or Loop Electrosurgical Excision Procedure-where the abnormal cells are removed with a painless electrical current (Singer *et al.*, 2000)

2.7.3 Immunization Schedule and Cost of the Vaccine

The quadrivalent vaccine is given at baseline and again after 2 months and 6 months. A minimum interval of 4 weeks between the first and second dose, and a min- imum interval of 12 weeks between the second and third dose, are recommended by the manufacturer if flexibility in the schedule is necessary (Merck USA., 2008)

The bivalent vaccine is given at baseline and again after 1 month and 6 months. If flexibility in the schedule is necessary, the manufacturer recommends that the second dose be administered between 1 and 2.5 months after the first dose (GlaxoSmithKline Australia., 2007)

The HPV vaccines are only available in private hospitals in Kenya. None of the private hospitals have stocked the vaccine. The cost of the vaccines is Ksh. 10,000 per dose for Gardasil and Ksh. 3,500 per dose for cervarix as established from the Aga Khan Hospital and Nairobi Hospitals.

CHAPTER THREE MATERIALS AND METHODS

3.1 Study Area

The study was conducted at Mbagathi District Hospital (MDH) which is the only public district hospital in Nairobi County, Kenya. The hospital is located in Dagoretti Division, Nairobi West District, around three kilometers from Nairobi city center. MDH started functioning as a general hospital in July 1995 with an aim of decongesting the national referral hospital, Kenyatta National Hospital. MDH serves as a referral hospital for all the health centers and dispensaries in Nairobi County. The Hospital has a maternal-child health clinic that provides services to an average of 18,000 mothers every year.

3.2 Study Design

This was a cross-sectional descriptive study.

3.3 Study Population

The study population comprised of mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi.

3.3.1 Inclusion criteria

- All mothers 18 years and above seeking maternal-child health services at Mbagathi District Hospital, Nairobi
- Those who gave informed consent

3.3.2 Exclusion criteria

- All mothers 18 years and below seeking maternal-child health services at Mbagathi District Hospital, Nairobi
- Those mothers who did not give informed consent

3.4 Sample Size Determination

Thus N = 354.

The appropriate sample size for the study was calculated using Fisher's formula (Fisher, 1998), based on 95% confidence interval. An acceptance rate of HPV vaccine of 70% was used in a similar study conducted among a similar population (Stretch *et al.*, 2008) the required sample size was attained.

A systematic sampling of study participants was done based on the sampling frame of 1500 which is the average number of women attended to at the maternal child health clinic in Mbagathi District Hospital per month (Mbagathi District Hospital, Maternal-

Child Health patient register, 2013). Data collection was done within one month. The sampling interval was every 4th client (1500/354) who sought services at the Maternal-child health clinic. The first client was randomly selected; thereafter every 4th client was recruited and questionnaires administered; the next one was approached if the previous one declined, until

3.5 Data Collection Tools

Quantitative data was obtained by use of structured questionnaires administered to the mothers (Appendix II). The questionnaires contained both closed, and open-ended questions. Anonymity and confidentiality was assured. The first part of the questionnaire collected socio-demographic data while the second part assessed knowledge concerning HPV infection and risk factors associated with it and knowledge on the HPV vaccine. The third part of the questionnaire was structured to determine the degree of acceptance of the HPV vaccine.

Qualitative data was collected through three focus group discussions (FGDs) with women who had children and or were of child bearing age between 19 and 25 years. Each group had between 8-12 participants. A total of 26 women were interviewed. The interviews were recorded using digital tape recorders. The discussions were based on a pre-prepared interview guide (Appendix III). All FGDs were mostly carried out in Swahili and participants were encouraged to answer in whatever language they felt most comfortable with (English or Swahili). The guides were designed to capture information on the women's knowledge of STIs in general, specific knowledge of HPV as an STI, Cervical cancer and its causes, and information on the HPV vaccine and its use. Consent to participate in the FGDs and for them to be digitally recorded was obtained verbally from the participants.

3.6 Data Analysis

Quantitative data from the field was coded and double entered into a computer database designed using MS-Access application. Data cleaning and validation was performed to achieve a clean dataset. The clean dataset was stored in a computer hard drive for analysis. Back-up files were stored in flash discs and an external hard drive; this was regularly done to avoid any loss or tampering. All the questionnaires and interview forms were stored in a lockable drawer for confidentiality.

Quantitative data analysis was done using Stata version 11.0 (Stata Corporation, College Station, TX, USA). Univariable and multivariable analysis using logistic regression was undertaken to assess associations. Univariable logistic regression was used to select candidate covariates for the multivariable analysis, an inclusion criterion of P value<0.1 from a likelihood ratio test (LR test) was used. Backward-stepwise selection of covariates was used to generate the minimum adequate models.

For qualitative data: The FGD's were translated and transcribed in English. The transcripts were then validated with the audio files to check the accuracy of the translation. Transcripts were imported into NVivo 9 for coding. A coding tree was developed using themes from the interview guides and previous literature and was then used as an organizational framework in which data were summarized into each key node and salient features picked out and reported.

3.7 Ethical Considerations

Scientific and ethical approvals were granted by the KEMRI scientific steering committee and the ethical review committee, respectively (Appendix IV and V). Permission to carry out the study at Mbagathi District Hospital was sought from the hospital authorities.

All mothers seeking maternal and child health services at Mbagathi District Hospital were informed of the study before or at registration. Informed consent was sought from all participants who fell in the sampling procedure (section 3.4) after sufficient explanation of the study (Appendix 1). The purpose of the study was made clear to the participants. Participation was voluntary, and no one was forced to participate in the study against their will. Confidentiality and anonymity were assured and maintained by coding the questionnaires and restricting access.

Participants were free to withdraw from the study at any time without giving reasons, and this would not affect their access to normal health care and management. This process caused absolutely no harm to the participants.

CHAPTER FOUR

RESULTS

4.1 Socio-Demographic Characteristics of Mothers

A total of 348 from the targeted 354 women were included in the study. This was more than the required sample size which was 322 and adjusted to 354 to cater for non-response, which in total gave 98% coverage of the total sample size. The median age was 26 years (interquartile range 22-29 years), while the women had between 0 and 5 children.

A third 32.8% (114) of the women were married in monogamous marriages while 27.9% (97) were single and not in any relationship. Majority 89% (310) of the women had post primary education while 2.9% (10) had no formal education, 25.9% (90) of the women had a mean monthly income of less than Ksh. 5,000 and 29.3% (102) of the women reported having a mean income of more than Ksh. 25,000 per month which was the average income of the women (Table 4.1).

Table 4:1: Socio-Demographic Characteristics of Mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

Variable	n=348	%
Marital status		
Married-monogamous	114	32.8
Married-polygamous	36	10.3
In a relationship/cohabiting	101	29.0
Single/Divorced/Separated/Widowed	97	27.9
Education level		
No formal education	10	2.9
Primary education	24	7.0
Secondary education	146	42.4
Vocational training	73	21.3
College/University	91	26.4
Missing	4	1.2
Occupation		
Business/Self employed	114	32.8
Formal employment	92	26.4
Informal employment(Casual worker)	46	13.2
Unemployed	93	26.7
Student	3	0.9
Monthly income (Ksh.)		
<5,000	90	25.9
5,000-10,000	43	12.4
10,001-15,000	33	9.5
15,001-20,000	33	9.5
20,001-25,000	47	13.5
>25,000	102	29.3
Religion		
Christian	293	84.1
Muslim	53	15.2
Others	2	0.7
Residence		
Urban	268	77.0
Peri-urban	68	19.5
Rural	12	3.5

4.2 Mothers' knowledge on risk factors of cervical cancer and consequences of HPV infection

Knowledge of risk factors and consequences of HPV infection and awareness of HPV vaccine were assessed using 21 questions (Appendix II). Knowledge was defined on the basis of a composite score obtained from the responses to 21 questions, on the risk factors and consequences of HPV infection. Each correct response was given a score of 1, and a total score out of 21 for knowledge was generated for each respondent. A knowledge score of above 11 was considered good while below 11 was considered poor. This was based on literature review where most similar studies provided a cutoff point of 50% score for good and poor knowledge. A total of 286 (82.2%) respondents had a knowledge score of above 11.

The mean knowledge score was 12.5 with a range of between 0 and 18. A majority 87.9% (305) of women answered more than ten questions correctly, and three women answered all questions incorrectly. Figure 4.1 shows the frequency of correct responses. Almost all women knew that HPV infection did not cause HIV/AIDS, the infection maybe asymptomatic 94.3% (328), and that untreated HPV infections could cause cervical cancer 96.0% (334).

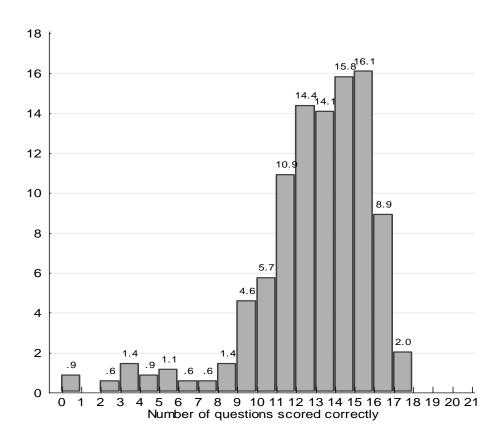


Figure 4.1 Frequency distribution of correct responses to classify knowledge levels

4.2.1Univariable analysis of factors associated with mothers' knowledge of cervical cancer, associated risk factors and consequences of HPV infection

Having children was associated with decreased odds of a knowledge score of above 11. In contrast, having formal education (P=0.014), having any form of employment (P=0.004) and income above Ksh. 5,000 (P=0.001), were associated with increased odds of a knowledge score of above 11. There was no evidence of an association between knowledge and age or knowledge and marital status of the respondents (Table 4.2.)

Table 4:2: Univariable analysis of factors associated with mother's knowledge of risk factors and consequences of HPV infection

Variable	Knowledge score > 50% n (%)	Univariable OR (95% CI)	P value ^a
Age			
17-24 years	121 (81.8)	1	
≥25 years	165 (82.5)	1.01 (0.60-1.83)	0.858
Marital status			
Married monogamous	94 (82.5)	1	
Married polygamous	26 (72.2)	0.55 (0.23-1.33)	
In a relationship/cohabiting	82 (82.0)	0.92 (0.46-1.84)	
Single/Divorced/Separated/Widowed	84 (86.6)	1.37 (0.64-2.93)	0.305
Religion			
Christian	245 (83.6)	1	
Muslim	40 (75.5)	0.60 (0.30-1.21)	0.167
Number of children			
No children	40 (93.0)	1	
1-2 children	207 (83.5)	0.38 (0.11-1.28)	
3-5 children	39 (68.4)	0.16 (0.04-0.60)	0.004
Level of education			
No education/ primary incomplete	8 (53.3)	1	
Primary complete	25 (73.5)	2.43 (0.68-8.64)	
Secondary incomplete	30 (75.0)	2.63 (0.76-9.08)	
Secondary complete	92 (86.8)	5.75 (1.80-18.34)	
College/university	128 (85.9)	5.33 (1.75-16.25)	0.014
Occupation			
Unemployed	67 (69.8)	1	
Casual employment	39 (84.8)	2.41 (0.97-6.02)	
Self-employed / business	100 (87.7)	3.09 (1.52-6.28)	
Formal employment	80 (87.0)	2.89 (1.37-6.09)	0.004
Monthly income (Ksh.)			
<5,000	62 (68.9)	1	
5,000-10,000	34 (79.1)	1.71 (0.72-4.03)	
10,001-15,000	32 (97.0)	14.45 (1.88-111.11)	
15,001-20,000	29 (87.9)	3.27 (1.51-10.20)	
20,001-25,000	40 (85.1)	2.58 (1.03-6.47)	
>25,000	89 (87.3)	3.09 (1.48-6.44)	0.001

^αP values are based on likelihood ratio tests.

4.2.2 Multivariable analysis of factors associated with mother's knowledge of cervical cancer, associated risk factors and consequences of HPV infection

In the final multivariable model, there was a significant relationship between the number of children a mother had and the level of knowledge on HPV infection. Women who had 3 to 5 children were 89% (OR=0.11, 95% CI 0.03-0.44) less likely to have a knowledge score of more than 11 compared to women who had no children. There was also a significant relationship between monthly income and the likelihood of having a knowledge score of above 11.

The Mothers that had a monthly income of above Ksh. 5,000 were 3 times more likely to score above 11 compared to those who had a monthly income of less than Ksh. 5,000. However, there was no significant relationship between age, religion, marital status, level of education, with having knowledge score of above 11 with regards to the mother's knowledge of cervical cancer, associated risk factors and consequences of HPV infection (Table 4.3).

 $\label{thm:constraint} \textbf{Table 4.3: Multivariate analysis of factors associated with knowledge of risk factors } \\$

and consequences of HPV infection, among mothers

Variable Variable	Knowledge score > 50% n (%)	Multivariable OR ^β P value ^α (95% CI)
Age		
17-24 years	121 (81.8)	Omitted from final model
≥25 years	165 (82.5)	
Marital status		
Married monogamous	94 (82.5)	Omitted from final model
Married polygamous	26 (72.2)	
In a relationship/cohabiting	82 (82.0)	
Single/Divorced/Separated/Widowed	84 (86.6)	
Religion		
Christian	295 (84.8)	Omitted from final model
Muslim	53 (15.2)	
Number of children		
None	40 (93.0)	1
1-2 children	207 (83.5)	0.22 (0.06-0.81)
3-5 children	39 (68.4)	0.11 (0.03-0.44) 0.002
Level of education		
No formal education/ primary incomplete	8 (53.3)	Omitted from final model
Primary complete	25 (73.5)	
Secondary incomplete	30 (75.0)	
Secondary complete	92 (86.8)	
College/university	128 (85.9)	
Occupation		
Unemployed	67 (69.8)	
Casual employment	39 (84.8)	
Self-employed / business	100 (87.7)	
Formal employment	80 (87.0)	*
Monthly income (Ksh.)		
<5,000	62 (68.9)	1
5,000-10,000	34 (79.1)	2.11 (0.82-5.42)
10,001-15,000	32 (97.0)	16.17 (2.01-129.79)
15,001-20,000	29 (87.9)	2.95 (089-9.77)
20,001-25,000	40 (85.1)	2.87 (1.08-7.66)
>25,000	89 (87.3)	3.06 (1.27-7.36) 0.005

^αP values are based on likelihood ratio tests.

All variables with a p-value of >0.05 were omitted from the final model

 $^{^{\}beta}$ Final multivariable model based on 344 observations due to missing data

^{*}Occupation omitted from the final model due to collinearity with occupation

4.3 Knowledge of Human Papilloma Virus (HPV) infection, risk factors and the consequences among mothers

Knowledge of HPV infection was assessed and 73.9% (257) of the Mothers knew that HPV is spread through sexual intercourse, 91.7% (319) knew that a person may be infected and be aware, 87.4% (304) of the mothers knew that Pap smear detects HPV. Among the mothers, 37.6% (131) knew that HPV can be cured, while 89.1% (330) knew that certain types of HPV cause cervical cancer. Only 39.4% (137) of the mothers knew that HPV can be transmitted from mother to child at birth and 87.4% (304) knew that HPV has harmful effects (Table 4.3).

Early age at first sexual intercourse was known as a risk factor for HPV infection by 60.3% (210) of the mothers, 66.4% (231) of them knew having multiple sexual partners was a risk factor. Family history of HPV infection was known as a risk factor to 71% (247) of the mothers while poor hygiene and long-term use of oral contraceptive were known as risk factors to 69.8% (243) and 76.7% (267) of the mothers respectively (Table 4.3).

Presence of warts that sometimes itch and bleed was known as a symptom of HPV infection to 80.5% (280) of the mothers, while having warty growths was known as a symptom to 79.6% (277) of the mothers. Having cervical cancer was known as a symptom of HPV infection to 83.3% (290) of the mothers and 2.6% (9) of the mothers thought there was no consequence of HPV infection (Table 4.3).

Concerning the consequences of HPV infection 96% (334) of the mothers thought it could result to cervical cancer, 21% (73) of them thought it could cause HIV/AIDS infection. Development of genital warts was mentioned as a consequence of HPV infection by 76.7% (267) of the mothers and 8.9% (31) thought there was no consequence of having HPV infection (Table 4.3).

Table 4.4: Awareness of HPV Vaccine among Mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

Variable	n	%
HPV is spread through sexual intercourse	257	73.9
HPV does not cause HIV/AIDS	319	91.7
A person may be infected and not know it	328	94.3
PAP smear detects HPV	304	87.4
HPV can't be cured	131	37.6
Certain types of HPV cause cervical cancer	330	89.1
HPV can be transmitted from mother to child at	137	39.4
birth		
HPV harms	304	87.4
Risk factors for HPV infection		
Early age at first sexual intercourse	210	60.3
Multiple sexual partners	231	66.4
Family history of HPV infection	247	71.0
Poor hygiene	243	69.8
Long-term oral contraceptive use	267	76.7
Symptoms of HPV infection		
Warts that sometimes itch and bleed	280	80.5
Warty growths	277	79.6
No consequences	9	2.6
Cancer of the cervix	290	83.3
Consequences of untreated HPV		
Cervical cancer	334	96.0
HIV/AIDS	73	21.0
Genital Warts	267	76.7
No consequences	31	8.9

4.4 Awareness of the HPV vaccine among the Mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

A total of 62.6% (218) of the mothers reported having heard about the HPV vaccine, 37.4% (130) of them said they had not heard about the HPV vaccine. The main source of information about HPV vaccine was friends, colleagues or relative 29.4% (64) of the mothers, 15.1% (33) from a hospital or clinic visit while 14.2% (31) of the mothers had heard about the vaccine from the media that included television, radio, and the internet. Other sources of information about the HPV vaccine were cancer awareness campaigns 9.6% (21), magazines/ journals/ health brochures 9.6% (21), doctors or nurses 6.9% (15), school or college 4.1% (9), and husband or partner 1.4% (3), while 9.2% (20) of the mothers could not remember their source of information Table 4.5).

Table 4.5: Awareness of HPV Vaccine among Mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

Variable	n	0/0
Awareness of HPV vaccine		
Yes	218	62.6
No	130	37.4
Main source of information about HPV vaccine		
Friends/Colleagues/Relatives	64	29.4
Hospital/Clinic	34	15.6
Media/TV/Radio/Internet	31	14.2
Cancer awareness campaigns	21	9.6
Magazines/Journals/Health brochures	21	9.6
Don't remember source	20	9.2
Doctor/Nurse	15	6.9
School/College	9	4.1
Husband/Partner	3	1.4

4.4.1 Univariable analysis of factors associated with awareness of HPV vaccine

In univariable logistic regression analysis, there was no significant relationship between marital status and awareness of HPV vaccine however, there was a significant association between level of education and awareness of HPV vaccine with the respondents having 6.51 odds of being aware of HPV vaccine with high level of education (95% CI=2.09-20.34; P<0.001).

There was also a significant relationship between type of occupation and awareness of HPV vaccine with an increased odd of 9.22 of those in formal employment being aware of HPV vaccine (95% CI=4.16-20.45; P<0.001). There was also a significant relationship between mean monthly income and awareness of HPV vaccine with an increased odd of 4.76 of being aware of HPV vaccine for those with a mean monthly income of >25,000 (95% CI=2.53-8.93; p<0.001). However, there was no significant relationship between religion and number of children a mother has, and awareness of HPV vaccine (P>0.001). (table 4.6)

Table 4.6: Univariate analysis of factors associated with awareness HPV vaccine Acceptability of the HPV Vaccine among Mothers Seeking Maternal-Child Health Services at Mbagathi District Hospital

Variable	Heard of HPV vaccine n (%)	Univariable OR (95% CI)	P value ^a
Age			
17-24 years	74 (50.0)	1	
≥25 years	144 (72.0)	2.57 (1.65-4.02)	< 0.001
Marital status			
Married monogamous	73 (64.0)	1	
Married polygamous	17 (47.2)	0.50 (0.24-1.07)	
In a relationship/cohabiting	63 (62.4)	0.93 (0.53-1.62)	
Single/Divorced/Separated/Widow	65 (67.0)	1.14 (0.64-2.02)	0.219
ed			
Religion	101 (61 0)	1	
Christian	181 (61.8)	1	0.250
Muslim	37 (69.8)	1.43 (0.76-2.69)	0.259
Number of children	20 (45.5)		
No children	20 (46.5)	1	
1-2 children	161 (64.9)	2.13 (1.11-4.09)	0.0=4
3-5 children	37 (64.9)	2.13 (0.95-4.78)	0.071
Level of education			
No education/ primary incomplete	5 (33.3)	1	
Primary complete	23 (67.6)	4.18 (1.15-15.22)	
Secondary incomplete	16 (40.0)	1.33 (0.38-4.63)	
Secondary complete	60 (56.6)	2.61 (0.83-8.16)	
College/university	114 (76.5)	6.51 (2.09-20.34)	< 0.001
Occupation			
Unemployed	48 (50.0)	1	
Casual employment	28 (60.9)	1.55 (0.76-3.18)	
Self-employed / business	59 (51.8)	1.07(0.62-1.85)	
Formal employment	83 (90.2)	9.22(4.16-20.45)	< 0.001
Monthly income (Ksh.)			
<5,000	39 (43.3)	1	
5,000-10,000	24 (55.8)	1.65 (0.79-3.44)	
10,001-15,000	19 (57.6)	1.77 (0.79-3.98)	
15,001-20,000	22 (66.7)	2.62 (1.13-6.03)	
20,001-25,000	34 (72.3)	3.42 (1.59-7.34)	
>25,000	80 (78.4)	4.76 (2.53-8.93)	< 0.001

^αP values are based on likelihood ratio tests.

4.4.2 Multivariable analysis of factors associated with awareness of HPV vaccine

In multivariable regression analysis, there was a significant relationship between the level of education and awareness of HPV vaccine with higher odds of being aware of the HPV vaccine in women who had any education compared to women who had no education (p=0.031). Similarly, there was a significant relationship between occupation and awareness of HPV, women who were in formal employment had higher odds 6.46 (95% CI=2.53 – 16.49; p<0.001) of awareness than women who were unemployed. However, there was no significant relationship between age, number of children and monthly income, and awareness of HPV vaccine (P>0.05) Table 4.7).

Table 4.7: Multivariate analysis of factors associated with awareness of HPV vaccine

vaccine	Heard of HPV	Multivariable		
Variable	vaccine n (%)	OR $(95\% \text{ CI})^{\beta}$	P value ^a	
Age				
17-24 years	74 (50.0)	1		
≥25 years	144 (72.0)	1.45(0.75 - 2.83)	0.067	
Marital status				
Married monogamous	73 (64.0)			
Married polygamous	17 (47.2)			
In a relationship/cohabiting	63 (62.4)			
Single/Divorced/Separated/Wido	65 (67.0)	-	-	
wed Religion				
Christian	181 (61.8)			
Muslim	37 (69.8)	-	_	
Number of children	2. (3.13)			
No children	20 (46.5)			
1-2 children	161 (64.9)			
3-5 children	37 (64.9)	-	-	
Level of education	` ,			
No education/ primary incomplete	5 (33.3)	1		
Primary complete	23 (67.6)	4.01 (1.09-15.42)		
Secondary incomplete	16 (40.0)	1.40 (0.39-5.05)		
Secondary complete	60 (56.6)	2.62 (0.79-8.64)		
College/university	114 (76.5)	3.90 (1.18-12.88)	0.031	
Occupation				
Unemployed	48 (50.0)	1		
Casual employment	28 (60.9)	1.23(0.58 - 2.61)		
Self-employed / business	59 (51.8)	0.78 (0.42 - 1.43)		
Formal employment	83 (90.2)	4.94 (2.03 – 11.98)	< 0.001	
Monthly income (Ksh.)				
<5,000	39 (43.3)			
5,000-10,000	24 (55.8)			
10,001-15,000	19 (57.6)			
15,001-20,000	22 (66.7)			
20,001-25,000	34 (72.3)			
>25,000	80 (78.4)	*	*	

^αP values are based on likelihood ratio tests.

 $^{^{\}beta}$ Final multivariable model based on 344 observations due to missing data

^{*}Monthly income omitted from the final model due to co-linearity with occupation

4.5 Attitude towards safety and efficacy of the HPV vaccine among mothers Mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

Among the 218 women who knew about the HPV vaccine, 89% (194) thought that the HPV vaccine is very safe, 6.9% (15) thought it was unsafe while 4.1% (9) did not know whether it was safe or not. On whether the vaccine could prevent cervical cancer 51.8% (113) of those who knew about the vaccine thought that it was extremely unlikely to prevent cervical cancer, 35.8% (78) thought it was somewhat unlikely to provide protection, 8.7% (19) had no opinion on whether it could provide protection while 2.8% (6) and 0.9% (2) thought that the vaccine was extremely likely and somewhat likely to prevent cancer respectively (Table 4.8).

Table 4.8: Attitudes towards safety and efficacy of the HPV Vaccine among others Seeking Maternal- Child Health Services at Mbagathi District Hospital

Variable	n=218	%
Is the vaccine safe?		
Very safe	194	89.0
Not safe	15	6.9
Don't know	9	4.1
Will vaccine prevent cervical cancer?		
Extremely unlikely	113	51.8
Somewhat unlikely	78	35.8
Neutral	19	8.7
Somewhat likely	2	0.9
Extremely likely	6	2.8
Know any advantages of HPV vaccine?		
Yes	159	72.9
No	59	27.1
Advantages of HPV vaccine		
Prevents HPV infection	109	50.0
Prevents cervical cancer	47	21.6
Kills the virus	3	1.3
None	59	27.1

4.6 Acceptability of the HPV vaccine among the mothers Seeking Maternal- Child Health Services at Mbagathi District Hospital

Among all the women, 67.8% (236) reported that they would vaccinate their adolescent child, 31.3% (109) reported they would not, while 0.9% (3) were undecided

Some of the main reasons given by the mothers who said they would vaccinate their adolescent child were to protect them from HPV infection 42.8% (101), to prevent them from cervical cancer or other cancers 28.4% (67), and to protect their child 16.1% (38). Other reasons given were that prevention is better than cure 5.5% (13), they would vaccinate if the vaccine was made available was reported by 3.0% (7) of the mothers, a similar number also reported that it is the right thing to do. A smaller proportion 0.8% (2) and 0.4% (1) reported that they would vaccinate because the husband recommended and to kill the virus respectively.

Among the 109 mothers who reported that they would not vaccinate their adolescent child, 31.2% (34) was said that it was too expensive, 23.9% (26) said they don't know much about the vaccine, and 12.8% (14) said they were not sure of its safety. The vaccine having side effects was mentioned by 8.3% (9) of them as a reason not to vaccinate, 6.4% (7) said the husband had not given them permission to vaccinate and a similar number also reported that they had no reason for not vaccinating.

Other reasons given for not vaccinating included 3.7% (4) don't believe in modern medicine, 1.8% (2) said they don't like the vaccine, 1.8% (2) said it may promote promiscuity, 1.8% (2) also said they don't have any family history of cancer. One respondent 0.9% said the vaccine may cause bareness and another one 0.9% said it was not approved by the Ministry of Health and hence could not use it (Table 4.6).

Table 4.9: Acceptability of the HPV Vaccine among Mothers Seeking Maternal-Child Health Services at Mbagathi District Hospital

Variable	N	%
Vaccinate adolescent child?		
Yes	236	67.8
No	109	31.3
Undecided	3	0.9
Main reason for vaccination		
Protect from HPV infection	101	42.8
Prevent cervical cancer	67	28.4
Protect the child	38	16.1
Prevention is better than cure	13	5.5
If made available	7	3.0
It's the right thing to do	7	3.0
Husband had recommended	2	0.8
To kill virus	1	0.4
Main reasons for not vaccinating		
It is expensive	34	31.2
Don't know about the vaccine	26	23.9
Not sure of its safety	14	12.8
Has side effects	9	8.3
Husband has not given permission	7	6.4
No reason given	7	6.4
Don't believe in modern medicine	4	3.7
Don't like the vaccine	2	1.8
May promote promiscuity	2	1.8
No family history of cancer	2	1.8
May cause bareness	1	0.9
Not approved by MOH	1	0.9

4.6.1 Factors associated with acceptability of HPV vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi

Acceptance of the vaccine was examined by assessing the participants' willingness to vaccinate their adolescent children with the HPV vaccine. Overall, 236 (67.8%) of women reported that they would vaccinate their adolescent children with HPV vaccine. In the univariate analysis, number of children, level of education and occupation were not significant predictors of acceptance of the HPV vaccine (P>0.001). In the multivariate analysis, women who had children were more likely to accept the HPV vaccine with women who had 1-2 children and 3-5 children 2.73 and 4.59 more times likely to accept than women who had no children respectively, (P=0.008) (Table 4.10). However, age and level of education were not significantly associated with acceptability of HPV vaccine.

Table 4.10: Univariate and multivariate analysis of factors associated with acceptability of HPV vaccine among mothers attending maternal and child health clinic at Mbagathi hospital.

Variable	Univariate OR (95% CI)	P value ^α	Multivariate OR (95% CI) ^β	P value ^α
Age				
17-24 years	1		1	
≥25 years	1.81 (1.14 - 2.86)	0.011	1.09 (0.62 - 1.93)	0.764
Marital status				
Married monogamous	1			
Married polygamous	0.64 (0.29 - 1.40)			
In a relationship/cohabiting	0.79 (0.44 - 1.40)			
Single/Divorced/Separated/Widowe	1.14(0.63 - 2.09)	0.437	-	
d				
Religion				
Christian	1			
Muslim	0.92(0.49 - 1.73)	0.801	-	-
Number of children				
None	1		1	
1-2 children	3.57(1.81 - 7.05)		2.73(1.32 - 5.65)	
3-5 children	3.95 (1.68 - 9.31)	0.001	4.59 (1.61 –	0.008
			13.05)	
Level of education				
No formal education/ primary incomplete	1		1	
Primary complete	2.06(0.55 - 7.67)		2.30 (0.58 – 9.01)	
Secondary incomplete	0.86 (0.24 - 3.00)		1.28 (0.34 – 4.80)	
			,	
Secondary complete	1.58 (0.49 - 5.03)	0.007	2.28 (0.66 – 7.86)	0.062
College/university	3.01 (0.95 – 9.58)	0.007	3.69 (1.05 – 12.95)	0.063
Occupation			12.73)	
Unemployed	1			
Casual employment	0.84 (0.41 - 1.74)			
Self-employed / business	1.04(0.59 - 1.85)			
Formal employment	2.05(1.06 - 3.96)	0.064	-	-
Monthly income (Ksh.)	,			
<5,000	1			
5,000-10,000	0.96(0.46 - 2.03)			
10,001-15,000	1.68(0.70 - 4.04)			
15,001-20,000	1.10(0.48 - 2.52)			
20,001-25,000	2.00(0.90 - 4.47)			
>25,000	1.84(0.99 - 3.42)	0.225	-	-

^αP values are based on likelihood ratio tests.

All variables with a p-value of >0.10 were omitted from the final model

4.7 Qualitative Analysis

4.7.1 Knowledge of STDs among mothers

Majority of the mothers had a general knowledge of STDs. The most commonly mentioned ones were gonorrhea and syphilis. Others mentioned included HIV/AIDS and candidiasis. None of the women on inquiry about STDs in general mentioned HPV infection. Though many reported having knowledge of genital warts, it was not clear from their responses that they actually knew exactly what warts were. Some pointed out various symptoms including, "genital area itch", "itchiness", "wounds", "rashes", "a foul discharge from the private parts" and "pain when passing urine". On inquiry as to where the participants had heard about genital warts from, most mentioned the hospital whereas others mentioned a clinic that particularly deals with women named SWOP.

4.7.2 Knowledge of Human Papilloma Virus Infection among mothers

Knowledge of Human Papilloma Virus Infection was low amongst the mothers some reported having heard of the HPV Infection. In reference to having heard of the infection, one of the participants stated "this is the first time". Of those who reported having heard of the infection, some reported hearing about it at the hospital, others reading about it in a newspaper or watching on TV.

Others mentioned the social workers at the clinic earlier mentioned named SWOP. One woman reported that she had learnt about it in school. "I have heard from the hospital, like the City Council once when we got there early in the morning. When you go in, you are taught as women" FGD Participant. It was unanimous amongst the participants that the HPV infection is an STD and a one went on to add that if it is an STD, "it can even affect men".

4.7.3 Knowledge of Cervical Cancer among Mothers

Some mothers reported having heard about cervical cancer, some of those who hadn't tended to confuse it with cancer of the breast. Of those who had heard, the commonest symptoms mentioned included: "itchiness", discharge, with one participant stating, "I've heard of it but the symptoms I think maybe there are some...there are some things coming out...from the cervix". Other symptoms mentioned were "scratching", "pain when passing urine", "miscarriage" and "weakness of the womb".

Although not commonly mentioned, it was pointed out that being difficult to diagnose, it was a "very serious", "lethal" and "dangerous" disease that "is expensive to treat" and if not prevented early would likely cause death. Only one participant was of the view that cervical cancer can affect men as well, especially if they have unprotected sex.

"It is not easy to diagnose. It can eat at you without your knowledge." FGD Participant

"Getting cured is fifty-fifty if it is not prevented." FGD participant

When asked about the causes of cervical cancer, only one participant felt that the cause was the Human Papilloma Virus. Other causes mentioned were sex, some qualifying it as "if you sleep around with everybody", "sharing panties" and family planning, specifically, condoms, coil, pills, injections and implants". A few other participants felt that foods eaten, such as use of spices, could possibly cause cervical cancer. In addition one participant felt that sharing the toilet with an infected person could possibly cause cervical cancer. "If you have sex with this one and then again with that one…maybe this one has and I don't. So if you have it with me then I can get infected." FGD participant

4.7.4 Knowledge of HPV vaccine and its acceptability among Mothers

Only one participant from the FGD's reported having heard of the HPV vaccine. The participant, who had heard about it, stated having heard about it at the hospital and on TV and in newspapers. She specifically mentioned a TV show on one of the local channels that discussed the vaccine. "I have heard about it in hospital, newspapers and the TV. At the hospital, it is when we go to the clinic and we are first taught before we receive services on what took us there." FGD participant. "On K24, there are times like nine-thirty, ten, thereabout, that is when they discuss matters on sex and about that disease." FGD participant.

On exploring participant views to allow their children to get the vaccine, a large majority mentioned that they would allow it as "prevention is better than cure". Others stated that they would allow due to the high costs of treatment and the reduction of risks. A few others expressed caution pointing out the need to get more information on the vaccine as well as its side effects. "You know why I can agree for them to be vaccinated? Because...the chances of getting that disease will be low," FGD Participant. "Before they have it given to them, I would inquire about it first....I would ask to be explained for first, about HPV so that I can get to know..." FGD Participant. "If the side effects are not bad, I can agree. And also if the cost is not high I will agree". FGD Participant

The majority of the mothers who were against their children getting the vaccine were of the strong opinion that having the vaccine would make their children "promiscuous" and "encourage them to be sexually active". They further pointed out that the vaccine could possibly make the children not even be afraid of contracting HIV and other STDs and even pregnancy. In addition, it was felt that the cost of the vaccine may be too high for them to afford and that the side effects may be harmful. "OK...I'll not...the child will not be afraid of...to be niniii...(Whatever). She will not be afraid...she will not fear being sexually active because she knows that, after all, she cannot get infected, the

vaccine is there" FGD Participant. "Because I cannot afford that thing of theirs...that eh...the cost...the cost of that vaccine, I would not agree to it. May be if they lowered the cost so that I can also afford" FGD Participant. "If that vaccine would be available and the price could be lowered so that the people in the ghetto...the people in the slums can also afford it." FGD Participant

4.7.5 Factors Associated with Acceptability of the HPV vaccine

Mothers felt it would be good to vaccinate the adolescents stating that it would confer protection; however, they strongly felt that the cost of the vaccine would be prohibitive to the poor and Low-income earners unless the government covered the costs. In addition, they felt that there may be side effects and that the vaccine would still likely lead to teenage promiscuity. "Yeah, as long as they assure us that the vaccine is good. It will not affect our children" FGD Participant. "We would be very happy.... Because I won't have to pay for it. The government will cover the cost" FGD Participant. "It's just like cancer itself. Don't you see that those who have the money are the ones who go for the treatment? (All: yeah) So they will have discriminated against the poor....Ok, we would plead for its cost to be lowered so that everyone can be vaccinated" FGD Participant. "I would refuse because it can encourage teenagers.... they would begin to indulge in sexual activity...... Because they will not have any more fear." FGD Participant

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussions

The HPV vaccine is critical in the prevention of cervical cancer especially in developing countries where the health care system is weak. For a HPV vaccination program to be successfully implemented, mother's knowledge on HPV and cervical cancer and willingness to use the HPV vaccine is very important and needs to be assessed correctly. Myths and misconceptions about side effects that may not be related to the vaccine need to be understood and other factors hindering uptake of the vaccine need to be addressed as these may negatively impact on public trust and adversely impact on the HPV immunization programming leading to collapse of the program altogether.

In this study comprehensive knowledge of cervical cancer, associated risk factors and the consequences of HPV infection were assessed using 21 questions and 286 (82.2%) of the respondents had a knowledge score above half that was classified as good, while only three women did not get anything right. Knowledge of cervical cancer was also high at 82%, this could be attributed to the socio-demographic characteristics of the respondents whereby a majority had more than secondary school education, having some form of occupation, being in an urban center and therefore, having access to different sources of information.

Similarly in a study on awareness of cervical cancer risk factors and Pap smear testing, among female primary school teachers in Kasarani division in 2012, the awareness level about cervical cancer was high at 87%, this high awareness level could be attributed to the socio-demographic characteristics of the study population, being educated and therefore enlightened (Ombech *et al.*, 2012).

In contrast to the study above, a number of studies have shown that the level of knowledge of HPV and cervical cancer, is low in the general public. In a study conducted in Kisumu, awareness of cervical cancer and cervical cancer screening was limited (Sylvia *et al.*, 2010). While 89% of women had heard of cancer, only 15% had heard of cervical cancer. Cervical cancer can be prevented if precancerous lesions are identified early through screening and then treated, or the HPV vaccine is administered to women before their sexual debut. Another study conducted in Thika among women in a low resource setting also revealed that the level of awareness and understanding of cervical cancer was low at 36.9% (Ngugi *et al.*, 2011). This could have been due to the low-resource setting that could mean lack of access to information. In many developing countries, women have a very low knowledge of cervical cancer (Amarin *et al.*, 2008).

High literacy levels increase the level of knowledge on cervical cancer as evidenced in a similar study conducted among local married teachers in Sharjah District of United Arab Emirates which showed that 84% of the teachers had good knowledge of cervical cancer (Bakheit and Haroon, 2004) and another study conducted among female undergraduates in Ibadan which showed that about 71% had knowledge about the cancer (Ayinde *et al.*, 2004).

Women interviewed in the qualitative study were able to identify some of the associated risk factors for cervical cancer although not comprehensively. This is because their main sources of information were not very reliable and included friends, family and colleagues. However, some of them mentioned having acquired the knowledge from a nearby health facility (SWOP). This is however contrary to other studies done in Kenya whereby the main source of information about cervical cancer was the media. In a study done among adult women in, Thika Municipality, the sources of information about cervical cancer were mainly from TV/Radio 12.2%, print media 0.8% (Ngugi *et al.*, 2011).

In another study among female primary school teachers in Kasarani, division the main source of information about cervical cancer were the media that included TV/radio and print media (Ombech *et al.*, 2012). A survey on knowledge of cervical cancer among patients in Kenyatta National Hospital in 2003 showed that only 52% knew about cervical cancer (Gichangi *et al.*, 2003). Knowledge on cervical cancer in this study could have been low because a decade ago, campaigns on cancer were not as much as they are now. Campaigns on cervical cancer are now being heightened, and this has increased knowledge on cervical cancer.

A survey of health care workers in Uganda showed that less than 40% knew the risk factors of cervical cancer (Mutyaba *et al.*, 2006). In a study of evaluation of cervical cancer screening program in a rural community in South Africa, at least 322 (64%) women gave correct answers to one or more risk factors whereas; only 2% knew all the risk factors (Hoque *et al.*, 2008).

In this study the awareness of associated risk factors or cervical cancer was generally high with more than 60% of the mother's being aware of the risk factors. Among all the risk factors asked, majority of the women thought that certain types of HPV and prolonged use of oral contraceptives would cause cervical cancer as compared to other risk factors. Compared to previous studies done in the country, knowledge of risk factors as identified from a given list was generally low with the highest awareness being of having multiple partners at 55% and the lowest awareness being having a circumcised partner at 7% (Ombech *et al.*, 2012). In the in-depth interviews of factors affecting uptake of cervical cancer early detection measures among women in Thika, Kenya, pathogenic organisms or "germs" also were stated as possible causes of the disease by the majority of those with a higher level of education (Ngugi *et al.*, 2012). The majority of them mentioned that the organism was sexually transmitted. Very few reported that the organism was the HPV (Ngugi *et al.*, 2012).

In this study, the awareness of having multiple sexual partners as a risk factor for HPV infection was high at 66.4%. Similarly, in a study on awareness of risk factors for cancer among British adults 60% of the respondents identified having many sexual partners as a cause for cervical cancer (Wardle *et al.*, 2001). This was also reported in an in depth interview by some of the women who were married as a possible cause of cervical cancer in a study among women in Thika (Ngugi *et al.*, 2011). Having multiple sexual partners and family history of HPV infection were also identified by 47.4% and 43.1% respectively as risks for developing cervical cancer in a study among nurses in Tanzania (Urasa and Darj, 2011).

In a recent study among primary school teachers in Kasarani division, having multiple sex partners was reported as a risk factor by 55% of the respondents (Ombech *et al.*, 2012). In the study among women in Thika, Kenya among those who reported to have other sexual partners, the highest proportion 10.2% (51) indicated that they have one partner apart from their current spouse (Ngugi *et al.*, 2011). A south African study conducted among female university students showed a high prevalence of major risk factors among the respondents with 73.6% having multiple sexual partners (Buga, 1998). Unlike other sexually transmitted infections that are preventable by condom use and other barrier contraceptives, the HPV infection can only be partially prevented by this method (Arowojolu *et al.*, 2002). A study conducted to evaluate the cervical cancer screening program in a rural community in South Africa, showed that only 7% of the respondents knew that an early onset of sexual activity and multiple sex partners can cause cancer of cervix (Hoque *et al.*, 2008).

In this study 73.9% of mothers had ever heard of HPV, this is contrary to a study on HPV vaccination among adult women in Kenya, only 18% of women had ever heard of HPV (Rositch *et al.*, 2012). In earlier studies, knowledge of HPV infection, risk factors, symptoms and consequences of HPV infection were very low compared to this study

and later studies probably because of the increasing campaigns against cancer that has raised knowledge. Knowledge of risk factors for cervical cancer development has also been observed to be associated with better uptake of screening services (Hislop *et al.*, 2004; Gatune and Nyamongo 2005).

In this study, 62.6% of the women had heard about the HPV vaccine, the awareness level is higher compared to some recent studies done in the country; of female primary school teachers in Kasarani division, only 14% of the respondents had ever heard about the HPV vaccine (Ombech *et al.*, 2012), and also compared to another study Thika, whereby the knowledge of the vaccine was 16.7% among the respondents (Ngugi *et al.*, 2011). In a study conducted in western Kenya, none of the women had heard of an HPV vaccination (Becker-Dreps *et al.*, 2010), an indication of the level of awareness of the cervical cancer vaccination in the region.

The main source of information about HPV vaccine for the mothers in this study was friends, colleagues or relatives. From the FGD's, only three participants reported having heard of the HPV vaccine. The participants, who had heard about it, stated having heard about it at the hospital, on TV and in newspapers. One participant specifically mentioned a TV show on one of the local channels that discussed the vaccine, this is in contrary to the study finding whereby the awareness is high and this can be attributed to the self-reported behavior and knowledge whereby some respondents over report their knowledge and behavior.

In this study, 68% of the respondents were willing to have their children vaccinated against HPV. This is almost consistent with the Mali study where 74.5% were, or would be, willing to vaccinate their child(ren) against HPV (Poole, 2013). On exploring participant views to allow their children to get the vaccine, a large majority mentioned that they would allow it as prevention is better than cure. The success of HPV vaccination depends on levels of acceptability and uptake of the vaccine: Due to the

need for parental consent, research into parental acceptance is very important. Although African women are at a high-risk for cervical cancer, there is still no sufficient evidence to show whether they will agree to get vaccinated, therefore more research on acceptability of the HPV vaccine is required to ascertain this and to evaluate measures that will increase its uptake(Brewer *et al.*, 2007).

Most parents, young women, and adolescents have minimal knowledge of HPV and its association with cervical cancer (Dell *et al.*, 2000; Waller *et al.*, 2003). In one study of 575 parents of 10- to 15-year-old children, education was provided and this significantly increased their acceptance of the HPV vaccine especially for those who were initially unable to make a decision on whether to have it or not (Davis *et al.*, 2004). In contrast, results from a randomized intervention study designed to assess the impact of a brief HPV informational brochure on parental acceptability of HPV vaccines for their 8- to 12-year-old children showed that an increase in knowledge did not translate to an increase in vaccine acceptability. To these parents, attitude and lifestyle were more important factors in increasing acceptability of the HPV vaccine (Dempsey *et al.*, 2006).

Primary prevention of cervical cancer can be achieved through prevention by vaccination and control of genital infection with oncogenic HPV types. The main challenges that would face a vaccination program are having it accepted as a routine STI vaccine and the feasibility of providing three doses in a period of six months. An acceptability rate of 80% was shown in a study conducted in the United Kingdom (Brabin *et al.*, 2006), however, in the general public, there was a low association of HPV and cervical cancer contributing to the low appreciation of the HPV vaccine for prevention of cervical cancer hence hindering its uptake (Waller *et al.*, 2004).

Educating the public about the importance of preventing sexually transmitted infections can be important in preventing genital HPV infection (Franco and Harper, 2005). Health education should emphasize on the importance of early detection, regular screening,

treatment option and also preventive measure including vaccination that targets teenagers and younger women. The possibility of overestimation should be taken into account with regard to the accuracy of this study.

In this study, 68% of the mothers were willing to vaccinate their adolescent children against HPV. Other factors like level of education, number of children and having an occupation did not influence the acceptance of the HPV vaccine, but mothers who had three to five children were more likely to accept the HPV vaccine. This shows that acceptability of the vaccine may be related to the socio-economic status of an individual. This is in contrary to a study among mothers of adolescents in Mexico, where acceptance was not associated with the number of live births (Lazcano-Ponce, 2001).

Cervical cancer remains an important public health problem in low-income countries, especially in Africa and in Latin America (Franco and Harper 2005). Therefore, focus has to be given in these regions because this is where HPV vaccination will be most valuable.

HPV vaccination will be very important in developing countries which bears more than 80% of the global cervical cancer burden annually and has poor pap screening programs (Franco & Harper, 2005). Most mothers said they would give the vaccine to their daughters because it prevents them from getting HPV infection and developing cervical cancer that is very expensive to treat. As for the mothers who would not vaccinate their adolescent child, their main reasons were that it was expensive and that they do not know much about the vaccine.

The HPV vaccine is available in Kenya, but most women cannot access it due to its high cost of about Ksh. 30,000 for Gardasil and Ksh. 10,500 for Cervarix for the entire dose. In other studies done, cost was also mentioned as a major barrier to receiving the HPV

vaccine (Boehner et al., 2003; Friedman & Shepeard, 2006; Hoover et al., 2000; Zimet et al., 2000).

Some mothers in this study expressed caution pointing out the need to get more information on the vaccine as well as its side effects; they thought that the side effects may be harmful to their children. Other barriers to vaccination that were stated in other studies included; Low perceived vaccine safety (Constantine & Jerman, 2007; Boehner et al., 2003; Dempsey et al., 2006); multiple vaccine shots (Gerend et al., 2006), and anticipated side effects from the HPV vaccine such as pain (Davis et al., 2004; Dempsey et al., 2006; Slomovitz et al., 2006). All these were reported to contribute to low acceptability of the HPV vaccine.

Among the barriers voiced by some mothers was that vaccination would promote adolescent sexual activity. Some of the mothers who were not for their children getting the vaccine were of the strong opinion that having the vaccine would make their children promiscuous and encourage them to be sexually active. They further pointed out that the vaccine could make the children not be afraid of contracting HIV and other STDs and even pregnancy. One perceived barrier is a concern among some parents that vaccination could promote adolescent sexual activity.

Fairly mixed views were expressed regarding mandatory vaccination in this study. Though many were for the idea, stating similar views as mentioned earlier that it would be a protection against HPV infection; some still felt very strongly that the costs of the vaccine would be prohibitive to the poor and low-income earners unless the government covered the costs. In addition, they felt that there may be side effects and that the vaccine would still likely lead to teenage promiscuity.

In a study on the acceptability of the HPV vaccine among mothers of adolescents in Cuernavaca Mexico, regarding knowledge of the usefulness of a vaccine, 84.2% of

participants held a correct perception of its benefits and after receiving an explanation on the possibility of preventing cervical cancer with an HPV vaccine, 83.6% of women interviewed said they would allow their teenage daughter to receive this vaccine (Lazcano-Ponce *et al*, 2001). The main factor associated with acceptability of HPV vaccine was the mothers' knowledge of the benefits of the vaccine (Lazcano-Ponce *et al.*, 2001)

The benefits of vaccination included reduced HPV infection, reduced cervical cancer, possibly a reduced frequency for recommended cervical cytological testing, and, for the vaccines that contains antigens against HPV types 6 and 11, and decreased genital warts (Zimmerman, 2006). Other benefits included decrease in other cancers and laryngeal papillomas (Zimmerman, 2006).

Due to the perception that HPV vaccine prevents HPV infection which is an STI, this could lead to a potential increase in sexual activity and increased number of sexual partners, decreased use of barrier contraceptive methods (Zimmerman, 2006). This will therefore result in increased pregnancies and abortions, increased rates of other HPV types and increased rate of other STIs including HIV (Zimmerman, 2006).

Greater knowledge about HPV may be associated with greater vaccine acceptability (Kahn *et al.*, 2003; Ferris *et al.*, 2007; Sauvage *et al.*, 2007; Donders *et al.*, 2008). A number of studies have shown that women have a great interest in learning more about HPV in general and the vaccine too vaccination (Friedman & Shepeard 2006; Anhang *et al.*, 2004; Holcomb *et al.*, 2004). In the U.S before the license was given, there was a lot of media campaigns and education about HPV which created massive awareness and increased women's knowledge about HPV and the vaccination. This could have greatly contributed to the high level of acceptability and uptake of the vaccine. This association is not known in most countries especially the low-income countries.

In order for vaccination to be highly effective, it must be given to children before they are exposed to sexual activity that is before sexual debut. Vaccination therefore targets young adolescents and thus parental acceptance of vaccination against HPV is an important consideration. Given a high uptake, HPV vaccines have the potential to reduce greatly the risk of cervical cancer (Hughes *et al.*, 2002). Those who receive the vaccine are however advised to continue seeking Pap smear testing because the vaccines available do not protect them against all the HPV types that cause cervical cancer. Although much has been gained in the last 50 years in reducing the burden of cervical cancer by organized or opportunistic cytology screening, the benefits have been seen particularly in high and middle-income countries (Franco & Harper, 2005).

Although there is a consensus that a future vaccine will have to include at least the most common high-risk HPV types there is considerable uncertainty with respect to the number of types to be included as immunogens (Franco & Harper 2005). The success of HPV vaccination depends on levels of acceptability and uptake of the vaccine: due to the need for parental consent, research into parental acceptance is very important. Although African women are at a high-risk for cervical cancer, it is unknown whether or not they will choose to get vaccinated.

The success of a vaccination program depends on the effectiveness of the vaccine and on acceptance by the public to take the vaccination. The higher the acceptance rate the higher the coverage of people vaccinated and thus the reduction in HPV infection and cervical cancer. Similarly, HPV vaccine trails will only be effective if an adequate number of people accept the vaccine (Brewer & Fazekas 2007). Utilization of the HPV vaccine is the best strategy for controlling cervical cancer in developing countries where there are poor screening programs due to scarcity of the services, lack of knowledge about the screening programs, poor health infrastructure to support the services, long

distances to health facilities especially in rural areas, inadequate health care workers both in quantity and skills to carry out the screening services.

Public health education is critical in attaining a successful vaccination program. For people to use the vaccine, they need to understand it importance, benefits and potential risks in order for them to make informed choices (Brewer & Fazekas 2007). More research is required especially in low-income countries to determine factors that will increase uptake of the HPV vaccine.

5.2 Conclusions

- 1. Knowledge about cervical cancer, associated risk factors and consequences of HPV infection among the respondents was high at 82.2% with the main sources of information being from friends, relatives or colleagues. The most known risk factor risk factor associated with cervical cancer was Long-term use of oral contraceptives at 76.7% with 89.1% of respondents being aware that certain types of HPV cause cervical cancer
- 2. Awareness of the HPV vaccine was at 62.2% with the mothers reporting that the main source of information about the vaccine was from friends, colleagues or relatives.
- 3. Acceptability of the vaccine was high with 67.8% of the respondents saying they would vaccinate their teenage daughters with the main reason being that it will protect them from HPV infection and prevent cervical cancer. However, among those who said they would not vaccinate their daughters stated the main reason as the vaccine was expensive, and that they did not know much about the vaccine.
- 4. There was no significance in any of the factors that could be associated with acceptance of the vaccine, although mothers having three to five children were 4.59 times more likely to accept the HPV vaccine.

5.2.1 Limitations of the Study

The study was conducted in a hospital whose catchment population is people from low socio-economic status, therefore, the results may not be generalized to other areas especially those with people from high socio-economic status.

5.3 Recommendations

- 1. There is need to educate the public on cervical cancer, its risk factors and how to prevent it. This should incorporate many channels of communication including aggressive campaigns with in-depth education, through health care providers, radio, television, bill boards and even social media.
- 2. The Ministry of Health needs to increase awareness about HPV vaccine and to strengthen the existing health care infrastructure to be able to educate women who come for services in the all the health centers. The Ministry of health can also incorporate HPV vaccination services in their routine primary care services and have a more pro-active approach to inviting women to learn about the vaccine.
- 3. The government through the Ministry of Health should come up with strategies that will increase the acceptability and uptake of the HPV vaccine among the target population.
- 4. Similar studies need to be conducted in other areas of the country especially rural areas in order to generalize the findings also to contribute to providing information that will help the Ministry of Health in Kenya in formulating policies and guidelines on HPV vaccination.
- 5. The government should seek support to procure the HPV vaccine at a discounted rate through the Global Alliance for Vaccines and Immunization (GAVI) and thus subsidize the vaccine to the public and as much as possible have it accessible to the entire population.

REFERENCES

- Adam, E., Berkova, Z., Daxnerova, Z., Icenogle, J., Reeves, W.C., and Kaufman, R.H. (2000). Papillomavirus detection: demographic and behavioral characteristics influencing the identification of cervical disease. *American Journal of Obstretrics and Gynecology 182*, 257-64.
- Amarin, Z.O., Badria, L.F., and Obeidat, B.R. (2008). Attitudes and beliefs about cervical smear testing in ever-married Jordanian women. *Eastern Mediterranean Health Journal*, *14*(2), 389-397.
- Anhang, R., Wright, T.C. and Smock, L. (2004). Women's desired information about human papillomavirus. *Cancer*, 100, 315–20.
- Arowojolu, A.O., Ilesanmi, A.O., Roberts, O.A. and Okunlola, M. A. (2002). Sexuality, contraceptive choice and AIDS awareness among Nigerian undergraduates. *African Journal of Reproductive Health*, 6(2), 60-70.
- Ayinde, A.O., Omigbodun, A.O. and OIlesanmi, A. (2004). Awareness of Cervical Cancer, Papanicolaou's Smear and Its Utilisation among Female Undergraduates in Ibadan. *Africa Journal of Reproductive Health*, 8(30, 68-80.
- Bakheit, N.M. and Haroon, A. I. (2004). The knowledge and attitude and practice of Pap smear among Local school teachers in the Sharjah District. *Middle East Journal of Family Medicine*, 4, 4.
- Barnabas, R. V., Laukkanen, P., Koskela, P., Kontula, O., Lehtinen, M. and Garnett, G. P. (2006). Epidemiology of HPV 16 and cervical cancer in Finland and the potential impact of vaccination: *mathematical modelling analyses*. *PLoS Med 3*, e138.

- Becker-Dreps, S., Otieno, WA., Brewer, NT., Agot, K. and Smith, J.S. (2010). HPV vaccine acceptability among Kenyan women; *Vaccine*, 28(31), 4864–4867.
- Boehner, C.W., Howe, S.R., Bernstein, D.I. and Rosenthal, S.L. (2003). Viral sexually transmitted disease vaccine acceptability among college students. *Sexually Transmitted Diseases*, *30*, 774–778.
- Bosch, F.X., Lorincz, A., Munoz, N., Meijer, C.J.L. and Shah, K.V. (2002). The causal relation between human papillomavirus and cervical cancer. *Journal of Clinical Pathology*, 55, 244-65.
- Bosch, F.X., Manos, M.M., Munoz, N., Sherman, M., Jansen, A. M., Peto, J., ... and Shan, K.V. (1995). Prevalence of human papillomavirus in cervical cancer: a worldwide perspective. International biological study on cervical cancer (IBSCC) Study Group. *Journal of National Cancer Institute*, 87, 796-802.
- Brabin, L., Stephen, A., Roberts, F., Henry, C. and Kitchener, C. (2006). Future acceptance of adolescent human papillomavirus vaccination: A survey of parental attitudes. *Vaccine* 24, 3087–3094.
- Brewer, N. T. and Fazekas, K. I. (2007). Predictors of HPV vaccine acceptability: A theory-informed literature review. *Preventive Medicine*; 45(1), 107.
- Brewer, N.T., Chapman, G.B., Gibbons, F.X., Gerrard, M., McCaul, K.D. and Weinstein, N.D., (2007). Meta-analysis of the relationship between risk perception and health behavior: the example of vaccination. *Health Psychology*, 26(2), 136–145.

- Brinton, L.A. (1992). Epidemiology of cervical cancer overview. In: Munoz N., Bosch F.X., Shah K.V. and Meheus A. (Eds). The epidemiology of cervical cancer and human papillomavirus, Lyon: International Agency for Research on Cancer.
- Bruni, L., Barrionuevo-Rosas, L., Serrano, B., Brotons, M., Cosano, R., Muñoz, J., ... and Castellsagué, X. (2014). Human Papillomavirus and Related Diseases in World Summary Report, *ICO Information Centre on HPV and Cancer (HPV Information Centre*
- Buga, G.A.B. (1998). Cervical cancer awareness and risk factors among female university students. *East African Medical Journal* 75(1), 411-416.
- Burchell, A.N., Winer, R.L., Sanjose, S. and Franco, E. L. (2006). Chapter 6: Epidemiology and transmission dynamics of genital HPV infection. *Vaccine*, 24(3), S3/52-61.
- Canavan T. P., and Doshi N. R. (2000). Cervical cancer. *American Family Physician* 61(5), 1369–1376.
- Castellsague, X. and Munoz, N. (2003). Chapter 3: Cofactors in human papillomavirus carcinogenesis-role of parity, oral contraceptives, and tobacco smoking. *Journal of National Cancer Institute Monogram*, 31, 20-8.
- Castellsagué, X., Bosch, F.X. and Muñoz, N. (2003). The male role in cervical cancer. Salud Publica de Mexico, 45(3), S345-S353.

- Chauke-Moagi, B.E. and Mumba, M. (2012) New vaccine introduction in the East and Southern African sub-region of the WHO African region in the context of GIVS and MDGs. *Vaccine*, *30*, C3–C8.
- Constantine, N.A. and Jerman, P. (2007). Acceptance of human papillomavirus vaccination among Californian parents of daughters: a representative statewide analysis. *Journal of Adolescent Health*, 40(1), 108–115.
- Cutts, F.T., Franceschi, S., Goldie, S., Castellsague, X., de Sanjose, S., Garnett, G., ... and Marko, P. (2007). Human papillomavirus and HPV vaccines: a review. *Bulletin of the World Health Organisation*, 85(9), 719–726.
- Davis, K., Dickman, E. D., Ferris, D. and Dias, J. K. (2004) Human papillomavirus vaccine acceptability among parents of 10- to 15-year-old adolescents, *Journal of Lower Genital Tract Diseases* 8, 188–194.
- Dell D.L., Chen H., Ahmad F. and Stewart D. E. (2000) Knowledge about human papillomavirus among adolescents, *Obstetric Gynecology*; 96, 653–656.
- DeMay, M. (2007). *Practical principles of cytopathology*, (Revised edition). 12 HPV: Type-Detect Medical Diagnostic Laboratories.
- Dempsey, A. F., Zimet, G. D., Davis, R. L. and Koutsky, L. (2006). Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV. *Pediatrics* 117(5), 1486–1493.
- Derkay, C.S. and Darrow, D.H. (2006) Recurrent respiratory papillomatosis. *Laryngoscope*, 115(1), 1–11.

- Donders, G.G., Gabrovska, M., Bellen, G., Kiersbilck, J.V., Bosch, T.V.D., Riphagen, I. and Verjans, M. (2008). Knowledge of cervix cancer, humanpapilloma virus (HPV) and HPV vaccination at the moment of introduction of the vaccine in women in Belgium. *Archives of Gynecology and Obstetrics* 277, 291–8.
- Edwards, L., Ferenczy, A., Eron, L., Baker, D., Owens, M.L., Fox, T.L., ... and HPV study group, (1998). Self-administered topical 5% imiquimod cream for external anogenital warts. *Archives of Dermatology 134*, 25-30.
- Emeny, R. T., Wheeler, C. M., Jansen, K. U., Hunt, W. C., Fu, T.M., Smith, J. F., ... and Paliard, X. (2002). Priming of human papillomavirus type 11-specific humoral and cellular immune responses in college aged women with a virus-like particle vaccine. *Journal of Virology*. 76, 7832–7842.
- Ferlay, J., Bray, F., Pisani, P. and Parkin, D.M. (2004). International Agency for Research on Cancer (IARC). *GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide*. Lyon, France: IARC Press.
- Ferris, D.G., Waller, J.L. and Owen, A. (2008). HPV vaccine acceptance among midadult women. *Journal of the American Board of Family Medicine*, 21, 31–7.
- Fisher, L.D. (1998). Self-designing clinical trials. Statistical Medicine 17, 1551-1562.
- Franco, E.L. and Harper, D.M. (2005). Vaccination against human papillomavirus infection: a new paradigm in cervical cancer control. *Vaccine*, 23, 2388 –94.

- Franco, E.L., Duarte-Franco, E. and Ferenczy, A. (2001). Cervical cancer: epidemiology, prevention and the role of human papillomavirus infection. *Canadian Medical Association Journal*, *164*(7), 1017-25.
- Friedman, A.L. and Shepeard, H. (2006). Exploring the knowledge, attitudes, beliefs, and communication preferences of the general public regarding HPV: findings from CDC focus group research and implications for practice. *Health Educucation Behaviour*, 22, 1-15.
- FUTURE II Study Group,(2007). Quadrivalent vaccines against human papillomavirus o prevent highgrade cervical lesions. *New England Journal Medical 356*, 1915–27.
- Garnett, G. P. (2005). Role of herd immunity in determining the effect of vaccines against sexually transmitted disease. *Journal of Infectious Diseases*; 191(suppl), S97–S106.
- Gatune, J.W. and Nyamongo, I.K. (2005). An ethnographic study of cervical cancer among women in rural Kenya: is there a folk causal model? *International Journal of Gynecological Cancer*, 15(6), 1049-59.
- Gerend, M.A., Lee, S.C. and Shepherd, J.E., 2006. Predictors of human papillomavirus, *Journal of papillomavirus*, *34*(7), 468-471
- Gichangi, P., Estambale, B., Bwayo, J., Rogo, K., Ojwang, S., Opiyo, A. and Temmerman, M. (2003). Knowledge and practice about cervical cancer and Pap smear testing among patients at Kenyatta National Hospital, Nairobi, Kenya. *International Journal of Gynecological Cancer*, 136, 827–33.

- Gilmour, S., Kanda, M., Kusumi, E., Tanimoto, T. and Kami, M. (2013). HPV vaccination acceptability among underserved women. *Sexually Transmitted Diseases*, *34* (7), 468–471.
- GlaxoSmithKline Australia and Cervarix® product information, (2007). Human papillomavirus vaccine type 16 and 18 (Recombinant AS04 adjuvanted), Boronia, Victoria, Australia,
- GLOBOCAN, (2012). Cancer Incidence MaPWi. Retrieved from: http://globocan.iarc.fr/ and http://www.who.int/hpvcentre.
- Green, J., Berrington, d. A., Sweetland, S., Beral, V., Chilvers, B.C., Deacon, J., and Vessey, M.P. (2003). Risk factors for adenocarcinoma and squamous cell carcinoma of the cervix in women aged 20-44 years: the UK National Case Control Study of Cervical Cancer. *British Journal of Cancer*, 89, 2078-86.
- Greenblatt R. J. (2005). Human papillomaviruses: Diseases, diagnosis, and a possible vaccine. *Clinical Microbiology Newsletter*, 27(18), 139-145.
- Harper, D. M., Franco, E. L., Wheeler, C. M., Moscicki, A. B., Romanowski, B., Roteli-Martins, C. M., ... and Dubin, G. (2006). Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. *Lancet*, 367(9518), 1247–1255.
- Harper, D.M., Gall, S., Naud, P., Quint, W., Dubin, G. and Jenkins, D. (2008). Sustained immunogenicity and high efficacy against HPV-16/18 related cervical neoplasia: Long-term follow up through 6.4 years in women vaccinated with CervarixTM (GSKs HPV 16/18 AS04 candidate vaccine). *Gynecology Oncology 2008;* 109(1), 158–9.

- Hislop, T.G., The, C., Lai, A., Ralston, J.D., Shu, J. and Taylor, V.M. (2004). Pap screening and knowledge of risk factors for cervical cancer in Chinese women in British Columbia, Canada. *Ethnicity and Health*, 9(3), 267-81.
- Ho, G.Y.F., Bierman, R., Beardsley, L., Chang, C.J. and Burk, R.D. (1998). Natural history of cervicovaginal papillomavirus infection in young women. *New England Journal of Medicine 338*, 423–8.
- Holcomb, B., Bailey, J.M. and Crawford, K. (2004). Adults' knowledge and behaviors related to human papillomavirus infection. *Journal of the American Board of Family Medicine*, 17, 26–31.
- Hoover, D.R., Carfioli, B. and Moench, E.A. (2000). Attitudes of adolescent/young adult women toward human papillomavirus vaccination and clinical. *Health Care Women International*, *21*, 375–391.
- Hoque, M., Hoque, E. and Kader, B.S. (2008). Evaluation of cervical cancer screening program at a rural community of South Africa. *East African Journal of Public Health*, *5*(2), 111-116.
- Hughes, J.P., G.P. and Koutsky, L. (2002). The theoretical population-level impact of a prophylactic human papilloma virus vaccine. *Epidemiology* 13, 631–639.
- Hussain, S.K., Sundquist, J, Hemminki, K. (2008). Familial clustering of cancer at human papillomavirus-associated sites according to the Swedish Family-Cancer Database *International Journal of Cancer 122*(8), 1873-8.
- IARC Monographs, (1995). On the evaluation of carcinogenic risks to humans: Human Papillomaviruses, (vol. 64). Lyon: International Agency for Research on Cancer Press.

- Inglis, S., Shaw, A. and Koenig, S. (2006). Chapter 11: HPV vaccines: commercial research & development. *Vaccine*, 24(3), S99-105.
- Joura, E.A., Sepp Leodolter, S., Hernandez-Avila, M., Wheeler, C.M., Perez, G., Koutsky, L.A., ... and Paavonen, J. (2007). Efficacy of a quadrivalent prophylactic human papillomavirus (types 6, 11, 16, and 18) L1 virus-like-particle vaccine against high-grade vulval and vaginal lesions: a combined analysis of three randomised clinical trials. *The Lancet*, 369(9574), 1693 1702.
- Kahn, J.A., Rosenthal, S.L., Hamann, T. and Bernstein, D.I. (2003). Attitudes about human papillomavirus vaccine in young women. *International Journal of STD&AIDS*, *14*, 300–6.
- Krogh, G., Lacey, C., Gross, G., Barasso, R. and Schneider, A. (2000). European Course on HPV associated pathology: Guidelines for primary care physicians for the diagnosis and management of anogenital warts: *Sexually Transmitted Infections*; 76, 162-168.
- Kumar., Vinay., Abbas., Abul, K., Fausto., Nelson., Mitchell., Richard, N. Robbins (2007) *Basic Pathology* (8th ed.) ed. *Saunders Elsevier. pp.* 348-51.
- Larson, HJ., Brocard, P. and Garnett ,G (2010) The India HPV-vaccine suspension. *Lancet.* 376(9741), 572-573.
- Lazcano-Ponce, E., Rivera, L., Arillo-Santillán, E., Salmerón, J., Hernández-Avila, M. and Muñoz, N. (2001). Acceptability of a Human Papillomavirus (HPV) Trial Vaccine Among Mothers of Adolescents in Cuernavaca, Mexico. *Archives of Medical Research*, 32(3), 243-247.

- Lowy, D. R. and Schiller, J. T. (2006). Prophylactic human papillomavirus vaccines. *Journal of Clinical Investigation; 116*(5), 1167-1173.
- Magnusson, P.K., Lichtenstein ,P. and Gyllensten, U.B. (2000). Heritability of cervical tumors. *International Journal of cancer*. 88(5), 698-701.
- Mao, C., Koutsky, L. A., Ault, K. A., Wheeler, C. M., Brown ,D. R., Wiley, D. J.,... and Barr E. (2006). Efficacy of human papillomavirus-16 vaccine to prevent cervical intraepithelial neoplasia: a randomized controlled trial. *Obstetric Gynecology*; 107(1), 18-27.
- Markowitz. L.E., Dunne. E.F., Saraiya, M., Lawson, H.W., Chesson, H.and Unger .E.R. (2007). Quadrivalent human papillomavirus vaccine. *Morbidity and Mortality Weekly Report*, 56(RR-2), 1-24.
- Merck, USA. (2008) Highlights of prescribing information: *GARDASIL* [human papillomavi- rus quadrivalent (Types 6, 11, 16, and 18) vaccine, Recombinant], *Whitehouse Station*. 29(46), 8279-8284.
- Moreno, V., Bosch, F.X., Munoz, N., Meijer, C., Shah, K., Wallboomers, J., Herrero, R. and Franceschi, S. (2002). Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection: the IARC multi-centric case control study. *Lancet*; *359*(9312), 1085-1092.
- Moscicki, A. B., Hills, N., Shiboski, S., Powell ,K., Jay,N., Hanson, E.,... and Palefsky ,J. (2001). Risks for incident human papillomavirus infection and low-grade squamous intraepithelial lesion development in young females *Journal of the American Medical Association*, 285(23), 2995–3002.

- Moscicki, A.B., Shiboski ,S, Broering ,J., Powell, K., Clayton, L., Jay N.,... and Palefsky J. (1998). The natural history of human papillomavirus infection as measured by repeated DNA testing in adolescent and young women. *The Journal of Pediatrics*, 132(2), 277–84.
- Muñoz, N., Bosch, F. X., de Sanjosé, S., Herrero, R., Castellsagué, X., Shah, K. V., Snijders, P. J. and Meijer, C. J. (2003). Epidemiologic classification of human papillomavirus types associated with cervical cancer. *New England Journal of Medicine*; 348(6), 518–527.
- Mutyaba, T., Mmiro, F.A. and Weiderpass, E. (2006). Knowledge, attitudes and practices on cervical cancer screening among the medical workers of Mulago Hospital, Uganda. *BMC Medical Education*, 6(1), 13.
- National Cancer Institute (2011). Human Papillomavirus (HPV) Vaccines Fact Sheet:

 US Department of Health and Human Sciences, National Institute of Health.

 Retrieved from http://www.cancer.gov/cancertopics/factsheet/risk/HPV-vaccine
- Newall, A.T., Beutels, P., Wood, J.G., Edmunds, W.J. and MacIntyre, C.R. (2007). Cost-effectiveness analyses of human papillomavirus vaccination. *Lancet Infectious Diseases*, 7(4), 289-296.
- Ngugi, C.W., Boga, H., Muigai, A.W.T., Wanzala, P. and Mbithi, J.N. (2011). Epidemiology of High-risk Human Papilloma Virus and factors affecting cervical cancer screening amongst volunteer adult women in Thika Municipality, Kenya. Unpublished PhD Thesis. Juja: Jomo Kenyatta University of Agriculture and Technology

- Ngugi, C.W., Boga, H., Muigai, A.W.T., Wanzala, P. and Mbithi, J.N. (2012). Factors Affecting Uptake of Cervical Cancer Early Detection Measures Among Women in Thika, Kenya. *Health Care for Women International*, 33(7), 595-613.
- Nindl ,I., Lotz, B., Kuhne-Heid R., Endisch ,U. and Schneider, A. (1999). Distribution of 14 high-risk HPV types in cervical intraepithelial neoplasia detected by a non-radioactive general primer PCR mediated enzyme immunoassay. *Journal of Clinical Pathology*; 52(1), 17–22.
- Ombech ,E.A., Muigai, A.W.T. and Wanzala, P. (2012). Awareness of cervical cancer risk factors and practice of pap smear testing among female primary school teacher in Kasarani Division, Nairobi Kenya. *African Journal of Health Sciences*, 21(2), 121-132.
- Paavonen ,J., Jenkins ,D., Bosch, F.X., Naud, P., Salmerón, J., Wheeler, ...and Dubin G. (2007). Efficacy of a prophylactic adjuvanted bivalent L1 virus-like-particle vaccine against infection with human papillomavirus types 16 and 18 in young women: an interim analysis of a phase III double-blind, randomized controlled trial. *The Lancet*, 369(9580), 2161–70.
- Parkin, D.M., Bray, F., Ferlay, J. and Pisani ,P. (2005). Global cancer statistics 2002. *CA Cancer Journal for Clinicians*: 55(2), 74-108.
- Parkin, D.M. and Bray, F. (2002). The burden of HPV related cancers. *Vaccine*; 24(Suppl 3), S11–S25.
- Patrick ,L.R., and Ross, C. B. (2011). Cancer Mortality Surveillance United States 1099-2000. Fifty Years of Progress in Chronic Disease Epidemiology and Control; *160*(04), 70-77.

- Pinto, L. A., Edwards, J., Castle, P.E., Harro, C. D., Lowy, D. R., Schiller, J., ... and Hildesheim, A. (2003). Cellular immune responses to human papillomavirus (HPV)-16 L1 in healthy volunteers immunized with recombinant HPV-16 L1 virus-like particles. *Journal of Infectious Diseases*, 188(2), 327–238.
- Poole, D.N., Tracy, J.K., Levitz, L., Rochas, M., Sangare, K., Yekta,...and De Groot, A.S. (2013) A Cross-Sectional Study to Assess HPV Knowledge and HPV Vaccine Acceptability in Mali. *PLoS ONE* 8(2).
- Rajeevan ,M.S., Swan ,D.C., Nisenbaum, R., Lee ,D.R., Vernon, S.D., Ruffin, M.T., Horowitz, I.R., Flowers, L.C., Kmak H., Tadros T., Birdsong G., Husain M., Srivastava S. and Unger E.R. (2005). Epidemiologic and viral factors associated with cervical neoplasia in HPV-16 positive women. *International Journal of Cancer*, 115(1), 114-120.
- Reichman, R. (1994) *Human papillomavirus Infections In: Harrison's Principles of Internal Medicine* (13th ed.). New York (NY): McGraw-Hill.
- Rositch ,A.F., Gatuguta, A, Choi, R.Y., Guthrie, B.L., Mackelprang, R.D., Bosire ,R. (2012). Knowledge and Acceptability of Pap Smears, Self-Sampling and HPV Vaccination among Adult Women in Kenya. *PloS ONE* 7(7), e40766.
- Sankaranarayanan, R., Budukh, A. M. and Rajkumar, R. (2001). Effective Screening Programmes for Cancer of the cervix in Low and middle income developing countries. *Bulletin of the World Health Organization*, 79(10),954-962.
- Santelli, J. S., Brener, N. D., Lowry, R., Bhatt, A. and Zabin, L.S. (1998). Multiple sexual partners among U.S. adolescents and young adults. *Family Planning Perspectives*; 30, 271–275.

- Saslow, D., Castle, P. E., Cox, J. T., Castle, P.E., Cox, J.T., Davey,...and Garcia F. (2007). American Cancer Society guideline for human papillomavirus (HPV) vaccine use to prevent cervical cancer and its precursors. *CA Cancer Journal for Clinicians* 57(1), 7-28.
- Sauvageau, C., Duval, B., Gilca, V., Lavoie, F. and Ouakki, M. (2007). Human papilloma virus vaccine and cervical cancer screening acceptability among adults in Quebec, Canada. *BMC Public Health*, 7(1), 304–9.
- Scheinfeld, N., and Lehman, D.S. (2006). An evidence-based review of medical and surgical treatments of genital warts. *12*(3), 5 5.
- Schiffman, M., Herrero, R., Hildesheim, A., Sherman, M.E., Bratti, M., Wacholder, S., ... and Lorincz, A.T. (2007). HPV DNA testing in cervical cancer screening: results from women in a high-risk province of Costa Rica. *Journal of American Medical Association*; 283(1), 87–93.
- Singer, A. and Monaghan, J. (2000). *Lower Genital Tract Pre cancer Colposcopy*, *Pathology and Treatment*. (2nd ed.). Oxford: Blackwell Science.
- Slomovitz, B.M., Sun, C.C., Frumovitz, M., Soliman, P.T., Schmeler, K.M., Pearson, H.C., ... and Bodurka, D.C. (2006). Are women ready for the HPV vaccine? *Gynecology Oncology*, 103(1), 151–154.
- Smith, J.S., Green J., Berrington de Gonzalez, A., Appleby, P., Peto, J., Plummer, M., Franceschi, S. and Beral, V. (2003). Cervical cancer and use of hormonal contraceptives: a systematic review. *Lancet*, *361*(9364), 1159-67.
- Stanley, K., Stjernsward, J. and Korolstchouk, V. (1987). Women and cancer. *World Health Statistics Quarterly*, 40, 267–78.

- Stanley, M., Lowy, D.R. and Frazer, I. (2006). Prophylactic HPV vaccines: Underlying mechanisms. *Vaccine*; 24(Suppl 3), S106–13.
- Steinbrook, R. (2006). The potential of human papillomavirus vaccines. *New England Journal of Medicine*, 354(11), 1109–1112.
- Stewart, B.W. and Kleihues, P. (2003). *World Cancer Report*. Lyon (France): IARC Press.
- Stretch, R., Chambers, G., Whittaker, J., Critchley, T., Jackson, F., Montgomery, M.B., Roberts, S. and Brabin, L. (2008). Implementing a school-based HPV vaccination programme. *Nursing Times* 104(48), 30–33.
- Sylvia, B. D., Walter, A. O., Noel, T. B., Kawango, A., Jennifer, S. S. (2010). HPV vaccine acceptability among Kenyan women. *Vaccine*, 28(31), 4864-4867.
- Thomas, D.B., Ray, R.M. and Qin, Q. (2002). Risk factors for progression of squamous cell cervical carcinoma in-situ to invasive cervical cancer: results of a multinational study. *Cancer Causes and Control*, *13*(7), 683-90.
- Urasa, M. and Darj, E. (2011). Knowledge of cervical cancer and screening practices of nurses at a regional hospital in Tanzania. *African Health Sciences*, 11(1), 48-57.
- Villa, L.L., Costa, R.L.R., Petta, C.A., Andrade, R.P., Paavonen, J., Iversen, O.E, ... and Barr, E. (2006). High sustained efficacy of a prophylactic quadrivalent human papillomavirus types 6/11/16/18 L1 virus-like particle vaccine through 5 years of follow-up. *British Journal of Cancer*, 95, 1459–66.

- Walboomers, J. M., Jacobs, M. V., Manos, M. M., Bosch, F. X., Kummer, J. A., Shah, K. V., ... and Muñoz, N. (1999). Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *Journal of Pathology*, 189(1), 12–19.
- Waller, J., McCaffery, K. and Jane, W. (2004). Beliefs about the risk factors for cervical cancer in a British population sample *Preventive Medicine*; *38*(6), 745–753.
- Waller, J., McCaffery, K., Forrest, S., A Szarewski, A., Cadman, L. and Wardle, J. (2003) Awareness of human papillomavirus among women attending a well woman clinic. *Sexually Transmitted Infections* 79(4), 320–322.
- Wardle, J., Waller, J., Brunswick, N. and Jarvis, M.J. (2001). Awareness of risk factors for cancer among British adults. *Public Health*, *115*(3), 173-174.
- Wharton, JT, and Tortolero-Luna, G. (2000). *Neoplasms of the Cervix.* (5th ed.) chap,12. Holland: Holland-Frei Cancer Medicine.
- WHO/ICO, (2010). Information Centre on HPV and Cervical Cancer (HPV Information Centre). Human Papillomavirus and Related Cancers in World Summary Report 2010, Retrieved from www.who.int/hpvcentre
- WHO/ICO, (2012). Information Centre on HPV and Cervical Cancer (HPV Information Centre). Human Papillomavirus and Related Cancers in World Summary Report 2012, Retrieved from www.who.int/hpvcentre
- Winer, R. L., Lee, S. K., Hughes, J. P., Adam, D.E., Kiviat, N.B. and Koutsky, L.A. (2003). Genital human papillomavirus infection: incidence and risk factors in a cohort of female university students. *American Journal of Epidemiology;* 157(3), 218–226.

- Winer, R.L., Hughes, J.P., Feng, Q., O'Reilly, S., Kiviat, N.B., Holmes, K.K. and Koutsky, L.A. (2006). Condom use and the risk of genital human papillomavirus infection in young women. *The New England Journal of Medicine*, *354*(25), 2645-54.
- Wittet, S. and Tsu, V. (2008). Cervical cancer prevention and the Millenium Development Goals. *Bulletin of the World Health Organization*, 86(6), 488-490.
- Zimet, G.D., Blythe, M.J. and Fortenberry, J.D. (2000). Vaccine characteristics and acceptability of HIV immunization among adolescents. *International Journal of STD&AIDS*, 11(3), 143–9.
- Zimmerman, R.K., (2006). Ethical analysis of HPV vaccine policy options. *Vaccine* 24(22), 4812–4820.

APPENDIXES

Appendix I: Consent form

TITLE OF STUDY

Knowledge on human papilloma virus and acceptability of human papilloma virus vaccine among mothers seeking maternal-child health services at Mbagathi district hospital, Nairobi.

Maarifa ya virusi vya binadamu papilloma na kukubalika kwa binadamu chanjo papilloma virusi kati ya akina mama wanaopata huduma za afya ya uzazi na mtoto katika hospitali ya wilaya Mbagathi, Nairobi.

PART A

You are invited to participate in a study on knowledge on Human Papilloma Virus and acceptability of Human papilloma virus vaccine among mothers seeking maternal-child services at Mbagathi district hospital. The objective of this study is to determine knowledge of HPV infection and acceptability of HPV vaccine in order to help improve its up take. You have been selected as a possible participant in this study, kindly read the form carefully and any questions arising will be addressed before you agree to take part in this study.

Unaalikwa kushiriki katika utafiti juu ya elimu juu ya virusi Papilloma Binadamu na kukubalika ya Binadamu chanjo papilloma virusi kati ya akina mama wanaopata huduma ya uzazi na mtoto katika hospitali ya wilaya Mbagathi. Lengo la somo hili ni kuonyesha elimu ya maambukizi ya HPV na kukubalika kwa chanjo ya HPV ili kusaidia kuboresha juu yake kuchukua Umechaguliwa kama mshiriki katika utafiti huu., tafadhali soma fomu kwa makini na maswali yoyote yanayotokana yatashughulikiwa kabla ya kukubali kushiriki katika utafiti huu.

Purpose of the study

To determine Knowledge on human papilloma virus and acceptability of human papilloma virus vaccine among mothers seeking maternal-child health services at Mbagathi district hospital, Nairobi.

LENGO LA UTAFITI

Maarifa ya kuamua juu ya virusi vya binadamu papilloma na kukubalika kwa binadamu chanjo papilloma virusi kati ya akina mama wanaopata huduma za afya ya uzazi na mtoto katika hospitali ya wilaya Mbagathi, Nairobi.

Study Procedures

If you agree to take part in this study, you will be required to fill a detailed questionnaire regarding yourself, your knowledge on HPV infection and the HPV vaccine and your perception regarding the vaccine.

TARATIBU ZA UTAFITI

Kama unakubali kushiriki katika utafiti huu, utatakiwa kujaza dodoso ya kina kuhusu wewe mwenyewe, maarifa yako juu ya maambukizi ya HPV na chanjo ya HPV na mtazamo wako kuhusu chanjo.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with this hospital or the other institutions involved. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

UTAFITI NI WA HIARI

Kushiriki katika utafiti huu ni kwa hiari. Uamuzi wako kama au kushiriki katika utafiti huu hauta athiri mahusiano yako ya sasa au ya baadaye na hii hospitali au taasisi nyingine husika. Kama hutaki kushiriki, uko huru kutoka wakati wowote bila kuathiri mahusiano hayo.

Research Related Risks or Injury

This study has no known risks. There is no known harm that could arise from this study.

MADHARA AU MAJERUHI KUTOKANA NA UTAFITI

Utafiti huu hauna mahdara yanayofahamika. Hakuna majeraha yeyote yatakayosababishwa kutokana na utafiti huu.

Benefits

Participating in this study will enhance your knowledge on Human Papilloma Virus Infection and the Vaccine and thus increase the chances of preventing the disease.

MANUFAA

Kwa kushiriki Katika utafiti huu utaweza kupata elimu kuhusu ugonjwa unaosababishwa na virusi vya Human Papilloma na ujuzi kuhusu chanjo chake ili uweze kukinga watoto wako dhidhi ya virusi hivi.

Study Costs

No costs will be incurred during this study

GHARAMA ZA UTAFITI

Kushiriki katika utafiti huu hakutakugharimu malipo yoyote

Privacy of records

All information provided will be kept confidential. Questionnaires will be coded and personal information from the interview will not be released without your written permission. You will not be personally identified in any publication of this study.

KUBANIWA KWA UTAFITI

Majibu yote ya utafiti yatawekwa siri. Makaratasi ya maswali yatakuwa na nambari tu bali si jina lako. Jina lako halitatajwa popote ila kupitia ruhusa yako tu.

Choice to withdraw or leave the study

You have the choice to or not to participate in this research study. If you choose not to participate or leave the study during the interview process, you may do so freely without any consequences against you.

HIARI YA KUJIONDOA KATIKA UTAFITI

Kushiriki katika utafiti huu ni kwa hiari. Unaweza kuacha kushiriki wakati wowote bila madhara yoyote kwako.

In case of any questions, please contact/ kwa maswali yoyote uliza:

Contacts and Questions /MASWALI NA WATAO YA JIBU

The researcher conducting this study is Ann Bosibori Masese. You may ask any

questions you have now, or if you have questions later, you are encouraged to contact

her through telephone number: 0722-626361, E-mail janmase@yahoo.com

Mtafiti anayefanya utafiti huu ni Ann Bosibori Masese. Unaweza kuuliza maswali

yoyote uliyonayo sasa ama ikiwa utakuwa nayo baadaye, unahimizwa umjulishe kwa

nambari ya simu: 0722-626361 au barua pepe janmase@yahoo.com

If you have any questions or concerns regarding the study and would like to talk to

someone other than the researcher(s), you are encouraged to contact the following:

Ikiwa una maswali yoyote kuhusu utafiti huu na ungependa kuuliza swali kwa mtu

mwengine asipokuwa mtafiti, unahimizwa ujulishe.

The Director, Institute of tropical medicine and infectious diseases (ITROMID),

Jomo Kenyatta University of Agriculture and Technology,

P. O. Box 62000 00200 Nairobi.

Tel. 067 - 52711,

E-mail: itromid@nairobi.mimcom.net

82

Mkurugenzi (ITROMID)

JOMO KENYATTA

S.L.P 62000-00200, NRB

Simu; 067-52711

Barua Pepe: itromid@nairobi.mimcom.net

AU/OR

Mkurugenzi,ITROMID-KEMRI OFFICE,

Kenya Medical Research Institute

S.L.P 54840-00200 Nairobi.

Simu: 020-2722541/4

Barua pepe: itromid@nairobi.mimcom.net

The Chairman KEMRI National Ethical Review Committee

P.O BOX 54840 – 00200 NAIROBI, KENYA

TEL: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003;

E-mail: info@kemri.org

You will be given a copy of this form to keep for your records.

Utapewa nakala ya fomu hii kuweka kama kumbukumbu.

PART B

CONSENT FORM / FOMU YA KUPEANA KIBALI

Please read the information sheet (PART A) or have the information read to you carefully before completing and signing this consent form. If there are any questions you have about the study, please feel free to ask them to the investigator prior to signing your consent form.

Tafadhali soma fomu A ama hakikisha kwamba umesomewa na kuelewa kabla ya kuweka sahihi fomu hii ya kutoa ruhusa. Kama una maswali yeyote kuhusu utafiti huu, tafadhali uliza mtafiti maswali hayo kabla ya kutia sahii fomu hii ya kupeana ruhusa.

Declaration of the volunteer /Arifa ya mhojiwa wa hiari

I Miss, Mrs......here by give consent to Ms. Masese to include me in the proposed study entitled Knowledge on Human Papilloma Virus and acceptability of Human Papilloma Virus Vaccine among mothers seeking maternal and child health services at Mbagathi District Hospital. I have read the information sheet concerning this study, I understand the aim of the study and what will be required of me if I take part in the study. The risks and benefits if any have been explained to me. Any questions I have concerning the study have been adequately answered.

I understand that at any time that I may wish to withdraw from this study I can do so without giving any reason and without affecting my access to normal health care and management.

I realize that I will be interviewed once. I consent voluntarily to participate in this study.

Mimi Binatoa ruhusa kwa Bi. Masese anihusishe kwa utafiti wake kuhusu "elimu juu ya virusi Papilloma Binadamu na kukubalika kwa Binadamu chanjo papilloma virusi kati ya akina mama wanaopata huduma ya uzazi na mtoto katika hospitali ya wilaya Mbagathi". Nimesoma habari zote kuhusu utafiti huu, nimeelewa lengo la utafiti huu na yanayohitajika kwangu kama nitashiriki katika utafiti huu. Madhara na manufaa ya utafiti huu yameelezwa kinaga ubaga kwangu. Maswali yote niliokuwa nayo yamejibiwa vilivyo. Nimeelewa kwamba naweza kuacha kushiriki wakati wowote bila madhara yoyote kwangu. Najua kwamba nitahojiwa mara moja. Ninatoa ruhusa kwa hiari nishiriki katika utafiti huu.
runusa kwa mari nishiriki katika utajiti nuu.
Subject's Name, Jina la mhojiwa
Signature or left thumb print Date /Tarehe
Sahihi/alama ya kidole gumba (kushoto)
Name of Investigator /Jina la mtafiti
Signature of Investigator / Sahihi ya mtafiti
Date/Tarehe
Duch I will the transfer of th

Appendix II: Questionnaire

PART 1				
Patient no	_			
Date//////				
The information collected is very confiden name at any point.	tial, you v	vill not l	be required	to give your
PART 2				
SOCIAL DEMOGRAPHIC DETAILS:				
1. Sex of respondent				
Female []				
2. How old are you in years?				
3. What is your current marital status?				
1) Married –monogamous]]		
2) Married –polygamous	[]		
3) Single –in a relationship]]		
4) Single –not in a relationship]]		
5) Divorced/separated]]		
6) Widowed	[]		
7) Cohabiting	[]		

8) Others (specify)			
4. What is the highest lev	el of education you	complete	d?
1) None		[]
2) Primary – incomplete		[]
3) Primary – complete		[]
4) Secondary – incomple	te	[]
5) Secondary – complete		[1
6) Vocational training aft	er primary	[]
7) Vocational training aft	er secondary	[1
8) College/university – in	complete	[]
9) College/university – c	omplete	[]
10) Other specify	_		
5. 1) How many children	do you have?	[]
2) What are their ages in	months?		
BIRTH ORDER	AGE IN MON	ГНЅ	

6. What is your occupation?		
1) Business/Self employed]]
2) Formal employment (civil service)	[]
3) Formal employment (private sector)	[]
4) Informal employment (casual worker)]]
5) Housewife]]
6) Unemployed	[]

[

]

7. In what range does your monthly income fall (KHS)?

8) Others (Specify)

7) Retired

1) Below 5,000	[]
2) >5,000 - 10,000	[]
3) >10,000 - 15,000	[]
4) >15,000 - 20,000	[]
5) >20,000 - 25,000	[]
6) Above 25,000	[]

8. What is your religion?						
1) Christian	[]				
2) Islam	[]				
3) Other religion specify						
9. Place of residence (where are you currently living)?					
1) Urban	[]				
2) Peri- Urban	[]				
3) Rural	[]				
KNOWLEDGE OF MOTHERS ON HPV INFECTION						
1=Yes						
2=No						
99=Don't Know						
10. HPV is spread through sexual intercourse	[]				
11. HPV is a virus that causes HIV/AIDS	[]				
12. A person may be infected and not know it	[]				
13. PAP smear detects HPV	[]				
14. HPV can be cured by using antibiotics	[]				
15.6						
15. Certain types of HPV cause cervical cancer	[]				

17. HPV harms					
1) Women more than men	[]			
2) Men more than women]]			
3) Both equally	[]			
18. Risk factors for HPV infection? (Good if corresponses)	respon	dent ma	ırked more	than 3 co	orrec
1=Yes					
2=No					
99=Don't Know					
1) Early age at first sexual intercourse	[]			
2) Multiple sexual partners	[]			
3) Family history of HPV infection	[]			
4) Poor hygiene	[]			
5) Oral contraceptive use	[]			
19. Symptoms of HPV? (Good if correspondent	markea	l more i	than 2 corr	ect respo	nses)
1=Yes					
2=No					
99=Don't Know					
1) Warts that sometimes itch and bleed	[]			
2) Warty growths	[]			
3) No consequences	[]			
4) Cancer of the cervix	[]			

20. Consequences of untreated HPV? (Good if cocorrect responses)	orresį	pondei	nt mark	ed more	e than 2	2
1=Yes						
2=No						
99=Don't Know						
1) Cervical cancer	[]				
2) HIV/AIDS	[]				
3) Genital Warts	[]				
4) No consequences	[]				
AWARENESS OF HPV VACCINE						
21. Have you heard about HPV vaccine?						
1) Yes	[]				
2) No	[]				
22. If yes, how did you hear about the vaccine						
ATTITUDES AND PERCEPTIONS ON ACC	СЕРТ	'ABIL	ITY O	F HPV	VAC	CINE
23. Safety of vaccine						
1) Very safe		[]			
2) Not safe		[]			
99) Don't Know		[]			
24. Will vaccine prevent cervical cancer?						
1) Extremely unlikely		ſ	1			

2) Some	ewhat unlikely		[]
3) Neut	ral		[]
4) Some	ewhat likely		[]
5) Extre	emely likely		[]
25. Do you kno	ow any advantages of HPV	vaccine?		
1) Yes			[1
2) No			[1
26. If yes, state				
27. Would you	vaccinate your adolescent	child against I	HPV?	•
1) Yes]]	
2) No		[]	
28. If yes, why				
29. If no, why?	·			

Appendix III: Focus group discussion guide

Issues and Questions

NB: There will be an ice breaker and rapport will be created before the questions are delved into.

- 1. Knowledge of STD's in general
 - 1) Which STD's do you know?
 - 2) Have you heard of genital warts?
- 2. Knowledge of HPV infection
 - 1) Have you heard of HPV infection?
 - 2) Do you know if it is an STD?
- 3. Knowledge of cervical cancer and associated risk factors
 - 1) What do you know about cervical cancer?
 - 2) What do you know causes cervical cancer?
- 4. Awareness of HPV vaccine
 - 1) Have you heard of HPV vaccine?
 - 2) If yes, how did you hear about the vaccine?
- 5. HPV vaccine acceptability
 - 1) How do you feel about your child getting the vaccine?
 - 2) If you would not allow your child to have the vaccine why?
- 6. Mandatory vaccination
 - 1) What are your views on making the HPV vaccine mandatory?

Appendix IV: Scientific Steering Committee Approval



KENYA MEDICAL RESEARCH INSTITUTE

P. O. Box 54840 - 00200, NAIROBI, KENYA Tel: +264 (0)20 2722541, 2713349, 0722-205901, 0733-400003; Fax: +254 (0)20 2720030 E-mail: director@kemri.org; info@kemri.org; Website: www.kemri.org

Ann Bosibori Masese

Thro'
Director, CPHR
NAIROBI

REF: SSC No. 2128 (Revised) – Knowledge on human papilloma virus and acceptability of human papilloma virus vaccine among mothers seeking maternal-child health services at Mbagathi District Hospital, Nairobi

I am pleased to inform you that the above mentioned proposal, in which you are the PI, was discussed by the KEMRI Scientific Steering Committee (SSC), during its 183rd meeting held on 4th October, 2011 and has since been approved for implementation by the SSC.

Kindly submit 4 copies of the revised protocol to SSC for onward transmission to ERC office.

We advise that work on this project can only start when ERC approval is received.

Sammy Njenga, PhD SECRETARY, SSC

In Search of Better Health

Appendix V: National Ethical Review Committee Approval



KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya Tell (254) (020) 2722541, 2713349, 0722-205901, 0733-400003, Fax: (254) (020) 2720030 E-mail: director@kernrl.org info@kernrl.org Website:www.kernrl.org

KEMRI/RES/7/3/1

April 11, 2012

TO:

Ms. ANNE BOSIBORI MASESE (PRINCIPAL INVESTIGATOR)

THROUGH:

DR. YERI KOMBE, THE DIRECTOR, CPHR,

NAIROBI

Dear Madam.

RE:

6-13/04/2012 SSC PROTOCOL No. 2128 - REVISED (RE-SUBMISSION): KNOWLEDGE ON HUMAN PAPILLOMA VIRUS AND ACCEPTABILITY OF HUMAN PAPILLOMA VIRUS VACCINE AMONG MOTHERS SEEKING MATERNAL-CHILD HEALTH SERVICES AT MBAGATHI DISTRICT HOSPITAL, NAIROBI

Reference is made to your letter dated March 29, 2012. We acknowledge receipt of the revised proposal on the 5th of April 2012.

This is to inform you that the Committee determines that the issues raised at the 197th meeting of 24th January 2012 are adequately addressed. Consequently, the study is granted approval for implementation effective this 11th day of April 2012 for a period of one year.

Please note that authorization to conduct this study will automatically expire on April 10, 2013. If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to the ERC Secretariat by February 27, 2013. The regulations require continuing review even though the research activity may not have begun until sometime after the ERC approval.

Note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of the ERC. You are also required to submit any proposed changes to this study to the SSC and ERC for review and approval prior to initiation and advise the ERC when the study is completed or discontinued.

Work on this project may begin.

Sincerely CHRISTINE WASUNNA, Ag. SECRETARY, KEMRI ETHICS REVIEW COMMITTEE

In Search of Better Health