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Understanding South African parents' decisions to participate in the state-sponsored Human Papilloma Virus (HPV) vaccination roll-out campaign: a cross sectional study in ten low-income peri-urban primary schools

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfillment of the requirements for the degree of MMed (Family Medicine)

Johannesburg,
2017:06:13

Declaration: Student's contribution to article(s) and agreement of co-author(s)

I, **Afolake Amodu** with student number 700537, declare that this Research Report is my own work and that I contributed adequately towards research findings to be published in the article(s) stated below which is included in my Research Report.

Signature of Student ..... **Date:** 14 June 2017

Name of Primary Supervisor: **Laurel Baldwin-Ragaven**

Signature of Primary Supervisor: Laurel E Baldwin **Date:** 13 June 2017

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of his/her Thesis/Dissertation/Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for his/her degree purposes.

Title: Understanding South African parents' decisions to participate in the state-sponsored Human Papilloma Virus (HPV) vaccination roll-out campaign: a cross sectional study in ten low-income peri-urban primary schools

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Comments by primary supervisor:

.....

.....

Explanation of Title and United States Spelling

1. Difference between titles of the research protocol and submission of the publication-ready manuscript

Title of approved research protocol:

Why should I talk to my 9-year old daughter about sex? Understanding parents' decisions to participate in the South African government's HPV vaccination programme of schoolgirls in Etwatwa-East, Gauteng

Title of manuscript in submissible format:

Understanding South African parents' decisions to participate in the state-sponsored Human Papilloma Virus (HPV) vaccination roll-out campaign: a cross sectional study in ten low-income peri-urban primary schools

Motivation for title change:

Upon reflection, I realised I have two articles arising from my research. The first one is about parental acceptance and factors affecting the decision-making process about the HPV vaccine. This is the article which I am submitting to fulfil the requirements for my MMed (Family Medicine) degree. The second article will discuss sex and communication between parents and daughters. Hence, the first part of the approved research protocol title has been reserved for the second research article that will also be concluded and published.

2. The article has been written in United States (US) English format because this article is publication-ready for a journal requesting US English.

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TITLE: Understanding South African parents' decisions to participate in the state-sponsored Human Papilloma Virus (HPV) vaccination roll-out campaign: a cross sectional study in ten low-income peri-urban primary schools

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ABSTRACT

Background: Cervical cancer is the second most common cancer amongst South African women. In 2014, the government embarked on a school-based Human Papilloma Virus (HPV) vaccination program for grade four girls, creating an important opportunity for primary cervical cancer prevention.

Objective: To determine the parental HPV vaccine acceptance rate in Etwatwa, Gauteng and to explore factors influencing parental decision-making. These factors include: socio-demographics; awareness and knowledge of cervical cancer HPV and HPV vaccination; health beliefs about HPV vaccine; and, the influence of external sources of information.

Methods: A cross-sectional study was conducted using self-administered questionnaires sent home to parents of vaccine eligible girls attending ten public primary schools in Etwatwa. Descriptive statistics including frequencies and percentages were generated for independent variables; and, bivariate analyses (Chi square test) were used to assess associations between independent and outcome variables. Data analysis was conducted using the statistical software program STATA 9.0.

Results: Four hundred and forty-six questionnaires were included in the analysis, a response rate of 90%. Parental HPV vaccine acceptance was 96%. Eighty per cent and 47% of all respondents said that prior to the campaign, they were aware of cervical cancer and HPV vaccination respectively. The mean total knowledge score for those who accepted was significantly higher compared to those who rejected (72%, SD+/- 20.80 vs 47% SD+/- 33.60, p=0.0033). Worry about side effects was unanimously stated as the reason for vaccine rejection. Logistic regression revealed that none of the socio-demographic factors or health beliefs was associated with acceptance of the HPV vaccine.

Discussion: Parental HPV vaccine acceptance is high; but, there is inadequate knowledge about cervical cancer, HPV and HPV vaccine among rejecters. To ensure continuous high uptake of the vaccine, there needs to be better efforts to address parental concerns about side effects. Trusted sources of information should also reinforce the message that HPV vaccination pre-sexarche is the best way to avert this preventable disease.

INTRODUCTION

Background

Cervical cancer is the fourth most common cancer in women worldwide.[1] Yearly, about 85% of newly diagnosed cervical cancer cases occur in developing countries.[1] Africa is the most dangerous place to be a woman with cervical cancer. Ten countries on the continent exhibit the highest age-standardized cervical cancer mortality rates globally.[2] In Sub-Saharan Africa alone, about 93,225 cervical cancer cases are reported annually, with a mortality risk of 22.5% per 100,000 compared to 3.3% per 100,000 for women in developed countries.[3] This disparity relates in large part to poorly accessed secondary prevention programs, in particular cytology screening.[4] In South Africa (SA), cervical cancer is the second most common cause of all female cancers and the leading cause of cancer in women aged 15-44.[5] South African data from 2012, the latest year that information is available, indicate that there were more than 7700 new cases and 4200 deaths from the disease, a growing trend from previous years.[3,5] The decades long Human Immunodeficiency Virus (HIV) pandemic in Sub-Saharan Africa (SSA) has amplified the prevalence of cervical cancer in South Africa, with HIV-seropositive women having a five-fold likelihood of developing cervical cancer compared to HIV sero-negative women.[6]

Cervical cancer is more than just a health issue. Due to the social and economic implications of developing cancer in the most productive years of life, prevention becomes not only an investment in the economic autonomy of women but in the country's development as a whole.

Human Papilloma Virus (HPV)

Human Papilloma Virus (HPV) is a sexually transmitted infection that has been implicated in the development of cervical cancer.[7] Studies have identified a causal association between high-risk oncogenic HPV types 16 and 18, which are responsible for more than 70% of cervical cancers.[7, 8] Primary prevention of cervical cancer is possible through the administration of a vaccine. HPV vaccines approach almost 100%

efficacy in preventing oncogenic infections when administered prior to the initiation of sexual activity.[7,8] Three safe and effective HPV vaccines, Gardasil (Merck) a quadrivalent vaccine, Cervarix (Glaxo SmithKline) a bivalent vaccine, and Gardasil-9 (Merck) a nonavalent vaccine were licensed for use in the United States by the Food and Drug Administration (FDA) in 2006, 2007 and 2014 respectively.[7] South Africa granted access to Gardasil and Cervarix in 2008, however only to the private sector which covers about 20% of the population.[9] In February 2014, the government initiated a publically funded school-based HPV vaccine program, making the vaccine available to all girls in grade four between 9-12 years of age.[10, 11]

HPV vaccine roll-out in Sub-Saharan Africa

Despite the staggering disease and societal burdens associated with cervical cancer, primary prevention strategies such as HPV vaccination are not well developed in Sub-Saharan Africa (SSA). While a review exploring the provision of free HPV vaccines by national governments in SSA identified financial constraints as the major obstacle,[12] other factors also contributed to the delay in developing state sponsored HPV vaccine programs. These included: lack of epidemiological data; health personnel shortages; weak or non-existent cancer service policies; and, a dearth of political will to address the public health complexities of cervical cancer, particularly in the face of other competing disease burdens such as HIV/AIDS, tuberculosis and malaria that have benefited from a strategic focus.[13]

Responding to such limited vaccine access in the Global South, the Global Alliance for Vaccines and Immunization (GAVI) was formed as a public-private partnership in 2000 with the mandate of accelerating access to life-saving vaccines, including the HPV vaccine, to children in developing countries[14,15] Although SA's per capita income is above the threshold for GAVI support, GAVI's efforts have significantly reduced morbidity and mortality from vaccine-preventable diseases in other low and middle-income countries (LMIC) in SSA.[16,17]

Considering HPV as the causative agent in cervical cancer as well as the cost effectiveness of mass vaccination efforts, together with South Africa's constitutional obligations to provide reproductive health care to the population in a progressive manner,[18] the government launched an ambitious nation-wide school-based HPV vaccine roll-out campaign as a joint initiative between the Departments of Health and Education.[19] A two-dose vaccination schedule was adopted to reduce costs while maintaining efficacy. The two doses are administered at zero and six months by school health nurses.[20] The SA government in this instance has demonstrated its political

commitment to women's reproductive health by introducing the HPV vaccine as part of the Integrated School Health Program.

Vaccine hesitancy and the challenges of HPV vaccination

Although vaccine development is one of the greatest public health achievements of the second half of the twentieth century and remains central to the post-2015 Sustainable Development Goals (SDG)[17] there have been serious concerns about downward trends in vaccine acceptance globally. Despite a two-thirds reduction in childhood mortality between 1990 and 2015 related to high vaccination coverage rates,[21] an increasing number of people are choosing to postpone or decline vaccines altogether.[22] This phenomenon, deeply rooted in notions of individual autonomy, spans a spectrum from complete rejection, to vaccine hesitancy, to total acceptance. The behavior ranges from those who may accept all vaccines but have concerns, to people who may accept only some vaccines, to those who may delay in taking up vaccines, or to those who may totally reject all vaccines.[23]

Such growing vaccine skepticism exists in both developed and developing countries and is linked to deeply held, but often scientifically suspect, beliefs.[24] Some of these include the perceived risks of narcolepsy following the novel H1N1 vaccine, and the Measles, Mumps and Rubella (MMR) vaccine as a causative agent in autism.[25] Aside from fears of personal risk, other issues have contributed to poor vaccine uptake in the Global South, specifically related to security threats and violence.[25] For example, the boycott of polio vaccination in northern Nigeria was linked to public distrust of Western medicine and myths about the vaccine's "contamination" with anti-fertility drugs, HIV, and cancerous agents.[26] Similarly, the 2013 polio vaccination campaign in Pakistan was halted after deadly attacks by militant groups on vaccination teams under suspicions of espionage and rumors about the oral drops causing infertility.[27] Public confidence is regarded as the linchpin of any successful immunization program. This disturbing global trend of vaccine hesitancy and public skepticism has led to a call to action among governments, international organizations and the research community to rebuild public trust.[28]

In the case of HPV vaccine, its popular association with sexual promiscuity and sexually transmitted infections has fuelled strong moral judgments and reinforced religious and cultural taboos against discussing female sexuality.[29] Despite its inclusion in the World Health Organization's Expanded Programme on Immunization (EPI) and proven safety record, concerns about the side effects of HPV vaccine are still expressed in various

communities and appear to be contributing to low HPV vaccine uptake rates.[30,31] Globally, parental acceptance of HPV vaccine for their children is between 54.9% and 81.0%.[32] In 2013, seven years after general availability, the United States reported HPV vaccination uptake rates of only 57.3%, with a series completion rate of less than 40%.[33] Similarly, HPV vaccine coverage rates in most European countries in 2011 ranged between 17–80%, with the exception of Denmark and Portugal with greater than 80% coverage rate.[34] In contrast, HPV vaccine acceptance rates in SSA appear to remain high.[10] Demonstration projects between 2009 and 2011 showed high vaccine acceptance rates in Tanzania (71.6%); Uganda (88.9%); Rwanda (93.2%); and, South Africa (97.8%).[10, 35, 36, 37] One explanation for the latter is that GAVI funding has reduced costs and increased the accessibility of these vaccines.[14]

Parental consent and decision-making for HPV vaccine

Parental consent before vaccine administration to minors is a legal requirement in some countries that has been found to impact negatively on HPV vaccine acceptance.[38] In SA, all grade four vaccine-eligible girls require parental consent prior to vaccination. This requirement for parental consent remains strongly debated with some scholars suggesting mandatory school HPV vaccination is necessary to achieve maximal coverage and the desire for herd immunity.[39] Alternatively, the 'vaccine opt–out option' balances the need for public protection with affording parents the opportunity to refuse vaccination for their daughters, provided they have been given adequate information and have a clear understanding of the implications of refusing the vaccination for their children.[40] Underlying all of these options, however, is the globally accepted human rights protections contained in the Convention on the Rights of the Child, reinforcing that parental decision-making should be guided only by the best interests of the child.[41]

Previous studies have shown positive attitudes and significant willingness of parents to accept the HPV vaccine for their pre-adolescent daughters.[10,34,35,36] However, the current decline in global vaccination rates and the slow HPV vaccine uptake in a number of countries have led researchers to explore the contributory factors that influence parental acceptance or rejection of the vaccine, namely: awareness and knowledge of cervical cancer, HPV and HPV vaccines; sociodemographic characteristics; cultural and political factors; worry about side effects; legal requirements for parental consent; and, cost constraints.[42, 43]

Socio-demographic factors: As one of the most culturally diverse and economically stratified countries on the African continent, it might be expected that South Africa would have variations across different segments of the population that may influence

the acceptance or rejection of the HPV vaccine. There have been mixed findings on the influence of socio-demographic characteristics on the acceptance or rejection of HPV vaccine in developed countries. While some studies have reported that parental age, race, educational levels, religion and income level did not influence parental acceptance or rejection of HPV vaccine,[44, 45] other studies found that religiosity, frequency of attendance at religious services, low socioeconomic status (SES) and identification as a racial/ethnic minority may reduce the chances of parents' knowing about the HPV vaccine and accepting it.[46, 47, 48, 49] Higher educational and income levels also influence vaccine acceptance in some communities positively.[50]

A systematic review of studies conducted in Africa also reported mixed findings about socio-demographic factors. Two of the studies conducted in Africa found that older respondents were more likely to accept the HPV vaccine,[51, 52] while a third study found no significant association between age of respondents and acceptance or rejection of the HPV vaccine.[53] Higher income and parental education levels were associated with acceptance of the vaccine in Ghana and Botswana respectively;[51, 53] while in Nigeria, higher educational levels were associated with rejection of the vaccine.[52] Studies from Ghana and Kenya cited no relationship between the two variables.[51, 54] Further, no association was found between income levels and HPV vaccine acceptance in some countries.[55]

Awareness and knowledge: Public education has been suggested to have a significant impact on increasing HPV vaccination uptake across different sociodemographic groups. An international comparison study of the USA, United Kingdom (UK), and Australia on the awareness and knowledge of HPV vaccine found high levels of awareness and knowledge about HPV and HPV vaccine, especially among women.[49] In SSA, a systematic review identified low levels of awareness and knowledge about cervical cancer, HPV and HPV vaccine despite high levels of HPV vaccine acceptability among all key demographics, with most parents citing the need for more information before accepting to vaccinate their daughters.[14, 55]

Factors influencing the decision to accept or reject the HPV vaccine: Factors that have been identified as predictors of parents' decision to accept or reject the HPV vaccine for their daughters include: lack of a health care professional's recommendation for the HPV vaccine; the belief that one's child is too young to get vaccinated for HPV; parent–child communication regarding adolescent sexual health; the perceived effectiveness of the vaccine; concerns about HPV vaccine adverse effects; safety; and cost.[56, 57,58]

While there has been a shift from the traditional paternalistic model of care, many patients still seek the advice of their physicians on health matters before making health decisions. Hence, parents who believe that their physician would recommend HPV vaccination for their adolescent daughters are more likely to accept vaccination compared to those who did not.[59] Interestingly, another study found that while HPV vaccine acceptability was reported to be higher among parents who were encouraged to vaccinate by their physician, parents who opposed the vaccination were less likely to be influenced by their physician.[60]

A systematic review of studies conducted in the USA about the barriers to HPV vaccine acceptance identified that parents preferred to vaccinate older girls, resulting in the rejection or delay in vaccination of younger girls.[57] Similarly, a recent study from India reported a significant association between the age of the child at vaccination and parental decision making with the majority of parents willing to accept HPV vaccination if administered at older ages. This preference in India is based on the perception that initiation of sexual activity in India begins at 22.9 years and thus may not be applicable in settings where age at sexarche is much lower.[61]

Another factor is the impact of open communication on sexual topics with daughters. It has been documented that parents who communicate more openly with their daughters on sex related topics are generally more accepting of the vaccine, and vice versa.[62]

There are mixed findings on the impact of cost on the HPV vaccine in developed countries with some studies reporting it as a barrier to vaccination, [62] while others have found a willingness to vaccinate regardless of the price of the vaccine.[63] In SSA, prior to GAVI's intervention, cost was a major barrier to the introduction of HPV vaccine. While some parents will not vaccinate their daughters until the vaccine is given freely, like other vaccines included in the EPI, other parents were prepared to share vaccine expenses with the government based on their perception that the benefits of the vaccine outweighed its cost.[64,65]

The lack of research following the initiation of HPV vaccination programs across SSA, coupled with the South African government's financial investment in a mass HPV vaccination program and the emergence of parental vaccine hesitancy have led to growing urgency to identify, analyze and understand the true drivers of HPV vaccination in the early days of the roll-out.

MATERIALS AND METHODS

This cross-sectional study was conducted between January and March 2015 during the second year of the national HPV vaccine roll-out campaign. Participants were parents of vaccine-eligible girls who attended one of the ten public primary schools located in Etwatwa township in the Ekurhuleni health district, Gauteng Province, South Africa.

Site of study

Etwatwa is a peri-urban township outside Johannesburg with a population of about 151,866.[66] Thirty-five percent of 43,483 households are female-headed. It spans an area of about 20.83 km^2 with a population density of 7,291.62 people per/km. About 30% of the population is below 15 years of age. All schools located in Etwatwa are in the Quintile 2 category, or no–fee schools, a measure of economic disadvantage. According to 2011 Statistics SA census data, there is a 37.3% unemployment rate. The most prevalent language is IsiZulu spoken by 45% of the population followed by XiTsonga with 12.97%. About 22% of the households have an annual income of between 19 000 and 38 000 rand, while 19% of households have no income at all.[66]

Sampling method

Research information sheets and self-administered questionnaires were sent home with all vaccine-eligible girls on the day of the administration of the first vaccine dose, whether or not their parents had consented. The questionnaire was designed in English and then translated into three other local languages, with back-translation to ensure accuracy. One single written reminder was sent home after two weeks. Return of the completed questionnaire implied consent.

The questionnaire assessed three domains: i) parental sociodemographic factors; ii) previous awareness of and knowledge about cervical cancer, HPV and HPV vaccine; and, iii) factors known to affect parental decision making on HPV vaccine uptake, adapted from prior research from other countries in different settings.[67, 68, 69] See Annexure 1.

Ethical approval to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC) Medical, Clearance Certificate No M141183. Permission to access the schools was granted by the Ekurhuleni Health District Research Committee (DRC), the Gauteng Provincial Department of Basic Education and the ten principals.

Outcome and analysis

The main outcome of the study was the acceptance or rejection of HPV vaccine, coded as either "yes" or "no", depending on whether a parent accepted to vaccinate their daughter (yes) or rejected to vaccinate their daughter (no). Descriptive statistics including frequencies, percentages and proportions were generated for the demographic data of the participating parents and guardians. These included: age, home language, religious affiliation, sex of decision maker and educational level. Basic associations with the outcome of study were tested with Chi square and Fisher's exact test for proportion. Awareness of cervical cancer, HPV and HPV vaccine prior to the HPV vaccine campaign was assessed with two questions, and either a "yes" or "no" response. In assessing decision-maker knowledge about cervical cancer and HPV, we calculated the participant response to a six question True-False test and then scaled to 100%. Finally, we assessed a list of thirteen possible factors known to affect parental decision making. Multivariate analysis (logistic regression) was done to ascertain the relationship between parental acceptance or rejection, and possible factors that may have impacted on parental decision-making.

Data analysis was conducted using the statistical software program STATA 9.0 (Stata Corporation, College Station, Texas).

RESULTS

Survey materials were sent home with 506 girls, representing the total number of eligible HPV vaccine recipients across all ten schools. Four hundred and seventy-six questionnaires were returned. Of these, 30 questionnaires were excluded from analysis due to incompleteness, for an overall response rate of 90% (446/506).

The main outcome: acceptance or rejection of HPV vaccine

Over 95% of parents or guardians accepted the HPV vaccine on behalf of their daughters (426/446); while only 20 parents rejected. We looked for significant associations between acceptance, sociodemographic factors, awareness and knowledge.

As indicated in Table 1, there were no significant sociodemographic factors associated with acceptance or rejection of the vaccine. However, previous awareness of HPV (204, 47.9%) was significant when compared with awareness of HPV in rejecters (4.20%) ($p< 0.02$). Also, the majority of parents who had rejected the vaccine had not heard of HPV previously compared to those who had heard of it previously (16.80% vs 4. 20%),

implying a significant different between accepters and rejecters (p<0.02). The mean knowledge score for those who accepted was significantly higher compared to those who rejected (72%, SD+/-20.80 vs 47% SD+/- 33.60, p-value of t-test: 0.0033). Parents who scored 50% or less on the knowledge test were least likely to accept the HPV vaccine for their daughters.

Table 1: HPV vaccine acceptance or rejection according to sociodemographic characteristics, awareness and knowledge

	Accepters (%)	**Rejecters(%)**	**p value**
	426 (95.5%)	**20 (4.5%)**	**(Fischer exact)**
Gender (n = 446)			
Female (n = 399)	382 (89.7)	17 (85)	0.69
Male (n = 47)	44 (10,3)	3 (15)	
Respondent relationship to child (n = 446)			
Primary parent (mother, father) (n = 376)	358 (84)	18 (90)	0.69
Other relatives (grandmother, grandfather, uncle, aunt) (n = 70)	68 (16)	2 (10)	
Age (Mean +/- SD)			
39.03+/-9.59	39.1+/-9.71	38.4+/-6.53	
Age (n = 446)			
<30 (n = 71)	67 (15.7)	4 (20)	
30-39 (n = 213)	207 (48.6)	6 (30)	

40-49 (n = 107)	97 (22.8)	10 (50)	0.06
50-59 (n = 38)	38 (8.9)	0	
>60 (n = 17)	17 (4)	0	
Language (n = 446)			
Inguni (isIndebele, isIXhosa, isIzulu, Siswati) (n = 354)	339 (79.6)	15 (75)	
Sotho (Sesotho, Seso Sa Leboa, Setswana) (n = 48)	46 (10.8)	2 (10)	0.58
Others (Xitsonga,Tshivenda,Sepedi) (n = 44)	41(9.6)	3 (15)	
Religion (n = 444)			
Traditional African (n = 115)	110 (25.8)	5 (25)	
Christianity (n = 161)	155 (36.4)	6 (30)	0.81
Born again (n = 168)	159 (37.3)	9 (45)	
Attendance at religious services			
None (n=35)	32 (7.5)	3 (15)	
1-2 services/ week (n = 304)	290 (68.1)	14 (70)	0.44
3 services / week (n = 104)	101 (23.7)	3 (15)	
Education (n = 446)			
No primary and some primary (n = 96)	94 (22.1)	2 (10)	0.46
Above primary (grade 8 to college) (n = 350)	332 (77.9)	18 (90)	

Awareness	Accepters	Rejecters	
Awareness of cervical cancer (n=358)	341 (80)	17 (85)	0.78
Unaware of cervical cancer (n=88)	85 (20)	3 (15)	
Awareness of HPV (n = 208)	204 (47.9)	4 (20)	0.02
Unaware of HPV (n = 238)	222 (52.1)	16 (80)	
Knowledge			
HPV knowledge test (mean score +/-SD)	71.95+/- 20.80	46.67+/-33.60	0.0033
Inadequate knowledge (< 50%)	32(7.5)	8 (40)	<0.001

In total, 78% of respondents scored 50% and above in the knowledge questions; 12% scored 50%; and, 11% of parents scored below 50%. Eight of the 20 respondents who rejected the vaccine had two or less correct answers out of the six questions. See Table 2.

Table 2: Respondents according to knowledge scores

Participant scores	n = 446	% of respondents
No of participants scoring 6/6	64	14.3
No of participants scoring 5/6	158	35.4
No of participants scoring 4/6	124	27.8

No of participants scoring 3/6	53	11.9
No of participants scoring 2/6	27	6.1
No of participants scoring 1/6	12	2.7
No of participants scoring 0/6	8	1.8

Table 3 shows that while a significant number of participants who answered most of the individual questions correctly (range between 65% - 87%), 78% of the respondents did not know that HPV was sexually transmitted.

Table 3: Participant test questions and respondents who answered correctly

Individual knowledge question scored	n = 446	% of respondents
Cervical cancer can be cured if found early enough	389	87.2
Vaccination is a safe way to prevent infection with HPV	387	86.8
Vaccination is an effective way to prevent infection with HPV	380	85.2
HPV infection can cause cancer of the cervix (mouth of womb)	340	76.2
A person may be infected with the HPV virus but not know it	297	66.7
HPV can be transmitted through sex from one person to another	102	22.9

Overall, most participants had heard of cervical cancer compared to HPV and HPV vaccine: 358 (80%) versus 208 (47%), as outlined in Table 4. Those who had heard of HPV prior to the HPV vaccination campaign scored higher in the knowledge test

questions (208, SD 75.6% +/-18.23%, p <0.0001), indicating a significant correlation between awareness and knowledge.

Table 4: Association between awareness and knowledge of cervical cancer and HPV

	n = 446	Knowledge % (Mean+/-SD)	p value
Awareness of cervical cancer	358	72.8 (+/-21.63)	<0.0002
Unaware of cervical cancer	88	62.9 (+/-22.42)	
	n = 446	**Knowledge% (Mean+/-SD)**	**p value**
Awareness of HPV	208	75.6 (+/-18.23)	<0.0001
Unaware of HPV	238	66.6 (+/-24.28)	

Factors affecting parental decision-making

The most important reasons why parents accepted or rejected HPV vaccination on behalf of their daughters are listed in Table 5. Concern about adverse effects was the most important reason that influenced parents who rejected the vaccine (100% vs 56.6%, p< 0.001). It is noted that although more than half of parents who accepted were also worried about adverse effects, they still chose to vaccinate their daughters. Most respondents who accepted the vaccine, compared to those who rejected, were influenced by: i) protection from cervical cancer (97% vs 5%, p< 0.001); ii) perception of the importance of the vaccine (95.31% vs 5%, p< 0.001); iii) the vaccine being given at no cost (93% vs 5%, p< 0.001); iv) provision of the vaccine in schools (91% vs 5%, p<0.001); v) the information received from the school (86.4% vs 10%, p< 0.001); vi) the government's recommendation to vaccinate (72% vs 5%, p<0.001); vii) media coverage of the vaccine (49% vs 10%, p <0.001); and, viii) the opinion of the daughter about receiving the vaccine (39.2% vs 0%, p <0.001).

Table 5: Factors influencing parental acceptance or rejection of HPV vaccine

	n = 426	n = 20	
	% accepted	% rejected	p value
Worry about side effects	55.6	100	0.001
My daughter's age	65	50	0.16
Religious beliefs	33.8	25	0.48
Information sent from school	86.4	10	0.001
Information through media	49.1	10	0.001
Protection from cervical cancer	97	5	0.001
Importance of vaccine	95.3	5	0.001
Vaccine being given free	93	5	0.001
Provision of vaccine in schools	91	5	0.001
Government recommendation	72	5	0.001
Recommendation from doctors	49.1	5	0.001
Recommendation by family and friends	40.6	5	0.001
Worry about promiscuity	20.7	5	0.15
Opinion of daughter	39.2	0	0.001
Information from church	12	0	0.15

Table 6 shows the relationship between HPV vaccine acceptance and other covariates. No socio-demographic factors were associated with acceptance. Having adequate

knowledge of HPV and HPV vaccine was significantly associated with increased acceptance (Odds ratio (SE), 8.29 (4.43), $p < 0.005$).

Table 6: Multiple logistic regression analyses of potential predictors of HPV vaccine acceptance (the modelling is in favour of acceptance)

	Odds Ratio (S E)	p-value
Sex (ref = female)	0.91(0.67)	0.90
Age (ref = 30 - 39)		
40 – 49	0.25 (0.14)	0.02
50 – 59	1	0.40
60 +	1	
<30	0.42 (0.30)	0.22
Education (ref = college)		
Grade 12	0.80 (0.93)	0.85
Grade 8	0.89 (1.07)	0.92
Some high school	0.74 (0.95)	0.81
Some primary	4.72 (7.27)	0.32
No primary	1.90 (2.97)	0.68
Religion (ref = born again)		
Other Christian	1.81 (1.07)	0.32
Traditional African	1.21 (0.78)	0.77
Number of Religious services (ref =2)		
	1.81 (1.39)	0.44
Adequate knowledge (ref = no)		
Yes	8.29 (4.43)	<0.005

DISCUSSION

To the best of our knowledge, this is the first study assessing factors that influenced parental decision-making to accept or reject the HPV vaccination of their daughters since the South African government began its national school-based roll-out campaign in 2014.

Previously, sociocultural issues, including low HPV knowledge and its relationship to cervical cancer, societal values and stigma had been identified as the primary barriers to successful HPV vaccination programs in LMICs.[70] Recently, health system constraints and political issues, such as finance, logistic considerations and involvement of multiple stakeholder groups have emerged as new obstacles in LMICs.[42]

From this study, several interesting themes have emerged.

We observed a significant relationship between parental awareness and acceptance or rejection of the HPV vaccine: 50% of accepters vs 80% of rejecters were unaware of HPV and HPV vaccine prior to the campaign. In contrast, previous awareness of cervical cancer was high in both study groups (341, 80% vs 17, 85%). This finding of high vaccine acceptance despite low awareness is similar to the trend in other countries in sub-Saharan Africa[15,71] as well as in the Global North, like Canada and Hong Kong.[72,73] In contrast, studies from Cameroon and the United States attribute higher levels of awareness of HPV and HPV vaccination (75% and 83%) to increased HPV and cervical cancer awareness programs.[74,75]

Awareness seems to prime knowledge as well as vaccine acceptance. Our findings indicated that respondents who were aware of cervical cancer, HPV and HPV vaccination prior to the campaign performed better in the knowledge test compared to their counterparts with no previous awareness. Hence, awareness and knowledge about cervical cancer, HPV and HPV vaccine informed parental decisions to accept or reject vaccination in this study population.

There have been mixed findings on the impact of educational levels on parental vaccine acceptance. In a review of various qualitative and quantitative studies, higher educational level was linked to better knowledge and vaccine acceptance.[50] However, other studies have reported no association between parental educational level and vaccine acceptance.[44,76] The latter is consistent with our findings indicating educational status was not a determinant of vaccine acceptance in this population. Other socio-demographic factors including: age of respondents; relationship of respondent to child; language; religion; and, number of religious services attended weekly did not influence

HPV vaccine acceptance. This is consistent with other studies in LMICs which indicate that pragmatic factors such as cost, accessibility through schools and integration into the EPI enable convenience, rendering it easy for parents to accept vaccination.[45]

Despite extensive research validating the safety and efficacy of the HPV vaccine,[53, 56] fear of side effects remains a common barrier to parental acceptance in both developed and developing countries,[77,78] as evident in this study with safety concerns expressed by both groups. Previous studies conducted in South Africa indicate there is parental desperation to protect the health and well-being of daughters especially against a backdrop of gender-based and sexual violence, endemic HIV and huge numbers of female-headed households.[10, 65] A significant factor observed in this study is a strong desire to protect daughters from cervical cancer influencing the decision to vaccinate at 97%. Hence, considerations of the vaccine's health benefits mostly took precedence over the fear of side effects amongst vaccine accepters.

Another barrier to HPV vaccine acceptance is the myth around vaccination predisposing daughters to sexual promiscuity. There are mixed reports about this concern, with some studies suggesting that parental beliefs about the HPV vaccination predisposing adolescents to sexual promiscuity influenced the decision to reject the vaccine.[57, 79] Contrasting results have been reported in other studies indicating that parents are not bothered by such concerns.[80, 81, 82, 83] In this study, there was no association between vaccine acceptance and worry about sexual promiscuity, indicating that these parents had no illusions that HPV vaccine leads to sexual promiscuity.

Parental perception of HPV vaccine side effects is linked to their sources of information. The media, which have been identified as one of the top sources of information in other studies,[84, 85] was found to have a significant association with parental acceptance in this study at 49.1%. The strength of the media is that it can exert both positive and negative influences on vaccine acceptance. While community leaders and vaccine advocates can express their opinions freely through media channels and motivate for vaccine acceptance, other organizations and social networks like anti-vaccine campaigners can become potential risks to vaccine uptake through misinformation. A limitation of this study is that questionnaire did not specify particular media sources that influenced parents' decisions.

Levels of trust or distrust in the government, health care workers and other recommending bodies have been linked to HPV vaccine acceptance.[86, 87,88] This study showed that parental trust in the government's recommendation to vaccinate daughters was significant for acceptance. This is an important consideration, especially in light of

the recent trend of declining public trust in the ruling political party as evidenced by the loss of key municipalities to opposition parties in 2016.[89]

While many studies have reported health care workers as key sources of information and positive influencers of HPV vaccine uptake[53,57,64] others found no association between these variables.[67] Similar to a South African study on intent to accept vaccination, our respondents indicated that health care workers also influenced their decision to accept the vaccine. The health care workers referred by our respondents are the dedicated school health nurses. Other trusted bodies include community leaders like religious leaders, family and friends whose influence can impact vaccine acceptance or hesitancy.[90,91] This study found that although information from churches did not influence the population, families and friends had significant impact on the decision to accept vaccination.

Finally, we analysed whether parents sought the opinion of the daughter being vaccinated because of reports that parent-daughter communication on HPV and other sexual topics impacts positively on parental decision-making for vaccine acceptance.[55] In this study, while 39% of parents sought their daughters' opinion before accepting the HPV vaccine, none of the rejecters reported discussing the HPV vaccine with their daughters before taking this decision on their behalf denying them a potential health benefit. It is important to note that despite the legal requirement for parental consent in this age group, the best interests of the child and child's ability to provide her assent [41,92] should outweigh other parental considerations, ensuring access to life saving opportunities.

Limitations of this study include the small number of parents who refused to vaccinate their daughters, making it impossible to draw broad conclusions about this cohort as well as the fact that we did not consider the migrant factor in the region.

CONCLUSION

South African parents appear to strongly accept the HPV vaccination for their adolescent daughters based on trust in the recommending bodies, factors of convenience and the general accessibility of the vaccine.

To maintain such broad public uptake, in addition to reinforcing the safety and efficacy of the HPV vaccine, it would be important to acknowledge the purpose of the vaccine, provide evidence-based explanations of the minor risks associated with HPV vaccination and address misinformation through health care workers, public health personnel and the

media. Also, these trusted sources of information should be encouraged to actively reinforce the benefits of the vaccine while responding to concerns about vaccine safety.

This study is consistent with other studies indicating that inadequacies of the health system and diminished political commitment in LMIC's are of greater influence on the sustainability of HPV vaccination campaigns than sociocultural issues.[2] Presently, the governing party has shown strong political will for the HPV vaccination program. However, considering the recent political landscape it is unclear whether this health promotion initiative would be sustained under different leadership.

Going forward, it is important to continue active campaigns that will bring about the health benefits of this vaccine in the long term and encourage parents to have discussions about cervical cancer, HPV, the HPV vaccine and sexual topics with their daughters. To this end, it has been suggested that reframing parental thinking around the severe health risks of non-vaccination may outweigh the minimal risks associated with vaccination.[93,94] Such campaigns should also aim to improve parental awareness and attitudes toward HPV vaccination through persistent communication and positive media messaging.

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References

[1] Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Int. J. Cancer.* 2015;136(5):E359–E386. doi:10.1002/ijc.29210 PMID:25220842

[2] Score card Research, Analysis, & Design By Africa Health, Human & Social Development Information Service (Afri-Dev. Info i.e. Formerly Africa Public Health .Info) & Africa Coalition On Maternal Newborn & Child Health © 2014.

[3] Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, et al; International Agency for Research on Cancer. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11. http://globocan.iarc.fr/ (Accessed 2017: 06: 09)

[4] Sankaranarayanan R, Atul Madhukar B, and Rajamanickam R. "Effective screening programmes for cervical cancer in low-and middle-income developing countries. Bull World Health Organ 2001;79(10):954-962. http://dx.doi.org/10.1590/S0042-96862001001000009

[5] Bruni L, Barrionuevo-Rosas L, Albero G, Serrano B, Mena M, Gómez D et al. ICO Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in South Africa. Summary Report 15 December 2016. www.hpvcentre.net/statistics/reports/ZAF.pdf (Accessed August, 2016)

[6] Moodley JR, Hoffman M, Carrara H, Allan BR, Cooper DD, Rosenberg L, et al. HIV and pre-neoplastic and neoplastic lesions of the cervix in South Africa: a case-control study. BMC Cancer. 2006;6:135. doi: 10.1186/1471-2407-6-135

[7] Human papillomavirus vaccines: WHO position paper. *Weekly epidemiological record.* 2017;92(19): 241–268. http://www.who.int/wer

[8] Centers for Disease Control and Prevention (CDC). Human papillomavirus vaccination. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR.* 2014;63 (5):1-30.

[9] McIntyre D, Gilson L, Wadee H, Thiede M, Okarafor O. Commercialisation and extreme inequality in health: the policy challenges in South Africa. J. Int. Dev. 2006;18:435–446. doi: 10.1002/jid.1293

[10] Katz IT, Nkala B, Dietrich J, Wallace M, Bekker L, Pollenz K et al. A Qualitative Analysis of Factors Influencing HPV Vaccine Uptake in Soweto, South Africa among adolescents and their caregivers. *PLoS ONE.* 2013;8(8):72094. doi:10.1371/journal.pone.0072094

[11] Moodley I, Tathiah N, Mubaiwa V, Denny L. High uptake of Gardasil vaccine among 9–12-year-old schoolgirls participating in an HPV vaccination demonstration project in KwaZulu-Natal, South Africa. *SAMJ.* 2013;103(5):318–321. doi:10.7196/SAMJ.6414.

[12] Graham JE, Mishra A. Global challenges of implementing human papillomavirus vaccines. *Int J Equity Health.* 2011;10(1):27. doi: 10.1186/1475-9276-10-27

[13] Louie KS, de Sanjose S, Mayaud P. Epidemiology and prevention of human papilloma virus and cervical cancer in Sub-Saharan Africa: a comprehensive review. *Trop Med Int Health.*2009; 14(10):1287-1302. doi: 10.1111/j.1365-3156.2009.02372.x

[14] Nguyen A, Datta SD, Schwalbe N, Summers D, Adlide G, and the GAVI Alliance. Working towards affordable pricing for HPV vaccines for developing countries: The role of GAVI. GTF.CCC Working Paper and Background Series, No. 3, Harvard Global Equity Initiative, 2011. http://www.gavialliance.org (Accessed 2017: 06: 09)

[15] Perlman S, Wamai RG, Bain PA, Welty T, Welty E, Ogembo JG et al. Knowledge and Awareness of HPV vaccine and acceptability to vaccinate in Sub-Saharan Africa: A Systematic Review. *PLoS ONE.* 2014;9(3):90912. doi:10.1371/journal.pone.0090912

[16] de Sanjosé S, Serrano B, Castellsagué X, Brotons M, Muñoz J, Bruni L et al. Human Papillomavirus (HPV) and related cancers in the Global Alliance for Vaccines and Immunization (GAVI) Countries. A WHO/ICO HPV Information Centre Report. *Vaccine* 2012; 30(4):D1-83. doi: 10.1016/S0264-410X(12)01435-1

[17] Feikin DR, Flannery B, Hamel JM, Stack M, and Hansen PM. Vaccines for Children in Low- and Middle-Income Countries. In: Black RE, Laxminarayan R, Temmerman M, et al, editors. Reproductive, Maternal, Newborn, and Child Health: Disease Control Priorities, Third Edition (Volume 2). Washington (DC): The International Bank for Reconstruction and Development / The World Bank; 2016 Apr 5. Chapter 10. Available from: doi: 10.1596/978-1-4648-0348-2 ch10 (Accessed 2017:06:09)

[18] Republic of South Africa. National Health Act – Act No. 61. Government Gazette 2004; 469(23):No.26595. http://www.chr.up.ac.za/undp/domestic/docs/legislation_55.pdf (Accessed 2017: 06: 09).

[19] Richter KL. Implementation of HPV vaccination in South Africa. PHASA 2015. https://www.phasa.org.za/implementation-hpv-vaccination-south-africa/

(Accessed 2017: 03: 10)

[20] Li X, Stander MP, Kriekinge GV. Cost-effectiveness analysis of Human papillomavirus

vaccination in South Africa accounting for Human Immunodeficiency virus prevalence. *BMC Infect Dis.* 2015;15:566. doi 10.1186/s12879-015-1295-z

[21] UN (United Nations). 2015. "UN Millennium Development Goals: Child Health." UN, New York. http://www .un.org/millenniumgoals /childhealth.shtml (Accessed 2017: 01:12)

[22] Gowda C, Dempsey AF. The rise (and fall?) of parental vaccine hesitancy. *Hum Vaccin Immunother.* 2013;9(8):1755-1762. http://dx.doi.org/10.4161/hv.25085

[23] Larson HJ, Jarrett C, Eckersberger E, Smith DMD, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: a systematic review of published literature, 2007-2012. *Vaccine.* 2014;32:2150–9.
doi: 10.1016/j.vaccine.2014.01.081

[24] Muñoz DC, Llamas LM, Bosch-Capblanch X. Exposing concerns about vaccination in low- and middle-income countries: a systematic review. *Int. J. Public Health.* Nov 2015;60(7):767-780. doi 10.1007/s00038-015-0715-6.

[25] Miller E. Controversies and challenges of vaccination: an interview with Elizabeth Miller. *BMC Medicine.* 2015;13:267. doi 10.1186/s12916-015-0508-z

[26] Renne E. Perspectives on polio and immunization in Northern Nigeria. *Soc Sci Med* 2006;63: 1857-69. doi: 10.1016/j.socscimed.2006.04.025 pmid: 16765498

[27] McGuinness W. CIA polio vaccine hoax condemned by public health deans. Huffington Post New York 2013.
www.huffingtonpost.com/2013/01/10/cia-polio-vaccine hoax_n_2450726.html

[28] The state of Vaccine confidence 2015
http://www.vaccineconfidence.org/The-State-of-Vaccine-Confidence-2015.pdf.
(Accessed 2016:12:12)

[29] Fisher H, Trotter CL, Audrey S, MacDonald-Wallis K, Hickman M. Inequalities in the uptake of Human Papillomavirus Vaccination: a systematic review and meta-analysis. *Int J Epidemiol.* 2013;42(3):896-908. doi:10.1093/ije/dyt049.

[30] Burnett RJ, Larson HJ, Moloi MH, Tshatsinde EA, Meheus A, Paterson P et al.

Addressing public questioning and concerns about vaccination in South Africa: A guide for healthcare workers. *Vaccine.* 2012;30(3):72–78.

http://dx.doi. org/10.1016/j.vaccine.2012.03.037

[31] Larson HJ, Cooper LZ, Eskola J, Katz SL, Ratzan S. Addressing the vaccine confidence gap. *Lancet* 2011;378:526–535. doi: 10.1016/S0140-6736(11)60678-8

[32] Tricco AC, Ng CH, Gilca V, Anonychuk A, Ba' Pham, Berline S. Canadian oncogenic human papillomavirus cervical infection prevalence: Systematic review and meta-analysis. *BMC Infectious Diseases* 2011;11:235. doi: 10.1186/1471-2334-11-235

[33] Overcoming barriers to low HPV vaccine uptake in the United States: Recommendations from the National Vaccine advisory committee: Approved by the National Vaccine Advisory Committee on June 9, 2015. *Public Health Reports.* 2016;131(1):17-25. doi: 10.1177/003335491613100106

[34] European Centre for Disease Prevention and Control. Introduction of HPV vaccines in EU countries – an update. Stockholm: ECDC; 2012. ISBN 978-92-9193-377-8 doi 10.2900/60814

[35] Watson-Jones D, Tomlin K, Remes P, Baisley K, Ponsiano R, Soteli S et al. Reasons for receiving or not receiving HPV vaccination in primary schoolgirls in Tanzania: a case control study. *PLoS ONE.* 2012;7(10): e45231. doi:10.1371/journal.pone.0045231

[36] LaMontagne DS, Barge S, Thi Le N, Mugisha E, Penny ME, Gandhi S et al. Human papillomavirus vaccine delivery strategies that achieved high coverage in low-and middle-income countries. *Bull World Health Organ.* 2011;89(11):821–830.
doi: 10.2471/BLT.11.089862

[37] Binagwaho A, Wagner C, Gatera M, Karema C, Nutt C, Ngaboa F. Achieving high coverage in Rwanda's national human papillomavirus vaccination programme. *Bull. World Health Organ.* 2012; 90: 623–628. doi:10.2471/BLT.11.097253

[38] Strode A, Slack C, Essack Z. Child consent in South African law: Implications for researchers, service providers and policy-makers. *S Afr Med J.* 2010; 100: 247-249.

[39] El-Amin AN, Parra MT, Kim-Farley R, Fielding JE. Ethical issues concerning vaccination requirements. *Public Health Rev.* 2012; 34(1): 1-20.

[40] Gostin LO, DeAngelis C D. Mandatory HPV Vaccination; Public Health vs Private Wealth. *JAMA.*2007; 297(17):1921-22. doi: 10.1001/jama.297.17.1921

[41] Article 3(1). UN Committee on the Rights of the Child (CRC), *General comment no. 5 (2003): General measures of implementation of the Convention on the Rights of the Child*, 27November2003, CRC/GC/2003/5.
Available at: http://www.refworld.org/docid/4538834f11.html (Accessed 2017:06:10)

[42] Winkler JL, Witter S, Bartolini RM, Creed-Kanashiro HM, Lazcano- Ponce E, Lewis-Bell K et al. Determinants of human papilloma virus vaccine acceptability in Latin America and the Caribbean. *Vaccine.* 2008;26(11):73-79. doi: 10.1016/j.vaccine.2008.05.027

[43] De Vuyst H, Alemany L, Lacey C, Chibwesha CJ, Sahasrabuddhe V, Banura C et al. The burden of Human Papillomavirus infections and related diseases in Sub-Saharan Africa. *Vaccine.* 2013;31:F32–F46. doi.org/10.1016/j.vaccine.2012.07.092

[44] Kester LM, Zimet GD, Fortenberry JD, Kahn JA, Shew ML. A National Study of HPV Vaccination of Adolescent Girls: Rates, Predictors, and Reasons for Non-vaccination. *Matern Child Health J.* 2013;17(5):879-885. doi:10.1007/s10995-012-1066-z

[45] Lenselink CH, Gerrits MM, Melchers WJ, Massuger LF, van Hamont D, Bekkers RL. Parental acceptance of Human Papillomavirus vaccines. *Eur J Obstet Gynecol Reprod Biol.* 2008;137(1):103-7. doi: 10.1016/j.ejogrb.2007.02.012

[46] Polonijo AN, Carpiano RM. Social Inequalities in Adolescent Human Papillomavirus (HPV) Vaccination: A Test of Fundamental Cause Theory". *Soc Sci Med.* 2013;82.

doi: 10.1016/j.socscimed.2012.12.020

[47] Constantine NA, Jerman P. Acceptance of human papillomavirus vaccination among California parents of daughters: A representative statewide analysis. *J Adolesc Health.* 2007;*40*:108-115. doi:10.1016/j.jado- health.2006.10.007

[48] Shelton RC, Snavely AC, De Jesus M, Othus MD, Allen JD. HPV Vaccine Decision-Making and Acceptance: Does Religion Play a Role? *J. Relig. Health.* 2013;52(4):1120-1130. doi:10.1007/s10943-011-9553-x.

[49] Marlow LA, Zimet GD, McCaffery KJ, Ostini R, Waller J. Knowledge of human papillomavirus (HPV) and HPV vaccination: An international comparison. *Vaccine.* 2013;31(5):763-769. doi: 10.1016/j.vaccine.2012.11.083

[50] Mortensen GL. Drivers and barriers to acceptance of human-papillomavirus vaccination among young women: a qualitative and quantitative study. *BMC Public Health.* 2010;10:68. doi:10.1186/1471-2458-10-68

[51] Coleman MA, Levison J, Sangi-Haghpeyka H. HPV vaccine acceptability in Ghana, West Africa. *Vaccine.* 2011;29(23):3945-3950. doi: 10.1016/j.vaccine.2011.03.093

[52] Iliyasu Z, Abubakar IS, Aliyu MH, Galadanci HS. Cervical cancer risk perception and predictors of Human PapillomaVirus vaccine acceptance among female University students in Northern Nigeria. *J. Obstet. Gynaecol.* 2010; 30: 857–862. doi: 10.3109/01443615.2010.511724

[53] DiAngi YT, Panozzo CA, Ramogola-Masire D, Steenhoff AP, Brewer NT. A cross-sectional study of HPV vaccine acceptability in Gaborone, Botswana. *PLoS ONE.* 2011;6(10):e25481. doi:10.1371/journal.pone.0025481.6, e25481.

[54] Omondi-Ogutu, M'Imunya, J.M, 2013. Parental acceptance of human papilloma virus vaccine for their pre-pubertal and teenage daughters. *East Afr. Med. J.* 2013;88(5): 163–170.

[55] Cunningham MS, Davison C, Aronson KJ. HPV vaccine acceptability in Africa: A systematic review. *Prev. Med.* 2014;69:274-279. http://dx.doi.org/10.1016/j.ypmed.2014.08.035

[56] Brabin L, Roberts SA, Farzaneth F, Kitchener HC. Future acceptance of adolescent human papillomavirus vaccination: a survey of parental attitudes. *Vaccine.* 2006;24:3087–3094. doi:10.1016/j.vaccine.2006.01.048

[57] Holman DM, Benard V, Roland KB, Watson M, Liddon N, Stokley S. Barriers to Human Papillomavirus Vaccination Among US Adolescents: A Systematic Review of the Literature. *JAMA pediatrics*. 2014;168(1):76-82. doi:10.1001/jamapediatrics.2013.2752

[58] Williams SE. What are the factors that contribute to parental vaccine-hesitancy and what can we do about it? *Hum Vaccin Immunother.* 2014;10(9):2584-2596. doi:10.4161/hv.28596.

[59] Olshen E, Woods ER, Austin SB, Luskin M, Bauchner H. Parental acceptance of the human papillomavirus vaccine. *Journal of Adolesc Health.* 2005;37:248–51. doi: 10.1016/j.jadohealth.2005.05.016

[60] Reynolds D, O'Connell KA. Testing a Model for Parental Acceptance of Human Papillomavirus Vaccine in 9- to 18-Year-Old Girls: A Theory-Guided Study. *J Pediatr Nurs.*2012;27:614-25. doi: 10.1016/j.pedn.2011.09.005

[61] Madhivanan P, Srinivas V, Marlow L, Mukherjee S, Narayanappa D, Mysore S et al. Indian parents prefer vaccinating their daughters against HPV at older ages. *Asian Pac J Cancer Prev.* 2014;15(1):107-110. doi:http://dx.doi.org/10.7314/APJCP.2014.15.1.107

[62] Gamble HL, Klosky JL, Parra GR, Randolph ME. Factors Influencing familial decision-making regarding Human Papillomavirus Vaccination. *J Pediatr Psychol.* 2010;35(7):704–715. doi:10.1093/jpepsy/jsp108. PMCID: PMC2915623

[63] Dahlstro LA, Tran TN, Lundholm C, Young C, Sundstro K, Sparen P. Attitudes to HPV vaccination among parents of children aged 12-15 years—a population-based survey in Sweden. *Int. J. Cancer.* 2010;126:500–7. doi: 10.1002/ijc.24712

[64] Francis SA, Nelson J, Liverpool J, Soogun S, Mofammere N,Thorpe RJ. Examining attitudes and knowledge about HPV and cervical cancer risk among female clinic attendees in Johannesburg, South Africa. *Vaccine.* 2010; 28(50):8026-8032. doi:10.1016/j.vaccine.2010.08.090

[65] Francis SA, Battle-Fisher M, Liverpool J , Hipple L, Mosavel M, Soogun S et al. A qualitative analysis of South African women's knowledge, attitudes, and beliefs about

HPV and cervical cancer prevention, vaccine awareness and acceptance, and maternal-child communication about sexual health. *Vaccine.* 2011;29:8760–8765. doi: 10.1016/j.vaccine.2011.07.116

[66] Etwatwa Community Survey 2012 (Datafile). Statistics South Africa 2011: http://www.statssa.gov.za (last accessed 2017: 03: 10)

[67] Brewer NT, Gottlieb SL, Reiter PL, McRee A, Liddon N, Markowitz L et al. Longitudinal Predictors of HPV Vaccine Initiation among Adolescent Girls in a High-Risk Geographic Area. *Sex Transm Dis.* 2011;38(3):197–204. doi: 10.1097/OLQ.0b013e3181f12dbf

[68] Fazekas K I, Brewer N T, Smith J S. HPV vaccine acceptability in a rural Southern area. *J Womens Health.* 2008;17(4):539-48. doi: 10.1089/jwh.2007.0489

[69] Jaspers L, Budiningsih S, Wolterbeek R, Henderson FC, Peters AA. Parental acceptance of human papillomavirus (HPV) vaccination in Indonesia: a cross- sectional study. *Vaccine.* 2011; 29(44):7785–93. doi: 10.1016/j.vaccine.2011.07.107

[70] Wigle J, Coast E, Watson-Jones D. Human papillomavirus (HPV) vaccine implementation in low and middle-income countries (LMICs): Health system experiences and prospects. *Vaccine.* 2013; 31(37):3811-3817. doi:10.1016/j.vaccine.2013.06.016

[71] Mouallif M, Bowyer H L, Festali S, Albert A, Filali-Zegzouti Y, Guenin S et al. Cervical cancer and HPV: Awareness and vaccine acceptability among parents in Morocco. *Vaccine.* 2014;32(3):409–416. http://dx.doi.org/10.1016/j.vaccine.2013.10.069

[72] Sauvageau C, Duval B, Gilca V, Lavoie F, Ouakki M. Human papilloma virus vaccine and cervical cancer screening acceptability among adults in Quebec, Canada. *BMC Public Health.* 2007;7:304. doi: 10.1186/1471-2458-7-304

[73] Lee PW, Kwan TT, Tam KF, Chan KK, Young PM, Lo SS, et al. Beliefs about cervical cancer and human papillomavirus (HPV) and acceptability of HPV vaccination among Chinese women in Hong Kong. *Prev Med.* 2007;45:130–4. doi: 10.1016/j.ypmed.2007.07.013

[74] Wamai RG, Ayissi CA, Oduwo GO, Perlman S, Welty E, Manga S, et al. Assessing the effectiveness of a community-based sensitization strategy in creating awareness about

HPV, cervical cancer and HPV vaccine among parents in North West Cameroon. *JCH.* 2012;37:917–26. doi: 10.1007/s10900-012-9540-5

[75] Hughes J, Cates JR, Liddon N, Smith JS, Gottlieb SL, Brewer NT. Disparities in how parents are learning about the human papillomavirus vaccine. *Cancer Epidemiology, Biomarkers & Prevention*: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology 2009;18:363–72. doi: 10.1158/1055-9965.EPI-08-0418

[76] Andrea Krawczyk, Bärbel Knäuper, Vladimir Gilca, Eve Dubé, Samara Perez, Keven Joyal-Desmarais & Zeev Rosberger.Parents' decision-making about the human papillomavirus vaccine for their daughters: I. Quantitative results, *Hum Vaccin & Immunother.*.2015;11(2):322-329. doi: 10.1080/21645515.2014.1004030

[77] Goncalves AK, Cobucci RN, Rodrigues HM, de Melo AG, Giraldo PC. Safety, tolerability and side effects of human papillomavirus vaccines: a systematic quantitative review. *Braz J Infect Dis.*2014;18(6):651–9. doi: 10.1016/j.bjid.2014.02.005

[78] Human papillomavirus vaccines: WHO position paper, October 2014-Recommendations. *Vaccine.* 2015;33:4383. doi: 10.1016/j.vaccine.2014.12.002

[79] Zimet GD, Liddon N, Rosenthal SL, Lazcano-Ponce E, Allen B. Chapter2: psycho-social aspects of vaccine acceptability. *Vaccine.* 2006;24(3):S201-S209. doi: 10.1016/j.vaccine.2006.06.017

[80] Zimet GD, Rosberger Z, Fisher WA, Perez S, Stupiansky NW. Beliefs, behaviors and HPV vaccine: correcting the myths and the misinformation. *Prev Med.* 2013;57:414-8. http://dx.doi.org/10.1016/j.ypmed.2013.05.013

[81] Cummings T, Zimet G D, Brown D, Tu W, Yang Z, Fortenberry J D et al. Reduction of HPV infections through vaccination among at-risk urban adolescents. *Vaccine.* 2012;*30*(37):5496-5499. doi: 10.1016/j.vaccine.2012.06.057

[82] Brewer NT, Fazekas KI. Predictors of HPV vaccine acceptability: a theory-informed, systematic review. *Prev Med.* 2007;45:107-14.

http://dx.doi.org/10.1016/j.ypmed.2007.05.013

[83] Forster AS, Marlow LA, Stephenson J, Wardle J, Waller J. Human papillomavirus vaccination and sexual behaviour: cross-sectional and longitudinal surveys conducted in England. *Vaccine.* 2012; 30:4939-44. http://dx.doi.org/10.1016/j.vaccine.2012.05.053

[84] Underwood NL Gargano LM, Jacobs S, Seib K, Morfaw C, Murray D et al. Influence of Sources of Information and Parental Attitudes on Human Papillomavirus Vaccine Uptake among Adolescents. *J Pediatr Adolesc Gynecol.* 2016;29(6):617-622.

doi: 10.1016/j.jpag.2016.05.003

[85] Donati S, Giambi C, Declich S, Salmaso S, Filia A, Atti ML et al. Knowledge, attitude and practice in primary and secondary cervical cancer prevention among young adult Italian women. *Vaccine.* 2012;30(12):2075-82. doi:10.1016/j.vaccine.2012.01.057

[86] Katahoire RA, Jitta J, Kivumbi G, Murokora D, Arube WJ, Siu G et al. An assessment of the readiness for introduction of the HPV vaccine in Uganda. *Afr J Reprod Health.* 2008;12:159–72. PMID:19435020.

[87] Nghi NQ, LaMontagne DS, Bingham A, Rafiq M, Phuong Mai LT, Phuong Lien NT et al. Human papillomavirus vaccine introduction in Vietnam: formative research findings. *Sex Health.* 2010;7:262–70. doi:10.1071/SH09123 PMID:20719213

[88] Marlow LA, Waller JO, Wardle J. Trust and Experience as Predictors of HPV Vaccine Acceptance. *Human Vacc.* 2007; 3(5):171-175. http://dx.doi.org/10.4161/hv.3.5.4310

[89] Haynes R. (2016). Were the 2016 local government elections the beginning of 'politics by consent'? 06 Sept. 2016. https://mg.co.za/article/2016-09-06-were-the-2016-local-government-elections-the-beginning-of-politics-by-consent.
(last accessed on 2017: 03: 30)

[90] Dempsey AF, Zimet GD, Davis RL, Koutsky L. Factors that are associated with parental acceptance of human papillomavirus vaccines: a randomized intervention study of written information about HPV. *Pediatrics* 2006;117:1486–93. doi: 10.1542/peds.2005-1381

[91] Gerend MA, Lee SC, Shepherd JE. Predictors of human papillomavirus vaccination acceptability among underserved women. *Sex Transm Dis.* 2007;34:468–71. doi: 10.1097/01.olq.0000245915.38315.bd

[92] American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics.* 1995;95(2):314-7.

[93] Omer SB, Salmon DA, Orenstein WA, de Hart MP, Halsy N.Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases. N Engl J Med. 2009;360:1981-8. doi: 10.1056/NEJMsa0806477

[94] Healy CM, Pickering LK. How to Communicate With Vaccine-Hesitant Parents Pediatrics 2011; 127: 127-133. doi: 10.1542/peds.2010-1722S

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Annexure 1

SELF - ADMINISTERED QUESTIONNAIRE:

UNDERSTANDING PARENTS' DECISIONS TO ACCEPT OR REJECT HPV VACCINATION FOR THEIR DAUGHTERS

There are approximately 30 questions we would like you to answer, which should take you between 15 – 20 minutes. Please try to answer all questions. The person answering the questions should be the same person who decided whether or not your daughter should receive the HPV vaccine. Thank you!

A) Socio-demographic Profile (Q1- 10)

1. Are you the parent /guardian who decided if your daughter should receive the HPV vaccine

   Yes ☐ No ☐

2. Did you accept or reject the HPV vaccine for your daughter Yes ☐ No ☐

3. What is your relationship to the child who brought home this questionnaire?

   Father ☐ Uncle ☐ Mother ☐

   Grandfather ☐ Aunt ☐ Grandmother ☐

   Others, Pls specify.....

4. In what year were you born?.....

5. What is your sex Male ☐ Female ☐

6. What religion do you currently practice?

   Traditional African belief ☐ Born again Christian ☐

   Moslem ☐ Zion Christian Church (ZCC) ☐ Jehovah 's witness ☐

   Anglican/ Methodist ☐ Others, Please specify ☐

. What language do you usually speak at home?

Afrikaans ☐ English ☐ IsiZulu ☐ IsiNdebele ☐

Sesotho ☐ IsiXhosa ☐ siSwati ☐ Sesotho sa leboa ☐

Tshivenda ☐ Xitsonga ☐ Setswana ☐

. How many times do you attend religious services per week?

0 ☐ 1-2 ☐ >3 ☐

). What is the highest level of school you completed?

Never been to school ☐

Primary school until Grade 8 ☐

Completed Matric (Grade 12) ☐

Some primary school ☐

Some high school ☐

Post-secondary (College/University) ☐

10. Besides your daughter in grade 4 who brought home the questionnaire? List all other living children you have (sons and daughters) Please circle the daughter who brought home the questionnaire.

	Date of Birth	Male/Female
First born		
Child No. 2		
Child No. 3		
Child No. 4		
Child No. 5		

11. Before this Human Papilloma Virus (HPV) vaccine roll-out campaign, had you ever heard about HPV?

Yes ☐ No ☐

12. Before this HPV vaccine roll-out campaign, had you ever heard about cervical cancer (cancer of the mouth of the womb)?

Yes ☐ No ☐

B) The next six (6) questions test your knowledge of the Human Papilloma Virus (HPV). Please check the box that you think is the correct answer.

13. A person may be infected with the HPV virus but not know it.

True ☐ False ☐ Not sure ☐

14. HPV can be transmitted through sex from one person to another.

True ☐ False ☐ Not sure ☐

15. HPV infection can cause cancer of the cervix (mouth of the womb).

True ☐ False ☐ Not sure ☐

16. Cervical cancer can be cured if found early enough.

True ☐ False ☐ Not sure ☐

17. Vaccination is an effective way to prevent infection with HPV.

True ☐ False ☐ Not sure ☐

18. Vaccination is a safe way to prevent infection with HPV.

True ☐ False ☐ Not sure ☐

C) We would like to understand how you made the decision to accept or reject the HPV vaccine for your daughter. Indicate which of the following factors influenced your decision to agree or not agree with vaccinating your daughter at school

	YES	NO
19. My belief that all childhood vaccines are important		
20. The knowledge that HPV vaccine can protect my daughter against cervical cancer (cancer of the mouth of the womb)		
21. The information sent home by the school about the vaccine		
22. The information I received about the vaccine from TV/radio/posters/ newspapers		
23. My worry about possible side effects		
24. My religious beliefs		
25. My daughter's age		
26. My doctor's advice		
27. My family and/or neighbour's advice		
28.The government's recommendation for the vaccine		
29. What I heard in church about the vaccine		
30.The vaccine is being given at school		
31. The vaccine is free		
32. My worry that the vaccine might lead to early sexual activity		
33. My daughter's opinion of the vaccine		

Other factors affecting your decision ....

34. Do you think you have an open communication channel with your daughter on sex topics, including the HPV vaccine?

Yes ☐ No ☐

Thank you very much for completing this questionnaire! Your answers will help us better understand how parents make decisions about vaccinating their daughters with the HPV vaccine. Please give this questionnaire to your daughter to return to school.

If you have any questions, please call: Dr. A. A. Amodu on 0796187030 or 0119997024.

Appendixes

Research Proposal

Ethics Clearance Certificate

Plagiarism Declaration

NAME: AFOLAKE AMODU

STUDENT NO: 700537

DEPARTMENT: FAMILY MEDICINE, THIRD YEAR REGISTRAR

TITLE: *Why should I talk to my 9-year old daughter about sex?* Understanding parents' decisions to participate in the South African government's Human Papilloma Virus (HPV) vaccination programme of schoolgirls in Etwatwa, Gauteng

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ABBREVIATIONS

Advisory Committee on Immunization Practices	ACIP
Age-Standardized Incidence Rate	ASIR
Age-Standardized mortality rate	ASMR
Cervical Intraepithelial Neoplasia	CIN
Expanded Programme on Immunization	EPI
Geometric Mean Concentrations	GMC
Human Immunodeficiency Virus	HIV
Human Papilloma Virus	HPV
Integrated School Health Programme	ISHP
Sexually Transmitted Infection	STI
United States America	USA
World Health Organisation	WHO

INTRODUCTION

Background

Primary prevention of cervical cancer can be achieved by eliminating infection with high-risk Human Papilloma Virus (HPV) serotypes 16 and 18, the acquisition of which is primarily linked to sexual activity.[1,2] The first HPV vaccine; Gardasil, a quadrivalent vaccine effective against HPV serotypes 6, 11, 16 and 18, became available in North America in 2006; while the second one, Cervarix, a bivalent vaccine effective against HPV types 16 and 18 was approved for use in 2009.[1] Both vaccines are safe and almost 100% effective against HPV types 16 and 18, which are the precursors of more than 70% of all cervical cancer cases.[1, 3,]

Estimates from modeling studies show that vaccination of 70% of girls aged 9 - 12 years against HPV types 16 and 18 will result in a 43% reduction in the lifetime risk of cervical cancer.[2] In 2012, more than 528,000 new cases of cervical cancer and 266,000 cervical cancer deaths were reported worldwide [4] accounting for about 13% of all cancer related deaths, 80% of which are in developing countries.[5, 6] This high incidence of cervical cancer in developing countries is a huge threat to women's health and the situation is worsened by poverty, poor medical infrastructure and limited access to health care and other resources.

In Africa, the age-standardized incidence rate for cervical cancer (ASIR) is about 50 per 100,000 women with an age-standardized mortality rate (ASMR) of 40 per 100,000 women.[7] In 1999, about 5743 new cases of cervical cancer were reported in South Africa, with an ASIR of 22.8 per 100,000 women; much higher than the global average of 15.8 per 100,000 and an ASMR of 14.8 per 100, 000 women.[8,9,10] The HIV pandemic in sub-Saharan Africa has also contributed to the growing cervical burden with HIV-seropositive women having a five-fold likelihood of developing cervical cancer compared to HIV sero-negative women.[11] In terms of racial distribution in South Africa, the lifetime risk of a black African woman developing cervical cancer is 1 in 34 compared to 1 in 93 for white women.[3]

Despite such a staggering disease burden, cervical cancer prevention strategies in sub-Saharan Africa have received little attention in comparison to other diseases like HIV/AIDS, tuberculosis and malaria.[12] The decade-long delay in the roll-out of an HPV vaccination programme can be attributed to multiple factors, including: lack of epidemiological data;

unknown incidence of cervical cancer; belief about the vaccine's connection with HPV; the lack of political will in the context of competing interests (such as addressing HIV and TB); as well as financial constraints.[12]

Cervical cancer is more than just a health issue. The disease has serious social and economic implications. Given that cervical cancer affects women in the most productive years of life, between ages 20 and 59, it can be a significant barrier to a country's economic development. Investing in the prevention of cervical cancer is therefore an investment not only in the economic power of women but the country as a whole.[13]

This is the starting point of most HPV vaccine campaigns.

The risk of contracting HPV increases after initiation of sexual activity.[1] This is the reason for vaccinating young adolescents at an early age before sexual debut as the vaccine is thought to prevent transmission.[1] Although, two HPV vaccines were licensed for use by the Medicines Control Council in South Africa since 2008; due to its high cost and calculations of the cost-benefit ratio, it was only in February 2014 that the South African government, through a collaboration between the Departments of Health and Education, began a national HPV vaccination programme for school-going girls aged 9 to 12 years old.[13,14]

The vaccination programme in South Africa kicked off in March 2014 with an invitation jointly signed by the Ministers of Health and Education addressed to parents encouraging them to make use of the vaccination opportunity for their daughters. (Appendix A)

It is this effort that my research attempts to study.

Rationale:

In 2009, the WHO recommended the inclusion of the HPV vaccination in national immunization programmes as well as mass vaccination programmes through school based or outreach programmes.[9] South Africa has an Expanded Programme on Immunization (EPI) programme, which provides free vaccination against childhood diseases, but, the EPI programme only vaccinates children up to age 6 and excludes the targeted age group for HPV vaccine. Hence, the need for a school based campaign of 9-12 year old girls.

Public reaction to the 2014 launch of the HPV vaccine campaign has been mixed with some parents expressing concerns about the vaccination of their daughters.[14] Most however, have given permission for their daughters to receive the vaccine.

Experience from other vaccination programmes around the world indicates that one of the most important factors influencing uptake is the acceptance of the vaccine by parents or caregivers.[15] Understanding how parents make decisions regarding HPV vaccine will assist in packaging the appropriate messages to parents of pre-adolescent girls in order to debunk any myths about HPV vaccination. Further, the knowledge of these factors may inform the development of strategies that can assist with improving the uptake of the vaccination in different communities leading to a reduction in the risk for cervical cancer.

Based on the results from the first of the vaccine series in March 2014, parental acceptance for HPV vaccination is expected to be as high as 85% amongst parents in the Etwatwa community

Research question:

What factors are associated with parents' decisions to participate or not participate in the South African government's HPV vaccination programme being rolled out in the Etwatwa community, Ekurhuleni, Gauteng?

Aim: To determine the rate of acceptance or rejection of the HPV vaccine, and to compare the factors associated with parents' decisions concerning the acceptance or rejection of the vaccination

Objectives:

1. To determine the overall acceptance or rejection of the vaccine, as indicated by the response obtained from the consent forms, of the HPV vaccine of pre-adolescent girls in Etwatwa

2. To examine the socio-demographic profile of the parents including:

i. Sex of the parent/guardian

ii. The age of parent/guardian

iii. The relationship of the adult who consents on behalf of their child

iv. Home language

v. Educational level of the parent/guardian

3. To identify which factors are associated with parents' decisions to vaccinate their daughters for HPV including:

i. Parental knowledge about cervical cancer and HPV vaccination□

ii. Religion and practice□

iii. Number of other children in the family□

iv. Opinions of other stakeholders, like: family members, medical practitioner, religious leaders, neighbours, government recommendation

v. Provision of vaccine in schools□

vi. Vaccine offered at no cost

vli. Parent-daughter communication about sex

Literature Review:

Parental decision-making processes may be culturally or country specific; hence, it is important to conduct studies of vaccine acceptance or rejection in a variety of settings.[16] Five factors have been associated with the successful introduction of cervical cancer vaccines into the public sector health programmes. These include: i) affordability considerations, ii) logistics of vaccine delivery, iii) political will, iv)knowledge of cervical cancer and, v) vaccine acceptability by the parents and community at large.[17]

The last factor is central to this study.

While public education has a definite impact on increasing vaccination uptake, it is uncertain whether increased HPV knowledge will influence the decision making process of parents regarding the HPV vaccine for their daughters.[18]

We have hypothesized that there are other factors besides cost and accessibility that may

influence parents' decisions to vaccinate their daughters. This literature review summarises what is already known about these other factors, albeit from research conducted mainly in developed countries, as few studies exist from developing countries.

Parental acceptance of HPV vaccine

Globally, the parental HPV vaccine acceptance rate ranges between 54.9% and 81.0%.[19] In British Columbia, Canada, a school based immunization programme for grade six girls showed that despite the absence of financial and organizational barriers in this programme, 35% of parents elected not to have their daughters receive the HPV vaccine. This reinforces our hypothesis that there are other determinants of parental HPV vaccine acceptance besides cost and accessibility.[19]

In another study from Indonesia, Jaspers et al reported that HPV vaccine acceptance was as high as 96.1%.[20] The high acceptance rate found in this study is multifactorial. Indonesia has a thriving and extensive national immunization coverage schedule, hence, parents are used to having their children vaccinated. There is significant association between the attitudes of parents towards vaccination in general and HPV vaccine acceptance in this community. Also, the high acceptance rate may be related to the perception that people give socially desirable answers more often and this could have affected the number of positive results obtained from this study. However, this is unlikely as anonymity was maintained during interviews and participants were assured that their responses would not influence their health care or treatment in any form.[20]

In Peru, the vaccine coverage achieved through a school-based HPV vaccination demonstration project was about 82.6 percent. The success of this project was attributed to the information package provided to parents.[21] The HPV vaccine was presented as a vaccine for combating cervical cancer and not as a vaccine related to sexually transmitted infections. This may have strengthened parental confidence in the relevance of considering the future health of their daughters. Limitations of this study include the selection bias of participants because the researcher reportedly contacted parents recommended by schoolteachers as possible-willing participants. Also, there was a relatively small sample size, which may limit the generalizability of the findings.[21]

Factors affecting parental acceptance of HPV vaccine

Socio-demographic profile

In a study by Brewer et al, born-again Christian parents were half as likely as other parents to get their daughters vaccinated with the HPV vaccine.[22] In the United States, the born-again population makes up about 34% of the entire population, and hence carries significant weight. The study also found higher vaccine uptake in girls of parents with a college education than in high school education. However, there was reportedly no difference in parental vaccine acceptance in terms of race, age groups and urbanization. The recommendations made include establishment of public health programs that would target educating and addressing the concerns of born-again Christian parents with the aim of increasing vaccine uptake.[22]

In another study in California, the findings were similar. Born-again and evangelical Christian parents were less likely than other parents to vaccinate their daughters before age 13 than at older ages.[23] This was in comparison to other religious groups, like the Catholics and the infrequent religious-service attenders, who reported higher vaccine acceptability with no age considerations. Strong religious beliefs prohibiting early sexual experience for young girls was the reason for this decision. Other findings in this population include racial differences and education, which impacted on vaccine acceptance. African American and Asian American parents were less likely to accept vaccination for their children compared to Hispanic Americans. Parents with high school education or less were more likely to accept vaccination than their more educated counterparts. An important limitation of this study is the language barrier, which excluded some eligible people within the racial groupings.[23]

In contrast to the previous two studies, a survey by Lenselink et al conducted in Nijmegen, in Eastern Netherlands revealed that religion, age, education and marital status had no significant relationship with parental HPV vaccine acceptance.[18] The findings from this study indicate that the only population characteristic that significantly influenced parental HPV vaccination acceptance was previous parental vaccination history. The limitation in this study was the low response rate of 31% because of poor participation of immigrant parents in the survey due to language barriers.[18]

Knowledge of HPV vaccine

There are dissimilar findings on the relationship between knowledge of HPV vaccination and acceptance of the vaccination. Some studies have found no association between knowledge about HPV vaccination and its influence on parental acceptance of the vaccine while others have reported differently.

In an intervention study by Davis et al in the United States, the use of brief educational fact sheets on HPV, HPV vaccine and cervical cancer increased the knowledge about HPV vaccination and subsequently increased parental acceptance amongst parents of 10-15 year old school children.[24] The study showed that the HPV acceptance level increased from 55% to 75% post intervention ($p \leq 0.001$). Amongst this population, 55% of parents initially accepted the vaccine, 23% did not, and 22% were undecided. Post intervention, 20% of those who had refused previously, and 65% of those who were undecided, changed their minds and consented to the vaccination of their children. The study also showed that the strongest predictor of parental acceptance of HPV vaccine was parental attitude to vaccines in general. Parents who wanted the vaccine for their adolescents believed in the safety and efficacy of vaccines for disease prevention. Further recommendations to facilitate parental acceptance include encouraging doctors' recommendation of the vaccine and mandatory school requirements. Expectedly, parents who opposed the vaccination were against the institution of the vaccine as a school requirement. This may be in rebellion to views of a paternalistic government.[24]

In contrast to the previous study, Dempsey et al, assessed the impact that some educational information about HPV and the HPV vaccine had on vaccine acceptance by parents of children aged 8-12 years.[25] In this study, the intervention group received a brief educational sheet giving some facts about HPV, HPV vaccine and cervical cancer. The findings reflect that although there was some improvement in the mean score of the knowledge assessment tool of the intervention arm, compared with the control arm, that is, 5.57 versus 4.17 respectively ($p \leq$ 001), there was no significant difference between the two groups with respect to the mean parental vaccine acceptability scale scores. The intervention group's parental acceptability score versus control group score was 6.56 to 6.28 respectively ($p = 0.17$).

It can be inferred from the above study that receiving the HPV vaccine brief educational sheet

did not have a significant effect on parental vaccine acceptance. The findings of this study imply that parental beliefs and attitudes may be more influential than knowledge on HPV. Also, the perception of the HPV vaccine as a sexually transmitted infection vaccine may reduce its acceptance, as STI's are still associated with social stigma.[25] The content of educational interventions provided to the community about the HPV vaccine is essential and should not only present factual information but address the socio-cultural myths and misconceptions which may pose barriers to vaccination uptake in different societies.[25]

Age at vaccination

Another predictor of HPV vaccine acceptance amongst parents of pre–adolescent girls is the age of vaccination. A recent study from India identified the relationship between age of vaccination in this community and parental decision on HPV vaccination. The findings of the study indicate that the majority of parents would be more accepting of HPV vaccination if it were administered at older ages. This preference is based on the perception that age at sexarche in India is 22.9 years and may not be applicable in settings where age at sexarche may be much lower.[26]

Opinion of other stakeholders in the society

Traditionally, patients often accept the opinion and recommendations of their doctors without any objections: the paternalistic model of care. While there is a shift towards patient-centeredness and shared decision-making, many patients still seek the advice of their physicians on health matters before taking decisions. Hence, parents who believe that their physician would recommend HPV vaccination for their adolescent daughters are more likely to accept vaccination.[27] The success of HPV vaccination programs, therefore, depends on physicians' willingness and ability to recommend HPV vaccines to their patient.[27] A survey by Mortensen on predictors of HPV vaccination found that more women who had discussed the HPV vaccination frequently with their family, friends or doctors accepted the vaccination much more than those who did not (92% vs 70%).[28]

Another study looked at the reference groups of parents when considering HPV vaccination for their children. Most parents consulted with spouses, family members, friends or their physician and acted based on the advice given by these reference groups. While HPV vaccine

acceptability was reported to be higher among parents who were encouraged to vaccinate by their physician, interestingly parents who opposed the vaccination were less likely to be influenced by their physician. [29]

Barriers to parental acceptance of HPV vaccination

Cost

One of the commonly expressed barriers to receiving HPV vaccine is cost.[3]

Unfortunately, this has been a prime reason for the delay in the provision of HPV vaccine in most developing countries.[25] In Sweden, a developed country, Dahlstro et al's findings indicate that there is a high level of acceptance of the HPV vaccine amongst parents of young adolescents; and, cost is not a major barrier. The acceptance level of parents was 63% for parents who accepted to vaccinate their daughters regardless of having to pay for the vaccine. Only 13.3% of parents indicated that they would accept the vaccine at no cost to them.[30] In comparison to the Swedish study population mentioned above, my study population is Etwatwa, Gauteng where unemployment rates are over 6 times as high as Sweden (87.4% vs 13.7%). South Africa and other GAVI funded countries are overcoming the cost barrier and are able to provide the vaccine gratis to the target group. This may impact positively on the uptake of the vaccine in developing countries.

Perceptions about predisposition to promiscuity

There have been mixed findings on the issue of HPV vaccine predisposing to increased sexual promiscuity. Woodhall et al reported that 42% of parents and 37% of adolescents believed that vaccination for STI increases the likelihood of early sexual debut and promiscuity.[31] In a school-based survey by Marlow et al, concern about the likelihood of the HPV vaccination increasing sexual promiscuity was identified as a deterrent to the vaccination of daughters.[32]

In contrast, Ferris et al's study, demonstrated that about 94% of the parent participants did not consider that the receipt of the HPV vaccine would predispose their sexually naïve children to early sexual experiences.[33] The study compared parental responses with demographic variables and found that parents with children in the 15-17 age bracket, those who were above the age of forty, those who had more than two daughters and those who had moral or religious

objections to vaccines in general, were significantly more likely to believe HPV vaccine would cause sexual promiscuity than other parents who did not fall in these categories.[33]

My inference is that although some parents may have some concerns about HPV vaccination and its association with sexual behavior, the majority of parents recognize that the benefits of the HPV vaccine significantly outweigh the risks, hence, the high rate of vaccine uptake.

Although, not assessed in this study, it is worth mentioning that in Uganda, South Africa, and other African countries, anti-fertility concerns have been raised in relation to vaccines and other health-related products. This reflects underlying suspicions about public health interventions in general.[33]

Conclusion

The burden of cervical cancer is high in South Africa. Since the cause of cervical cancer is HPV, vaccination remains the most effective and available primary prevention method. Against the backdrop of competing health demands, poverty, ignorance, religion, culture, and the establishment of effective inter-sectoral collaboration, efforts need to be made to increase HPV vaccine uptake. Important strategies that have been successful in other countries include education of stakeholders, effective communication and public health outreach programmes. Changing individuals' attitudes and beliefs about their risk of infection may be difficult, but interventions that will correct myths and misconceptions, address concerns and improve the understanding of the risk of HPV infection among pre-adolescents and parents need to be considered. From all the studies reviewed, despite some scientifically unfounded concerns about the safety of HPV vaccination, most parents desired to protect their daughters from cervical cancer and followed vaccine recommendations as evidenced by the high rate of vaccine uptake.

Methodology

Study design

The rates of parental acceptance or rejection of HPV vaccine will be obtained from the consent forms sent home with grade 4 girls at 10 Etwatwa schools. See Appendix B1 for samples of these forms. This counting will be completed by March 2015, the date of administration of the

first dose of HPV vaccine.

Socio-demographic and other factors affecting the decision to vaccinate or not will be obtained via a self-administered questionnaire. This questionnaire will be pilot in 2014 before mass distribution.

The second part is a cross sectional, quantitative descriptive study and will look at the factors that influence parents' decisions to accept or reject the HPV vaccine for their daughters in Etwatwa. 991 invitation letters and questionnaires will be sent home to parents of grade 4 girls between ages 9-12 on the day of vaccine administration. Completing the questionnaire will imply consent to participate in the study.

Reminders will be sent home two weeks later and the survey closed after another two weeks. (See Schema in Appendix C)

Site of Study

The proposed research will be carried out in Etwatwa, a semi–urban sub-locality in the Benoni region of the Ekurhuleni district on the East Rand, Gauteng Province in South Africa. Etwatwa has a population of about 151,866 with 43,483 households. It spans an area of about 20.83 km^2 and has a population density of 7,291.62/km. About 45,786 people are below 15 years of age, close to 30% of the population. The schools located in Etwatwa belong to the Quintile 2 category or no–fee school, a measure of economic disadvantage with 100% of children receiving a food subsidy. According to 2011 Statistics SA census data, 40,352 people are employed whilst 24,096 are unemployed. The most prevalent language is IsiZulu spoken by 45% of the population followed by Xitsonga with 12.97%. [34]

Study Population

The study population is parents/guardians of grade four, 9-12 year old girls attending ten primary schools in Etwatwa.

Sample size:

Sample size calculation is based on estimation of the extent (percentage) parents/guardians who accept the HPV vaccine for their daughter. The focus is on acceptance. The sample size

will be the same if we had focused on 15% rejection (the two outcomes are complementary. This sample size was calculated with the help of a statistician. We projected 85% acceptance rate. Adjusted for a precision of 7.5% (δ=0.075) and at an expected 60% response rate (40% non-response rate).

The sample size estimation was done on n Query Advisor, Release 7.0, and is based on the large sample normal approximation adjusted for a population size of 991. In order to provide for an expected non-response rate of 40% a sample size of 135 parents/guardians is proposed for the study.
This sample of **135** will be drawn proportionately from the ten schools.

Sampling Method

All ten primary schools in Etwatwa will be sampled. All these schools have the same socio-demographic characteristics according to Statistics South Africa.[42]

Inclusion criteria: All participants must be parents of school-attending girls who are eligible for the HPV vaccine and who give consent to participate.

Questionnaire

A self-administered structured questionnaire will be used. (Annexure G) Questions are adapted from three previously validated questionnaires used in studies referenced as 20, 22 and 35. I obtained permission from each of the authors via e-mail to adapt their questionnaires for the purposes of my study. (See Appendix E) My questionnaire is divided into three parts namely; A) socio-demographics characteristics, B) knowledge about HPV and HPV vaccine and C) factors affecting parental acceptance of HPV vaccination. Questions 3-17 were obtained from the questionnaire used by Jaspers L, Budiningsih S, Wolterbeek R, Henderson F.C, Peters A.A.W. Parental acceptance of human papillomavirus (HPV) vaccination in Indonesia: A cross-sectional study. *Vaccine* 2011; 29(44): 7785–7793.

Questions 1-2 and 31-32 were adapted from Brewer NT, Gottlieb SL, Reiter PL, McRee A, Liddon N, Markowitz L et al. Longitudinal Predictors of HPV Vaccine Initiation among Adolescent Girls in a High-Risk Geographic Area. *Sex Transm Dis.* 2011; 38(3): 97–204

These questions explore shared decision making about the vaccination as well as the parent-daughter communication about HPV and sex topics.

Finally, questions 18-30 were adapted from the questionnaire used in the study Fazekas K I, Brewer N T, Smith J S. HPV vaccine acceptability in a rural Southern area. *Journal of Women's Health* 2008; 17(4): 539-48

My questionnaire will be translated into IsiZulu, then translated back into English to ensure the validity and non-distortion of the questions asked.

Pilot Study

Twenty questionnaires will be sent home through convenience sampling to parents of grade 4 girls who accepted the HPV vaccination and ten questionnaires to parents who rejected the vaccination during the vaccination programme in 2014 for face validity in South Africa.

Ethical considerations and confidentiality

Permission to conduct the study will be obtained from the University of Witwatersrand Human Research Ethics Committee (HREC), Ekurhuleni Health District Research Committee (DRC) and the Department of Basic Education (Appendix F).

No names will be required in the questionnaires. All collected data will be stored on my computer and the information will be accessible to the researcher and supervisor only. Codes will be assigned to all data files stored on the computer using a password known only to the researcher and supervisor.

Informed Consent

Invitation letters to participate in the study will be printed on two different coloured papers (red for parents who accepted the vaccine and blue for parents who rejected the vaccine). (Appendix D) The invitation letters will accompany the questionnaires to be sent home on the day of vaccination in 2015 to the parents through their daughters and follow up reminder letters will be sent home two weeks later. Filling the questionnaire implies consent

Data Analysis and Management:

The rate of acceptance will be estimated followed by a comparison of the factors for the acceptance and rejection groups.

The various variables will be compared separately between the acceptance and rejection groups. Section B of the self-administered questionnaire deals with the Exposure: Knowledge, has six questions. The number of questions answered correctly will be counted and expressed as a percentage out of six as an overall measure of the respondents' knowledge. Mean values of the percentages for the acceptance /rejection groups will then be compared by a t test or a non- parametric Wilcoxon rank sum test.

A logistic regression analysis will be performed with acceptance (Yes or No) as dependent variable and gender, age, religion, home language, education, knowledge, number of other children, opinions of stakeholders, provision of vaccine and parent-daughter communication as predictor variables towards acceptance. Statistical analysis will be done with the help of a statistician.

All statistical procedures will be performed on SAS, release 9.3, running under Microsoft Windows for a personal computer. Statistical significance testing will be at the 0.05(5%) level. (See table below)

Summary table on my planned data Analysis

OBJECTIVES	VARIABLES	METHOD OF ANALYSIS
Acceptance	**Outcome** :(Yes/No)	Proportions
A1. Socio-demographics	**Outcomes:** Sex Age groups Religion Home language Education	Proportions Mean(+ S. D.) Proportions Proportions Proportions
A2. Socio-demographics (Association)	**Outcome:**Acceptance/Rejection Exposure: Sex **Outcome**: Acceptance/Rejection Exposure: Age groups **Outcome**: Acceptance/ Rejection Exposure: Religion **Outcome**: Acceptance/Rejection Exposure: Home language **Outcome**: Acceptance/Rejection Exposure: Education	Chi-square Chi- square Chi –square Chi-square Chi-square
B) Knowledge	**Outcome**: Acceptance/Rejection Exposure: Knowledge	Percentage% of total from the 6 questions Comparisons of the mean values of the % of the acceptance /rejection groups will be done by a t test or a nonparametric Wilcoxon rank sum test
C) Factors associated with parents decision (accept or reject vaccination)	**Outcome**: Acceptance/Rejection Exposure: No of other children in the family **Outcome**: Acceptance/Rejection Exposure: Opinions of stakeholders **Outcome**: Acceptance/Rejection Exposure: Provision of vaccine in schools **Outcome**: Acceptance/Rejection Exposure: Vaccine offered at no cost **Outcome**: Acceptance/Rejection Exposure: Parent-daughter communication about sex	Chi-square Chi-square Chi-square Chi-square Chi-square

Time line: Gaant Chart

Activities	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Submit proposal to Wits HREC										
Obtain HREC Approval										
Meet with 10 school principals and 2 district based school nurses										
Translate to IsiZulu										
Pilot questionnaires										
Obtain the results of the consent forms (Yes /No). Send home questionnaires on vaccination day										
Data entry and preliminary analysis										
Completion of analysis and results and discussion										
Writing retreat Review and corrections Of research work before submission										

Budget

1. Printing of 1000 copies of double-sided 3 paged questionnaires at R1.70 each. .....R5100.00 □

2. Printing of 1000 copies of a double-sided 1 paged invitation letter on colored paper at R2.80 each..... R2800.00 □

3. Printing of 1000 copies of reminders.....R1000.00

4. Transportation cost of researcher to schools. From Phillip Moyo CHC to the ten schools covers 150km at R3.24 per km. (SARS recommended price for reimbursement for

transportation. □.....R1500 .00

5. Payment for translation to IsiZulu and back translation.....R1000.00

6. Payment to Statistician for data analysis R2500.00

7. Printing ink for the letters and questionnaires.....R600.00 □

8. Printing paper (TYPEK) X4.....R200.00

9.Tokens of appreciation (gift card) for the 2 district nurses at R250 each □.....R500.00

10. Envelopes x1000 at R3.00 each..... R3000.00

Total cost **R18200.00**

References

[1] Litton AG, Desmond RA, Gilliland J, Huh WK, Franklin FA. Factors associated with intention to vaccinate a daughter against HPV: A statewide survey in Alabama. *J Pediatr Adolesc Gynecol.* 2011; 24: 166-71

[2] Moodley I, Thatiah N, Mubaiwa V, Deeny L. High uptake of Gardasil vaccine among 9 – 12 - year- old schoolgirls participating in an HPV vaccination demonstration project in Kwazulu – Natal, South Africa. *S Afr Med J.* 2013; 103 (5): 318-21

[3] Moodley M, Cervical cancer in Southern Africa: The challenges. *South Afr J Gynaecol Oncol* 2009; 1(1): 11 -14

[4] D'Addario M, Scott P, Redmond S, Low N. Evidence based recommendations on Human Papilloma Virus (HPV) Vaccines Schedules. Background paper for SAGE discussions March 11,2014. (last 23-07-2014). Available from http://www.who.int/immunization/sage/meetings/2014/april/1_HPV_Evidence_based_recommendationsWHO_with_Appendices2_3.pdf?ua=1

[5] Hoque ME, Ghuman S, Van Hal G. Human papilloma virus vaccination acceptability among female university students in South Africa. *Asian Pac J Cancer Prev* 2013; 14(8): 4865- 9

[6]Denny LA, Franceschi S, de Sanjose S. Human papillomavirus, Human Immunodeficiency Virus and Immunosuppression. *Vaccine* 2012; 30 Suppl 5: F168-74.

[7] Francis SA, Battle –Fischer M, Liverpool J, Hipple L, Mosavel M, Soogun S et al. A qualitative analysis of South African women's knowledge, attitudes and beliefs about HPV and cervical cancer prevention, vaccine awareness and acceptance, and maternal-child communication about sexual health. *Vaccine* 2011; 29: 8760-5.

[8] Bello FA, Enabor OO, Adewole IF. Human papilloma virus vaccination for control of cervical cancer: A challenge for developing countries. *Afr J Reprod Health* 2011; 15(1): 25- 30.

[9] WHO/ICO Information Centre on HPV and Cervical Cancer (HPV Information Centre), Human papilloma virus and related cancers in South Africa. Summary report. Geneva: World Health Organisation, 2010. http://www.who.int/hpvcentre (last accessed 15-02-2014)

[10] Richter K, Becker P, Horton A, Dreyer G. Age specific prevalence of cervical human papillomavirus infection and cytological abnormalities in women in Gauteng Province, South Africa. *S Afr Med J.* 2013; 103 (5): 313-317

[11] Katz IT, Nkala B, Dietrich J, Wallace M, Bekker L, Pollenz K et al. A qualitative analysis of factors influencing HPV vaccine uptake in Soweto, South Africa among adolescents and their caregivers. *PLoS ONE* 2013; 8(8): 1-7
doi:10.1371/journal.pone.0072094 (last accessed 16-02-2014)

[12] Louie KS, de Sanjose S, Mayaud P. Epidemiology and prevention of human papilloma virus and cervical cancer in Sub-Saharan Africa: a comprehensive review. *Trop Med Int Health.* 2009; 14(10): 1287-302.

[13] Ramatamo S. It's no breeze to explain birds 'n bees. The Mail and Guardian 02 May 2014.(last accessed 07-11-2014)

[14]National Department of Health. National School Health Policy and Implementation Guidelines 2011. Pretoria: National Department of Health, 2011

[15] Gordon D, Waller J, Marlow LA. Attitudes to HPV vaccination among mothers in the British Jewish community: reasons for accepting or declining the vaccine. *Vaccine* 2011; 29: 7350-7356

[16] Lenselink CH, Gerrits MJG , Melchers WJG, Massuger L F, van Hamont D, Bekkers RL. Parental acceptance of Human papillomavirus vaccines. *Eur J Obstet Gynecol Reprod Biol.* 2008; 137(1): 103-7

[17] Winkler JL, Witter S, Bartolini RM, Creed-Kanashiro HM, Lazcano- Ponce E, Lewis-Bell K et al. Determinants of human papilloma virus vaccine acceptability in Latin America and the Caribbean. *Vaccine* 2008; 26(11): 73-79

[18] Pitts MJ, Tufts KA. Implications of the Virginia Human papillomavirus vaccine mandate for parental vaccine acceptance. *Quality Health Research* 2012; 23(5): 605-17.

[19] Ogilvie G, Anderson M, Marra F, McNeil S, Pielak K, Dawar M et al. A Population-Based Evaluation of a Publicly Funded, School-Based HPV Vaccine Program in British Columbia, Canada: Parental Factors Associated with HPV Vaccine Receipt. *PLoS Med 2010;* 7(5): e1000270- 73
doi: 10.1371/journal.pmed.1000270

[20] Jaspers L, Budiningsih S, Wolterbeek R, Henderson F.C, Peters A.A.W. Parental acceptance of human papillomavirus (HPV) vaccination in Indonesia: A cross-sectional study. *Vaccine* 2011; 29(44): 7785–7793

[21] Bartolini RM, Winkler JL, Penny ME, La Montagne DS. Parental Acceptance of HPV Vaccine in Peru: A Decision Framework. *PLoS ONE* 2012; 7(10): e48017. doi: 10.1371/journal.pone.0048017(last accessed 10-05-2014)

[22] Brewer NT, Gottlieb SL, Reiter PL, McRee A, Liddon N, Markowitz L et al. Longitudinal Predictors of HPV Vaccine Initiation among Adolescent Girls in a High-Risk Geographic Area. *Sex Transm Dis.* 2011; 38(3): 197–204

[23] Constantine NA, Jerman P. Acceptance of human papillomavirus vaccination among Californian parents of daughters: a representative statewide analysis. *J Adolesc Health* 2007; 40(2): 108–15

[24] Davis K, Dickman ED, Ferris D, Dias JK. Human Papillomavirus Vaccine Acceptability Among Parents of 10- to 15-Year-Old Adolescents. *Journal of Lower Genital Tract Disease* 2004; 8 (3): 188-94

[25] Dempsey AF, Zimet GD, Davis RL, Koutsky L. Factors that are associated with parental acceptance of Human papillomavirus vaccines: a randomized intervention study of written information about HPV. *Pediatrics* 2006; 117: 1486

[26] Madhivanan P, Srinivas V, Marlow L, Mukherjee S, Narayanappa D, Mysore S et al. Indian parents prefer vaccinating their daughters against HPV at older ages. *Asian Pac J Cancer Prev.* 2014; 15(1): 107-110.

[27] Olshen E, Woods ER, Austin SB, Luskin M, Bauchner H. Parental acceptance of the human papillomavirus vaccine. *Journal of Adolesc Health* 2005; 37: 248–51

[28] Mortensen: Drivers and barriers to acceptance of human-papillomavirus vaccination among young women: a qualitative and quantitative study. *BMC Public Health* 2010; 10: 68

[29] Reynolds D, O'Connell KA. Testing a Model for Parental Acceptance of Human Papillomavirus Vaccine in 9- to 18-Year-Old Girls: A Theory-Guided Study. *Journal of Pediatric Nursing* 2012; 27: 614-25

[30] Dahlstro LA, Tran TN, Lundholm C, Young C, Sundstro K, SparenP. Attitudes to HPV vaccination among parents of children aged 12-15 years—a population-based survey in Sweden. *Int. J. Cancer* 2010; 126: 500–7

[31] Woodhall SC, Lehtinen M, Verho T, Huhtala H, Hokkanen M, Kosunen E, Anticipated Acceptance of HPV Vaccination at the Baseline of Implementation: A Survey of Parental and Adolescent Knowledge and Attitudes in Finland. *Journal of Adolesc Health* 2007; 40(5): 466–69

[32] Marlow LA, Waller J, Wardle J. Parental attitudes to pre-pubertal HPV vaccination. *Vaccine* 2007; 25(11): 1945-52

[33] Ferris AG, Cromwell L, Waller JL, Horn L. Most Parents Do Not Think Receiving Human Papillomavirus Vaccine Would Encourage Sexual Activity in Their Children. *Journal of Lower Genital Tract Disease* 2010; 14 (3): 179-84

[34] Statistics South Africa. Thomas Brinkhoff: City Population. http://www.citypopulation.de (last accessed on 09-08-2014)

[35] Fazekas K I, Brewer N T, Smith J S. HPV vaccine acceptability in a rural Southern area. *Journal of Women's Health* 2008; 17(4): 539-48

Appendix A

Basic Education
Health

15 January 2014

Dear Parent/Guardian/Caregiver

Invitation to receive Human Papillomavirus (HPV) vaccination

Cervical cancer is an important health problem in our country. As Ministers this is of great concern to us because:

- It is one of the most common cancers affecting women in South Africa
- Many women die from cervical cancer

The leading cause of cervical cancer is the human papillomavirus which we call HPV. We now have a very safe vaccine which protects against HPV and cervical cancer. The World Health Organization recommends that this vaccine be given to young girls.

The South African government is for the first time offering the HPV vaccination to all girls in grade 4 throughout the country.

It gives us great pleasure to invite your daughter to receive this vaccination at her school.

She will receive the first dose of the HPV vaccine in March 2014 and then the second dose will be given to her in September-October 2014.

This vaccination cannot be given to your daughter without your permission. If you would like to take up our invitation please complete the attached consent documents.

For more information about the HPV vaccine you can talk to the clinic sister or visit the Department of Health website: www.doh.gov.za

Yours faithfully

Dr A Motsoaledi, MP
Minister of Health

Ms A Motshekga, MP
Minister of Basic Education

Appendix B_1

Basic Education
Health

Human Papillomavirus (HPV) Vaccination Consent* Form

The Department of Health in partnership with the Department of Basic Education and other partners will be introducing the Human Papillomavirus (HPV) vaccination programme in schools as part of the Integrated School Health Programme (ISHP). The HPV vaccination programme aims to reduce the number of cases of cervical cancer in the country. Cervical cancer is one of the most common cancers in women and many women die from it. HPV, which is a sexually transmitted infection, is the leading cause of cervical cancer. HPV infection can be prevented if young girls receive the HPV vaccination early in life which will reduce their chances of developing cervical cancer later in life.

The HPV vaccination is being provided to all Grade 4 girls who are nine years and older. The HPV vaccination is given in two doses, the first dose will be given in March/April and the second dose will be given in September/October, 6 months after the first dose. Participation in the HPV vaccination programme is **voluntary** and your child's privacy and confidentiality will be maintained. Parents/guardian/caregivers of all Grade 4 girls will be required to sign this consent form. There is further information on the HPV vaccination programme on the other side of this page. Contact the school principal or local clinic should you require any additional information.

Please note that the HPV vaccination **cannot be given** to girls who are under 9 years, or if they have had a recent severe illness, or are very ill on the day of the vaccination. The HPV vaccination will also not be given to girls who are pregnant or have already had the HPV vaccination.

Please complete and sign the consent form below, provide information about your child's health on the other side of the form and return this form to school.

*Consent means giving permission for your child to participate in the programme.

**Girls who are 12 years and older can assent by signing in the space provided.

Cut Here

Reply Slip HPV Vaccine : **Please complete both sides of this section and return to school**

Name of learner: _____ Surname: _____

I.D. Number of learner: _____ Date of birth: _____

Name of School: _____ Grade : _____

I _____ hereby **grant/do not grant** permission for my child
(name and surname of parent/guardian/cage giver) *(delete which is not applicable)*

_____ to receive two doses of the HPV vaccination.
(name and surname of child)

I understand that participation in the HPV vaccination programme is voluntary.

_____ _____

Signature of Parent/Guardian/Caregiver ****Girls 12 yrs and older can assent by signing here**

Some facts about the HPV vaccination

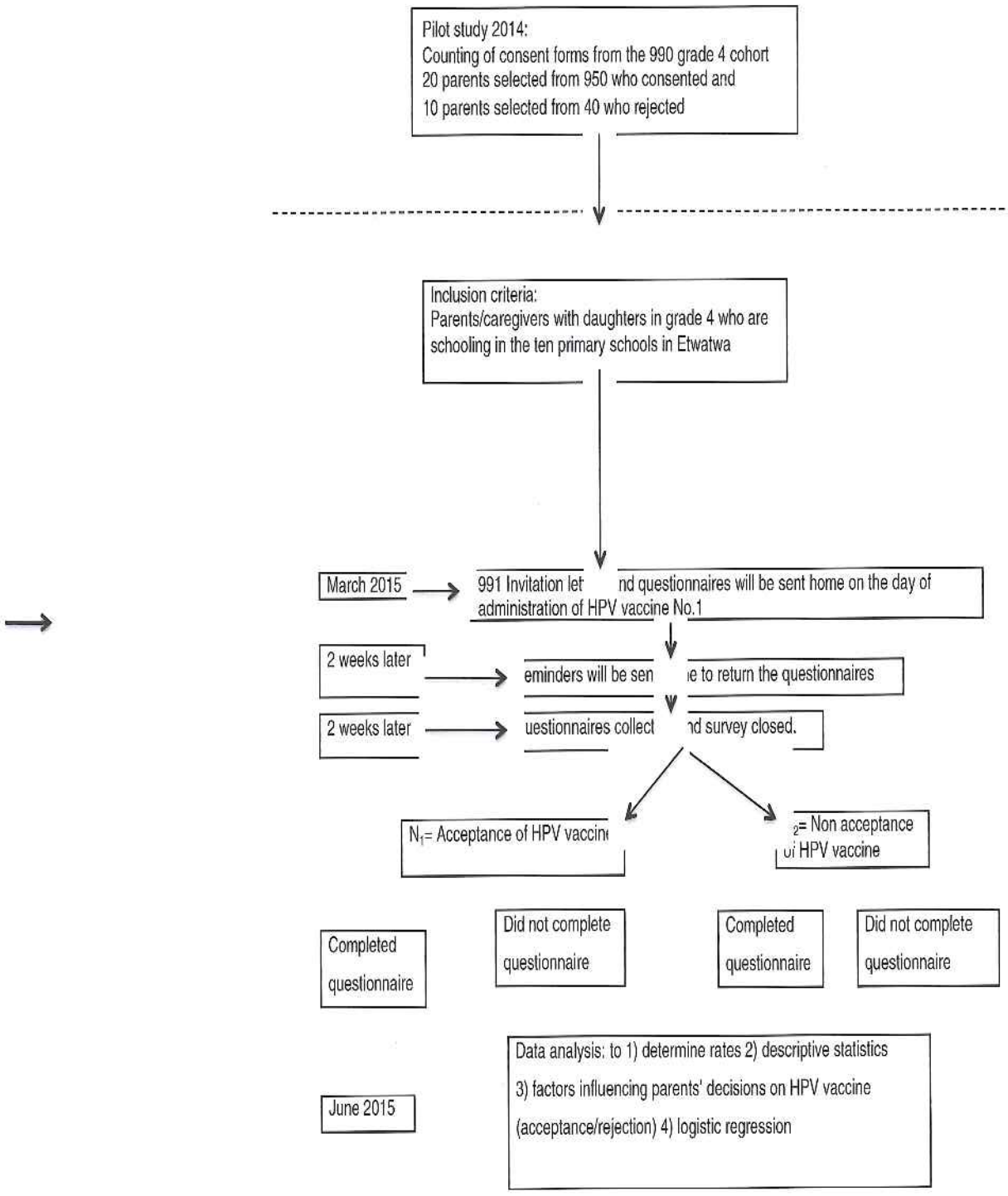
1. The **vaccine is safe** with minimal risk to the girl.
2. The vaccination will be given as an injection by nurses that will visit schools.
3. The injection is given in the upper arm.
4. The child will feel the needle prick.
5. After vaccination the arm may feel a little sore and red.
6. Do not apply anything to the arm to avoid infection.
7. There is a very small chance of developing a slight fever, headache, dizziness or feeling faint.
8. If any of these problems get worse go to the nearest clinic or hospital and take the HPV immunisation card with you.
9. Also report the incident to your school principal or class teacher as soon as you return to school.
10. All information provided will be kept confidential.

Cut Here

Please also complete this section **Medical History**	**Answer "Yes" or " No" with a cross X in the box below**
In the past has your daughter had a reaction to any vaccination or had any problems after a vaccination ? (For example an allergic reaction)	Yes / No
If yes explain what happened:	
Does your daughter have a problem with prolonged bleeding?	Yes / No
If yes please explain:	

Appendix C

STUDY DESIGN FOR PROPOSED RESEARCH



Appendix D_1

Information sheet to parents who accepted the HPV vaccine

Date

Dear Parent(s),

Congratulations!

Your daughter received her first HPV vaccine today at school.

I am Dr. A. A. Amodu, a medical doctor studying at the University of the Witwatersrand to become a specialist in Family Medicine.

As part of my training, I am studying why parents decide to accept the Human Papilloma Virus (HPV) vaccination for their daughters in Etwatwa
I would like to invite you to participate in my research study.

Why am I doing this study?

Research from other countries has made the South African government decide to give the HPV vaccination to all grade 4 girls in order to prevent cervical cancer (cancer of the mouth of the womb). I would like to find out what has made you decide to accept the HPV vaccination for your daughter.

What do I expect from you as a participant in this study?

I would like you to read and answer the questions that are attached to this letter. I estimate that it will take you between 15 and 20 minutes to do this. I do not need your name or ID number. I do, however, ask information about your year of birth, your language at home, educational background and family profile. When you are finished answering all the questions, please put the questionnaire in the envelope provided and send it back to school with your daughter. If you complete the questionnaire, I will assume that you are happy to take part in my study.

May I refuse or withdraw from the study?

Yes, you are under no pressure to take part in my study. Taking part in my study is completely voluntary. You do not have to answer any of these questions—and, once you start filling in the survey, you can stop at any time. If you decide for any reason not to answer all of the questions, there will be no penalty to either you or your daughter.

What about confidentiality?

I am not collecting information that can be traced back to you or your daughter because I do not need your ID number or name. The questions you complete will be kept locked in an office. The information from many parents will be looked at together; and, I will write up a report when I am finished putting together everyone's responses.

What about protection?

The Wits University Human Research Ethics Committee (HREC) has approved this study. The contact details are as follows: Professor Peter Cleaton-Jones, Chairperson HREC (Medical) on 011 717 2301, email- peter.cleaton-jones1@wits.ac.za. Secretariat: Ms Zanele Ndlovu and Mr Langutani Masingi, zanele.ndlovu@wits.ac.za, langutani.masingi@wits.ac.za on 011 717 1252/2700/1234/2656. If you would like more information about my study, please call the Supervisor for this Research project, Professor Laurel Baldwin-Ragaven (Head of Department, Family Medicine, University of Witwatersrand) on 011 717 2058, email- Laurel.Baldwin-Ragaven@wits.ac.za.

Once again, if you complete the questions and return them back to school with your daughter, you are giving your permission to take part in my study.

Thank You.

Dr. A. A. Amodu

Appendix D_2

Information sheet to parents who rejected the HPV vaccine

Date

Dear Parent(s),

Your daughter did not receive the first dose of the HPV vaccine today at school.

I am Dr. A. A. Amodu, a medical doctor studying at the University of the Witwatersrand to become a specialist in Family Medicine.

As part of my training, I am studying why parents decide to reject the Human Papilloma Virus (HPV) vaccination for their daughters in Etwatwa.
I would like to invite you to participate in my research study.

Why am I doing this study?
Research from other countries has made the South African government decide to give the HPV vaccination to all grade 4 girls in order to prevent cervical cancer (cancer of the mouth of the womb). I would like to find out what has made you decide not to accept the HPV vaccination for your daughter.

What do I expect from you as a participant in this study?
I would like you to read and answer the questions that are attached to this letter. I estimate that it will take you between 15 and 20 minutes to do this. I do not need your name or ID number. I do, however, ask information about your year of birth, your language at home, educational background and family profile. When you are finished answering all the questions, please put the questionnaire in the envelope provided and send it back to school with your daughter. If you complete the questionnaire, I will assume that you are happy to take part in my study.

May I refuse or withdraw from the study?

Yes, you are under no pressure to take part in my study. Taking part in my study is completely voluntary. You do not have to answer any of these questions—and, once you start filling in the survey, you can stop at any time. If you decide for any reason not to answer all of the questions, there will be no penalty to either you or your daughter.

What about confidentiality?

I am not collecting information that can be traced back to you or your daughter because I do not need your ID number or name. The questions you complete will be kept locked in an office. The information from many parents will be looked at together; and, I will write up a report when I am finished putting together everyone's responses.

What about protection?

The Wits University Human Research Ethics Committee (HREC) has approved this study. The contact details are as follows: Professor Peter Cleaton-Jones, Chairperson HREC (Medical) on 011 717 2301, email- peter.cleaton-jones1@wits.ac.za. Secretariat: Ms Zanele Ndlovu and Mr Langutani Masingi, zanele.ndlovu@wits.ac.za, langutani.masingi@wits.ac.za on 011 717 1252/2700/1234/2656. If you would like more information about my study, please call the Supervisor for this Research project, Professor Laurel Baldwin-Ragaven (Head of Department, Family Medicine, University of Witwatersrand) on 011 717 2058, email- Laurel.Baldwin-Ragaven@wits.ac.za.

Once again, if you complete the questions and return them back to school with your daughter, you are giving your permission to take part in my study.

Thank You.

Dr. A. A. Amodu

Appendix E

PERMISSIONS FROM AUTHORS FOR USE OF QUESTIONNAIRES

A) From: Lisen Arnheim Dahlström <lisen.arnheim.dahlstrom@ki.se>
Subject: Re: Request for use of questionnaire
Date: 19 May 2014 8:42:04 AM SAST
To: folake amodu <flakypee@yahoo.com>

Dear Dr Amodu,

Please find the questionnaires in English attached. Good luck with your study and in improving vaccination coverage.
Don't hesitate to contact me if you have any questions regarding the questionnaires.

Kind regards
Lisen Arnheim-Dahlström
Lisen Arnheim Dahlström, Associate Professor (Docent)

Institutionen för medicinsk epidemiologi och biostatistik
Department of Medical Epidemiology and Biostatistics
Karolinska Institutet
Nobels väg 12A
171 77 Stockholm, Sweden

Phone: +46 8 5248 2364
Mobile: + 46 709 495 221

B) From: Loes Jaspers <loesjaspers@gmail.com>
Subject: Re: Request for questionnaire use.
Date: 28 May 2014 9:17:13 PM SAST
To: "Dr. afolake adeola amodu" <flakypee@yahoo.com>

Dear dr. Amodu,

Thanks for your e-mail. It is great news to hear that HPV vaccination has started in South-Africa; and unfortunate to hear that parents are refusing it. I hope your study can give some

insights in the felt barriers.

Please find attached the questionnaire that we used in our study.
Please let me know if you have any questions that remain, I would be happy to answer them.

If you remember by the time you are finished, I would be very interested to read the results of your study.

Good luck!
Regards,
Loes Jaspers
Oude Boomgaardstraat 61
2513 TP Den Haag
Tel: 0031-6-38046883

C) From: "Marlow, Laura" <l.marlow@ucl.ac.uk>
Subject: RE: Request for use of questionnaire
Date: 27 May 2014 9:31:39 AM SAST
To: "Wardle, Jane" <j.wardle@ucl.ac.uk>, "Dr. afolake adeola amodu" <flakypee@yahoo.com>

Dear Dr Amodu,

I have attached the questionnaire we used for this study along with some notes on where the items came from (many were adapted from previous studies).

If you have any further questions I'd be happy to help. Good luck with your work.

Kind Regards,
Laura Marlow.

Dr Laura Marlow□Cancer Research UK Post-doctoral Fellow□Health Behaviour Research Centre□Department of Epidemiology & Public Health, UCL□Gower Street London WC1E 6BT UK□Tel: 020 7679 1798□www.ucl.ac.uk/hbrc/screening/marlowl□l.marlow@ucl.ac.uk

D)From: "Yeganeh, Nava" <NYeganeh@mednet.ucla.edu>
Subject: RE: Request for questionnaire
Date: 18 July 2014 6:52:39 PM SAST
To: folake amodu <flakypee@yahoo.com>

Of course. I've attached the survey to this email. Good luck with your endeavors.

Nava Yeganeh MD, MPH
Department of Pediatrics
Division of Infectious Diseases
David Geffen School of Medicine at UCLA
10833 Le Conte Ave. MDCC 22-442
Los Angeles, CA 90095-1752
Phone: 310-825-5235
Fax: 310-206-4764

education
Department: Education
GAUTENG PROVINCE

Enq: Poovan Chetty
Directorate: EOS
Tel :0844125969

GAUTENG EAST DISTRICT

TO : The School Principals
The Ethics Committee

FROM : Poovan Chetty
Education Operations and Support

DATE : 05 November 2014

SUBJECT : Confirmation/Approval – Dr A Amodu

The Gauteng East District hereby grants permission for Dr. A. Amodu, Registrar, Family Medicine University of Witwatersrand to conduct her research at the following schools based in the Etwatwa Region.

1. Zamukhanyo Primary
2. Thembelihle Primary
3. Kgolagano Primary
4. Tshipi Noto Primary
5. George Mbilase Primary
6. Dan Pharasi Primary
7. JS Malaza Primary
8. Thopodi Primary
9. Rolihlahla Primary
10. WJ Mpengesi Primary

We do hope that the above letter serves as confirmation for her approval for her studies in our District.

Thank You

Poovan Chetty
Policy and Planning

Appendix G

SELF - ADMINISTERED QUESTIONNAIRE:

UNDERSTANDING PARENTS' DECISIONS TO ACCEPT OR REJECT HPV VACCINATION FOR THEIR DAUGHTERS

There are approximately 30 questions we would like you to answer, which should take you between 15 – 20 minutes. Please try to answer all questions. The person answering the questions should be the same person who decided whether or not your daughter should receive the HPV vaccine. Thank you!

A) Socio-demographic Profile (Q1- 10)

1. Are you the parent /guardian who decided if your daughter should receive the HPV vaccine

   Yes ☐ No ☐

2. Did you accept or reject the HPV vaccine for your daughter Yes ☐ Nc ☐

3. What is your relationship to the child who brought home this questionnaire?

   Father ☐ Uncle ☐ Mother ☐

   Grandfather ☐ Aunt ☐ Grandmother ☐

   Others, Pls specify.....

4. In what year were you born?.....

5. What is your sex Male ☐ Female ☐

6. What religion do you currently practice?

Traditional African belief ☐ Born again Christian ☐

Moslem ☐ Zion Christian Church (ZCC) ☐ Jehovah 's witness ☐

6. What religion do you currently practice?

Traditional African belief ☐ Born again Christian ☐

Moslem ☐ Zion Christian Church (ZCC) ☐ Jehovah 's witness ☐

Anglican/ Methodist ☐ Others, Please specify ☐

7. What language do you usually speak at home?

Afrikaans ☐ English ☐ IsiZulu ☐ IsiNdebele ☐

Sesotho ☐ IsiXhosa ☐ siSwati ☐ Sesotho sa leboa ☐

Tshivenda ☐ Xitsonga ☐ Setswana ☐

8. How many times do you attend religious services per week?

0 ☐ 1-2 ☐ >3 ☐

9. What is the highest level of school you completed?

Never been to school ☐

Primary school until Grade 8 ☐

Completed Matric (Grade 12) ☐

Some primary school ☐

Some high school ☐

Post-secondary (College/University) ☐

10. Besides your daughter in grade 4 who brought home the questionnaire? List all other living children you have (sons and daughters) Please circle the daughter who brought home the questionnaire.

	Date of Birth	Male/Female
First born		
Child No. 2		
Child No. 3		
Child No. 4		
Child No. 5		

11. Before this Human Papilloma Virus (HPV) vaccine roll-out campaign, had you ever heard about HPV?

Yes ☐ No ☐

12. Before this HPV vaccine roll-out campaign, had you ever heard about cervical cancer (cancer of the mouth of the womb)?

Yes ☐ No ☐

B) The next six (6) questions test your knowledge of the Human Papilloma Virus (HPV). Please check the box that you think is the correct answer.

13. A person may be infected with the HPV virus but not know it.

True ☐ False ☐ Not sure ☐

14. HPV can be transmitted through sex from one person to another.

True ☐ False ☐ Not sure ☐

15. HPV infection can cause cancer of the cervix (mouth of the womb).

14. HPV can be transmitted through sex from one person to another.

True ☐ False ☐ Not sure ☐

15. HPV infection can cause cancer of the cervix (mouth of the womb).

True ☐ False ☐ Not sure ☐

16. Cervical cancer can be cured if found early enough.

True ☐ False ☐ Not sure ☐

17. Vaccination is an effective way to prevent infection with HPV.

True ☐ False ☐ Not sure ☐

18. Vaccination is a safe way to prevent infection with HPV.

True ☐ False ☐ Not sure ☐

C) We would like to understand how you made the decision to accept or reject the HPV vaccine for your daughter. Indicate which of the following factors influenced your

	YES	NO
19. My belief that all childhood vaccines are important		
20. The knowledge that HPV vaccine can protect my daughter against cervical cancer (cancer of the mouth of the womb)		
21. The information sent home by the school about the vaccine		
22. The information I received about the vaccine from TV/radio/posters/ newspapers		
23. My worry about possible side effects		
24. My religious beliefs		
25. My daughter's age		
26. My doctor's advice		
27. My family and/or neighbour's advice		
28.The government's recommendation for the vaccine		
29. What I heard in church about the vaccine		
30.The vaccine is being given at school		
31. The vaccine is free		
32. My worry that the vaccine might lead to early sexual activity		
33. My daughter's opinion of the vaccine		

Other factors affecting your decision ....

4. Do you think you have an open communication channel with your daughter on sex ›pics, including the HPV vaccine?

Yes ☐ No ☐

hank you very much for completing this questionnaire! Your answers will help us etter understand how parents make decisions about vaccinating their daughters with ıe HPV vaccine. Please give this questionnaire to your daughter to return to school.

you have any questions, please call: Dr. A. A. Amodu on 0796187030 or 119997024.

Appendix H

OBJECTIVES	VARIABLES	METHOD OF ANALYSIS
Acceptance	**Outcome** :(Yes/No)	Proportions
A1. Socio-demographics	**Outcomes:** Sex Age groups Religion Home language Education	Proportions Mean(+ S. D.) Proportions Proportions Proportions
A2. Socio-demographics (Association)	**Outcome** : Acceptance/Rejection Exposure: Sex **Outcome:** Acceptance/Rejection Exposure: Age groups **Outcome**: Acceptance/ Rejection Exposure: Religion **Outcome**: Acceptance/Rejection Exposure: Home language **Outcome**: Acceptance/Rejection Exposure: Education	Chi-square Chi- square Chi –square Chi-square Chi-square
B. Knowledge	**Outcome**: Acceptance/Rejection Exposure: Knowledge	Percentage% of total from the 6 questions Comparisons of the mean values of the % of the acceptance /rejection groups will be done by a t test or a nonparametric Wilcoxon rank sum test

C. Factors associated with parents decision (accept or reject vaccination)	**Outcome**: Acceptance/Rejection Exposure: No of other children in the family	Chi-square
	Outcome: Acceptance/Rejection Exposure: Opinions of stakeholders	Chi-square
	Outcome: Acceptance/Rejection Exposure: Provision of vaccine in schools	Chi-square
	Outcome: Acceptance/Rejection Exposure: Vaccine offered at no cost	Chi-square
	Outcome: Acceptance/Rejection Exposure: Parent-daughter communication about sex	Chi-square

R14/49 Dr Amodu Afolake Adeola

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M141183

NAME: (Principal Investigator) Dr Amodu Afolake Adeola

DEPARTMENT: Family Medicine
Etwatwa, Ekurhuleni District

PROJECT TITLE: Why Should I Talk to my 9-year Old Daughter about Sex? Understanding Parents' Decisiosn to Participate in the South African Government's Human Papilloma Virus (HPV) Vaccination Programme of Schoolgirls in Etwatwa, Gauteng

DATE CONSIDERED: 28/11/2014

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof Laurel Baldwin-Ragaven

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 12/01/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature

Date 15/01/2015

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I **AFOLAKE ADEOLA AMODU** (Student number: **700537**) am a student registered for the degree of **MMed (Family Medicine)** in the academic year **2017**.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: _____ Date: 14 JUNE 2017