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Barriers for immunization against HPV in developing countries (India)

Sandhya Ghanta

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Barriers for Immunization against HPV in Developing Countries (India)

by

Sandhya Ghanta

Thesis

Submitted to College of Health and Human Services

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

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in

Clinical Research and Administration

Thesis Committee:

Stephen A. Sonstein, Ph.D., Chair

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Abstract

Cervical cancer is one of the most common cancers in women. Incidence and mortality rates of cervical cancer are high in less developed and developing countries. In some countries, the acceptance of the HPV vaccine to prevent cervical cancer is low. Previous studies revealed that lack of awareness, income, and education were major barriers for accepting the HPV vaccine. Apart from the above-mentioned barriers, some socio-cultural barriers for accepting the HPV vaccine exist in less developed and developing countries. This study surveyed 250 women in India of age groups 18 years and above. The sample population for the study was chosen from a clinic's database. Survey questionnaires and informed consents were mailed to the participants. The results of this study exposed various concerns of women like lack of knowledge about vaccine, fear about the impact on their relationships, and embarrassment to talk about the vaccine.

Contents

Acknowledgments.....	ii
Abstract.....	iii
List of Tables	vi
List of Figures.....	viii
Chapter 1: Introduction.....	1
Chapter 2: Background	3
HPV Screening Methods.....	3
HPV Available Treatments	4
HPV Preventive Methods.....	4
Chapter 3: Thesis Statement	7
Purpose of the Study	7
Research Questions	7
Chapter 4: Research Design and Methodology	8
Target Population	8
Sample Population.....	8
Development of Research Instrument or Questionnaire	10
Human Subjects Protection	10
Method of Data Collection.....	11
Chapter 5: Analysis and Presentation of Data	12

Overview of Demographics	12
Overview of Responses.....	12
Chapter 6: Summary, Conclusions and Inferences	22
Understanding of Social Concerns	24
Based on financial status	24
Based on age.....	25
Barriers for Taking the HPV Vaccine	26
Chapter 7: Recommendations to Improve Vaccine Awareness.....	27
Chapter 8: Limitations of the Study and Recommendations for Future Research	30
References.....	31
<i>Appendix A: Approval Letter from IRB</i>	<i>64</i>
<i>Appendix B: Clinic Approval Letter to Conduct Survey.....</i>	<i>66</i>
<i>Appendix C: Letter Explaining about Survey and Informed Consent.....</i>	<i>67</i>
<i>Appendix D: Survey Questionnaire</i>	<i>70</i>
<i>Appendix E: Letter of Translation</i>	<i>82</i>

List of Tables

<u>Table</u>	<u>Page</u>
Table 1. HPV Type and Disease Association	36
Table 2. Treatments for HPV Virus Infections	37
Table 3. Vaccines for HPV	38
Table 4. Other Types of HPV Vaccines.....	39
Table 5. Survey Respondents by Age Group.....	40
Table 6. Survey Respondents Based on Religious Demographics	41
Table 7. Survey Respondents Based on Their Level of Education.....	42
Table 8. Survey Respondents Based on Their Employment Status.....	43
Table 9. Survey Respondents Based on Family Income Status	44
Table 10. Survey Respondents Based on Marital Status	45
Table 11. Survey Respondents Based on Parental Status	46
Table 12. Survey Respondents Based on Past Vaccination with Any Vaccine.....	47
Table 13. Survey Respondents Based on Different Vaccines Taken.....	48
Table 14. Survey Respondents Based on Place of Vaccination.....	49
Table 15. Survey Respondents Based on Decision Makers About Their Vaccination.....	50
Table 16. Survey Respondents Based on Knowledge About Cervical Cancer.....	51
Table 17. Survey Respondents Based on Awareness About HPV Vaccine	52
Table 18. Survey Respondents Based on Sources Through Which They Gained Knowledge About HPV Vaccine	53
Table 19. Survey Respondents Based on Awareness About Uses of HPV Vaccine	54
Table 20. Survey Respondents Based on Their HPV Vaccination Status	55

Table 21. Number of HPV Doses Taken by the Respondents	56
Table 22. Survey Respondent's Reasons for Not Taking HPV Vaccine	57
Table 23. Survey Respondents Based on Their Willingness to Communicate About Their HPV Vaccination Status.....	58
Table 24. Survey Respondents Based on the Kind of Information They Are Willing to Share	59
Table 25. Survey Respondents Based on Reasons Why they Are Not Willing to Share Information About HPV Vaccine	60
Table 26. Survey Respondents Based on Religious Restrictions for Accepting HPV Vaccine.....	61

List of Figures

<u>Figure</u>	<u>Page</u>
<i>Figure 1.</i> Estimated incidence and mortality of cervical cancer	35
<i>Figure 2.</i> Age group of survey respondents.....	40
<i>Figure 3.</i> Religious demographics of survey respondents.....	41
<i>Figure 4.</i> Level of education of survey respondents.....	42
<i>Figure 5.</i> Employment status of the survey respondents.....	43
<i>Figure 6.</i> Family income status based on rupees INR earned by each family member per month.	44
<i>Figure 7.</i> Marital status of survey respondents.....	45
<i>Figure 8.</i> Survey respondents' parental status.....	46
<i>Figure 9.</i> Past vaccination status of survey respondents.	47
<i>Figure 10.</i> Type of vaccines taken by survey respondents.....	48
<i>Figure 11.</i> Place of vaccination for previous vaccines.....	49
<i>Figure 12.</i> Decision makers of survey respondents about taking vaccines.	50
<i>Figure 13.</i> Knowledge of respondents about cervical cancer.....	51
<i>Figure 14.</i> Survey respondents aware of HPV vaccine.	52
<i>Figure 15.</i> Sources through which respondents gained knowledge about HPV vaccine. ...	53
<i>Figure 16.</i> Respondent's knowledge about uses of HPV vaccine.	54
<i>Figure 17.</i> Respondents HPV vaccination status.....	55
<i>Figure 18.</i> Reasons for not taking HPV vaccine.	57
<i>Figure 19.</i> Respondent's willingness to share about their HPV vaccination status.	58
<i>Figure 20.</i> Type of information respondents were willing to share about HPV vaccine. ...	59

Figure 21. Inhibitions respondents have for sharing information about HPV vaccine. 60

Figure 22. Religious restrictions respondents have for taking HPV vaccine. 61

Figure 23. Understanding of variation in level of social concerns among respondents of different economic classes. 62

Figure 24. Understanding variation in social concerns among respondents of different age groups. 63

Chapter 1: Introduction

Cervical cancer is the fourth most common cancer in women. It is estimated that there were 528,000 new cases of cervical cancer in 2012. There were 266,000 cervical cancer deaths estimated worldwide in 2012. Cervical cancer deaths constitute about 7.5% of all female cancer deaths. Nine out of 10 deaths of cervical cancer occur in less developed regions (World Health Organization, 2012).

As shown in Figure 1, statistics indicate the incidence and mortality rates due to cervical cancer are higher in less developed countries than in the developed nations (World Health Organization, 2012). This may be attributed to the low resources for diagnosis, treatment, and prevention methods in the developing countries. In addition to the above mentioned factors, there are etiological factors such as low socioeconomic status, low nutrition, and multiple sexual relationships at a young age that increase the incidence of cervical cancer (Kamangar, Dores, & Anderson, 2006). The human papilloma virus (HPV) is a primary cause of cervical cancer, but it is not the only cause. There are many other cofactors responsible for progression from cervical HPV infection to cancer. Tobacco smoking, having many borne children (high parity), long-term hormonal contraceptive use, and co-infection with HIV have been identified as established cofactors. Co-infection with *Chlamydia trachomatis* and herpes simplex virus type-2, immunosuppression, and certain dietary deficiencies are other probable cofactors. Genetic and immunological host factors and viral factors other than type, such as variants of type, viral load and viral integration, are likely to be important but have not been clearly identified (Munoz, Castellsague, de Gonzalez, & Gissmann, 2006). HPV 16 and 18 also account for 40% of penile cancers in men as well as 25%– 30% of oral and neck cancers in men and women (Parkins & Bray,

2006). It is estimated that by 2030 developing countries will have 98% of cervical cancer case deaths (Cover et al., 2012). Now, there is a pressing need to address the methods of treatment and lower the further occurrence of disease.

This study focuses on cervical cancer and acceptance of its preventive HPV vaccine in developing countries (India). HPV is considered the most common sexually transmitted infection. Most of the times HPV infections are asymptomatic (Sexually Transmitted Diseases Treatment Guidelines, 2015). HPV primarily affects the skin and moist membranes of the human body. Various types of HPV's infect the genital areas, mouth, or throat of males and females, as shown in Table 1 (Bosch et al., 1995). Low-risk type HPV viruses are associated with benign cervical lesions and genital warts while high risk type is the root of cervical cancer in females. Of the different types of HPV, types 16 and 18 cause about 70% of cancers of the cervix (Cutts et al., 2007).

Chapter 2: Background

HPV Screening Methods

The US Food and Drug Administration has approved cobas HPV test as a primary screening test to detect the DNA from high risk HPV types. According to Roche Molecular Inc. (2014), “Cobas test is a qualitative multiplex assay that simultaneously provides specific genotyping information for HPV types of 16 and 18, and a pooled result of 12 high risk strains of HPV DNA” (p.10). Women testing positive for one or more of the 12 other high-risk HPV types should have a Papanicolaou (Pap) test to determine the need for a colposcopy. The Pap test is a procedure in which cells are scraped from the cervix and examined under a microscope. Presence of any abnormal cells is identified, and the appropriate follow up is taken. There is a chance of false negative results as uneven spread of cells may be mistaken as a clump of cells. Abnormal cells can go unnoticed sometimes when present along with blood, bacteria, and yeast (Nishino, Rosemary, Tambouret, & Wilbur, 2011).

Cervical screening used to be the old Pap smear test, which is still used in many parts of the world (Kitchener, Castle, & Cox, 2006). In addition to the Pap smear test, liquid based cytology is another screening method for HPV infections. This method is considered to be accurate when compared to the Pap smears. Unlike the Pap smears, this test uses fluids to preserve the cells and preparation of slide is automated due to which errors like uneven slide thickness or debris on the slides are very minimal. Liquid based cytology is expensive due to the equipment used in the process, which makes it less affordable in under developed countries (PATH, 2007). There are currently two Food and Drug Administration (FDA)-approved liquid-based monolayer cytology methods: the Prep Stain system (formerly the AutoCyte PREP system) (TriPath Imaging Inc., Burlington, NC.) and the Thin Prep Pap

Smear method (Cytoc Corp., Boxborough, Mass). The FDA has also approved two new devices, the AutoPap 300QC (NeoPath, Redmond, Wash.) and the Pap Net (Neuromedical Systems, Suffern, N.Y.), which are designed to help ensure consistent and objective evaluation of Pap smears without Fatigue (Rosenthal, 1998). Biopsy, colposcopy, and cone biopsy are some of the other methods for diagnosis of cervical cancer (American Cancer Society, 2015). These treatment methods are accessible commonly in developed countries while in developing countries, accessibility is low due to limited resources being available. These diagnostic methods need complex settings like expensive equipment and trained persons for operation, which many developing countries lack (PATH, 2007).

HPV Available Treatments

The problems caused by HPV can be treated when diagnosed early. These infections can be treated by the treatments mentioned in Table 2 (PATH, 2007).

HPV Preventive Methods

The HPV vaccine was the first vaccine developed for cervical cancer and can be considered a great accomplishment (Basu, Banerjee, Singh, Bhattacharya, & Biswas, 2013). The advent of this vaccine has fostered the hope of eradication of cervical cancer. The perception of the etiologic role of carcinogenic HPV types paved the way for a novel primary prevention strategy against cervical cancer through vaccines targeting the virus. The vaccine is gender specific, and the target group for this vaccine is adolescent females. Gardasil and Cervarix are the novel vaccines approved as represented in Table 3 (PATH, 2007). Current HPV vaccines are designed to protect against HPV 16 and 18; the quadrivalent vaccine also protects against low-risk genotypes 6 and 11. Gardasil is a recombinant quadrivalent vaccine that protects against HPV types 6, 11, 16, and 18. (Merck Sharp & Dohme Corp, 2013) .

Cervarix is a bivalent vaccine that gives protection against HPV types 16 and 18. Cervarix is prepared by combining the adsorbed VLPs (virus like particles) of HPV type 16 and 18 together with some adjuvants (Glaxo & Smith Kline, 2015). Gardasil is recommended for females aged 9–26 (Merck Sharp & Dohme Corp, 2013) and Cervarix from ages 9–25 (Glaxo & Smith Kline, 2013). Three doses of either of these vaccines should be taken to get protection from sexually transmitted infections (STI) caused by HPV virus. As HPV virus is sexually transmitted, a vaccine administered prior to sexual activity would prevent the risk of infection. Apart from the Merck's Gardasil and Cervarix there are other HPV vaccines as shown in Table 4 (Kwang, Shin, Kyung-Nam, Seokjae, & Yang, 2014).

Though preventive vaccines are available, access to these vaccines is lower in developing countries like India. Additionally, vaccine cost is a major barrier for access to the vaccine in low income countries. The cost of three doses of Merck's Gardasil is \$350 in the USA, and the introductory price of the HPV vaccine in India was set as \$120, which is unaffordable by many people in the country (Madhivanan et al., 2009). For developing countries, the cost has to be as low as \$1–2 per dose to be cost-effective and affordable (Agosti & Goldie, 2007). Lack of knowledge about the vaccine and its importance and cost of the vaccine were major barriers in India (Purnima et al., 2009). As cited by Tissot et al. (2007) “One participant noted that Muslims in her community were ‘culturally more modest in terms of how they approach sexual issues ... you'd see that in conservative Christian cultures as well.’ These parents might feel that if you give [their child] that vaccine, they're almost condoning that behavior.” (Results section, Para. 1).

It is evident from the literature that these social and cultural factors may also contribute to the low vaccination rates in developing countries with multi-religious

populations. There are certain sociocultural issues associated with the HPV vaccine because it targets a sexually transmitted infection (STI) and primarily targets female children and adolescents of ages 9–26 years (Merck Sharp & Dohme Corp, 2013) or 9–25 years (Glaxo & Smith Kline, 2013) for whom this vaccination is recommended. These issues will significantly influence the willingness of health policy makers, health care providers, parents, adolescent and young girls to receive vaccine. Parental awareness and attitude towards the HPV vaccine are likely to be major determinants of acceptability (Kessels et al., 2012). With the recent approval of the HPV vaccine by the Indian health system, there is a demand to survey the acceptance levels of this vaccine in India. Although considerable research regarding the acceptance of the HPV vaccine has been done in developing countries and even in parts of India, there is still a need to know the impact of religious and sociocultural aspects affecting the decision making in developing countries with diverse populations.

Chapter 3: Thesis Statement

Purpose of the Study

The purpose of the study is to identify the barriers for immunization against HPV in a developing country like India.

Research Questions

Question 1:

1. What are the barriers for immunization against HPV in developing countries like India with multi-religious populations?

Question 2:

2. Is there any variation based on their age and economic status in the level of people's concern regarding the socio-cultural aspects of the HPV vaccine?

Chapter 4: Research Design and Methodology

Target Population

Target population refers to the entire group of individuals or objects to which researchers are interested in generalizing the conclusions. The target population usually has varying characteristics and it is also known as the theoretical population. The target population for this study is females age 18 and above. Unlike in the western countries, in India parents and schools would not like to teach or talk about topics pertaining to sex and sexually transmitted infections with children. So, it is most likely that girls would be knowledgeable about the sexually transmitted infections and their prevention methods when they start their college which is usually at 18 years in India. As the main aim of this study is to understand the knowledge of women about the HPV vaccine and its acceptance, females of age 18 and above are chosen assuming they would have some knowledge about cervical cancer, its causes and preventive methods.

Sample Population

A sample population is simply a subset of the target population. The notion of sample emerged from the inability of the researchers to test all the individuals in a given population. The sample must be representative of the population from which it was drawn, and it must have good size to proclaim statistical analysis (Population Sampling Techniques, 2009). The main function of the sample is to allow the researchers to conduct the study with individuals from the population, so that the results of their study can be used to derive conclusions that will apply to the entire population. It is much like a give-and-take process. The population “gives” the sample, and then it “takes” conclusions from the results obtained from the sample.

The sample population for this study were 250 females of age 18 years and above and was selected based on the inclusion criteria of gender and age from a clinic's database in Andhra Pradesh, India. This clinic is considered ideal for the study because it is a women's clinic located in a semi-urban area visited by many female patients of various economic classes.

Development of Research Instrument or Questionnaire

I conducted a literature review of previous surveys on HPV and generalized the nature of questions needing to be present in the survey to arrive at conclusions. Taking the advice of my thesis chair, Dr. Stephen Sonstein, I developed a questionnaire comprised of 23 questions. The survey is available in English and also in the regional language (Telugu). In the survey, questions 1–7 ask for demographic information; questions 8–11 captures subject's general approach to vaccines, acceptance of different vaccines, and different means through which they gained knowledge about vaccines; questions 12–17 address the subject's knowledge of cervical cancer and its preventive vaccine and her HPV vaccination status; and questions 18–23 address the acceptance and concerns subjects may have about HPV vaccine acceptance.

Human Subjects Protection

Prior to conducting the survey, I submitted an application for review and approval to conduct research or a survey involving human subjects (Clinical Research Coordinators) to the College of Health and Human Services IRB (Institutional Review Board) at Eastern Michigan University. On January 27, 2015, IRB approved the study to conduct the survey. (see Appendix A: Approval Letter from IRB).

All of the possible participants were informed clearly about the purpose of the study, procedure for responding to the survey, voluntariness and withdrawal, protecting the rights of the participant, and contact information by means of a survey consent form (see Appendix B: Clinic Approval Letter to Conduct Survey). An informed consent form and an attached survey questionnaire were mailed to the patient's address. The patients were asked to sign the consent form if they were willing to participate in the study. After the consent was signed,

participants were asked to complete the survey attached. By signing the consent form, the participant agreed to the conditions of the study. It is mentioned in the consent form that there were no direct benefits or risks associated with their participation, and all the responses to the survey were anonymous and confidential.

Method of Data Collection

Finally, with the approval of the IRB, I (Principal investigator) sent out the surveys along with a consent form to the subjects selected randomly from a clinic's database (see Appendix C: Letter Explaining about Survey and Informed Consent). The consent form explained the purpose of the study and asked for participant's signature stating that she was willing to take part in the study. Once the subjects signed the consent form, they were asked to complete the survey questionnaire.

After completing the survey, subjects were asked to seal the completed survey and send it to the clinic's address provided in the consent form.

Chapter 5: Analysis and Presentation of Data

This chapter presents the analysis of data obtained by surveying the sample population chosen for this study. The sample population chosen for this study was 250 females over 18 years of age living in the state of Andhra Pradesh, India. The participants were selected from a clinic's database based on the inclusion criteria of gender female and age 18 and over. An informed consent and survey questionnaire were mailed to each participant's address. The participants were asked to sign the consent if they were willing to take part in the study. The informed consent stated that participation in the study is voluntary and that confidentiality will be maintained. Once they completed the survey, the participants were instructed to mail back the surveys to the address provided in the consent forms. Out of 250 females selected for the study, 128 females responded to the survey, resulting in a response rate of 51.2%.

Overview of Demographics

The survey consisted of two parts: demographic questions and vaccine-related questions. The first part of the survey consisted of seven questions related to demographics. It included questions on age, religion, educational status, employment status, financial status, marital status, and number of children. The second part of the survey consisted of questions related to vaccination history, knowledge about cervical cancer and its treatments, knowledge about the HPV vaccine, and reasons for or concerns about taking the HPV vaccine.

Overview of Responses

Question 1. *Which category below includes your age?*

Survey respondents were asked to select from the following options: a) 18–20, b) 21–29, c) 30–39 or d) 40 and above.

The objective of this question was to assess the age group of the sample population that participated.

As shown in Table 5, 38% of the respondents were between 30–39 years old, 26.2% of the respondents were between 21–29 years old, 18.3% of the respondents were between 18–20 years old, and 17.5% respondents were aged 40 years or above.

Question 2. *Do you identify with any of the following religions?*

Survey respondents were asked to select from the following options: a) Hinduism, b) Islam, c) Christianity, d) Buddhism or e) others (please specify).

The objective of this question was to assess the religious makeup of the sample population participated.

As shown in Table 6, 73% of the respondents identified as Hindu, 19% of the respondents identified as Christian, 6.3% of the population identified as Islamic, 0.8% of the respondents identified as Buddhist, and 0.8% of the respondents identified with other religions, such as Jainism.

Question 3. *Which is the highest level of school you completed or highest level of education you are pursuing?*

Survey respondents were asked to select from the following options: a) less than high school degree, b) high school degree or equivalent, c) bachelor's degree or equivalent, d) master's or equivalent, or e) No education.

The objective of this question was to evaluate survey respondents' level of education.

As shown in Table 7, 35.7% of the respondents held a bachelor's degree or equivalent, 28.6% of the respondents held a high school degree or equivalent, 18.3% of the respondents

held less than high school degree, 10.3% of the survey respondents held a master's or equivalent, and 7.1% of the respondents admitted to no formal education.

Question 4. *Which of the following categories best describes your employment status?*

Survey respondents were asked to select from the following options: a) employed, b) unemployed, looking for job, c) retired, d) owns a business, or e) other (please specify).

The objective of this question was to evaluate the current employment status of respondents. This in-turn determines the influence on their financial status.

As shown in Table 8, 32.5% of the respondents were employed, 27% of the respondents were unemployed, looking for job, 15.9% of the respondents owned a business, 2.4% of the respondents were retired, and among others 10% were studying and 18% were housewives.

Question 5. *How would you describe your financial status?*

Survey respondents were asked to select from the following options: a) low income/poor (income of 1,035 rupees per person per month), b) middle class (income between 1,035-Rs and 10,354 per person per month) or c) rich (income > 10,354 per person per month).

The objective of this question was to evaluate respondents' financial status, which may affect their access to some health services and vaccines not administered by the government of India, such as the HPV vaccine.

As shown in Table 9, 69.5% of the respondents were middle class (income between 1,035-Rs and 10,354 per person per month), 21.6% were low income/poor (income of 1,035 rupees per person per month), and 8.8% were rich (income > 10,354 per person per month).

Question 6. *Which of the following best describes your current relationship status?*

Survey respondents were asked to select from the following options: a) married or b) single

The objective of this question was to evaluate the respondents' marital status.

As shown in Table 10, 71.1% of the respondents were married, and 28.9% of the respondents were single.

Question 7. *Do you have any children?*

Survey respondents were asked to select from the following options: a) yes or b) no. If yes, please specify how many male and female children you have.

As shown in Table 11, 61.6% of the respondents had children, and 38.4% of respondents did not have any children.

Question 8. *Have you taken any vaccines until now?*

Survey respondents were asked to select from the following options: a) yes or b) no.

The objective of this question was to evaluate whether the respondents have taken any vaccines.

As shown in Table 12, 96% of the respondents had taken vaccines, and 4% of the respondents had not taken any vaccines.

Question 9. *What vaccines have you received among the following?*

Survey respondents were asked to select from the following options: a) hepatitis B, b) polio, c) MMR, d) DTP, e) HPV, or f) others (please specify).

The objective of this question was to evaluate which vaccines respondents had taken in order to understand the respondents' general acceptance towards any vaccine.

As shown in Table 13, 66.1% of the respondents had taken the Polio vaccine, 10.9% of the respondents had taken the MMR vaccine, 10.3% of the respondents had taken the DTP vaccine, 8.3% of the respondents had taken the Hepatitis B vaccine, 1.1% of the respondents had taken the HPV vaccine, and 2.9% of the respondents had not taken any vaccine.

Question 10. *Where did you take your previous vaccines?*

Survey respondents were asked to select from the following options: a) hospital or clinic, b) government vaccination camps, c) school, or d) others (please specify).

The objective of the question was to evaluate the means through which respondents received previous vaccines. From this question we might get an idea why respondents have not taken the HPV vaccine, such as no nearby hospitals or no access to vaccination camps.

As shown in Table 14, 61.2% of the respondents were vaccinated in a hospital or clinic, 31.8% of the respondents were vaccinated in government vaccination camps, and 7% of the respondents were vaccinated in schools.

Question 11. *Who would make the choice to vaccinate for your family?*

Survey respondents were asked to select from the following options: a) father, b) mother, c) husband, d) self decision, e) others (please specify).

The objective of the question was to understand the impact of decision making on vaccination.

As shown in Table 15, 63.8% of the respondents selected mother, 28.5% of the respondents selected father, 3.8% of the respondents selected husband, and equally 3.8% of the respondents selected self-decision.

Question 12. *What do you know about cervical cancer?*

Survey respondents were asked to select from the following options: a) cancer that affects the cervix or garbhasaya, b) sexually transmitted disease caused by the HPV virus, c) caused due to multiple sexual contacts, improper hygiene, d) all of the above, or e) none of the above

The objective of the question was to evaluate respondents' knowledge of cervical cancer and to assess how much awareness the respondents had about the causes and effects of cervical cancer, which might aid their decision to get the HPV vaccine.

As shown in Table 16, 46.8% of the respondents believed cervical cancer is a cancer that affects the cervix or garbhasaya, 15.9% of the respondents believed it is caused due to multiple sexual contacts and improper hygiene, 12.7% of the survey respondents believed it is a sexually transmitted disease caused by the HPV virus, 12.7% of the survey respondents believed it is caused by all of the above options, and the remaining 11.9% of the survey respondents selected none of the above.

Question 13. *Have you heard about the HPV (human papilloma virus) vaccine?*

Survey respondents were asked to select from the following options: a) yes or b) no.

The objective of the question was to evaluate whether the survey respondents were aware of the preventive HPV (human papilloma virus) vaccine.

As shown in Table 17, 78.6% of the respondents were not aware of the HPV vaccine, and 21.4% of the respondents were aware of the HPV vaccine.

Question 14. *If Yes, How did you know about the HPV vaccine?*

Survey respondents were asked to select from the following options: a) physicians/doctor, b) friends/community, c) media (newspapers/television), d) government education campaigns, or e) other (please specify).

The objective of the question was to understand how the respondents gained the knowledge about the vaccine. Through this information, we can analyze means to create more awareness among wide populations.

As shown in Table 18, 33.3% of the survey respondents came to know about the HPV vaccine through friends/community, 25.9% of respondents from media (newspapers/television), 22.2% of the respondents from physicians/doctor, and 18.5% of the respondents from government education campaigns.

Question 15. *What knowledge do you have about the HPV vaccine?*

Survey respondents were asked to select from the following options: a) gives protection from infections caused by some types of human papilloma virus, b) prevents cervical cancer, c) It's a vaccine given to protect from all sexually transmitted infections, d) none of the above, or e) all of the above.

The objective of the question was to evaluate the survey respondents' knowledge of the HPV vaccine, which in-turn might affect their decision to take the vaccine.

As shown in Table 19, 36.5% of the respondents believed the HPV vaccine gives protection from all of the above reasons, 23.8% of the respondents believed it gives protection from infections caused by some types of human papilloma virus, 16.7% of the respondents selected none of the above, 12.7% of the respondents believed it prevents cervical cancer, and 10.3% of the respondents believed it is a vaccine given to protect from all sexually transmitted infections.

Question 16. *Have you taken the HPV vaccine?*

Survey respondents were asked to select from the following options: a) yes or b) no.

The objective of the question was to know whether the survey respondents have taken the HPV vaccine.

As shown in Table 20, 98.4% of the respondents had not taken the vaccine, and 1.6% of the respondents had taken the vaccine. The respondents who took the vaccine were above 30

years. None of the respondents from the recommended age group of 9–25 years or 9–26 years have taken the vaccine.

Question 17. *If yes, how many doses have you taken?*

Survey respondents were asked to specify the number of doses of HPV vaccine taken.

The objective of the question was to check their HPV vaccination status.

As shown in Table 21, only two respondents had taken the HPV vaccine. One had taken a single dose and the other two doses.

Question 18. *If No, what is the reason for not taking the vaccine?*

Survey respondents were asked to select from the following options: a) vaccine is unavailable/expensive, b) fear about side effects, c) do not know about the vaccine and its importance, d) other reasons (please specify).

The objective of the question was to evaluate the reasons behind the survey respondents not taking the vaccine.

As shown in Table 22, 64.8% of the respondents did not know about the vaccine and its importance, 17.6% of the respondents were afraid of any side effects they might incur due to the vaccine, 14.4% of the respondents indicated that the vaccine was unavailable/expensive, and 3.2% of the respondents did not take the vaccine due to other reasons.

Question 19. *Would you like to tell your friends/others that you have taken the HPV vaccine and recommend them to take it?*

Survey respondents were asked to select from the following options: a) yes or b) no.

The objective of the question was to understand how positively the respondents felt about taking the HPV vaccine.

As shown in Table 23, 60.3% of the respondents were willing to tell about the HPV vaccine, and 39.7% of the respondents were not.

Question 20. *If yes, what information would you give them about HPV vaccine?*

Survey respondents were asked to select from the following options: a) uses of the vaccine, b) Its availability and cost, c) others (please specify).

The objective of the question was to understand what information about the HPV vaccine were the respondents willing to share.

As shown in Table 24, 56.9% of the respondents were willing to talk about the uses of the HPV vaccine, 27.5% of the respondents were willing to talk about the availability and cost, and 15 % of the respondents were unsure and unwilling to explain.

Question 21. *If No, Is there any reason for you to not tell/recommend HPV vaccine to your friends/others?*

Survey respondents were asked to select from the following options: a) It's embarrassing to speak and explain about this vaccine as it is for a sexually transmitted disease, b) fear that people may think badly/negatively about you and avoid you, c) you have fear that your personal and social relationships may be affected, d) other reasons (please specify).

The objective of the question was to evaluate the inhibitions the respondents might have in talking about the HPV vaccine.

As shown in Table 25, 35.9% of the respondents were afraid that their personal and social relationships may be affected, 29.1% of the respondents were afraid that people may think badly/ negatively about them and avoid them, 21.4% of the respondents felt it was embarrassing to speak and explain about this vaccine as it is for a Sexually Transmitted Disease, and 13.7% had other reasons like being uneducated or unsure.

Question 22. *Do you have any objections or restrictions in your religion for taking this vaccine?*

Survey respondents were asked to select from the following options: a) yes or, b) no.

The objective of the question was to evaluate any religious restriction that the respondents might have to avoid taking the HPV vaccine.

As shown in Table 26, 91.2% of respondents did not have any religious restrictions, and 8.8% of the respondents had religious restrictions.

Question 23. *If yes, what might be the objections about?*

Survey respondents were asked to select from the following options: a) purity of vaccine (please specify), b) spiritual belief (please specify), c) other concerns (please specify).

The objective of the question was to evaluate what were the religious restrictions the respondents had for not taking the HPV vaccine. Though the question's purpose is to identify religious concerns, majority of participants mentioned other concerns they have. Not with a numerical, three respondents were skeptical about the purity of vaccine, two respondents avoided due to some spiritual beliefs, and 47 respondents had other concerns such as fear of side effects, they did not feel it important, fear of complications leading to other diseases, no information on vaccination-importance, opposition from family, opposition from religious leaders, spiritual beliefs, and some were unsure. Seventy-four women participated did not give any response to this question.

Chapter 6: Summary, Conclusions, and Inferences

The objective of this study was to explore the social and religious barriers among people in developing countries for accepting the HPV vaccine that prevents cervical cancer and other sexually transmitted infections caused by HPV.

The data from this study reveals the existence of barriers among Indian women belonging to different religions, ages, and economic backgrounds. The study was able to identify the kind of social barriers women have for accepting the HPV vaccine, but there was not enough evidence to identify the kind of religious barriers. This study also highlighted some of the major barriers for HPV vaccine acceptance, such as lack of awareness about the vaccine, its importance, and cost of the vaccine.

From the study results, it is evident that the majority of women participating in the study identified from Hinduism, while women from other religions, such as Christianity, Islam, Buddhism, and Jainism, also participated. A large group of women in the study came from a middle-class background while some women were from poor/low economic status, and very few were from the high economic background. Also, more than half of the women in the study held a high school degree or equivalent, bachelor's, or a master's degree, or had employment or a business. Very few women participated in this study did not have a high school degree or any formal education and were unemployed or housewives. Women who were continuing education also participated in the study.

Based on the response to the questions regarding the vaccines, over 90% of women had taken some kind of vaccine in the past while only a few women have not taken any vaccine. Most of the women were vaccinated in hospitals and clinics, while others were vaccinated in government vaccination camps and schools. The percentage of women who were vaccinated in schools is less compared to percentage of women vaccinated in the

hospitals and vaccination camps. Also, as a part of the study, women were asked about the decision-making choice about vaccines in their family. The majority of the women said that fathers were the decision makers in the family, while mothers made the decision in a few families. Some women depended on their husband's opinion, and only a few women made their own choice. In majority of the families in India, male members are considered to be the head of the family, and thus the decisions regarding the family were mostly taken by them. Vaccination is not an exception.

Based on the responses from the questions regarding the knowledge about cervical cancer and its preventive vaccine HPV, the majority of women had some idea about the causes of cervical cancer. Some women were clearly aware of all causes of cervical cancer while a very few women were not clear about the causes. Only 21.4% of the women who participated in the study were aware of the preventive vaccine for HPV. Women who were aware of the HPV vaccine gained knowledge through friends/community, media, physicians, and a few of them from government education campaigns.

From the analysis of the survey responses, it is evident that most of the women (96%) had taken vaccines, such as polio, DTP, MMR, or hepatitis B, in the past. Only very few women had not taken any of the vaccines. On the contrary, only 1.6% of the participating women had taken the HPV vaccine. None of the respondents from recommended age group for HPV vaccine received the vaccine. Lack of awareness about the vaccine and its importance was the major reason for not taking the HPV vaccine. Without numerical fear about the side effects, cost of the vaccine, opposition from family and religious leaders, spiritual beliefs, skepticism about the purity of vaccine were other reasons expressed by a very few women for not taking the HPV vaccine. Also, some women were unsure about the

reasons for not taking the vaccine, while a few others did not feel taking the vaccine was important.

As a part of understanding the social concerns for taking HPV vaccine, women were asked if they would be willing to share information regarding HPV vaccine or their HPV vaccination history. Among the 21.4% of women who were aware of HPV vaccine, majority of them were willing to share information such as its uses, cost, and availability. While many women who were not aware of vaccine also answered that they will be willing to share the knowledge if they know, few women who were not willing to talk about the HPV vaccine expressed the fear of social stigma, the fear that their personal and social relationships might be affected, and embarrassment to talk about the vaccine as it is for a sexually transmitted infection (STI). Some women were not ready to talk about the vaccine as they were unsure and not educated.

Understanding of Social Concerns

The author attempted to understand the variation in the levels of social concerns women had about sharing the information about HPV vaccine and their status of HPV vaccination based on the responses given in the survey.

Based on financial status. Based on the responses from the survey regarding the willingness to share information about the HPV vaccine and their HPV vaccination status, the author analyzed the variations in the level of social concerns women had based on their financial status. As shown in the Figure 23, women from a rich/high economic status were more concerned about their personal and social relationships when compared to the women from middle class and low-income class/poor. The majority of the women from the middle class background expressed the fear that society or people might think negative

about them. While not many of the women from poor and rich families expressed the concern, the majority of women from the poor financial class were unwilling to share information about the HPV vaccine as they felt embarrassment because the vaccine is to prevent a STI. Women from middle-class and wealthy backgrounds did express the concern of embarrassment, but the concern was higher in women from poor economic class compared to women from other classes.

Based on age. The author analyzed the variation in the levels of social concern in the women of different age groups who were unwilling to share the information about the HPV vaccine. As shown in the Figure 24, many women in the age range of 21–29 years and 30–39 years were concerned about their social and personal relationships, while fewer women in the age group of 18–20 years were concerned about the impact on their relationships when compared to the other age groups. A high number of women in the age groups of 40 years and above expressed a fear that people might think badly about them. Also, many women from age groups 18–20 years and 21–29 years equally expressed this concern. A higher number of women in the age group of 18–20 years expressed embarrassment as a major barrier for talking about the HPV vaccine, followed by the other age groups of 30–39 years, 40 years and above and 21–29 years. Apart from the above concerns, the 18–20 years age group women had other concerns, such as they were unsure and they could not explain the reasons why they are unwilling to share the information. Women from other age groups mentioned that they were uneducated and did not have enough awareness about the vaccine to share it with others.

Barriers for Taking the HPV Vaccine

Based on the responses from the survey, women in a developing country like India have the following reasons for not taking the HPV vaccine:

- Unawareness about the HPV vaccine and its importance
- Vaccine is unavailable/expensive
- Fear about side effects
- Opposition from family
- Skepticism about the purity of vaccine
- Opposition from religious leaders
- Spiritual beliefs

Chapter 7: Recommendations to Improve Vaccine Awareness

Cervical cancer deaths in less developed and developing countries have not decreased, and it is estimated that there will be a rise in cancer deaths in the future. Although there is a preventive vaccine available for cervical cancer, the HPV vaccination rates are not prominent in developing countries. This might be attributed to many barriers like illiteracy, poverty, and socio-cultural concerns. Now, there is a high need for these nations to work on improving HPV vaccination rates.

This study again shows that unawareness still remains even after years of marketing of HPV vaccine in India. Lack of knowledge about the vaccine is one of the factors preventing women from taking the HPV vaccine in developing countries. To overcome this, education campaigns have to be conducted to increase awareness about the vaccine and its uses. These campaigns will help to clarify the myths people have about the vaccine. Governments and non-governmental organizations (NGOs) should organize these education campaigns.

The data from this study showed that women were not willing to share information about the HPV vaccine and their vaccination status due to embarrassment as the vaccine is for a STI. Other concerns, such as fear that people might think badly about them or fear about the impact on their relationships are preventing women from sharing information about the vaccine. The data also revealed that women were worried about the side effects of the vaccine. Physicians and medical professionals should volunteer to explain to people the benefits of vaccination, about the safety and effectiveness and benefits of sharing knowledge with others. Education materials, such as flyers with information about the HPV vaccine, should be given to patients who visit hospitals and clinics. Advertising in various media, such as television, newspapers, and radio, will also increase awareness among people about the

vaccine and its importance. Considering as a social responsibility, hospitals and charitable trusts should allocate funds to conduct awareness programs.

According to Nigam, Saxena, Acharya, Mishra, and Batra (2014), in India the target population for HPV vaccine should be from 9–13 years of age. A survey conducted on college students in India showed that youth are sexually active before the legal age of marriage. Therefore, vaccinating children when they are sexually inactive (9–13 years) would be effective. Many parents might not be aware of the vaccine and its importance or are unwilling to vaccinate their children because of various concerns. Hence, schools should take an initiative of explaining to parents about the importance of vaccinating their children with the HPV vaccine. Also, conducting vaccination camps in schools and colleges will increase the access of vaccine to many children and adolescents. Government should take steps to make vaccination mandatory in schools, which would improve the vaccination rates of HPV vaccine and thus reduce the burden of cervical cancer in future.

In developing countries like India, cost and unavailability remain to be the major barriers for many people. The data from this study showed that women have not taken HPV vaccine because it was expensive. With the support of Global Alliance for Vaccines and Immunizations (GAVI), in the next five years 1 million children in developing countries and less developed countries will receive the HPV vaccine (Global Alliance for Vaccines and Immunizations, 2015). GAVI's support will increase the vaccination rates and reduce the cervical cancer burden in many countries of the world.

In summary, higher vaccination rates can be achieved in less developed and developing countries by creating awareness among people about the importance of

preventive vaccines and by increasing the vaccine accessibility to people thus reducing the burden of cervical cancer in future.

Chapter 8: Limitations of the Study and Recommendations for Future Research

This study has certain limitations. Firstly, the sample was small. Conducting the survey with a larger sample population could possibly allow for more detailed conclusions about the concerns. Secondly, this survey was not conducted face-to-face. So, the respondents might not have expressed their concerns clearly in writing. An interactive survey with individuals and families could possibly help the researcher understand the participants' major concerns about accepting the HPV vaccine. A survey with families would also help to understand the perceptions of male heads of the family as they are the decision makers in many families. This study captured only perceptions or concerns of a female population of 18 years and over. A study conducted with broader inclusion criteria might help understanding the concerns and awareness among different ages of people. This sample might not be representative, and the results of this study were based on the population who participated in the study and their responses.

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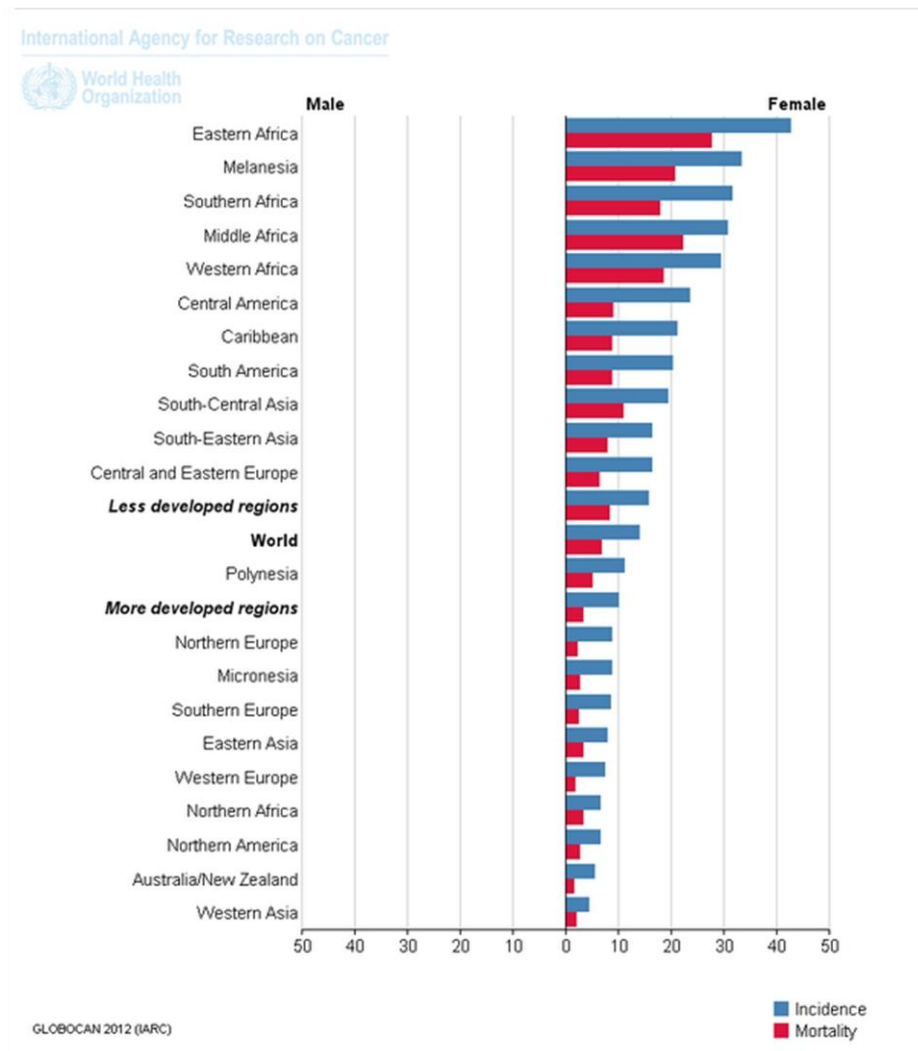


Figure 1. Estimated incidence and mortality of cervical cancer.

Note: Adapted from World Health Organization. (2012). *Globocon 2012: Estimated incidence, mortality and prevalence worldwide in 2012*. Retrieved from International Agency for Research on Cancer — Globocon: <http://globocan.iarc.fr/Default.aspx>.

Table 1

HPV Type and Disease Association

Disease	HPV type ^b
Plantar warts	1, 2 , 4, 63
Common warts	2, 1, 7 , 4, 26, 27, 29, 41, 57, 65, 77, 1, 3, 4, 10, 28
Other cutaneous lesions (e.g., epidermoid cysts, laryngeal carcinoma)	6, 11, 16, 30, 33, 36, 37, 38, 41, 48, 60, 72, 73
Epidermodysplasia verruciformis	2, 3, 10, 5, 8, 9, 12, 14, 15, 17 , 19, 20, 21, 22, 23, 24, 25, 36, 37, 38, 47, 50
Focal epithelial hyperplasia of Heck	13, 32
Recurrent respiratory papillomatosis	6, 11
Conjunctival papillomas/carcinomas	6, 11, 16
Condyloma acuminata (genital warts)	6, 11 , 30, 42, 43, 45, 51, 54, 55, 70
Cervical intraepithelial neoplasia Unspecified	30, 34, 39, 40, 53, 57, 59, 61, 62, 64, 66, 67, 68, 69
Low risk	6, 11, 16, 18, 31, 33, 35, 42, 43, 44, 45, 51, 52, 74
High risk	16, 18, 6, 11, 31, 34, 33, 35, 39, 42, 44, 45, 51, 52, 56, 58, 66
Cervical carcinoma	16, 18 , 31, 45, 33, 35, 39, 51, 52, 56, 58, 66, 68, 70

b Order indicates relative frequency; bold type indicates most frequent association.

Note: Adapted from Bosch, F.X., Manos, M.M., Munoz, N., Sherman, M., Jansen, A.M., Peto, J., . . . Shah, K.V. (1995). Prevalence of human papilloma virus in cervical cancer: A worldwide perspective. International Biological Study on Cervical Cancer (IBSCC) study group. *Journal of National Cancer Institute*, 87(11).

Table 2

Treatments for HPV Virus Infections

Treatment	Description	Effectiveness	Common Adverse Effects	Comments
Cryotherapy	Freezing tissue using a metal cytoprobe that has been cooled by nitrous oxide or carbon dioxide gas circulating within the probe	85–95%	Slight cramping, watery discharge, risk of infection	Can be performed by non-physician in a single visit; simple equipment; advisable only when the affected area is small; no anesthesia required
Loop electro-surgical excision procedure(LEEP)	Removal of the diseased area of the cervix using electrically heated wires; sample is then further evaluated	90–98%	Bleeding, either immediately or later	Fast (5–10 min); must be performed by a physician complex procedure; requires local anesthesia
Cold knife conization	Removal of cone-shaped area from the cervix	90–94%	Bleeding, infection, stenosis, cervical incompetence	Requires anesthesia, hospitalization and highly skilled staff

Note: Adapted from PATH. (2007, June). Preventive cervical cancer: Unprecedented opportunities for improving women's health. *Outlook*, 23(1), 1-11.

Table 3

Vaccines for HPV

Vaccine	Manufacturer	Type	Composition
Gardasil	GlaxoSmithKline biologicals	Bivalent	Aluminum hydroxide, modified diphosphoryl lipid A derived from <i>Salmonella Minnesota</i> R595 that removes the phosphate and fatty acid groups.
Cervarix	Merck	Quadrivalent	The detail combination of the vaccine is 20 µg of HPV type 6 11 protein, 40 µg of HPV type 11 11 protein, 40 µg of HPV type 16 11 protein, 20 µg of HPV type 18 11 protein, and 225 µg of aluminum hydroxyphosphate sulfate

Note: Content taken from PATH. (2007, June). Preventive cervical cancer: Unprecedented opportunities for improving women's health. *Outlook*, 23(1), 1-11.

Table 4

Other Types of HPV Vaccines

Researcher	Synthesis	Status
Innovax YST Biotech Co. Ltd. (Haicang, Xiamen, China)	<i>Escherichia coli</i>	clinical trial phase III
Takeda Pharmaceutical Company Ltd. (Takeda, Osaka, Japan).	-	pre-clinical study stage
Eyegene Inc., Seoul, Korea	<i>Escherichia coli</i>	clinical trial phase I

Note: Content taken from Kwang, S. K., Shin, A.P., Kyung-Nam, K., Seokjae, Y., & Yang, J.C. (2014). Current status of human papilloma virus vaccines. *Clinical and Experimentation Vaccine Research*, 3(2), 168-175. doi: 10.7774/cevr.2014.3.2.168.

Table 5

Survey Respondents by Age Group

Response or answer	Frequency	Percent (%)	Cumulative frequency	Cumulative Percentage (%)
18 to 20	23	18.3%	23	18.3%
21 to 29	33	26.2%	56	44.4%
30 to 39	48	38.1%	104	82.5%
>=40	22	17.5%	126	100.0%
TOTAL	126	100%		

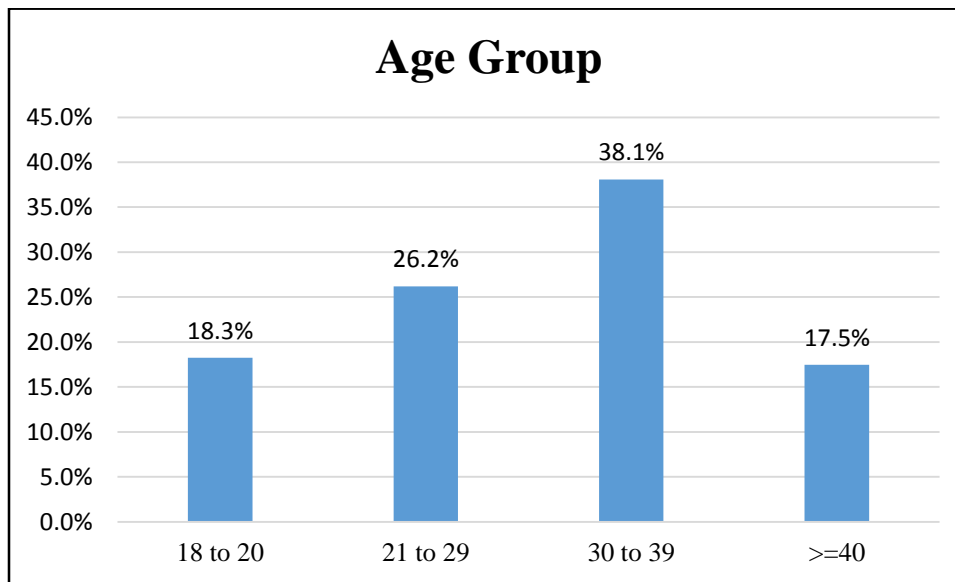
*Figure 2. Age group of survey respondents.*

Table 6

Survey Respondents Based on Religious Demographics

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Hinduism	92	73.0%	92	73.0%
Islam	8	6.3%	100	79.4%
Christianity	24	19.0%	124	98.4%
Buddhism	1	0.8%	125	99.2%
Other-Jainism	1	0.8%	126	100.0%
TOTAL	126	100%		

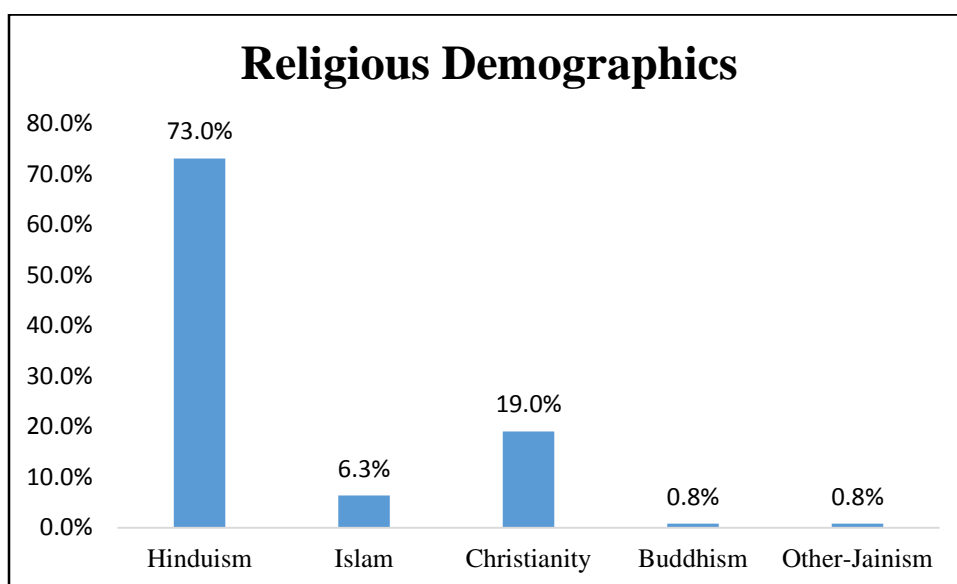
*Figure 3. Religious demographics of survey respondents.*

Table 7

Survey Respondents Based on Their Level of Education

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Less than high school degree	23	18.3%	23	18.3%
High school degree or equivalent	36	28.6%	59	46.8%
Bachelor's degree or equivalent	45	35.7%	104	82.5%
Masters or equivalent	13	10.3%	117	92.9%
No education	9	7.1%	126	100.0%
TOTAL	126	100%		

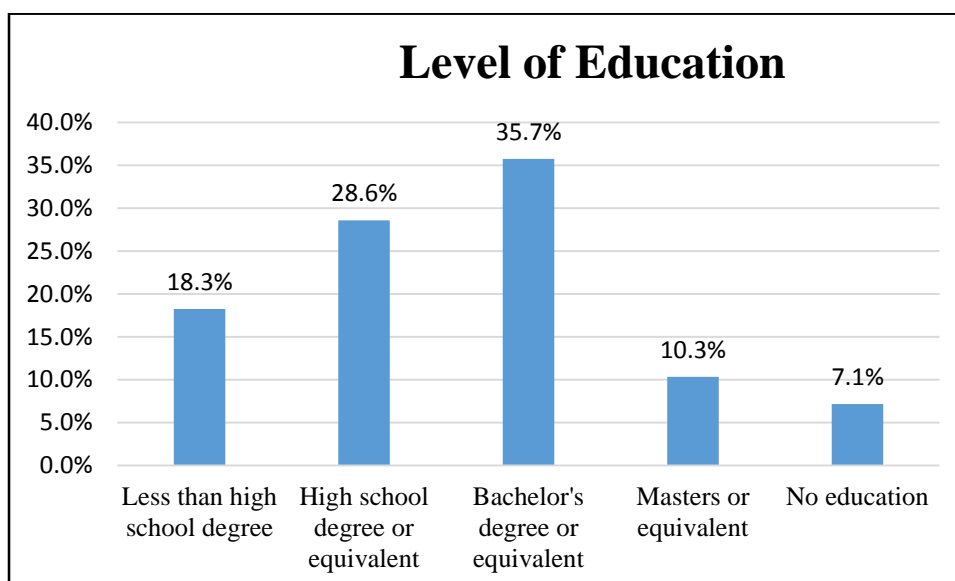
*Figure 4. Level of education of survey respondents.*

Table 8

Survey Respondents Based on Their Employment Status

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Employed	41	32.5%	41	32.5%
Unemployed, looking for job	34	27.0%	75	59.5%
Retired	3	2.4%	78	61.9%
Owens a Business	20	15.9%	98	77.8%
Others	28	22.2%	126	100.0%
TOTAL	126	100%		

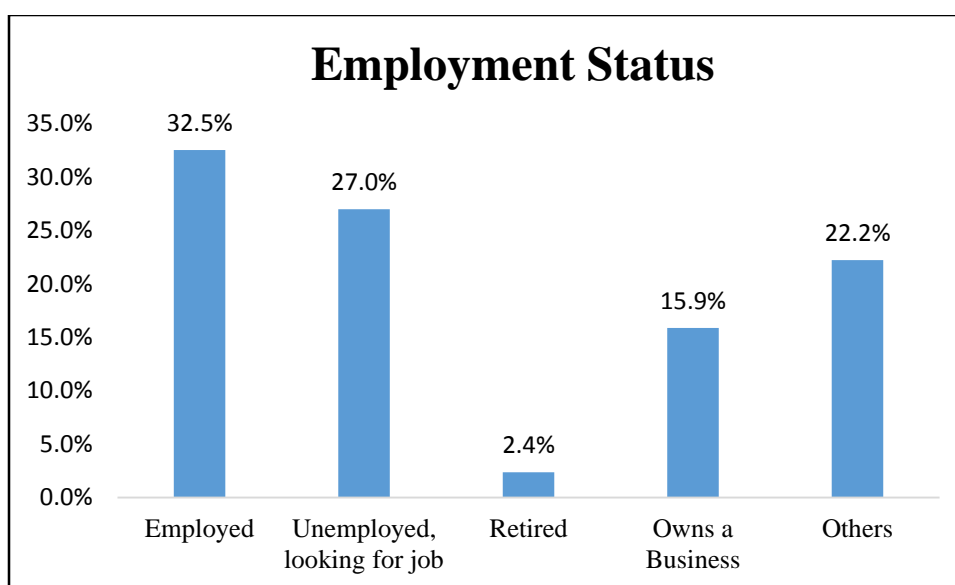
*Figure 5. Employment status of the survey respondents.*

Table 9

Survey Respondents Based on Family Income Status

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Low income/Poor (Income of 1,035 rupees per person per month)	27	21.6%	27	21.6%
Middle Class (Income between 1,035-Rs and 10,354 per person per month)	87	69.6%	114	91.2%
Rich (Income > 10,354 per person per month)	11	8.8%	125	100.0%
TOTAL	125	100%		

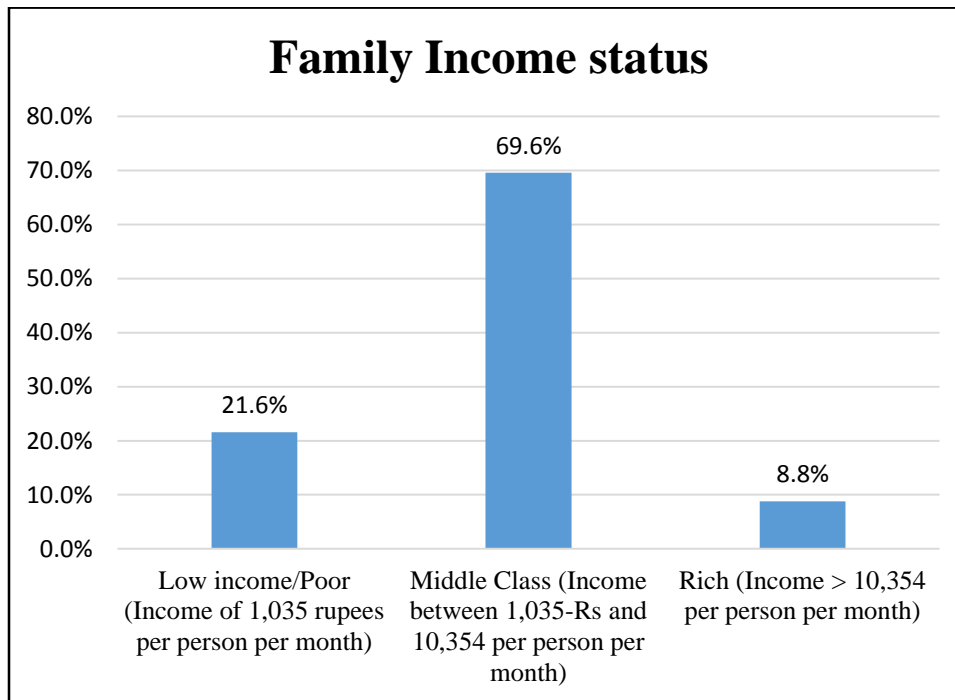
*Figure 6. Family income status based on rupees INR earned by each family member per month.*

Table 10

Survey Respondents Based on Marital Status

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Married	86	71.1%	86	71.1%
Single	35	28.9%	121	100.0%
TOTAL	121	100%		

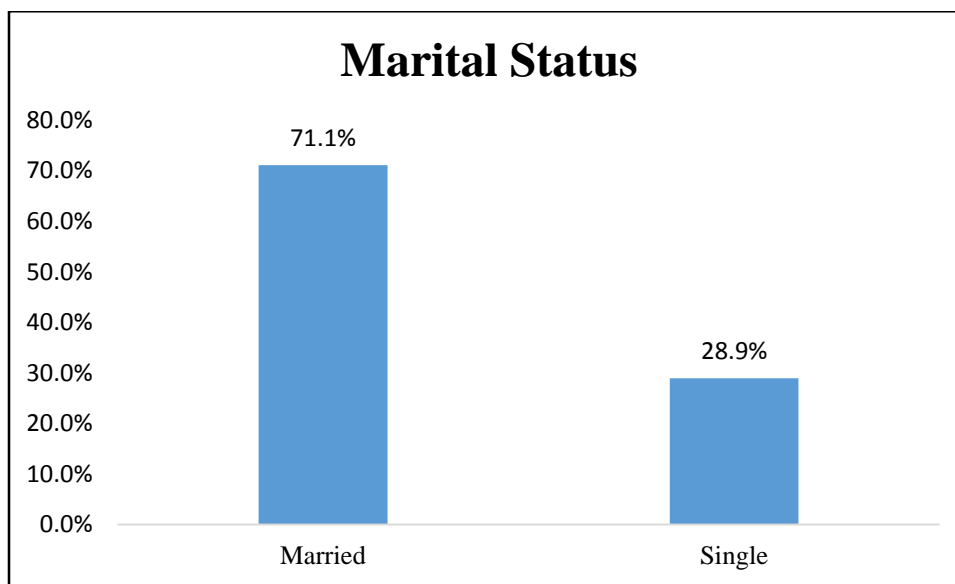
*Figure 7. Marital status of survey respondents.*

Table 11

Survey Respondents Based on Parental Status

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Yes	77	61.6%	77	61.6%
No	48	38.4%	125	100.0%
TOTAL	125	100%		

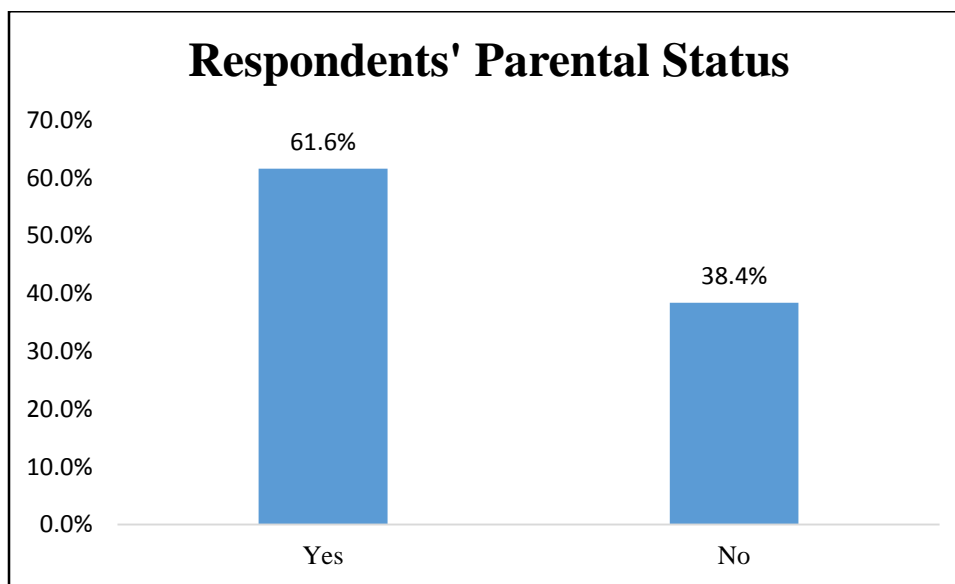
*Figure 8.* Survey respondents' parental status.

Table 12

Survey Respondents Based on Past Vaccination with Any Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Yes	121	96.0%	121	96.0%
No	5	4.0%	126	100.0%
TOTAL	126	100%		

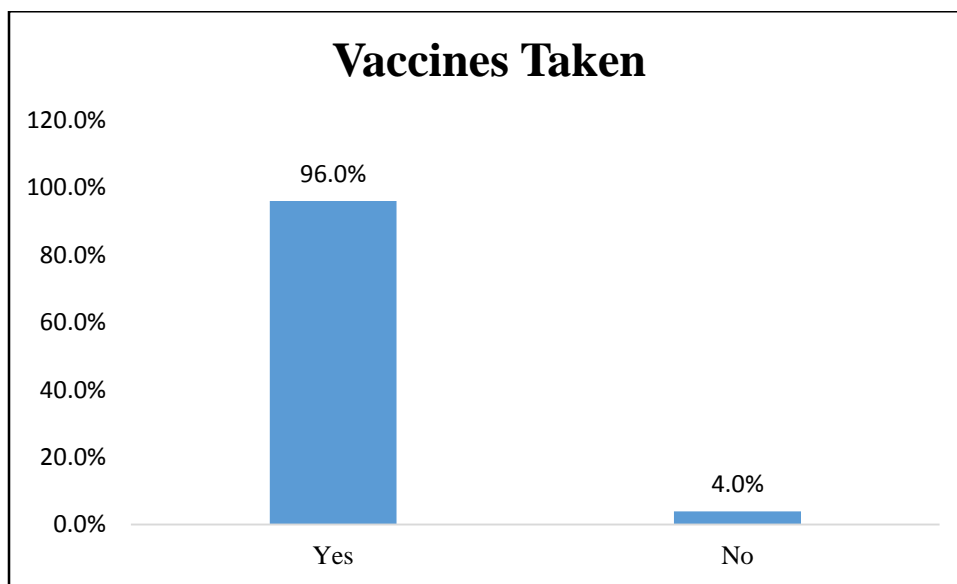


Figure 9. Past vaccination status of survey respondents.

Table 13

Survey Respondents Based on Different Vaccines Taken

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Hepatitis B	15	8.6%	15	8.6%
Polio	115	66.1%	130	74.7%
MMR	19	10.9%	149	85.6%
DTP	18	10.3%	167	96.0%
HPV	2	1.1%	169	97.1%
No vaccination	5	2.9%	174	100.0%
Total	174	100%		

Survey respondents may select more than one answer or response to this question, due to which frequency (N=174) is more than actual number of respondents (126).

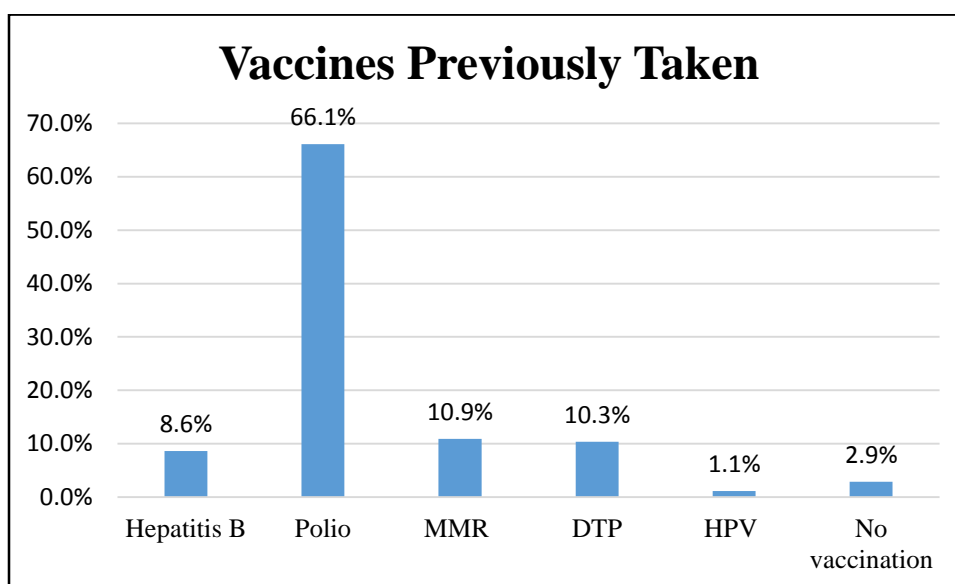


Figure 10. Type of vaccines taken by survey respondents.

Table 14

Survey Respondents Based on Place of Vaccination

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Hospital or Clinic	79	61.2%	79	61.2%
Government Vaccination Camps	41	31.8%	120	93.0%
School	9	7.0%	129	100.0%
TOTAL	129	100%		

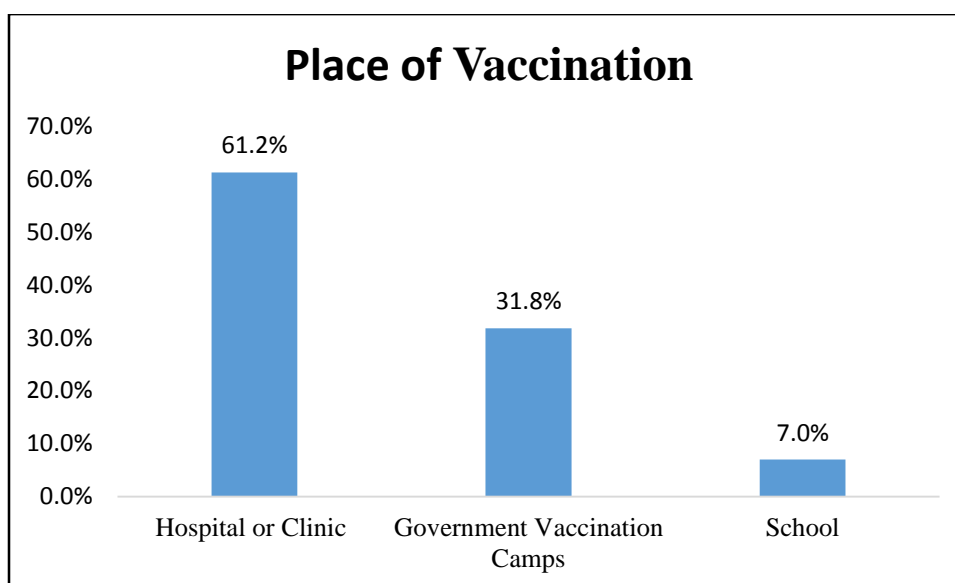
*Figure 11.* Place of vaccination for previous vaccines.

Table 15

Survey Respondents Based on Decision Makers About Their Vaccination

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Father	37	28.5%	37	28.5%
Mother	83	63.8%	120	92.3%
Husband	5	3.8%	125	96.2%
Self-Decision	5	3.8%	130	100.0%
TOTAL	130	100%		

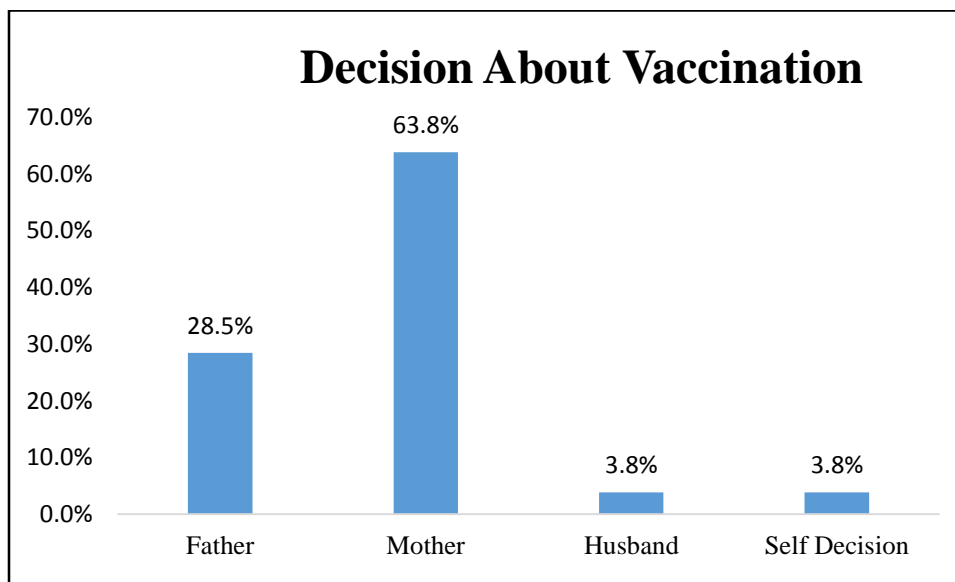


Figure 12. Decision makers of survey respondents about taking vaccines.

Table 16

Survey Respondents Based on Knowledge About Cervical Cancer

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Cancer that affects the cervix or garbhasaya	59	46.8%	59	46.8%
Sexually transmitted Disease caused by HPV virus	16	12.7%	75	59.5%
Caused due to multiple sexual contacts, improper hygiene.	20	15.9%	95	75.4%
All of the above	16	12.7%	111	88.1%
None of the above	15	11.9%	126	100.0%
TOTAL	126	100%		

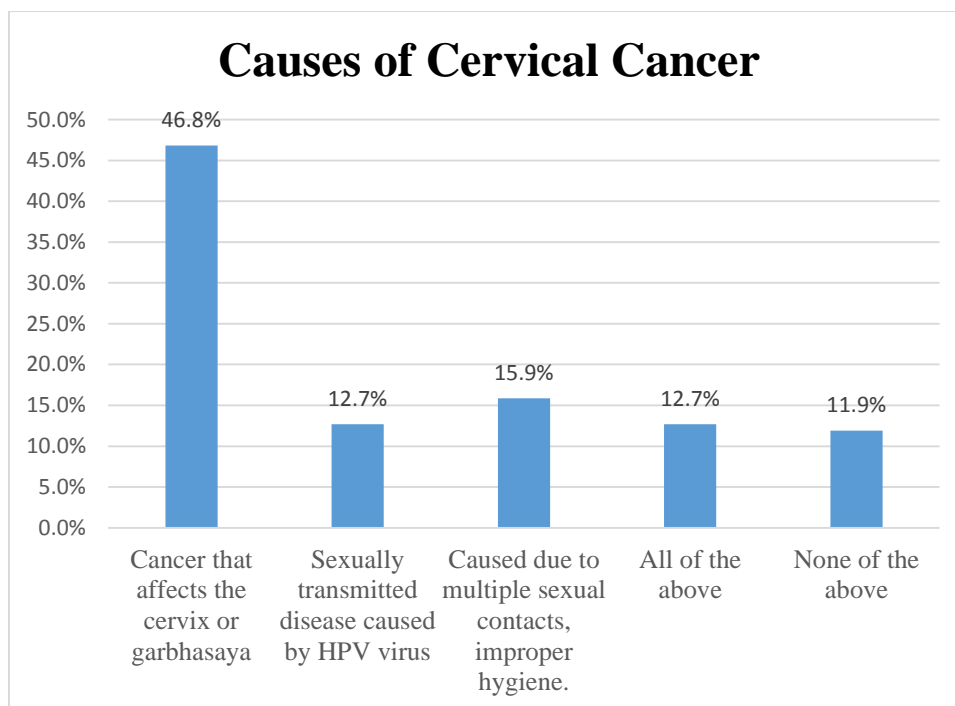
*Figure 13.* Knowledge of respondents about cervical cancer.

Table 17

Survey Respondents Based on Awareness About HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Yes	27	21.4%	27	21.4%
No	99	78.6%	126	100.0%
TOTAL	126	100%		

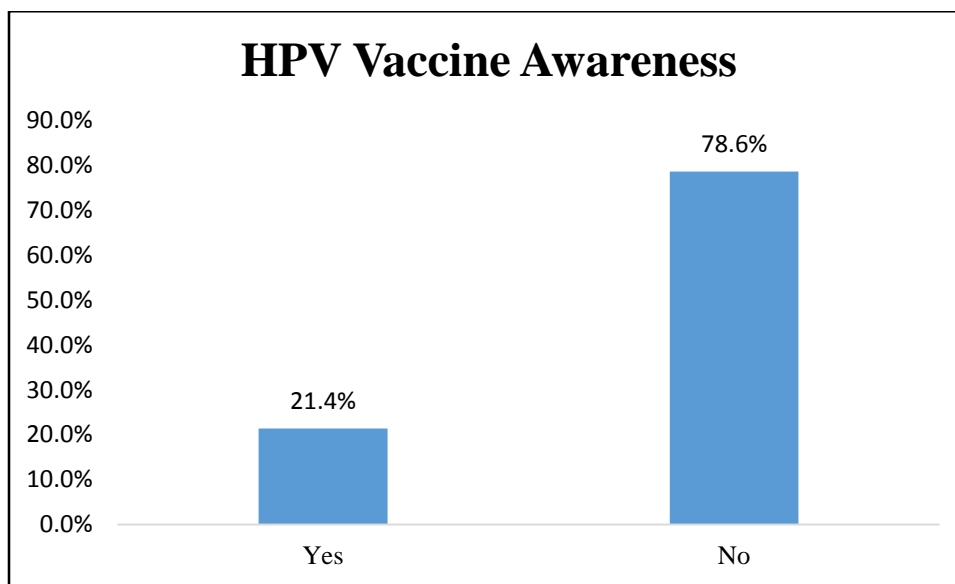
*Figure 14.* Survey respondents aware of HPV vaccine.

Table 18

Survey Respondents Based on Sources Through Which They Gained Knowledge About HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Physicians/Doctor	6	22.2%	6	22.2%
Friends/ Community	9	33.3%	15	55.6%
Media(Newspapers/ Television)	7	25.9%	22	81.5%
Government Education Campaigns	5	18.5%	27	100.0%
Others	0	0.0%	27	100.0%
TOTAL	27	100%		

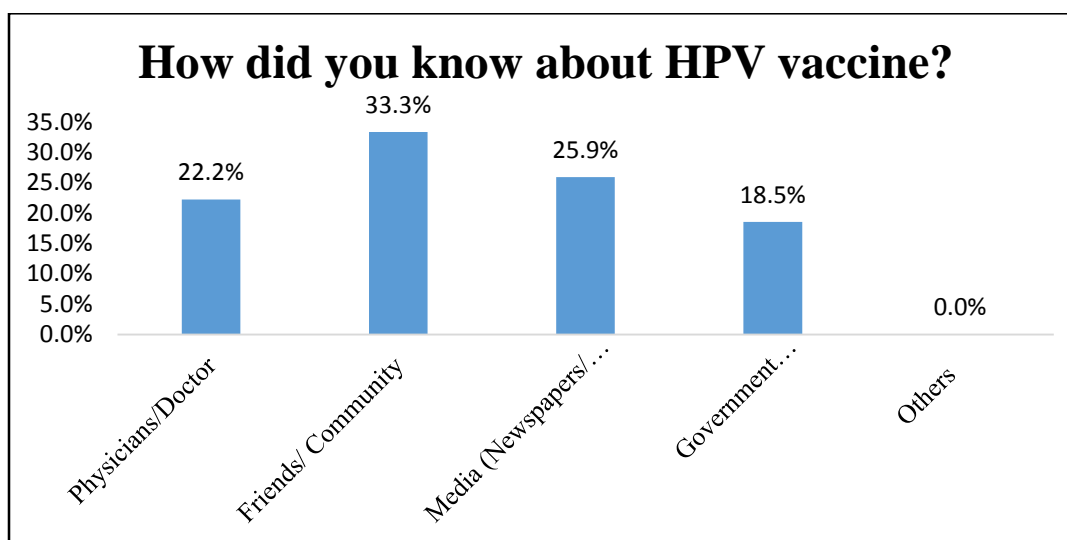


Figure 15. Sources through which respondents gained knowledge about HPV vaccine.

Table 19

Survey Respondents Based on Awareness About Uses of HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Gives protection from infections caused by some types of Human Papilloma Virus	30	23.8%	30	23.8%
Prevents cervical cancer	16	12.7%	46	36.5%
It's a vaccine given to protect from all sexually transmitted infections	13	10.3%	59	46.8%
None of the above	21	16.7%	80	63.5%
All of the above	46	36.5%	126	100.0%
TOTAL	126	100%		

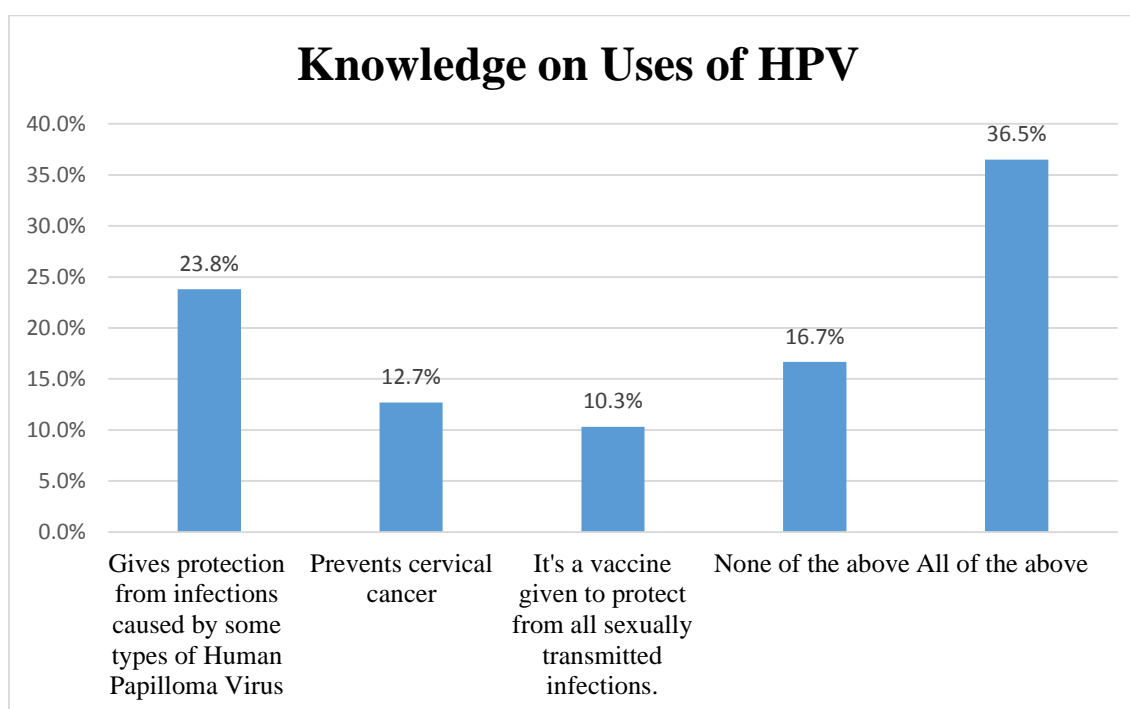
*Figure 16. Respondent's knowledge about uses of HPV vaccine.*

Table 20

Survey Respondents Based on Their HPV Vaccination Status

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Yes	2	1.6%	2	1.6%
No	124	98.4%	126	100.0%
TOTAL	126	100%		

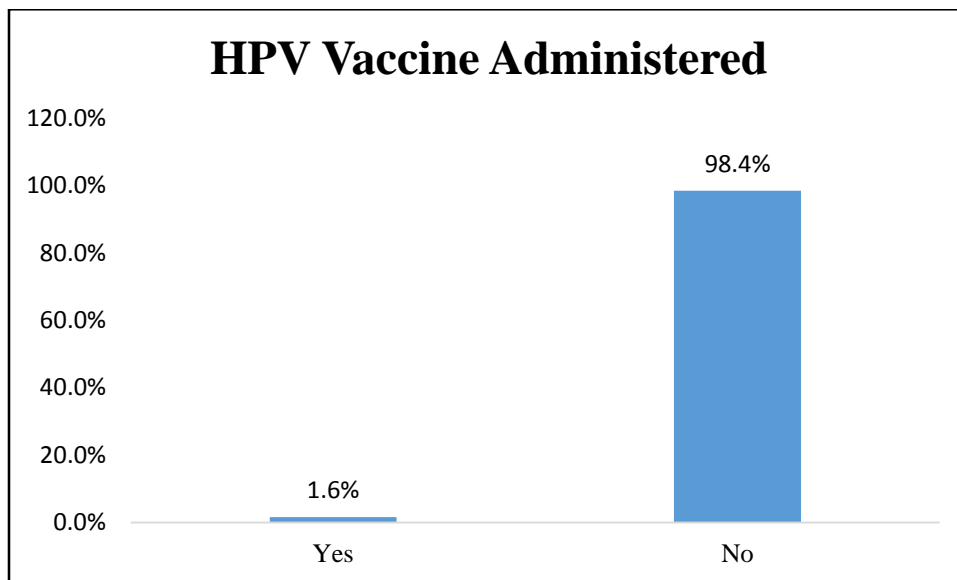
*Figure 17. Respondents HPV vaccination status.*

Table 21

Number of HPV Doses Taken by the Respondents

No of doses taken	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
1	1	50%	1	50.0%
2	1	50%	2	100.0%
TOTAL	2	100%		

Table 22

Survey Respondent's Reasons for Not Taking HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Vaccine is unavailable/expensive	18	14.4%	18	14.4%
Fear about side effects	22	17.6%	40	32.0%
Do not know about the vaccine and its importance	81	64.8%	121	96.8%
Other reasons	4	3.2%	125	100.0%
TOTAL	125	100%		

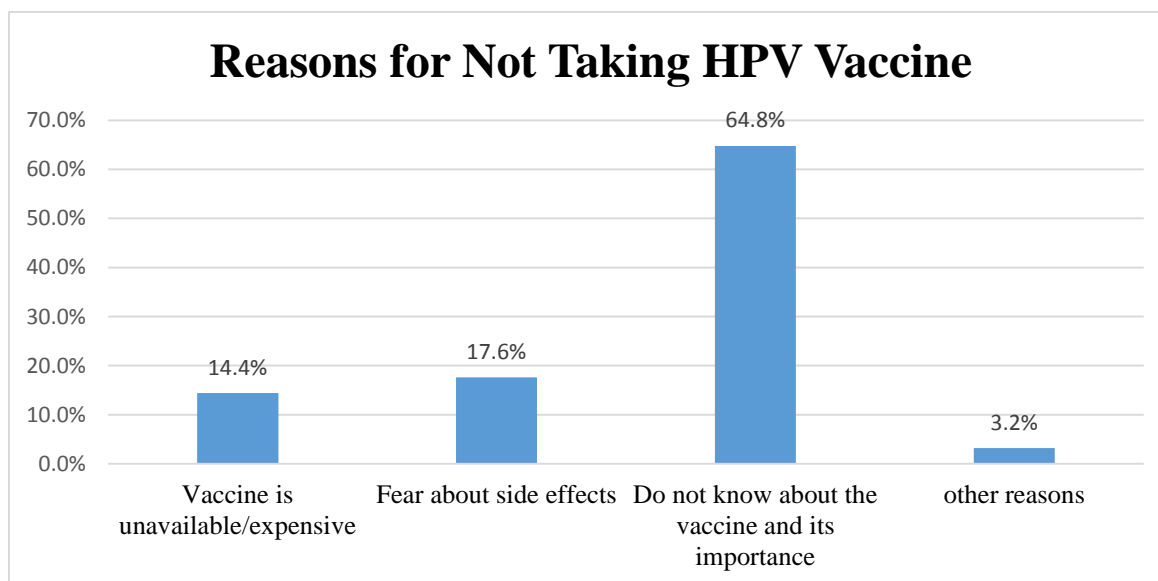
*Figure 18. Reasons for not taking HPV vaccine.*

Table 23

Survey Respondents Based on Their Willingness to Communicate About Their HPV Vaccination Status

Response or answer	Frequency	Percent (%)	Cumulative frequency	Cumulative percentage (%)
Yes	76	60.3%	76	60.3%
No	50	39.7%	126	100.0%
TOTAL	126	100%		

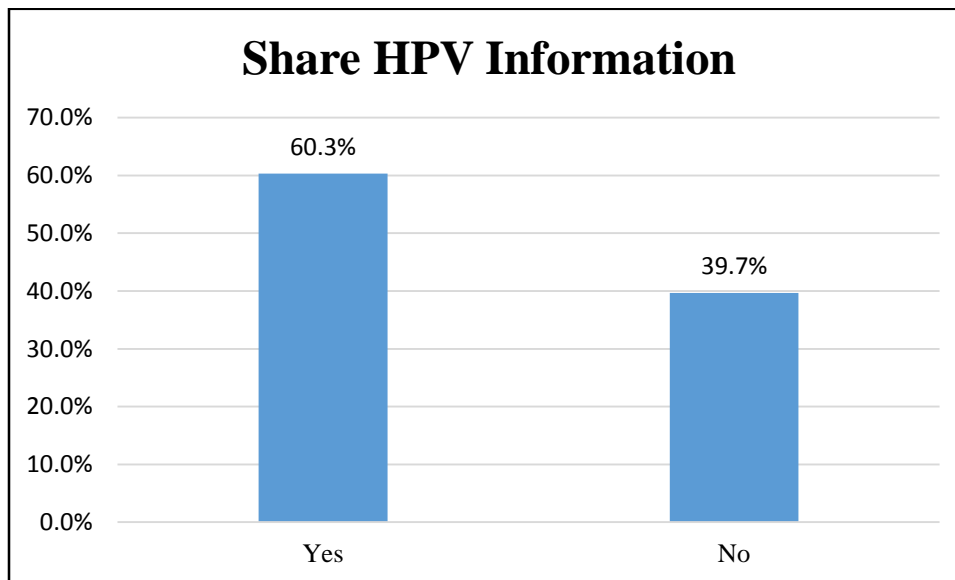


Figure 19. Respondent's willingness to share about their HPV vaccination status.

Table 24

Survey Respondents Based on the Kind of Information They Are Willing to Share

Response or answer	Frequency	Percent (%)	Cumulative frequency	Cumulative percentage (%)
Uses of the vaccine	58	56.9%	58	56.9%
Its availability and cost	28	27.5%	86	84.3%
Others	16	15.7%	102	100.0%
TOTAL	102	100%		

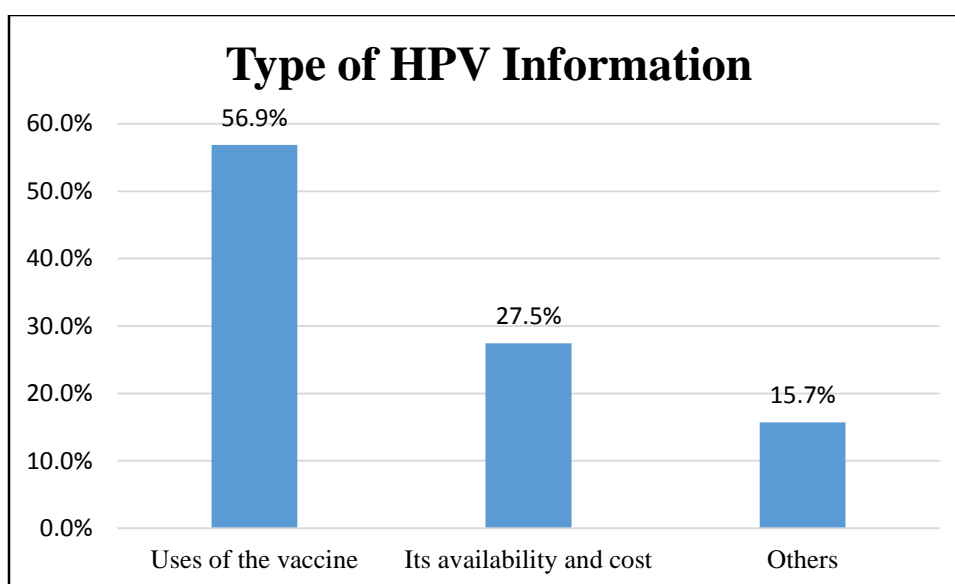


Figure 20. Type of information respondents were willing to share about HPV vaccine.

Table 25

Survey Respondents Based on Reasons Why They Are Not Willing to Share Information About HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative frequency	Cumulative Percentage (%)
It's embarrassing to speak and explain about this vaccine as it is for a sexually transmitted infection	25	21.4%	25	21.4%
Fear that people may think bad/negative about you and avoid you	34	29.1%	59	50.4%
You have fear that your personal and social relationships may be affected	42	35.9%	101	86.3%
Other reasons	16	13.7%	117	100.0%
TOTAL	117	100%		

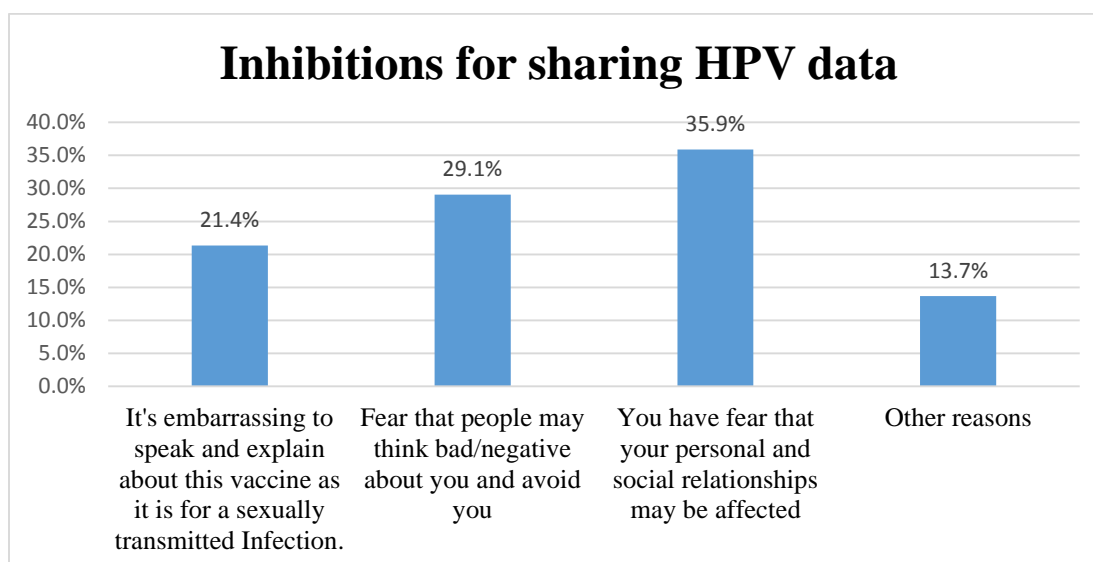


Figure 21. Inhibitions respondents have for sharing information about HPV vaccine.

Table 26

Survey Respondents Based on Religious Restrictions for Accepting HPV Vaccine

Response or answer	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percentage (%)
Yes	11	8.8%	11	8.8%
No	114	91.2%	125	100.0%
TOTAL	125	100%		

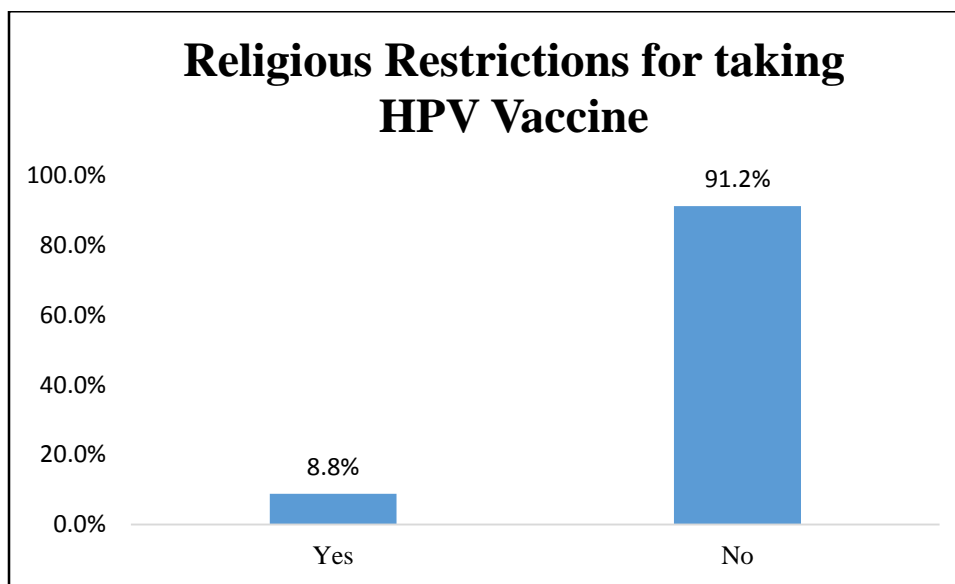


Figure 22. Religious restrictions respondents have for taking HPV vaccine.

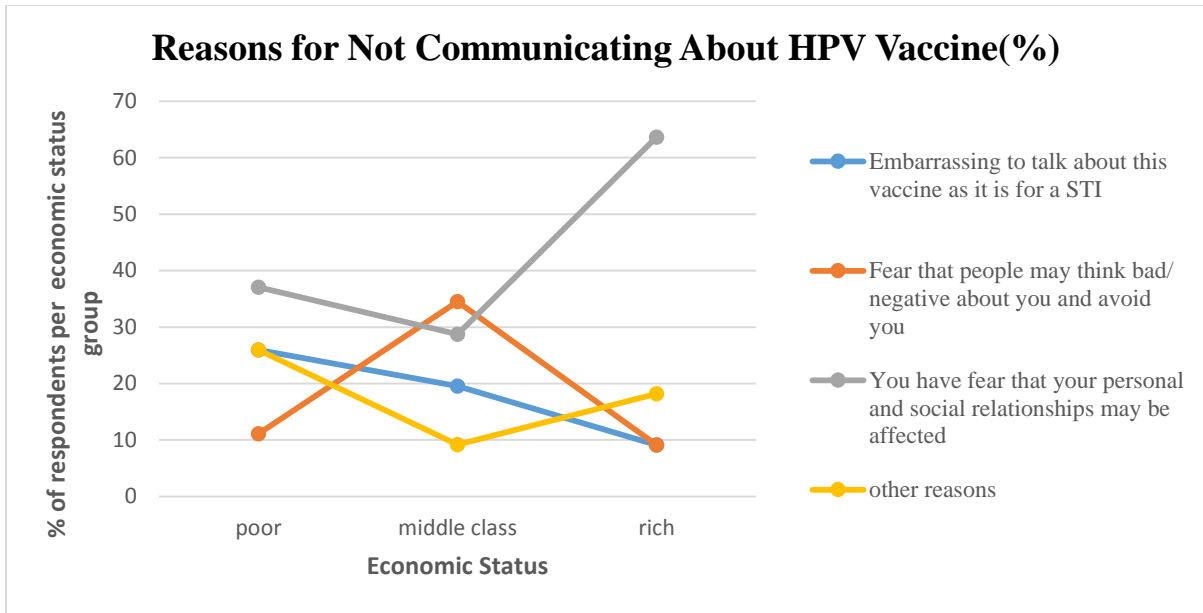


Figure 23. Understanding of variation in level of social concerns among respondents of different economic classes.

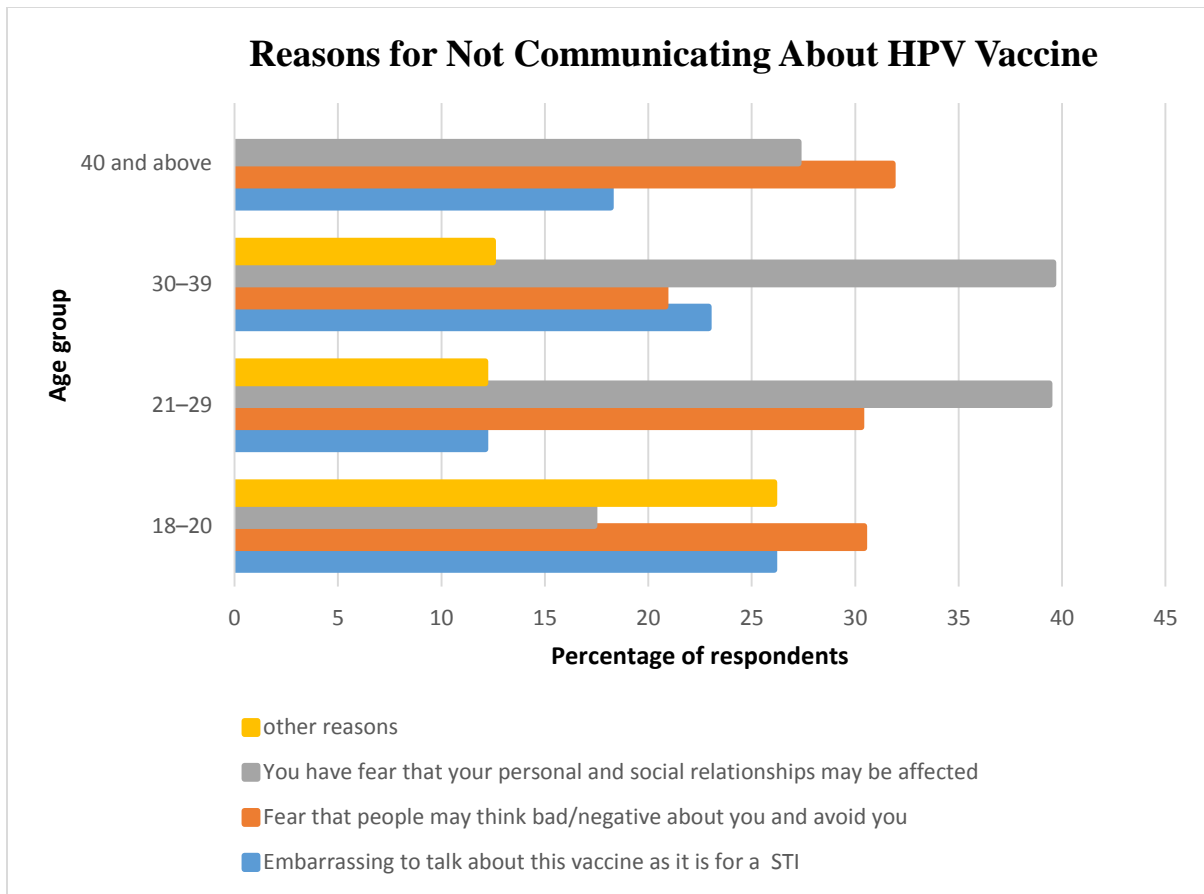


Figure 24. Understanding variation in social concerns among respondents of different age groups.

*Appendix A: Approval Letter from IRB***RESEARCH @ EMU**

UHSRC Determination: EXEMPT

DATE: January 27, 2015

TO: Sandhya Ghanta
Department of *Clinical Research Administration*
Eastern Michigan University

Re: UHSRC: # 687865-1
Category: Exempt category 2
Approval Date: January 27, 2015

Title: Barriers for Immunization against HPV in Developing Countries (India)

Your research project, entitled **Barriers for Immunization against HPV in Developing Countries (India)**, has been determined **Exempt** in accordance with federal regulation 45 CFR 46.102. UHSRC policy states that you, as the Principal Investigator, are responsible for protecting the rights and welfare of your research subjects and conducting your research as described in your protocol.

Renewals: Exempt protocols do not need to be renewed. When the project is completed, please submit the **Human Subjects Study Completion Form** (access through IRBNet on the UHSRC website).

Modifications: You may make minor changes (e.g., study staff changes, sample size changes, contact information changes, etc.) without submitting for review. However, if you plan to make changes that alter study design or any study instruments, you must submit a **Human Subjects Approval Request Form** and obtain approval prior to implementation. The form is available through IRBNet on the UHSRC website.

Problems: All major deviations from the reviewed protocol, unanticipated problems, adverse events, subject complaints, or other problems that may increase the risk to human subjects or change the category of review must be reported to the UHSRC via an **Event Report** form, available through IRBNet on the UHSRC website

Follow-up: If your Exempt project is not completed and closed after **three years**, the UHSRC office will contact you regarding the status of the project.

Please use the UHSRC number listed above on any forms submitted that relate to this project, or on any correspondence with the UHSRC office.

Good luck in your research. If we can be of further assistance, please contact us at 734-487-3090 or via e-mail at human.subjects@emich.edu. Thank you for your cooperation.

Sincerely,

EASTERN MICHIGAN UNIVERSITY**University Human Subjects Review Committee**

200 Boone Hall • Ypsilanti, Michigan 48197 • Phone: 734.487.3090 • E-mail: human.subjects@emich.edu
www.emich.edu/ord (see Research Compliance)

DATE: April 13, 2015
TO: Sandhya Ghanta
FROM: University Human Subjects Review Committee
PROJECT TITLE: [687865-2] Barriers for Immunization against HPV in Developing Countries (India)
UHSRC #: 87865-2
ACTION: ACKNOWLEDGED


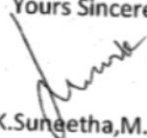
Thank you for submitting your application and supporting materials for this project. The UHSRC has ACKNOWLEDGED your submission.

The following items are acknowledged in this submission:

- Amendment/Modification - Minor change request form (UPDATED: 04/8/2015)
- Questionnaire/Survey - survey questionnaire for subjects (UPDATED: 04/6/2015)

If you have any questions, please contact the UHSRC at human.subjects@emich.edu or 734-487-3090. Please include your project title and UHSRC number in all correspondence with this committee.

Appendix B: Clinic Approval Letter to Conduct Survey

 <p>complete family care</p>	<p>SRI LAKSHMI MATERNITY & SURGICAL NURSING HOME</p> <p>Beside Sivalayam, KOTHAPET GUNTUR - 522 001. (A.P.)</p>	Hospital : 2222740
		<p>☎ Res : 2220198 2230198</p>
<p>Dr. K. Suneetha, M.S., OBG. Regd. No. 62823</p>		Date. 17/9/14.....
<p><u>To whom so ever it may concern</u></p>		
<p>Please allow this letter to serve as permission for Ms.Sandhya ghanta to access Hospital patient's contact details to conduct a survey for her project titled, "Barriers for immunization against HPV in developing countries" The purpose of this study is to understand the socio-economic and religious concerns of people who belong to varied cultures and backgrounds for accepting Human Papilloma Virus (HPV) Vaccine.</p>		
<p>Yours Sincerely,  Dr.K.Suneetha,M.S.(OBG).</p>		
<p>Dr. K. SUNEETHA Regd. No: 62823 M.S (OBG) SRI LAKSHMI MATERNITY AND SURGICAL NURSING HOME Kothapet, GUNTUR-522 00</p>		

*Appendix C: Letter Explaining about Survey and Informed Consent***Informed Consent Form**

Purpose of the study: This is a study in Clinical Research and Administration Program that is being conducted by Miss Sandhya Ghanta (master's student), Eastern Michigan University. The purpose of the study is to understand the views of women and adolescent girls about Human Papilloma Virus (HPV) vaccine, the socio-cultural and religious concerns they have for taking the HPV vaccine.

What will be done in the study: We have some evidence from the past studies conducted in various countries that women have expressed some sort of social and religious concerns for accepting HPV vaccine. These concerns and beliefs may have attributed to the low vaccination rates in developing countries. As, the beliefs and concerns about vaccines vary among different religions, people and countries, we would like to study the barriers for immunization against HPV in Indian population and analyze if there is impact of these barriers on vaccination rates. We have chosen Vijayawada as a site for our study because it has population of varied religious, cultural and economic backgrounds. As a part of the study we will conduct a survey on women and adolescent girls of Vijayawada. We will send out surveys to around 250 participants who are 18 years and above. Interested people will be asked to sign the consent and complete the survey. After all the surveys are collected we will analyze the surveys and examine the prevalence of any religious and socio-cultural barriers for taking HPV vaccine in the Indian population. We will also compare the religious concerns expressed by people of different religious, variation in the levels of people's concern regarding the socio-cultural barriers based on age, education and financial

backgrounds. We will analyze if any of these barriers have an impact on vaccination rates in India.

About the survey: You will complete a 15-20 minute survey. In the first part of the survey, we would ask some demographic information like age, marital status, and financial status in order to accurately describe the general traits of the groups who participate in the study. In the second part of the study, we would ask questions about your vaccination history (vaccines that you have taken in the past), your views about cervical cancer (knowledge about the disease and its causes), and preventive vaccine for cervical cancer caused by HPV (Human Papilloma Virus). In the third part of the survey, we would ask some questions about the social and religious problems or concerns that you might have for accepting the HPV vaccine.

After you complete your survey you are asked to send back the signed consent form and survey to the address provided. After receiving all the surveys, we would utilize this information to answer the questions regarding the prevalence of religious and socio-cultural barriers people have for accepting / taking HPV vaccine.

Benefits of the study: You will be contributing to knowledge regarding the awareness of people about the vaccine and understanding people's concerns about HPV vaccine. No personal benefits gained from the study.

Risks or Discomforts: No risk is anticipated in the study. There are no procedures involved in the study. If you feel any question is uncomfortable to answer, you may skip the question and go to the next one. If you have changed your decision to participate you may withdraw or discontinue from the study anytime without any loss or penalty.

Confidentiality: Your personal information and the survey answers will be kept confidential and used solely for research purposes. After the study is completed and results are obtained your information will be erased. No names or identification elements of the participants will be mentioned in the results or elsewhere if study is published.

How the data is used: The data is used for scholarly purposes only. The data we get from this survey will be used to analyze the concerns women have for accepting HPV vaccine in developing countries like India. The results of the study may be presented in educational settings or published in scientific journals.

Consent: If you are willing to participate in the study, please sign the consent form and start taking the survey. This informed consent states that you are participating in the survey voluntarily and have choice to withdraw from the study anytime without any penalty.

Signature of the participant: _____

NOTE: After completing the survey please seal the survey to maintain confidentiality of your answers.

Contact information: If you have any questions or concerns about the study please contact

1. Sandhya Ghanta at sghanta@emich.edu
2. Dr.K.Suneeta M.S, OBG at ph.: 0863- 2222740

Address to mail the surveys: Dr.K.Suneeta M.S, OBG

Sri Lakshmi Maternity and Surgical Nursing home

Besides Sivalayam, Guntur -522001.

Appendix D: Survey Questionnaire

HPV Acceptance

1. Which category below includes your age?

a) 18-20

b) 21-29

c) 30-39

d) 40 and above

1. మీ వయస్సు ఈ క్రింది వాటిలో ఏ వర్గానికి చెందినది?

(ఎ) 18 - 20

(బి) 21- 29

(సి) 30 - 39

(డి) 40 లేక ఆపైన

2. Do you identify with any of the following religions?

a) Hinduism

b) Islam

c) Christianity

d) Buddhism

e) Others (please specify) _____

2. మీరు ఈ క్రింది వాటిలో ఏ మతమునకు చెందిన వారు?

- ఎ) హిందూ
- బి) ఇస్లాం
- సి) క్రిస్టియన్
- డి) బౌద్ధమతము
- ఇ) ఇతరులు

3. Which is the highest level of school you completed or highest level of education you are pursuing?

- a) Less than high school degree
- b) High school degree or equivalent
- c) Bachelor's degree or equivalent
- d) Masters or equivalent
- e) No education

3. మీరు ఎంతవరకు విద్యను అభ్యసించి వున్నారు?

- (ఎ) ఉన్నత పాఠశాల పట్టా కంటే తక్కువ
- (బి) హైస్కూల్ డిగ్రీ లేదా తత్సమానం
- (సి) బ్యాచిలర్స్ డిగ్రీ లేదా తత్సమానం
- (డి) మాస్టర్స్ డిగ్రీ లేదా తత్సమానం
- (ఇ) ఎటువంటి చదువు లేదు

4. Which of the following categories best describes your employment status?

- a) Employed
- b) Unemployed, looking for job

- c) Retired
- d) Owns a Business
- e) Others (Please specify) _____

4. ఈ క్రింది వాటిలో మీరు ఏ ఉద్యోగ స్థితికి చెందిన వారు?
- (ఎ) ఉద్యోగి
- (బి) నిరుద్యోగి, ఉద్యోగ ప్రయత్నంలో ఉన్నవారు
- (సి) పదవీ విరమణ
- (డి) సొంత వ్యాపారం
- (ఇ) ఇతరములు

దయచేసి పేర్కొనండి :

5. How will you describe your financial status?

- a) Low income/Poor (Income of 1,035 rupees per person per month)
- b) Middle Class (Income between 1,035-Rs and 10,354 per person per month)
- c) Rich (Income > 10,354 per person per month)

5. మీరు మీ ఆర్థికస్థితిని ఎలా పేర్కొనెదరు?

- ఎ) అల్పదాయ/పేద (నెలకు తలసరి ఆదాయము 1035 రూపాయలు)
- బి) మధ్య తరగతి (నెలకు తలసరి ఆదాయము 1035 రూపాయలు మరియు 10,354 రూపాయలు కన్నా తక్కువ)
- సి) ఉన్నత స్థితి (నెలకు తలసరి ఆదాయము 10,354 రూపాయలు)

6. Which of the following best describes your current relationship status?

- a) Married
- b) Single

6. ప్రస్తుతం మీరు ఎటువంటి ఉత్తమ సంబంధ స్థితి కలిగి వున్నారు?
 (ఎ) వివాహితుడు
 (బి) అవివాహితుడు / ఒంటరి / ఒక్కడే

7. Do you have any children?

a) Yes

b) No

If yes, please specify how many male and female children you have. _____

7. మీరు సంతానం కలిగి వున్నారా?

(ఎ) అవును

(బి) కాదు

సంతానం కలిగి ఉన్నట్లైతే దయచేసి అబ్బాయిలు ఎంతమంది? అమ్మాయిలు ఎంతమంది చెప్పగలరు?

.....

8. Have you taken any vaccines till now?

a) Yes

b) No

8. మీరు ఇంతవరకు ఎటువంటి డీకా అయిన తీసుకొని ఉన్నారా?

(ఎ) అవును

(బి) లేదు

9. What vaccines have you received among the following?

a) Hepatitis B

- b) Polio
- c) MMR
- d) DTP
- e) HPV
- f) Others (Please specify) _____

9. క్రింది వాటిలో మీరు ఏ డీకా తీసుకొని ఉన్నారు?

- (ఎ) హైపర్టెటిస్-బి
- (బి) పోలియో
- (సి) యమ్.యమ్.ఆర్.
- (డి) డి.టి.పి.
- (ఇ) హెచ్.పి.వి.
- (ఎఫ్) ఇతరములు

దయచేసి పేర్కొనండి :

10. Where did you take your previous vaccines?

- a) Hospital or Clinic
- b) Government Vaccination Camps
- c) School
- d) Others (Please specify) _____

10. మీరు చివరిగా తీసుకొన్న టీకా ఎక్కడ తీసుకున్నారు?

- (ఎ) ఆసుపత్రి లేక క్లినిక్
- (బి) ప్రభుత్వ టీకా శిబిరం
- (సి) పాఠశాల
- (డి) ఇతరములు

దయచేసి పేర్కొనండి :

11. Who would make the choice to vaccinate for your family?

- a) Father
- b) Mother
- c) Husband
- d) Self Decision
- e) Others (Please specify) _____

11. ఎవరు మీ కుటుంబం కోసం టీకాలను ఎంపిక చేస్తారు?

- (ఎ) తండ్రి
- (బి) తల్లి
- (సి) భర్త
- (డి) స్వీయ నిర్ణయం
- (ఇ) ఇతరులు

దయచేసి పేర్కొనండి :

12. What do you know about cervical cancer?

- a) Cancer that affects the cervix or garbhasaya
- b) Sexually transmitted Disease caused by HPV virus

- c) Caused due to multiple sexual contacts, improper hygiene.
- d) All of the above
- e) None of the above

12. మీకు గర్భాశయ క్యాన్సర్ గురించి ఏమి తెలుసు?
- (ఎ) గర్భాశయ ముఖద్వారం క్యాన్సర్ లేక గర్భాశయంను ప్రభావితం చేయు క్యాన్సర్
 - (బి) హెచ్.పి.వి. వైరస్ వల్ల వ్యాపించు సుఖవ్యాధి
 - (సి) విచ్చలవిడి లైంగిక సంబంధాలు మరియు అపరిశుభ్రత వలన
 - (డి) పై అన్ని కారణాలు
 - (ఇ) పైవేవి కావు

13. Have you heard about the HPV (Human Papilloma virus) vaccine?

- a) Yes
- b) No

13. మీరు ఎప్పుడైనా హెచ్.పి.వి. (హ్యూమన్ ప్యాపిలోమా వైరస్) టీకా గూర్చి విన్నారా?
- (ఎ) అవును
 - (బి) లేదు

14. If Yes, How did you know about HPV vaccine?

- a) Physicians/Doctor
- b) Friends/ Community
- c) Media (Newspapers/ Television)
- d) Government Education Campaigns

e) Others (Please specify) _____

14. ఒకవేళ అవును అయితే, మీకు హెచ్.పి.వి. టీకా గురించి ఎలా తెలుసు?

(ఎ) వైద్యులు / డాక్టర్

(బి) స్నేహితులు / కమ్యూనిటీ

(సి) ప్రసార సాధనాలు (పెపర్ / టి.వి.)

(డి) ప్రభుత్వ ఆరోగ్య విద్యా బోధన శిబిరాలు

(ఇ) ఇతరములు

దయచేసి పేర్కొనండి :

15. What knowledge do you have about HPV Vaccine?

a) Gives protection from infections caused by some types of Human Papilloma Virus

b) Prevents cervical cancer

c) it's a vaccine given to protect from all sexually transmitted Infections.

d) None of the above

e) All of the above

15. మీకు హెచ్.పి.వి. టీకా గురించి ఎటువంటి పరిజ్ఞానం కలిగి ఉన్నారు?

(ఎ) హెచ్.పి.వి. వైరస్ వలన కలుగు ఎన్.పెక్షన్స్ నుంచి రక్షణ కల్పిస్తుంది

(బి) గర్భాశయ ముఖ క్యాన్సర్ ను నిరోధిస్తుంది

(సి) సుఖవ్యాదుల వలన కలుగు ఇన్.పెక్షన్స్ నుంచి రక్షణ కల్పిస్తుంది

(డి) పైవేవి కావు

(ఇ) పైవి అన్ని

16. Have you taken HPV vaccine?

a) Yes

b) No

16. మీరు హెచ్.పి.వి. టీకా తీసుకున్నారా?

(ఎ) అవును

(బి) లేదు

17. If yes, how many doses you have taken? _____

17. ఒకవేళ టీకా తీసుకొన్న యెడల, ఎన్ని మోతాదులు తీసుకున్నారు ?

18. If No, What is the reason for not taking the vaccine?

a) Vaccine is unavailable / expensive

b) Fear about side effects

c) Do not know about the vaccine and its importance

d) Other reasons (Please specify) _____

18. టీకా తీసుకోని యెడల, దానికి గల కారణం?

(ఎ) టీకా అందుబాటులో లేకుండుట / ఖరీదైన

(బి) దుష్ప్రభావాలు గురించి భయం

(సి) టీకా మరియు దాని ప్రాముఖ్యత గురించి తెలియదు

(డి) ఇతర కారణములు

దయచేసి పేర్కొనండి :

19. Would you like to tell your friends/ others that you have taken HPV vaccine and recommend them to take?

a) Yes

b) No

19. మీరు హెచ్.పి.వి. టీకా తీసుకున్న, మీ స్నేహితులు / ఇతరులకు కూడా టీకా తీసుకోవలసిన ఆవశ్యకతను గూర్చి చెప్పగలరా?

(ఎ) అవును

(బి) కాదు

20. If yes, what information would you give them about HPV vaccine?

a) Uses of the vaccine

b) Its availability and cost

c) Others (please specify)

20. అవును అయినట్లయితే, హెచ్.పి.వి. టీకా గూర్చి ఎటువంటి సమాచారం వారికి అందివ్వగలరు?

(ఎ) టీకా యొక్క ఉపయోగాలు

(బి) టీకా యొక్క అందుబాటు మరియు ఖరీదు

(సి) ఇతరములు

దయచేసి పేర్కొనండి :

21. If No, Is there any reason for you to not tell/ recommend HPV vaccine to your friends/others?

a) It's embarrassing to speak and explain about this vaccine as it is for a

Sexually Transmitted Disease.

b) Fear that people may think bad/ Negative about you and avoid you

c) You have fear that your personal and social relationships may be affected

d) Other reasons (please specify) _____

21. కాదు అయినట్లయితే, మీ స్నేహితులకు, ఇతరులకు టీకా గూర్చిన వివరములు తెలియపరచలేక పోవుటకు గల కారణాలు?

ఎ) ఇది ఒక లైంగిక సంక్రమణ వ్యాధి కనుక దీని గురించి మాట్లాడటం మరియు టీకా గురించి వివరించడం ఇబ్బంది.

(బి) ప్రజలు చెడుగా భావిస్తారు అనే ఆందోళన / మిమ్మల్ని దూరం చేస్తారు అనే భయం

(సి) మీకు మీ యొక్క వ్యక్తిగత మరియు సామాజిక సంబంధాలు ప్రభావితం కావచ్చు అనే భయం

(డి) ఇతర కారణాలు

దయచేసి పేర్కొనండి :

22. Do u have any objections or restrictions in your religion for taking this vaccine?

a) Yes

b) No

22. మీరు ఈ టీకా తీసుకొనేందుకు మీ మీ మతంలో ఏమైనా అభ్యంతరాలు లేదా పరిమితులు ఉంటాయి?

(ఎ) అవును

(బి) కాదు

23. If yes, what might be the objections about?

a) Purity of vaccine

Please specify _____

b) Spiritual belief

Please specify _____

c) Other concerns

Please specify _____

23. అవును అయినట్లయితే, ఎటువంటి పరిమితులు ఉంటాయి?

(ఎ) డీకా యొక్క స్వచ్ఛత

దయచేసి పేర్కొనండి :

(బి) మతపరమైన నమ్మకం

దయచేసి పేర్కొనండి :

(సి) ఇతర ఆందోళనలు

దయచేసి పేర్కొనండి :

Appendix E: Letter of Translation

Regd No. 59/87 Estd : 1979

CAMBRIDGE SCHOOL

(A Project of Sri Satyanarayana Educational Society) Phone No: 276186
(Recognised by Govt. of A.P.)

Residential & Non Residential, (English & Telugu Medium)
SRUNGAVARAPUKOTA - 535145
Vizianagaram Dist.

Date : _____

To _____

Dear Sir/ Madam,

This letter is to state the content of survey questionnaire for the thesis "Barriers for Immunization against HPV in Developing countries (India)" by Sandhya Ghanta is translated accurately into regional language Telugu

Thanking you,

[Signature]
23/6/15
HEAD MASTER
Cambridge School
KOTA

Proceedings of L.Dis. No. 108 / A1/ 2010 of the D.E.O. V.Z.M. Dated 04-05-2011
I to V - E.M & TM

Proceedings of R.C., No. 1558 / A5/ 2010 of the R.J.D. Kakinada Dated 24-07-2010
I to V - E.M & TM

[Stamp: CAMBRIDGE SCHOOL SRUNGAVARAPUKOTA]