

# The Human Papillomavirus Vaccination Barriers and Initiatives

By Rachel Eccles

A thesis presented to the Honors College of Middle Tennessee State University in partial fulfillment of the requirements for education from the University Honors College.

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# The Human Papillomavirus Vaccination Barriers and Initiatives

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## ABSTRACT

The Human Papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the world. This study aims to examine why the HPV vaccine administration rates remain so low even when the vaccine has been proven safe and effective while heavily recommended by healthcare professionals and the media. The hypothesis of this study is if MTSU students are surveyed about their HPV vaccination rates, then under vaccination will be found to occur due to three primary reasons: low awareness, insufficient patient-doctor communication, and lack of acceptance.

The survey instrument was administered to five different courses at MTSU for a total of 107 responses to the survey with ages ranging from 18-45. According to the results, 14% of respondents have never heard of HPV before the survey. When asked how many doses they had received, 37% had successfully completed the HPV vaccine three-part series while 37% had not received a single dose. There were 47% of the students who did not know that HPV can cause cancer, and 32% of the survey population who were still unsure of how the virus is spread.

The results showed that fewer people than expected were aware of HPV. Hopefully, this project will be able to eliminate the variable that insurance is a major factor that affects vaccination rates for the HPV vaccine in that students are able to receive it for free through government funding (Gardasil 9, 2018). The information gained from this project has been shared with the Middle Tennessee State University students who participated in the study and the university faculty in an effort to increase awareness.

# Table of Contents

LIST OF FIGURES .....	vi
Introduction.....	1
Hypothesis.....	7
Methodology .....	8
Timeline .....	10
Results.....	11
Discussion .....	16
Low awareness .....	16
Insufficient Patient- Doctor Communication .....	18
Lack of Acceptance .....	19
Conclusion .....	21
Appendices.....	23
Survey Instrument .....	24
Bibliography.....	28

## LIST OF FIGURES

Figure 1 - Based on the sample, this chart illustrates all the places people have heard about HPV. The participants were asked to select all that applied. ....12

Figure 2 - Based on the sample, this chart shows the number of people who have received the HPV vaccine. The pie chart shows that over a third of respondents have not received the vaccination. ....13

Figure 3 - Based on the sample, this chart illustrates the number of vaccines people have received. ....14

## **Introduction**

The most common sexually transmitted infection (STI) in the world is the Human Papillomavirus (HPV). HPV affects both males and females and is commonly contracted when people become sexually active. High school to college aged students are the most affected population with ages 15-24 making up 75% of HPV cases worldwide (Huang, 2008). There are an estimated 6.2 million HPV cases per year, including ongoing diagnoses (Huang, 2008). This is a serious health concern as HPV can lead to several different types of cancers, such as cervical, oropharynx, and anal cancers.

A vaccine was created and approved by the FDA in 2006 that can prevent the HPV infection from types of HPV 6, 11, 16 and 18 that could lead to cervical cancer, genital warts, and certain precancerous lesions, called a quadrivalent vaccination. A second bivalent version of the vaccine was created in 2009. This form targets HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 5, which was approved by the FDA to prevent cervical cancer and various effect of HPV like genital warts (National Cancer Institute, 2018). Throughout the vaccination trials, each was found to be 100% effective for the types they claim to be preventing (National Cancer Institute, 2018). Both vaccines are recommended by the Advisory Committee on Immunization Practices (ACIP) for girls aged 11-12 and up to 26. The bivalent vaccine, which only needs two doses, is recommended for males for ages 9-15 (CDC, 2007).

An immunization protects a person against illnesses and vaccine-preventable diseases such as measles, hepatitis B, tetanus, polio, pneumonia, and, in the case of HPV, cervical cancer. Immunizations work by preparing the body to fight certain diseases by pre-making the appropriate antibody to counteract the virus. The small dose makes it, so

the body does not experience any symptoms. Currently, there are preventable diseases and outbreaks occurring in foreign countries and in the U.S. from people not vaccinating their children. In 2018 alone, there were 17 measles outbreaks in the U.S. that came from an increase in the number of travelers who had measles, but the disease was allowed to spread and turn into an outbreak due to communities of unvaccinated people (CDC, 2019). According to the World Health Organization, there is an increasing amount of the population that is getting vaccinated with newer vaccines like Gardasil. However, the global vaccination coverage remains at 86%. Although this number is high, the people who are not vaccinated create pockets of epidemics that threaten all people with the disease and increases the likelihood of new strains being formed, an issue of concern with HPV. Each new strain is 90% of the same DNA as the HPV type it changed from, but the 10% difference can render the new type no longer protected against with the current vaccine (Burd, 2003).

The amount of knowledge and understanding of HPV, the vaccine, and cervical cancer as well as provider and physician communication with patients were found in a study to be consistently low among people in the rural Appalachia states in the United States. The study found a measurable difference in vaccination rates by geographical locations, finding the rates of initiation of vaccines in the South were 48.4 % compared to 53.4% in the Northeast, 51.4% in the Midwest, and 61.6% in the West (Ryan et al., 2018). The study also attributed this to the nature of the rural, conservative region located within the “Bible Belt,” and the older generation’s attitude to the vaccination were less than receptive. Recent work has focused on increasing vaccine uptake by concentrating on factors that affect the rates (Ragan, 2018).



One study found that, among insured women 19- 26 years old, those who had talked with their physician about HPV and received a recommendation were more likely to be vaccinated (Good, 2011). The strength of the physician's approval played a major role in the decision to be vaccinated. Physicians are represented as a position in power as an expert in the medical field and, with the additional information they give, have a significant impact on parents' thoughts. It has also been shown that women who received the HPV vaccine become more careful with their sexual activity in order to avoid other STIs (Ports, 2015), (Mather, 2012).

Another major influence on the uptake of the HPV vaccine is insurance. Insurance companies cover the price of the vaccine at different ages depending on the individual's plan. With insurance, it is much easier to agree to get a vaccine if it is already covered and not an extra expense. A study found that "[p]ersons without health insurance were less likely than those with health insurance to be vaccinated for influenza ( $\geq 18$  years), pneumococcal (18–64 years with high-risk conditions), tetanus ( $\geq 18$  years), Tdap ( $\geq 18$  years), and HPV (women 18–26 years)" (Lu, 2018). However, most people do not know that local clinics administer the vaccine at no charge.

University of Michigan Medicine Practice Guide (2018) suggests the following:

Gardasil is a newly licensed vaccine, currently recommended for females 9-26 years old, used to protect against cervical cancer caused by infection with the human papilloma virus (HPV). Although this is a very important new vaccine, not all insurance plans will be paying for this vaccine. Mcare and Blue Care Network (BCN) insurance are covering the cost of this vaccine for females age 9-26 years old. Medicaid is covering this vaccine for females age 19- 26 years old; for females 9- 18 years old who are Medicaid eligible or have no insurance, the vaccine will be available in clinics enrolled in the Vaccines for Children (VFC) program or at local Health Departments. Coverage under Blue Cross/Blue Shield varies by the employer group and whether they have selected immunizations as a plan benefit. Other insurance plans may have similar coverage to Blue

Cross/Blue Shield. It is important that you check with your plan to determine if they will pay for the cost of the vaccine. If your health plan does not cover the vaccine, you will be responsible for the cost if you choose to receive the vaccine. The cost of the HPV vaccine is \$195 plus an administration fee of \$27 per injection. Three shots are required to complete the series.

The uninsured have the option to get the vaccine for free because Gardasil 9, the new HPV vaccine, is a part of the Vaccine for Children (VFC) Program, a federally funded program that ensures that children can receive the vaccine even when their parents cannot afford it. The VFC administers free vaccines to children 18 or under who qualify for Medicaid, do not have health insurance, or have a health insurance that does not fully cover the vaccinations. If their physician is not a VFC provider, then there are local health clinics, Federally Qualified Health Centers (FQHC), or Rural Health Clinics (RHC) that can supply the vaccine. It is also a part of the Merck Vaccine Patient Assistance Program (MVPAP), which is funded by Merck for adults 19 to 26 years of age who cannot afford vaccines and do not have health insurance (Gardasil 9, 2018).

Within the literature review, two studies were found that had performed a similar project in foreign countries. It was much more difficult to find a study as in-depth as the ones in different areas around the world. The original study performed throughout China in 2012 contained an oral interview administered to a large study population of government officials, healthcare providers, and women in rural and urban areas. The results of the interviews showed that there were low levels of HPV knowledge; however, there was strong support for the HPV vaccine. The survey population also indicated a large amount of trust for healthcare professionals (Zhao, 2012). The intent of this study shifted a part of the focus of this thesis project to look more at physician influence on

patients. Future studies could examine how the U.S. compares to other countries in the general population level of knowledge about HPV.

The next study was set in Thailand, which has the world's highest numbers of HPV diagnoses. Parents of children between the ages of 9-12 were surveyed and resulted in 301 responses. This particular study found that a better knowledge about HPV increases the acceptance of the vaccination. In Thailand, the cervical cancer screenings occur in much lower rates, with four out of ten mothers never receiving a screening. The results of the questionnaires demonstrated positive attitudes towards the HPV vaccine. The researchers concluded that the future implementation of the HPV vaccine for children would be a possibility with proper information given to parents (Grandahl, 2018). The results of the Thailand study initiated an additional focus of this project aimed at educating the public about HPV and its vaccination rates. A similar study in the U.S. found that the way the information is provided to the population impacts the attitudes toward vaccine acceptance (Gerend, 2007). The data needs to be able to be widely spread and come across positive towards its audience.

As a person living in rural Appalachia, I am knowledgeable about this topic and have first-hand experience with physicians recommending vaccines. Being right outside of Appalachia, MTSU draws 89% of the student population from Tennessee, which belongs in the Appalachia region (NCES, 2016). The topics of lack of acceptance, lack of awareness, and low HPV communication go hand in hand, each affecting the other. I personally know people who have not received the HPV vaccine and, based on the data above, I propose to study these three demographic characteristics among college students

at MTSU. This study aims to examine why the HPV vaccine administration rates remain so low even when the vaccine has been proven safe and effective while heavily recommended by healthcare professionals and the media.

## **Hypothesis**

This project will investigate the primary factors driving low rates of HPV vaccination. The hypothesis of this study is if MTSU students are surveyed about their HPV vaccination rates, then under vaccination will be found to occur due to three primary reasons: low awareness, insufficient patient-doctor communication, and lack of acceptance.

## Methodology

A short survey instrument that can be administered to the MTSU student body was the most appropriate methodology to study this issue. It was given in willing professor's courses in order to get a large enough sample to study on paper with scantrons. The survey instrument was optional but presented to the entire class. Anonymity was extremely important in this case to allow students to answer questions about insurance, where they are from, personal health issues (i.e.: have they received the HPV vaccine), and general knowledge about HPV and its effects along with questions about the vaccination.

Collecting the data by a survey reduces bias by asking neutrally worded questions without leading answer choices, ensuring that each response is due to the same exact question, and keeping the volunteer anonymous. The data is more reliable because it is formatted as a survey instrument, a neutral environment in which people are given the survey. The responses were quantified by coding their responses. Qualitative research methods were used to address the issue, and then quantified for the results. Weiss notes this from his research stating that, "In general, if statistical analysis is our goal, we would do better to use a survey approach" (Weiss, 1994, 3).

However, surveys offer an inflexible design with fixed questions and limited answers. Surveys can easily become biased by loaded phrases. Each question needed to be specifically placed in an order to avoid leading the respondent to a certain answer. When dealing with a controversial topic, students may be under a social pressure to answer a certain way, leading to inaccurate results from false preferences (Kuran, 1997).

The survey instrument has been designed to hopefully mitigate these issues as shown in the appendix.

It was first necessary to gain approval from the Institutional Review Board (IRB) of MTSU. This included applying to the IRB as well as completing CITI training in social and behavioral research. After the IRB has approved the project, gathering of data from the surveys created was started.

After collecting data from MTSU students over 18 with controlling certain demographic factors, statistical analysis was performed on the data to compare factors from birthplace, health insurance coverage, and general knowledge about the HPV vaccine.

## **Timeline**

*February 2019*

Submit final thesis proposal

Submit application for exempt review to the IRB

Complete CITI training

*March 2019*

Continuing extensive research and literature review

*April 2019*

Register for UH 4950

*May 2019*

Submit for IRB approval

*June 2019*

Begin collecting data

First analysis of data

Drafting of final thesis

Revision of drafts and data

Final analysis of data

*July 2019*

Drafting of final thesis

Submit final thesis

Thesis defense

Revision and submission of final copies

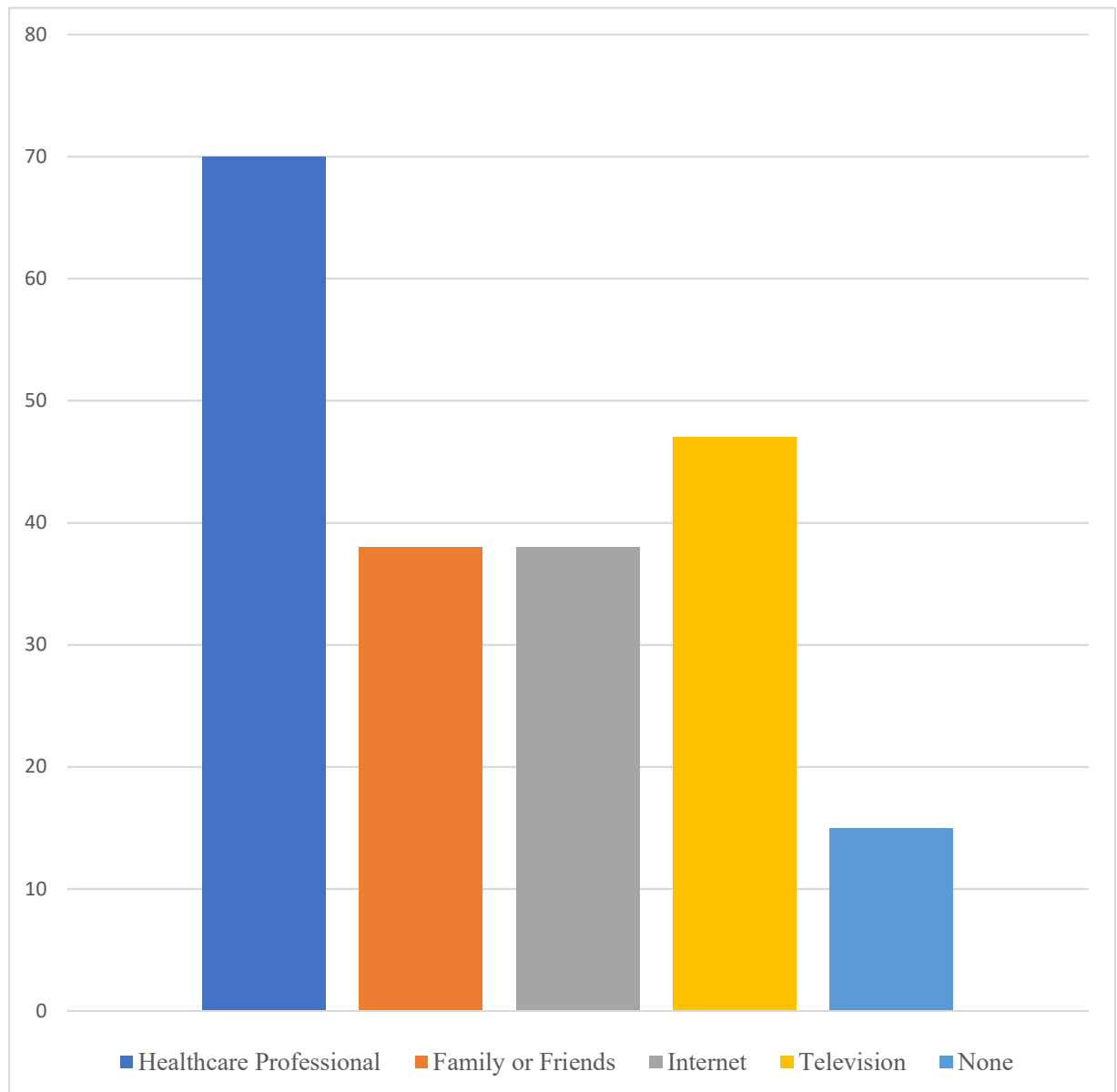


## **Results**

The main purpose of the survey was to find the reasons for the low uptake for the Human Papillomavirus vaccination, the level of acceptance of the vaccine, and the barrier between physicians and patients. The survey instrument was administered to five different courses at MTSU during the summer 2019 term. Participants were asked to answer eighteen multiple choice questions relating to HPV and its vaccine. In total, there were 107 responses to the pre-written survey with 83 females and 24 male responses with ages ranging from 18-45. The survey was aimed at college students, and there was an 86% majority of the respondents between the ages 18 and 24. This was completely random, but the fact that there are more females relates further to this study in that females are more impacted by HPV.

The beginning of the survey asked about the general knowledge of HPV. According to the responses, 14% of respondents have never heard of HPV before the survey. The rest of the participants had heard about HPV from multiple places including doctors, nurses, or healthcare professionals (65.4%), family and friends (35.5%), the internet (35.5%), and the television (43.9%). The comparison of responses is listed below in a bar graph for clarity.

**Figure 1 Source of HPV Awareness-** Based on the sample, this chart illustrates all the places people have heard about HPV. The participants were asked to select all that applied.

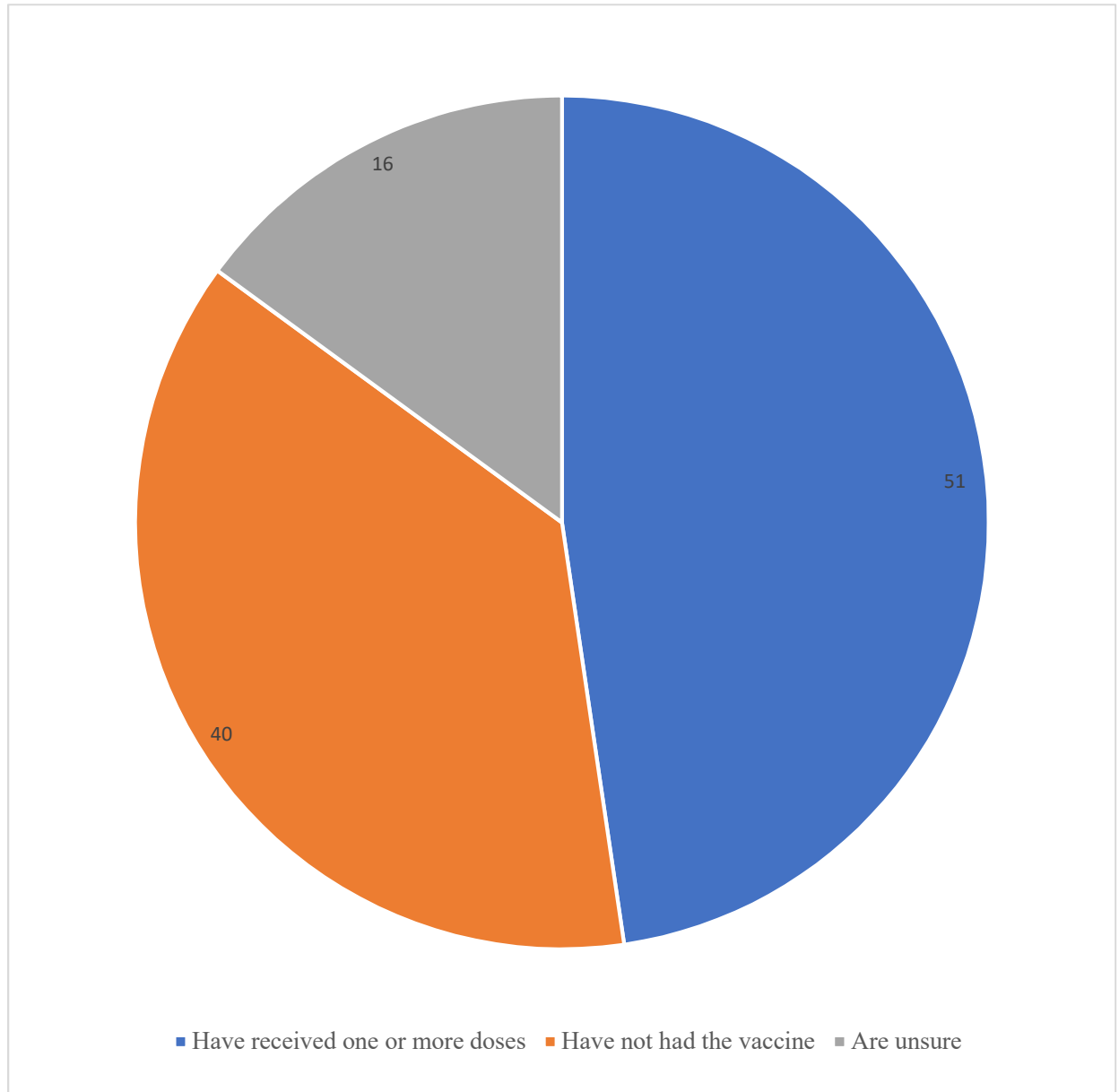


When asked about vaccines, a strong majority of people (98%) claimed they knew how vaccines work. However, 6.5% of respondents stated that they do not agree with vaccination. For the specific HPV vaccines invented in 2006, Gardasil or Cervarix, 28% of people said they have never heard of it.

The following question was asked within the survey instrument, and the responses are charted on the graph below:

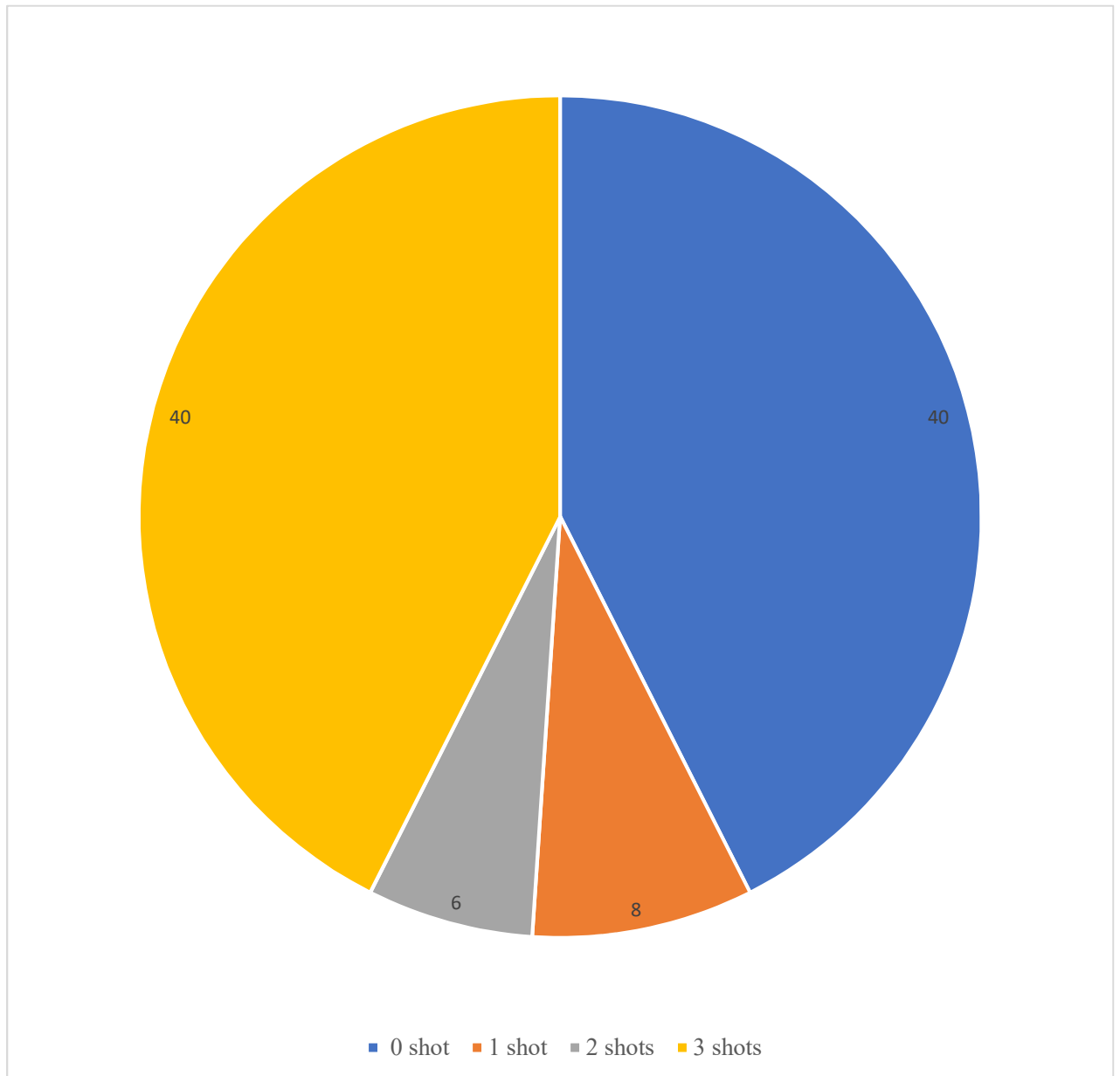
Human Papillomavirus (HPV) vaccine is given to prevent genital warts and cervical cancer. It is given in 3 separate doses over 6 months and has been recommended since June 2006. Have you ever received one or more doses of the HPV vaccine?

**Figure 2 Recipients of the HPV Vaccine-** Based on the sample, this chart shows the number of people who have received the HPV vaccine. The pie chart shows that over a third of respondents have not receive the vaccination.



When asked how many doses they had received, 37% had successfully completed the HPV vaccine three-part series. The number of doses is charted below, but there are less than 107 responses due to the fact that 12 people had preferred to not answer.

**Figure 3 Number of HPV Shots Received** -Based on the sample, this chart illustrates the number of vaccines people have received.



There were 12% of participants who said that they or someone they knew have been told that they had HPV. The major concern of HPV is that it can cause cervical cancer in women, as well as various other health problems. When asked, 47% of the students did not know that HPV can cause cancer, and 32% of the survey population were still unsure of how the virus is spread. However, 75% agreed that HPV requires treatment by a medical professional. Insurance does play a minor factor in receiving the vaccine. From the survey population, 90% of people have health insurance, but 51% are unsure if their insurance will cover the vaccine. Healthcare providers play a major role in the uptake of the vaccine. When they suggest the HPV vaccine, most parents will opt to get it for their children. Only 45% of respondents said that their physicians endorsed the vaccination.

For the participants who had not received the vaccine, a question asked what the primary factors were against it. Twenty-one percent of people said that they were unaware of the vaccine. This statistic means that there is a little more than five out of every 20 people unaware of this life-saving vaccine. Each year, 4,000 women die in the United States from the symptoms of HPV (ASHA, 2018). Insurance prevented 5% of respondents from receiving the vaccine, and 6% had personal beliefs that prevented them from getting the vaccination. Some of the personal beliefs may have been due to the social stigma on people, specifically women, who receive the HPV vaccine. 20% of people agreed that there was a humiliation put on people who get the vaccination with 28% still unsure if there was or not.

## **Discussion**

The results show that the topic of HPV vaccination can be difficult to study. Participants receive the vaccine relatively early in their lives. Figure 2 demonstrates that over half of the sample population are unsure of whether or not they received the vaccine. This makes the decision of vaccination mostly up to the parent's discretion until a patient is of age to decide for themselves. Even at an older age, the probability of a person reporting to receive an unknown vaccination is very low. The results will be discussed in the categorized sections below.

### **Low awareness**

The results of this project were lower than the expected values, with fewer people knowing about the common STI. Overall, there is a high number of students who have never heard about HPV at all, let alone that the HPV vaccine can prevent cancer. After supposedly being taught about subject in middle and high school health classes, the up and coming educated population is unaware of a common sexually transmitted infection (STI). According to Tennessee's education standards for Lifetime Wellness and Fitness under the Sexuality subcomponent, students are to "[r]ecognize abstinence from all sexual activity as a positive choice" and to "[i]dentify preventative methods and potential outcomes of engaging in sexual behaviors (e.g., pregnancy, abstinence, adoption, Hepatitis B, STIs)" (TN Dept. of Edu, 2018). This holistic approach to health and lifetime physical activities in Tennessee high schools does not seem to be achieving the desired result for the state with 14% of people not knowing what HPV is and with 12% of the respondents knowing someone with HPV. People are still unsure of how HPV is

transmitted (32%), which is by sexual contact, and that HPV can cause cervical cancer or genital warts (47%).

Since the HPV vaccine is given at a younger age, it is common for children to be unaware of why a shot is given to them. This demonstrates that the decision to vaccinate their children relies on the children's parents. There were 14% of the survey population that were uninformed about the vaccines they received as shown in Figure 2.

It is shown through Figure 3 that when one person receives one dose of the vaccine, they are more likely to complete the series. This illustrates that they are aware of the benefits of the vaccine and want a greater immunity to HPV. It also shows that the more information that the general public receives, the more likely it will be for people to obtain the vaccination.

Although only 12% reported that they knew someone with HPV, that number is most likely much higher. HPV is the most common sexually transmitted infection within the United States but is not nationally recorded due to different types having different symptoms. The main types recorded are usually type 16 and 18 since they are the strains responsible for causing cervical cancer. It is estimated that 80% of sexually active people contract HPV in their lifetime with 14 million new infections each year. At a given time, there are about 79 million people who have an active HPV infection (ASHA, 2018).

## **Insufficient Patient- Doctor Communication**

Although a 70 people stated that they had heard about HPV from a healthcare professional, there were still 37 people, or 35%, of people who had not been told the importance of this vaccine by a person in a position of authority. The information about the vaccine falls to healthcare providers and advertisements to be distributed. As stated before, most of the information respondents knew about HPV, other than from a professional, came from television or from the internet. The authority of a physician can sway people's opinions when they hear about the positives associated with certain vaccines, and it creates a better argument than a commercial on a TV.

The healthcare profession, in general, is responsible for vaccine uptake. Insurance is also considered heavily as it is the way a majority of Americans can afford medical treatment. Unfortunately, some of the respondents do not have insurance, and over half do not know if the vaccine is covered by their policy. This vaccine costs around \$222 per dose, as mentioned earlier, and could end up being over \$700 out of pocket for the full series if insurance does not cover it. However, people who cannot afford healthcare and are eligible for Medicaid can receive the vaccines for free at their local clinic (University of Mississippi Medical Center, 2018). When a patient is not offered a vaccine by their doctor because they do not have the insurance, they more than likely do not go and research possible vaccines in their free time. These patients are completely unaware of the vaccine and therefore will not go to a local clinic for the HPV vaccine.



## **Lack of Acceptance**

Since the HPV immunization is given by a vaccine, some groups have reason not to agree with the medical practice of vaccination with misconceptions about potential side effects. It was recorded that 6.5% of respondents stated that they do not agree with vaccination, which is a little lower than the national average of 9% according to PEW Research Center (Blake, 2015). The administered survey showed that people against vaccines will not receive even a cancer preventing vaccination. Commonly called anti-vaxxers are often against vaccination due to low awareness on how immunizations work or religious beliefs (Brennan, 2018). Although not everyone agrees with vaccines, 105 participants said they knew how vaccination works.

People who know that HPV is sexually transmitted expect there to be a high level of stigma when a young girl receives the vaccine. Receiving the vaccine does not mean that a 12-year-old will start to be sexually active. The way that this vaccine works is to prevent a person from ever receiving HPV, which underscores the need for it to be administered before their first sexual encounter (Lo, 2006). This is why it is recommended for children between the ages of 11-12, exactly as the kids are starting puberty. One study found that 6-12% of participants from 28 different studies in the United States believes that the vaccine encourages younger sexual activity (Brewer, 2007). This could prevent children from receiving the vaccine, even if the parents approve of vaccinations in general. A different study conducted in Canada found that there was no correlation between the HPV vaccination and increased sexual behavior in recipients of the vaccine (Donken, 2018). The correlation between these two thoughts

were not specifically tested in this study; however, 20% of participants believe that there was a social stigma placed on women who get the vaccine. Out of the survey population, 28% were unsure if there was a stigma, and this may be in part due to 33% of those surveyed were unaware that HPV was spread through sexual contact.

## **Conclusion**

Through analysis of the responses from the survey instrument, the hypothesis was proven to be accurate in this survey pool. There were low numbers of college students who are well-informed about HPV, its vaccine, and the effects of the virus. There was also less than half (37%) of the students who have not received the HPV vaccination, which was lower than anticipated. There is much to be done to raise the uptake level of the HPV vaccine. It all starts with educating the general public about the virus itself. The tactic of public education was proven to work in the case of reducing smoking rates. Once people become aware of the possible issues they could experience, they would be more likely to receive the vaccine. The harder aspect would be to remove the social stigma placed on those who receive the vaccination, since it is passed down through families, similar to certain traditions.

The results showed that less people than expected were aware of HPV. The good news is that most of the participants in this study are still young and within the target age group for receiving the vaccine series. This project can help students become more educated on the Human Papillomavirus. If they are willing, most students are still eligible to receive the vaccination if they were unaware of its benefits until now.

Hopefully, this project will be able to eliminate the variable that insurance is a major factor that affects vaccination rates for the HPV vaccine in that students are able to receive it for free through government funding (Gardasil 9, 2018). Each participant in the study was given an overview of this project, which included the background information of the Human Papillomavirus. The results of this survey and project will also be shared

with the university to educate and increase awareness about the vaccine. This information was already provided to participating students. There are also pamphlets located in the student health center about HPV, and the staff within the health center are very knowledgeable on the subject for any related questions.

## **Appendices**

Survey Instrument

IRB Approval Letter

Bibliography

### Survey Instrument

1. What is your age?
  - A. 18-24 years old
  - B. 25-34 years old
  - C. 35-45 years old
2. What is your sex?
  - A. Male
  - B. Female
  - C. Other
3. Have you ever heard of HPV before this survey?
  - A. Yes
  - B. No
4. Where have you heard about HPV? Select all that apply.
  - A. Doctor, nurse, or health care professional
  - B. Family or friends
  - C. Internet
  - D. Television
  - E. Other
5. Some groups do not agree to vaccination for different reasons. In general, do you agree with these groups?
  - A. Yes
  - B. No
6. In general, do you understand how vaccines work?
  - A. Yes
  - B. No
7. Has anyone you know ever been told by a health care provider that they had a human papillomavirus or HPV infection?
  - A. Yes
  - B. No
  - C. Prefer not to answer
8. According to your understanding, can HPV cause cervical cancer?
  - A. Yes
  - B. No
  - C. Unsure
9. According to your understanding, can someone get HPV through sexual contact?
  - A. Yes
  - B. No
  - C. Unsure
10. According to your understanding, does HPV require medical treatment?
  - A. Yes
  - B. No
  - C. Unsure

11. A vaccine to prevent HPV infection is available and is called the cervical cancer vaccine or by the brand names, Gardasil or Cervarix. Before today, have you ever heard of the cervical cancer vaccine or HPV vaccine?
- A. Yes
  - B. No
  - C. Unsure
12. Human Papillomavirus (HPV) vaccine is given to prevent genital warts and cervical cancer. It is given in 3 separate doses over 6 months and has been recommended since June 2006. Have you ever received one or more doses of the HPV vaccine?
- A. Yes
  - B. No
  - C. Unsure
  - D. Prefer not to answer
13. How many HPV shots have you received?
- A. 0
  - B. 1
  - C. 2
  - D. 3
  - E. Prefer not to answer
14. Do you have health insurance?
- A. Yes
  - B. No
  - C. Unsure
  - D. Prefer not to answer
15. Does your insurance provider cover the HPV vaccine?
- A. Yes
  - B. No
  - C. Unsure
  - D. Prefer not to answer
16. Did your healthcare provider suggest the HPV vaccine?
- A. Yes
  - B. No
  - C. Unsure
17. If you have not received the HPV vaccine, what were the primary factors?
- A. Insurance
  - B. Unaware of vaccine
  - C. Personal beliefs
  - D. Other
18. Do you believe that there is a social stigma against women who receive the HPV vaccine?
- A. Yes
  - B. No
  - C. Unsure

# IRB

## INSTITUTIONAL REVIEW BOARD

Office of Research Compliance,  
010A Sam Ingram Building,  
2269 Middle Tennessee Blvd  
Murfreesboro, TN 37129



### IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Friday, May 10, 2019

Principal Investigator	<b>Rachel Eccles</b> (Student)
Faculty Advisor	Judith M. Iriarte-Gross
Co-Investigators	NONE
Investigator Email(s)	<i>rae3v@mtmail.mtsu.edu; judith.iriarte-gross@mtsu.edu</i>
Department	Chemistry
Protocol Title	<b><i>The human papillomavirus vaccination barriers and initiatives</i></b>
Protocol ID	<b>19-2240</b>

Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU Institutional Review Board (IRB) through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category (7) *Research on individual or group characteristics or behavior*. A summary of the IRB action and other particulars in regard to this protocol application is tabulated below:

IRB Action	<b>APPROVED for ONE YEAR</b>		
Date of Expiration	<b>5/31/2020</b>	Date of Approval	5/10/19
Sample Size	300 (THREE HUNDRED)		
Participant Pool	Primary Classification: <b>Healthy Adults - 18 years or older</b> Specific Classification: <b>MTSU Students</b>		
Exceptions	1. Verbal recruitment is permitted. 2. Allowed to administer anonymous informed consent		
Restrictions	1. <b>Mandatory signed informed consent; the participants must have access to an official copy of the informed consent document signed by the PI.</b> 2. <b>Data must be deidentified once processed.</b> 3. <b>All identifiable data/artifacts that include audio/video data, photographs, handwriting samples, and etc., must be used only for research purpose and they must be destroyed after data processing.</b> 4. <b>Identifiable information must be destroyed as described in the protocol</b>		
Comments	NONE		

This protocol can be continued for up to THREE years (**5/31/2022**) by obtaining a continuation approval prior to **5/31/2020**. Refer to the following schedule to plan your annual project reports and be aware that you may not receive a separate reminder to complete your continuing reviews. Failure in obtaining an approval for continuation will automatically result in cancellation of this protocol. Moreover, the completion of this study **MUST** be notified to the Office of Compliance by filing a final report in order to close-out the protocol.



### Post-approval Actions

The investigator(s) indicated in this notification should read and abide by all of the post-approval conditions imposed with this approval. [Refer to the post-approval guidelines posted in the MTSU IRB's website.](#) Any unanticipated harms to participants or adverse events must be reported to the Office of Compliance at (615) 494-8918 within 48 hours of the incident. Amendments to this protocol must be approved by the IRB. Inclusion of new researchers must also be approved by the Office of Compliance before they begin to work on the project.

#### Continuing Review (Follow the Schedule Below:)

*Submit an annual report to request continuing review by the deadline indicated below and please be aware that **REMINDERS WILL NOT BE SENT.***

Reporting Period	Requisition Deadline	IRB Comments
First year report	4/30/2020	NOT COMPLETED
Second year report	4/30/2021	NOT COMPLETED
Final report	4/30/2022	NOT COMPLETED

#### Post-approval Protocol Amendments:

**Only two procedural amendment requests will be entertained per year.** In addition, the researchers can request amendments during continuing review. This amendment restriction does not apply to minor changes such as language usage and addition/removal of research personnel. .

Date	Amendment(s)	IRB Comments
NONE	NONE.	NONE

#### Other Post-approval Actions:

Date	IRB Action(s)	IRB Comments
NONE	NONE.	NONE

**Mandatory Data Storage Requirement:** All of the research-related records, which include signed consent forms, investigator information and other documents related to the study, must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data storage must be maintained for at least three (3) years after study has been closed. Subsequent to closing the protocol, the researcher may destroy the data in a manner that maintains confidentiality and anonymity.

IRB reserves the right to modify, change or cancel the terms of this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board  
Middle Tennessee State University

#### Quick Links:

[Click here](#) for a detailed list of the post-approval responsibilities.  
More information on expedited procedures can be found [here](#).

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