

HUMAN PAPILLOMAVIRUS VACCINATION STATUS ASSOCIATION WITH
SUBSEQUENT HEALTH BEHAVIORS

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Submitted to the faculty of the University Graduate School
in partial fulfillment of the requirements
for the degree
Doctor of Philosophy
in the Richard M. Fairbanks School of Public Health,
Indiana University

July 2016

Accepted by the Graduate Faculty, Indiana University, in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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DEDICATION

To my family, for teaching me the value of education.

Their support made me who I am today.

ACKNOWLEDGEMENTS

I would like to thank committee for their time, expertise, and dedication. I am especially grateful for Dr. Gregory Zimet, my primary advisor, for his leadership and guidance throughout my entire program of study. His unwavering support of my abilities gave me the confidence I needed to achieve academic success. I am indebted to Dr. Terrell Zollinger, my advisor and dissertation co-chair. He provided invaluable guidance and support even after he left his active role as a faculty member. I would especially like to thank Dr. Brian Dixon, my dissertation co-chair, for his expertise as I navigated important methodological decisions and generous use of his data from his current study. I am grateful to Dr. Nathan Stupiansky for his extensive knowledge in health behaviors without which I would not have been able to conceptualize this dissertation.

I acknowledge the faculty, staff, and students of the Richard M. Fairbanks School of Public Health for their support of me as an individual as well as the PhD program as a whole. I would particularly like to thank Dr. Chunyan He for being my academic advisor as I made important initial decisions toward this work and my future career. I am also thankful for Dr. Tamara Leech, my advisor for my Social and Behavioral Sciences minor, for her thoughtful consideration and guidance.

I express appreciation to all who provided necessary resources toward my graduate study completion as well as the individual studies included in this dissertation. I am much obliged to Dr. Victoria Champion for her support through the Training in Research for Behavioral Oncology and Cancer Control Program. I also thank the Center for HPV Research for support in survey data collection at the INShape Indiana Black and Minority Health Fair. I acknowledge my personal funding through the Behavioral

Cooperative Oncology Group with the Walther Cancer Center and the Training in Research for Behavioral Oncology and Cancer Control Program (R25-CA117865). I thank the Merck-Regenstrief collaboration (Project #14) for support for Manuscript 2.

I would like to acknowledge my co-authors for the individual manuscripts. Dr. Zeev Rosberger and Gilla Shapiro at McGill University as well as Dr. Jessica Kahn at Cincinnati Children's Hospital all gave necessary support in authorship of the systematic review. Dr. Stephen Downs and Dr. Amit Kulkarni gave generous contributions to manuscript preparation and the use of the qualitative data. I am indebted to Shannon Wilson for assistance in qualitative coding and manuscript preparation. Moreover, Chapter 2 of this dissertation has been published in *Human Vaccines and Immunotherapeutics* and Chapter 3 has been published in *Papillomavirus Research*. Both journals generously give authors permission to republish these portions for the purpose of a dissertation.

I appreciate my family and friends for their unwavering support throughout my education. To my parents and sisters, I am grateful for instilling in me a desire to help others and work hard. Two qualities that have been crucial to my success during this arduous journey and beyond.

Monica Louise Kasting

Human Papillomavirus Vaccination Status Association with Subsequent Health
Behaviors

Introduction

Human papillomavirus (HPV) infection results in serious health issues including cervical, anal, vulvar, penile and oropharyngeal cancers. There are three vaccines against HPV but vaccination rates in the United States remain low. One barrier to uptake is a concern that individuals who are vaccinated may increase their risky sexual behaviors or decrease their use of cervical cancer screenings, an adjustment in perceived level of risk for HPV that can be studied using risk compensation theory.

Methods

Three distinct studies examined risk compensation after HPV vaccination. A systematic review examined literature from January 1, 2008-June 30, 2015, using three databases. A qualitative study using semi-structured interviews of 22 healthcare providers that assessed their beliefs regarding sexual disinhibition and cervical cancer screening following vaccination. A cross-sectional survey that assessed cervical cancer screening practices, awareness and comfort with recommendations, and knowledge regarding the purpose of a Papanicolaou (Pap) test.

Results

Twenty articles were included in the systematic review. None of the studies of sexual behaviors and/or biological outcomes found evidence of riskier behaviors after HPV vaccination. Instead, the studies found vaccinated individuals were less likely to

report risky sexual behaviors, sexually transmitted infections (STIs), and pregnancy. Qualitative interviews found no healthcare providers believed the HPV vaccine would result in increased risky sexual behavior or decreased cervical cancer screening, and these concerns would not influence their vaccination recommendations. The survey included 291 women 21-35 years old; 62% were non-Hispanic black, 84% had a Pap test in the last three years, and 33% had at least one HPV vaccine. Logistic regression showed that vaccinated women did not have greater odds of having a Pap test in the past three years (OR=1.32; 95% CI=0.66-2.65; p=0.427). However, this odds ratio was significant when controlling for age and race (AOR=3.06; 95% CI=1.37-6.83; p=0.006).

Conclusion

These studies found no evidence of increased risky sexual behaviors or decreased cervical cancer screening rates after HPV vaccination. Furthermore, vaccinated women showed less evidence of risk compensation. These results should alleviate concerns about administering the HPV vaccination among parents and providers.

Terrell Zollinger, Dr.P.H., Co-chair

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CHAPTER 1

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) estimates 79 million Americans were infected with human papillomavirus (HPV) in 2015, making it the most common sexually transmitted infection (STI) in the U.S.¹ While HPV prevalence is decreasing among youth, there has been no decrease in prevalence in the older population.² Infection with HPV results serious health issues including cervical cancer, anal cancer, penile cancer, oropharyngeal cancers, genital warts, and recurrent respiratory papillomatosis.³ The worldwide prevalence of HPV DNA in cervical cancer is 99.7%, resulting in HPV being listed as having a causal role in the etiology of cervical cancer.^{4,5} The CDC estimates 360,000 people get genital warts every year in the United States, 12,000 women get cervical cancer, and over 4,000 women die from cervical cancer.^{1,6}

Currently there are three different HPV vaccines licensed by the U.S. Food and Drug Administration (FDA): a bivalent (2vHPV), a quadrivalent (4vHPV), and a nine-valent (9vHPV) vaccine. A series of three doses is required for each vaccine.⁷ Detailed information about all of the vaccines can be found in Petrosky *et al.*⁸ The Advisory Committee on Immunization Practices (ACIP) recommends routine HPV vaccination for boys and girls age 11 or 12 and catch up vaccination for women up to age 26, all men up to age 21, and for men who have sex with men, up to age 26.⁷ The 9vHPV vaccine was licensed for women ages 9 to 26 and men ages 9-15 in December, 2014.⁹ In February, 2015, the ACIP issued the same age-based recommendations for 9vHPV as it did for 4vHPV.⁸

HPV vaccination rates in the U.S. remain lower than desired to best protect the population against HPV infection.¹⁰ In 2014, only 60.0% of adolescent girls and 41.7% of adolescent boys between the ages of 13 and 17 received one or more doses in the HPV vaccine series.¹¹ The percentages are even lower for series completion (39.7% of girls and 21.6% of boys).¹¹ Barriers to HPV vaccination include cost of the vaccine, lack of knowledge about HPV transmission, and parental concerns about vaccinating their children against a sexually transmitted infection (STI).¹² Recent research has shown that a sizeable portion of physicians do not strongly endorse the HPV vaccine (27%) and do not deliver timely recommendations (26% for girls, 39% for boys).¹³ This is of particular concern because one of the strongest predictors of vaccine uptake is healthcare provider (HCP) recommendation and a lack of HCP recommendation has been listed as a reason for non-vaccination among those who are unvaccinated.¹⁴⁻¹⁸ An additional concern is that women who have received the HPV vaccine may be less likely to obtain screening for cervical cancer, or will cease cervical cancer screening altogether due to a perceived lack of susceptibility to cervical cancer.¹⁹⁻²² One concern among parents, clinicians, and public health officials, which has received particular attention in the media, is that the introduction of the HPV vaccine will lead to risk compensation, a concept introduced by Wilde in the 1980s that he called Risk Homeostasis Theory and has been used more broadly as Risk Compensation Theory (RCT).²³ RCT suggests that individuals have innate set points for risk tolerance and that they change their behaviors based on perceived risk in order to maintain their set point. According to RCT, then, if an individual believes that a measure protects him/her from a certain risk, then he/she would be more likely to engage in risky behaviors.²³ This dissertation will explore Risk

Compensation Theory in the context of HPV vaccination in three distinct but interrelated manuscripts.

1.1 Theoretical Background: Risk Compensation Theory

The idea of risk compensation has been studied for decades and G.J. Wilde introduced this concept in the context of seat belt use and automobile safety in the 1980s.²⁴ He proposed a Risk Compensation Theory that elaborated on the more well-known Health Belief Model in order to explain risk compensation (also known as disinhibition). Risk Compensation Theory suggests that each individual has an innate set point for risk tolerance and they change their behavior based on their perceived risk. If an individual believes that a protective measure protects them from a certain risk, they are more likely to practice risky behaviors in order to get back to their set point.²⁴ Wilde explains this theory in the context of seatbelt laws. His theory states there are four factors that influence risk: (1) The expected benefits of risky behavior alternatives (i.e. gaining time by speeding) (2) The expected costs of risky behavior alternatives (i.e. speeding tickets) (3) The expected benefits of safe behavior alternatives (i.e. insurance discounts for accident-free periods) and (4) The expected costs of safe behavior alternatives (i.e. being late). The amount of risk a person is willing to take is greater if factors 1 and 4 are higher and factors 2 and 3 are lower.²³

1.2 Risk Compensation for HPV Vaccination

Risk compensation has been a primary concern surrounding HPV vaccination. There are two separate areas of concern when it comes to disinhibition and risk

compensation with the HPV vaccine. First, there is concern that a vaccine against an STI will result in adolescents engaging in more risky sexual behaviors. One study using qualitative interviews of mothers described it as giving girls a “carte blanche” to engage in behaviors that put them at risk for pregnancy, HIV, and STIs.²⁵ Other studies have also found that parents had strong concerns that getting their child vaccinated for HPV would be seen as condoning sexual activity.^{12,26,27}

Parental concerns might be influenced by stories they heard in the media.^{28,29} A U.S. study found a majority of news articles about HPV vaccination were neutrally toned, but the results also indicated that there were several important informational facts that were omitted in the articles, namely information about side effects, duration of protection, and information about catch-up vaccination.³⁰ Internet use and accuracy of internet information regarding the HPV vaccine are important considerations because some studies have found that vaccine concerns can be influenced by negative (and often inaccurate) media reports.³¹ Media reports and inaccurate information could cause parents concern prior to getting their children vaccinated, specifically in regard to risk compensation.

Between 16 and 26% of parents have indicated they are concerned that HPV vaccination will increase the likelihood that their child will engage in riskier sexual behavior.³²⁻³⁵ However, this worry about sexual disinhibition was not usually listed as a reason for non-vaccination with just 3 to 6% citing it as a reason for refusing vaccination.^{36,37} The parents who did list it as a reason for non-vaccination were more likely to be older and have conservative political views.^{34,37} One qualitative study found that some mothers indicated they would keep the fact that HPV is sexually transmitted a

secret in order to reduce their worry about sexual disinhibition.³¹ These concerns can be alleviated by research examining risky sexual behavior intent following vaccination. Existing studies show no evidence of disinhibition due to vaccination and this effect was mediated by increased knowledge about HPV and the vaccine.³⁸⁻⁴¹

Secondly, an additional area that is addressed when risk compensation is examined is a possibility that women who have received the HPV vaccine may choose to get screened for cervical cancer less due to a perceived lack of susceptibility to cervical cancer.^{19,42,43} Knowledge regarding cervical cancer screening following vaccination was generally low among participants in one study but increased knowledge was positively associated with intent to get screened.³⁹

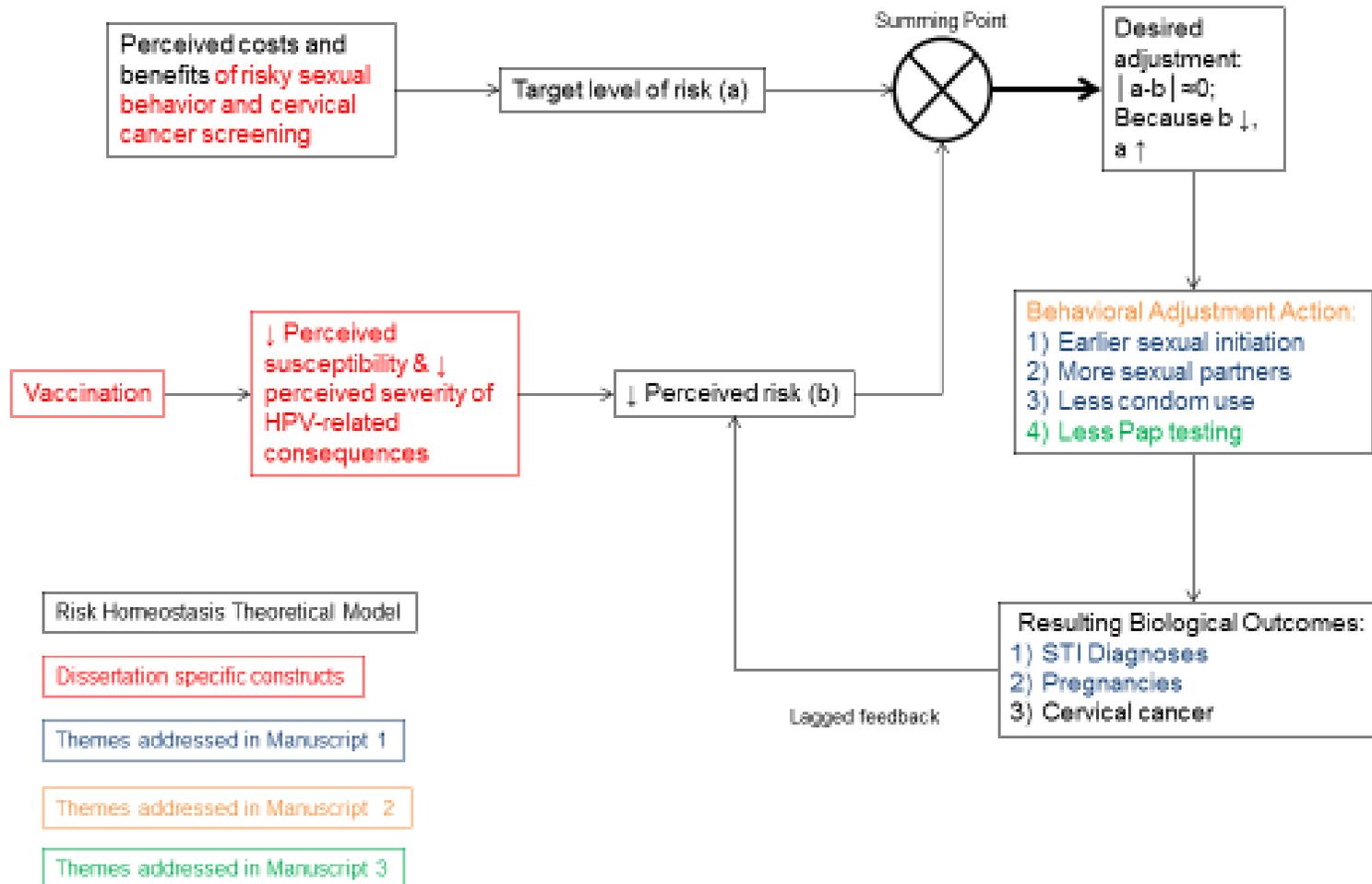
While there has been extensive research regarding sexual behavior intent post-vaccination, there has been little research regarding cervical cancer screening intent and even less research examining actual screening behaviors post-vaccination. This dissertation is divided into three distinct articles all examining the concept of risk compensation following HPV vaccination. The conceptual model for this dissertation as guided by Risk Compensation Theory is shown in Figure 1.1. The aims of the dissertation are:

Aim 1: To examine if there is consistent-replicated evidence in the literature of increased risky sexual behaviors among youth as a result of receiving the HPV vaccination.

Aim 2: To assess health care providers' concerns regarding risk compensation and whether these concerns influence their vaccination practices.

Aim 3: To evaluate if HPV vaccination status impacts women's cervical cancer screening behaviors.

Figure 1.1 Dissertation Conceptual Model Using Risk Compensation Theory



CHAPTER 2

TEMPEST IN A TEAPOT: A SYSTEMATIC REVIEW OF HPV VACCINATION AND RISK COMPENSATION RESEARCH

2.1 Abstract

Background

There has been some concern among parents and in the media that vaccinating children against human papillomavirus could be seen as giving children permission to engage in risky sexual behaviors (also known as sexual disinhibition). Several studies have found this concern to be unfounded but there have been no attempts to synthesize the relevant studies in order to assess if there is evidence of sexual disinhibition. The aim of this study was to synthesize recent literature examining sexual behaviors and biological outcomes (e.g., sexually transmitted infections) post-HPV vaccination.

Methods

We reviewed literature from January 1, 2008, to June 30, 2015, using PubMed, CINAHL, and Embase with the following search terms: [(sex behavior OR sex behaviour OR sexual) AND (human papillomavirus OR HPV) AND (vaccines OR vaccine OR vaccination)] followed by a cited reference search. We included studies that examined biological outcomes and reported behaviors post-vaccination in both males and females. Studies were reviewed by title and abstract and relevant studies were examined as full-text articles.

Results

We identified 2,503 articles of which 20 were eventually included in the systematic review. None of the studies of sexual behaviors and/or biological outcomes

found evidence of riskier behaviors or higher rates of STIs after HPV vaccination.

Instead, the studies found that vaccinated compared to unvaccinated individuals were less likely to report vaginal intercourse without a condom (OR=0.5; 95% CI=0.4-0.6) and non-use of contraception (OR=0.27; 95% CI=0.15-0.48) and unvaccinated participants had higher rates of Chlamydia (OR=2.3; 95% CI=1.06-5.00).

Conclusion

These results should be reassuring to parents and health care providers.

Keywords for indexing:

Behavior, Risk compensation, Sexual disinhibition, Adolescent, HPV vaccination, Infectious disease, Pediatrics

2.2 Introduction

In 2015, the Centers for Disease Control and Prevention (CDC) reported that there are approximately 79 million Americans who are currently infected with human papillomavirus (HPV) and 14 million new infections occur every year, making it the most common sexually transmitted infection (STI).¹ It is estimated that the worldwide prevalence of HPV infection in women without cervical abnormalities is 11 to 12%. This varies by region with higher rates in sub-Saharan Africa (24%), Eastern Europe (21%) and Latin America (16%).⁴⁴ Infection with HPV is a risk factor for serious health issues including genital warts, cervical cancer, anal cancer, penile cancer, oropharyngeal cancers, and recurrent respiratory papillomatosis.¹ Currently, there are three different HPV vaccines: 1) A bivalent vaccine (2vHPV) that protects against HPV types 16 and 18, two types that are responsible for about 70% of cervical cancer diagnoses;⁴⁵ 2) A quadrivalent vaccine (4vHPV) that protects against HPV-16 and 18 as well as HPV-6 and 11, the two types that cause about 90% of the cases of genital warts;⁴⁶ and 3) A nine-valent HPV vaccine (9vHPV) was recently licensed by the U.S. Food and Drug Administration, and protects against the four HPV types in 4vHPV as well as five additional oncogenic types (HPV types 31, 33, 45, 52, and 58). The 9vHPV has the potential to prevent 80 to 90% of cervical cancers, and many vulvar, vaginal, and anal cancers in addition to 90% of genital warts.⁴⁷

Despite the recommendations made by national immunization advisory committees around the world, HPV vaccination rates, especially in the United States, remain suboptimal.^{10,48} For example, only 60.0% of adolescent girls and 41.7% of adolescent boys between the ages of 13 and 17 received one or more doses in the HPV

vaccine series in the United States in 2014.¹¹ These rates are even lower when examining the percentages of adolescents who have completed the series, which is necessary in order to receive the maximum protection from the vaccine.⁴⁹ Several barriers to HPV vaccination exist including cost of the vaccination, lack of knowledge about HPV transmission, and parental concerns about vaccinating their children against an STI.¹²

One concern among parents, clinicians, and public health officials, which has received particular attention in the media, is that the introduction of the HPV vaccine will lead to risk compensation, a concept introduced by Wilde in the 1980s called Risk Compensation Theory (RCT).²³ RCT suggests that individuals have innate set points for risk tolerance and that they change their behaviors based on perceived risk in order to maintain their set point. According to RCT, then, if an individual believes that a measure protects him/her from a certain risk, then he/she would be more likely to engage in risky behaviors.²³ Critics of the HPV vaccine have expressed concern that the receipt of the vaccine could cause adolescents to engage in riskier sexual behavior due to perceived protection from sexually transmitted infections.²¹ This is a concern that has arisen throughout the world. For example, several Roman Catholic bishops in Canada discouraged vaccination, stating that school-based vaccination “sends a message that early sexual intercourse is allowed”⁵⁰ and that abstinence is the “only truly healthy choice.”^{51,52} One study using qualitative interviews of mothers in the United Kingdom found it described as giving girls a “carte blanche” to engage in behaviors that put them at risk for pregnancy, HIV, and STIs.²⁵

These parental concerns might have been influenced by stories they encountered in the media.^{28,29,53} A U.S. study found a majority of news articles about HPV vaccination

were neutrally toned but the results also indicated that there were several important informational facts that were omitted in the articles, namely information about side effects, duration of protection, and information about catch-up vaccination.³⁰ Internet use and accuracy of internet information regarding the HPV vaccine are important considerations because some studies have found that vaccine concerns can be influenced by negative (and often inaccurate) media reports.³¹ Media reports and inaccurate information could cause parents concern prior to getting their children vaccinated, specifically in regard to risk compensation.

Across several studies between 16% and 26% of parents indicate that they were concerned that HPV vaccination would increase the likelihood that their child would engage in riskier sexual behavior.³²⁻³⁵ However, this worry about sexual disinhibition was not usually listed as a reason for non-vaccination, and only 3 to 6% of parents cited this concern as a reason for refusing vaccination.^{36,37}

The objective of the present study was to conduct a systematic review of research literature to evaluate whether there is evidence (via either self-report of sexual behaviors or biological outcomes such as sexually transmitted infections) of sexual disinhibition following HPV vaccination. Our aims were to answer the following research questions:

1) Is there consistent, replicated evidence of increased self-reported risky sexual behaviors after HPV vaccination? and 2) Is there consistent, replicated evidence of increased incidence of sexually transmitted infections or pregnancies after HPV vaccination?

2.3 Materials and Methods

A systematic review of the literature was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol and searching the PubMed, CINAHL, and Embase databases. The following search terms were used: [(sex behavior OR sex behaviour OR sexual) AND (human papillomavirus OR HPV) AND (vaccines OR vaccine OR vaccination)] and the results were limited to studies from January 1, 2008, to June 30, 2015. The January 1, 2008, start date was chosen in order to capture articles examining behaviors post-vaccination. The 4vHPV was first licensed in the U.S. in mid-2006 and the Advisory Committee on Immunization Practices (ACIP) voted to routinely recommend it for girls in June 2006, at which point it was covered by the majority of insurers.⁵⁴ These recommendations were published in the Morbidity and Mortality Weekly Report in March 2007.⁵⁵ Therefore, relevant research examining post-vaccination behaviors was not published until 2010. Nevertheless, the 2008 start date for the search was chosen as a conservative estimate in order to ensure that we captured all relevant research.

To answer the outlined research questions, study outcomes were divided into two groups: self-reported behaviors (age at sexual initiation, reported number of sexual partners, and reported condom usage), and biological outcomes (pregnancy and STI diagnoses). Articles were included if they examined reported behaviors and/or biological outcomes post-vaccination. Studies were not restricted by age, gender, or geographic location. Articles were excluded if they examined worry or behavioral intent but not actual behaviors. Studies were also excluded if they were not original, peer-reviewed

research articles (e.g. published abstracts for conferences, press releases, or commentaries on other articles).

First, studies were screened for inclusion by reviewing the titles and abstracts (MLK & GKS). Additional studies were excluded by a closer examination of the remaining abstracts (MLK & GDZ). The remaining studies were examined as full-text articles. Two authors independently reviewed each study to determine the relevance for inclusion. Each reviewer completed a data extraction and quality assessment sheet for each article. Most of the quality assessment tools for systematic reviews were developed and validated for intervention research.⁵⁶⁻⁵⁹ The data extraction sheet used in this systematic review was developed by combining relevant portions of previously validated data quality assessment tools from the Agency for Healthcare Research and Quality's (AHRQ), Cochrane, PRISMA, and the NIH Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies.

2.4 Results

2.4.1 Study Characteristics

The initial search of the three databases resulted in 2,503 returns. Once duplicates were deleted, 1,584 articles remained. After screening by title and abstract, there were 29 full-text articles to be reviewed by all of the authors. The final selection resulted in 20 articles being included in this study. For the full PRISMA flow diagram, see Figure 2.1.

Of the 20 studies included in this systematic review, 2 were qualitative, 12 were cross-sectional, and 8 were longitudinal studies. It is important to note that these categories are not mutually exclusive. If a study used more than one study design and the

results were presented separately, it was counted in both relevant categories. Although we searched for studies between 2008 and 2015, the relevant studies for this review were published between 2011 and 2015. Furthermore, although we did not restrict by age or gender, all of the studies examined exclusively female populations and all of them studied populations within the 10 to 46 year-old age range. The descriptive statistics of the included studies are reported in Table 2.1. The full list of qualitative, cross-sectional, and longitudinal study results from the review are included as Tables 2.2, 2.3, and 2.4, respectively.

Figure 2.1 PRISMA Flow Diagram

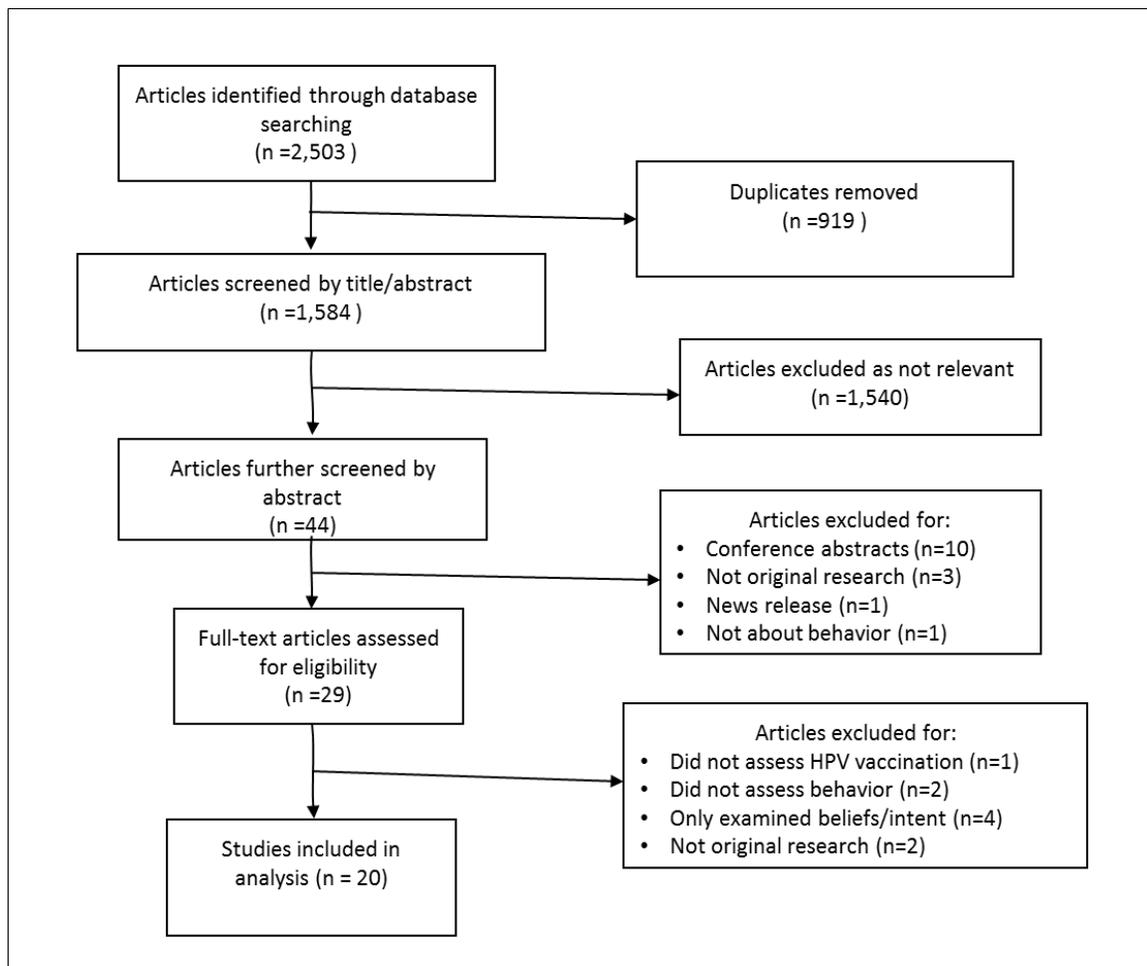


Table 2.1 Descriptive Statistics and Quality Assessment

Total Studies (20)	N (%)
<i>Study Design</i>	
Qualitative	2 (10%)
Cross-Sectional	12 (60%)
Cohort	8 (40%)
<i>Used Unvaccinated Control Group</i>	16 (80%)
<i>Outcome Assessed</i>	
<u>Behavioral</u>	17 (85%)
Reported Sexual Activity	12 (60%)
Age at Sexual Debut	7 (35%)
Number of Partners	13 (65%)
Contraception Use	16 (80%)
<u>Biological</u>	9 (45%)
STI Testing/Diagnosis	6 (30%)
Pregnancy/Abortion/Composite Measure	5 (25%)
<i>Average Study Quality Score (1-10)</i>	6.2

Table 2.2 Qualitative Studies

First author, year, location	Data collection method, date	Participant details	Analysis	Primary Findings
*Aujo, 2014, Uganda ⁶⁰	Semi-structured focus groups, date unclear	52 girls aged 12-15 years old	Thematic analysis	Vaccinated and unvaccinated girls engaged in sexual activity. Effect vaccination might have on sexual behaviors had varying responses.
Ports, 2014, United States ⁶¹	Semi-structured individual phone interviews, 2013	30 women 19-25 years old (mean age=28.87), received all 3 HPV vaccine doses	Thematic analysis	83% said that having been vaccinated against HPV had no influence on their romantic relationships and did not have any effect on their participation in safer sex (50%). 27% reported that getting vaccinated made them more aware of sexually transmitted diseases, and more cautious with sexual activity.

* Aujo *et al.* (2014) utilized both qualitative and cross-sectional study designs and as such is listed in both tables. Only the results from the qualitative portion of the study are reported in this table.

Table 2.3 Cross-Sectional Studies

First author, year, location	Data collection method, date	Participant Details		Outcomes assessed	Main findings
		Study population	Comparison population		
*Aujo, 2014, Uganda ⁶⁰	Survey questionnaire, vaccination status verified through vaccine registry, date unclear	200 girls 12-15 years old (m=12.8) from Nakasongola district, HPV vaccinated	200 girls 12-15 years old (m=13.1) from Luwero district, HPV unvaccinated	<u>Behavioral outcomes:</u> Sexual intercourse any time from the time of HPV vaccination or any time from 10 years of age for unvaccinated	No significant differences were found between groups for sexual activity.
**Forster, 2012, United Kingdom ⁶²	Survey questionnaire, 2009	433 girls 16-17 years old (m=17.1) from four schools that offered school-based HPV vaccination	620 girls 16-17 years old (m=17.0) from three schools that did not offer school-based HPV vaccination	<u>Behavioral outcomes:</u> reported number of sexual partners, age at sexual debut	The group that had been offered the vaccine was not significantly more sexually active than the group that had not been offered the vaccine (41.2% vs 41.6%; OR=.98; 95% CI=0.7-1.4).

Table 2.3 Cross-Sectional Studies (continued)

<p>Hansen, 2014, Denmark, Norway, Sweden⁶³</p>	<p>Self-administered structured questionnaire, 2011-2012.</p> <p>Sociodemographic data were obtained from Statistics Denmark, Statistics Norway and Statistics Sweden</p>	<p>3,805 women 18-46 years old, received HPV vaccine</p>	<p>40,247 women 18-46 years old, had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> age at first intercourse, non-use of contraception during first intercourse, the number of sexual partners</p>	<p>The rates of sexual debut and number of sexual partners did not differ significantly for women who were vaccinated before sexual debut and unvaccinated women. <u>Vaccinated</u> participants were less likely to have had 4+ partners before age 18 (AOR=0.56; 95% CI=0.40-0.78), and report non-use of contraception during first intercourse (AOR=0.27; 95% CI=0.15-0.48).</p>
<p>Liddon, 2012, United States⁶⁴</p>	<p>National Survey of Family Growth, 2007-2008.</p>	<p>279 females 15-24 years old, received HPV vaccine</p>	<p>964 females 15-24 years old, had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> age at first sex (older or younger than 15), lifetime number of partners, consistent condom use in the past 4 weeks <u>Biological outcomes:</u> received STD service in the last year</p>	<p>No significant differences were found between groups for lifetime sex partners, consistent condom use in the past 4 weeks, and having received an STD service in the past year. Compared with those who reported never using a condom, participants always using a condom were more likely to report <u>receipt of HPV vaccine</u> (AOR=3.0, 95% CI=1.1-7.9).</p>

Table 2.3 Cross-Sectional Studies (continued)

<p>Lutringer-Magnin, 2013, France⁴²</p>	<p>Self-administered questionnaire, 2008- 2009</p>	<p>135 females 14-23 years old, received HPV vaccine</p>	<p>181 females 14-23 years old, had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> Condom use (during first and most recent sexual intercourse), condom use behavior (non-risky, indeterminate, etc.), time in years from first sexual intercourse, number of partners, history of emergency, contraception, <u>Biological outcomes:</u> abortion, requests for HIV serology</p>	<p>No significant differences were found between groups for sexual activity, requests for HIV serology, history of abortions, or emergency hormonal contraception.</p>
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Table 2.3 Cross-Sectional Studies (continued)

<p>Marchand, 2013, United States⁶⁵</p>	<p>Web-based survey, 9/2011-11/2011</p>	<p>42 female students 18-26 years old, received any doses of HPV vaccine</p>	<p>72 female students 18-26 years old, had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> ever had sex with anyone of the opposite sex, age at first intercourse, number or partners in the last year, frequency of condom use in the last year</p>	<p>No significant differences were found between groups for any sexual behaviors including age at first intercourse (p=0.32), number of partners (p=0.97), or frequency of condom use (p=0.94) in either the bivariate or the multivariate analyses.</p>
<p>Mather, 2012, Australia⁴³</p>	<p>Web-based survey, 5/2011-8/2011</p>	<p>119 women 18-29 years old (m=19.2), received any doses of HPV vaccine</p>	<p>74 women 18-30 years old (m=19.5), had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> condom use, monogamous for more than 3 months</p>	<p><u>Vaccinated</u> participants were more likely to be sexually active (61.3%) than non-vaccinated participants (45.9%) [p<.05]. Among subsample of sexually active participants, no significant differences were found between groups for safer sexual behavior (p=0.84) or consistent condom use (p=0.88), after controlling for effects of age.</p>

Table 2.3 Cross-Sectional Studies (continued)

<p>Mattebo, 2014, Sweden⁶⁶</p>	<p>Written self-report questionnaire completed in classroom (n=338) or via mail (n=17), 1/2013-3/2013</p>	<p>227 girls 17-21 years old (median=18), received any doses of HPV vaccine</p>	<p>121 girls 17-21 years old (median=18), had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> experience of intercourse, condom use during intercourse, oral sex, protection during oral sex, anal sex, protection during anal sex, group sex, friends-with-benefits relationship, one night stand. <u>Biological outcomes:</u> Self-reported history of STI diagnosis</p>	<p>No significant differences were found between groups for STIs, condom use (p=0.79), oral sex (p=0.15), anal sex (p=0.80), group sex (p=0.80). <u>Vaccinated</u> participants were more likely to have initiated intercourse (84%) than non-vaccinated participants (70%; p<.005). <u>Vaccinated</u> participants more likely to report a one-night stand (41%) than non-vaccinated (29%; p<.04).</p>
<p>Ratanasiripong, 2014, United States⁶⁷</p>	<p>Web-based survey, Spring 2012</p>	<p>209 females 18-26 years old (m=20.75 in total sample), received any doses of HPV vaccine</p>	<p>175 females 18-26 years old, had not received HPV vaccine</p>	<p><u>Behavioral outcomes:</u> number of lifetime sex partners, number of sex partners in the last year, age at initiation, condom use.</p>	<p>No significant differences were found between groups for condom use (p=.98), lifetime sexual partners (p=.39), number of sexual partners in the last year (p=.98), number of partners before and after vaccination (p=.07).</p>

Table 2.3 Cross-Sectional Studies (continued)

Ruiz-Sternberg, 2014, Colombia ⁶⁸	Self-administered survey, 5/2011-3/2012	506 women up to 26 years old (m=19.6)	930 women up to 26 years old (m=19.5)	<u>Behavioral outcomes:</u> ever had sex, initiation before 15 years old, more than 3 sex partners, condom use, contraception use	No significant differences were found between groups for initiation of sexual intercourse before 15 years of age (p=0.167), number of sexual partners (p=0.381), and use of alcohol or drugs at last intercourse (p=0.553). <u>Vaccinated</u> adult women were more likely to have had sex (OR=1.89) but also showed more consistent condom use (OR=1.49), and contraception use (OR=2.02)
Rysavy, 2014, United States ⁶⁹	Computer assisted interviews, 2009-2011	153 girls 13-23 years old (m=19.2), received HPV vaccination	70 girls 13-23 years old (m=20.1), had not received HPV vaccine	<u>Behavioral outcomes:</u> Age at initiation, number of partners, condom use, age at anal and oral intercourse <u>Biological outcomes:</u> STI diagnosis, pregnancy	No significant differences were found between groups for age at first intercourse (p=0.768), number of partners (p=0.513), condom use (p=0.407), and STI diagnoses (p-values ranging from 0.242 to 0.763). <u>Non-vaccination</u> as associated with having been pregnant (20% vs 8.6%; p=0.016) in bivariate analysis; however, this difference was not significant in multivariate regression.

Table 2.3 Cross-Sectional Studies (continued)

Sadler, 2015, United Kingdom ⁷⁰	Data collection method unclear, 9/2010-10/2011	231 women 14-20 years old (n=18 for total sample), received at least one dose of the HPV vaccine	132 women 14-20 years old, unvaccinated	<u>Behavioral outcomes:</u> age at first intercourse, condom use, anal intercourse, drugs, alcohol, number of partners, emergency contraception use, sexual activity abroad <u>Biological outcomes:</u> history of abortion, received STI treatment, STI symptoms	<u>Non-vaccination</u> positively associated with: having more than three partners in the last 6 months (OR=2.12; 95% CI=1.08-4.17), attending the clinic with symptoms (OR=1.78; 95% CI=1.09-2.92), having anal intercourse with their last sexual contact (OR=4.34; 95% CI=1.23-14.29) and receiving a positive <i>C. trachomatis</i> diagnosis from the clinic (OR=2.3; 95% CI=1.06-5). <u>Vaccination</u> positively associated with condom use at first intercourse (OR=0.55; 95% CI=0.32-0.96).
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*Aujo *et al.* (2014) utilized both qualitative and cross-sectional study designs and as such is listed in both tables. Only the results from the cross-sectional portion of the study are reported in this table.

**Forster *et al.* (2012) utilized both cross-sectional and longitudinal study designs and as such is listed in both tables. Only the results from the cross-sectional portion of the study are reported in this table.

Table 2.4 Longitudinal Studies

First author, year, location	Data collection method, date	Participant Details		Outcomes assessed	Length of Follow-Up	Main findings
		Study population	Comparison population			
Al Romaih, 2011, United States ⁷¹	Chart audits, date not reported	499 female adolescents, (mean age=16.05), all vaccinated	Pre-, post-design, each girl served as her own control	<u>Behavioral outcomes</u> : self-reported sexual activity and number of sexual partners	Outcome was assessed prior to vaccination (at an unspecified time interval), at vaccination, and one-year post vaccination.	No significant differences in reported sexual activity or number of partners before and after vaccination. No statistical analysis reported.

Table 2.4 Longitudinal Studies (continued)

<p>Bednarczyk, 2012, United States⁴¹</p>	<p>Electronic medical record audits, 2006-2007, follow-up through 2010</p>	<p>493 females 11-12 years old (m=11.9), received at least 1 HPV vaccine</p>	<p>905 females 11-12 years old (m= 11.6), received no HPV vaccines</p>	<p><u>Biological outcomes:</u> “Testing/Diagnosis/ Counseling” (any occurrence of testing for C. trachomatis or pregnancy; diagnoses of C. trachomatis infection, pregnancy, or VD-NOS; and physician counseling on contraceptives). “Diagnosis Only” (any occurrence of diagnostic outcomes for C. trachomatis infection, pregnancy, or VD-NOS)</p>	<p>3 years retrospective</p>	<p>No significantly increased incident rate ratios were found for outcomes comparing HPV vaccine–exposed and unexposed girls. This includes STI testing/diagnosis (IR=1.29; 95% CI=0.92-1.80), and pregnancies (IR=1.89; 95% CI=0.33-10.79)</p>
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Table 2.4 Longitudinal Studies (continued)

<p>Brown, 2013, Peru⁷²</p>	<p>Sequential survey data; date not reported</p>	<p>200 female sex workers, 18-26 years old (m=22.9), all received at least 1 HPV vaccine</p>	<p>No comparison group</p>	<p><u>Behavioral outcomes:</u> reported sex with new clients, reported condom use</p>	<p>7 months prospective</p>	<p>Reported sexual activity with all clients decreased significantly from day 0 to month 7 (p<0.001). Frequency of reported intercourses with new clients over the same time period was lower (p< 0.001). Reported condom use with all clients and with non-paying partners did not change over time. Number of FSWs having nonpaying sexual partners increased significantly (OR=3.96; 95% CI=1.88-8.35) as did frequency of intercourse with non-paying sexual partners (p<0.001).</p>
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Table 2.4 Longitudinal Studies (continued)

<p>Cummings, 2012, United States⁷³</p>	<p>Study population-questionnaire, in-person interview, self-collected vaginal swab; 2010 Controls-questionnaire, in-person interview, clinician obtained or self-collected vaginal swab; 1999-2005</p>	<p>75 females 14-17 years old (m=15.5), received at least 1 HPV vaccine</p>	<p>150 females (2:1 match) 14-17 years old (m=15.3), unvaccinated</p>	<p><u>Behavioral outcomes:</u> number of sex partners in the last 2 months, frequency of sexual activity, condom use; <u>Biological outcomes:</u> Gonorrhea, chlamydia, Trichomoniasis diagnoses, HPV-type prevalence.</p>	<p>Comparison group: 2 years retrospective Study population: one-time questionnaire</p>	<p>Instances of vaginal intercourse without a condom (over the last 2 months) were significantly lower in the vaccinated as compared to those in the unvaccinated (p< 0.001). This was the only sexual behavior found to be different between the two cohorts. No significant differences were found in chlamydia and Trichomoniasis rates between the unvaccinated and vaccinated cohorts.</p>
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Table 2.4 Longitudinal Studies (continued)

<p>**Forster, 2012, United Kingdom⁶²</p>	<p>Sequential survey data, 2009-2010</p>	<p>148 females 16-17 years old (m=17.5), received at least one HPV vaccine</p>	<p>259 females 16-17 years old (m=17.5), received no HPV vaccines</p>	<p><u>Behavioral outcomes:</u> sexual debut, number of sex partners, condom use</p>	<p>6 months prospective</p>	<p>The change in the proportion of girls who were sexually active from baseline to follow-up was not significantly greater in the vaccinated group than the unvaccinated group (OR=0.80; 95% CI= 0.04–1.59). The change in number of sexual partners from baseline to follow-up was not significantly different between groups (p= 0.38). Change in condom use between baseline and follow-up did not differ by vaccination group (OR=0.88; 95% CI= 0.58–1.33).</p>
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Table 2.4 Longitudinal Studies (continued)

<p>Jena, 2015, United States⁴⁰</p>	<p>Medical and pharmaceutical claims, 2005-2010</p>	<p>21,610 females 12-18 years old (m= 15.0), vaccinated against HPV</p>	<p>n=186,501 age-matched females 12-18 years old (m= 14.9), not vaccinated against HPV</p>	<p><u>Biological outcomes:</u> at least one medical claim for any of the following: chlamydia, gonorrhea, herpes, human immunodeficiency virus or AIDS, or syphilis.</p>	<p>One year before vaccination to one year after vaccination</p>	<p>The rates of STIs in the year before vaccination were higher among HPV-vaccinated females compared with age-matched non-vaccinated females (AOR=1.37; 95% CI= 1.09-1.71). The rates of STIs increased for the vaccinated and nonvaccinated groups in the year after vaccination. The difference-in-difference odds ratio was 1.05 (95% CI= 0.80-1.38), implying that HPV vaccination was not associated with an increase in STIs. Similar associations held among age subgroups.</p>
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Table 2.4 Longitudinal Studies (continued)

<p>Mayhew, 2014, United States⁷⁴</p>	<p>Sequential survey data, date not reported</p>	<p>339 females 13-21 years old (m=16.8), received at least one HPV vaccine</p>	<p>No comparison group</p>	<p><u>Behavioral outcomes:</u> initiation of sexual intercourse, perceived risk for STIs other than HPV after vaccination, perceived need for safer sexual behaviors after vaccination, sexual behaviors at 2 and 6 month follow up appointments. For sexually inexperienced at baseline: sexual initiation. For sexually experienced at baseline: number of sexual partners, condom use at last intercourse.</p>	<p>6 months prospective</p>	<p>No significant associations between risk perceptions and subsequent sexual behaviors among all sexually inexperienced and experienced participants (p=0.59). In age-stratified analyses of sexually inexperienced participants: those 16 to 21 years of age who had higher scores on the scale measuring perceived risk for STIs other than HPV, indicating lower perceived risk for other STI (an inappropriate perception) were less likely to initiate sex over the next 6 months. (OR=0.13; 95% CI= 0.03-0.69).</p>
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Table 2.4 Longitudinal Studies (continued)

Smith, 2015, Canada ⁷⁵	Audit of population-based administrative database	128,712 females, 13-17 years old (m=13.17 for total sample at cohort entry), eligible for the HPV vaccination program	131,781 females, 13-15 years old (m=13.17 for total sample at cohort entry), not eligible for HPV vaccination program	<u>Biological outcomes:</u> a composite measure of incident pregnancy and non-HPV-related sexually transmitted infections. These were also assessed separately.	4 years (grade 8 to grade 12)	Controlling for birth timing in the year, no statistically significant increase in risk of the composite measure (OR=0.98; 95% CI=0.84-1.14), pregnancy (OR=1.00; 95% CI=0.83-1.21), or STIs (OR=0.81; 95% CI=0.63-1.04) in relation to HPV vaccination.
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**Forster *et al.* (2012) utilized both cross-sectional and longitudinal study designs and as such is listed in both tables. Only the results from the longitudinal portion of the study are reported in this table.

2.4.2 Critical Appraisal of the Studies

The 20 studies were divided among all of the co-authors, such that each study was reviewed by two co-authors, who then filled out corresponding data extraction sheets (the data extraction sheet used for this study is provided as Appendix A). The data extraction sheet contained items from previously validated data quality assessment tools including the Agency for Healthcare Research and Quality's (AHRQ), Cochrane, PRISMA, and the NIH Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies. Items on the data extraction sheet included assessment of study design, inclusion/exclusion criteria, study population and comparison group, length of follow-up, outcomes, limitations, generalizability, and an assessment of overall study quality. Overall study quality was assessed by each coauthor on a scale of 1-10 with higher numbers indicating greater study quality. The authors were given criteria with which to judge the studies and if the quality assessment from each author varied by more than two points, disagreements were resolved through discussion. The study's quality score was then averaged between the two reviewers' scores. Average study quality score ranged from 1.8 to 9.0 (mean=6.2; standard deviation=2.04).

2.4.3 Behavioral Outcomes

All but three studies examined self-reported behavioral outcomes (n=17, 85%). A widely studied behavior was sexual activity, which was assessed in many of the studies included in the review (n=12) but was only statistically evaluated in 10 of the studies. Sexual activity was defined differently across studies, and included reported sexual intercourse any time after receipt of HPV vaccine (or any time after 10 years of age for

the unvaccinated controls),⁶⁰ ever having sex with someone of the opposite sex,⁶⁵ and any experience of intercourse.^{66,74} Other behaviors examined in the studies were: age at sexual debut (n=7), number of sexual partners (n=13), use of contraception (n=16), and other sexual risk behaviors (n=5).

2.4.3.1 Self-Reported Sexual Activity

One study, by Aujo *et al.* (2014), used both qualitative and quantitative methods to examine self-reported sexual activity in two different communities (one vaccinated and one unvaccinated community) in Uganda. The qualitative component of the study found that most girls indicated they were not engaged in sexual activity themselves but they knew of others who were. The cross-sectional survey portion of the study found that young girls engaged in sexual activity in both the vaccinated and unvaccinated districts, but vaccinated girls had a lower reported rate of sexual intercourse than unvaccinated girls (1.5% vs. 2.5%).⁶⁰

The majority of the studies examining self-reported sexual activity were cross-sectional in nature and some of these cross-sectional studies did find that vaccinated participants were more likely to have engaged in sexual intercourse than unvaccinated participants.^{43,66,68} However, these studies also noted that many of their participants (between 45% and 62%) were sexually active prior to HPV vaccination.^{65,66} Due to the cross-sectional nature of these studies, these results may be more indicative of a woman engaging in sexual behavior and then seeking out protective measures as opposed to the vaccination causing the increased sexual behavior. Furthermore, previous studies have shown that providers are more likely to offer or strongly recommend the vaccine to

patients they believe are sexually active or are not in a monogamous relationship.^{13,76,77} Other cross-sectional studies found no statistical difference in sexual activity between vaccinated and unvaccinated participants (odds ratios between 0.88 and 1.07).^{42,62-64}

The longitudinal studies did not demonstrate that vaccinated women were more sexually active than unvaccinated women when post-vaccination behavior change was assessed. Some of these studies found that there was no statistically significant difference in baseline to follow-up sexual activity between vaccinated and unvaccinated women,^{62,71,73} while others found *decreases* in sexual activity after vaccination. One study of female sex workers conducted by Brown *et al.* (2013) in Peru found female sex workers decreased sexual activity with all clients after vaccination ($p < 0.001$).⁷² And another study (Mayhew *et al.* 2014) of a fully vaccinated sample found that participants between 16 and 21 years of age who inappropriately perceived lower risk for non-HPV STIs after vaccination were actually less likely to initiate sex over the following six month period (OR=0.13; 95% CI= 0.03-0.69).⁷⁴

2.4.3.2 Self-Reported Age at Sexual Debut

Seven of the studies examined age at first intercourse as a risky behavior post-vaccination. The studies defined the variable differently with some looking at age as a continuous variable and some categorizing the variable as sexual debut before or after a certain age (usually 15 or 16). Regardless of how the variable was defined, none of the studies that examined age at sexual debut found a statistically significant difference between vaccinated and unvaccinated groups.^{63,65,67-70} Only one study (Liddon *et al.* 2012) found an association between HPV vaccine and age at first intercourse. But this

was only significant in the bivariate model of a subset of 20 to 24 year olds and was not significant in the multivariable model.⁶⁴

2.4.3.3 Self-Reported Number of Sexual Partners

Most of the studies examining the number of sexual partners between groups found no association between vaccination status and number of partners. This result held true in cross-sectional studies when the researchers examined number of lifetime partners,^{42,62-65,67-69} number of partners in the last 12 months,⁶⁷ and number of partners before 18 years of age.⁶³ It also held true in studies that followed cohorts longitudinally, which found vaccinated women did not have more sexual partners at follow-up.^{62,71,73} A Mayhew *et al.* (2014) study of a fully vaccinated sample did not see a significant increase in the number of sexual partners after the sample was vaccinated.⁷⁴

In fact, some of the studies found that vaccinated women had *fewer* sexual partners than unvaccinated women. One population-based study of Nordic women (Hansen *et al.*, 2014) found that women who were vaccinated opportunistically (i.e., those that were vaccinated but not during an organized vaccination program) were significantly less likely than unvaccinated participants to have had four or more partners before reaching age 18 (AOR=0.56; 95% CI= 0.40-0.78).⁶³ A similar finding was reported in a study conducted by Sadler *et al.* (2015) in the United Kingdom that found that non-vaccination was positively associated with having three or more partners in the last six months (OR=2.12; 95% CI=1.08-4.17).⁷⁰ A study conducted by Lutringer-Magnin *et al.* (2013) in France, found that vaccinated girls between the ages of 17 and 20 had had fewer partners than unvaccinated girls ($p=0.01$).⁴² Furthermore, a study of

Peruvian female sex workers by Brown *et al.* (2013) found that participants had a significantly lower frequency of intercourse with new clients after vaccination ($p < 0.001$).⁷²

2.4.3.4 Use of Contraception

Several of the studies examined use of contraception. Some assessed condom use while others examined use of hormonal contraception or counseling on contraception. While there has been some concern that an erroneous belief that the HPV vaccine protects against all STIs would result in a decrease in condom use, a study examining risk perceptions found that this erroneous belief did not result in decreased condom use.⁷⁴ A qualitative study by Ports *et al.* (2014) found that none of the women they interviewed reported that the HPV vaccine had an influence on their use of condoms during sexual activity.⁶¹ Cross-sectional studies assessing condom use utilized different definitions for their studies including an assessment of general condom use,^{66,67,69} consistent condom use in the last month,⁶⁴ condom use during most recent intercourse,⁴² condom use during first intercourse,^{42,70} and consistent condom use during all sexual encounters.^{43,65,67,68} Regardless of how condom use was defined, none of the aforementioned studies found any statistically significant relationship between HPV vaccination and condom use. However, some studies did note that vaccinated women *were more likely* to take protective measures and found a positive association between condom use and HPV vaccination. A study by Hansen *et al.* (2014) found that non-use of contraception during first intercourse was significantly less frequent among women who were vaccinated before sexual debut as opposed to their matched unvaccinated counterparts (OR=0.27;

95% CI=0.15-0.48 for those vaccinated during an organized vaccination program; OR=0.69; 95% CI=0.52-0.93 for those vaccinated opportunistically).⁶³ Liddon *et al.* (2012) found that a higher percentage of those who reported always or at least inconsistently using condoms reported being vaccinated as opposed to those who never used condoms.⁶⁴ Ruiz-Sternberg *et al.* (2014) reported a similar finding, that vaccinated women were more likely to report consistent condom use than unvaccinated women.⁶⁸ Additionally, Sadler *et al.* (2015) reported condom use at first intercourse was positively associated with HPV vaccination (OR=0.55; 95% CI=0.32-0.96).⁷⁰ There were two studies that examined use of emergency hormonal contraception (Lutringer-Magnin *et al.* 2013 and Sadler *et al.* 2015). Neither study found any differences in the use of emergency contraception between those who had been vaccinated and those who had not.^{42,70}

Contraceptive behavior was also examined by several longitudinal studies. Bednarczyk *et al.* (2012) used data from a managed care organization to assess the relationship between a patient seeking counseling on contraceptives and HPV vaccination. This study found that vaccinated participants were more likely to seek counseling on contraceptive use as opposed to unvaccinated participants, although the adjusted incident rate ratio was not significant (OR=2.31; 95% CI=0.99-5.38).⁴¹ This result is consistent with a study by Forster *et al.* (2012) that found no change in condom use from baseline to follow up by vaccination group (OR=0.88; 95% CI=0.58-1.33).⁶² A study of female sex workers found no change in condom use with all clients after vaccination but they did note that condom use with non-paying partners increased, although not significantly (p=0.38).⁷² Another longitudinal study (Cummings *et al.* 2012)

found instances of vaginal intercourse without a condom over the last two months was significantly lower in the vaccinated group ($p < 0.001$).⁷³ The findings from all of the studies combined demonstrated that there was either no association between HPV vaccination and condom use/contraception counseling or they demonstrated that vaccinated participants engaged in safer behaviors than unvaccinated participants.

2.4.3.5 Other Risk Behaviors

Many of the included studies also examined risky behaviors that did not fit in the above categories. Several of the studies examined relationship status. Most of them defined being in a monogamous relationship as a “safe” behavior and being in non-exclusive relationships or having “one-night stands” as constituting “unsafe” behavior. One study conducted in Uganda that used dating and sexual activity as measures of risky behavior found that unvaccinated girls were dating at higher rates than vaccinated girls (5% vs. 2.5%) but the authors did not assess if those specific dating relationships involved risky sexual behaviors.⁶⁰ Another study (Mather *et al.* 2012) compared “safe sexual behavior” between vaccinated and unvaccinated individuals by creating a composite measure that included condom use, use of other contraception, and having been in a monogamous relationship for at least three months. Using this measure, authors found no relationship between HPV vaccination and engaging in safe sexual behavior.⁴³ Rysavy *et al.* (2014) used a similar technique to examine “high risk sexual behaviors” such as frequency of condom use, number of partners, as well as experience of anal and oral intercourse, and age at first anal and oral intercourse to create a risk behavior score. This study found that there were no differences between the vaccinated and unvaccinated

groups on the composite risk behavior score.⁶⁹ This relationship was still not significant when the high risk behaviors were examined individually. Another study (Mattebo *et al.* 2014) examined high risk behaviors individually and assessed the effect of experiencing “one-night stands,” group sex, “friends with benefits” relationships, oral sex, and anal sex. In this study the authors did find that vaccinated women were more likely to have experienced a one-night stand ($p=0.046$) but this cross-sectional study noted that 62% of their sample had reached sexual debut before vaccination so the temporal relationship between sexual experience and vaccination cannot be assessed and it is possible a person engaging in high-risk sexual behaviors was more likely to seek vaccination.⁶⁶ Furthermore, this study found no differences when comparing vaccinated and unvaccinated individuals with respect to experiencing a “friends with benefits” relationship, group sex, giving oral sex, receiving oral sex, or anal sex.⁶⁶ Lastly, a cross-sectional study examined several risk behaviors including anal intercourse, sexual experiences abroad, use of drugs or alcohol, and being a current smoker. Among other risk behaviors previously discussed (i.e., contraception use, number of partners, etc.) this study found that the unvaccinated group was more likely to have experienced anal intercourse as their last sexual contact (OR=4.43; 95% CI=1.23-14.29) and to be a current smoker.⁷⁰ Smoking status is an important factor to examine because smoking is also a risk factor for cervical cancer, even when controlling for the effects of HPV infection and other potential cofactors.^{78,79}

2.4.4 Biological Outcomes

Along with reporting behavioral outcomes, several studies also examined biological outcomes (n=9, 45%). For the purposes of this review, they have been divided into two general categories: STI testing/diagnosis and pregnancy (including a composite measure of STI and pregnancy)/abortions.

2.4.4.1 STI/HIV Testing or Diagnosis

All of the studies in this subset had some measure of STI testing or diagnosis. Of the studies that examined STI or HIV testing or diagnosis, none of them found HPV vaccination to increase STI rates. Of the cross-sectional studies, one (Liddon *et al.* 2012) found no association between HPV vaccination and receiving STI services in the past year in both the 15 to 19 and the 20 to 24 year old age groups.⁶⁴ Two cross-sectional studies examining reported STI diagnoses^{66,69} and one examining HIV serology⁷⁰ found no significant differences between the vaccinated and unvaccinated groups. Additionally, one study (Sadler *et al.* 2015) found that unvaccinated women were more likely to have received a positive Chlamydia trachomatis diagnosis (OR=2.3; 95% CI=1.06-5.00).⁷⁰

Two longitudinal studies (Cummings *et al.* 2012 and Jena *et al.*, 2015) examined the association between STIs and HPV vaccination.^{40,73} One cohort study by Jena *et al.* (2015) found that the difference-in-difference odds ratios in the year after vaccination was similar between the vaccinated and unvaccinated cohorts.⁴⁰ This held true for both the 12 to 14 and the 15 to 18 year-old groups. Another cohort study found no differences in Chlamydia or Trichomoniasis rates between vaccinated and matched unvaccinated cohorts.⁷³

2.4.4.2 Abortion/Pregnancy or a Composite Measure of STI and Pregnancy

Several studies used composite measures of STI diagnosis and pregnancies. One cohort study (Bednarczyk *et al.* 2012) looked at a composite measure of testing or diagnosis of *Chlamydia trachomatis* infection, pregnancy, or venereal disease not otherwise specified (referred to as testing/diagnosis/counseling) found that girls receiving HPV vaccine did not have significantly higher rates of testing/diagnosis/counseling for these conditions. They found the same results when they examined diagnosis-only rates between the vaccinated and unvaccinated groups.⁴¹ Another cohort study (Smith *et al.* 2015) found no statistically significant differences in a composite measure of STIs and pregnancy in relation to HPV vaccination. This result held true when STIs and pregnancy were examined separately as well.⁷⁵

Studies also examined pregnancy and abortions individually. Sadler *et al.* (2015) found no association between vaccination status and abortion (referred to in the paper as “termination,” $p=0.85$).⁷⁰ Another (Lutringer-Magnin *et al.* 2013) assessed abortion rates between vaccinated and unvaccinated groups found that 7.1% of their population had had an abortion and all of these participants were unvaccinated.⁴² Additionally, a study with a population between 13 and 23 years of age found that unvaccinated women were more likely to have been pregnant (20% vs. 8.6%, $p=0.016$), a result that runs contrary to the notion of risk compensation.⁶⁹

2.5 Discussion

There have been several studies examining the association between HPV vaccination using self-report or biological markers of increased risky sexual behaviors. Twenty studies were identified for this systematic review. The included studies were all published between 2011 and 2015 and varied in study design and sample size. Each of the studies had limitations and the results of each individual research effort should be interpreted with caution. However, when this body of literature is examined as a whole, with similar findings reported across studies, the evidence consistently indicates that HPV vaccination does not lead to risk compensation/sexual disinhibition. The finding that adolescents do not appear to respond to vaccination with increased risky sexual behavior suggests no support for RCT as applied to HPV vaccination. This conclusion is supported both by studies that focused on self-reported sexual behavior as well as studies that examined biological markers of risk (e.g., STI diagnosis).

Furthermore, there appeared to be more support for the fact that vaccinated women actually showed less involvement in risky behaviors than unvaccinated women, which was evidenced by lower numbers of sexual partners and increased use of contraception. This finding is not entirely surprising in light of previous research reporting that pro-health behaviors tend to cluster together, such that a person who engages in one protective health behavior (e.g., getting vaccinated) is more likely to engage in another (e.g., using condoms).⁸⁰ Additionally, an HPV vaccination visit to a healthcare provider may present families and providers with opportunities to discuss and promote health and disease prevention behaviors.

Several studies that examined risk perception merit discussion, even though they did not meet the inclusion criteria for the systematic review, and therefore were not presented in the Results section. Some of these studies examined the perception of risk in a completely vaccinated sample and compared a decreased risk perception post-vaccination to subsequent sexual behaviors. These studies found that vaccinated individuals perceived a need for safer sexual behavior after vaccination.^{39,81,82} It is notable that these studies' findings were consistent with the results of studies included in this review. Furthermore, authors of a recent literature review of HPV vaccine attitudes and uptake found that the concern about risk compensation following vaccination was a “myth” rather than a valid concern.⁸³

This systematic review does have limitations so conclusions should be drawn with caution. First, the studies included are heterogeneous in both population and outcome definitions, which could reduce the specificity and precision of the findings. This issue is common in systematic reviews of this nature. For instance, one recent systematic review examining HPV vaccination or vaccine intent found varied evidence between HPV vaccination or vaccine intent and sexual behavior primarily due to the heterogeneous nature of the included studies.⁸⁴ At the same time, the fact that similar results are reported across studies that varied so widely in methodology and population, suggests that the findings of no association between vaccination and sexual risk compensation are robust. Secondly, the desire to engage in risky sexual behavior might cause a person to seek out vaccination which would make it appear that the vaccinated group practices more risky sexual behavior. This can be difficult to assess, particularly in cross-sectional studies because, as some research has shown, there are times when physicians have vaccinated

their patients based on perceived risk status.^{13,76,77} This should not be confused with an implication that the vaccination is the *cause* of the risky behavior. Finally, this review of the literature is reliant on the findings of the studies included in the review. Each of these individual studies had limitations of their own including: a lack of a comparison group, recall bias, and social desirability of responses, among others. Nevertheless, this study thoroughly examined three different databases with relevant search terms in order to capture the appropriate studies. To our knowledge, this is the first systematic review examining the association (or lack thereof) between HPV vaccination and subsequent sexual behaviors and adds credibility to the literature by combining the results and showing there is no consistent, replicated evidence of sexual disinhibition after HPV vaccination.

2.6 Conclusion

The consistent, replicated evidence found across the 20 studies examined in this systematic review provides a strong body of evidence refuting an association between HPV vaccination and risky sexual behavior. The 20 different studies, utilizing at least four distinct study designs and including a total of 521,879 participants, found no evidence of increased numbers of sexual partners, younger age of sexual initiation, decreased use of contraception (including both condoms and hormonal contraceptives), increased STI diagnoses, increased pregnancy rates, or increased history of abortion among those vaccinated against HPV. In fact, some studies found vaccinated women showed *lower* risky behaviors than unvaccinated women, indicating a tendency toward less risky health behaviors. These findings should alleviate parental and provider

concerns that HPV vaccination will lead to risky sexual behaviors. Furthermore, as others have noted, even if risk compensation was identified as an issue related to HPV vaccination, this would not be justification for withholding vaccination, but would argue for effective pre- and post-vaccination counseling.⁸³

CHAPTER 3

HEALTHCARE PROVIDERS' BELIEFS AND ATTITUDES REGARDING RISK COMPENSATION FOLLOWING HPV VACCINATION: A QUALITATIVE ANALYSIS

3.1 Abstract

Background

Provider recommendation is one of the strongest predictors of HPV vaccine uptake. Research has shown that concerns regarding risk compensation could cause some providers to hesitate recommending the HPV vaccine.

Methods

During 15 to 30 minute semi-structured interviews in early 2015, 22 U.S. pediatric providers were asked about their beliefs regarding sexual disinhibition and cervical cancer screening following HPV vaccination. Providers were asked if these beliefs result in reservations in their recommending the vaccine. Interviews were audio-recorded, transcribed, and analyzed using inductive content analysis.

Results

None of the providers believed the HPV vaccine would result in risky sexual behavior. Half indicated it was better to start vaccination early, before sexual activity was a worry. Others noted that patients' risky behavior decisions happen independently of vaccination. When providers were asked if they were concerned about decreased cervical cancer screening, half said they did not know and some stated they had never thought about it before. The main themes addressed were the significant time lapse between

vaccination and screening and that women tend to get over-screened as opposed to under-screened.

Conclusion

Providers were generally in favor of HPV vaccination and did not perceive risk compensation as a barrier to HPV recommendation.

Keywords for indexing:

Behavior, Risk compensation, Sexual disinhibition, HPV vaccination, Cervical cancer screening, Healthcare provider

3.2 Introduction

In 2015 the Centers for Disease Control and Prevention (CDC) estimated that approximately 79 million Americans were currently infected with human papillomavirus (HPV) and 14 million new infections occur every year, making it the most common sexually transmitted infection (STI) in the U.S.¹ Infection with HPV is a causal factor for serious health issues including cervical cancer, anal cancer, penile cancer, oropharyngeal cancers, genital warts, and recurrent respiratory papillomatosis.

Currently there are three different vaccines against HPV licensed by the U.S. Food and Drug Administration (FDA). The bivalent vaccine (2vHPV) protects against HPV types 16 and 18.⁴⁵ These two HPV types are responsible for about 70% of cervical cancer diagnoses worldwide. The quadrivalent vaccine (4vHPV) protects against HPV-16 and 18, as well as HPV-6 and 11, which cause about 90% of the cases of genital warts.⁴⁶ The FDA licensed a 9-valent HPV vaccine (9vHPV) in December, 2015. This vaccine protects against the four types included in 4vHPV as well as five additional oncogenic types and has the potential to prevent up to 80% to 90% of cervical cancers.⁴⁷ The 2vHPV vaccine is licensed for females ages 9 to 26 and the 4vHPV vaccine is licensed for both males and females ages 9 to 26. The Advisory Committee on Immunization Practices (ACIP) routinely recommends HPV vaccination for boys and girls age 11 to 12 and catch up vaccination for women up to age 26, all men up to age 21, and for men who have sex with men up to age 26.⁷ The 9vHPV vaccine was licensed for women ages 9 to 26 and men ages 9 to 15 in December, 2014.⁹ In February, 2015, the ACIP issued the same age-based recommendations for the 9-valent vaccine as it did for 4vHPV.⁸

HPV vaccination rates in the U.S. remain very low.¹⁰ In 2014, only 60.0% of adolescent girls and 41.7% of adolescent boys between the ages of 13 and 17 received one or more doses in the HPV vaccine series.¹¹ The numbers are even lower for series completion (39.7% of girls and 21.6% of boys) Barriers to HPV vaccination include cost of the vaccine, lack of knowledge about HPV transmission, and parental concerns about vaccinating their children against a sexually transmitted infection (STI).¹² Recent research has shown that a sizeable portion of physicians (27%) do not strongly endorse the HPV vaccine and do not deliver timely recommendations (26% for girls, 39% for boys).¹³ This is of particular concern because one of the strongest predictors of vaccine uptake is healthcare provider (HCP) recommendation and a lack of HCP recommendation for the HPV vaccination has been listed as a reason for non-vaccination among those who are unvaccinated.¹⁴⁻¹⁸

One concern among parents, clinicians, and public health officials that has received particular attention in the media is that the introduction of the HPV vaccine may lead to risk compensation. These beliefs can be explained by a broader health belief theory known as Risk Compensation Theory. This theory states that each person has an innate set point for risk and if some aspect of risk is reduced, he or she will increase risky behavior in order to get back up to that set point.^{23,24} Opponents of the HPV vaccine have argued that vaccination could cause adolescents to engage in more risky sexual behavior (disinhibition) due to a perceived decreased risk of sexually transmitted infections,²¹ a concern that has no empirical support.⁸⁵ Furthermore, an additional area that is addressed when risk compensation is examined is a possibility that women who have received the HPV vaccine may be less likely to adhere to cervical cancer screening recommendations,

or may cease cervical cancer screening altogether.^{19,42,43} It is therefore important to understand if HCPs are concerned about risk compensation and if these concerns affect their HPV vaccination practices.

The purpose of this study was to understand healthcare provider beliefs surrounding risk compensation with regards to sexual behaviors and cervical cancer screening adherence and ascertain how these beliefs affect their HPV vaccination recommendation practices. In order to increase HPV vaccination rates, the concerns and barriers to vaccination need to be addressed. If the principal concerns can be addressed and alleviated, vaccine uptake will likely increase with the potential to save thousands of lives and billions of dollars in healthcare costs.

3.3 Methods

3.3.1 Study Participants

As part of a larger study examining computerized HCP reminders for HPV vaccination, we conducted semi-structured in-person qualitative interviews from January to March 2015. The study was approved by the Indiana University Institutional Review Board and the relevant portion of the interview guide is attached as Appendix B. Participants for this study were pediatrician HCPs working in publicly-funded urban health clinics, had patients between the ages of 11-12 who were in need of vaccination, and consented to be interviewed. All eligible HCPs were contacted via e-mail. Two additional follow-up e-mails were sent to each participant who did not respond to the initial e-mail. A total of 39 HCPs were eligible to be interviewed and 22 (56.4%)

consented and completed the interview. Participants were recruited until saturation was reached, that is, until we were acquiring no new information from the interviews.⁸⁶

3.3.2 Interviews and Data Analysis

Qualitative methodology is ideal when exploring an area where little is known because it allows the investigators to identify, via in-depth probes, personal and contextual factors.⁸⁷ The interviews lasted 15 to 30 minutes and participants were compensated with a \$50 gift card. After being provided with brief information regarding the study, participants were asked about their general beliefs regarding HPV and HPV vaccination. They were also asked additional questions for the larger study pertaining to the effectiveness and acceptability of computerized reminders prompting HPV vaccine recommendation. Finally, HCPs were asked: 1) if they believe their patients will likely practice riskier sexual behaviors (for both male and female patients) after they are vaccinated, 2) if they believe vaccination will result in their female patients feeling they do not need to get screened for cervical cancer, and 3) if either of these issues affect HCP recommendations for the HPV vaccination. Along with these questions, demographic characteristics reported during the interview and vaccination practices of the providers, accessed from EHRs, were also collected.

Interviews were audio-recorded, transcribed, and analyzed using inductive content analysis.⁸⁸ Transcripts of the interviews were read to identify meaningful themes; two investigators then independently coded each interview according to those themes. The codes were reviewed and areas of disagreement were resolved through discussion.

3.4 Results

3.4.1 Sample Description

A total of 39 HCPs were contacted and the sample who agreed to be interviewed consisted of 21 physicians and 1 nurse practitioner (17 females, 5 males), all specializing in pediatrics. The participants averaged 14 years in practice. The hospital system, Eskenazi Health, is one of the five largest safety-net health systems in the U.S. The health system contains a 315-bed hospital and nine community health centers located across the metropolitan area of Indianapolis. Each community health center provides adult primary care, pediatrics, obstetrics, gynecology, and mental health services. Over 70% of the pediatric patient population in this healthcare system receives Medicaid benefits, 3.3% receives charity care, and 5.5% is self-pay.

3.4.2 Sexual Disinhibition

None of the HCPs indicated they believed that getting vaccinated against HPV would lead a young adolescent to engage in riskier sexual behavior. Within that question, five of the HCPs pointed the interviewer to research supporting their opinion. This seemed to be an interesting way for the HCP to avoid giving their own personal opinion on the matter and instead of stating their personal beliefs, they would state evidence from the literature by saying, for example, “I think that’s been shown in not just one publication but multiple publications to not be true.” For a list of themes and exemplar quotes, see Table 3.1.

Table 3.1 Qualitative Themes and Exemplar Quotes

Concept	Theme	Exemplar Quotes
Sexual Disinhibition		
	<i>Sexual behaviors are independent of vaccination</i>	<p>"...it's case dependent. So you have those children who are going to be more at risk, but you have a majority of the children who are not going to deal with those type of issues at this early on age."</p> <p>"No. I'm really not...they're going to do what they want to do anyway. It's a good time to educate them, of course, but I'd rather just protect them. It doesn't really give them a license to do anything."</p> <p>"[T]he reasons why teenagers engage in sex, risky or not, are really multi-factorial and the degree to which vaccination status plays into it is probably zero-to-none."</p> <p>"This is about the idea that the vast majority of people at some point in their life are sexually active. And so we want this protection before that starts."</p>
	<i>Patients are unaware of the purpose of vaccination</i>	<p>"Kids don't have an idea of what shots they really get... [Children] go glossy eyed and not even listening...they're just concerned about how many shots they're getting, but they don't know what they're for."</p> <p>"My thoughts are that most adolescents don't know which vaccines they have or haven't gotten. And so the idea that they would so aware of it that it would influence their behaviors is a little far-fetched and there's also data to say that's not true."</p>
	<i>No support for disinhibition in the literature</i>	<p>"I think the literature doesn't support that. I think there might be parents who think that, but I think there's no evidence of it."</p> <p>"I very much go back to the data on we don't decide when to give people shots based on behavior, we decide on when they're most efficacious. Like, we know you mount your best immune response during this window, so the vaccine is most effective for people if they get it at this time."</p>

Table 3.1: Qualitative Themes and Exemplar Quotes (continued)

	<i>No support for disinhibition in the literature</i>	"I think that's been shown in not just one publication but multiple publications to not be true."
Decrease in cervical cancer screening		
	<i>Physicians haven't thought about it</i>	"I don't know. I don't know, actually. It's a good question. I've never suggested that, or implied that, or even thought about it, so I would think that the patients probably haven't made that connection, would be my guess."
		"There are so many reasons why the girls that I vaccinate or the boys that I vaccinate are going to fall out of care that the HPV vaccine has truthfully not crossed my worry"
		"I don't know the data around this one- I haven't looked for that data specifically"
		"That's a really interesting point that you're bringing up now"
	<i>Women are unaware of the purpose of a Pap smear</i>	"I honestly don't think most people know why they're getting pap smears, but everybody kind of expects to get one. So I haven't experienced that or heard that at all with people saying, 'Oh, I don't need to get pap smears now.'"
		"I think they might make the connection with cervical cancer because that's—I talk about that. But I don't know that they make a connection between that and not needing to get a Pap smear."
		"They're not thinking about cervical cancer so we're trying to explain what we're doing it for but I'm not sure they really make the connection."
	<i>Time lag between vaccination and Pap testing</i>	"No, because I think by the time our girls are going for Pap screens they are going to have forgotten that they got HPV vaccines. So no, I don't think it will. I don't think it will impact them getting Pap smears. I hope it won't... I don't know that it's that deep."

Table 3.1: Qualitative Themes and Exemplar Quotes (continued)

	<p><i>Time lag between vaccination and Pap testing</i></p>	<p>“[H]onestly I don’t know if they recollect and maybe we don’t put those pieces together, you know, later on.”</p> <p>“I think a majority of the kids I see that we do start the HPV are usually 10, 11, 12 so those conversations, ten years from now when you’re going for you annual exams, don’t forget to do this, this, and this, it’s probably not going to be appropriate.”</p> <p>“I don’t think that when they’re 21 years old, that link is -- they’re thinking in their head, ‘Oh, well I got the shot 10 years ago, I’m not going to get my pap now.’ I just think that link is too long.”</p> <p>"I would agree that I think the teenagers aren’t thinking that far ahead. They have risky behavior anyway, so I don’t know that this has anything to do with it.”</p>
<p>55</p>	<p><i>Women tend to get over-screened</i></p>	<p>"They’re either good about getting their Pap smears and want to get them all the time because we actually backed off from yearly Pap smears for a lot of people to every three years, but still people want to come in every year and get their Pap smear, or people are just not good about getting them anyway. I don’t think the vaccine affects that."</p> <p>“[F]olks are typically more resistant to the idea of not having enough Pap smears as opposed to feeling overprotected and not needing to go get a Pap smear."</p> <p>“I actually think that a lot of people will default to getting screened more often than they really need to. There's still a lot of, like, you need an annual Pap myth that's out there among the providers and patient.”</p> <p>"That's not something I'm particularly worried about and I actually think that a lot of people will default to getting screened more often than they really need to.”</p>

3.4.2.1 Belief that sexual behaviors are independent of vaccination

Half of HCPs specifically mentioned that they feel it is better to start vaccinating their patients before sexual activity was a worry. Some felt that this was important in order to ensure their patients are protected before they are sexually active and providers would communicate this by saying, “This is about the idea that the vast majority of people at some point in their life are sexually active. And so we want this protection before that starts.” While other HCPs prefer to vaccinate before sexual activity is a worry, so they do not have to talk about sexual activity in the context of vaccination, for example, “If somebody asks me—like I usually talk about how [HPV] is the number one cause for cervical cancer, and things like that, but I don’t actually talk about sexual activity in the context of the vaccine.” A participant said they tell their parents, “[Y]ou can certainly believe that you can control the behavior of your child, but you certainly can’t control the behavior of other peoples’ children and that’s what immunization is all about; herd immunity,” indicating that even if a parent states their child does not need it because they will abstain from sexual activity until marriage, they cannot predict the behavior of their child’s future spouse. One HCP did indicate the opposite belief, stating that bringing up sexual activity at a young age would make the parents more averse to vaccination.

Some HCPs believed that in general, people who engage in risky behaviors will do so regardless of vaccination status. One said, “[T]he reasons why teenagers engage in sex, risky or not, are really multi-factorial and the degree to which vaccination status plays into it is probably zero-to-none.” This quote echoes the sentiment expressed by most of the HCPs which was that vaccinating their patients was a good time to educate

them about safe sex but it was better to protect them if at all possible because their decision to engage (or not engage) in risky behaviors was independent of vaccination status.

3.4.2.2 Patients are unaware of which vaccine they are getting

One of the crucial components of risk compensation is that the person engaging in the risky behavior has to be aware of what the protective behavior is protecting them from and they have to understand the connection between the risky behavior and the protective behavior. If a patient is not aware that they are getting vaccinated against HPV, not aware that HPV is sexually transmitted, or not aware that the vaccine is protecting them against a STI, then they will be unlikely to respond to vaccination with riskier sexual behavior. Some HCPs indicated that many of their patients do not know or pay attention to the vaccines being administered. One participant in the study said, "My thoughts are that most adolescents don't know which vaccines they have or haven't gotten. And so the idea that they would [be] so aware of it that it would influence their behaviors is a little far-fetched."

While none of the providers thought sexual disinhibition happened, it should also be noted that none of them indicated that it would influence their vaccination practices even if they did think it happened. Generally, most of the HCPs seemed almost exasperated when they were asked this question with one of them asking, "Is it unprofessional for me to say that I think that's the dumbest thing I've ever heard?"

3.4.3 Concern about a decrease in cervical cancer screening

In general, when the HCPs were asked if they thought getting the HPV vaccine would result in their patients feeling completely protected from cervical cancer and therefore less likely to get screened in the future, half of them (n=11) said they did not know and a few (n=3) stated they had not ever thought about it before. If an HCP has not even thought about the possibility that their patient might reduce cervical cancer screening, the idea that this might be a reason an HCP would be hesitant to recommend the vaccine is unfounded. Five of the HCPs said it was an interesting question indicating it could be an area for future research in order to educate HCPs on patient behavior post-vaccination in an attempt to increase vaccine uptake.

When the HCPs thought about it, all but one of them said they did not think their patients would get screened for cervical cancer less often after they were vaccinated. The one who did think patients would get screened less stated it more as a fact that she thought they did not need to be screened as much and the guidelines would probably change soon to allow for decreased screening frequency. She said, “I don’t see why we should be doing as frequent cervical or Pap smears if they have an effective vaccine to prevent cervical cancer.”

3.4.3.1 Women are unaware of the purpose of a Pap smear

The HCPs who did not think their patients would get screened less frequently said that they believed that most women do not understand the purpose of a Pap smear. Therefore, it would be unlikely for the patient to make the connection that the HPV vaccine protects against HPV, HPV causes cervical cancer, a Pap smear is a screening

test for cervical cancer, and they could therefore reduce their screening. "I think they might make the connection with cervical cancer because ... I talk about that. But I don't know that they make a connection between that (HPV vaccination) and not needing to get a Pap smear." Or, "They're not thinking about cervical cancer so we're trying to explain what we're doing it for but I'm not sure they really make the connection. With us doing Pap smears at later ages anyway, delaying the onset of Pap smears is really not in their mind anyway."

3.4.3.2 Time lag between vaccination and Pap testing

There is also a significant time lapse between the age of vaccination and when a woman needs to start cervical cancer screening. Most HCPs indicated they think their patients have probably forgotten they were vaccinated and what it was for by the time they have to make the decision to get screened. "I think the teenagers aren't thinking that far ahead. They have risky behavior anyway, so I don't know that this has anything to do with it."

3.4.3.3 Women get over-screened

Largely, the HCPs indicated the problem they face with their patients is that they are screened too often, as opposed to not often enough. They noted that most patients and providers are unaware of the current guidelines and tend to think screening should occur on a yearly basis. "That's not something I'm particularly worried about and I actually think that a lot of people will default to getting screened more often than they really need

to.” Some providers have also noted that annual screening is just part of a woman’s routine and some of them feel uncomfortable decreasing screening to every three years.

Even if a reduction in cervical cancer screening was identified, HCPs indicated this would not influence their vaccination practices. They said they do not think their patients would get screened less but if they did, the HCP would still want to vaccinate as many people as possible. They stated preventing cancer is almost always better than screening and catching it early. One stated that it is important to emphasize that to the patient and said, “Discussing that even though you’ve had the HPV vaccine, this is—this (cervical cancer) could still be an issue, so you need to get your regular Pap screens.” Furthermore, since there are many other reasons patients fall out of care, the thought that they would choose not to continue to be screened for cervical cancer based solely on having the HPV vaccination is unlikely. “Like people that don't get Paps, it's not because they don't think they're at risk it's because they're doing resource allocation differently in terms of time and money and access to healthcare.”

3.5 Discussion

Our results indicate that none of the HCPs in our sample believed sexual disinhibition occurred as a result of HPV vaccination. The HCPs were up-to-date on current literature stating that there is no evidence of sexual disinhibition following HPV vaccination when examining both biological outcomes and reported sexual behaviors.^{40,41,62,73} Furthermore, HCPs indicated a concern about sexual disinhibition would not result in them being hesitant to offer the HPV vaccine to their patients.

HCPs also seemed not to be concerned about a decrease in cervical cancer screening behavior following HPV vaccination. Most of the providers in this study indicated that they did not think patients would decrease cervical cancer screening. They indicated several reasons for this belief. The first is that most women do not make a connection between HPV, Pap smears, and cervical cancer. The providers in this study also stated that frequently women tend to get over screened for cervical cancer and not under screened. The providers in this study shared the belief found in similar studies that vaccination and screening are both preventive health behaviors and a woman who engages in one is more likely to engage in the other due to an emphasis on positive health behaviors and access to healthcare. This is consistent with a 2015 study that found that unvaccinated women were actually less likely to have had a recent Pap test as compared to vaccinated women.⁸⁹ HCPs in this study indicated that even if they did believe cervical cancer screening would decrease, it would not be a reason to withhold vaccination. They stated preventing cancer is better than screening so they would prefer to prevent it if at all possible.

This study has some limitations to note. Participants were a convenience sample of HCPs in an urban hospital system that generally serves minority and economically disadvantaged patients and their responses may not be representative of all HCPs. Selection bias might have occurred as the HCPs who agreed to participate might have different attitudes to vaccination than the participants who did not wish to participate. Furthermore, the face-to-face nature of the study might have contributed to HCPs answering questions in a way they deemed socially desirable as opposed to indicating their actual personal beliefs. This bias was limited by assuring the participants their

individual responses would be kept in strict confidence and all study information would be de-identified.

Opponents of the HPV vaccine have argued that the receipt of the vaccine could cause adolescents to engage in more risky sexual behavior due to a perceived decreased risk of sexually transmitted infections.²¹ Some clinicians have expressed concern that women who have received the HPV vaccine will be less likely to get screened for cervical cancer, or will cease cervical cancer screening altogether.¹⁹ Since HCP recommendation is one of the strongest predictors of HPV vaccine uptake, it is important to understand if HCPs believe risk compensation occurs after HPV vaccination and if this belief results in the HCP being hesitant to recommend the vaccine. This is one of the first studies to qualitatively analyze HCP beliefs regarding risk compensation in the context of both sexual disinhibition and cervical cancer screening.

3.6 Conclusion

Overall, HCPs in this study indicated they were not concerned about HPV vaccination leading to risk compensation. This was true in the context of both sexual disinhibition and decreases in cervical cancer screening behaviors. Furthermore, the reasons HCPs cited for their lack of concern, including patients not knowing what they have been vaccinated against, women not understanding the connection between HPV and Pap screening, and women's preferences for over-screening are also areas that are necessary to examine in future research. This study is the first of its kind to examine HCP beliefs regarding disinhibition following HPV vaccination and adds to the growing body

of literature that disinhibition does not occur post-vaccination and is not a reason for non-vaccination.

CHAPTER 4

DIFFERENCES IN CERVICAL CANCER SCREENING KNOWLEDGE, PRACTICES, AND BELIEFS: AN EXAMINATION OF A LOCAL SURVEY OF WOMEN

4.1 Abstract

Background

This study examined the relationship between cervical cancer screening rates and human papillomavirus (HPV) vaccination.

Methods

We conducted a cross-sectional survey of 21 to 35 year-old women attending a local minority health fair in July 2015. The outcomes assessed were: receiving a Papanicolaou (Pap) test within the last three years, awareness and comfort with current cervical screening recommendations, and knowledge regarding the purpose of a Pap test.

Results

A total of 291 survey participant women were included in the analyses. Their mean age was 28.5 years and 62% were non-Hispanic black. Most (84%) had received a Pap test in the last three years and one-third (33%) had received at least one HPV vaccine. Logistic regression results showed that women who had been vaccinated did not have lower odds of having a Pap test in the past three years (OR=1.32; 95% CI=0.66-2.65). In fact, in an adjusted multivariable logistic regression that controlled for age and race, vaccinated women were significantly more likely to have had a Pap test (AOR=3.06; 95% CI=1.37-6.83). Two-thirds (64%) of respondents thought average-risk women should get a Pap test every year. Only 26% of women knew the purpose of a Pap

test and the proportion who correctly answered this question varied by race. Participants who answered incorrectly were over four times as likely to be non-Hispanic black as compared to those who were white (OR=4.20; 95% CI=2.00-8.81; p<0.001).

Conclusion

Analysis of this sample of women shows that women who have been vaccinated for HPV are more likely to have been screened for cervical cancer. Furthermore, women were unaware of the purpose of a Pap test and current screening recommendations.

Impact

These results should alleviate concerns among healthcare providers regarding whether would decrease cervical cancer screening due to HPV vaccination. A lack of knowledge regarding the purpose of a Pap test and current recommendations are areas for future interventions.

Keywords for indexing:

Cancer screening, cervical cancer, HPV vaccination, knowledge, risk compensation

4.2 Introduction

The Centers for Disease Control and Prevention (CDC) estimates 79 million Americans are currently infected with human papillomavirus (HPV) and 14 million new infections occur every year, making it the most common sexually transmitted infection (STI) in the U.S.¹ Infection with HPV results serious health issues including cervical cancer, anal cancer, penile cancer, oropharyngeal cancers, genital warts, and recurrent respiratory papillomatosis.³

Currently there are three different HPV vaccines licensed by the U.S. Food and Drug Administration (FDA): a bivalent (2vHPV), a quadrivalent (4vHPV), and a nine-valent (9vHPV) vaccine. A series of three doses is required for each vaccine.⁷ Detailed information about all of the vaccines can be found in Petrosky *et al.*⁸ The Advisory Committee on Immunization Practices (ACIP) routinely recommends HPV vaccination for boys and girls age 11 or 12 and catch up vaccination for women up to age 26, all men up to age 21, and for men who have sex with men up to age 26.⁷ The 9vHPV vaccine was licensed for women ages 9 to 26 and men ages 9-15 in December, 2014.⁹ In February, 2015, the ACIP issued the same age-based recommendations for 9vHPV as it did for 4vHPV.⁸

HPV vaccination rates in the U.S. remain lower than desired to best protect the population against HPV infection.¹⁰ In 2014, only 60.0% of adolescent girls and 41.7% of adolescent boys between the ages of 13 and 17 received one or more doses in the HPV vaccine series.¹¹ The percentages are even lower for series completion (39.7% of girls and 21.6% of boys). Barriers to HPV vaccination include cost of the vaccine, lack of knowledge about HPV transmission, and parental concerns about sexual disinhibition as a

result of vaccinating their children against a STI.¹² An additional concern is that women who have received the HPV vaccine may be less likely to seek screening for cervical cancer, or will cease cervical cancer screening altogether due to their perceived lack of susceptibility to all cervical cancers.¹⁹⁻²²

Compared to sexual disinhibition, there has been less research conducted on cervical cancer screening behavior post-HPV vaccination, particularly regarding knowledge and uptake among minority women. Studies have shown that non-Hispanic black women have higher incidence of cervical cancer⁹⁰ and are less likely to get screened⁹¹ than their white counterparts. One study found cervical cancer screening awareness was lower in ethnic minorities. However, this study did not assess knowledge and examined minorities in England, which constitute largely different groups than minorities in the United States.⁹² Preliminary studies assessing knowledge about cervical cancer screening recommendations have shown that women are generally unaware of screening guidelines.⁴³ This is understandable considering cervical cancer screening guidelines have changed four times in the last 30 years and the most recent recommendations have only been in place since 2012.⁹³ The current CDC recommendations for average risk women state that women should be screened with a Papanicolaou (Pap) test every three years from age 21 to 29. That screening period can be extended to five years from age 30 to 65 if the woman has an HPV DNA test along with the Pap test and both are negative. Screening is not recommended after age 65.⁹⁴ One study of 193 college-aged women found that 28% incorrectly thought HPV vaccinated and unvaccinated women could get screened at different frequencies. This knowledge did not differ based on the participants' vaccination status.⁴³ Other studies have found similar

results in which Pap screening was either positively associated with vaccination or no association was found.⁹⁵⁻⁹⁷ Using a national dataset, one of these studies found that a lower percentage of women who had not initiated the HPV vaccination series reported having a recent Pap test as compared to women who had initiated the series (81.0% vs. 90.5%).⁸⁹ The findings of research to date suggest that the impact of having been vaccinated against HPV on women's participation in cervical cancer screening is not yet well understood particularly within minority populations.

The current study examined the relationship between HPV vaccination and Pap testing using responses to a survey of mostly minority women. We used both quantitative and qualitative methodology in order to: 1) examine if cervical cancer screening rates differed between those who had been vaccinated and those who had not; 2) assess if women understood the purpose of a Pap test; and 3) assess if women were aware of the current recommendations for Pap testing and their comfort level with the current recommendation.

4.3 Materials and Methods

4.3.1 Participants and Procedures

This survey data collected at a minority health fair was approved by the Indiana University Institutional Review Board and conducted in July 2015. The target population was women between the ages of 21 to 35 who attended the 46th Annual Indiana Black Expo event in Indianapolis. This is one of the nation's largest cultural events for African-Americans and draws an estimated 40,000 attendees from across Indiana as well as from surrounding states. The minority health fair is a component offered at the Indiana Black

Expo event. Visitors to the health fair were invited to participate in the survey if they met the study criteria.

Exclusion criteria included women with a hysterectomy and women who received the vaccine less than three years prior to the survey because there would not be sufficient time to assess their post-vaccination screening behaviors. A total of 317 women started the survey; 291 of them were included in analysis after excluding those with a history of hysterectomy (n=8), those who were vaccinated for HPV less than three years ago (n=13), and those who started but did not complete the survey (n=5). It was not possible to determine the declination rate due to the nature of the study setting. The oldest age that women are recommended to receive the HPV vaccination is 26 years old; therefore, if a woman was vaccinated at age 26 when the vaccine became available in 2006, that woman would have been 35 years old in 2015. Women between the ages of 21 and 35 are eligible for both HPV vaccination and cervical cancer screening.

4.3.2 Measures

The web-based survey was administered via notebook computers. Questions were modeled after relevant items from the National Health Interview Survey (NHIS), a population survey administered by the Centers for Disease Control and Prevention. The questions assessed if participants received the HPV vaccine, how many shots they received, and at what age. We also assessed if participants ever had a Pap test, if they had a Pap test in the last 12 months, and when they had their last Pap test. We then expanded on the NHIS questions by asking if participants were aware of the new cervical cancer screening recommendations and how comfortable they were with the frequency of the

screenings in the new recommendations. We also asked open-ended questions to assess if participants knew the purpose of a Pap test and the connection between vaccination and a Pap test by asking, “What is the purpose of a Pap smear or Pap test?” and “What is the connection between HPV vaccination and Pap testing?” The relevant portion of the survey is attached as Appendix C.

4.3.3 Analysis

4.3.3.1 Quantitative Analysis

The main outcome assessed was whether the women were up-to-date on cervical cancer screenings. Women who indicated they had been screened within the last three years were considered current; women who indicated their last screening was over three years ago or had never been screened were considered not current. We compared the demographic characteristics of women who were current with women who were not current using bivariate analyses. Demographic variables independently related to Pap testing behaviors, derived from the bivariate analyses, were further analyzed using multivariable logistic regression to assess the impact of HPV vaccination on cervical cancer screening status, controlling for the potential confounding variables. In order to explain the interaction between age and vaccination status, stratified logistic regression models were conducted separately for each age group in five-year increments. Additionally, we assessed women’s knowledge and comfort with cervical cancer screening guidelines using frequency tables and regression analyses. All quantitative analyses were performed using SPSS v. 22.0 (IBM Corp., Armonk, NY, USA). P-values less than 0.05 were considered statistically significant.

4.3.3.2 *Qualitative Analysis*

The survey included open-ended questions which were analyzed using inductive content analysis.⁸⁸ Responses to questions were assessed to identify meaningful themes. Two investigators (MLK & SW) independently coded each response according to those themes. The coded responses were reviewed and areas of disagreement were resolved through discussion. For one of the questions, “What is the purpose of a Pap smear or Pap test,” participants were assessed on whether they correctly answered the question. In order to consider the response to the question correct, the participant had to indicate that a Pap test checks for cancer or abnormal cells of the cervix. If a participant did not mention the cervix, or she indicated the test also checks for STIs, she was marked as answering the question partially correct. All other answers were considered incorrect. Answers were discussed until a consensus could be reached. With this qualitative coding, we could then assess racial differences between those who answered correctly and those who did not. In order to assess racial disparities in knowledge regarding cervical cancer screening, we examined differences in answers between non-Hispanic blacks and non-Hispanic whites. For these questions only, we excluded women who indicated that their race was “Hispanic,” “other” and “multiracial” because the number of respondents were relatively small and heterogeneous. Therefore, all analyses commenting on differences in knowledge between non-Hispanic blacks and non-Hispanic whites were conducted as bivariate analyses with participants in the “Hispanic,” “other” and “multiracial” category coded as missing.

4.4 Results

4.4.1 Sample Description

A full description of the respondents, including differences by screening status, is shown in Table 4.1. The respondents' ages ranged from 21 to 35 with a mean of 28.5 (standard deviation=4.7). Race was assessed by self-report and nearly two-thirds of the respondents (62.5%, n=182) were non-Hispanic black; the rest self-identified as non-Hispanic white (22.7%, n=66) or Hispanic, other, or multiracial (14.8%, n=43). A majority of the women in the study received a Pap test in the last three years (84.2%, n=245), and one-third (n=97) had received at least one HPV vaccination. There were also demographic differences in the bivariate comparisons between the participants who were current on their Pap testing as compared to those who were not. As compared to those who were current on their cervical cancer screening, those who were not current were more likely to be younger ($p<0.001$) and Hispanic, other, or multiracial ($p=0.004$).

Table 4.1 Sample Description by Cervical Cancer Screening Status (Current vs. Not Current)

	Total Sample (n=291)	Current (n=245)	Not Current (n=46)	Bivariate analysis p-value
Mean Age	28.5	29.1	25.3	<0.001*
Race				0.004*
Non-Hispanic White	22.7%	22.9%	21.7%	
Non-Hispanic Black	62.5%	65.3%	47.8%	
[†] Other	14.8%	11.8%	30.4%	
Education				0.112
Some high school/high school graduate/GED	12.0%	11.0%	17.4%	
Some college/trade school/4-year degree	52.9%	55.5%	39.1%	
Some post-grad/graduate degree	35.1%	33.5%	43.5%	
HPV Vaccine Status				0.497
Received ≥1 dose	33.3%	34.3%	28.3%	
Never received HPV vaccine or unsure	66.7%	65.7%	71.7%	
Purpose of a Pap Test				0.317
Incorrect	35.7%	34.3%	43.5%	
Partially Correct	37.8%	39.6%	28.3%	
Correct	26.5%	26.1%	28.3%	
Pap Recommendation Awareness				<0.001*
Aware	45.4%	50.0%	21.7%	
Unaware	54.3%	50.0%	78.3%	
Guideline Comfort				0.005*
Very uncomfortable	21.6%	24.2%	8.9%	
Somewhat uncomfortable	21.0%	21.3%	20.0%	
Neither comfortable nor uncomfortable	17.5%	16.0%	26.7%	
Somewhat comfortable	13.4%	11.1%	26.7%	
Very comfortable	25.8%	27.5%	17.8%	

*The difference between those who were current and those who were not current for a Pap test was significantly different between groups at $p < 0.05$.

[†]“Other” category includes people who indicated “other” for their race, people who indicated multiple races, and Hispanics.

4.4.2 Quantitative Results

4.4.2.1 Association between HPV Vaccination and Cervical Cancer Screening

In bivariate logistic regression, women who indicated receiving at least one HPV vaccine were not less likely to have received a Pap test when compared to unvaccinated women (OR=1.32; 95% CI=0.66-2.65; p=0.427). In contradistinction to the prediction of risk-compensation theory, multivariable logistic regression, which controlled for the independently significant demographic variables age and race, showed that vaccinated women were actually more likely to obtain the cervical cancer screening than their non-vaccinated counterparts (AOR=3.06; 95% CI=1.37-6.83; p=0.006). For all regression analyses, see Table 4.2.

An interaction analysis was then performed to assess if age was the driver in the relationship between vaccination status and Pap testing. The interaction between age and vaccination status was then entered into the model and was statistically significant (OR=1.62; 95% CI=1.05-2.50; p=0.003). In order to explain this relationship between age and vaccination status, stratified logistic regression models were conducted separately for three age groups, defined in five-year increments. We found that the relationship between vaccination status and cervical cancer screening frequency was not significant for 21 to 25 year olds while controlling for race (OR=2.0; 95% CI=0.8-5.0). For the 26 to 30 and 31 to 35 age groups, of the women who were overdue for Pap testing (n=9 and 7 respectively), none had been vaccinated for HPV. We then performed a Fisher's exact test and found that the relationship between vaccination status and Pap testing was significant for the middle age group (p=0.03) but was not significant for the youngest or oldest age groups (p=0.13 and 0.59, respectively).

Table 4.2 Regression Analyses Assessing the Receipt of a Pap Test in the Last Three Years Controlling for Demographic Variables

	Bivariate Odds Ratio (95% CI)	Multivariable Odds Ratio (95% CI)
Ever received HPV vaccine		
No	Ref	Ref
Yes	1.32(0.66-2.65)	3.06 (1.37-6.83)*
Race		
Non-Hispanic White	Ref	Ref
Non-Hispanic Black	1.30(0.58-2.91)	0.94 (0.39-2.27)
Other	0.37(0.15-0.94)*	0.30 (0.11-0.82)*
Age (continuous)	1.21(1.12-1.31)*	1.26 (1.15-1.38)*
†Education		
Some high school/high school graduate/GED (ref)	Ref	
Some college/trade school/4-year degree	2.24(0.88-5.67)	
Some post-grad/ graduate degree	1.22(0.48-3.07)	

*Significant at $p < 0.05$

†These variables were not significant in the bivariate analysis and were subsequently excluded from multivariable regression model.

4.4.2.2 Beliefs about Post-Vaccination Screening Frequency

When asked if vaccinated women should get screened less frequently than unvaccinated women, 17% (n=50) incorrectly said “yes,” 68% (n=198) said “no,” and 15% (n=43) said they did not know. Women who answered the question correctly were no more likely to have had a Pap test in the last three years than women who answered the question incorrectly (OR=1.18; 95% CI=0.48-2.92; $p=0.72$). However, response patterns varied by HPV vaccination status, in that women who answered the question correctly were more likely to be vaccinated than women who answered it incorrectly (OR=2.77; 95% CI=1.31-5.85; $p=0.008$). The accuracy of the responses to the question about whether HPV vaccinated women should be screened for cervical cancer at a

different frequency than non-vaccinated women also varied by race; participants who answered incorrectly were more likely to be non-Hispanic black than participants who answered correctly (OR=3.19; 95% CI=1.27-7.97; p=0.013).

When asked how often a woman should get a Pap test if she has never had cervical cancer or an abnormal Pap test, 64% (n=187) incorrectly responded they thought she should get screened every year. There were variations by race; those who answered incorrectly had double the odds of being non-Hispanic black (OR=2.0; 95% CI=1.11-3.58). Women were then told the current recommendation for average risk women is every three years and were asked if they were aware of this recommendation. Almost half (45.3%, n=132) indicated they were aware of the recommendation. Of the women who were aware of the current recommendation, 53% (n=70) indicated that they knew the recommendation was every three years, but still stated the women should get screened every year. When asked on a five-point scale how comfortable they were with the new screening recommendations (from very uncomfortable to very comfortable), 43% (n=124) indicated they were either very or somewhat uncomfortable, 40% (n=114) reported they were either very or somewhat comfortable, and 18% (n=51) indicated they were neither comfortable nor uncomfortable.

4.4.3 Qualitative Results

4.4.3.1 Understanding of the Purpose of a Pap Test

At the beginning of the survey, prior to defining the term “Pap smear.” respondents were asked “What is the purpose of a Pap smear or Pap test?” in order to measure awareness. Almost half (49%, n=143) stated that a Pap smear checks for cancer,

although not all participants knew it tested specifically for cervical cancer. Additionally, 20% (n=57) stated it checked for abnormal or precancerous cells and 41% (n=119) knew that a Pap smear checks the cervix. Some were vague in their answers suggesting they did not fully understand the purpose of a Pap test for example, 9% (n=25) indicated that a Pap smear checked for STIs in general and 4% (n=11) indicated the Pap smear was a test for the presence of HPV. An additional 25 women (9%) stated the Pap smear checked for “disease” but did not specifically say what disease. Some participants thought a Pap smear tested other body parts including the ovaries, uterus, breasts, and generic terms such as “organs” and “down there.” Almost one-third (29%, n=85) gave generic answers such as “to make sure everything is okay” and “to check for abnormalities.” These categories are not mutually exclusive and most of the women answered in a way that they were counted in more than one category.

We also examined whether participants answered the question about the purpose of a Pap test correctly or incorrectly. We examined the total sample using the previously described system for measuring correctness, 77 women (26%) answered correctly, 110 women (38%) were partially correct, and 104 women (36%) answered incorrectly. We then excluded the “other” race category and compared non-Hispanic blacks and non-Hispanic whites on whether they answered this question correctly. Correct answers varied by race and participants who answered incorrectly had more than four times the odds of being non-Hispanic black as compared to those who answered correctly (OR=4.20; 95% CI=2.00-8.81; $p < 0.001$). A breakdown of percentages who answered correctly in the sample of just the non-Hispanic black and white groups as well as differences between

rases and exemplar quotes of what was qualitatively coded as correct, partially correct, and incorrect, are all included in Table 4.3.

Table 4.3 Comparison between Non-Hispanic Blacks and Non-Hispanic Whites and their answers to “What is the purpose of a Pap smear or Pap test?”

Purpose of a Pap	Overall n (%)	Non-Hispanic White n (%)	Non-Hispanic Black n (%)	Example Quotes
Correct	64 (25.8)	29 (43.9)	35 (19.2)	<p>“For early detection of cancerous cells in the cervix.”</p> <p>“Screening test which detects pre-cancerous or cancerous cervical cells.”</p> <p>“Screening for cervical cancer.”</p>
Partially Correct	93 (37.5)	22 (33.3)	71 (39.0)	<p>“The check for any abnormalities and to screen for cervical cancer as well as STDs.”</p> <p>“Check for healthy/non-healthy cells.”</p> <p>“To check up on feminine health. It is a preventative screening.”</p> <p>“To ensure there are no abnormalities that may lead to ovarian or cervical cancer.”</p>
Incorrect	91 (36.7)	15 (22.7)	76 (41.8)	<p>“To determine if you possibly have breast cancer.”</p> <p>“Check for irregular uterine cells.”</p> <p>“...to collect cervical cells for testing of STDs, viruses, etc.”</p> <p>“To check for STDs and make sure everything is good with female organs.”</p>

4.5 Discussion

4.5.1 Behaviors and Beliefs around Vaccination and Cervical Cancer Screening

We examined a convenience sample of mostly non-Hispanic black women surveyed to obtain data needed to compare cervical cancer screening practices between HPV vaccinated and unvaccinated women. We also examined their knowledge regarding the purpose of a Pap test, current screening recommendations, and their level of comfort with the current screening recommendations. In contrast to the prediction of risk-compensation theory, the results suggest no relationship between vaccination status and subsequent cervical cancer screening behaviors. Moreover, when the relationship is examined controlling for age and race of the respondent, we found that women who had been vaccinated had a three times greater odds of having been screened for cervical cancer within the last three years. This is consistent with our multivariable regression analysis findings in that vaccinated women generally were more likely to obtain the cervical cancer screening than unvaccinated women. It is also consistent with recent research that used a national sample and found uptake of Pap testing was lower among those who had not initiated the HPV vaccination series.⁸⁹

Most women knew that HPV vaccinated women are recommended to obtain cervical cancer screening at the same frequency as unvaccinated women. Results varied by vaccination status but did not vary by whether the women were current on their cervical cancer screenings. The majority of women thought an average-risk woman should get screened every year, even though 45% of women claimed to know that the recommendation changed to every three years. This might be because the participants did not like admitting they were unaware of current screening recommendations or it may be

indicative of how uncomfortable women may be with the new screening recommendations. More women were uncomfortable than comfortable with the new screening recommendations and almost one-fifth were neither comfortable nor uncomfortable, which might suggest that the problem is not that women are unaware of the current screening recommendations but rather that they are uncomfortable with them. This could be an area for a future intervention targeted at reminding physicians to educate their patients on the purpose of Pap tests and the current cervical cancer screening recommendations as well as for a broader public health campaign aimed at increasing knowledge around current cervical cancer screening guidelines.

4.5.2 Cervical Cancer Screening Beliefs and Understanding

Most women knew that Pap testing checked for cancer or abnormal cells but less than half knew it was checking the cervix. Some women thought a Pap test checked for the presence of HPV. While abnormal cervical cells might indicate the presence of HPV, a negative Pap test does not indicate the absence of HPV. This could be a point of confusion for some women. Additionally, women believed they were being checked for additional STIs during the course of a Pap test and some thought they were also being checked for uterine or ovarian cancer. Only one-fourth of the sample correctly answered the question stating a Pap test checked for cervical cancer only.

We wanted to explore if risk compensation in the form of decreased cervical cancer screening could happen after HPV vaccination. In order for risk compensation to happen, women would have to understand three different concepts: 1) That the HPV vaccine protects against HPV, 2) that HPV causes cervical cancer, and 3) that a Pap

smear checks for cervical cancer. This question would have been more effective if asked in an in-person interview in which the interviewer could ask probing questions since some of the incorrect responses could have been due to an unclear question, as opposed to a lack of understanding of the concept. However, as it was asked, it seemed that women did not seem to understand that the HPV vaccine is a primary prevention measure for cervical cancer and Pap screening is secondary prevention for cervical cancer. Because women do not understand that Pap screening checks for something that HPV vaccination prevents, it is not reasonable that risk compensation in the form of decreased cervical cancer screening would occur among HPV-vaccinated women.

4.5.3 Racial Disparities in Cervical Cancer Knowledge

There were racial disparities seen in questions concerning knowledge of cervical cancer screening. Non-Hispanic black participants were less likely than their white counter-parts to be aware that vaccinated women should be screened at the same frequency as unvaccinated women and fewer of them were aware of current screening recommendations. They were also less likely to correctly identify the purpose of a Pap smear which means that not only are non-Hispanic black women substantially less aware of screening recommendations, but they also lack a fundamental knowledge regarding the purpose of a Pap test. This could be due to differences in education between the two groups but also indicates there is significant room for improvement in educating particularly minority women regarding the purpose of and guidelines for cervical cancer screening. It is important for healthcare providers to know about these differences in

order to target minority women for educational opportunities and tailor their education and screening messages that would be sensitive to the needs of different populations.

4.5.4 Limitations

This study gathered survey data from a convenience sample, thus the women in the sample may not be representative of the general population. However, our survey results were consistent with those from previous studies.⁸⁹ The measures for receipt of HPV vaccination and Pap screening were both self-reported and are subject to recall bias and reporting errors. However, since we were examining a behavioral outcome, it should be noted that for this study it was more important to know if the woman *believed* she was vaccinated as opposed to knowing if she was actually vaccinated.

4.6 Conclusion

The current study extends previous work in a national sample and was replicated more recently in a sample with a different sociodemographic make-up and sampling methodology. This kind of replication helps to support the generalizability of the findings. If risk compensation in the form of decreased cervical cancer screening were to occur, we'd expect to see an inverse relationship between vaccination and screening practices. However, we found that screening practices between the vaccinated and unvaccinated participants were not significantly different. In the multivariable analysis we found that there was a positive relationship between vaccination and cervical cancer screening when adjusted for age and race. Therefore, there is no evidence that risk compensation due to HPV vaccination is occurring and in fact, it appears as if the

opposite is occurring. This finding adds credibility to the hypothesis that the reason for higher screening rates among vaccinated women may have more to do with access to healthcare and pro-health attitudes rather than a false sense of security leading to decreased screening. A strength of this study is that it included a large number of minority participants. Findings from this study may assist healthcare providers in tailoring messages to their patients based on their specific needs.

CHAPTER 5

CONCLUSIONS

Findings from the three studies provide important insights about risk compensation after HPV vaccination. Taken together, the results of these three studies do not support the Risk Compensation Theory in the context of HPV vaccination. The findings holds true in the context of sexual behaviors as well as cervical cancer screening and could have implications for clinical practice or future interventions aimed at increasing vaccination uptake.

In regards to sexual disinhibition, the research findings presented in this dissertation found that there was no evidence of increased risky sexual behaviors after HPV vaccination. This was evidenced by the systematic review across 20 including a total of 521,879 participants that found no evidence of increased numbers of sexual partners, younger age of sexual initiation, decreased use of contraception (including both condoms and hormonal contraceptives), increased STI diagnoses, increased pregnancy rates, or increased history of abortion among those vaccinated against HPV. In fact, some studies found vaccinated women showed *lower* risky behaviors than unvaccinated women, indicating a tendency toward less risky health behaviors.

The Risk Compensation Theory was not supported when examining HPV vaccination and subsequent adherence to cervical cancer screening guidelines. If risk compensation in the form of decreased cervical cancer screening were to occur, we would expect to see an inverse relationship between prevalence of HPV vaccination and screening practices. However, what we found in the bivariate analysis was that screening

practices between the vaccinated and unvaccinated participants were not statistically different. The multivariable analysis found there was actually a positive relationship between vaccination and cervical cancer screening when adjusted for age and race. Therefore, there's contrary evidence that risk compensation is occurring. The finding adds credibility to the hypothesis that the reason for higher screening rates among vaccinated women may have more to do with access to healthcare and pro-health attitudes rather than a false sense of security leading to decreased screening. Furthermore, there were significant racial disparities in terms of knowledge regarding cervical cancer screening. Since knowledge is positively associated with vaccine uptake,^{98,99} it is important to be aware of disparity when creating interventions for vaccine uptake and targeting programs for specific populations.

One of the strongest predictors of vaccine uptake is recommendations by HCPs. It is important to know if there is concern about risk compensation from the HCPs and if this could be a reason HCPs are hesitant to strongly recommend the vaccine.^{98,100} This research found that overall, HCPs indicated they were not concerned about HPV vaccination leading to risk compensation. This was true in the context of both sexual disinhibition and decreases in cervical cancer screening behaviors. Furthermore, the reasons HCPs cited for their lack of concern, included patients not knowing what they have been vaccinated against, women not understanding the connection between HPV and Pap screening, and women's preferences for over-screenings. These are also important areas to examine in future research.

In conclusion, Risk Compensation Theory was not supported in the context of HPV vaccination. The findings from this dissertation research should alleviate concerns

that physicians and parents may have about HPV vaccination for youth. There are several areas for future research including how to better tailor interventions at the community level to increase knowledge and awareness among the minority populations. There is also a need for broader public health campaigns aimed at dispelling the myths associated with HPV vaccination and advocating for vaccine uptake.

APPENDIX A: Observational Study Data Extraction Sheet for Behavioral Outcomes

Authors:		Title:		Year published: Year data collected:	
Journal:	Extracted by:	Date extracted:	Qualitative or quantitative:		
Study type: Qualitative: Focus groups/In-person interviews/Structured interviews Quantitative: Cohort/Case Control/Cross-Sectional; Matched/Unmatched					
Research question/study aims: As stated by the authors.					
Study Setting: Geographic location (including city/country), as well as a description of the location where the data were collected.		Study population description (and sample size):		Comparison population description (and sample size):	
Inclusion criteria:					
Exclusion criteria:					
Outcome assessed:			Outcome measurement tool:		
Time-frame/Length of follow-up:			Possible biases of the study:		
Statistical/ analytical methods:					
Study Limitations:					
Main results:					
Interpretation:			Generalizability:		
Overall strength of evidence to refute evidence of risk compensation (scale of 1-10):					
Additional notes:					

APPENDIX B: Qualitative Interview Guide

[Interviewer]: It has been suggested that getting vaccinated against HPV could lead a young adolescent to engage in riskier sexual behavior because they might believe they are protected from the negative consequences of those actions.

1. What are your thoughts about this issue?
2. As a provider, do you believe HPV vaccine could lead your patients to practice riskier sexual behaviors in the future? If yes, why? If no, why not?
 - 2.A. If yes, does this concern have any influence on your HPV vaccination practices? [who/when you vaccinate?]

Some people wonder if a young woman who is vaccinated against HPV might be less inclined to get screened for cervical cancer as an adult.

3. What are your thoughts about this issue?
4. Do you believe the HPV vaccine could result in your patients feeling protected from cervical cancer and they are therefore less likely to get screened for cervical cancer in the future?
 - 4.A. If yes, why? If no, why not?
 - 4.B. If yes, does this concern have any influence on your HPV vaccination practices? [who/when you vaccinate?]
5. Do you discuss the importance of cervical cancer screening in the future regardless of HPV vaccination status?

APPENDIX C: INShape Indiana Black and Minority Health Expo Questionnaire

1. How old are you?

Under 21

21-35

36-50

Over 50

2. Please type in your exact age _____

3. What is your sex? (circle one)

Female

Male

Other

4. Have you had a hysterectomy?

Yes

No

I don't know

5. What is your race? (mark all that apply)

White/European

Black/African American

Asian

Native Hawaiian/Pacific Islander

Native American/Alaskan Native

Other

6. Are you Latina/Hispanic?

Yes

No

7. What is the highest grade you completed in school?

Some high school

High school graduate or GED

Trade school or some college

4-year college degree

Some post-college education

Graduate degree

8. What is the purpose of a Pap smear or Pap test? (Open-ended response)

9. How often should you get a Pap test? (Open-ended response)

10. What is the connection between HPV vaccine and Pap testing? (HPV stands for human papillomavirus (pap-uh-LOW-muh-vi-rus), the vaccines are sometimes called CERVARIX or GARDASIL). (Open-ended response)

11. Should women who have been vaccinated for HPV get a Pap test less frequently than women who haven't received the vaccine?

Yes No I don't know

12. Have you ever received an HPV shot or vaccine? Yes No I don't know

13. How many HPV shots did you receive? _____ (Skip if answer to 13 was "no" or "I don't know")

14. How old were you when you received your first HPV shot? _____ (Skip if answer to 13 was "no" or "I don't know")

15. Have you ever had a pap test? (A Pap smear or Pap test is a routine test for women in which the doctor examines the cervix, takes a cell sample from the cervix with a small stick or brush, and sends it to the lab.)

Yes no I don't know

16. Have any of your pap tests been abnormal?

Yes No I don't know Prefer not to answer

17. Have you had a Pap smear or Pap test during the past 12 months? (A Pap smear or Pap test is a routine test for women in which the doctor examines the cervix, takes a cell sample from the cervix with a small stick or brush, and sends it to the lab.) (Skip if the answer to 16 was "no" or "I don't know")

Yes no I don't know

18. When did you have your most recent Pap smear or Pap test? (Skip if the answer to 16 was "no" or "I don't know")

A year ago or less

More than 1 year but not more than 2 years

More than 2 years but not more than 3 years

More than 3 years but not more than 5 years

Over 5 years ago

Don't know

19. Was your most recent pap test abnormal?

Yes No I don't know Prefer not to answer

20. When do you expect to have your next Pap smear or Pap test?

A year or less from now

More than 1 year to 3 years from now

More than 3 years to 5 years from now

More than 5 years from now

When doctor recommends it

Never, had HPV DNA test

Never, had HPV vaccine

Never, other reason

Don't know

21. If a woman has never had cervical cancer or an abnormal Pap test, how often should she get a Pap test?

Every year

Every 1-2 years

Every 3-5 years

Every 5-10 years

I don't know

22. In 2012 the recommendation for Pap testing for most women went from every year to every three years. Did you know this?

Yes No

23. How comfortable are you with this new screening recommendation?

Very uncomfortable

Somewhat uncomfortable

Neither comfortable nor uncomfortable

Somewhat comfortable

Very comfortable

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CURRICULUM VITAE

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RESEARCH INTERESTS

cancer prevention, epidemiology, HIV prevention, health behavior, physician-patient communication, cancer screening. Human Papillomavirus (HPV) vaccination

PUBLICATIONS

- Kasting ML**, Shapiro G, Rosberger Z, Kahn JA, Zimet GD. (2016). Tempest in a Teapot: A review of HPV vaccination and risk compensation research. *Human Vaccines and Immunotherapeutics*, 12(6). doi: 10.1080/21645515.2016.1141158.
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- Cummings TE, **Kasting ML**, Rosenberger JG, Rosenthal SL, Zimet GD, Stupiansky NW. (2015). Catching up or missing out? HPV vaccine acceptability among 18-26 year old men who have sex with men in a U.S. national sample. *Sexually Transmitted Diseases*, 42(11), 601-606. doi: 10.1097/OLQ.0000000000000358.
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- Kasting ML**, Wilson S, Dixon BE, Downs SM, Kulkarni A, Zimet GD. (2016). Healthcare providers' attitudes and beliefs regarding sexual disinhibition and cervical cancer screening behaviors following HPV vaccination: a qualitative analysis. *Papillomavirus Research. Under review.*
- Dixon BE, **Kasting ML**, Wilson S, Kulkarni A, Zimet GD, Downs S. (2016). Healthcare provider use of technology-based vaccine reminders: A randomized clinical trial. *In preparation.*
- Kasting ML**, Wilson S, Zollinger T, Dixon BE, Stupiansky NW, Zimet GD. (2016). Differences in cervical cancer screening knowledge, practices, and beliefs between HPV-vaccinated and unvaccinated minority women. *In preparation.*

CONFERENCE PRESENTATIONS

- Kasting ML**, Zollinger T, Dixon BE, Stupiansky NW, Zimet GD. (2016). "An examination of HPV vaccination and cervical cancer screening using the National Health Interview Survey." Society of Behavioral Medicine, 37th Annual Meeting & Scientific Sessions, Washington, DC. *Podium presentation.*
- Sturm L, Donahue K, **Kasting ML**, Brewer NT, Kulkarni A, Zimet GD. (2016). "Health care provider communication about HPV vaccination: An analysis of audio-recordings." National Conference on Immunization Coalitions and Partnerships, Indianapolis, IN. *Workshop.*
- Kulkarni A, Sturm L, Donahue K, **Kasting ML**, Brewer NT, Zimet G. (2016). "Pediatrician communication about HPV vaccination: An analysis of recorded conversations." EUROGIN: International Multidisciplinary Congress, Salzburg, Austria. *Podium presentation.*
- Kasting ML**, Wilson S, Zollinger T, Dixon BE, Stupiansky NW, Zimet GD. (2016). "Differences in cervical cancer screening knowledge, practices, and beliefs: A local survey of minority women." Indiana University Simon Cancer Center Annual Cancer Research Day. Indianapolis, IN. *Poster presentation.*
- Kasting ML**, Shapiro GK, Rosberger Z, Kahn JA, Zimet GD. (2015). "Tempest in a teapot: A review of research about risk compensation after HPV vaccination." International Papillomavirus Society, 30th Annual Conference and Clinical & Public Health Workshops, Lisbon, Portugal. *Podium presentation.*
- Kasting ML**, Wilson S, Dixon BE, Downs SM, Kulkarni A, Zimet GD. (2015). "A qualitative study of physician awareness and informational needs regarding the nine-valent HPV vaccine." International Papillomavirus Society, 30th Annual Conference and Clinical & Public Health Workshops, Lisbon, Portugal. *Poster presentation.*
- Kasting ML**, Zimet GD. (2015). "Tempest in a teapot: A review of HPV vaccination and risk compensation research." Indiana University Simon Cancer Center Annual Cancer Research Day. Indianapolis, IN. *Poster presentation.*
- Kasting ML**, Cummings TE, Zimet GD, Rosenberger JG, Stupiansky NW. (2014). "Lack of knowledge has consequences: HPV vaccination among young MSM." International Papillomavirus Society, 29th Annual Conference and Clinical & Public Health Workshops, Seattle, WA. *Poster presentation.*

Kasting ML, Cummings TE, Zimet GD, Rosenberger JG, Stupiansky NW. (2014). “Lack of knowledge has consequences: HPV vaccination among young MSM.” Indiana University Simon Cancer Center Annual Cancer Research Day. Indianapolis, IN. *Poster presentation.*

Kasting ML, Cox AD, Cox D, Fife K, Zimet GD. (2014). “Health messages and HIV test acceptance in women.” Society of Behavioral Medicine, 35th Annual Meeting & Scientific Sessions, Philadelphia, PA. *Poster presentation.*

GRANTS AND FUNDING

NIH Training in Research for Behavioral Oncology and Cancer Control Program – R25 (R25-CA117865) Predoctoral Research Fellowship (Role: Predoctoral Fellow; PI: Victoria Champion)	2015 - present
Behavioral Cooperative Oncology Group (BCOG) Center for Bio Behavioral Oncology Research and Training Program and Walther Cancer Foundation Pre-Doctoral Fellowship (Role: Predoctoral Fellow; PI: Victoria Champion)	2013 - 2015
International Papillomavirus Society Travel Grant for International Oral Presentation, Lisbon, Portugal (Role: PI)	2015
Indiana University Institutional Graduate Student Research Fellowship (Role: Predoctoral Fellow)	2012 - 2013
Educational Enhancement Travel Grant, Indiana University (Role: PI)	2012 & 2014

TEACHING EXPERIENCE

Advanced Epidemiology, Indiana University, Master of Public Health Program, Teaching Assistant, Spring 2015

Fundamentals of Epidemiology, Indiana University, Master of Public Health Program, Teaching Assistant, Fall 2014 & Spring 2015

Principles of Epidemiology, Indiana University, Undergraduate Public Health Program, Teaching Assistant, Spring 2014

Introduction to Genetic Epidemiology, Indiana University, Master of Public Health Program, Teaching Assistant, Fall 2014

Molecular & Genetic Epidemiology, Indiana University, Master of Public Health Program, Teaching Assistant, Fall 2013.

Cell and Molecular Biology, Purdue University, Undergraduate Biology Program, Teaching Assistant, Fall 2008 & Fall 2009

INVITED LECTURES AND PANEL DISCUSSIONS

“Preparing for Junior Faculty Positions in Academia,” panel discussion moderator for R25 research fellows, 2015

“Implementation of Healthcare System Change and the Role of Technology, a student update.” Oral presentation at the Behavioral Cooperative Oncology Group Annual Conference in Indianapolis, 2014

“Risk compensation following HPV vaccination.” Oral presentation at the Behavioral Cooperative Oncology Group Fall Meeting at The Ohio State University, 2014

“Genetic Epidemiology of Infectious Diseases,” invited guest lecture for Genetic and Molecular Epidemiology course, 2014

“Biobehavioral research; New directions, a student update.” Oral presentation at the Behavioral Cooperative Oncology Group Annual Conference in Indianapolis, 2013

“What is Epidemiology?: Outbreak Investigation,” invited guest lecture for Preparing for Careers in Academia course, 2013

“Graduate Careers in the Sciences,” invited panel discussion participant for the School of Science Career Office, 2013

“Protection of Human Subjects, Sensitivity to Subjects’ Concerns about Research Studies, Obtaining IRB Approval,” invited guest lecture for Design and Implementation of Observational Studies course, 2012

SERVICE AND PROFESSIONAL AFFILIATIONS

Tutor, Biostatistics, Registered Nurse to Bachelor of Science in Nursing Program, Indiana University, 2015-present

Tutor, Biostatistics, Primary Care Family Nurse Practitioner Program, University of Indianapolis, 2014-present

Tutor, Ayuda y Aprende Spanish Service-Learning, Purdue University, 2008-2009

Vice President, Fairbanks School of Public Health PhD Student Association, Indiana University, 2013-2014

Volunteer, Indiana University Public Health Zombie Outbreak Simulation, Project Stepping Stone, 2015

Volunteer, Society of Behavioral Medicine Annual Conference, 2015

Volunteer, INShape Indiana Black & Minority Health Fair, Cervical Cancer Free Indiana Informational Booth, 2015

Volunteer, Public Health Corps, Indiana University, 2013-2015

Student Ambassador, Purdue College of Science, 2009-2010

Student Ambassador, Purdue Alumni Association, Vice President of Service, 2007-2009

Student Member, International Papillomavirus Society, 2015-present

Student Member, Society of Behavioral Medicine, 2014-present

Student Member, American Public Health Association, 2012-2013

Ad Hoc Reviewer, *Vaccine*, 2015-present

Ad Hoc Reviewer, *Journal of Adolescent Health*, 2015-present

Ad Hoc Reviewer, *Health Psychology*, 2014-present

Ad Hoc Reviewer, *Pediatrics*, 2014-present

WORK EXPERIENCE

Pre-Doctoral Research Fellow, Indiana University, Indianapolis 2013 - Present

Hours: 20 hours/week

Description of duties:

- Participate in various stages of research including: study development, IRB approval, data collection, data analysis, manuscript preparation, dissemination of results

- Conduct and analyze qualitative interviews with healthcare providers regarding electronic reminders for HPV vaccination.
- Qualitatively analyze interactions between healthcare providers', patients', and parents' discussions about HPV vaccination
- Conduct quantitative analysis of nationally available datasets
- Develop and collect original survey data

Graduate Research Assistant, Indiana University, Indianapolis 2012 - 2013

Hours: 20 hours/week

Description of duties:

- Collected and analyzed data for the I Need You to Listen, Hear, and Understand Me youth empowerment project
- Qualitatively analyzed data and prepared manuscript for HIV-related project through the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
- Performed program evaluation for Healthcare Education and Training (HCET) text messaging program and disseminate results

Cancer Health Policy Intern, Indiana State Department of Health, Indianapolis 2011

Hours: 10 hours/week

Description of duties:

- Responsible for fulfilling deliverables on a cancer health policy grant from the Centers for Disease Control and Prevention
- Worked closely with the chronic disease epidemiologist in monitoring the effects of health changes after the implementation of smoke free air policies
- Researched and prepared a report on the economic and health impacts of an increase in cigarette taxes
- Assisted in coordination of the annual Cancer Consortium meeting

ACADEMIC AND PROFESSIONAL HONORS

Delta Omega Honor Society in Public Health, 2016

Indiana University Simon Cancer Center Annual Cancer Research Day: Certificate of Achievement for Excellence in Cancer Research, 1st place Population Science/Epidemiology by a Graduate Student, 2016

Indiana University Simon Cancer Center Annual Cancer Research Day: Certificate of Achievement for Excellence in Cancer Research, 1st place Behavioral Research by a Graduate Student, 2014 & 2015

Indiana Resident Top Scholar Full-tuition Scholarship for Academic Merit, Purdue University, 2006-2010

Alpha Epsilon Delta Honor Fraternity, Purdue University, 2008-2009

Purdue Cooperative Council Merit Scholarship, Purdue University, 2009

President's Leadership Class, Purdue University, 2006-2007

Academic Success Award Merit Scholarship, Purdue University, 2006