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An Assessment of Selected Factors Associated with HPV Vaccination Completion among the African American Adolescents in United States: 2012 National Immunization Survey - Teen

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An Assessment of Selected Factors Associated with HPV Vaccination Completion among the African American Adolescents in United States: 2012 National Immunization Survey - Teen

By:

Vaishali Sahu

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An Assessment of Selected Factors Associated with HPV Vaccination Completion among the African American Adolescents in United States: 2012 National Immunization Survey - Teen

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ABSTRACT

BY VAISHALI SAHU

An Assessment of Selected Factors Associated with HPV Vaccination Completion among the African American Adolescents in United States: 2012 National Immunization Survey - Teen

(Under the direction of Dr. Shanta R. Dube, Associate Professor, School of Public Health)

Background: Human Papillomavirus is the most common sexually transmitted infection in United States and is most prevalent among the adolescents and young adults. HPV is responsible for great psychosocial and economic burden by causing cervical cancer, anal, vulvar, vaginal, penile, oropharyngeal cancers and ano-genital warts. Certain populations are found to be at higher risk such as African Americans. Three doses of HPV vaccine are recommended to adolescents before sexual debut to immunize against HPV. However, the HPV vaccination completion rates remain low in US, particularly among high risk populations. The purpose of this study was to assess the factors associated with the completion of 3 dose HPV vaccination series particularly among the African American adolescents.

Methods: National Immunization Survey – Teen 2012 data was used to assess the association of factors such as, healthcare provider recommendation for HPV vaccination, poverty status, health insurance and maternal education with the completion of 3 dose HPV vaccination series among the African American adolescents. Binary logistic regression was conducted to assess the association of each of the factors with the completion of 3 dose HPV vaccination series. Multivariate analysis was performed to assess the strength of the predictors.

Results: Based on NIS-Teen 2012, among the African American adolescents, gender is the strongest predictor influencing the completion of HPV vaccination series. The Black female adolescents are 5 times more likely to complete the HPV vaccination series as compared to males. The 15 year old Black adolescents are thrice more likely to complete the HPV vaccination series as compared to 13 year olds. Adolescents with maternal education equal to or higher than high school are twice more likely to complete the HPV vaccination series. The receipt of healthcare provider recommendation for HPV vaccination and being above poverty level also show positive but, statistically non-

significant association with the completion of HPV vaccination series among the non-Hispanic Blacks.

Conclusion: Among the African American adolescents, socio-demographic factors influence the completion of HPV vaccine series. Females are more likely to complete the HPV vaccination series as compared to males. The maternal education is the significant factor that influences the completion of HPV vaccination series. Thus, this study provides a direction to public health practices to focus Black male adolescents and subpopulations with low maternal education in order to improve HPV vaccination in US and thus reduce disparities related with HPV associated cancers and genital warts.

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CHAPTER I

INTRODUCTION

1.1 Background:

Human papillomavirus (HPV) is the most common sexually transmitted infection (STI) in the United States (CDC, 2014). HPV is spread through contact with infected genital skin, mucous membranes and bodily fluids. It can also be passed through sexual intercourse, anal sex and oral sex. During infection HPVs reside in the epithelial cells which are flat, thin cells found on the skin surface and also on the surface of vulva, vagina, cervix, penis, anus, mouth and throat. Though HPV infections are common, majority of infections do not lead to disease. It is estimated that about half of the sexually active people acquire HPV infection at some point in their lives. Studies show that 70% of these HPV infections get cleared in a year and 90% in two years without presenting any clinical symptoms (Ho, Bierman, Beardsley, Chang, & Burk, 1998). But, persistent infections by high risk HPVs are a cause of precancerous lesions and invasive cancer (Schiffman & Castle, 2003). The HPV types which have the ability to cause cancer are called High Risk HPV or Oncogenic HPV. The high risk HPVs constitute HPV type 16 and 18.

Clinical manifestations of HPV infection include ano-genital warts, cervical cancer precursors and cancers such as cervical, anal, penile, vulvar, vaginal and oropharyngeal (CDC, 2012). CDC estimates that 26,000 new cancers attributable to HPV occur each

year in United States, where 18,000 occur among females and 8,000 among males. Out of these 18,000 cases in females, 12,000 are cases of cervical cancer. HPV is the cause of nearly all cervical cancers and 90% of genital warts. The annual direct medical cost of preventing and treating HPV associated disease is estimated to be $8 billion (Chesson et al., 2012). Thus, HPV is responsible for causing a great psychosocial and cost burden among populations.

HPV infection is most common among adolescents and young adults (Dunne et al., 2007). Up to 75% of new HPV infections occur among 15-24 years old (Weinstock, Berman, & Cates, 2004). The prevalence of HPV infection is highest among young women. According to the study conducted by Dunne et al., based on 2003-2004 National Health and Nutrition Examination Survey (NHANES) the prevalence of HPV infection is found to be 24.5% among the 14-19 years females and 44.8% among the 20 – 24 years females (Dunne et al., 2007). An increased risk of HPV infection in women is found to be strongly associated with younger age, Hispanic ethnicity, Black race, an increased number of vaginal sex partners, high frequency of vaginal sex, anal sex, alcohol consumption and partner having increased number of sexual partners (Ho et al., 1998). However, it is to be noted that these studies were conducted prior to the availability of HPV vaccines.

It has been determined that HPV infection is a cause of nearly all cervical cancers (Walboomers et al., 1999). Therefore, in the United States, cervical cancer prevention is focused on both the primary and secondary levels. Secondary prevention of HPV

includes routine Pap test screening (Lowy, Solomon, Hildesheim, Schiller, & Schiffman, 2008) while primary prevention is through administration of HPV vaccine (Markowitz, Unger, & Saraiya, 2009). Implementation of HPV vaccination program along with cytological screening is the most effective strategy to reduce morbidity and mortality associated with cervical and other HPV associated cancers and genital warts (Baseman & Koutsky, 2005).

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of both males and females between the ages of 11 to 12 years with 3 doses of HPV vaccine at 0 months, 2 months and 6 months interval. The vaccination series can be started as early as 9 years. The catch up vaccination is recommended for individuals aged 13 through 26 years who did not receive the complete 3 dose series of the vaccine (CDC, 2011). The HPV vaccine that provides protection against the 4 HPV types 16/18/6/11 is called the quadrivalent (HPV4/ Gardasil) vaccine while the HPV vaccine that provides protection against the 2 HPV types 16/18 is called bivalent (HPV2/ Cervarix) vaccine. The ACIP recommends females to be vaccinated with either quadrivalent or bivalent HPV vaccine but, males to be vaccinated with only quadrivalent HPV vaccine. The HPV vaccines are most efficacious when administered before exposure to HPV; that is before sexual debut. Most recent report from CDC's Youth Risk Behavior Surveillance System indicates that nationally, 46.8% of high school students had ever had sexual intercourse (CDC, 2014). Therefore, adolescents are the target population for the HPV vaccine.

In United States, the HPV vaccine was recommended as routine adolescent vaccine earlier for females in 2006, while later for males in 2011. However, current trends indicate low HPV vaccination coverage in United States (CDC, 2013). According to CDC report based on the National Immunization Survey – Teen, the HPV vaccination coverage in United States is defined in terms of vaccine initiation rate and vaccine completion rate where receipt of at least 1 dose of HPV vaccine by an individual is defined as vaccine initiation and the receipt of all 3 doses of HPV vaccine is defined as vaccine completion (CDC, 2013). Studies show that HPV vaccine completion rates lag behind the vaccine initiation rates. Based on CDC report assessing the HPV vaccination coverage in adolescent females from 2007 – 2011, they reported that the HPV vaccine initiation rates increased from 25.1% to 53%, but have stagnated to 53.8% in 2012 and the HPV vaccination completion rates increased from 16.6% to 33.4% (2009 - 2011) but have stagnated to 34% in 2012 (CDC, 2013).

While assessing the HPV vaccination coverage among adolescent males in United States, it is important to note that the quadrivalent HPV vaccine was approved by United States Food and Drug Administration (FDA) for use in male adolescents in 2009 and was recommended by the ACIP as a routine vaccine in 2011. As a result, the HPV vaccination coverage rates for male adolescents have significantly increased in 2012. According to Curtis et al., the 3 dose HPV vaccine completion rate in males is found to increase from 1.3% (2011) to 6.8% (2012) and the vaccine initiation rate is found to increase from 8.3% (2011) to 20.8% (2012). Though these vaccination rates among male adolescents have increased significantly since 2011, improvement to increase coverage rates is needed.

In United States, it is observed that the HPV vaccination initiation rates are higher than the HPV vaccination completion rates. However, initiation of one dose of HPV vaccine is not enough to provide adequate protection from HPV infection. According to a study conducted by Crowe et al., the effectiveness of one dose of HPV vaccine is not found to be statistically significant (Crowe et al., 2014). Other studies show, administering 2 doses out of the series of 3 recommended doses may provide temporary protection but, their long term population impact is unknown (Jit et al., 2014). Also, it has been determined that maximum risk reduction of ano-genital warts is obtained by 3 doses of HPV vaccine (Herweijer et al., 2014). Therefore, in order to obtain maximum benefits of HPV vaccination, the completion of 3 dose HPV vaccine series is necessary.

There are many factors that determine HPV vaccination coverage among adolescents vary by certain factors. First, healthcare provider's recommendation for HPV vaccination is with an 18 fold increased likelihood of HPV vaccine uptake (Lau, Lin, & Flores, 2012). Despite this fact, low socioeconomic status (SES), minority populations, black race and uninsured are less likely to receive provider's recommendations for HPV vaccination (Polonijo & Carpiano, 2013). Studies show that low income and minority adolescents are equally or more likely to initiate the HPV vaccination, but are less likely to complete the 3 dose series (Jeudin, Liveright, del Carmen, & Perkins, 2014). Also, HPV vaccination completion rates are found to be relatively low among certain populations such as African Americans, Hispanics and those living below poverty level. It has been determined that these subpopulations are known to have high cervical cancer

rates (Watson et al., 2008), thereby underscoring the importance of assessing factors that influence HPV vaccination, especially in high risk populations.

HPV infection and cervical cancer disproportionately affect low income and minority women (Saraiya et al., 2007). Also, Blacks and low income minority individuals are reported to initiate HPV vaccination, however, they have been shown to be unable to complete the vaccination series. High HPV vaccination rates could substantially reduce disparities in cervical cancer, but lower rates of HPV vaccination series completion in vulnerable populations could widen the racial/ethnic and socioeconomic disparities in cervical cancer in future.

According to a CDC report, it is estimated that each year about 21,000 HPV related cancers can be prevented by HPV vaccine (CDC, 2014). By increasing 3 dose HPV vaccine completion rates to 80%, it is estimated that an additional 53,000 cases of cervical cancer can be prevented over the lifetime of girls who are target age for prevention efforts (CDC, 2013). Moreover, for every year the increase in HPV vaccine completion rate is delayed another 4,400 women will develop cervical cancer (CDC, 2013). Thus, increasing the HPV vaccination completion among adolescents in United States is an important public health goal.

1.2 Purpose of the Study:

The United States government has made HPV infection and its associated diseases a priority by including them in several Healthy People 2020 Objectives. They are described as follows:

- *Sexually Transmitted Disease Objectives:*

❖ STD-9: To reduce the proportion of females with HPV infection (STD Objectives, Healthy People 2020).

- *Cancer Objectives:*

❖ C-4: To reduce the death rate from cancer of uterine cervix by 10%. Target is 2.2/100,000 (Cancer Objectives, Healthy People 2020).

❖ C-10: To reduce invasive uterine cervical cancer rates by 10%. Target is 7.1/100,000 (Cancer Objectives, Healthy People 2020).

- *Immunization and Infectious Disease Objectives:*

❖ IID-11: To increase routine vaccination coverage levels for adolescents (IID Objectives, Healthy People 2020).

❖ IID-11.4: To increase the vaccination coverage level of three doses of HPV vaccine for females by age 13-15 years. The target is 80% coverage of females, an increase from the 16.6% coverage in 2009 (IID Objectives, Healthy People 2020).

Though Healthy People 2020 objectives target to increase HPV vaccination among females, the ACIP recommends routine HPV vaccination of adolescent females as well as

adolescent males. The objective to vaccinate males is to protect them and their future sexual partners from HPV infections (CDC, 2011). Although males benefit directly from HPV vaccination by preventing genital warts and penile, anal and oropharyngeal cancers, vaccinating males also protect females from HPV related diseases. Thus, immunizing males as well as females against HPV decreases the virus pool within the population. From a public health point of view this is an important measure to reduce HPV infections and the related disease burden in United States.

Currently, the HPV vaccination rates are low in United States (CDC, 2013). Compared to HPV vaccine initiation rates, the HPV vaccine completion rates are even lower. It has been determined that vaccination rates vary among populations and are driven by certain socioeconomic factors. Therefore, the assessment of the factors and how they influence HPV vaccination completion among populations is of immense importance. The factors that are examined in the present study include, the healthcare provider recommendation for HPV vaccination, poverty status, health insurance and maternal education. Thus, the purpose of this study is to assess the association of these factors with the completion of 3 dose HPV vaccination series among the African American adolescent population which has been identified as high risk. This assessment would guide and help public health practice as a means to improve HPV vaccination in United States and thus reduce disparities related with cancer and genital warts.

1.3 Research Questions:

Question#1:

Are demographic factors (*Gender, Age*) associated with the completion of HPV vaccination series among African American adolescents in United States?

Alternative Hypothesis 1: Gender is associated with completion of HPV vaccination series among African American adolescents in United States.

Alternative Hypothesis 2: Age is associated with completion of HPV vaccination series among African American adolescents in United States.

Question#2:

Are socioeconomic factors (*Health insurance, Poverty status, Maternal education*) associated with the completion of HPV vaccination series among African American adolescents in United States?

Alternative Hypothesis 1: Health insurance is associated with completion of HPV vaccination series among African American adolescents in United States.

Alternative Hypothesis 2: Poverty status is associated with completion of HPV vaccination series among African American adolescents in United States.

Alternative Hypothesis 3: Maternal education is associated with completion of HPV vaccination series among African American adolescents in United States.

Question#3:

Is *Healthcare provider recommendation* for HPV vaccination associated with the completion of HPV vaccination series among African American adolescents in United States?

Alternative Hypothesis 1: Healthcare provider recommendation for HPV vaccination is associated with completion of HPV vaccination series among African American adolescents in United States.

CHAPTER II

REVIEW OF THE LITERATURE

2.1 HPV Virology and Immunology:

Human papillomavirus (HPV) are non-enveloped, double stranded DNA viruses in the family *Papillomaviridae*. Isolates of HPV are classified as "types" and the numbers are assigned in the order of their discovery (de Villiers, Fauquet, Broker, Bernard, & zur Hausen, 2004). HPV is capable of infecting the epithelium in humans and are a group of more than 150 types of related viruses. Of these, more than 40 types are transmitted by sexual contact and infect the mucosal epithelium of ano-genital region (CDC, 1999).

Based on their epidemiologic association with cancer, HPVs are categorized into two types. The first type HPVs are called High Risk HPV or Oncogenic HPV which can cause cancer. HPV type 16 and 18 are the most commonly found high risk HPV. The second type HPVs are called Low Risk HPV which can cause genital warts (NCI, 2012). The low risk HPVs constitute HPV type 6 and 11. According to Munoz et al., 15 HPV types are categorized as high risk, 3 HPV types are categorized as probable high risk, 12 HPV types are categorized as low risk and 3 HPV types are categorized as undetermined risk type (Munoz et al., 2003).

HPVs infect the epithelial cells. The epithelial cells are organized in layers. They cover the inside and outside surfaces of the body including the skin, the throat, the genital tract and the anus. When the HPV enters a cell, it starts making its protein. The proteins of high risk HPVs interfere with the normal function of the cell, enabling the cell to grow in an uncontrolled manner and avoiding cell death (NCI, 2012). Many times these cells are recognized by the body's immune system and are eliminated from the body. However, when these cells are not eliminated, they result in persistent infection. Persistent infection with high risk HPVs may progress to precancerous lesions and invasive cancer (Schiffman & Castle, 2003). It has been determined that HPV infection is a cause of nearly all cervical cancers (Walboomers et al., 1999).

2.2 Epidemiology of HPV Infection in United States:

In United States, ano-genital HPV infection is the most common sexually transmitted infection. According to CDC report, about 79 million people are currently infected with HPV and about 14 million get infected every year (CDC, 2014). HPV infection is mainly transmitted through sexual intercourse. Other modes of HPV transmission are oral sex and anal sex. The major risk factor for HPV infection among women is the increased number of sexual partners, immune status and the sexual behavior of the partner. Nonsexual route of HPV transmission is from mother to newborn baby, which is very rare.

Though HPV infections are common, majority of infections do not lead to disease. Probably, this depends whether the HPV infection in an individual gets cleared or persists. Most HPV infections are found to get cleared on their own without forming a disease. Clearing of HPV infection in an individual is defined as when a HPV positive person shows HPV negative test in his subsequent tests (Louvanto, Syrjänen, Rintala, Grénman, & Syrjänen, 2010). Thus, clearing of HPV infection means, no more detection of HPV DNA in a HPV positive person. A woman is considered to have persistent HPV infection, if a woman tests HPV DNA positive in 2 or more consecutive tests (Woodman, Collins, & Young, 2007). Persistent infections by oncogenic HPVs are a cause of precancerous lesions and invasive cancer (Schiffman & Castle, 2003). Studies conducted in women show that 70% of HPV infections clear in 12 months period while 80% HPV infections get cleared in 18 months period (Ho et al., 1998). The persistence of HPV infection for more than 6 months is found to be associated with older age, HPV types associated with cervical cancer and infection with multiple types of HPV (Ho et al., 1998). Studies show that incidence of oncogenic HPV types is higher than the incidence of non-oncogenic HPV types (Franco et al., 1999). The probable reason for this is that non-oncogenic HPVs get cleared at a rate higher than oncogenic HPV types (Franco et al., 1999). The oncogenic HPV type 16 has been found to have a particularly long period of clearance as compared to other HPV types (Richardson et al., 2003).

HPV infection is most common among adolescents and young adults. Up to 75% of new infections occur among 15-24 years old (Weinstock et al., 2004). The prevalence of HPV infection is highest among young women and decreases with the increase in age. An

increased risk of HPV infection in women is found to be strongly associated with younger age, Hispanic ethnicity, Black race, an increased number of vaginal sex partners, high frequency of vaginal sex, anal sex, alcohol consumption and partner having increased number of sexual partners (Ho et al., 1998). Therefore, the ABC approach (abstain, be faithful, use condom) for prevention of HIV (Cohen, 2004) is somewhat applicable for HPV prevention as well. However, there is no evidence that condom use reduce the risk of HPV infection (Baseman & Koutsky, 2005) Therefore, HPV vaccines are regarded to be the most effective mode of prevention of HPV infections.

2.3 Epidemiology of HPV Associated Cancers:

An HPV associated cancer is the cancer that is diagnosed in the part of the body where HPV is usually isolated. HPV associated cancers include cervical cancer, vaginal, vulvar, anal, penile, oropharyngeal cancers. In United States every year, about 33,000 new cancer cases are diagnosed which are HPV associated (CDC, 2014). The common HPV associated cancers are described as follows:

- **Cervical Cancer:**

Every year about 12,000 women in US are diagnosed with cervical cancer and about 4,000 women die from it (CDC, 2014). HPV is responsible for almost all cervical cancers (Walboomers et al., 1999). Of them, about 70% of all cervical cancers are caused by HPV type 16/18 (Munoz et al., 2003) and 20% are caused by HPV type 31/33/45/52/58

(de Sanjose et al., 2010). The newly developed nonavalent vaccine provides protection against all nine HPV types which cause cervical cancer. But, the nonavalent vaccine is not yet licensed to be used in United States and its efficacy is under clinical trials.

The time between initial HPV infection and development of cervical cancer is usually decades. HPV infection may be asymptomatic, but cervical infection with HPV can lead to histologic changes in the cells of the cervix known as cervical lesions. These are classified as cervical intraepithelial neoplasia (CIN) grades 1, 2 or 3 on the basis of increasing degree of abnormality in the cervical epithelium (CDC, MMWR, 2007). These CIN may clear spontaneously or may progress to cancer in the absence of the treatment. CIN1 usually clears spontaneously and rarely, only 1% cases progress to cancerous stage while CIN2 and CIN3 do not clear very spontaneously and have more chances of progressing to cancerous stage (>12% cases), if not treated appropriately (Ostör, 1993). Cervical cancer screening with Pap test can detect cytological changes that reflect the underlying tissue changes. Therefore Pap testing/ cervical cancer screening has contributed to the reduction of cervical cancer incidence rates to 75% since 1950 (Saslow et al., 2002).

Substantial differences exist in the cervical cancer incidence and mortality by racial/ethnic groups in United States. The incidence for black women is found to be 1.5 times higher than white women. The incidence for Hispanic women is also higher than white women. Death rates of black women are found be twice the death rates for white women. Also, notably higher incidence and mortality rates are found to be higher in

Southern states (Saraiya et al., 2007). Factors associated with cervical cancer in epidemiologic studies include cigarette smoking, increased parity, increased age, other sexually transmitted infections, immune suppression, long-term oral contraceptive use (Castellsague & Munoz, 2003).

- **Other cancers:**

Oropharyngeal Cancer:

Cancers in the oropharynx are usually caused by tobacco and alcohol, but it is recently found that 72% of the oropharyngeal cancers are caused by HPV (CDC, 2014). Studies show that incidence rates for most cancers decreased in US. But, the incidence rates for anal and oropharyngeal cancers have been found to increase since 2000 (Jemal et al., 2013). In United States, about 8,400 new cases of HPV associated oropharyngeal cancers are detected every year. Oropharyngeal cancers are about 3 times more common in men than women and Non-Hispanics are affected more than Hispanics (CDC, 2014). The efficacy of HPV vaccines in the prevention of HPV related oropharyngeal cancers is not yet verified (CDC, 2014).

Anal Cancer:

It is found that HPV is responsible for 91% of all anal cancers. In United States every year about 3,000 new cases of anal cancer are detected among women and 1,700 new cases of anal cancer are detected among men. Anal cancer is most frequently diagnosed

among people aged 55 – 64 years (SEER, 2014). The anal cancers are more common in White women as compared to women of other races. Anal cancers are more common in Black men as compared to men of other races.

2.4 Other Clinical Manifestations of HPV:

- **Genital Warts:**

In United States, about 1% of sexually active young adults have clinically apparent genital warts and 15% have subclinical infections (Koutsky, 1997). About 360,000 people in United States get genital warts every year (CDC, 2014). The highest rates of genital warts are found in young adults aged 18-28 years (Koutsky, 1997). Females are more prone to be affected by genital warts as compared to males (Chuang, 1987). Major risk factor for acquiring genital warts is having multiple sex partners. All anogenital warts are caused by HPV. About 90% of all genital warts are caused by HPV type 6 and 11 (Greer et al., 1995). Anogenital warts can be treated, although many warts (20%-30%) regress spontaneously. Recurrence of anogenital warts is common (approximately 30%) irrespective of the fact whether clearance occurs spontaneously or following treatment (Chuang, 1987).

Though genital warts are non-life threatening, they carry a substantial psychosocial and economic burden. Stressors include the shame and embarrassment related to diagnosis, as well as the inconvenience and discomfort of treatment and the fear of recurrence,

transmission, and the possible threat of cancer. The economic burden relates to treatment of genital warts, and the management and follow-up of malignancies (Bhatia, Lynde, Vender, & Bourcier, 2013). Thus, HPV vaccination in adolescents is an important and most effective measure to prevent genital warts and related psychosocial stress in individuals.

- **Recurrent Respiratory Papillomatosis:**

Recurrent Respiratory Papillomatosis is a rare condition which occurs by infection with low risk HPV types 6 and 11. This condition is characterized by formation of warts in respiratory tract, particularly larynx. Recurrent Respiratory Papillomatosis is of 2 types: Juvenile Onset Recurrent Respiratory Papillomatosis (JORRP) and Adult Onset Recurrent Respiratory Papillomatosis (AORRP). The median age of diagnosis of JORRP is 4 years and it occurs as a result of vertical HPV transmission from mother to newborn baby during delivery. Though this condition is found very rarely, it is associated with great morbidity and requires a lifetime of 13 surgeries to get rid of the recurrent warts in the respiratory tract. Much is not known about the AORRP (CDC, MMWR, 2007).

2.5 Overview of HPV vaccines:

In United States, two types of HPV vaccines are available for use. They are quadrivalent (HPV4/ Gardasil, Merck and Co.) and bivalent (HPV2/ Cervarix, GlaxoSmithKline). HPV4 is directed against the two oncogenic types of HPVs (HPV type 16 and 18) and

two non-oncogenic types of HPVs (HPV type 6 and 11) while HPV2 is directed only against the two oncogenic types of HPVs (HPV type 16 and 18). Both HPV4 and HPV2 are composed of virus like particles (VLPs) which are prepared from recombinant L1 capsid protein of HPV. Neither of the vaccines are live vaccines. Both vaccines have high efficacy against HPV type 16 and 18 related precancer lesions. HPV4 provides additional protection against the HPV type 6 and 11 related genital warts. Both vaccines are proven to be most efficacious when administered in individuals before sexual debut, when there is no exposure to HPV through sexual contact. The recommended dosage for both HPV2 and HPV4 are the same. A series of 3 doses are recommended at 0, 2 months and 6 months interval. Each dosage is 0.5 ml and to be administered intramuscularly, preferably in deltoid muscle (CDC, 2010). HPV vaccines are contraindicated in pregnancy and in persons with hypersensitivity.

The Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination of females aged 11-12 years with 3 doses of quadrivalent HPV vaccine in 2006 and bivalent HPV vaccine in 2009. The vaccination series can be started as early as 9 years. The catch up vaccination is recommended for females aged 13 through 26 years (CDC, 2010).

In 2011, the ACIP recommended HPV vaccination among adolescent males aged 11-12 years with routine use of 3 doses of quadrivalent/HPV4 vaccine and catch up vaccination for 13-21 years old, who did not complete the 3 dose vaccine series. The vaccine is also

recommended for gay and bisexual men and immune-compromised men (such as affected with HIV) aged 13 through 26 years (CDC, 2011).

2.5.1 Quadrivalent HPV Vaccine (Gardasil):

Gardasil is the first vaccine for HPV vaccination in United States. It is the quadrivalent vaccine and provides protection against 4 HPV types 6/11/16/18. It was licensed by United States Food and Drug Administration (USFDA) in June 2006 to be used in females aged 9-26 years. Later, in October 2009, it was licensed by USFDA to be used in males aged 9-26 years (CDC, 2011). It has been verified by clinical trials that the *quadrivalent* HPV vaccine has a high efficacy for prevention of HPV type 6, 11, 16, 18 related persistent infection, CIN, CIN 2/3, genital warts when analyses were restricted to participants who received all 3 doses of vaccine, had no protocol violations, and no evidence of infection with relevant HPV type. However, no evidence of protection exist for individuals who were exposed to HPV type at vaccination baseline. Also, there is no evidence of protection against the HPV types other than types 6/11/16/18. Studies and clinical trials to assess the duration of protection from the vaccine are currently underway with a follow up period of 14 years (CDC, 2007). Thus, through these studies researchers expect that the quadrivalent vaccine will substantially reduce the anogenital warts cases shortly after the onset of HPV vaccination program (Van de Velde et al., 2012).

2.5.2 Bivalent HPV Vaccine (Cervarix):

Cervarix is the second vaccine licensed for HPV vaccination in United States. It is the bivalent vaccine and provides protection against oncogenic HPV types 16 and 18. It was licensed by FDA in October 2009 (CDC, 2010). The clinical trials provide evidence that HPV2 is effective against HPV type 16 and 18 related CIN2 and CIN3 and adenocarcinoma insitu (CIN2+), with an efficacy of 92.9% (Paavonen et al., 2009). In addition to protection from HPV type 16/18, HPV2 vaccine also provides cross protective efficacy for 4 non-vaccine HPV types 31/33/45/51 (Wheeler et al., 2012) Thus, the bivalent vaccine is expected to be more effective in reducing the cervical intraepithelial lesions (CIN2 and CIN-3) and squamous cell carcinoma (SCC) in the long term (Van de Velde et al., 2012).

2.5.3 Nonavalent HPV Vaccine:

The newly developed Nonavalent vaccine is designed to protect against the 9 HPV types - 6/11/16/18/31/33/45/52/58. However, the efficacy of nonavalent HPV vaccine is under clinical trials. Researchers believe switching to nonavalent vaccine has the potential to further reduce the precancerous lesions and cervical cancer (Van de Velde et al., 2012). A study conducted by Drolet et al. assumed the efficacy of nonavalent HPV vaccine to be 85% and found that nonavalent HPV vaccine is even more cost effective than the quadrivalent HPV vaccine, with efficacy 95%. However, if the efficacy of nonavalent vaccines is found to be less for HPV types 16 and 18, then it is unlikely to use nonavalent HPV vaccine (Drolet, Laprise, Boily, Franco, & Brisson, 2014).

2.6 HPV Vaccine Efficacy in United States:

The HPV vaccine is found to be 100% effective against oncogenic high grade cervical, vaginal and vulvar lesions as well as genital warts, when given to individuals before sexual debut (Munoz et al., 2003). The HPV vaccine is found to be 21% effective in individuals receiving 2 doses of HPV vaccine (Crowe et al., 2014). The efficacy of quadrivalent HPV vaccine has been found to be 100% for HPV type 16 and 18 related cervical intraepithelial lesions, 98.9% for HPV type 6/11/16/18 related genital warts and 89.5% for the prevention of HPV type 6/11/16/18 related persistent infection or disease (CDC, 2007). Clinical studies provide the evidence that HPV vaccination is highly efficacious and potentially lifesaving if administered to females naïve or unexposed to vaccine HPV types (Armstrong, 2010). Also, administering 2 doses out of the series of 3 recommended doses may provide temporary protection but, their long term population impact is unknown (Jit et al., 2014).

2.7 HPV Vaccination Coverage Rates in United States:

In United States the HPV vaccine was licensed and recommended as a routine vaccine to be used in females as early as in 2006 and in males in 2009. However, studies show low HPV vaccination coverage among adolescents. According to latest reports based on National Immunization Survey – Teen 2012, the national estimates for HPV vaccination coverage for females is 33.4% for completing the 3 dose HPV vaccine series and 53.8% for initiating the HPV vaccine series (CDC, 2013). While the national estimates for HPV

vaccination coverage for males is only 6.8% for completing the 3 dose vaccine series and 20.8% for initiating the HPV vaccine series (Curtis et al., 2013).

The HPV vaccination coverage rates vary widely among the States in US. The reports from latest data from NIS-Teen 2012 show that among females, coverage for ≥1 HPV vaccine dose varied from 39.4% (Florida) to 73.7% (Rhode Island), and for ≥3 HPV vaccine doses, from 12.1% (Mississippi) to 57.7% (Rhode Island). Among males, coverage for ≥1 HPV vaccine dose ranged from 11.2% (Wyoming) to 55.2% (Rhode Island). No state met the national target (80%) for the HPV vaccination rates (CDC, 2013).

National estimates for HPV vaccination vary greatly by gender. The quadrivalent HPV vaccine was licensed for females earlier (in 2006) and was recommended as a routine vaccine for protection mainly from cervical cancer. While the quadrivalent HPV vaccine was licensed to be used in adolescent males in 2009 as a mode of protection against genital warts and later in December 2010, the additional protection against anal cancer was licensed by FDA. Finally in 2011, the ACIP recommended the routine use of quadrivalent HPV vaccine among adolescent males (CDC, MMWR, 2011). This time lag between the licensure of HPV vaccine among the females and males is one of the probable reasons for the vaccination rates being higher in females compared to males, despite the overall low HPV vaccination coverage rates.

The studies assessing HPV vaccination coverage rates for 2008 – 2012 show that HPV vaccination coverage rates are low for Hispanic women (Schmidt & Parsons, 2014). However, the latest reports based on 2012 National Immunization Survey- Teen (NIS-Teen) show that HPV vaccine initiation rates are found to rise among Hispanic adolescent females, despite their low vaccine completion rates. Also, the vaccine completion rates are found to be low in Black females compared to Whites (Curtis et al., 2013). Among males, the HPV vaccine initiation rates are higher for blacks compared with whites, but 3-dose series completion rates are lower for blacks (Curtis et al., 2013).

According to a study conducted by Jemal et al., based on NIS-Teen 2008 – 2010 survey data, the HPV vaccine coverage was found to be significantly lower among the uninsured (Jemal et al., 2013). The low-income and minority adolescents are more likely to start the HPV vaccination series than are white and higher-income adolescents, but are less likely to complete the 3 dose vaccination series (Jeudin et al., 2014). Based on NIS-Teen 2012 report, the HPV vaccine initiation rates are higher for females living below poverty level, but the series completion is found to be higher among the females living above poverty level (Curtis et al., 2013).

The literature evidences the existence of racial ethnic disparities in relation to HPV vaccination rates. There are variations in HPV vaccination rates by socioeconomic factors such as, poverty level and health insurance. Parental permission is required for vaccination in adolescents under 18 years of age, therefore parental attitudes play a

central role in HPV vaccine uptake. In addition to this, the healthcare provider recommendation for HPV vaccination among the adolescents is the other important factor that has been found to impact the HPV vaccination rates.

Studies show that healthcare provider recommendation is the most important factor for parents of adolescents in their decision to vaccinate their children with HPV vaccine (Holman et al., 2014). According to a study based on National Children's Health Survey 2007 -2008, nearly half of all the girls who received healthcare provider's recommendation for HPV vaccination, received the vaccine (Palli, Mehta, & Aparasu, 2012). Thus, receipt of a health professional's recommendation to vaccinate is strongly associated with vaccine uptake, however the odds of receiving a recommendation are negatively associated with low SES and black racial/ethnic status (Polonijo & Carpiano, 2013).

Lack of HPV knowledge, its health hazards and awareness of HPV vaccine among parents of adolescents is one of the reasons for low HPV vaccination rates in United States. The literature suggests, most frequently reported reasons by parents for not vaccinating their children with HPV vaccine are lack of knowledge about the HPV vaccine, potential concerns for vaccine side effects, fear of vaccination increasing sexual promiscuity and also the belief that their adolescent children were not sexually active and were too young to receive HPV vaccine (Oldach & Katz, 2012). Studies show, specifically parents of low socioeconomic and racial /ethnic minority parents have significantly lower odds of knowing about the vaccine (Polonijo & Carpiano, 2013).

2.8 Importance of HPV Vaccination in the African American Population:

HPV infection and cervical cancer disproportionately affect the low income and minority women. The HPV vaccines have the potential to reduce racial disparities in HPV related diseases including cervical cancer (Jeudin et al., 2014). Blacks and low income minority individuals are reported to initiate the HPV vaccination, but, they are the ones who are unable to complete the vaccination series. High HPV vaccination rates could substantially reduce disparities in cervical cancer, but lower rates of HPV vaccination series completion in vulnerable population as African Americans could widen the racial/ethnic and socioeconomic disparities in cervical cancer in future.

According to the study conducted by Hariri et al., based on National Health and Nutrition Examination Survey (NHANES) 2003 – 2006, the HPV prevalence is found to be significantly higher among those living below poverty (56.5%) compared to those living above poverty (39.7%) (Hariri et al., 2011). Nearly 15% of Americans live below the poverty level, with poverty concentrated among the blacks (27.6%) as compared to whites (9.8%) (Jeudin et al., 2014). Black women have higher rates of HPV infection than do women of other races and this increases the importance of HPV vaccination in black girls (Hariri et al., 2011). It has been found that black girls complete puberty earlier compared to girls of other races (Sun et al., 2002) which in turn may influence the age of sexual debut.

The 2013 Youth Risk Behavior Surveillance report states that prevalence of having had first sexual intercourse before 13 years of age was higher in Blacks (14%) as compared to Whites (3.3%). Also, more black teens (60%) report to have sexual intercourse as compared to white teens (44%). Nearly 14% of black girls initiate sex prior to 13 years of age as compared to white girls (3.9%). At the time of college entry, about 87% of blacks are sexually experienced with an average of 6 lifetime partners (Bynum et al., 2012). This underscores the importance of timely HPV vaccination among the blacks to maximize vaccine efficacy.

Summary:

The goals of current HPV vaccination recommendations in United States are two folded: 1) To prevent persistent HPV infections and the occurrence of ano-genital warts beginning in young adulthood. 2) To prevent the cervical, vaginal, vulvar, penile, oropharyngeal and anal cancers that occur later in life (Jemal et al., 2013). HPV infection and cervical cancer disproportionately affect the low income and minority women. The HPV vaccines have the potential to reduce racial disparities in HPV related diseases including cervical cancer. Therefore, increasing HPV vaccination uptake among adolescents by completing the recommended 3 dose vaccine series can be an effective mode of reducing HPV related disease burden. This can be facilitated by an understanding of the factors that influence HPV vaccination rates especially among the high risk populations. Therefore, the objective of the present study is to assess selected

factors that affect the completion of HPV vaccine series among the high risk African American adolescent population.

CHAPTER III

METHODOLOGY

3.1 Data Source:

The data for this study is obtained from a publicly available secondary dataset, 2012 National Immunization Survey – Teen (NIS-Teen). NIS is a random digit dialed telephone survey that has been administered by the Centers for Disease Control and Prevention (CDC) since 1994 to estimate the vaccination coverage of children aged 19 – 35 months in United States. In 2006, NIS was expanded to include a national sample of adolescents aged 13 – 17 years and was named NIS-Teen (Jain, Singleton, Montgomery, & Skalland, 2009). The NIS-Teen is used to produce timely estimates of vaccination coverage rates for all teen vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) in United States. The NIS-Teen is sponsored by the National Center for Immunization and Respiratory Diseases (NCIRD). It is conducted jointly by NCIRD and the National Center for Health Statistics (NCHS) (CDC, NCIRD and NCHS, 2013). The NIS is considered non-exempt research involving human subjects and its approval by Institutional Review Board is obtained at CDC. The NIS is listed as a secondary de-identified, anonymous dataset and approved by Georgia State University Institutional Review Board for this study.

The NIS-Teen is a random digit dialing telephone survey of households followed by a mailed survey to teens' immunization healthcare providers to monitor immunization coverage. Parent consent is obtained before conducting the interview. After interviewing the parent of eligible child in household, the consent is obtained to contact the immunization provider to verify immunization records. The contact of all the providers who have administered the vaccines to the eligible child is obtained from the parent. Then the Immunization History Questionnaires (IHQs) are mailed to the provider and the provider is requested to send eligible child's immunization history from their medical record (Jain et al., 2009). The NIS-Teen collects data from the 57 geographic strata in United States, which include 50 states, U.S. Virgin Islands and 6 primarily urban city/county areas in order to obtain estimates that are representative of US adolescents aged 13 – 17 years (CDC, NCIRD and NCHS, 2013).

3.2 Study Population:

The target population for this study are Non-Hispanic Black adolescents aged 13- 17 years old, living in non-institutionalized households in United States, who answered the NIS-Teen 2012 survey. The total sample size of the NIS – Teen, 2012 was 32,825, of which 4148 Non-Hispanic Blacks constitute the study population for this study. The sample size of the healthcare provider data is 2476.

3.3 Study Measures and Variables:

3.3.1 Dependent Variable:

The dependent variable for this study is *Completion of 3 dose HPV vaccine series*, which is a dichotomous variable. It is defined based on the healthcare provider reports indicating the number of HPV vaccine shots received by the adolescent. Each shot of administered HPV vaccine is regarded as one dose irrespective of the type of HPV vaccine administered, whether quadrivalent or bivalent. The number of HPV shots administered to adolescents are recorded as 0/1/2/3/4 doses. Those adolescents who receive either 1/2/3/4 doses are regarded to initiate the HPV vaccine series. Among the adolescents who initiate the HPV vaccine series, those who receive 3 or 4 doses are defined as having completed the HPV vaccine series. While the adolescents who received one or two doses of HPV vaccine are defined as having incomplete HPV vaccine series. In this study only 4 females and none of the males report to receive 4 doses of HPV vaccine.

3.3.2 Independent Variables:

Four independent variables of interest were chosen for this study: 1) Healthcare provider recommendation for HPV vaccination 2) the poverty status 3) health insurance 4) maternal education level.

Healthcare provider recommendation for HPV vaccination is defined based on parent response to the question, “Has a doctor or healthcare professional ever recommended that

the teen receive HPV vaccination?" This variable was categorized and coded as '1' for adolescents who received healthcare provider recommendation for HPV vaccination and coded as '0' for the adolescents who did not receive healthcare provider recommendation for HPV vaccination.

Poverty status is defined into two categories, above poverty level (coded as '1') and below poverty level (coded as '0'). The NIS 2012 codes poverty level based on 2011 US Census threshold of $15,504 in a two person household with one child under 18 years of age (US Census Bureau, 2014).

Health insurance is the dichotomous variable in the current study. It is represented as adolescents who do not have any health insurance (coded as '0') versus adolescents who have at least one of the following types of health insurance: Medicaid, S-CHIP, Indian Health Services, Military Health Care/Tricare/CHAMPUS/CHAMP-VA or the health insurance from the employer or any other type of healthcare plan or health insurance (coded as '1').

Maternal education indicates the educational level of the adolescent's mother. This is a dichotomous variable, coded as 0 and 1. '0' represents adolescents whose mother have education less than high school while '1' represents adolescents whose mother have education equal to or higher than high school.

3.4 Statistical Analysis:

The statistical analyses in this study were performed using Statistical Analysis System (SAS) version 9.3. Statistical Package for Social Sciences (SPSS) version 19 was used to recode the variables in the data for the study. Descriptive statistics, including frequencies were used to describe the study population. Weighted estimates were calculated. Binary logistic regression analyses were conducted to assess the association of each independent variable with the dependent variable in the study. Odds ratios were used to describe associations of selected independent variables with the dependent variable. A p-value of <0.05 and 95% confidence intervals were used to establish statistical significance. Also, multivariate logistic regression was conducted to assess the most significant predictor of the dependent variable in the study after adjusting for confounders.

CHAPTER IV

RESULTS

4.1 Frequencies and Descriptive Statistics:

The study population constitutes of 49.2% (n= 1953) female and 50.7% (n= 2195) male Non –Hispanic Black adolescents aged 13 – 17 years old. The mean age of the study sample is 14.9 years (s.d.= 1.4). The socio-demographic characteristics of the study population are presented in the Table 1. As shown, 95.3% of the study population has health insurance and 61.5% of the study population is above the poverty level. Among the adolescents in the study population, 85% have maternal education equal to or higher than high school. 47.9% of the participants reported to have received the healthcare provider recommendation for the HPV vaccination. Approximately 38% of the study participants initiated the HPV vaccine regimen. Among those who initiated the HPV vaccine series, 45.1% completed the 3 dose HPV vaccination series.

Table1: Socio-demographic Characteristics and HPV Vaccine Status Among Non-Hispanic Black Adolescents Aged 13 – 17 Years, NIS-Teen 2012

Variables	Non-Hispanic Blacks (n=4148)		
	n	Weighted %	95% CI
Gender			
Females	1953	49.2	45.5 - 53
Males	2195	50.7	46.9 - 54.5
Age			
13	840	19.2	16.4 - 22
14	869	21.2	18 - 24.3
15	859	21.1	18.1 - 24.1
16	800	20.6	17.6 - 23.7
17	780	17.7	14.8 - 20.6
HCP Recommend			
Yes	1675	47.9	44.1 - 51.7
No	2076	52.1	48.2 - 55.8
Total	3751*		
Health Insurance			
Yes	2799	95.3	94 - 96.6
No	1344	4.7	3.3 - 6
Poverty Status			
Above Poverty	2679	61.5	57.9 - 65.1
Below Poverty	1228	38.5	34.8 - 42.1
Total	3907*		
Maternal Education			
< High School	554	15	12.4 - 17.6
=> High School	3594	85	82.3 - 87.5
Initiated HPV vaccine			
Yes	887	37.8	34.2 - 41.4
No	1589	62.2	58.6 - 65.8
Total	2476*		
Complete HPV vaccine			
Yes	404	45.1	39.3 - 50.8
No	483	54.9	49.1 - 60.6
Total	887**		

*Some observations are missing in the data: Healthcare Provider Recommendation (Missing = 397), Poverty status (Missing = 241) and Initiation of the HPV Vaccine Series (Missing = 1672)

** The completion of HPV Vaccine Series is assessed among those who initiated the HPV Vaccine Series.

The socio-demographic characteristics of the study population, stratified by gender are presented in Table 2. As shown in the table, there was almost equal distribution of participants across all study age groups. There was a significant difference in terms of having received the healthcare provider recommendation for HPV vaccination, where more females report having received provider recommendation (63%) compared to males (33%). The majority of adolescents in the study population have health insurance, where 95.7% females and 94.9% males have health insurance. Assessing the poverty status, 61.4% females and 61.6% males are above the poverty level. Similarly, for maternal education, 87.5% females and 82.4% males have maternal education equal to or higher than high school. There are wide differences among the females and males in terms of initiating and completing the HPV series. As shown in Table 2, approximately, 50% of the females, while only 26% of males report to initiate the HPV vaccine series. Among the adolescents who initiate the HPV vaccine series, 57.9% females and 20.9% males complete the 3 dose HPV vaccine series.

Table2: Socio-demographic Characteristics and HPV Vaccine Status Among the Non-Hispanic Black Adolescents Aged 13 – 17 Years, Stratified by Gender, NIS-Teen 2012

Variables	FEMALES (n = 1953)			MALES (n= 2195)		
	n	Wtd %	95% CI	n	Wtd%	95% CI
Age						
13	406	18.8	15.1 - 22.5	434	19.6	15.5 - 23.7
14	401	20.2	15.9 - 24.4	468	22.2	17.6 - 26.7
15	399	22.1	17.4 - 26.7	460	20.2	16.2 - 24.1
16	386	22.1	17.5 - 26.8	414	19.2	15.3 - 23
17	361	16.6	12.2 - 20.9	419	18.7	14.8 - 22.6
HCP Recommend						
Yes	1013	62.8	57.5 - 68	662	32.8	28.1 - 37.5
No	773	37.2	31.9 - 42.4	1303	67.2	62.4 - 71.9
Total	1786*			1965*		
Health Insurance						
Yes	1344	95.7	93.9 - 97.5	1455	94.9	93 - 96.7
No	609	4.3	2.4 - 6.1	740	5.1	3.2 - 6.9
Poverty Status						
Above Poverty	1256	61.4	56.1 - 66.6	1423	61.6	56.6 - 66.7
Below Poverty	57	38.6	33.3 - 43.8	658	38.3	33.2 - 43.4
Total	1826*			2081*		
Maternal Edu						
< High School	237	12.5	9.1 - 15.8	317	17.6	13.6 - 21.6
>=High School	1716	87.5	84.2 - 90.9	1878	82.4	78.4 - 86.3
Initiated HPV vac						
Yes	566	50.1	44.7 - 55.3	321	25.9	21.3 - 30.4
No	608	49.9	44.6 - 55.2	981	74.1	69.5 - 78.6
Total	1174*			1302*		
Completed HPV vac						
Yes	328	57.9	50.7 - 65.1	76	20.9	14.1 - 27.7
No	238	42.1	34.8 - 49.2	245	79.1	72.2 - 85.9
Total	566**			321**		

*Some observations for Healthcare Provider Recommendation, Poverty status and

Initiation of the HPV Vaccine Series for Black female and male adolescents are missing in the data.
**The completion of HPV Vaccine Series is assessed among those who initiated the HPV Vaccine Series.

Table 3 presents the socio-demographic characteristics and the completion of HPV vaccine series in the study population. As shown, more females complete the HPV vaccination series as compared to males in the study population. Among the females, the column percentages show an increasing trend with age, from 13 to 16 years. This means, as the age increases from 13 – 16 years, a higher percentage of females complete the HPV vaccination series. Among the females who complete the 3 dose HPV vaccination series, majority (15.9%) of them belong to the 16 year old age group while among the males, majority (6.2%) belong to the 15 year old age group. However, the number and percentages of males completing the HPV vaccination series are less than females.

As shown in Table 3, among the females and males completing the HPV vaccination series, 43.7% females and 17.5% males receive the healthcare provider recommendation for HPV vaccination. Among those who complete the HPV vaccination series, 55.3% females and 20.2% males possess health insurance. Among those who complete the HPV vaccination series, 31.5% females and 18.3% males are above poverty level. Among the adolescents who complete the HPV vaccination series, 51.7% females and 18.3% males have maternal education equal to or higher than high school.

Table 3: Socio-demographic Characteristics and Completion of HPV Vaccine Series Among the Non-Hispanic Black Adolescents Aged 13 – 17 Years, Stratified by Gender, NIS-Teen, 2012

Variables	Completion of 3 Dose HPV Vaccination Series					
	FEMALES (n=1174)			MALES (n=1302)		
	n	Weighted Column %	95% CI	n	Weighted Column %	95% CI
Age						
13	59	7.6	4.2 - 11.1	17**	5.2	1.6 - 8.8
14	60	8.2	5.1 - 11.5	12**	1.8	0.4 - 3.2
15	65	14.9	9.8 - 20.1	16**	6.2	1.8 - 10.7
16	79	15.9	10.8 - 21.1	13**	3.1	0.6 - 5.6
17	65	11.2	6.1 - 16.3	18**	4.5	1.7 - 7.4
HCP Recommend						
Yes	241	43.7	36.2 - 51.2	55	17.5	10.8 - 24.1
No	67	14.3	9.2 - 19.4	16**	5.1	1.2 - 8.9
Total	308*			71*		
Health Insurance						
Yes	306	55.3	48.1 - 62.6	70	20.2	13.4 – 27
No	22**	2.6	0.5 - 4.7	6**	0.6	0 - 1.6
Poverty Status						
Above Poverty	198	31.5	24.4 - 38.5	49	15.1	8.6 - 21.5
Below Poverty	116	25.4	19.1 - 31.6	22**	5.4	2.1 - 8.6
Total	314*			71*		
Maternal Edu						
<High School	39	6.2	2.5 - 9.9	13**	2.6	0.2 - 4.9
>=High School	289	51.7	44.2 - 59.2	63	18.3	11.8 - 24.7

*Some observations for Healthcare Provider Recommendation and Poverty status for Black female and male adolescents are missing in the data.
**Very small sample size (<30) in the data

4.2 Univariate Analysis:

Univariate analysis using binary logistic regression assessed the association of socio-demographic factors, such as gender, age, healthcare provider recommendation, health

insurance, poverty status and maternal education with completion of 3 dose HPV vaccination series in the study population. The results are presented in Table 4 and 5.

Table 4: Univariate and Multivariate Analysis of Socio-demographic Factors and Completion of HPV Vaccine Series Among the Non-Hispanic Black Adolescents Aged 13 – 17 Years, NIS-Teen, 2012

Variables	Non-Hispanic Blacks (n=2476)			
	Completion of 3 Dose HPV Vaccination Series			
	UNIVARIATE ANALYSIS		MULTIVARIATE ANALYSIS	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Gender				
Males	Referent		Referent	
Females	5.2*	3.1 - 8.8	4.7*	2.8 - 8.1
Age				
13	Referent		Referent	
14	0.9*	0.5 - 1.9	0.9*	0.4 - 1.9
15	3.1*	1.5 - 6.5	3.1*	1.3 - 6.9
16	2.3	1.1 - 4.8	2.1	0.9 - 4.3
17	2.1	0.9 - 4.6	1.7	0.7 - 3.9
Maternal Education				
< High School	Referent		Referent	
=> High School	2.2*	1.1 - 4.6	1.9*	0.9 - 3.7
HCP Recommendation				
No	Referent			
Yes	1.5	0.9 - 2.6	-	-
Health Insurance				
No	Referent		-	-
Yes	1.01	0.3 - 2.7		
Poverty Status				
Below Poverty Level	Referent		-	-
Above Poverty level	1.3	0.7 - 2.0		

* p-value <0.05

As a result of uni-variate analysis of the socio-demographic factors with the completion of HPV vaccine series, *gender, age and maternal education* have statistically significant

association with the completion of HPV vaccine series among the Non-Hispanic Black adolescent study population. As shown in Table 4, females are 5 times more likely to complete the HPV vaccination series as compared to males in the study population. Assessing the association of age group among the Non-Hispanic Black adolescents, 15 year olds are 3 times more likely to complete the HPV vaccination series as compared to 13 year olds. Also, the adolescents with maternal education equal to or greater than high school, are 2.2 times more likely to complete the HPV vaccination series as compared to those adolescents with maternal education less than high school.

As a result of uni-variate analysis of the socio-demographic factors with the completion of HPV vaccine series (as shown in Table 4), the factors, healthcare provider recommendation, health insurance and poverty status show association with the completion of HPV vaccination series, however the associations are not statistically significant.

Table 5 presents the associations of socio-demographic factors with the completion of HPV vaccination series, stratified by gender. As shown in Table 5, only the factor poverty status among males has statistically significant association with the completion of HPV vaccination series. The males above poverty level are 2.7 times more likely to complete the HPV vaccination series as compared to males below poverty. However, the sample size of the males is very small. Among the females, the poverty status does not have any association with the completion of HPV vaccination series.

Table 5: Univariate Association of Socio-demographic Factors with Completion of HPV Vaccine Series Among the Non-Hispanic Black Adolescents Aged 13 – 17 Years, Stratified by Gender, NIS-Teen, 2012

Variables	FEMALES (n= 1174)			MALES (n=1302)		
	HPV Vaccine Series Completion			HPV Vaccine Series Completion		
	ROW %	ODDS RATIO	95% CI	ROW %	ODDS RATIO	95% CI
Age						
13	7.6	Referent		5.2	Referent	
14	8.2	1.3	0.6 - 3	1.8	0.3*	0.1 - 1.1
15	14.9	3.3*	1.4 - 8.2	6.2	2.2*	0.6 - 7.2
16	15.9	2.6	1.1 - 6.2	3.1	0.8	0.2 - 3.2
17	11.2	1.8	0.7 - 4.9	4.5	1.8	0.4 - 6.7
Maternal Education						
<High School	6.2	Referent		2.6	Referent	
=>High School	51.7	1.6	0.6 - 3.9	18.3	2.6	0.8 - 8.2
HCP Recommend						
No	14.3	Referent		5.1	Referent	
Yes	43.7	1.3	0.7 - 2.5	17.5	1.9	0.7 - 5.2
Poverty Status						
Below Poverty Level	25.3	Referent		5.4	Referent	
Above Poverty Level	31.5	1.0	0.5 - 1.8	15.1	2.7*	1.1 - 6.5
Health Insurance						
No	2.6	Referent		0.6	Referent	
Yes	55.3	1.2	0.3 - 4	20.2	1.1	0.2 - 6.2
*p-value < 0.05						

As shown in Table 5, age is associated with the completion of HPV vaccination series. Among the females, 15 year olds are 3.3 times and 16 year olds are 2.6 times more likely to complete the HPV vaccination series as compared to 13 year olds. Among the males,

15 year olds are 2.2 times more likely to complete the HPV vaccination series as compared to 13 year olds. However, these findings are not statistically significant.

As shown in Table5, the factors, healthcare provider recommendation, health insurance and maternal education show association with the completion of HPV vaccination series when assessed separately for females and males. However, these associations are not statistically significant, as their odds ratios have wide confidence intervals and include 1.

4.3 Multivariate Analysis:

In order to assess the strongest predictor of HPV completion in the Non-Hispanic Black adolescent population, multivariate analysis is performed by logistic regression. The variables that show statistically significant association in univariate analysis, as *gender, age and maternal education* are included in the multivariate model. As shown in Table 4, gender is the strongest predictor of the completion of HPV vaccine series among the Black population. Females are approximately 5 times more likely to complete the HPV vaccination series as compared to males. 15 year olds are thrice more likely to complete the HPV vaccination series as compared to 13 year olds. The adolescents with maternal education equal to or greater than high school are roughly twice more likely to complete the HPV vaccination series as compared to the adolescents with maternal education less than high school.

CHAPTER V

DISCUSSION AND CONCLUSION

5.1 Discussion:

The study objective was to assess the selected factors and their association with the completion of 3 dose HPV vaccination series in the high risk Black adolescent population on the basis of the 2012 National Immunization Survey – Teen. The multivariate analysis in the study shows that gender and the 15 year old age group are the predictive factors associated with completion of HPV vaccination series in the Non-Hispanic Black adolescent population. The females are more likely to complete the HPV vaccination series as compared to males. The following reasons may be accounted for it. First, in United States the HPV vaccine was licensed to be used in females earlier and was recommended as a routine adolescent vaccine by ACIP in 2006. But, the HPV vaccine was licensed to be used in males in 2009 and was recommended as a routine adolescent vaccine by ACIP in 2011. It is because of this time lag for vaccine availability for males, HPV vaccine gained more popularity among the females. Second, HPV infection is a cause of nearly all cervical cancers (Walboomers et al., 1999), therefore HPV vaccination is regarded to be of more importance among the females. Third, studies show that healthcare provider recommendation is the most important factor for parents of adolescents in their decision to vaccinate their children with HPV vaccine (Holman et al., 2014). More

females as compared to males in this study received the healthcare provider recommendation, therefore more females complete the HPV vaccination series.

In the current study, the results obtained from the univariate analyses of the socio-demographic factors with the completion of HPV vaccine series among the non-Hispanic Black adolescents show that associations despite being positive have wide confidence intervals, have p-value > 0.05 and the confidence limits include 1. This may be attributed to the fact, small sample sizes of the survey respondents in the study population. NIS-Teen is the random digit dialed, probability sampled, population based secondary dataset. In the current study, the study sample is limited to only the Non-Hispanic Black adolescents, which constitute only 14.1% (n=4148) of the total NIS–Teen 2012 (N= 32825) study population. This sample size is reduced, when we stratify the results by gender (n for females = 1953 and males = 2195). These sample sizes are further reduced, when we assess the number of Black adolescents completing the 3 dose HPV vaccination series (n = 887, females = 566, males = 321) among those who initiated the HPV vaccine series (n=2476, females=1174, males=1302). It is for this reason the obtained sample sizes for various factors and their associations are very small and this reduces the statistical significance of the associations and provide wide confidence intervals, making result inferences imprecise. This is very clear from the Table 3, where among the males, the respondents completing the HPV series and with no healthcare provider recommendation (n=16), no health insurance (n=6), below poverty (n=22) and maternal education less than high school (n=13). Thus, this highlights one of the drawbacks of

using secondary dataset for a research study, where the researcher does not have the freedom to tailor the data to answer the questions of researcher, as in present study where the requirement is to assess associations of socio-demographic factors with the completion of HPV vaccine among the subpopulation which is at high risk for HPV infections and related disparities.

In this study, the results of the univariate analysis of the maternal education with the completion of HPV vaccination series show that maternal education equal to or higher than high school is positively associated with the completion of 3 dose HPV vaccination series among Black adolescents. The studies conducted in past show that African Americans are more skeptical about effectiveness of HPV vaccine and are concerned about the side effects of vaccine (Scarinci, Garcés-Palacio, & Partridge, 2007). But, educated parents have more knowledge and awareness of the HPV vaccine and health hazards of HPV infection and therefore are more likely to vaccinate their adolescent children with HPV vaccine. However, the literature shows that perceptions among mothers that facilitated HPV vaccination are 1) the belief that vaccination was beneficial 2) provider recommendation 3) knowing peers who were vaccinated 4) having had a personal experience with HPV-related disease (Scarinci et al., 2007).

In this study, the results of the univariate analysis of the poverty status with the completion of HPV vaccination series show that being above poverty level is positively associated with the completion of 3 dose HPV vaccination series among the Black adolescents. However, this association is not statistically significant. These results are in

agreement with the study conducted by Curtis et al., where the rates of completion of HPV vaccination series are higher for adolescents living above the poverty level (Curtis et al., 2013). In this study, the non-significant association of poverty status with the completion of HPV vaccination series for Non-Hispanic Black (OR=1.3, 95% CI = 0.7–2.0, p-value= 0.3) adolescents and confidence intervals, including 1 may be due to reduced sample size, as only Non-Hispanic Black population is considered and other races are excluded.

5.2 Limitations and Strengths:

This is a cross sectional study using secondary data which involves data collection at one specific point of time. Therefore, the researcher is dependent on the information that data provides and do not have the flexibility to tailor the data to answer his questions. In the study, the study population is limited to the Non-Hispanic Black population in the NIS-Teen 2012 data, which reduces the sample size of the actual data. Due to this reduction in sample size, wider confidence intervals of the associations are obtained, yielding imprecise results. Second, the information for the outcome variable in the study is obtained from the healthcare provider's immunization records of the adolescents. The completeness of these records at the health facility is unknown. Third, the NIS-Teen questionnaire and the data provides the information about the mother's education alone, and the information about father's education is nowhere mentioned or provided. Fourth, this study undertakes only selected factors for the assessment of the association with the

HPV series completion. Other factors, that are excluded in the study, such as type of health insurance, may also have some impact. Despite of these limitations, one of greatest strength of the study is obtaining verified information of HPV vaccine administration from the medical records at the health facility. This provides us reliable information on the number of vaccine doses actually administered to the adolescents. Also, this omits the other limitations as recall bias among the parents regarding the information of HPV vaccine administration and lack of availability of shot card.

5.3 Conclusion:

HPV infections are the most common sexually transmitted infections in United States with a disproportionate burden among the adolescent population. HPV cause a great disease burden by causing cervical cancer, cancers of vulva, vagina, anus, penis, oropharynx and external ano-genital warts. HPV infection and cervical cancer disproportionately affect the low income and minority women, predominantly including the Blacks. HPV vaccines can be an effective mode to reduce morbidity and mortality associated with HPV related disease. Therefore, ACIP recommends routine vaccination of 11-12 year old females and males with 3 doses of HPV vaccine for protection against HPV infections. Despite the availability of safe and effective HPV vaccines, the HPV vaccination rates are low in United States. The Healthy People 2020 objective is to increase the 3 dose HPV vaccine completion rates among females to 80%. In order to attain this target, it is important to assess the factors that influence the HPV vaccination completion rates, especially among the populations that are at most risk of HPV infection

and cervical cancer. This study used the 2012 National Immunization Survey – Teen data to assess the selected associative factors such as, healthcare provider recommendation, poverty status, health insurance and maternal education affecting completion of 3 dose HPV vaccination series among the African American/ Black adolescents. As a result of multivariate analysis, gender is the strongest and most significant factor influencing the completion of 3 dose HPV vaccination series among the non-Hispanic Black adolescent population, where more females are found to complete the HPV vaccine series than males. As a result of univariate logistic regression, maternal education shows significant association with completion of HPV vaccine series among the non-Hispanic Black adolescents. The 15 year old Black adolescents are more likely to complete the HPV vaccination series as compared to 13 year olds. Thus, this study provides a direction to public health practices to focus on Black male adolescents and subpopulations with low maternal education in order to improve HPV vaccination in US and thus reduce disparities related with HPV associated cancers and genital warts.

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