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# Human Papillomavirus Vaccine Policy in the U.S.

Jennifer C. Jarrell

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## ABSTRACT

JENNIFER C. JARRELL

Human Papillomavirus Vaccine Policy in the United States  
(Under the direction of RUSS TOAL, FACULTY MEMBER)

HPV vaccine school entry mandates and vaccine funding by state was examined using the Diffusion of Innovations (DOI) theory. The DOI was applied to HPV immunization policy to evaluate the rate of vaccine adoption and to determine whether associations existed between an empirical need for vaccine adoption and action by the states. State-level data on political characteristics, health and policy were collected from several secondary sources. Data analyses were performed utilizing SPSS logistic regression models. Odds ratios were used to evaluate the associations between the independent and dependent variables to determine whether there was a statistical significance level of .05. Cervical Cancer incidence in a state was significantly associated with HPV school entry mandates (proposed or enacted), but it did not show a significant association with HPV vaccine funding. Diffusion of vaccine innovation is slow, which may offer additional opportunities to evaluate effective policy strategies for coverage and use of the HPV vaccine.

Index words: human papillomavirus, vaccine, immunization policy, diffusion of innovations

HUMAN PAPILLOMAVIRUS VACCINE POLICY IN THE UNITED STATES

by

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B.A., GEORGIA STATE UNIVERSITY

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## GLOSSARY OF TERMS

**Adenocarcinoma in situ** - a type of cervical cancer

**Adverse health outcomes** - harmful illness, injury, or disease

**Booster** - additional vaccine, which serves to lengthen the efficacy of a previous vaccine

**Cervical intraepithelial neoplasia** - abnormal, precancerous cells on the cervix

**Efficacy** - the ability to produce a desired effect

**Erythema** - abnormal reddening of the skin

**Herd Immunity** - high numbers of vaccinated people provide protection from a disease to unvaccinated individuals

**Incidence** - number of new cases of a disease within a specified time, usually a year

**Local reactions** - injection site irritations such as erythema, itching, swelling

**Medical intervention** - healthcare treatment

**Persistent infection** - infection that the body does not clear

**Precursor lesions** - precancerous lesions that left untreated can become cancerous

**Prevalence** - total number of a disease cases in a population at a specified time

**Prophylaxis** - preventive treatment

**Quadrivalent HPV vaccine** - vaccine that covers four different human papillomavirus types

**Self-clear** - the body successfully “clears” the virus without medical treatment

**Sexual debut** - time when a person first becomes sexually active

**Study endpoints** - primary goals of the clinical study

**Underinsured** - people who have inadequate insurance coverage

**Uninsured** - people who do not have health insurance coverage

## CHAPTER I

### INTRODUCTION

Since 2004, several studies have found that the Human Papillomavirus (HPV) is the most common sexually transmitted infection in the U.S., with an estimated 6.2 million newly infected people annually (Centers for Disease Control and Prevention, 2007a; Weinstock, Berman, & Cates, 2004). In response, Merck and Company, a multinational pharmaceutical company, developed the first HPV vaccine, Gardasil®. Gardasil®, as a medical innovation, addressed the growing prevalence of HPV types 6, 11, 16, and 18 associated cervical cancer and genital warts. Following the completion of Gardasil® clinical trials, the U. S. Food and Drug Administration (FDA) evaluated the safety and efficacy of vaccine. In June 2006, the FDA concluded the evaluation of Gardasil® and licensed the vaccine for use in the U.S. for females ages 9 to 26 years (Food and Drug Administration, 2006). Within the same month, the Advisory Committee on Immunization Practices (ACIP), the committee charged by Secretary of the U. S. Department of Health and Human Services with establishing national immunization schedules and outlining vaccine usage, voted to add the vaccine to the national adolescent immunization schedule. The ACIP recommendation for the standard use for the HPV vaccine is 11 and 12 year old girls, with catch-up vaccine for females 13 to 26 (Centers for Disease Control and Prevention, 2007a).

Since June 2006, states have been considering whether the HPV vaccine recommendation warrants state policy changes. Some states are deliberating policies that

mandate the HPV vaccine for school entry among sixth grade girls. Additionally, some states are assessing funding options to address the associated costs of mandating an additional vaccine. Requiring the HPV vaccine for school entry among school-aged females would require additional resources, as the demand for the new vaccine would increase rapidly. As noted in Chapter II, these states are evaluating whether the HPV vaccine creates a need for additional funds to cover the cost Gardasil® imposes on their vaccine programs.

State immunization programs are experiencing an increase in the number of new, expensive vaccines (Institute of Medicine, 2003). The total cost to fully vaccinate a child has risen from \$155 in 1995 to \$1,170 in 2007 (Centers for Disease Control and Prevention, 2007c, 2007d; Davis, Zimmerman, Wheeler, & Freed, 2002; Lee, Santoli, Hannan, Messonnier, et al., 2007). Moreover, the HPV vaccine is the most expensive vaccine on the market to date (Centers for Disease Control and Prevention, 2007d). According to the 2005 childhood/adolescent immunization schedule, the HPV vaccine costs one-third the total amount to fully immunize a child (American Academy of Pediatrics, 2005).

### ***Theoretical Framework and Hypothesis***

Since Gardasil® is a medical innovation, the Diffusion of Innovation Theory can demonstrate the adoption of innovation policy across state populations (Cain & Mittman, 2002; Rogers, 2003). The scope of this research will explore factors associated with the innovation policy has reached a point of majority adoption. For the purposes of this paper, the following concepts are presented:

- *Majority adoption* will be measured by proposed or enacted policy that would mandate the HPV vaccine for school entry or provide funding for the HPV vaccine.
- *The empirical need for vaccine adoption* will be represented by a number of state health characteristics: cervical cancer incidence, Pap screening percentage, percentage of uninsured women, and the state's United Health Foundation score.
- *Political characteristics* will represent the social climate of a state. These are measured by which political party controls the state's legislature and gubernatorial seat. These characteristics also serve to establish general division of the state's population into groups.

The research will evaluate:

- Whether the empirical need for vaccine adoption is associated with policy adoption, and
- Whether state political characteristics are associated with majority policy adoption.

The Diffusion of Innovation theory can be used to assess whether a majority acceptance of this innovation is likely to exist at a particular point in time. The hypothesis of this study (H1) is that there is an association between mandating use of or funding for the HPV vaccine and such variables as state health and political characteristics (for the time period studied). The null hypothesis (Ho) is that there is no significant association with HPV vaccine mandating or funding policy and state characteristics.

The following Chapter II discusses HPV and the HPV vaccine, school entry vaccine mandates, vaccine programs and funding, and the Diffusion of Innovation theory. Chapter III contains the methodology and variables used in the study. Chapter IV describes the descriptive and logistic regression analysis results, and the final Chapter V discusses the study implications, limitations and recommendations.

## CHAPTER II

### LITERATURE REVIEW

#### *Human Papillomavirus Background*

HPV is the most common sexually transmitted infection in the U.S. An estimated 6.2 million people are infected with HPV annually (Weinstock et al., 2004). The HPV prevalence estimates among U.S. women ranges between 16% and 28% of the sampled population (Centers for Disease Control and Prevention, 2005; Dunne et al., 2007). Incidence, the number of new infections annually, and prevalence of HPV is most common among those 14 to 24 years of age (Dunne et al., 2007; Weinstock et al., 2004). Mathematical modeling estimates 80% of sexually active females in the U.S. contract an HPV infection by age 50 (Centers for Disease Control and Prevention, 2007a; Centers for Disease Control and Prevention, 2005; Myers, McCrory, Nanda, Bastian, & Matchar, 2000).

HPV infected individuals transmit the virus through genital-genital contact, most frequently through sexual intercourse. Risk factors for HPV include sexual debut at a young age, increased number of sexual partners, sexual relations with partners that have had an increased number of sexual partners, and other high-risk sexual behaviors (Centers for Disease Control and Prevention, 2007a; Dunne et al., 2007; Winer, Lee, Hughes, Adam, & Kiviat, 2003). Early age at sexual debut increases the risk of contracting STIs due to the increase in lifetime cumulative risk from three or more sexual



partners (Dunne et al., 2007). Having three or more lifetime sexual partners puts an individual at increased risk for contracting HPV (Centers for Disease Control and Prevention, 2007a; Dunne et al., 2007; Sellors et al., 2003; Winer et al., 2003).

Similarly, those who engage in sexual activity with partners who have had three or more sex partners are at increased risk of contracting HPV. This is due to their partner's increased risk of exposure to the virus (Centers for Disease Control and Prevention, 2007a; Winer et al., 2003). Other high-risk sexual behavior, such as inconsistent use of condoms, increases the risk of exposure to HPV and other STIs (Centers for Disease Control and Prevention, 2005; Shew et al., 2006).

Since many HPV infections are asymptomatic and self-clear, most infected women never know they were infected. The CDC estimates that the body clears 70% of new HPV infections within one year and 90% within two years without any medical intervention or adverse health outcomes (Centers for Disease Control and Prevention, 2007a). Researchers categorize HPV types into high-risk and low-risk groups based on the type's risk of contributing to the development of cervical cancer or other precancerous cervical lesions (Centers for Disease Control and Prevention, 2007a).

A persistent infection with one or more high-risk HPV types, primarily type 16 and type 18, can result in cervical cancer or precursor lesions (Munoz et al., 2003). An HPV infection is necessary for the development of cervical cancer and precursor lesions, though, it is not always sufficient to cause cervical abnormalities (Centers for Disease Control and Prevention, 2007a). Although the HPV infection is not treatable, cervical cancer and precursor cervical lesions are treatable if identified through Pap screening. Approximately 11,000 cases of cervical cancer (8.1 per 100,000 women) occur in the

U.S. annually. Roughly 4,000 of these cancer cases result in death each year (National Cancer Institute, 2006; Ries et al., 2007).

Infections of low-risk types can develop into genital warts; types 6 and 11 are associated with approximately 90% of genital warts (Centers for Disease Control and Prevention, 2007a). Healthcare providers can remove genital warts, but the virus may persist leading to a reoccurrence of warts (Centers for Disease Control and Prevention, 2007a). Unlike other STIs, HPV and genital warts are not reportable to local, state, or federal agencies. Therefore, research estimates must calculate the probable incidence rates (Centers for Disease Control and Prevention, 2005). Since HPV is most often asymptomatic and self-clears without detectable adverse events, accurate HPV reporting is difficult (Sellors et al., 2003). Additionally, the estimated HPV related genital warts and cervical cancer cases are small when compared with the total number of HPV infections (Centers for Disease Control and Prevention, 2007a; Dunne et al., 2007; Myers et al., 2000; Weinstock et al., 2004). Though HPV affects males and females, FDA currently licenses Gardasil® only for females. Therefore, vaccinating females before sexual debut is one of the most effective methods for reducing the transmission of HPV 6, 11, 16, 18 and preventing cervical cancer (Centers for Disease Control and Prevention, 2007a; Hampl, Sarajuuri, Wentzensen, Bender, & Volkmar Kueppers, 2006).

### ***The HPV Vaccine: Gardasil®***

Merck produces the HPV quadrivalent vaccine, Gardasil®. The conclusion of the Merck HPV vaccine clinical trials demonstrated nearly 100% efficacy rates among females against HPV types 6, 11, 16, and 18 (Garland et al., 2007; Shi et al., 2007).

When examining clinical study endpoints, the vaccine efficacy against HPV related cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ was 95%-100% (Garland et al., 2007). The study also demonstrated 99% vaccine efficacy for HPV 6 and 11 related genital warts (Zimmerman, 2007). Follow up studies are planned to determine long-term efficacy and safety of the vaccine (Centers for Disease Control and Prevention, 2007a; Zimmerman, 2007). Currently, it is unclear if a booster dose will be required to maintain immunity. However, at the 5-year mark, immunological studies showed no reduction in protection among the vaccinated population (Garland et al., 2007; Shi et al., 2007).

Vaccine safety and adverse events are generally mild injection-site reactions common to other vaccines. Most reported adverse events are injection-site pain, swelling and erythema (Garland et al., 2007). Long-term safety of the vaccine is still unknown since the vaccine is relatively new. The Vaccine Adverse Event Reporting System (VAERS) and the CDC's Vaccine Safety Datalink monitor the vaccine's long-term safety (Centers for Disease Control and Prevention, 2007a; Iskander, 2007). Other concerns exist regarding the HPV vaccine's safety. These include the belief that the vaccine reduces routine cervical cancer screenings and encourage unsafe sex practices. Also, the belief exists that the vaccine may encourage promiscuity and increase STI infections among young females (Zimmerman, 2007).

As noted herein, the FDA license for Gardasil® only permits 9 to 26 year old females to receive the vaccine. Healthcare providers administer the three shot series at months 0, 2, and 6. The ACIP recommended the HPV vaccine for routine use among females age 11 and 12, though healthcare providers can administer the vaccine to nine

and 10 year olds at a parent's request. The ACIP recommends catch-up vaccination among females age 13 through 26. The vaccine is most effective when given before sexual debut. This reduces the chances of previous HPV exposure, which maximizes the full benefit of vaccination (Centers for Disease Control and Prevention, 2007a; Garnett, 2005). The addition of the HPV vaccine to the immunization schedule makes Gardasil® a highly recommended part of the adolescent immunization series. The recommended vaccines on the adolescent immunization schedule are the tetanus, diphtheria, pertussis vaccine, meningococcal vaccine, and the HPV vaccine (Centers for Disease Control and Prevention, 2007a, 2007c). A recommendation without a state school entry mandate leaves the decision to vaccinate between healthcare providers, parents, and patients.

### ***School Entry Vaccine Mandates***

U.S. laws relating to immunization requirements date back to the early 1900s with the Massachusetts universal compulsory smallpox vaccine policy. In 1905, the Supreme Court upheld the right of a state to implement compulsory immunization regulations in the interest of public health in *Jacobson v. Massachusetts* (*Jacobson v Massachusetts*, 1905). Since this time, the Supreme Court constantly supported the right of states to safeguard public health through the implementation of school entry vaccine mandates (Evans, Harris, & Levine, 2004; Orenstein, Rodewald, & Hinman, 2004). However, school entry vaccine mandates and enforcement did not become institutionalized methods for reducing the vaccine-preventable disease burden until the 1970s, when this tactic was shown to be helpful in reducing measles outbreaks (Orenstein & Hinman, 1999; Orenstein et al., 2004).

The effectiveness of school entry vaccine mandates in increasing and maintaining high immunization coverage rates necessary to decrease disease among school and daycare age groups is evident with other vaccine-preventable diseases (Dailard, 2006; Orenstein & Hinman, 1999). In an analysis of adolescent Hepatitis B vaccine coverage rates, Wilson and Fishbein, et al. found that ninth graders in states with Hepatitis B school entry mandates had coverage rates of 72%, while only 18% of ninth graders were vaccinated for Hepatitis B in states without such mandates (Wilson, Fishbein, Ellis, & Edlavitch, 2005). Another analysis of Hepatitis B and Varicella vaccine coverage among insured adolescents across 28 states found significantly higher coverage rates among the adolescents of states where state mandates for these vaccines were in place (Olshen, Mahon, Wang, & Woods, 2007).

The high vaccine coverage for childhood vaccine-preventable diseases and a reduction of health disparities among school-aged children in the U.S. is directly attributable to school entry vaccine mandates (Dailard, 2006; Hinman, 2003; Orenstein & Hinman, 1999; Stewart, 2007a, 2007b). For this reason, school entry vaccine requirements are “safety net” policies since the regulation improves vaccine coverage levels among the minority and disadvantaged children, thus reducing the vaccine-preventable disease burden among these children (Institute of Medicine, 2003; Orenstein & Hinman, 1999).

### *School Entry Vaccine Mandates: a State Perspective*

States determine school entry vaccine mandates through regulatory and legislative actions. Vaccine mandates exist in all 50 states, but vary from state to state, though mandates for more communicable diseases are typically standard (Centers for Disease Control and Prevention, 2006; Evans et al., 2004; Institute of Medicine, 2003; Orenstein & Hinman, 1999; Stewart, 2007a). Nearly all states require proof of vaccination against diphtheria, measles, rubella, polio, tetanus, and pertussis for school entry. (Centers for Disease Control and Prevention, 2006; Orenstein & Hinman, 1999).

All 50 states offer exemptions from school entry mandates, though the allowable categories of exemption vary depending on state regulations and law. There are three categories of exemptions: medical, religious, and philosophical. All states offer medical vaccine exemptions to excuse individuals from receiving the mandated vaccine if a healthcare provider determines the vaccine may pose a medical danger to the person's health (Orenstein et al., 2004). Most states (48) offer religious exemptions to excuse individuals from vaccination due to a conflict in religious belief. Only a few states (15) offer philosophical exemptions for immunizations, whereby those who are philosophically opposed to vaccination are exempt from the vaccine mandate (Centers for Disease Control and Prevention, 2006; Orenstein & Hinman, 1999; Orenstein et al., 2004). Exemption requirements vary from state to state in terms of the public burden of filing for an immunization exemption. Some states require official forms signed by a parent while others only require a simple letter of objection (Orenstein et al., 2004).

## *Vaccine Financing Mechanisms*

Vaccine program funding comes from federal and state sources. The federal government established two sources of vaccine financing mechanism to aid in increasing immunization coverage rates in the U.S. These funding sources are Vaccines for Children (VFC), a federal entitlement program, and the 317 Grants, a federal grant program that receives direct annual funding from Congress (Institute of Medicine, 2003; Orenstein et al., 2004). In addition, states allocate funds to immunization programs as part of the regular state budgetary process.

VFC funds account approximately 43% of vaccine expenditures (Lee et al, 2007). The federal VFC program was established in 1994 to provide free immunization services to uninsured children at their regular healthcare provider (Institute of Medicine, 2003). VFC provides vaccines for qualified children to private providers and provides free vaccines to children at Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC). Children less than 19 years of age and either uninsured, Medicaid-eligible, or of Alaskan/American Indian decent are considered eligible for VFC. Additionally, underinsured children less than 19 years old are VFC eligible when vaccinated at a FQHC or RHC (Centers for Disease Control and Prevention, 2007b; Institute of Medicine, 2003; Orenstein et al., 2004). Once the ACIP adds a vaccine to the recommended childhood/adolescent immunization schedule and votes to include the vaccine for use under the VFC program, the vaccine must be subsidized under VFC for qualified children (Orenstein et al., 2004). The CDC negotiates federal contracts with vaccine manufacturers for VFC vaccines and states, in turn, order the vaccines at the CDC negotiated purchase price (Institute of Medicine, 2003).

The 317 funding is part of the Public Health Service Act of 1972, which was designed with the purpose to assist state immunization programs build and maintain vaccine infrastructure as well as purchase vaccine (Institute of Medicine, 2003). Additionally, the 317 Federal Grant provides states with funds, which are often used to vaccinate children who are not VFC eligible, particularly underinsured children seeking immunization services. However, federal 317 Grant reductions over the past decade have placed substantial strain on states to contribute more to finance immunization programs (Freed, Clark, & Cowan, 2000; Lee et al., 2007). The growing cost of fully vaccinating the increasing number of underinsured children, compounded with a reduction in 317 Grant funding and an increase in number of new, expensive vaccines on the immunization schedule, there are many financial challenges facing state immunization budgets (Institute of Medicine, 2003; Lee et al., 2007). Disparities in vaccination coverage rates are emerging between VFC-eligible (uninsured) and VFC-ineligible (underinsured) children, particularly with newer vaccines (Lee et al., 2007).

Private funding for immunization services is another method through which many children receive immunization services. Private funding accounts for approximately 46% of vaccine purchase and vary depending on insurance status and insurance benefits coverage (Lee et al., 2007). Private vaccine financing occurs when either the family, insurance company, or combination of both funds the cost of immunizing a child. When a child has insurance coverage for recommended vaccines, the insurance company reimburses the provider or the family for some or all of the vaccine cost. When the child is underinsured (has insurance coverage but immunization services are not a covered benefit) the family is responsible for the cost of vaccination, except in states that provide



funding mechanisms for those children. Since the number of underinsured children in the U.S. is growing, the financial strains of covering vaccination of underinsured children have increased. Many states have passed legislation to require insurance companies to cover immunization services (Freed et al., 2000; Institute of Medicine, 2003; Lee et al., 2007).

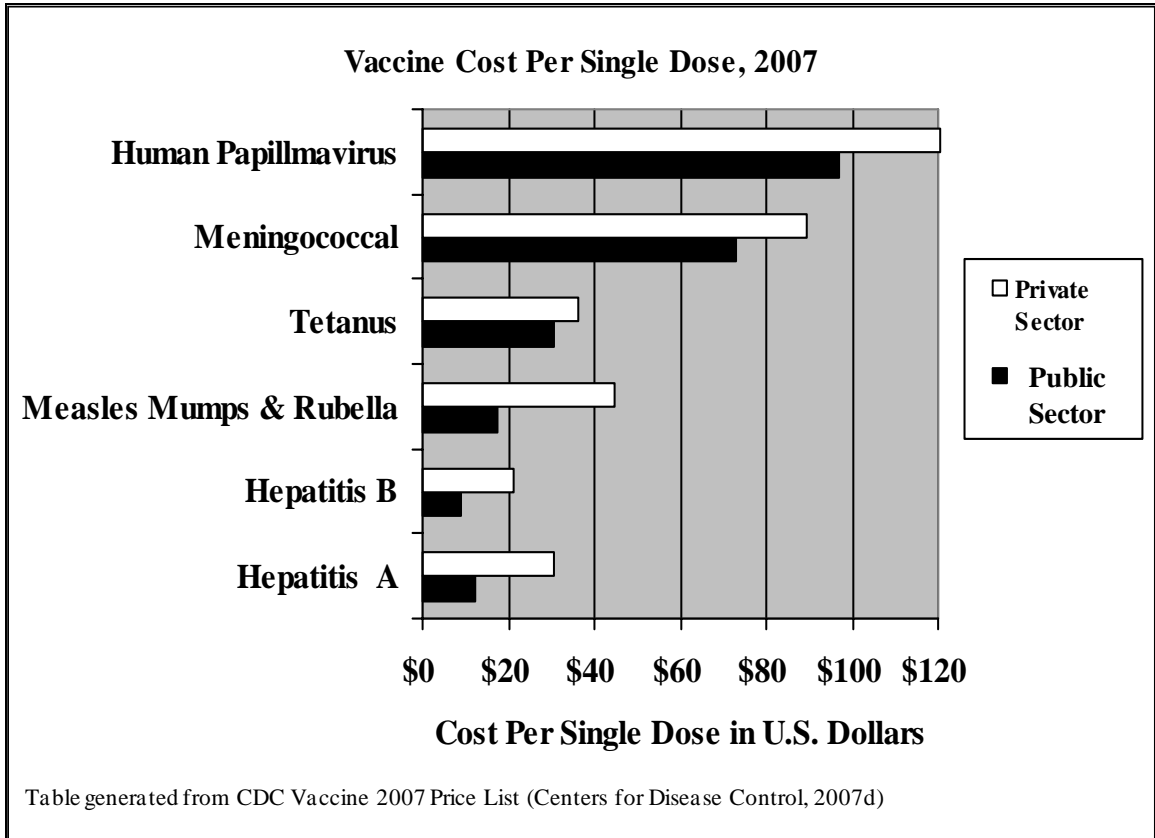
Through March of 2007, 16 states have proposed compulsory insurance coverage of the HPV vaccine specifically (National Conference of State Legislatures, 2007). However, compulsory insurance coverage of the HPV vaccine does not automatically define the terms for which children can receive the vaccine. For instance, insurance companies can still require increased monthly premiums, deductibles, and co-pays to offset the costs associated with mandated vaccine coverage. In this manner, the insurance companies can still pass the cost on to the patient, creating more barriers for vaccination (Institute of Medicine, 2003; Lee et al., 2007).

### ***HPV Vaccine: Costs v. Benefits***

According to the CDC Vaccine 2007 Price List, the cost of the HPV vaccine per dose is significantly higher than other recommended vaccines (Centers for Disease Control and Prevention, 2007c, 2007d). Figure 1 illustrates the cost differential between the HPV vaccine and other recommended vaccines. As shown, the private sector and VFC cost of the HPV vaccine per dose ranges between \$65 and \$100 more than other vaccines, except for the Meningococcal vaccine, which is \$30 less. Both Meningococcal vaccine and HPV vaccine cost more than older vaccines, primarily because both vaccines

are newly created medical innovations (Centers for Disease Control and Prevention, 2007d).

**Figure 1.** *Vaccine Cost Per Dose*



The cost of the vaccine in relation to HPV vaccine related diseases is an important factor when evaluating policy implications of vaccine mandates. The estimated cost of treating and preventing HPV related diseases in the U.S. is approximately \$5 billion annually (Insinga, Dasbach, & Elbasha, 2005). Mathematical models predict that vaccination of adolescent females against HPV will be cost-effective only after achieving high coverage rates, i.e., over 70 percent coverage (Elbasha, Dasbach, & Insinga, 2007; Goldie et al., 2004). The Goldie et al. model for an HPV 16/18 protective vaccine shows

an increased economic cost-benefit ratio when high coverage rates exist and cervical cancer screenings decrease from annually to once every three years (Goldie et al., 2004). However, the Elbasha model, which includes the four HPV types (6/11/16/18) in Gardasil® is cost effective with annual cervical cancer screenings, which is the current recommended strategy of the ACIP (Centers for Disease Control and Prevention, 2007b; Elbasha et al., 2007). The high coverage rate required for cost effectiveness further strains state vaccine budgets.

When states implement a widespread vaccination strategy, the vaccine cost combines with the cost of treatment, creating a larger financial burden for the state. This burden of double payout for both prevention and treatment of HPV continues until the falling number of treatments reduces the cost to such a point that the vaccine strategy costs less than the cost of treating HPV related diseases (Miller & Hinman, 2004). After this crossing point, the costs decrease below the pre-vaccination treatment payout.

### ***HPV Vaccine: The Debate***

A school mandate for HPV vaccination of sixth-grade females is likely to be an effective tool to increase vaccination coverage in this population. The anticipated results of high coverage may conceivably decrease HPV 6, 11, 16, and 18 rates and eventually reduce national cervical cancer incidence (Elbasha et al., 2007; Garnett, 2005; Orenstein & Hinman, 1999). Without a mandate, there will likely be health disparities in HPV vaccination coverage between those with access to the vaccine and those without (Stewart, 2007). However, there are many aspects of HPV vaccination mandates that create opposition among some groups.

Much of the editorial and media reported concern centers on relation to parental rights, vaccination mandates, and adolescent sex (Charo, 2007; Gibbs, 2006; Moreno, Berger, & Singer, 2006; "A necessary vaccine [Editorial]," 2007; Stewart, 2007; The Associated Press, 2007). The concern expresses two main themes: first, whether parents or the government should determine when and if an adolescent receives HPV vaccine, and secondly, whether a reduction in the risk of HPV will modify adolescent sexual behaviors.

Since a person can contract HPV only through sexual, rather than casual contact, a debate exists surrounding the state's right to mandate versus the parents' right to raise their children in a manner they see fit (Gibbs, 2006; Moreno et al., 2006; Stewart, 2007; Associated Press, 2007). Traditionally, state governments mandate vaccines to prevent the spread of highly infectious diseases. Therefore, state mandates provide positive consumption externalities, such as herd immunity (Institute of Medicine, 2003). Thus, HPV vaccine school entry mandates step outside the norm of policy precedent and some parents oppose government mandate of the vaccine (Gibbs, 2006; Stewart, 2007a, 2007b). In addition, some parents think vaccinating 11 and 12 year olds for an STI is too early due to the belief that sex does not occur the mid- to late- teenage years (Gibbs, 2006; "A necessary vaccine [Editorial]," 2007).

Some conservative groups, such as the Family Foundation, Family Research Council, and Focus on the Family, fear that a preventive HPV vaccine will condone and promote promiscuity among adolescents. By vaccinating their adolescent daughters, some fear they will be sending their daughters the message premarital sex is acceptable, which contradicts the "abstinence until marriage, fidelity in marriage only" message

(Charo, 2007; Gibbs, 2006; Moreno et al., 2006; "A necessary vaccine [Editorial], 2007; Associated Press, 2007. However, there is no empirical evidence to suggest that the HPV prophylaxis vaccine will increase sexual activity among adolescents (Monk & Wiley, 2006). Regardless of empirical evidence, several groups support HPV education and voluntary vaccination programs instead of a school entry mandate (Gibbs, 2006; "A necessary vaccine [Editorial]," 2007; Associated Press, 2007; Wilson, 2007).

Some of the controversy surrounding the HPV vaccine is in response to the actions of the pharmaceutical manufacturer, Merck. When the ACIP recommended Gardasil®, they instructed Merck not to engage in lobbying activities that would promote school entry mandates for the vaccine. Jon Abramson, ACIP chair explains: "HPV vaccinations should not be mandated because HPV is not a contagious disease and also because states have not shown that the funds are available to vaccinate every child (Lopes, 2007)." Since a vaccine mandate would generate substantial revenue for Merck, Merck began an aggressive lobbying campaign to mandate the vaccine at the state level. Merck started funneling funds to the non-profit advocacy group, Women in Government (WIG), to assist in lobbying (Allen, 2007; McGee & Johnson, 2007; Wilson, 2007; Wynia, 2007). Some WIG annual conference participants claimed that WIG's conference educational material and agenda centered on Merck's agenda to encourage vaccine mandates. In addition, WIG recruited female lawmakers to gain greater influence on state legislation to pass HPV vaccine school entry mandates (Allen, 2007; Wilson, 2007; Wynia, 2007). In an interview with National Public Radio, Merck medical director Richard Haupt explained Merck supported state vaccine mandates because they increase vaccine coverage and "...reach under-served populations, certain ethnic and

socio-economic groups that wouldn't be reached otherwise... (Wilson, 2007).” By late February of 2007, Merck agreed to stop its lobbying campaign and focus solely on marketing and education (Allen, 2007; Lopes, 2007).

### ***Diffusion Of Innovations***

In his quintessential work, *Diffusion of Innovations*, sociologist Everett Rogers describes the process by which individuals and social groups adopt innovations. Rogers describes the diffusion of an innovation as “process by which (1) an innovation (2) is communicated through certain channels (3) over time (4) among the members of a social system (Rogers, 2003).” The basic Rogers Diffusion of Innovation model is a multidisciplinary theory used to describe the diffusion of many types of innovations. For the purpose of this study, the general Diffusion of Innovations will be discussed along with medical and political diffusion as it relates to the HPV vaccine.

### ***The Population of Diffusion***

In studying the process of innovation diffusion, Rogers discovers the existence of distinct sub-groups in a population. The *innovators* are the first to adopt an innovation. They typically hold higher socio-economic status and are more capable of weathering the result of a poor innovation than those in the other groups (Rogers, 2003). Innovators are generally more educated and better adapted to understand and apply complex concepts. Innovators are seen as pioneers, risk takers who cope well with uncertainty (Rogers, 2003).

The second subgroup to adopt an innovation, the *early adopters*, is more integrated in the social network than the innovators. Rogers states, “The early adopter is respected by his or her peers, and is the embodiment of successful, discrete use of new ideas.” As such, the early adopters have the greatest concentration of *opinion leaders*, group leaders whose opinions influence the actions of their affiliated groups. This group is often the primary target for marketing campaigns, as the influence of the opinion leaders determines the adoption of an innovation by the general population (Rogers, 2003).

The *early majority* comprises one of the largest subgroups of the population. The early majority typically adopts an innovation just before the average member. While seldom possessing positions of opinion leadership in the population, their interpersonal connections act as a catalyst to continue innovation diffusion. In deciding to adopt an innovation, the early majority tends to deliberate, adopting slower than the innovators and early majority, but faster than the remaining groups (Rogers, 2003).

The fourth group to adopt an innovation is the *late majority*. The *late majority* are nearly as large as the early majority. Unlike the internal deliberation of the early adopters, late adopters feel the weight of peer pressure to adopt an innovation. The skepticism and cautious attitude of the late majority usually means that adoption occurs at the risk of financial necessity (Rogers, 2003).

The last to adopt an innovation, the *laggards*, have the longest decision process time. They are typically suspicious of any innovation, as their socio-economic standing usually limits their resources available. Isolated from the majority of the population, this

group never holds positions of opinion leadership. As a result of their “slow to change” temperament, other subgroups use the laggards as a point of reference to the past when referring to innovation (Rogers, 2003).

### ***Innovation Attributes and Adoption Rates***

The rate of adoption, or the “speed with which an innovation is adopted by members of a social system,” determines how quickly an innovation should reach maximum adoption (Rogers, 2003). Since the perceived attributes of the innovation guide the innovation decision process, the perceived attributes of an innovation play an important role in how quickly, or slowly, an innovation will be adopted. Rogers outlines a number of attributes that act as independent variables that affect the rate of adoption: relative advantage, compatibility, trialability, and observability (Rogers, 2003).

*Relative advantage* speaks to cost-benefit of the innovation over the current method. According to Rogers, “Diffusion scholars have found relative advantage to be one of the strongest predictors of an innovation’s rate of adoption (Rogers, 2003).” He notes:

Subdimensions of relative advantage include economic profitability, low initial cost, a decrease in discomfort, social prestige, a saving of time and effort, and immediacy of reward. This latter factor explains in part why preventive innovations generally have an especially slow rate of adoption.... A preventive innovation is a new idea that an individual adopts now in order to lower the probability of some unwanted future event. Examples are stopping smoking... getting inoculations against disease... and adopting contraceptive methods. The relative advantage of preventive innovations is difficult for change agents to demonstrate, because the advantages occur at some future and unknown time, and may not happen at all. Thus the relative advantage of preventive innovation is highly uncertain. (Rogers, 2003)



However, it is important to denote the difference between scientific findings and personal experience. While scientists can empirically prove, for example, a vaccine is efficacious, only deliberate, direct known exposure can prove efficacy for an individual. For example, Coleman's findings on Tetracycline diffusion among doctors found that "teaching at the expert level cannot substitute for the doctor's own testing of the new drug.... (Coleman, Katz, & Menzel, 1966)." Additionally, policy diffusion among states has been shown to diffuse by state lawmakers observations of other states that have enacted similar policy, rather than information alone (Walker, 1969). The relative advantage is the *perceived* relative advantage, and not necessarily the documented advantage.

The next greatest factor in the rate of adoption is *Compatibility*. "*Compatibility*," according to Rogers, "is the degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters (Rogers, 2003). As the innovation more closely matches the social-cultural values and beliefs, previously held ideas, and the need for the innovation, the rate of adoption increases (Rogers, 2003). If a state adopts a policy, then the policy is more likely to diffuse to bordering states with similar ideological characteristics than bordering states with different ideological characteristics (Grossback, Nicholson-Crotty, & Peterson, 2004; Walker, 1969)

However, *complexity* is inversely proportional to rate of adoption; the more complex the innovation is to understand and implement, the slower it will be to adopt. Complexity is not as grave a determining factor as relative advantage or compatibility, though it still can play a vital role in some innovations (Rogers, 2003).

*Trialability*, the ability for an individual to use the innovation on a limited, noncommittal basis, gives the individual to test to see if the innovation does meet the needs in a beneficial manner. Trialability is more important to earlier adopters, like innovators and early adopters, because there is a lack of precedent set for true results among peer usage. Trialability becomes less important as more people in the social network use the innovation, as “trial by proxy” increases (Rogers, 2003). The more an individual is capable of trying out an innovation, the more likely the innovation will have a higher rate of adoption (Rogers, 2003). States also follow this pattern of diffusion by watching the actions and results of policy adoption in other states and then either adopting or rejecting the policy. Most often, states will adopt policies adopted that have been adopted by other states, particularly neighboring states (Grossback et al., 2004; Mooney, 2001; Walker, 1969).

Finally, “*Observability*” according to Rogers, “is the degree to which the results of an innovation are visible to others.” Innovations that have observability that is more concrete are more likely to have a higher adoption rate (Rogers, 2003).

### ***The Consequences of Innovating***

Rogers recognizes the *consequences* or changes that occur when an individual chooses to adopt an innovation are not merely the intended effects of the innovation. Rogers states, “We find it useful to analyze three dimensions of consequences: (1) desirable versus undesirable, (2) direct versus indirect, and (3) anticipated versus unanticipated.” Rogers generalizes that, “The undesirable, indirect, and unanticipated consequences of an innovation usually go together, as do the desirable, direct, and

anticipated consequences.” This means that the innovation’s intent demonstrates, and the adopter’ expectations require, that the anticipated results from the innovation’s direct use are desirable. However, the undesirable consequences are frequently an indirect and unanticipated result of adoption. Moreover, a “principle of inseparability” exists, where, as Rogers writes, “The effects of an innovation usually cannot be managed so as to separate the desirable from the undesirable.”

One of the difficulties in speaking of consequences is the subjectivity involved. By assigning desirable or undesirable, for example, the individual must make a value-based judgment (Rogers, 2003). This subjective judgment may not be understood between social groups, resulting in an undesirable consequence for one group, while another sees a desirable consequence. One example, as Rogers outlines, is the case of the Old Order Amish. Rogers writes, They willingly forgo the advantages of tractors and modern farm equipment (such as larger farms, higher crop yields, and increased income) in order to avoid the undesirable consequences of increased dependence on non-Amish businesses (such as farm machinery dealers), lessened farm labor requirements, and the pressure for larger-sized farms. (Rogers, 2003)

Naturally, the characteristics of the innovation and the social group in which diffusion takes place help determine how quickly the innovation will be adopted. In policy actions, if the policy adoption may influence election results, lawmakers will likely consider the desired effect of their judgment on voter satisfaction (Grossback et al., 2004).

### ***Preventive Innovations***

Preventive Innovations can be incredibly slow to adopt. Since their relative advantage is only measurable in the distant future under theoretical circumstances, the reward for innovating is delayed. Moreover, depending on circumstances of the individual, the reward may be thwarted by some other external force. Given that the

result of preventive innovations, like vaccines, is a nonevent, the proof that the innovation works is impossible to contrive in real-time. As with the case of disease, infection is exposure nearly always determined by contraction (Rogers, 2003).

In certain cases, the relative advantage is so low that the change agents must offer individuals *incentives* to adopt the innovation. Incentives, which are direct or indirect monetary benefits for adopting, often change the behaviors of certain groups. For example, Rogers finds “When a relative adopter incentive is paid to family-planning adopters, for example, individuals of the *lowest* socioeconomic status adopt.” As discussed earlier in this chapter, programs fund free or subsidized vaccines to lower socioeconomic groups, such as the VFC, 317 Grants, and state vaccine funding. These free and discounted vaccine services encourage earlier vaccine adoption from lower socioeconomic populations that might otherwise be incapable of adopting (Rogers, 2003).

Alternatively, when the public’s health is of concern, governments can mandate an innovation. When a government chooses to mandate an innovation, the government artificially increases the relative advantage for adopting the innovation (Rogers, 2003). The net result is that the individual perceives a greater relative advantage for innovating and chooses to adopt to remain in compliance with the law.

### ***HPV Vaccine through the Diffusion of Innovation Lens***

HPV vaccine is a preventive innovation, in that Merck created Gardasil® to prevent cervical cancer and genital warts; Gardasil® addresses the empirical need to reduce the infection rates of HPV and HPV-related diseases. Policymakers across the

country are considering laws and policy to adopt mandates and funding for the HPV vaccine. According to the Diffusion of Innovation theory, Gardasil®'s low relative advantage, incompatibility with some beliefs, lack of trialability, and lack of observability make the vaccine less capable of integrating easily into the population and state as an adoptable innovation (Rogres, 2003). The relative advantages of the innovation are low due to the high cost of the vaccine and the existing funding strain on state immunization programs. Given the relatively low "immediacy of reward" for adopting the innovation, state populations and lawmakers may find that adopting the innovation yields few, immediate results (Grossback et al., 2004; Rogers, 2003). Since the vaccine will take several years to yield maximum results, reducing the incidence of HPV related disease, HPV policy's positive externalities will also take years to show the full effect.

Additionally, state policymakers risk alienating voters that disagree with HPV vaccine policy due to the incompatibility of the innovation with the voters' beliefs. Given the disease transmission route (sexually rather than casually), some parents and special interest groups oppose widespread adoption. The vaccine is thought to conflict with the abstinence before marriage message supported by social conservatives. Other obstacles to adoption are the fear that a preventive vaccine will change sexual behaviors of adolescents (Charo, 2007; Gibbs, 2006; "A necessary vaccine [Editorial]," 2007; Associated Press, 2007; Wilson, 2007). These public concerns may influence the policy actions of state elected representatives that will require continued voter support to retain his or her elected position through the next election cycle.

The preventive nature of this new innovation can influence policy actions taken

across states. Vaccines, as a preventive innovation, are different from other innovations since they lack direct trialability and observability (Rogers, 2003). Individuals cannot try a vaccine prior to full adoption; one must fully adopt or reject of the vaccine from the onset. If an individual accepts a vaccine, that person must willingly accept all the consequences of adoption outright. Finally, observability is difficult because one cannot absolutely prove a benefit without known exposure. Moreover, no one is likely to intentionally challenge his or her own disease immunity.

The HPV vaccine has been on the market for under two years and policy related to HPV is new. Newness alone can contribute to slow policy adoption. Mooney explains the slow nature of new policy diffusion as well as the influence of trialability;

Early in a diffusion, little information is available to help policymakers reduce uncertainty in decision making. The policy may be untested and its long-term consequences unknown. Having the policy recently adopted by a neighbor increases the information available about both its policy and political consequences. (Mooney, 2001)

As policy options diffuse through states, the increasing acceptability of HPV policy options increases. Additionally, the intervention cost-benefit is examined in relation to the state economic characteristics to assess economic feasibility of adopting the policy (Karch, 2006). HPV funding allocation has to be a feasible economic option for diffusion of the policy to have a greater relative advantage.

### ***The Groups of Innovators***

The voting population of a state generally can be divided into party affiliation. The Pew Research Center's population survey reports identify these party affiliations and their self-reported ideological beliefs. The political platform of Republicans (social

conservatives) is traditionalist, pro-family, rooted in morality and a conservative belief structure (Pew Research Center, 2006a, 2006b). This platform of conservative, social ideology may make them less likely to adopt an innovation whereby children can more freely choose to engage in sexual behaviors. The conservative, traditional beliefs held by the Republicans may be incompatible with the belief that an HPV vaccine should be required. The result of the conflict of beliefs could result in a delayed adoption of the vaccine by Republicans. The structure of this paper theorizes that Republican-controlled states, as defined in Chapter III, will be less likely to adopt mandate or funding incentives to ensure the vaccine reaches large numbers of children.

The political platform of Democrats (social liberals) is more moderate on social issues such as family structures, premarital and safe sex, and healthcare according to the Pew Research Center reports (Pew Research Center, 2006a, 2006b). The Democratic platform is more likely to support policy which encourages safe sex practices over abstinence only. The Democratic belief structure could be said to be more compatible with the beliefs required to adopt an HPV vaccine mandate. Thus, states controlled by Democrats, as defined in Chapter III, are more likely to accept new preventive innovations, mandates, and funding incentives to encourage vaccine adoption, such as mandating Gardasil®.

### ***Policy as Adoption***

Mandates are negative incentives. Through mandates, states ensure population adoption by restricting non-compliant individuals from using state government programs and services, such as the public school system (Evans, Harris, & Levine, 2004; Orenstein,

Rodewald, & Hinman, 2004). In the case of school entry required vaccines, punishments for non-compliance without proper documentation vary from state to state (Orenstein et al., 2004). In November 2007, the state of Maryland ordered parents of 2,300 students to court in an effort to ensure compliance of the state vaccine mandates. Their punishments varied from immediate compulsory vaccination of the student to fines or the arrest and detention of the students' parents in the Maryland penal system. The results of the Maryland mandate crackdown included 1,400 correctly immunized students and a host of upset parents (Kuchment, 2007; Manning, 2007).

Rather than restricting individuals from using government programs, funding mechanisms offer the positive incentive of free or reduced-cost vaccine services to influence voluntary adoption. By subsidizing vaccines, a government encourages adoption by raising the relative advantage, since a reduction in cost at the individual level increases the cost-effectiveness (i.e. relative advantage) of innovating (Rogers, 2003). Moreover, when combined with a mandate, funding ensures compliance for those in lower socio-economic groups.

### ***Summary***

As discussed earlier, HPV is the most prevalent STI, and is associated with cervical cancer and genital warts (Centers for Disease Control and Prevention, 2007a; Weinstock, Berman, & Cates, 2004). In response to this growing threat, Gardasil® quadrivalent HPV vaccine was introduced to address the cancer and warts associated with HPV. As an innovation that addresses a prevalent disease, many politicians have attempted to encourage adoption of this vaccine, either through mandate or funding



(National Conference of State Legislatures, 2007).

Past court rulings have held that states have the right to mandate vaccines in the interest of public health. Traditionally, these vaccines covered diseases that were highly contagious and casually communicable (Evans, Harris, & Levine, 2004; *Jacobson v Massachusetts*, 1905; Orenstein, Rodewald, & Hinman, 2004). HPV, as a disease, varies from previously mandated diseases in that HPV requires direct genitalia contact between two people and is not casually communicable (Centers for Disease Control and Prevention, 2007a). This variance has sparked critical debate between social liberals (Democrats) and social conservatives (Republicans), where social liberals tend to side in favor of mandate, while social conservatives tend to argue against mandate.

As an innovation, Gardasil® can be observed to diffuse among a population. Its characteristics lend itself toward potentially having a long decision period prior to adoption. Its preventive nature, high cost, and unknown, unintended societal consequences create a low relative advantage that will likely make the adoption process slow.

Since adoption at the individual level is much more difficult to observe, observance at the state level can produce quantifiable results with easy to interpret comparisons between social liberals and social conservatives through party affiliation of elected representatives (Grossback et al., 2004; Mooney, 2001; Walker, 1969). Through proposing or passing legislation that mandates or provide funds for the HPV vaccine, states can be said to adopt the innovation through the actions of the elected representatives.

## CHAPTER III

### METHODOLOGY

To test the hypothesis (H1) that there is an association between mandating use of or funding for the HPV vaccine and such variables as state health and political characteristics (for the time period studied), logistic regression analyses were conducted using SPSS. The data used for this research was secondary, quantitative data collected on state proposed and enacted mandated use of and funding for the HPV, as well as potential influencing state factors. These potential influencing factors are state health and political characteristics. Odds ratios were used to evaluate the associations between the independent and dependent variables using a statistical significance level 0.05. The data used for state health and political characteristics was the most recent data available in March of 2007. The sources of the data will be discussed by variable below.

#### *Independent Variables*

The state health characteristics (independent variables) used in this study are state cervical cancer incidence rates per 100,000 women, Pap smear screening percentage, percentage of uninsured women by state, and United Health Foundation state health score. The state political characteristics (independent variables) in this study are state legislative political control (Democrat majority of state legislature, Republican majority

of state legislature, or House and Senate controlled by different parties) and gubernatorial political party affiliation.

Cervical cancer incidence rates by state were collected from the 2005 Centers for Disease Control State Cancer Registry and the National Program of Cancer Registries Cancer Surveillance System (National Cancer Institute, 2006). The most current state level cervical cancer age-adjusted incidence rates (between 2003 and 2004) for all females were utilized. These invasive cervical cancer rates were calculated by CDC using SEER\*Stat, a statistical software used for studying cancer, and reported on the National Cancer Institute *State Cancer Profile* (National Cancer Institute, 2006).

Pap screening percentages were collected from the CDC's 2004 Behavioral Risk Factor Surveillance System (BRFSS) Data. The BRFSS is the largest phone health survey which is conducted annually on a variety of health issues across all 50 states and U.S. territories (BRFSS, 2007). The BRFSS 2004 surveyed U.S. women over 18 years of age to determine the percentage of women who have had a pap screen in the last three years by state (*Women's Health*, 2007).

The Kaiser Family Foundation analysis of the insurance status for women ages 19 to 64 by state reported the percentage of uninsured women, which was utilized for the variable "uninsured women" in this study. The Kaiser Family Foundation based its report on insurance status on data collected from the Census Bureau's 2006 and 2007 *Current Population Survey (Health Insurance Coverage*, 2006).

The National Governors Association (NGA) report entitled *Governors of the American States, Commonwealths and Territories* was used for the source of the political

affiliations of governors for each state (*Governors: The American States, Commonwealths, and Territories*, 2007). The NGA is a non-partisan organization of governors that provides education, support, collaboration forums, and advocacy. Gubernatorial party affiliation identifies the state governor's political affiliation as reported by the National Governors Association: Republican, Democrat, or other.

The state legislative composition of the state legislatures is reported by the National Conference of State Legislatures (National Conference of State Legislatures, 2006). The state legislative composition was reviewed to determine the political party control of the two chambers of a state legislature. In cases where one party controls both chambers, the legislature majority control was assigned to the controlling political party. When the Republican Party controls one chamber and the Democratic Party controls another, the legislative majority is determined to be split. Any outlying political power distribution where political control differs from these two dominant scenarios, such as one chamber is controlled by one party and the other has no clear dominating party, the variable determined mixed.

United Health Foundation (UHF) is a non-profit, private foundation based in Minnetonka, Minnesota. The UHF assigns scores to states based on numerous health factors in its annual assessment *America's Health Rankings: A Call to Action for People & Their Communities* (United Health Foundation, 2006). The health factors used to evaluate the overall health fall into the following categories:

- Personal behaviors - prevalence of smoking, motor vehicle deaths, prevalence of obesity, high school graduation rate;

- Community environment - violent crime, occupational fatalities, infectious disease, children in poverty;
- Public health and health policies - lack of health insurance, per capita public health spending, immunization coverage;
- Health services - adequacy of prenatal care, quality of care, cost efficiency; and
- Health outcomes - poor mental health/physical health days, infant mortality, cardiovascular deaths, cancer deaths, premature deaths.

The 2006 overall state health score was used as an indicator of overall state public health. This score assigned based on numerous health factors. The national average (0) is considered the baseline and scores are determined to have a positive or negative score based on its health factors in comparison to the national average (United Health Foundation, 2006).

### ***Dependent Variables***

The dependent variables were HPV vaccine school entry mandates proposed or enacted, and vaccine funding legislation with funds earmarked for HPV vaccine or general funding increases to vaccine programs proposed or enacted. The source of the HPV vaccine school entry mandate variable was from data reported by the Women in Government (WIG) in its state activity policy update, *Women in Government Challenge to Eliminate Cervical Cancer Campaign State Activity, Activity as of March 17, 2007* (Women in Government, 2007a). WIG is a non-profit, bi-partisan association of elected

women lawmakers which specializes in education and networking. It is a comprehensive source of standardized state level political HPV vaccine actions.

The HPV vaccine funding variable data were reported by the National Conference of State Legislatures (NCSL) on its website under State and Federal Issues: HPV Vaccine 2007 tracking, which was updated March 2007 (National Conference of State Legislatures, 2007). This site provides updates from each state's legislative session. NCSL is a non-profit, bi-partisan organization that offers state and territorial legislative bodies research, education, advocacy, and collaborative assistance. The NCSL HPV report offered a standardized, cross-sectional view of state legislative action(s). Without this overview of state legislative activity, data would have to have been collected from each state's legislative body.

Given the difficulty of measuring individual adoption of the innovation, elected officials serve as proxy for the general population they represent for this study. Since elected officials can be divided by political party (except in the Nebraska legislature) a study can determine if a correlation exists between an elected political majority of a state and the decision of that state to adopt the vaccine (Adams, 2006; National Conference of State Legislators, 2006). For the purpose of this paper, elected officials demonstrate state-wide adoption through proposing or passing a HPV vaccine mandate or through proposing or passing a HPV vaccine funding bill. As such, HPV vaccine school entry mandates and HPV vaccine funding symbolize vaccine policy adoption.

### *Variables and Diffusion of Innovations*

The Diffusion of Innovations concepts of relative advantage, compatibility, and adoption have direct application in this study. For example, the independent variable of state health characteristics utilized in this study can demonstrate the relative advantage of a state adopting HPV mandates or funding. The independent variable of state political characteristics demonstrates the compatibility of the vaccine policy adoption. As discussed in Chapter II, the social liberals may be more likely to adopt the innovation than social conservatives because social conservative beliefs vary from the beliefs required to adopt the vaccine voluntarily. The two-party system of American politics, Republicans (social conservatives) and Democrats (social liberals), easily divides a population of legislators and governors into groups from which a correlation between ideology and policy making can be measured. The corollary measurement, through use of the elected body as proxy of the state's population, describes the vaccine policy adoption over entire state's population.

Similarly, the dependent variables of proposal or passage of a mandate and proposal or passage of a funding bill represent the adoption of a vaccine policy as an innovation. As previously mentioned, individual adoption is difficult to ascertain within the scope of this paper. As such, the vaccine policies proposed or passed in state governments serve as a proxy for individual adoption, just as the elected serve as proxy for the states' individuals.

The Trialability, Observability, and complexity aspects of the Diffusion of Innovations theory serve act as constants for this study. The study represents a snapshot in time across the United States, and the study's scope is limited to the innovation of

Gardasil alone. Trialability, Observability, and Complexity are characteristics that are more typically used to compare between innovations and the results of an innovation over time. As such, these dynamic characteristics are “frozen” as constants because there is no baseline for comparison between states for these characteristics.

The Diffusion of Innovations concepts discussed assist the evaluation of policy diffusion. Through measuring the association between state characteristics and the diffusion of HPV vaccine policy across states a policy diffusion trend may emerge. The results of the logistic regression analyses are reviewed in depth in Chapter IV.



## CHAPTER IV

### RESULTS

#### *Descriptive Statistics*

HPV vaccine mandates have been proposed or enacted in 26 (52.0%) states. HPV vaccine funding initiatives or a general increase in state vaccine funding legislation have been proposed or enacted in 9 (18.0%) states. See Table 1. Data from 11 (22.0%) states were unreported.

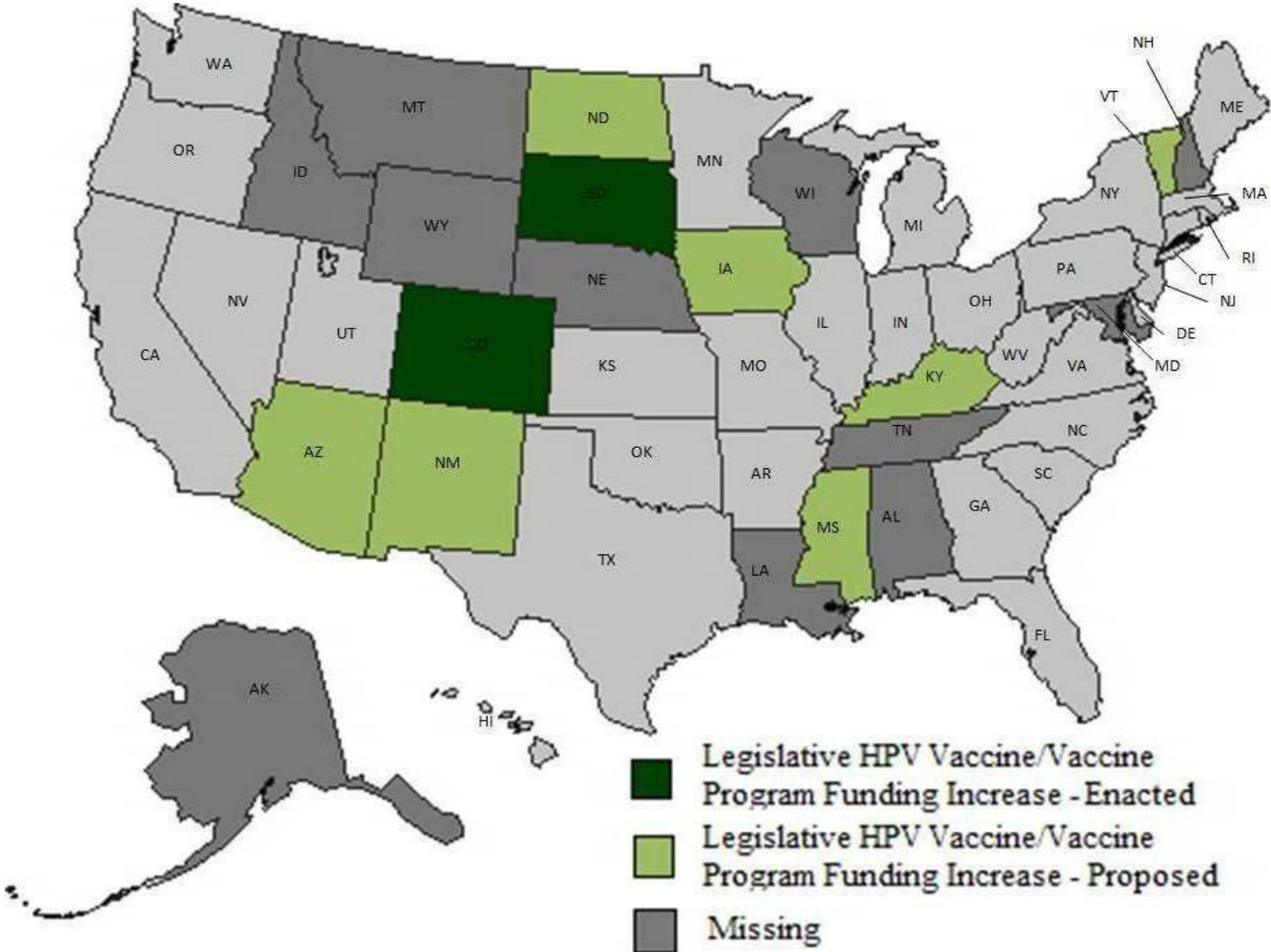
**Table 1.** *Descriptive Statistics: HPV Vaccine Proposed and Enacted Policy*

Dependent Variable	<u>Yes</u>		<u>Missing</u>	
	n (%)	n (%)	n (%)	n (%)
HPV Vaccine School entry Mandate (Yes)	26	52	0	0
Legislated HPV Vaccine Funding and General Vaccine Funding Increase (Yes)	9	18	11	22

In total, 25 states have proposed an HPV vaccine mandate and one state (Texas) has implemented a state vaccine mandate for school entry as of March 2007. See Figure 2. As of March 2007, seven states have proposed an increase in vaccine funding, while two states have approved an increase in vaccine funding. However, 11 states are missing data. See Figure 3.



**Figure 3. Proposed and Enacted HPV Vaccine or General Vaccine Program Funding by State**



(National Conference of State Legislatures, 2007)

State political characteristics are shown below in Table 2. The 2006 Gubernatorial party affiliation was relatively even across the 50 states: 22 Republicans (44%) and 28 Democratic (28%). State legislatures were also divided evenly with Republicans holding majorities in 20 states (40%) and Democrats holding majorities in 19 states (38%). In 10 states (20%), no clear majority was held by a single party. One state's data (Nebraska) was missing from this variable because Nebraska is a unique state with a unicameral, nonpartisan legislature (Adams, 2006).

**Table 2.** *Descriptive Statistics: State Political Characteristics*

Independent Variable			Missing	
	n	(%)	n	(%)
Gubernatorial Party Affiliation	50	100	0	0
Republican	22	44		
Democrat	28	56		
Legislature Party Majority	49	98	1	2
Republican	20	40		
Democrat	19	38		
Mixed	10	20		

State health characteristics are shown in Table 3. The data source for cervical cancer incidence rates did not include data on six states (National Cancer Institute, 2006). The median cervical cancer incidence rate per 100,000 women was 7.7. The Pap screening percentage had a range of 11.6 and a median of 86.0. Only Hawaii was missing from the primary data source. The median percent of uninsured women was

16%. No data was missing from the reported rate of uninsured women by state. The United Health Foundation overall state health score median was 3.7. No data were missing from this variable.

**Table 3.** *Descriptive Statistics: State Health Characteristics*

Independent Variable	Median	Range	(Min, Max)	N Missing	
Cervical Cancer Incidence	7.70	6.5	(4.4, 10.1)	44	6
Pap Screening Percentage	86	11.6	(78.2, 89.8)	49	1
Percentage of Women Uninsured	16	20	(9, 28)	50	0
United Health Foundation Score	3.7	41.6	(-20.4, 21.2)	50	0

### ***Logistic Regression Analysis***

Since this study was conducted using dichotomous dependent variables, logistic regression analysis was chosen to evaluate to association between the independent and dependent variables. The logistic regression model includes the variables of state policy proposed or enacted (either HPV vaccine school entry mandate or HPV vaccine or general vaccine funding legislation), cervical cancer incidence, Pap screening rate, percentage of uninsured women, the United Health Foundation score, political control of legislature, and gubernatorial party affiliation. In addition to the multivariable logistic regression model, univariate logistic regression models were analyzed to evaluate the significance of each variable to assist in model building independent from the full model.

The hypothesis (H1) that there is an association between mandating use of or funding for the HPV vaccine and such variables as state health and political characteristics (for the time period studied) was neither proven nor disproved. When using logistic regression analysis to test the association between the proposal or enactment of an HPV vaccine mandate and independent variables, only one variable (cervical cancer incidence rate) showed a significant association with the majority acceptance of an HPV vaccine school entry mandate. Within the multivariate model of HPV vaccine school entry mandate, cervical cancer incidence rate showed an odds ratio of 3.54 with a strong significance of 0.05 (Table 4). For each unit increase of cervical cancer, the probability of that state proposing or enacting a school entry HPV vaccine mandate increases 3.5 times. When examining the univariate analysis, the association is somewhat weaker, but it is extremely significant (0.019). For each unit increase of cervical cancer within the univariate analysis, the probability of that state proposing or enacting a school entry HPV vaccine mandate increases 1.82 times. Other independent variables included in the model were not shown to be associated with proposed or enacted HPV vaccine mandates. Similarly, HPV vaccine funding or general vaccine program funding shows no associations with the independent variables. See Table 5.

To test the validity of the logistic regression results, the same regression analysis was conducted using the latest available data on HPV state mandates and funding policy. The data was collected in the same manor and from the same sources as the data used in this study (March 2007) as noted in Chapter III; however, policy actions had been updated to October 2007 (National Conference of State Legislatures, 2007; Women in Government, 2007b). The logistic regression was conducted using the same methods and

analyses and the results yielded virtually identical results. As with the March 2007 data, the October 2007 data showed cervical cancer was the only significant variable associated with HPV state policy mandates. No additional associations were shown between the independent and dependent variables. These results are available in the Appendices.

**Table 4.** *Logistic Regression Model: HPV Vaccine School Entry Mandate Proposed or Enacted*

	<u>Univariate Model</u>			<u>Multivariable Model</u>		
	OR	95% CI	Sig.	OR	95% CI	Sig.
Cervical Cancer Incidence	1.823	1.103 - 3.011	0.019	3.540	1.462 - 8.572	0.005
Pap Screening Rate	1.040	0.831 - 1.301	0.733	1.207	0.859 - 1.695	0.277
Percentage of Women Uninsured	1.010	0.899 - 1.134	0.872	1.015	0.791 - 1.303	0.907
United Health Foundation Score	0.991	0.944 - 1.040	0.721	1.099	0.981 - 1.231	0.102
Legislative Majority - Democratic	0.727	0.228 - 2.316	0.590	1.938	0.358 - 10.501	0.443
Gubernatorial Party Affiliation	1.200	0.392 - 3.676	0.750	1.409	0.321 - 6.193	0.650



**Table 5.** *Logistic Regression Model: HPV Vaccine or General Vaccine State Funding Increase*

	<u>Univariate Model</u>			<u>Multivariable Model</u>		
	OR	95% CI	Sig.	OR	95% CI	Sig.
Cervical Cancer Incidence	0.639	0.344 - 1.188	0.157	0.618	0.259 - 1.479	0.280
Pap Screening Rate	1.041	0.760 - 1.426	0.801	1.187	0.700 - 2.012	0.524
Percentage of Women Uninsured	1.032	0.886 - 1.202	0.690	1.162	0.813 - 1.661	0.409
United Health Foundation Score	1.001	0.937 - 1.069	0.977	1.042	0.886 - 1.226	0.620
Legislative Majority - Democratic	0.956	0.213 - 4.284	0.953	1.361	0.115 - 16.128	0.807
Gubernatorial Party Affiliation	1.635	0.365 - 7.326	0.521	1.665	0.257 - 10.774	0.593

## CHAPTER V

### DISCUSSION AND CONCLUSION

#### *Summary of Results*

As shown in Chapter IV, the results of the study neither prove nor disprove the hypothesis (H1) that there is an association between mandating use of or funding for the HPV vaccine and such variables as state health and political characteristics (for the time period studied). Since conclusive results supporting or rejecting the hypothesis have not been demonstrated, further studies will be necessary to determine the extent that state health and political characteristics may be associated with state policy diffusion. The notable logistic regression results will be summarized below.

The state health characteristics had a variance of significance in association with state proposal or passage of a HPV school entry mandate. The logistic regression analyses showed a significant association between rates of cervical cancer and the likelihood that a state had implemented or proposed a HPV vaccine school entry mandate. States with high cervical cancer incidence rates (per 100,000 women) were significantly more likely to have proposed or enacted a HPV vaccine school entry mandate. However, the logistic regression analyses showed no association between other state health characteristics used in this study and the likelihood that a state implemented or proposed a HPV vaccine school entry mandate. Similarly, no association existed between state health characteristics and proposed or enacted state funding allocated for HPV vaccine or general vaccine programs.

The logistic regression analysis did not show associations between state political characteristics and the likelihood of a state proposing or enacting school vaccine mandates or vaccine funding policy. Neither gubernatorial party affiliation nor state legislature party majority were associated with HPV vaccine mandate. Similarly, a state's likelihood of proposing and enacting a funding initiative for HPV vaccine or general vaccine programs had no association with either state political characteristics examined in this study.

### *Implications*

Although the hypothesis was neither proved nor disproved, there are some implications for the results of this study. Specifically, there are three implications which directly relate to this study: relative advantage, compatibility, and dysfunction.

The association between mandate and cervical cancer incidence may speak to the concept of relative advantage. The study found that as the risk factor of cervical cancer incidence increased, the likelihood that a mandate would be proposed or passed also increased. The reasons for this are unknown. Since Gardasil®, as designed, prevents cervical cancer, it may be that state policymakers understood Gardasil®'s role as a cervical cancer reduction tool or perhaps they were influenced by the result of advocacy by Merck or others. That states with high incidence tend to propose or enact mandate policy may also suggest that those states' policymakers may have wanted to find a solution to prevent the long-term costs associated with high cervical cancer incidence. In these states, the risk of not innovating was higher, and when coupled with the costs of treatment, the cost-benefit of innovating was reduced.

In states with lower cervical cancer incidence, the lower relative advantage of innovating may have slowed their policy adoption. The lower risk states may experience a higher relative cost of adopting, as they are likely to spend less on cervical cancer treatment per capita than would a high cervical cancer incidence state. Moreover, the higher relative cost to prevent cervical cancer per capita, i.e., the costs associated with the vaccine compared to the current treatment per capita costs may explain the slow adoption of HPV policy in lower cervical cancer incidence states. The idea of relative advantage, as seen within the context of both high and low incidence states, supports the association shown in the study. The empirical rationale for innovation adoption may be weaker in lower cervical cancer states.

The lack of association between state political characteristics and state HPV policy may serve to illustrate that ideology did not significantly influence policymakers' HPV policy decisions. This has important implications when viewed as compatibility. Traditional Diffusion of Innovations theory would claim that compatibility has a significant impact on adoption rates (as discussed in Chapter II). However, instead of seeing a division of mandate or funding along party lines, the study found that regardless of state political characteristics, the only association with policy action was with cervical cancer incidence. While this may illustrate a bipartisan effort to overcome a common threat, it is possible that the newness of the innovation has yet to diffuse even among social liberals. Nevertheless, it is notable that Democratic and Republican representative affiliation was not associated with HPV policy proposed or enacted.

Finally, the study found that a dysfunction between state mandate policy and funding policy existed in that the two were not associated with the same variable

(cervical cancer). The study showed that mandate proposal or passage was significantly associated with cervical cancer incidence rates. However, the study did not find the same correlation with proposed or passed HPV vaccine funding or general vaccine funding. Several scenarios could account for the dysfunction between mandate and funding. One possibility is that the reason for this lack of correlation is that policymakers may tend to create a mandate prior to funding a vaccine. The inconsistency demonstrated between the two HPV vaccine policies may be due to other factors not reviewed in this study, such as variation in state budgets.

### *Limitations*

Given the observational nature of this study, a few limitations exist. These limitations include: the inability to meaningfully assess the impact of lobbying from special interest groups like Merck, use of secondary data instead of primary, the use of proxies to establish ideological compatibility with innovation adoption, and the short period of time elapsed since Gardasil®'s FDA approval and the ACIP recommendation.

The significant limitation of this study is the verified involvement of special interest lobbies discussed in Chapter II. Merck's direct involvement with WIG to lobby for vaccine mandates of Gardasil® may have added to the significance shown in the study between states with high cervical cancer incidence and state mandates proposed and enacted. Rationally speaking, Merck may have selected those states for the higher relative advantage. High cervical cancer incidence states already would have an empirical rationale for adopting, which might reduce the cost to market the policy innovation of a mandate for the vaccine. If their lobby efforts were successful, there

exists a possibility that the significance of cervical cancer as a factor affecting the likelihood of a proposed or passed mandate could have been overemphasized.

While Merck's involvement is documented, other special interest groups may have swayed the political process. Both social conservatives and social liberals may use special interest lobbies to advance their position, but the impact of special interest groups was not measured in the study.

A second limitation of this study is the use of secondary data. A more thorough survey of individual policymakers may have yielded more telling results and may have provided more information about how HPV policy is diffused through the political process. However, the resources and scope of this study eliminated this possibility.

The use of proxies to establish ideological compatibility with innovation adoption also limits the study. Proxies, while a convenient substitute for the purpose of this study, do not always mimic their assigned host. One example of a lack of mimic between origin and proxy evident in this study may be the nature of political assignment. Here, while politicians typically self-identify a single political party, many of their constituents may not self-identify with a single political party. Moreover, elected official's political party and ideology reflects only the party and ideology of the majority of voters, rather than the whole population represented by the official.

A final limitation is the short period of time elapsed since FDA approval and ACIP recommendation of the vaccine. Given that preventive innovations are slower to adopt than other innovations, the study was conducted at the infancy of the policy innovation. Furthermore, no "trial by others" at the state level exists. Follow-up studies may demonstrate differing results as time passes.

### ***Recommendations for Policymakers***

A lack of mandate or subsidized funding for vaccines may result in negative health outcomes for disadvantaged populations. As discussed in Chapter II, lower socioeconomic groups do not traditionally have high rates of vaccination in the absence of mandates and funding. If the lower socioeconomic groups do not receive the vaccination, the population will be at increased risk of the vaccine-preventable disease. As it relates to HPV, the long term disparity in HPV vaccination coverage rates could result in higher rates of cervical cancer among the disadvantaged socioeconomic groups. Given the potential disparities that may arise between socioeconomic groups, remedies should be addressed.

Where high incidence is coupled with a large population of underprivileged children who may be at high risk of not having access to the vaccine, mandates should be put in place. By mandating the vaccine, policymakers ensure access to the least advantaged by enforcing compliance as a school entry mandate. The result likely would be a reduction in statewide cervical cancer incidence and a reduction in treatment costs associated with cervical cancer for the state.

Where there is a mandate, states should provide funding to adequately cover the costs of vaccinating underprivileged children. Without funding, lower income families are at risk of not being able to access the vaccine, which may result in the loss of state services, like childhood education (as discussed in Chapter II). Funding ensures disadvantaged children the opportunity to adopt.

States with low cervical cancer incidence rates should wait to adopt HPV vaccine mandates to evaluate to cost-benefit of policy adoption. By waiting, low cervical cancer

incidence states could use “trial by others” to determine if potential unintended consequences are bearable. The knowledge gained by “trial by others” would confirm or discredit the relative advantage of the innovation for that particular state. In cases where public outcry for mandate is high, state policymakers in low incidence states should consider a funding only option.

Finally, policymakers should conduct a case study on Texas, since Texas was the only state to have enacted HPV vaccine mandate policy at the time of the study. A case study could help states understand the challenges and opportunities associated with implementing a state HPV vaccine mandate.

### ***Recommendations for Research Scientists***

Research scientists should utilize population surveys in future studies of innovation for more accurate individual adoption patterns. For example, the CDC National Immunization Survey (NIS) annually conducts surveys to determine vaccine attitudes and usage across the U.S. The NIS survey data is planning to add questions starting in 2009 about the HPV vaccine (Singleton, Wooten, & Jain, 2007). The future NIS data could measure vaccine adoption rates among the population to evaluate the groups of people adopting the innovation.

### ***Recommendations for Improving the Adoption of Gardasil®***

The focus of any marketing effort to encourage adoption of the HPV vaccine should be on educating key stakeholders about the association between HPV and cervical cancer. This allows the medical innovation to gain majority acceptance and start



movements toward greater adoption. By allowing families additional time to weigh the relative advantage of innovation adoption and discuss it with their healthcare provider, families may feel free to make the best health decision for their children. This also avoids the possible incompatibility with groups that oppose the vaccine.

Marketing which targets opinion leaders, such as healthcare providers and faith-based organizations, in education efforts also is an important strategy for diffusion of the HPV vaccine innovation. It is essential to educate these opinion leaders on the importance of adoption of the vaccine so they can give informed advice to others in their community. This may have a positive effect on innovation adoption by increasing the moral compatibility of the innovation through the demonstrated acceptance of community leaders.

Change agents should be rallied to engage community organizations that encourage voluntary vaccine adoption. This may reduce the need for a burdensome mandate, especially in low incidence states. For example, school districts should provide immunization drives. Given the plethora of vaccines, parents may appreciate the opportunity to ensure compliance with required state mandates, and provide proof of all vaccinations in a “one-stop-shop” idea. Moreover, if the vaccines could be provided at reduced cost voluntary adoption may increase.

Finally, Merck should be encouraged to provide discounted or donated vaccine to underprivileged groups, the states, or organizations that serve such groups.

## *Conclusion*

HPV prevalence as an STI has been documented. It also has been demonstrated that Gardasil®, as an innovation, addressed the looming risk of treatment of cervical cancer and genital warts. The study further demonstrated that Gardasil®, as an innovation, generally follows the notion of a preventive innovation as described by the Diffusion of Innovations theory. Moreover, it was determined through logistic regression models that cervical cancer incidence affects the likelihood that a state may propose or enact a mandate requiring the HPV vaccine for school entry. Using the Diffusion of Innovations lens, the correlation roughly equates to a high relative advantage for high incidence states.

While several avenues for policymakers, research-scientists, and leaders exist, a multidisciplinary, multi-tiered approach seems to address the complex nature of policy adoption among varying populations in varying states that each have their own unique needs and challenges. Regardless of how an individual state addresses the issue of HPV prevalence, their policy should include graduated mandate or funding depending on cancer incidence of the state, funding for mandates where mandates exist, and education coupled with financial consideration for the underprivileged. Policymakers may lack the understanding that funding alone may be an economical resolution to their state's cervical cancer incidence rate by immunizing a large percentage of the state's population without engaging in the political battles associated with the debates for a mandate. Additional study on reactions of states over the next few years is recommended.

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## APPENDICES

	State	Legis_Majority	Cervical_Cancer_Inc	Uninsured_Perc	Pap_Screening	United_Health_Focus	School_Mandate_Policy	Funding_HPV_vaccin	Legis_Majority	Legis_Majority	Gov_Political_Affiliation
1	Alabama	Demo	8.4	19	87.4	-14.8	No	.	No	Ye	Republica
2	Alaska	Repub	.	20	88.8	-8	No	.	Yes	No	Republica
3	Arizona	Repub	.	23	85.2	-4.0	No	Yes	Yes	No	Democrat
4	Arkansas	Demo	9.8	23	81.8	-16.1	No	No	No	Ye	Democrat
5	California	Demo	8.0	21	84.8	4.7	Yes	No	No	Ye	Republica
6	Colorado	Demo	6.8	18	88.3	8.9	Yes	Yes	No	Ye	Democrat
7	Connecticut	Demo	7.2	12	87.8	17.2	Yes	No	No	Ye	Republica
8	Delaware	Split	5.9	12	87.7	-.6	No	.	No	No	Democrat
9	Florida	Repub	9.2	24	84.1	-10.6	Yes	No	Yes	No	Republica
10	Georgia	Repub	9.6	20	87.9	-11.7	Yes	No	Yes	No	Republica
11	Hawaii	Demo	6.3	11	.	17.9	No	No	No	Ye	Republica
12	Idaho	Repub	6.5	18	78.8	6.5	No	.	Yes	No	Republica
13	Illinois	Demo	9.3	16	87.5	3.7	Yes	No	No	Ye	Democrat
14	Indiana	Repub	7.8	15	82.5	-3.7	Yes	No	Yes	No	Republica
15	Iowa	Mixed	6.2	12	86.0	12.5	No	Yes	No	No	Democrat
16	Kansas	Repub	7.9	14	86.2	7.9	Yes	No	Yes	No	Democrat
17	Kentucky	Split	9.8	18	85.0	-10.1	Yes	Yes	No	No	Republica
18	Louisiana	Demo	9.2	27	85.2	-20.4	No	.	No	Ye	Democrat
19	Maine	Demo	8.0	11	88.8	13.7	Yes	No	No	Ye	Democrat
20	Maryland	Demo	9.3	15	89.0	-2.7	No	No	No	Ye	Democrat
21	Massachus	Demo	5.2	11	89.3	15.3	Yes	No	No	Ye	Democrat
22	Michigan	Repub	7.6	13	86.5	2.3	Yes	No	Yes	No	Democrat
23	Minnesota	Split	6.7	9	87.9	21.2	Yes	No	No	No	Republica
24	Mississippi	Demo	.	21	84.5	-19.9	Yes	Yes	No	Ye	Republica
25	Missouri	Repub	7.9	17	84.8	-4.1	Yes	No	Yes	No	Republica
26	Montana	Mixed	6.0	19	86.1	4.9	No	.	No	No	Democrat
27	Nebraska	Unkno	7.6	13	85.8	12.4	No	.	.	.	Republica
28	Nevada	Split	9.8	20	84.8	-8.4	No	No	No	No	Republica
29	New Hamp	Repub	6.6	13	89.8	18.9	No	.	Yes	No	Democrat
30	New Jersey	Demo	9.2	16	84.3	11.0	Yes	No	No	Ye	Democrat
31	New Mexic	Demo	9.3	27	84.7	-10.4	Yes	Yes	No	Ye	Democrat
32	New York	Split	8.5	15	85.4	1.1	Yes	No	No	No	Democrat
33	North Carol	Demo	7.0	19	88.4	-4.3	No	No	No	Ye	Democrat
34	North Dako	Repub	6.4	11	83.3	15.0	No	Yes	Yes	No	Republica
35	Ohio	Repub	8.1	13	86.5	3.7	Yes	No	Yes	No	Democrat
36	Oklahoma	Split	9.4	24	82.9	-13.1	Yes	No	No	No	Democrat
37	Oregon	Split	6.3	20	83.5	6.5	No	No	No	No	Democrat
38	Pennsylvan	Repub	7.6	11	84.3	1.8	No	No	Yes	No	Democrat
39	Rhode Isla	Demo	6.8	12	89.0	11.4	No	No	No	Ye	Republica
40	South Carol	Repub	8.2	20	87.1	-16.4	Yes	No	Yes	No	Republica
41	South Dako	Repub	4.4	14	87.3	7.5	No	Yes	Yes	No	Republica
42	Tennessee	Split	.	15	87.3	-16.2	No	.	No	No	Democrat
43	Texas	Repub	10.1	28	82.1	-4.7	Yes	No	Yes	No	Republica
44	Utah	Repub	6.4	20	78.2	16.3	No	No	Yes	No	Republica
45	Vermont	Demo	7.3	12	87.7	20.5	Yes	Yes	No	Ye	Republica

	State	Legis_Majority	Cervical_Cancer_Inc	Uninsured_Percent	Pap_Screening	United_Health_Fund	School_Mandate_Policy	Funding_HPV_vaccin	Legis_Majority	Legis_Majority	Gov_Political_Affiliation
46	Virginia	Repub	.	14	87.4	5.7	Yes	No	Yes	No	Democrat
47	Washington	Demo	6.8	14	85.4	10.2	No	No	No	Ye	Democrat
48	West Virgin	Demo	9.3	20	82.6	-12.8	Yes	No	No	Ye	Democrat
49	Wisconsin	Repub	6.6	10	85.7	13.3	Yes	.	Yes	No	Democrat
50	Wyoming	Repub	.	19	86.0	4.7	No	.	Yes	No	Democrat

*Logistic Regression Analysis, October 2007 Data: HPV Vaccine Policy (Proposed and Enacted)*

	<u>HPV Vaccine School Entry Mandate</u>			<u>HPV Vaccine/General Vaccine Funding</u>		
	<u>Multivariable Model</u>			<u>Multivariable Model</u>		
	OR	95% CI	Sig.	OR	95% CI	Sig.
Cervical Cancer Incidence	2.833	1.251-6.414	0.013	0.662	0.283-1.547	0.341
Pap Screening Rate	1.266	0.884-1.813	0.199	1.551	0.782-3.076	0.209
Percentage of Women Uninsured	0.996	0.784-1.266	0.975	1.278	0.848-1.927	0.241
United Health Foundation Score	1.082	0.972-1.204	0.150	1.046	0.873-1.254	0.628
Legislative Majority - Democratic	1.015	0.212-4.863	0.985	1.196	0.089-16.102	0.893
Gubernatorial Party Affiliation	1.093	0.260-4.597	0.904	0.885	0.129-6.069	0.901