

Attitudes, Practices, and Beliefs About
Human Papillomavirus Vaccine Among
Young Adult African-American Women:
Implications for Effective Implementation

By
Chastity L. Walker

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Approved by:

Chair: Suzanne Havala Hobbs, DrPH

Sandra Greene, DrPH

Michel D. Landry, PhD

Elizabeth Randall-David, PhD

Mona Saraiya, MD

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ABSTRACT

Chastity L. Walker: Attitudes, Practices, and Beliefs About
Human Papillomavirus Vaccine Among Young Adult African-American Women:
Implications for Effective Implementation
(Under the direction of Suzanne Havala Hobbs, DrPH)

Cervical cancer is both a preventable and treatable disease. Racial and ethnic minorities and those of low-socioeconomic status tend to experience the greatest morbidity and mortality due to cervical cancer. Vaccination against the human papillomavirus (HPV) has been shown to prevent cervical cancer and genital warts, and subsequently reduce the number of women requiring follow-up and treatment of abnormal Pap Tests. There is relatively little published evidence to assess acceptance and utilization of the HPV vaccine among minority and low socioeconomic groups. The purpose of this study was to generate knowledge and inform policy considerations to reduce cervical cancer incidence and mortality by use of the HPV vaccine among African-American women, aged 18-26. A qualitative descriptive study design sought to characterize the barriers to, and potential facilitators of HPV vaccine introduction to young adult African-American women, aged 18-26, while recommending strategies for implementation. The study comprised a mix of both primary and secondary data collection and analysis methods. Interviews were conducted with stakeholders demonstrating expertise in cervical cancer prevention and an assessment of the literature on vaccines, diffusion of innovation, and policy adoption was conducted to inform policy alternatives to promote receipt of the

vaccine among the target group. Several overarching themes emerged to suggest factors that might deter or promote use of the vaccine including: mistrust of government, access to vaccination, attitudes about health, varying opinions regarding HPV vaccine guidelines, social determinants contributing to cervical cancer disparities, and a comprehensive strategy for introducing vaccination among others.

Strategic recommendations to support implementation of HPV vaccination catch-up programs, specifically designed for African-American women, aged 18-26, include addressing gaps in knowledge thru expansion of a cervical cancer prevention social marketing educational campaign to Historically Black Colleges and Universities (HBCU's) and enhancing access by evaluating how best to integrate HPV immunization and cervical cancer screening delivery. These findings confirm that introduction of HPV vaccination to African-American women will require an incremental and targeted approach, and can be used by public health officials and policy-makers as they strive to improve the overall quality and delivery of cervical cancer prevention services.

Dedication

In memory of my beloved Grandmother,

Maeola Harriet Hooks-

A woman whose spirit exemplified *faith, strength, and compassion.*

Thank you for inspiring me and giving me the wings to soar!

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LIST OF ABBREVIATIONS

AA	African-American
ACIP	Advisory Committee on Immunization Practices
ACS	American Cancer Society
AED	Academy for Educational Development
CCC	Comprehensive Cancer Control
CDC	Centers for Disease Control and Prevention
DCPC	Division of Cancer Prevention and Control
FDA	Food and Drug Administration
HBCU	Historically Black Colleges and Universities
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HSI	Hispanic-Serving Institution
IRB	Institutional Review Board
MERCK	MERCK Pharmaceuticals, Inc.
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCCCP	National Comprehensive Cancer Control Program
OB/GYN	Obstetrician/ Gynecologist
REACH	Racial and Ethnic Approaches to Community Health
ROCC!	Reaching Out Against Cervical Cancer
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection

Abbreviations continued

S-CHIP	State Children's Health Insurance Program
UNC	University of North Carolina
VFC	Vaccine for Children Program
VPAP	Vaccine Patient Assistance Program (MERCK, Inc)
WIG	Women in Government

CHAPTER I: INTRODUCTION

A. Statement of the Issue

Cervical cancer incidence rates in developed countries such as the United States (US) are much lower than those in developing countries. Eighty percent of global cervical cancer cases and deaths occur in less developed nations,¹⁻³ and most of these deaths occur in Sub-Saharan Africa, South Asia and Latin America^{4,5}. In the United States, approximately 11,000 women are diagnosed with invasive cervical cancer, and 4,120 die from it annually.^{6,7} At one time, cervical cancer was the leading cause of cancer death among US women. However, regular use of the Papanicolaou Test (Pap Test), beginning in the 1970s, moved cervical cancer to the seventh most common cancer in the United States. Nonetheless, not all populations and geographic regions of the US have experienced equal declines in morbidity and mortality. In the US, groups with the highest mortality include African-American women in the South, Hispanics along the Texas-Mexico border, Whites in Appalachia, American Indians of the Northern Plains, Vietnamese-American, and Alaskan natives.⁸

The statistics related to African-American women are alarming considering cervical cancer can be detected through Pap screenings and treated when caught early. Recent data from the *2005 United States Cancer Statistics Report* show significantly higher age-adjusted incidence rates of cervical cancer among African-American women- at 10.3 per 100,000 (7.7 per 100,000 for Whites).⁷ African-American women are twice as likely to be diagnosed at

later stages as compared to white women, particularly in the Southern region of the United States.^{9,10} Similarly, the mortality rate for African-American women was 4.4 per 100,000, twice that of non-Hispanic White (2.2 per 100,000) women.^{9,11}

While some studies show that African-American women have similar rates of cervical cancer screening as their white counterparts, more recent data suggest disparities in cervical cancer screening, morbidity and mortality remain.^{11,12} African-American women over the age of forty have higher incidence rates of invasive cancer than white women but lower or equivalent rates to those <40 yrs of age.⁹ Studies confirm the highest rates of HPV infection occur among African-American women 20-29 years of age.^{13,14} Ley et al. concluded, the determinants of genital HPV infection are consistent with those associated with an increased risk of cervical cancer, particularly among African-American women.¹⁴ Hence, considerable racial and ethnic differences exist with regard to the burden of HPV infection and cervical cancer.

B. Background

The human papillomaviruses (HPVs) are a group of more than 100 viruses that may cause warts or benign tumors. Of these, over thirty types can be passed from person to person through sexual contact. HPV is the most common sexually transmitted infection (STI) worldwide.^{8,15-17} The incidence rates of HPV among men and women in the US are approximately 5.5 million per year, while the prevalence is even greater at 20 million. Prevalence rates for young adult women (18 to 30 years) typically range from 28 to 46 percent.¹⁸ The Alliance for Cervical Cancer Prevention (ACCP) estimates that fifty to eighty percent of sexually active women will be infected with the virus at least once in their

lifetime.¹⁶ The majority of women are infected during their teens, 20s, or early 30s. Most HPV infections occur without any symptoms and go away without any required treatment.¹⁹

Persistent infection with high-risk HPV types increases a woman's risk of developing invasive cervical cancer.^{19,20} Two types of HPV, 16 and 18, account for approximately 60 to 70% of cervical cancer cases.²¹ The rates of most STIs are higher among adolescents, young adults, minority populations, and populations with low socioeconomic status.²² The data appear to signal that race, ethnicity, and socioeconomic status are in some way associated with the burden and treatment of STIs, including HPV.

Studies confirm that in the United States there is a 50 percent higher incidence of cervical cancer among African-Americans compared to Whites.¹⁰ Data from the most recently published United States Cancer Statistics (USCS) report showed that in 2005, approximately 12,000 women in the U.S. were diagnosed with cervical cancer and nearly 3,900 women died in that year. Of those diagnosed in 2005, 1,794 were African-American women; 783 African-American women died as a result of cervical cancer in 2005. Thus, the rates of cervical cancer morbidity and mortality exceeded the proportion of this population in the larger U.S. population.⁷

In 2009, the U.S. Food and Drug Administration (FDA) approved Gardasil®, a new vaccine developed to prevent cervical cancer, precancerous genital lesions, and genital warts due to HPV. Gardasil®, manufactured by Merck, prevents infection of four HPV types, HPV types 16 and 18, which cause a large proportion of cervical cancer cases, and types 6 and 11 which cause 90 percent of genital warts cases.^{21,23,24} Steps are underway to approve Glaxo Smith Kline's Cervarix®, a bivalent vaccine against HPV types 16 and 18. Most of the research to date regarding the HPV vaccine has focused on adolescent girls, and the vaccine

has been extensively tested in females aged 9 to 26 years old. The vaccine has been shown to be highly effective in preventing the four types of HPV²⁴ in young women not previously exposed to the virus or prior to the onset of sexual activity. The current research suggests the vaccine is effective for five years.^{8, 24}

There has been much controversy associated with the vaccination of women in the upper age range, 19-26 years, in terms of effectiveness of the HPV vaccine and previous exposure to HPV. The prevalence rates of infection with HPV-6,-11.-16, or -18 shortly after sexual debut are well documented.^{25, 26} The current HPV vaccines are most certain to yield the greatest advantage to those girls and women who have not engaged in sexual activity, limiting their exposure to HPV. Though the benefit of vaccination among women who are sexually active may be less, catch-up vaccination of 13 to 26 year olds is recommended. According to Dr. Lauri Markowitz, “women infected with one HPV vaccine type could essentially benefit from protection against the other type(s) in the vaccine and may benefit from boosting the antibody response from future re-infection with the same HPV type.²⁷” Likewise, conclusions presented in a report from the Gardasil® FUTURE II Study Group support universal catch-up vaccination among young adult women, including those showing evidence of previous or current infection with 1 or more HPV vaccine types.²⁵ The prophylactic HPV vaccine has no therapeutic effect nor does it have a role in treatment. Further data from ongoing vaccine trials is needed to support recommendation in women older than 26 years.²⁴

The federal Advisory Committee on Immunization Practices (ACIP), who issues recommendations for use of vaccines in the US, in 2006 recommended the routine vaccination of girls 11 to 12 years of age for HPV.²⁸ Furthermore, the recommendation

allows for girls as young as nine years old, as well as girls and women ages 13-26 years, to be vaccinated.^{28 29} Gardasil® is to be dispensed in three doses over a six month period.⁸ Similarly, the American Cancer Society (ACS) published its own recommendations in early 2007 for HPV vaccine use. These guidelines are generally consistent with those of the ACIP, with the exception of routine screening for women aged 19-26. According to ACS, the efficacy and potential benefit of universal prophylactic vaccination of women aged 19 to 26 years diminishes, as the likelihood of sexual intercourse and exposure to HPV has occurred among this group. The ACS states there is currently insufficient evidence to recommend for or against universal vaccination of women aged 19-26 years in the general population. Catch-up vaccination is recommended for females aged 13-18 years.³⁰

As a result of the ACIP recommendation, the HPV vaccine will be administered through the Vaccine for Children (VFC) program, which provides free vaccines for children and adolescents through age 18 who are uninsured or receive Medicaid. Many young adult women who do not qualify will likely face significant challenges in accessing the HPV vaccine due to cost. There remains a lack of coverage for low-income women between 19 and 26 years of age, as there is no public purchase program for non-elderly adult recommended vaccines. Efforts to reduce the cost of HPV vaccination and facilitate the delivery of the vaccine through governmental, private and charitable support must continue to ensure equitable access.

C. Significance of Issue

Researchers and health professionals alike are encouraged by a vaccine against HPV²⁴ for millions of women, not only in the United States, but globally. Widespread

vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds.³¹ In addition, the potential to reduce both the economic and emotional burdens faced by women with an abnormal Pap test result who require additional testing and treatment will be a welcome benefit. The healthcare costs associated with follow-up of abnormal results are estimated to be as much as \$6 billion USD annually.^{21, 32-34 35} Although research on the uptake of the HPV vaccine among young women is limited, evidence suggests that this group would greatly benefit from immunization. Thus further study is warranted to determine the attitudes, beliefs, and practices regarding the uptake of HPV vaccines for young adult women, especially for high-risk populations such as racial and ethnic minorities.

Cancer disproportionately affects racial and ethnic minorities. The HPV vaccine has the potential to significantly reduce morbidity and mortality associated with cervical cancer.^{11, 36, 37} As a result, increasing uptake of the vaccine among certain populations may impact the disparities. Access to, and acceptance of HPV vaccinations may be influenced by factors ranging from insurance coverage, availability of vaccine, healthcare provider attitude, ability to navigate healthcare system, and potentially, the ability to pay out of pocket.³⁶⁻³⁸ In addition, other factors may influence one's ability to receive appropriate and timely health care.^{16, 37, 39, 40}

D. Purpose & Specific Aims

The purpose of this study is to more fully understand the issue of HPV vaccination among African-American women by addressing the following research questions:

1. What are the attitudes, practices, and beliefs about human papillomavirus vaccine among young adult African-American women?
2. What factors would be likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction among young adult African-American women, aged 18-26?

The research aims were:

1. Describe attitudes, practices, and beliefs about HPV vaccine among young adult African-American women;
2. Explore factors associated with nonparticipation in HPV vaccine use among African-American women;
3. Identify related attitudes and health practices associated with use or nonuse of HPV vaccine among young adult African-American women; and
4. Use the data collected to recommend policy considerations for enhancing acceptance of the HPV vaccine among young adult African-American women.

CHAPTER II: REVIEW OF THE LITERATURE

While access is important, there is a known relationship between knowledge, attitudes, and beliefs about preventive health; HPV vaccination; and intention to receive the vaccine.^{36, 41} Studies show that, in general, women have a vague or poor knowledge of HPV and how the infection is transmitted and treated. The literature also suggests there is a significant gap in knowledge of the association between genital HPV and cervical cancer.⁴²⁻⁴⁴ Furthermore, there are concerns around the efficacy and safety of the new HPV vaccine. Awareness and knowledge about the HPV vaccine could affect acceptance and a woman's ability to make an informed decision about vaccination.⁴⁵ According to Mays et al,⁴⁶ "the preponderance of existing research in this area has targeted women's knowledge of Pap smear testing or cervical cancer or both." This statement lends support to the need for additional research related to HPV vaccine knowledge and attitudes, especially among the African-American population.

There are unique challenges associated with a vaccine that targets an STI.⁴⁷ Social stigma and fear are often related to sexually transmitted diseases. Social processes are considered to have a key role in making healthcare decisions for certain population groups. The opinions of family members, friends, and significant others- those who form one's social network- are highly valued. Several elements of social support have been identified as having a strong influence on the health and well-being of individuals: emotional support, informational support, and instrumental support^{48, 49}.

Therefore, this literature will review factors that influence or deter young adult women from receiving the HPV vaccine. Definitions of key terms for the purposes of this literature review are as follows: (1) *Knowledge* is defined as one's awareness and understanding of HPV, the HPV vaccine, cervical cancer, and the relationship between the two (i.e, knowing how HPV is transmitted, diagnosed, and treated and that HPV is a precursor to cervical cancer, etc). (2) *Attitude* relates to one's acceptability of a vaccination to prevent HPV and willingness to be immunized (i.e. physician recommendation and/or consultation and issues around safety and efficacy, etc). (3) *Young Adult Women* refers to females between the ages of 18 and 26, all races.

This chapter reviews the literature (See Table 2.1) in two areas of inquiry related to this issue:

- Part 1: Knowledge of HPV and cervical cancer, and
- Part 2: Attitudes regarding HPV and the HPV vaccine

In addition, a portion of the literature will address the development of policy to inform decision-making:

- Part 3: Policy Analysis and Interpretation

A. Part One: Knowledge of HPV and cervical cancer

Knowledge of Human Papillomavirus

Despite the prevalence of human papillomavirus and its potentially harmful consequences, many people are not aware of HPV. Numerous studies^{18, 43, 44, 50-52} demonstrate that the US population generally has little awareness or knowledge of HPV a

lack of understanding that HPV is a sexually transmitted disease and that it is linked to cervical cancer. For example, the Moreira et al ⁵³ study showed that women demonstrated a vague understanding of how HPV is diagnosed and treated. While women participating in this study have a higher rate of awareness of HPV in comparison to the general public, the majority remain unaware that persistent infection with high-risk HPV types is associated with almost all cervical cancers. ^{53, 54}

Dempsey and Davis (2006) ⁵⁰ reported that among a sample of college students less than one third had ever heard of HPV; approximately 17 percent correctly indicated HPV as a sexually transmitted disease; and only 2 percent identified HPV infection as a risk factor for cervical cancer. This general lack of awareness about HPV correlated to low perception of risk of acquiring HPV infection and/or developing HPV-related disease.

In an effort to inform HPV education efforts, Friedman and Sheppard conducted thirty-five focus groups with members of the general public in six geographically dispersed U.S. sites. The study explored knowledge, attitudes, and communication preferences regarding HPV and its associated conditions. The results confirmed a lack of knowledge about HPV which was shown to serve as a barrier to acceptance of a vaccine. ⁵⁴

Giles and Garland ⁵⁵ conducted a survey of ninety women, aged 18-30 years, from three different groups: those attending a dysplasia clinic, a local university health service, and participants of Phase 3 HPV vaccine trial, about their knowledge of HPV infection, cervical cancer, Pap tests and HPV vaccine. Their results suggest that the majority of respondents have a good understanding of the Pap test; however, they did not understand the risk factors for HPV infection and the long-term consequences of persistent HPV infection such as cervical cancer. Likewise, most of the women surveyed had not heard of the HPV

vaccine. Similar results were noted in the Hoover, Carfioli, Moench⁴² study in which a convenience sample of sixty women were asked to complete a short survey that evaluated their HPV knowledge and priorities. Once again, the need for more education on HPV was identified. Although knowledge of HPV was low, the concern about cervical cancer was high among this group of women.

More recent work, as exemplified by Tiro et al⁵² documented an inverse correlation between factors associated with HPV awareness and factors associated with HPV-cervical cancer knowledge. Familiarity with HPV does not necessarily guarantee accurate knowledge about its link to cervical cancer.⁵⁶ The findings also suggest a woman's knowledge is likely to increase once she has had an adverse consequence from an HPV infection.

B. Part Two: Attitudes Toward/ Perception of Human Papillomavirus

Attitudes Toward Human Papillomavirus

Human papillomavirus is the most common sexually transmitted infection in the United States.^{18, 42, 50, 51, 54, 55, 57} The diagnosis of an STI like HPV can be embarrassing. Numerous studies show an association between the term sexually transmitted disease/infection or STD/STI with 'promiscuity', 'infidelity,' 'shame,' and 'guilt'.^{53, 54, 56, 58} Results from a study conducted by Waller et al suggest awareness that HPV is sexually transmitted was associated with significantly higher levels of stigma and shame.⁵⁹ HPV-based technologies may be associated with stigma that could adversely affect women's use of them and acceptance of HPV vaccination programs.⁵²

Mayeaux⁶⁰ proposes that patients are less anxious and more comfortable about their diagnosis if they are educated about their condition and available treatment options. Waller et al confirms, higher knowledge regarding the prevalence and cause of HPV is associated with

lower anxiety, suggesting that information may have a “normalizing” effect.⁵⁹ Conversely, Tiro et al⁵² state that the majority of women do not receive treatment for HPV and therefore miss the opportunity to learn about the infection and its effects from a health care provider. The Friedman study found a relationship between fear of being labeled as promiscuous if one received a vaccine against an STD as rationale for not seeking more information about HPV and not being immunized.⁵⁴ Waller et al⁵⁸ report increasing awareness of the link between HPV and cervical abnormalities might cause women with abnormal Pap smears to resent or distrust their partner and to feel unable to disclose their test results for fear of stigma.

Acceptance of Human Papillomavirus Vaccine

Gardasil®, a quadrivalent vaccine, targets HPV types that are responsible for approximately 70% of cervical cancer cases and 90% of genital warts. Cervarix®, a bivalent vaccine is expected to be introduced and considered for approval in the U.S. some time in late 2009. An important component to ensuring successful implementation of the vaccine is public acceptance. According to Mayeaux,⁶⁰ creating the foundation for acceptance begins with determining what people need to know about HPV through education and candid discussions about HPV-related diseases and the potential benefits of HPV vaccines.

Increasing general awareness and understanding of HPV infection and its effects, as well as assuring vaccine safety and efficacy, are key elements to vaccine acceptance.⁵¹ Hymel⁵¹ surmises that public and patient educational efforts must be consistent and promote messages that are clear and appropriate for the intended audiences. In addition, recommendation of the vaccine by a healthcare provider is essential to vaccine acceptability.^{51, 53, 61, 62} A study involving both adolescents and adults suggested that physician recommendation was one of the most important factors leading to the decision to

be vaccinated.⁵¹ In general, healthcare providers are more likely to recommend use of an HPV vaccine based on the following factors: 1) endorsement by a professional organization, 2) efficacy of the vaccine, 3) preference to administer vaccine to older versus younger patients, and 4) vaccination against both cervical cancer and genital warts rather than cervical cancer alone.^{61, 63, 64}

Likewise, individual acceptance is dependent on a number of factors including personal beliefs about the vaccine, as well as perceptions of the beliefs of others such as partners and parents. Health beliefs and prior behavior are important in motivating future health protective actions such as STI vaccination.⁶⁵ Khan et al¹⁸ explored the attitudes about and intention to receive an HPV vaccine among young women using a theory based model. The results of this study associated knowledge with intent to receive the vaccine and suggest that perceived beliefs of people within ones social network would significantly impact one's decision to be vaccinated.¹⁸ Similarly, studies suggest that education and information actively designed to inform men about cervical cancer have an impact on their female partners' willingness or ability to access services.⁶⁶

Perception of risk was identified as a strong predictor of vaccine acceptance in a study conducted by Moreira et al.⁵³ A sample of 204 women attending a public outpatient gynecological clinic was administered a questionnaire to assess their knowledge and attitudes toward HPV vaccination and clinical trials. They found that sexually active women and those with a history of three or more sexual partners were more likely to enroll in the HPV immunization trial. This suggests that one's perceived risk of the disease and benefits of the vaccine were factors associated with vaccine acceptability.^{53, 54, 56}

HPV vaccination has numerous public health benefits and holds remarkable promise for alleviating the clinical burden of illnesses related to HPV infection, as demonstrated in several studies.^{18, 42, 50, 51, 62} Zimet et al^{45, 62} found in their study examining the attitudes of a hypothetical HPV vaccine among women in a clinical setting that acceptability of the vaccine was dependent on how efficacious it was. Safety of the vaccine, side effects, cost, and degree of protection have been identified as contributing factors to a woman's acceptance of the vaccine. These conclusions are consistent with those of other studies of STD vaccine acceptability.^{54, 62}

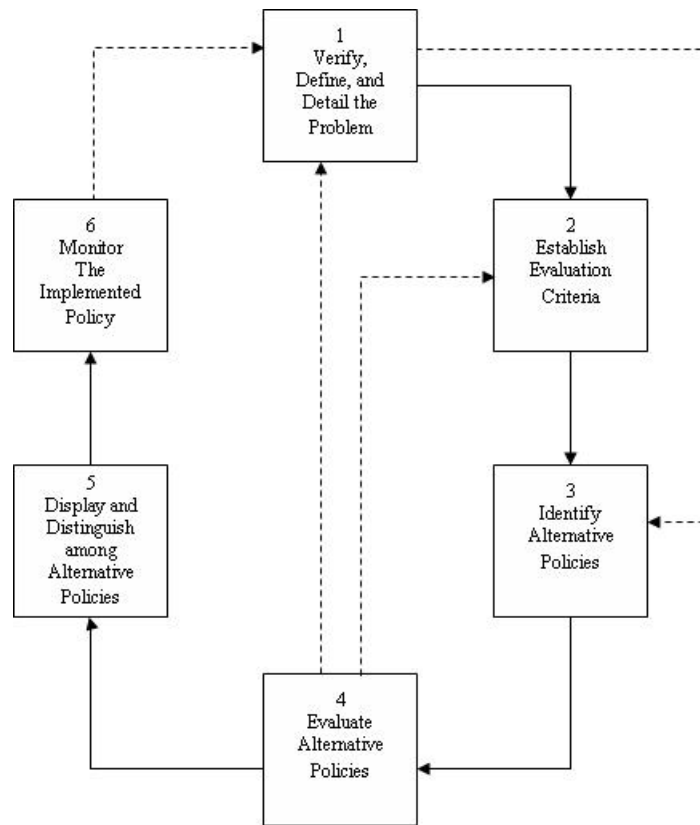
C. Part Three: Policy Analysis and Interpretation

In addition to reviewing the literature on human papillomavirus, an assessment of policy analysis and development was conducted. Policy refers to plans, positions, and guidelines of an organization (government or private sector), groups, and individuals which influence decisions to achieve a desired outcome. Policy analysis can be described as the breaking up of a policy problem into its component parts, understanding them, and developing ideas about what to do.⁶⁷ As a result of these processes, alternative policies or programs are identified and evaluated that can be used to lessen or resolve social, economic, or physical problems.

In thinking about policy, Stone presumes that policy is shaped in political communities in a somewhat orderly sequence of stages.⁶⁸ Policy analysis and development is therefore a systematic evaluation of the technical and economic feasibility and political viability of alternative policies (plans or programs), strategies for implementation, and the consequences of policy adoption. Both quantitative and qualitative information, as well as various perspectives to approaching the problem, can be integrated into the analysis and

development of policy. Patton and Sawicki ⁶⁷ offer six-steps of a basic policy analysis process: 1) Defining the problem and objectives to be pursued, 2) Determining the evaluation criteria, 3) Generating a range of alternative policies, 4) Evaluating the policy options, 5) Comparing alternatives, and 6) Evaluating and assessing the policy outcomes.

Figure 2.1: A Basic Policy Analysis Process



Adopted from Basic Methods of Policy Analysis and Planning 2nd Edition Patton and Sawicki

At the most fundamental level, Stone describes policy issues within a three part framework: goals, problems, and solutions.^{67, 68} Formation of policy involves political actors or a group of actors who are concerned about the selection of goals and the means of

achieving them within a specified situation, where those decisions should be, within the power of those actors to achieve.^{67,68} Community values such as equity, efficiency, security and liberty, express goals and serve as standards for evaluating existing situations and policy proposals. Problems occur when there is a divergence between social goals and the current state of affairs; they are defined in terms of causes-what generated the issue; interests- who is lined up on each side; and decisions- what kind of choice they pose. Solutions then are an attempt to resolve this conflict by employing policies, which in some way, involve changing behavior. In *Policy Paradox*, the author addresses mechanisms for bringing about such change which include: creating incentives and penalties (inducements), mandating rules, informing and persuading, stipulating rights and duties, and reorganizing authority.⁶⁸

There are various direct and indirect actions that can be undertaken to address public policy issues when the private market or government does not allocate goods efficiently or there are equity or distributional problems. Policy analysis is political argument which involves choices to include some things, while excluding others.⁶⁸ Utilizing a framework for policy analysis and planning has shown to reduce problems to a manageable size, allow others to evaluate the analysis and lessen subjectivity.⁶⁷ A systematic approach to policy analysis combines diverse ideas, which leads to better evaluation of alternatives.

Table 2.1. Results of Literature Review

AUTHOR(S) AND YEAR	TITLE	METHOD(S)/ STUDY TYPE	PURPOSE	KEY THEMES
Dempsey, A., & Davis, M. 2006	<i>Overcoming Barriers to Adherence to HPV Vaccination Recommendations</i>	Descriptive Analysis	Describe barriers to effective implementation of HPV vaccines	<ul style="list-style-type: none"> ▪ Attitudes Toward/ Perception of HPV ▪ Knowledge of HPV
Friedman, A. & Shepeard, H. 2007	<i>Exploring the Knowledge, Attitudes, Beliefs and Communication Preferences of the General Public Regarding HPV: Findings from CDC Group Research and Implications for Practice</i>	Focus Groups	Explore knowledge, attitudes and beliefs about HPV and HPV vaccine	<ul style="list-style-type: none"> ▪ Knowledge of HPV ▪ Attitudes Toward/ Perception of HPV
Giles, M. & Garland, S. 2006	<i>A study of women's knowledge regarding human papillomavirus infection, cervical cancer and human papillomavirus vaccines</i>	Survey	Assess knowledge regarding HPV infection, cervical cancer, Pap tests and HPV vaccines	<ul style="list-style-type: none"> ▪ Knowledge of HPV
Hoover, D., Carfioli, B & Moench, E. 2000	<i>Attitudes of Adolescent / Young Adult Women Toward Human Papillomavirus Vaccination and Clinical Trials</i>	Survey	Evaluate HPV knowledge and priorities, vaccine acceptability, and willingness to participate in HPV vaccine clinical trial	<ul style="list-style-type: none"> ▪ Knowledge of HPV
Hymel, P. 2006	<i>Decreasing Risk: Impact of HPV Vaccination on Outcomes</i>	Descriptive Analysis	Discuss issues related to US vaccine implementation	<ul style="list-style-type: none"> ▪ Acceptance of HPV vaccine

AUTHOR(S) AND YEAR	TITLE	METHOD(S)/ STUDY TYPE	PURPOSE	KEY THEMES
Kahn, J., Rosenthal, S., Hamann, T., & Bernstein, D. 2003	<i>Attitudes about human papillomavirus vaccine in young women</i>	Survey	Assess knowledge, attitudes about HPV vaccination and risk behaviors & Identify association between attitudes and intention to receive vaccine	<ul style="list-style-type: none"> Acceptance of HPV vaccine
Lambert, E. 2001	<i>College Student's Knowledge of Human Papillomavirus and Effectiveness of a Brief Educational Intervention</i>	Survey Longitudinal Study Cohort Pre and post-test (3months after intervention) Educational intervention	Assess college student's knowledge of HPV	<ul style="list-style-type: none"> Knowledge of HPV
Mays, R., Zimet, G., Winston, Y., Kee, R., Dickes, J., & Su, L. 2000	<i>Human Papillomavirus, Genital Warts, Pap Smears, and Cervical Cancer: Knowledge and Beliefs of Adolescent and Adult Women</i>	Descriptive Study/ Semi-structured Interviews	Examine knowledge and beliefs about genital warts, HPV, cervical cancer and Pap tests	<ul style="list-style-type: none"> Knowledge of HPV
Mayeaux, E. 2005	<i>Overcoming Barriers to HPV Vaccine Acceptance</i>	Descriptive Analysis/	Assess knowledge about HPV among women & psychosocial issues of HPV infection	<ul style="list-style-type: none"> Knowledge of HPV Attitudes Toward/ Perception of HPV Acceptance of HPV vaccine
Moreira, E., Oliveira, B., Neves, R., Costa, S., Karic, G., & Filho, J. 2006	<i>Assessment of Knowledge and Attitudes of Young Uninsured Women toward Human Papillomavirus Vaccination and Clinical Trials</i>	Cross-sectional study Interview	Assess knowledge and attitudes toward HPV vaccination	<ul style="list-style-type: none"> Knowledge of HPV Acceptance of HPV vaccine

AUTHOR (S) AND YEAR	TITLE	METHOD(S)/ STUDY TYPE	PURPOSE	KEY THEMES
Phillip, Z., Johnson, S., Avis, M. & Whynes, D. 2003	<i>Human Papillomavirus and the value of screening: young women's knowledge of cervical cancer</i>	Descriptive Study/ Survey	Assess knowledge of cervical cancer and screening and its relationship to HPV	<ul style="list-style-type: none"> Knowledge of HPV
Pitts, M. & Clarke, T. 2002	<i>Human Papillomavirus infections and risks of cervical cancer: what do women know?</i>	Descriptive Analysis/ Questionnaire	Assess knowledge of cervical cancer screening , risk factors for cervical cancer and its link to HPV	<ul style="list-style-type: none"> Knowledge of HPV
Tiro, J., Meissner, H., Kobrin, S. & Chollette, V. 2007	<i>What Do Women in the U.S. Know about Human Papillomavirus and Cervical Cancer?</i>	Survey Descriptive Analysis/ Cross-sectional study	Assess factors associated with women's awareness of HPV and link to cervical cancer	<ul style="list-style-type: none"> Knowledge of HPV Attitudes Toward/ Perception of HPV
Waller, J., McCaffery, K., Forrest, S., Szarewski, A., Cadman, L. & Wardle, J. 2003	<i>Awareness of human papillomavirus among women attending a well woman clinic</i>	Survey Descriptive Analysis	Assess knowledge of HPV	<ul style="list-style-type: none"> Knowledge of HPV
Waller, J., McCaffery, K., Forrest, S. & Wardle, J. 2004	<i>Human Papillomavirus and Cervical Cancer: Issues for Biobehavioral and Psychosocial Research</i>	Literature Review	Assess psychosocial impact of HPV testing and cervical cancer screening Risk factors associated with persistent HPV infection Prevention of HPV infections	<ul style="list-style-type: none"> Knowledge of HPV Attitudes Toward/ Perception of HPV
Zimet, G., Mays, R., Winston, Y., Kee, R., Dickes, J. & Su, L 2000	<i>Acceptability of Human Papillomavirus Immunization</i>	Individual Interviews	Examine attitudes about HPV vaccine	<ul style="list-style-type: none"> Acceptance of HPV vaccine

A total of 64 articles and abstracts were identified by searching a variety of databases using a variety of search terms in various combinations (See Appendix A). After applying the inclusion and exclusion criteria (See Appendix A), a total of 18 papers were reviewed and 16 were considered appropriate for inclusion in this review. Study results offered mixed conclusions regarding the knowledge and attitudes of young adult women as it relates to an HPV vaccine. The majority of the studies indicated a generally low level of knowledge regarding HPV. Attitudes toward HPV and vaccination against the sexually transmitted disease were varied. In addition, two texts, *Basic Methods of Policy Analysis and Planning* (Patton and Sawicki) and *Policy Paradox-The Art of Political Decision Making* (Stone), were used to review the literature on policy analysis and development.

D. Discussion

While awareness about HPV has increased over the past decade, understanding about HPV, how it is diagnosed and treated, and its link to cervical cancer remains low.^{52, 53, 56} Common barriers to HPV vaccination, in general, fall into 3 broad categories: 1) lack of knowledge about the vaccine or target disease, 2) problems of access to medical care, and 3) fears about vaccine safety. Vaccine efficacy, physician endorsement, and cost have shown to be important predictors of vaccine acceptability. Results emphasize the importance of informing and training healthcare providers about the vaccines and about the contribution of provider recommendations to decision making about health.⁵⁵ Moreover while most family physicians are aware of new information about human papillomavirus, including new DNA tests and a prophylactic vaccine, many remain unaware of information that may influence counseling messages and clinical management of HPV-related conditions.⁶⁹

Three principal findings emerged from this review of knowledge and attitudes of young adult women about human papillomavirus. The first and most definitive finding across

the literature confirmed the dearth of knowledge about HPV among the general population, specifically among young adult women. The development of appropriate and effective HPV communications must be based on an in-depth understanding of the target audience's current knowledge, attitudes, perceptions, and beliefs about HPV as well as their information needs and communication preferences.⁵⁴

Significant and sustained public education efforts designed to raise awareness about HPV and the benefits of HPV immunization will become necessary to ensure the wide use and successful implementation of the HPV vaccine. To be effective, HPV immunization initiatives aimed at young adults should provide accurate information about HPV infection and its link to cervical cancer and genital warts; should emphasize efficacy, safety and benefits of vaccination; and should assess normative beliefs about vaccination.

Furthermore, an air of skepticism and distrust of the government exists among certain populations that have historically been discriminated against in health research. Receptivity to public health information and vaccination messages is likely to be negatively affected as a result. Special efforts may be needed to reach certain populations such as African-Americans and American Indians with HPV messages that are perceived to be trustworthy.

The second major finding dealt with attitudes toward HPV. The public health and medical community must disconnect HPV from notions of promiscuity and stigma. While significant media attention has focused on the sexual nature of HPV transmission, much of the information is incomplete and fails to emphasize the importance of the link between high-risk HPV types and cervical cancer.⁵⁴ Whereas the preponderance of studies support increasing knowledge about HPV, it should be noted that raising public awareness has been associated with increased anxiety and fear among some groups. In addition, previous

research findings suggest that raising awareness of the HPV-STD-cervical cancer link could potentially result in further stigmatization of HPV, cervical cancer, cervical cancer screening, and HPV vaccination.^{54, 58}

Given the lack of a cure for HPV or agreement on effective prevention strategies for sexually active adults, and no approved test to detect HPV in men or no vaccine approved for boys, the public health community must be careful not to cause undue public alarm while promoting HPV awareness. Framing HPV as a cause of cervical cancer and universal public health issue as opposed to an STI will improve education efforts and the public's attitude toward HPV. The sexually transmitted nature of HPV could have further implications for vaccine adoption and the establishment of supportive state vaccination policies in the U.S.

The third finding addresses acceptance of the HPV vaccine. Misperceptions about vaccine safety pose additional barriers to use and add to the fear of vaccination. There appear to be reservations related to the newness and efficacy of the vaccine and its potential side effects.⁷⁰ Support from national medical organizations and professional associations will play an important role in facilitating vaccine implementation.

Reidesel et al⁶¹ reported that provider practice characteristics, knowledge about HPV, and attitudes were independently associated with intention to recommend HPV vaccination. Physicians whose focus is on women's health issues and those that work with patients at high risk for HPV-related disease may have a better understanding of HPV infection recognizing the potential health benefits of an HPV vaccine and thus more likely to recommend immunization.⁶¹ In contrast, there are some providers who may not recommend the vaccine to women who are sexually active or may have been exposed to HPV. Nevertheless, healthcare providers are an important source of information regarding the vaccine and recommendation from a doctor is known to be associated with acceptance of

HPV vaccination.^{71, 72} Results of a survey of physicians conducted by Raley et al⁶⁴ suggest that gynecologists are widely accepting of the HPV vaccine as a result of recommendation by the American College of Obstetricians and Gynecologists.⁷³

As the number of suggested vaccines rise along with escalating costs, financing for newly recommended vaccines is a potential barrier, particularly among young adults without private health insurance who may be left with the decision to pay out of pocket. Young women will be responsible for the full list price of the vaccine series (\$375.00) and additional expenses related to the administration of the vaccine and personal costs will be incurred. While the HPV vaccine has been added to the Vaccine for Children's (VFC) program, individual states will have to decide whether to make it available in public health departments or covered as a benefit through state Medicaid programs. It is likely that financial barriers may impede achievement of high vaccination coverage among those for whom the vaccine is recommended and most likely to benefit.

Although attitudes about HPV vaccination are broadly positive, parents have concerns about vaccinating young girls against STIs. Similarly, conservative Christian groups and pro-abstinence lobbies have spoken out against the vaccine.⁷⁰ The HPV vaccine should be seen and marketed as a cervical cancer prevention approach rather than one that promotes sexual promiscuity. Based on the literature, acceptability of the vaccine and its use should increase as the vaccine becomes more familiar and efficacy is proven over time.

There is also a concern that accomplishing effective implementation of an HPV vaccination program will lead to a reduction in adherence to Pap test screening. It is possible that as a result of this "success," the number of cervical cancer cases could potentially increase. Implications for public health policy should be directed at timely vaccination in conjunction with prescheduled screening times to detect and treat cervical lesions.⁵¹

E. Limitations of Literature Review

On the whole, there is a paucity of empirical research on HPV knowledge and even less regarding the attitudes and beliefs about HPV of young women. The papers included in this review represent the majority of research currently available. As pointed out by Waller et al,⁵⁸ studies investigating knowledge and awareness of HPV have tended to concentrate on the visible effects of the STI, such as genital warts, rather than the cancer-causing HPV types. Further emphasis should be placed on HPV and its link to cervical cancer.

Much of the available research is purely descriptive in nature. Few of the studies identified a particular theoretical framework, limiting the ability to examine whether a theoretical model explains how HPV knowledge influences attitudes and acceptance of a vaccine. The majority of the articles describe studies using survey methodology. Sample sizes were varied, ranging from small samples for focus groups or in-depth interviews to moderate and large sample sizes for studies conducted on a national level. Moreover, there is considerable variability in the format and a lack of standardized measures among the questionnaires used. Therefore, comparisons between and across studies were difficult to make.

Generally, the demographic characteristics of the samples examined were biased toward White women with a higher level of knowledge. Samples that are heterogeneous with respect to SES, age, and ethnicity are needed. Research to assess knowledge and acceptance of the HPV vaccine among minority and low socioeconomic status (SES) subgroups were not well represented and inadequate to a certain extent. As such, this suggests that the results of this body of research may not be generalizable to the broader population.

The methods used in this search are not exhaustive nor representative of all the literature available on the subject. Limiting the search primarily to the scholarly literature

could have resulted in the exclusion of relevant literature from other data sources. The search was conducted over a short period of time by a single author, and as such, limitations were placed on the number of articles reviewed. Future work in this area should include additional reference identification from the “grey literature” (e.g. papers, reports, technical documents) and material or publications from organizational websites.

For the purposes of this review, the literature is deficient and significant gaps in knowledge exist. With that said, the current body of knowledge offers a springboard for further analysis. In the coming months and years, the amount of literature related to HPV and immunization against the virus is expected to increase significantly. Additional research should focus on specific groups, for example high-risk populations, boys, and older women above thirty-five years of age who might make use of the vaccine, if the vaccine were approved.

Use of the HPV vaccine is an urgent public health policy issue. Further study from a socio-ecological approach will be required at all levels of influence including 1) policies and legislation at the institutional level, 2) cultural and social norms at the community level, 3) social support and social networks at the interpersonal level, and 4) personal knowledge, attitudes and behaviors at the individual level. This will help gain a better understanding of the issue and to prevent growth in the current socio-demographic inequalities that exist relating to cervical cancer incidence and mortality.

CHAPTER III: METHODOLOGY

Qualitative research methods permit an in-depth exploration of individual's intentions, actions, and interpretations and allow for a close examination of the context in which actions occur.⁷⁴ Additionally, qualitative research methods are useful for generating detailed descriptions of how context and action interrelate in specific cases.⁷⁴ A qualitative inquiry design was used in this study to learn more about the barriers and potential facilitators to increasing acceptance and use of the HPV vaccine among young adult African-American women. As will be described in this section, this research study included three separate but interrelated stages along with the two guiding research questions. This chapter describes the approach used to address the research questions posed in this study. Specifically, the guiding research questions and aims in this study were:

Research Questions

- 1. What are the attitudes, practices, and beliefs about human papillomavirus vaccine among young adult African-American women?*
- 2. What factors would be likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction among young adult African-American women, aged 18-26?*

Study Aims

Aim 1: To describe attitudes, practices and beliefs about HPV vaccine among young adult African-American women;

Aim 2: To explore factors associated with nonparticipation in HPV vaccine use among African-American women;

Aim 3: To identify related attitudes and health practices associated with use or nonuse of HPV vaccine among young adult African-American women;

Aim 4: To apply data collected to an analysis of and recommendations for policy considerations for enhancing acceptance of the HPV vaccine among young adult African-American women

A. Conceptual Framework

Many ecological factors have the potential to improve or harm health, and the “ecological perspective” offers a framework for understanding the complex interplay of individual, relationship, social, political, cultural, and environmental factors to addressing health problems.⁷⁵ The *Social Ecological Model*, also called *Social Ecological Perspective*, is a framework that examines multiple effects and the interrelatedness of social elements in an environment.⁷⁶ Elder et al⁷⁷ concluded that socio-ecological frameworks are essential in programs or studies that employ multi-level interventions and measurement strategies. The model recognizes that many external forces (intrapersonal, interpersonal, organizational/ community, and societal) influence individual determinants (Table 3.1). To facilitate behavior change, it is important to address these external forces.

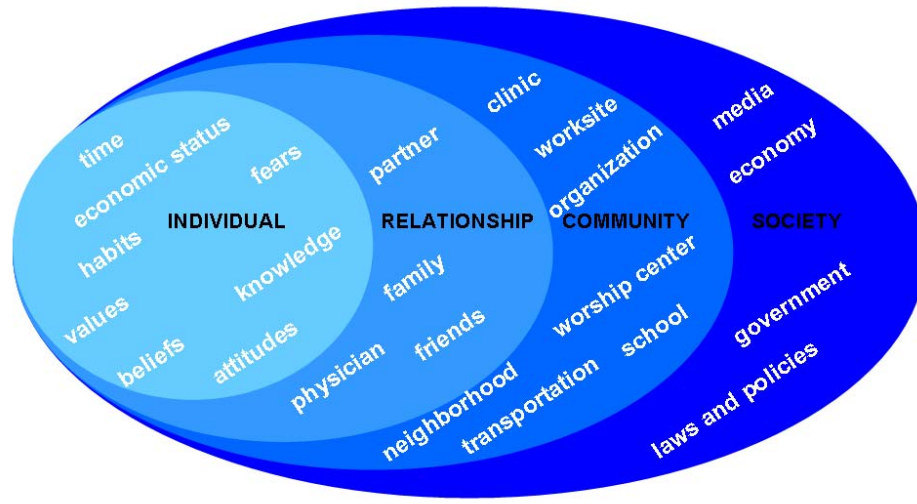
Table 3.1: Social Ecological Model

LEVEL OF INFLUENCE	INTERVENTION TARGET	VARIABLE OF INTEREST
Intrapersonal	Individual	Psychological (<i>attitudes, knowledge, beliefs, perceived risk, perceived benefits, self-efficacy</i>) Biological (<i>health status, risk factors, ethnicity</i>)
Interpersonal	Relationship	Partner influence; Peer/Family influence; Social support; Social Networks; Healthcare Provider
Community/Organization	Community, Schools, Worship Centers, Neighborhoods, Religious community, work setting	Social Norms; Cultural Norms & Beliefs; Rules; Access to resources and services; Social Capital
Society	Local, State, Federal Laws Public Health Community (governmental agencies & advocacy organizations) Media	Legislative and/or Regulatory approaches at multiple levels, Educational Campaigns Health Promotion Messages

Adapted from National Cancer Institute -Theory at a Glance: Summary of Theories (2005)

A conceptual model (Figure 2) was designed and used to guide the research. The model included factors supported by the existing literature and informed by the socio-ecologic framework. This model allowed for the integration⁷⁶ of multiple levels and contexts to establish the “*big picture*” associated with health behavior change, specifically uptake of the HPV vaccine for the purposes of this study. Research that focuses on any one level has been reported to underestimate the effects of other contexts.⁷⁸⁻⁸⁰ Hence, constructs of the Health Belief Model (HBM) are embedded within the ecological framework at the intrapersonal or individual levels. The Health Belief Model assumes that people’s beliefs about whether or not they are susceptible to disease, and their perceptions of the benefits of trying to avoid it may influence their readiness to act.^{75, 81, 82} This framework was used to identify facilitators and barriers to HPV vaccine acceptance and develop appropriate strategies to address the issue (Appendix A).

Figure 3.1. Socio-Ecological Model- Determinants of HPV Vaccine Acceptance and Use



B. Study Design

Multiple data sources were triangulated including an extensive review of the literature, data from semi-structured interviews, and a review of documents related to HPV vaccine, to reduce the validity threat of mono-methods bias.⁸³ Due to the exploratory nature of this study and novelty of the subject- HPV vaccine – a qualitative descriptive approach for this dissertation was most appropriate for creating knowledge and contributing to the body of research.⁸⁴ The formative research for this paper was conducted over several phases: Phase 1- Review of the Literature; Phase 2- Semi-structured Key Informant Interviews and; Phase 3- Policy Analysis and Interpretation. Systematic data collection methods such as interviews and document analysis were used. This process involved systematically gathering detailed and in-depth information about a person, social settings, phenomenon or group to allow researchers to understand how it operates or functions. For the purposes of this research study, and because it is an investigation into emerging health policy, the qualitative research design employed a multiple data gathering strategy to gain a detailed understanding of

facilitators and barriers to HPV vaccine acceptance and use while assessing policy considerations to promote immunization and cervical cancer prevention measures among young adult African-American women.

C. Phase One: Review of Literature February 2007 to July 2008

In the first phase of the research, an extensive review of both published and the “grey” literature was conducted describing factors that influence and/or deter young adult women from receiving the HPV vaccine. There were very few published manuscripts that dealt with the specific issues of HPV, cervical cancer, and HPV vaccine knowledge and/or attitudes among young adult African-American women, during the time in which the systematic review was conducted. Study results offered mixed conclusions regarding the knowledge and attitudes of young adult women as it related to HPV vaccination. In addition, the literature on policy analysis and development was reviewed.

D. Phase Two: Key Informant Interviews December 2008 to January 2009

During phase two of the research, a series of key informant interviews were conducted to supplement the publicly available literature and to explore the perceptions of individuals who are likely to have the greatest potential to inform policy considerations for improving vaccine use. Building upon data regarding HPV vaccine acceptance and use, individual health practices and cervical cancer prevention themes identified through review of the literature, a series of semi-structured interviews were conducted with key informants. The interviews were conducted to learn more about the determinants of HPV vaccine use among African-American women aged 18-26 years and to identify factors that may hinder or facilitate acceptance of the HPV vaccine. This phase of the study gathered information regarding preventive health of African-American women and knowledge of HPV and

cervical cancer. Additionally, the data collected included overarching HPV vaccination issues such as education, fiscal matters, implementation strategies, and barriers and facilitators to vaccination. Key informants offered insight into the issues around acceptance and use of the HPV vaccine and were able to offer recommendations to address them.

Selection of Key Informants

Political scientists categorize stakeholder groups across varied constituency groups. For this study, key informants from three principal stakeholder groups: healthcare professionals, government officials, and public interest groups were included. The participants represented a variety of sectors such as consumers, cervical cancer survivors, healthcare professionals (physicians of various specialties and non physicians), government and interest groups. Included in the sample were several national experts who offered extensive insight around the issues. Purposeful sampling of key informants with extensive knowledge of cervical cancer prevention, allowed for in-depth study and understanding of the proposed research questions.

Data Collection

To identify potential informants, a list of individuals with expertise in cancer prevention and control across stakeholder groups was generated, in collaboration with dissertation committee members. The initial list included 30 people representing the following: healthcare professionals (7); government officials (7); and public interest groups (16). The study design used a maximum variation purposive sampling approach to ensure that perspectives were representative of the major stakeholder groups.⁸⁵ Under the paradigm of maximum variation, data were collected to ensure inclusion of representative perspectives, while identifying new and emerging issues and important common patterns.⁷⁴

An invitation to participate in the interviews was extended to twenty-eight individuals. Due to time constraints and reasons of feasibility, two individuals who responded in the affirmative after the cut-off date of January 31, 2009 were not invited to participate. Overall, a total of nineteen interviews (N=19) were conducted in Phase 2 (See Table 3.2 below).

Table 3.2: Phase Two-Informant Interviews

Stakeholder Category	# Participants
Healthcare Professionals	5
Government Officials	5
Public Interest Group Stakeholders	9
Total Interviews	19

Initially, a goal was set to interview 24 individuals, however once theoretical saturation had been reached by the 15th interview, an additional 4 informants were interviewed to ensure strong consensus in addressing the research questions and to confirm that saturation had been reached. In this study theoretical saturation was defined as having been achieved when no new information or relevant themes were obtained from the interviews. The study thus included 5 practicing healthcare professionals (4 female, 1 male), including a nurse practitioner, pediatrician and obstetrician/gynecologists; 5 government officials (4 female, 1 male) representing various areas of expertise in public health; and 9 public interest group stakeholders (8 female, 1 male) reflecting the views of African-American women, the pharmaceutical industry, cervical cancer groups, and professional health and policy organizations. The interviews took place between December 2008 and January 2009.

Potential subjects were contacted by telephone or email to request their participation, at which time a brief description of the study was shared using a standardized script in English (See Appendix C-Recruitment script). For those agreeing to participate, a follow-up email was sent further explaining the nature of the study and the participant's role along with an informed consent form (See Appendix D- Informed Consent). Participants were asked to review, sign, and return informed consent forms at the time of or prior to the interview session. Appointments for interviews were also scheduled and confirmed by telephone and/or email.

Semi-structured interviews were conducted in person or over the telephone in an office setting. All interviews were conducted in English. A standardized instrument was developed and submitted to the UNC Institutional Review Board (*IRB Study# 08-1601*) for approval. The interview guide(s) contained both semi-structured and open-ended questions and related to each individual's role and experience in one of the three principal stakeholder groups (i.e. healthcare professionals, government officials, public interest groups). The full set of interview questions are available in Appendices E thru G. Stakeholders' perspectives were explored broadly, allowing the researcher to uncover hidden and emerging themes while maintaining the study focus. At the time of the interview session, subjects were asked to verbally confirm their permission to be audio recorded. All interviews were digitally recorded and detailed field notes were taken during and immediately afterward. The length of the interviews varied from 45 minutes to 75 minutes with the average interview taking approximately 55 minutes. Participants were extremely engaged and the general tone for all of the interviews was conversational. Each subject was sent a thank you note along with a \$25 gift card. Several participants declined the gift card.

Data Analysis

Immediately after each interview, the digitally recorded files were uploaded and saved onto a password-protected computer in the researcher's home office. The interview files were sent electronically in two separate sets to an individual external to the research team for transcription. Interviews were transcribed verbatim and verified against the audio recording to ensure that all thoughts and opinions were included in the analysis. Once verification of the transcripts was complete, the investigator conducted a content analysis, which involved identifying themes and categories prior to coding the data. In addition to the principal investigator, three individuals not involved in the research independently reviewed 15% or (3 of 19) of the transcripts to ascertain themes and categories. As a result, a set of codes and code definitions were developed. Each subject was given an alphanumeric identifier so their specific comments could not be linked to the data.

Upon completion of the content analysis, the interviews were imported into NVivo8™, a qualitative analysis software program for systematic analysis. The primary investigator performed all of the coding. Interviews were coded for important themes related to the phenomena under investigation. A variety of themes and patterns emerged through this multi-phase coding process. The themes included in the coding were based on the collective knowledge, perceptions, and experiences of the researcher, members of the research team, and informant interview participants, allowing for a robust analysis of each issue or topic that was being researched.

The codes that were used in *Phase 2* were designed to reflect the research questions being asked, but also to allow for sufficient opportunity for informants to expand upon the issues. The primary categories of "Attitudes, Practices, Beliefs", "Barriers", "Facilitators" and "Implementation Strategies" were subdivided or branched into more specific groupings,

and an “Other category” was added to include information that was important, but did not necessarily address the research questions being explored. Please refer to Appendix H for the primary codes, sub-codes, and definitions, used in *Phase 2*. Following the coding of all interviews, coding reports were generated for each of the codes in order to systematically analyze the information from the informants. The results of Phase 2 are presented in *Chapter 4: Results* of this dissertation.

E. Phase Three: Policy Analysis & Interpretation

During this phase of the research study a review and interpretation of relevant literature was performed associated with vaccine policy, diffusion of medical innovations, and the adoption of policies. A review of the vaccine literature was conducted to assess the current state of immunization policy in the U.S. and identify evidence-based approaches that may influence the determinants to increasing acceptance of the HPV vaccine. Two frameworks, the Socio-Ecological Model and Kingdon’s Three Stream Model, were employed in the evaluation of policy options addressing both the individual and public health perspective associated with increasing acceptance and use of a vaccine to prevent cervical cancer. The Diffusion of Innovations theory served as a framework for adopting new innovations, which has direct application to this study in relation to HPV vaccine adoption; concepts of this theory also aided in evaluation of policy diffusion. Furthermore, interpretation of the policy analysis will be used to guide development of the policy intervention and advocacy plan.

F. Ethics & Confidentiality

A request for ethics approval was submitted to the Office of Human Research Ethics-Institutional Review Board (IRB) at the University of North Carolina in September 2008, and

approval from the Public Health-Nursing IRB was obtained in early November 2008 (See Appendix D). As per the guidelines of ethical research, each individual who participated in this study was first contacted either by telephone or email. If the individual willingly chose to participate in this research by agreeing to an interview, they were emailed a cover letter describing the study, a follow-up email to schedule a time for the interview, and the consent form. As described elsewhere, the participants were then asked to review and return the signed consent form by fax to the primary investigator. All informants in this study provided voluntary, written and informed consent, gave verbal permission to tape record the interview, and understood fully that their answers were provided with anonymity. Once the data had been analyzed and the study completed, all recordings were destroyed to ensure that no responses would be linked to an individual or institution. The results are presented in aggregate and the names of the individuals held as confidential. Descriptors of key informants are attached to respondent's comments as depicted in *Chapter 4: Results*; in order to maintain confidentiality of the respondent, the participants name and organization are not included.

CHAPTER IV: RESULTS

This chapter reports the analysis and results of interviews conducted with key informants to learn more about the determinants of HPV vaccine use among African-American women aged 18-26, and to identify factors that may hinder or facilitate acceptance of the vaccine. The findings are presented and answer the studies research *Aims 1, 2, and 3*.

Research Question 1: What are the attitudes, practices, and beliefs about human papillomavirus vaccine among young adult African-American women?

Aim 1: Describe attitudes, practices, and beliefs about HPV vaccine among young adult African-American women;

Aim 2: Explore factors associated with nonparticipation in HPV vaccine use among young adult African-American women; and

Research Question 2: What factors would be likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction among young adult African-American women, aged 18-26?

Aim 3. Identify related attitudes and health practices associated with use or nonuse of HPV vaccine among young adult African-American women.

The questions posed to key informants were developed specifically for each of the three stakeholder groups 1) healthcare professionals, 2) government officials, and 3) public interest groups represented in the study, based on their area of expertise. It should be noted that

subjects' responses cannot be generalized to all African-American women but offer insight into the issues some may face.

A. Descriptive Analysis

The individuals included in this portion of the study embody a wealth of knowledge and expertise with regard to cervical cancer prevention and African-American women's health. Table 4.1 describes the interview participants- representatives of a variety of sectors including consumers, cervical cancer survivors, practicing healthcare professionals (physicians of various specialties and non physicians), government officials- representing a range of expertise in public health- cervical cancer, immunization, women's health and sexually transmitted diseases and representatives of public interest groups reflecting the views of African-American women. The participants included a group of national experts who offered extensive insight into the issues, underscoring their levels of experience and commitment, domestically and internationally.

Table 4.1: Key Informant Interview Participants by Stakeholder Group

STAKEHOLDER CATEGORIES	NUMBER OF PARTICIPANTS	SECTOR
Healthcare Professionals	5	Nurse Practitioner Pediatrician Obstetrician/Gynecologist
Government Officials	5	Public Health professionals: ◦ STD/HIV ◦ Immunization ◦ Cancer ◦ Women's Health
Public Interest Groups	9	Women Legislators Cervical Cancer Survivor Cancer Professional Org University Health Pharmaceuticals Educational Development African-American Health African-American Sororities

Nineteen individuals, out of a possible twenty-eight, participated in the key informant interviews for a total response rate of 68%. The following distribution of key informants across stakeholder groups: five healthcare professionals (27%), five government officials (27%) and nine members of public interest groups (48%), constituted the sample. A total of 19 semi-structured interviews were conducted, reflecting a diversity of knowledge, experience, and perspectives across the stakeholder groups. Work environments/settings of the sample were varied and included: private practices, public health department, non-profit healthcare organization, academia, federal and state government, academia (university), pharmaceutical industry, professional health and policy organizations, and civil society groups. Interview questions may be found in Appendices E-G.

B. Emergent Themes

Upon further review and analysis, codes that were associated or similar with each other were merged and organized into overarching themes. Through the analysis of the interviews, several themes emerged to suggest factors that may hinder or facilitate acceptance and use of the HPV vaccine among young adult African-American women. The themes are described below in Table 4.2.

Table 4.2: Emergent Themes

THEMES	
1.	AA perceptions of prejudice and a healthcare system rooted in racism and discriminatory practice's exacerbates disparities in HPV-related disease and is likely to impede vaccination.
2.	The high cost of the HPV vaccine is a significant barrier to both patients and providers.
3.	Health beliefs are influenced in numerous ways, having implications on health behavior decision-making.
4.	Social support and trust are essential in fostering HPV vaccination to AA women and building community buy-in.

5.	Concerns about the HPV vaccine, such as safety and side effects must be thoroughly addressed within communities of color prior to introduction.
6.	Overcoming barriers to HPV vaccination requires a multifaceted approach based upon community engagement.
7.	Preventive health and cervical cancer reduction should be considered within the context of overall health for AA women.
8.	Provider role and experience with HPV vaccination is a key component to vaccine delivery and patient decision-making.
9.	Benefits of HPV Vaccination to AA women 18-26 extend beyond protection against genital warts and cervical cancer.
10.	HPV knowledge and awareness is deficient across audiences- general public, patients and providers
11.	HPV education and communications would benefit from the use of technology and celebrity spokespersons.
12.	Effectively integrating HPV vaccination policies & strategies is critical to advancing reductions in cervical cancer incidence and mortality.
13.	Issues surrounding acceptance and uptake of vaccination against HPV extend beyond the women themselves and would benefit from further exploration (e.g. male vaccination and community confidence in vaccination).

After evaluation of the data based on these themes, the data were assessed in relation to the research aims. The various statements within the themes are organized to address research question one (*Aim 1 & 2*) and research question two (*Aim 3*). The results are reported in this dissertation from this perspective. Following is an overview of the themes along with illustrative comments by the interview subjects.

C. Key Findings

Key Finding 1: An inherent mistrust of government, the healthcare system, and industry is pervasive throughout the African-American community. Perceived or real discrimination and mistrust create skepticism, influencing the choices one does or does not make about his/her health. The significance of mistrust in the AA community is demonstrated on several levels.

Mistrust emerged as an issue of high importance, a barrier to a multitude of problems that plague the African-American community, including health. The overwhelming majority of informants agreed that uncertainty in terms of vaccines and suspicion of the healthcare

system in general hamper efforts to increase use of the HPV vaccine in this population. These findings are consistent with results of a study examining acceptability of HPV vaccination conducted by Scarinci et al, which confirmed a historical lack of trust in the medical system as a concern among African-American women.³⁶ Several respondents were familiar with the Tuskegee Study^{86, 87} and acknowledged its role and the nation's history of racism and discrimination, in shaping the negative views about government, the medical community and pharmaceutical industry, for generations of people of color.

I think overall, you know, African-American people have kind of a distrust with new things and new medicines and feel like things are experimental and that there's potential harm. (Government Official)

People still feel that the African-American population is still at risk of being tested on. (Healthcare Professional)

You know there are the traditional barriers, everything from history to genocide, to suspicions of the "man". (Public Interest Group- Pharmaceutical Industry)

Ramming it down people's throats is not a good idea and is potentially going to do more harm than good. I mean some people in some communities see it as "look at what the man is trying to make us do". (Public Interest Group- University Health nonprofit)

A participant who is a cervical cancer survivor speaks passionately about the consequences for African-American women who focus on medical abuse from the past:

I think the worse thing we do to ourselves as African-American women, we take care of everybody else and we don't take care of ourselves. We always say how we're left out, we're underserved. But I think we miss out on good quality healthcare when we have this preconceived notion of our past, of what's happened in our past. Are we going to keep living in the past, or demand and have access to good quality health care? (Public Interest Group- Cervical Cancer nonprofit)

Another informant representing a public interest group spoke about African-American people feeling as though they are being targeted for vaccination, which has considerable repercussions for acceptance of the vaccine. She states, "*When Gardasil® first came out, and the commercial had a number of black and brown girls in it, we [MERCK] were accused of trying to target them.*" She went on to explain that bearing a

disproportionate share of disease makes black and brown women targets, and if women of color understood this, perhaps they would be more aggressive in seeking out the vaccine.

Aware of the disparities in HPV infection and cervical cancer mortality rates, the vast majority of respondents pointed to the need to share data about the burden of disease among this population. On the contrary, a few respondents raised concerns that there is an underlying sentiment of ‘*bad news fatigue*’ among communities of color and especially within the African-American community; that disclosing these differences would have harmful implications.

Because we were talking about disparities and messages and things like that, you know, there should be no program and no messaging about black people getting more STD’s than white people. I think that is something that is not going to encourage anybody to go get an HPV vaccine or get a pap smear. (Public Interest Group- Health Education nonprofit)

The respondent went on to suggest that framing the statistics differently so as not to blame the victim would perhaps engender a feeling of receptivity.

I mean, this whole notion of saying black people are at higher risk, you have to then say why they’re at higher risk I guess. I mean, you know, why not just say, black people are at higher risk and one of the reasons is because, we so often historically had less access to getting early care and we deserve to get that early care and you know, there are ways to get that. Maybe that is more palatable than saying black folks are out there having unprotected sex more than white folks, which just can get people really pissed off and defensive and, you know, it’s very blame oriented. (Public Interest Group- AA Health nonprofit)

The above finding reveals a sentiment which suggests that emphasizing negative health outcomes may detract African-Americans from taking action to improve their health status. Rather than motivating people, the unintended consequences of framing health disparities and messages negatively may actually steer minorities away from participation in services and further reinforce mistrust. Consensus on the effectiveness of positively versus negatively framed messages has not been reached in health communications.

Skepticism about the validity of the data and how it is reported was expressed on several occasions. At a minimum these highlight respondents concerns about information bias, and mistrust of the medical establishment. One respondent suggested that all of the data about rates of infection and disease weren't being reported consistently across racial groups; that it was dependent on where one received healthcare (i.e. public health clinic versus private provider or not at all)

I know when I see that data I'm like I cannot believe that data, I'm skeptical. How do they, how do they prove that more black people get STD's than white people? You know, more black people use the public health system so they definitely have to track it that way but, these private docs, are they? I'm not clear on how that data gets collected. I'm absolutely not clear at all. (Public Interest Group- Health Education nonprofit)

As illustrated above, fundamental to these particular findings is the recognized need for information to be perceived as unbiased by both young adult women and the African-American community as a whole.

I think the education has to come from the community themselves, and for people who look like them because they think that's the only way that they feel that there's not a bias in how it's being brought to the community.(Government Official).

Several informants suggested that the government take a less prominent role, given historical and current events resulting in racist and discriminatory practices against blacks committed by government entities.

These particular findings suggest that high levels of medical mistrust hinder participation in preventive health practices, for instance vaccination and screening; as a result, individuals are more likely to present at more acute stages of illness when conditions have worsened. Medical behaviors such as this place an additional burden on the individual and systems of healthcare. Consequently, segments of society suffer from conditions that are preventable because of lack of confidence in the systems responsible for delivering high quality care to all.

Key Finding 2: Access to HPV vaccination by young adult African-American women is hampered, due to lack of affordability and availability, substantially limiting entrée by this population.

A number of questions were posed to informants about perceived barriers to HPV vaccination among African-American women. While there was no one response to this question, subjects repeatedly emphasized affordability of the HPV vaccine as a barrier. The high cost of the vaccine, at \$120 per dose with a requirement of three doses, was deemed a formidable obstacle for young adult women seeking vaccination, as this group is generally low-income and uninsured. One informant, an expert in immunization, noted that this was the most expensive vaccine of all of those recommended by the ACIP. For those over the age of 18, without private insurance that covers it, there is no system of financing in place to support full or subsidized payment for adult immunizations. Informants commented:

The issue of cost is something that I think in and of itself is a barrier to young adult females- if you have to pay \$300 then it's going to be a huge barrier, so all the communication messaging and attempts to influence its use are inconsequential without some kind of system that helps them cover it. I mean, if they can't afford it, they won't get it. (Government Official)

Expense of the HPV vaccine to providers was also viewed as a barrier because it affects their ability to adequately stock and administer the vaccine.

Reimbursement is not adequate, you don't always get paid for the vaccine from the insurance company..... In my opinion, Merck has priced the vaccine too high. The cost of the vaccine is about the same as what insurance companies reimburse. Which means there's no ability to have any overhead coverage, no profit in the vaccine. (Healthcare Professional)

These findings illustrate how cost can serve as tremendous obstacle in the receipt and administration of the HPV vaccine to both patients and providers. Currently, the high price is an impediment to the availability of the vaccine thereby reducing access, and subsequently,

introduction and uptake are likely to be delayed, particularly among certain populations. Furthermore, consideration must be given to the resources required to administer an immunization program beyond the purchase of vaccine, such as monitoring and surveillance functions, which contribute to the costs born by governments, insurers, and individuals. Ensuring access, especially to vulnerable populations, is a precursor for successful implementation.

Key Finding 3: The interplay of external forces in one’s environment, at multiple levels (individual, relationship, community, society) are influential in determining attitudes about health and health behaviors, particularly as it relates to AA woman’s acceptance of the HPV vaccine. These forces can either pose barriers or facilitate behavior change.

Barriers

Echoing the findings of numerous studies, respondents recognized that sociocultural issues of African-Americans and other minorities are germane to furthering efforts that support HPV vaccination to at-risk populations. Beyond identifying these factors, a thorough examination of how they impact attitudes toward immunization against HPV and consideration of the ways in which these attributes can be exploited to benefit these groups is critical to the development and employ of strategies for vaccine introduction. Table 4.3 summarizes the barriers that may hinder acceptance and uptake of HPV vaccination by young African-American women.

Table 4.3 : Barriers that Hinder Acceptance/Use of HPV Vaccine

BARRIERS	INFORMANT RESPONSES
Lack of Knowledge about Issues	<ul style="list-style-type: none"> ▪ Lack of knowledge/ information about HPV/ cervical cancer/ HPV vaccination ▪ Unaware of risks & benefits ▪ Lots of misinformation ▪ Awareness has not translated into knowledge
Access	<ul style="list-style-type: none"> ▪ Cost- unaffordable ▪ Availability
Lack of Perceived Risk/Need	<ul style="list-style-type: none"> ▪ Unaware of personal risk factors ▪ Preventive health is generally not a priority among this age group- feelings of invulnerability ▪ Sexual behavior- monogamous relationship ▪ Age group not part of routine vaccination schedule
Stigma associated with HPV and STI	<ul style="list-style-type: none"> ▪ Taboo subject ▪ Implies promiscuity
Personal and Cultural Beliefs	<ul style="list-style-type: none"> ▪ Religious beliefs ▪ Opposition to vaccines ▪ Not motivated ▪ Fear
Safety/Efficacy Concerns	<ul style="list-style-type: none"> ▪ Side effects ▪ New vaccine-hasn't been out long enough ▪ Duration of Protection
Patient Compliance	<ul style="list-style-type: none"> ▪ 3 dose compliance
Providers	<ul style="list-style-type: none"> ▪ Recommendation (lack of) ▪ Interpretation of guideline not favorable to older cohort
Mistrust of Healthcare System, Government and Pharmaceutical Industry	<ul style="list-style-type: none"> ▪ Skepticism ▪ Racism/discrimination ▪ Past negative experience with medical community ▪ African-Americans perceived as being targeted ▪ Biased information (disparities among AA)

Lack of perceived risk and need for vaccination, for example whether a young woman thought her own behaviors put her at risk, was highlighted as a barrier. Several informants suggested that the importance of taking preventive measures and being proactive about one's health is generally not a priority among this demographic. Two respondents stated that regular vaccination was generally outside the norm for 18-26 year olds; they also discussed getting a vaccine to prevent cancer was not considered an important issue because at this age there is a sense of invulnerability.

I mean often, you know, a lack of perceived need is kind of a barrier. Lack of perceived risk for HPV or cervical cancer, misunderstanding sometimes, you know, that cervical cancer is hereditary, and that the vaccine just won't work. (Government Official)

Yet another common theme that surfaced was the view that educational efforts need to be communicated in a way that was not perceived to be stigmatizing; that HPV not be considered a taboo subject. Several respondents suggested that the stigma associated with getting the HPV vaccine impeded acceptance and use, because for some it implies promiscuity. They argued that a concerted effort should be made by the medical community to market immunization against HPV as a cervical cancer prevention issue; removing language from the vaccine guideline which recommends its routine use prior to the onset of sexual activity.

MERCK has done a really good job at kind of promoting it without that kind of stigma and keeping as far away from the issue, you know, of STDs. (Healthcare Professional)

On the contrary, one informant felt as if the vaccine was being mismarketed because of its focus on cervical cancer; arguing that the main emphasis should be getting people to protect themselves from acquiring HPV, secondary to protection from the common complications of HPV. The respondent noted that while the virus is sexually transmitted; vaccination and prevention are NOT about sexual activity or promiscuity.

Additional barriers expressed by informants identified personal and cultural beliefs, views on vaccination, and an individual's motivation as having the potential to hinder use of the vaccine. Several individuals suggested there are those who are ideologically opposed to vaccines, feeling as though they do more harm than good.

Another recognized that even when individuals are educated and well informed, they may not have the motivation to take further action. In some ways, this correlates to the value of health

and wellness in the African-American community, another key finding brought forth during the interviews.

Concerns around safety, side effects and fear of a new vaccine were expressed as barriers to use and acceptance. Several informants suggested that some believe there is a risk associated with the use of new vaccines; that the HPV vaccine hasn't been out long enough, and both females and parents want to see more evidence of its safety before making a decision. On more than one occasion, informants expressed that, in general, people don't like taking new medications and once they hear of one bad outcome or potential side effects, regrettably, they become afraid. Likewise, several informants raised issues concerning the mass of misinformation being exchanged about the HPV vaccine

The barriers are lack of, what I would call, real information..... understanding who it's for and understanding what side effects it's going to cause. (Healthcare Professional)

Just basically people say, oh, you know, there have been deaths and I think the media and the internet have done a bad job about that, putting that stuff out that's unfounded per se. I think that's the number one barrier. (Government Official)

As was mentioned previously, several informants also stated that requiring three doses of the vaccine posed significant challenges. For a variety of reasons there will likely be a fall off in the proportion of women who get the second and third shots.

As these findings suggest, the variety and complexity of issues that may hinder acceptance and uptake of the HPV vaccine among young African-American women are wide-ranging. Successfully addressing these obstacles is expected to contribute to willingness to recognize the importance of primary prevention and consent to vaccination. The extent to which they can be overcome will require the collective efforts of many, centered around: community engagement, education, transparency and the investment of resources.

Facilitators

Along with identifying barriers associated with HPV and HPV vaccination, subjects were asked to consider what actions should be taken to support women in overcoming them. Similarly, they were asked to offer insight into approaches that could potentially facilitate acceptance of the vaccine. As was expected, there was no one consistent answer for addressing the obstacles that discourage the practice of healthy behaviors and use of preventive health services among young adult African-American women. The majority of responses fell within the following categories: 1) Education, 2) Access, 3) Social Support, and 4) Trust. Participants identified factors that encourage acceptance and use of HPV vaccination presented below in Table 4.4.

Table 4.4: Facilitators that support Acceptance and Use of HPV Vaccine

FACILITATORS	INFORMANT RESPONSES
Education	<ul style="list-style-type: none">▪ Peer education (particularly for this age group)▪ Appropriate information needed to make informed decisions▪ Accessible information▪ Simple, accurate, consistent messages▪ Culturally competent▪ Dispel myths▪ Increase acceptance▪ Knowledge is Power- empowerment over bodies▪ Physicians to educate/recommendation
Access	<ul style="list-style-type: none">▪ Reduce cost of vaccine▪ Expand public funding for adult vaccination▪ Availability in multiple venues
Social Support	<ul style="list-style-type: none">▪ Encouraged by partner, family, peers, community▪ Peer education (particularly for this age group)▪ Credible source communicating information (AA, someone from community/identify with)▪ Cervical cancer survivors▪ Physicians of color community outreach
Trust	<ul style="list-style-type: none">▪ Needs to be built from within community

The value and importance respondents attached to education and information for making health decisions cannot be overstated. Across stakeholders, education about HPV, cervical cancer, and primary and secondary prevention methods was suggested to enhance

knowledge, but it was also seen as a way of dispelling myths while increasing acceptance. Motivating individuals to apply that knowledge, assess the risks and benefits, and understand what the information means was seen as one way of empowering people to want better health for themselves.

Educating women in this way was also perceived as a form of empowering African-American women to take control of their bodies; and consider issues of health and prevention. One respondent suggested that becoming informed about HPV encouraged young women to better understand how their bodies work and what actions can be taken to protect their sexual health. Another stated enthusiastically, “*knowledge is power*” and that this preventive measure was an opportunity *deserved* by African-American women, who have historically had less and/or delayed access to care. Informants also cited the importance of accurate, consistent, and transparent information. Such messages framed without stigma would be well received by African-American women.

Respondents raised several issues associated with the expense of the HPV vaccine: 1) need for cost reduction, 2) need for options to help underwrite the cost for people who can’t afford it, and 3) expansion of insurance coverage and increasing reimbursement rates. One government official suggested that the cost of the vaccine would decrease over time, improving availability. The respondent went on to say, this will likely have a substantial impact on the provider’s willingness to administer the vaccine and increase access to young adult women.

Routine funding for adult immunization is limited at best and in some cases non-existent. Four informants expressed familiarity with a couple of programs designed to increase financial support of adult vaccination- CDCs Section 317 Program and MERCKs Vaccine Patient Assistance Program. They suggested expansion and greater use of these

programs to enhance access to the HPV vaccine among African-American women, 19-26 years of age. Additionally, subsidizing the cost of the vaccine through use of a sliding fee scale or at no cost; as well as a combination of public and private financial support, were recommended by a number of subjects. Another respondent noted that cost was not the only barrier to accessing the vaccine; enhancing availability of the vaccine through multiple venues in the community was also perceived as a strategy to promote use. Examples included having a mobile vaccine clinic, providing transportation, and enhancing hours of operation.

Encouraging vaccination against HPV by family, a spouse/partner, community and knowing someone who had been vaccinated were mentioned as facilitators to use and acceptance by several informants. As mentioned previously the use of peer educators to facilitate discussions was seen as a way to increase knowledge and acceptance. One informant stated:

I think that if you had peer groups... educators, having information where people within the age group, actually bring it up and discuss it. At this point, speaking about HPV in a social situation is really not common. So it's one of those of making it more common, making it known, making it not a hard thing to say and not a hard thing to discuss. (Public Interest Group- AA Health nonprofit)

The key is engaging young women..... Their willingness to participate will probably persuade those around them, their peers to get involved. (Public Interest Group- Health Education nonprofit)

The significance of having a trusted and credible source to communicate information was highlighted often. One respondent noted the value in having someone from within the community, whom African-Americans can identify with to discuss the vaccine's efficacy, safety and concerns about side effects, with an emphasis on health and wellness. Another respondent spoke of her success with cervical cancer survivors from the African-American community telling their stories and the impact on young women opting to be vaccinated. A

celebrity that resonates with young women, who is a proponent or perhaps recipient of the HPV vaccine, opinion leaders, athletes, musical figures, entertainers were examples given.

Patients look to physicians for guidance on decisions regarding their health. The benefit of having a provider of the same racial background disseminating information, conducting community outreach and recommending use of the vaccine was recognized as a means to fostering acceptance.

Key Finding 4: There is no consensus on how important the prevention of cervical cancer is in African-American women, but it should be considered in the context of overall women's health rather than a stand alone issue.

According to respondent's taking a proactive stance toward a healthy lifestyle and ensuring one's health and well being has taken a backseat to more pressing issues and competing priorities. Thus, when asked the question '*How much of a priority is cervical cancer reduction for preventive health among African-American women?*' one informant suggested that discussions about health for African-American women should focus on her *overall* health- a woman's reproductive, sexual, and mental health because they are so interconnected. This was not meant to imply that cervical cancer was not a priority; however, given the significance of other health issues currently faced by African-American women and communities of color, a more holistic approach to prevention was offered. Additionally, taking action against competing chronic disease conditions such as diabetes, obesity, hypertension, and cancer in general was given preference over cervical cancer prevention. It was also suggested that the medical community places more emphasis on these other chronic disease conditions. As one respondent, a healthcare provider, noted, "*I have to say that I look at all of the other diseases, you look at, the U.S. Preventive Services Task Force, you look at*

the CDC Healthy People Guidelines, and you realize that if we could prevent diabetes or if we could prevent hypertension, or if we could increase exercise and prevent obesity, we would have a much bigger impact, a much bigger number of people than with cervical cancer.”

Amongst African-American women and those of other population groups, disparities in cervical cancer morbidity and mortality persist. In addition, the rates of sexually transmitted infection, including HPV are higher among this population. Several subjects cited the differences in cervical cancer diagnosis, treatment, and survival among women of color as a motivating factor in preventing the disease. The responses of informants were mixed regarding cervical cancer risk reduction as a priority for preventive health among African-American women. The continuum of responses ranged from cervical cancer prevention being a high priority, of moderate importance, to no concern at all.

Since black and brown women are disproportionately affected by cervical cancer and are more likely to get the disease and more likely to die from this disease, this should be a major public health concern in our community. (Public Interest Group- Pharmaceutical Industry)

Not as important. Diabetes and hypertension and mainly weight and obesity. And I think that comes from providers and what they emphasize as well as what a lot of African-American women are concerned about. (Healthcare Professional)

Across respondents, a general lack of understanding about cervical cancer was expressed frequently as one of the primary reasons prevention of the disease was less of a priority among African-American women. This included the link between HPV and cervical cancer and use of the Pap test as a tool for cervical cancer screening. As one public interest group respondent put it, “*Well, I don’t know how many African-American women honestly make the connection between cervical cancer and HPV....*” It was suggested on numerous occasions that individuals are not sufficiently informed about their risk of acquiring HPV and thus their perceived risk of cervical cancer is minimal at best. Knowing someone personally

with the disease was commonly associated with a woman perceiving herself to be at increased risk and taking action toward prevention.

I think it's still not a priority the way that it should be because I think people still think that it won't happen to them and even with all the commercials that are out now, I still get plenty of calls like what is HPV?..... How is it linked to cervical cancer? (Public Interest Group-Cervical Cancer nonprofit)

Among young adults, pregnancy and acquiring other STDs such as HIV and Chlamydia were mentioned as priorities for prevention. This is due in part to the fact that these conditions disproportionately affect African-Americans (AA women) in greater numbers when compared to cervical cancer alone. When looking specifically at young adult women, aged 18-26, respondents were consistently of the same opinion; that the benefits and importance of preventive health was not something that was highly valued among this population. As a group, young adults 19-26 are generally healthy and utilize the healthcare system less frequently. They are also more likely to be low-income and uninsured.

Key Finding 5: Deficiencies in understanding of HPV, the HPV vaccine, cervical disease and prevention remain among the general public and healthcare providers, as an obstacle to vaccine acceptance and decisions regarding vaccination. Addressing the educational needs of these multiple audiences will require that messages successfully attend to the views and concerns of each group.

The overwhelming consensus among those interviewed is that health literacy in general is poor in this country and improvements in this area alone would be a big step toward reducing some of the health disparities that currently exist. Inadequate channels for communicating health information to individuals, communities, and the public further limits the ability for enhancing knowledge about HPV and cervical cancer prevention. It was also

mentioned that women of color often times have less access to health information which influences their understanding and decision-making. A universal theme across stakeholder groups was the need for more education about cervical cancer issues encompassing understanding HPV, primary and secondary prevention measures and education at appropriate levels which incorporate messages that are culturally tailored to specific populations.

Overall, the topic of HPV was described as confusing to both the general public and a large majority of the healthcare community. Several reasons for this were given such as: the complexities associated with HPV's prevalence - at some point everyone will likely be exposed to one or more of the virus types and its ability to clear on its own; the sexually transmitted nature of HPV and; being unaware of its relation to cervical cancer. On several occasions, informants make a distinction between the patient's lack of understanding of HPV and the provider's limited knowledge, and the need for targeting educational messages for specific audiences.

Patients were perceived as not having a basic understanding of HPV or their risk of acquiring the virus to make an informed decision about vaccination. An informant noted that women needed to understand the risk of the disease prior to receiving information on how to prevent it. In general, informants indicated that African-American women should become more aware of their personal risk of exposure to HPV and development of cervical cancer, based on a variety of individual factors. The disparities in cervical cancer morbidity and mortality and higher rates of sexually transmitted infections among this population certainly place this group at higher risk. Two respondents specifically took issue with use of the term *cervical cancer risk behavior* because it evoked a negative connotation of something abnormal; they noted that the primary *behavior* associated with infection of HPV is sexual

activity, a natural human behavior. Herein lies some of the controversy associated with HPV and vaccination against the virus: the nature of transmission.

What is the main behavior that causes HPV infection? Sex, ok? Now are we going to say that having sex is a risk behavior? I mean, sex is a normative human behavior so that's why it's kind of like, ah, you know, it's a little uncomfortable to say that, you know, how do we address that risk behavior?(Public Interest Group- Pharmaceutical Industry)

Sex is part of a healthy life for adults and HPV is the water in the swimming pool of sex and if you have sex, you're going to be exposed to HPV, so let's protect ourselves against the complications of it (Public Interest Group- University Health nonprofit)

Nevertheless, the general consensus was there are ways one can limit exposure to different types of HPV and likewise the number of exposures, to reduce the risk of developing cervical cancer. Some strategies for risk reduction included things like reducing the number of sexual partners, smoking cessation, proper nutrition/diet, and condom use especially if a young woman had multiple sex partners.

Similar to being educated about one's personal risk of acquiring HPV, it was important for African-American women to understand the risks and benefits of vaccination in order to make informed decisions. Incorporation of a decision tool similar to those used to help men decide whether to be screened for prostate cancer was recommended as one method for ensuring that women have enough information.

I think that there could very easily be a really wonderful decision aid to put together that would list the pros and list the cons, including safety issues that have arisen, and include the magnitude of those issues, ... something about the woman and her own values are being protected against HPV and that decision aid could then very clearly guide them into helping them make a decision about whether they wanted it or not.(Healthcare Professional)

The vast majority of respondents indicated the need for physicians to be well informed and deliver information in such a way that it becomes a routine part of healthcare. One respondent, an OB/GYN, commented on the importance of provider knowledge in relation to improving health literacy about HPV and cervical cancer prevention among

patients. This finding suggests a connection between providers that are educated on the issues and their ability to supply information to patients.

Understanding the disease process and available modalities to prevent HPV related disease, was identified as one of the key components necessary to effectively educate and inform patients. In some instances, healthcare providers were criticized for conveying messages that were characterized as ‘stigmatizing’ and not helpful to the patient. All respondents suggested that providers needed to be equipped with the appropriate information and tools to communicate in ways that are meaningful to the patient. Several informants agreed that providers who were most knowledgeable about HPV exhibited greater buy-in regarding the importance of vaccination and had higher levels of comfort discussing HPV information.

Key Finding 6: In the face of complex and ever-changing information demands regarding HPV and cervical cancer prevention, a comprehensive communication strategy that is relevant, culturally appropriate, and tailored to meet the needs of African-American women is desirable for fostering acceptance and uptake of the HPV vaccination.

Considering the importance of education for increasing acceptance and uptake of the HPV vaccine, the types of messages, how they are disseminated, and to whom is a piece of the puzzle with which many in practice struggle. When attempting to reach minority communities regarding health matters, a multi-faceted approach should be used. The findings below illustrate the need to clarify the role of education and information in understanding HPV, the etiology of cervical cancer, and the HPV vaccination decision-making process for multiple audiences.

Conveying information and communicating messages about HPV occurs analogously at the patient and provider level. Both patients and providers need to have a general understanding of HPV prior to any conversations or decisions about vaccination. Respondents emphasized the need for information that is presented in simple terms, using common language, and that learning about this particular issue should begin early. One respondent, a government official stated, *“If we [African-American women] don’t understand it, we’re not going to do it.”*

Messages were classified into two categories: 1) a general HPV message and 2) one specific to African-American women, underscoring the importance of customizing health communications to the audience. According to respondents, HPV messages should include: a basic understanding of the virus and related disease process, ones individual risk of acquiring HPV, prevention methods- what can be done to prevent the disease, the pros and cons of vaccination, and the need for continued Pap testing. The message was clear that cervical screening needs to continue after vaccination and that providers should stress this point to women. This message should coincide with any education about HPV vaccination.

As a healthcare professional, I personally think continued cervical screening has to be the first message. And then the second message is HPV vaccination will help your cervical cancer screenings be more likely to remain normal. There is a tremendous amount of misunderstanding about what the vaccine can and cannot do, which is why I would put the cancer screening message first. (Healthcare Professional)

For young women in particular it was also important to emphasize the vaccines safety and 100% effectiveness against those HPV types, even after becoming sexually active.

Acknowledging safety concerns- that side effects may occur and duration of protection were also issues that have to be attended to.

With regard to young adult African-American women, informants consistently affirmed that the women themselves should be involved in crafting messages and developing

programs intended to reach them. African-American media and those who are familiar with AA audiences should also be involved in designing messages and educational tools along with members of the community that are recognized as credible, those with communication, language and marketing expertise, sociologists/ anthropologists, religious leaders, and parents.

Cervical cancer prevention messages aimed at African-American women were similar to the general messages discussed above. According to several informants, educational campaigns and materials designed for African-American communities should be culturally and instructionally appropriate. Not only was this deemed as a way to increase understanding, it was also believed to be a way to reject some of the myths and dispel many of the fears that exist to move toward action. Evaluating how the messages are understood and how individuals relate that to the benefits that might occur is especially critical, given the complexities of HPV.

So language has to be tailored in a way that when someone says I get it or I understand you know that there's at least a, you know, a 90% chance that they really do get it. (Government Official-Cancer)

Without exception, across informants/stakeholder groups, no one individual or organization was identified as the best or most appropriate to deliver HPV/cervical cancer prevention messages. Several informants felt that medical specialty groups with expertise in cancer prevention and vaccination – family planning, OB/GYNs, pediatricians, teen clinics at health departments, student health clinics on college campuses- needed to come together with a more cohesive message and understanding of who should benefit from HPV vaccination.

I don't think there is any one organization because people listen to different organizations according to what their exposures are and what their lifestyles like. (Public Interest Group-Health Education nonprofit)

Celebrity spokespersons of color were mentioned; someone recognized by the intended audience, such as Jennifer Hudson or Alicia Keys, perhaps a female of prominence within this demographic that has been vaccinated themselves. Other potential messengers included cervical cancer survivors and young women who have suffered the negative consequences of abnormal Pap tests. African-American young men also surfaced as individuals who should be part of the solution when it comes to increasing knowledge and awareness about HPV and reducing transmission of the virus.

Given that communications between the two are highly important, it is critical that patients see clinicians as a credible and trusted source. The responses were mixed when it came to utilizing providers as the primary authority to educate and communicate information to young adult African-American women, on what is considered to be a sensitive issue by many. Some argued that healthcare providers should be at the forefront; while others were steadfast in their belief that physicians of color are most appropriate for delivering HPV education. For example:

I certainly think healthcare providers have responsibility in, in disseminating the message one on one. (Government Official)

African –American healthcare providers, including doctors, nurse practitioners, PA’s, whoever the appropriate person is, but I think appropriately seeing the face of an African-American health professional.(Healthcare Professional)

I’m not sure that a doctor is absolutely the best...particularly with an African-American audience. I think there is some distrust of the medical community. (Public Interest Group-Cancer Professional Organization)

Among young adult African-American women, information channels about health related matters were varied. A personalized one-on-one approach to educating women of color/African-American about HPV and cervical cancer prevention was a commonly expressed view. Proponents of this approach stressed the importance of providers being

visible out in the communities that they serve, providing information, and education. Most assumed that women with access to healthcare received cervical cancer prevention messages from a health professional; however given that this age group uses the healthcare system less often, that is likely not the norm.

Television and the internet were seen as primary sources by which African-American women generally got information about HPV. Respondents recognized that African-American women in this age group are heavy users of the internet, especially if they are enrolled in college. According to several informants, the internet was recognized as an essential medium for increasing awareness and knowledge, but that also brought forth a fair amount of concern regarding the amount of inaccurate information accessed on the internet. This finding illustrates the need for accurate information on the world-wide- web from credible sources that is easy to navigate due to the influence and broad reach the internet has on this age group. Below, Table 4.5 describes the various communication channels of young adult African-American women identified by key informants.

Table 4.5: Communication Channels of young adult AA women

COMMUNICATION TYPE	COMMUNICATION CHANNEL
Electronic Media	Internet, Text Messaging
Public Media	Television, Radio (Urban), Billboards, PSAs, Entertainment Channels/Music/Videos
Healthcare Providers	Physicians, Nurses
Entertainment & Sports Venues	Celebrity spokespersons
Social Networks	Peers, Family, Community Groups, Beauty Salons
Survivor networks	Cervical Cancer Survivors
Greek Lettered Fraternal Organizations	Historically African American Sororities

Word-of-mouth (Oral Networks), peers, family, and social networks were cited as equally important ways of sharing information, particularly among African-American women and those who don't routinely see a healthcare provider. Because of the significant influence

these networks have, it was evident by many that the communities themselves need to become better informed and educated; grandmothers, mothers, daughters, opinion leaders, and in fact the male partners of these women.

That for us, you know, we may see something on TV, but you know, our networks are our biggest part of where our information comes from because we will see something on TV and then, you know, go talk to Aunt Bessie, and Aunt Bessie, um hum, I heard, you know, and then, and then it goes on, and.....before you know it, you are not necessarily getting information that is valid or accurate.(Public Interest Groups-Pharmaceutical Industry)

These findings speak to the perceived role and power of social influences on knowledge and understanding of HPV related issues. Interestingly enough, MERCK's "One Less" campaign promoting the vaccine Gardasil® was acknowledged to be very successful in increasing awareness about HPV because of the multiple-media (print, television, radio and internet) channels used to promote their message. However, this heightened awareness has not necessarily translated into increased acceptance and understanding among certain racial/ethnic groups.

Collective responsibility for disseminating information to as many people, using a variety of approaches to ensure that the messages connected and resonated with people, appear to be the general consensus. Opportunities to get information out about HPV, risk reduction, and preventive measures in as many different venues that young African-American women gather and are responsive to, was encouraged by the majority of informants. Multiple avenues for dissemination were offered including: provider offices and student health clinics, community programs, beauty salons, television, billboards, public service announcements on urban radio, internet, African-American sororities, entertainment and sports venues, and faith-based activities. Use of technology and electronic media were endorsed for the college-aged, 18-23 year olds. The internet, pop-up messages, text

messaging, music videos and entertainment channels on television were examples referenced as ideal venues for discussing health issues.

In particular, these findings speak to the importance of identifying the information needs of individuals, how best to educate them, and who should be involved in the educational process. Assessing these unique variables, in advance of implementing immunization efforts, is critical element of making informed decisions to be vaccinated.

Strategies/ Ways to Improve Knowledge

Methods suggested to improve knowledge about HPV and cervical cancer prevention were wide ranging. Woven throughout was the importance of prevention and health promotion in general and engaging members of the community to support these efforts.

You have to do the right kind of research upfront like focus groups, for parents, different race and ethnic groups, socioeconomic, etc., and figure out what works. (Government Official)

Training existing community leaders to deliver messages and gain buy-in was repeated quite often. Organized groups that deliver preventive health messages to their stakeholders should incorporate information about HPV and cervical cancer prevention. For this age group in particular, 18-26 year olds, the use of a peer educator model emerged as a well-known method for educating on a variety of issues, with measurable success. Informants suggested this as an effective strategy implemented across college campuses for increasing knowledge and acceptance; a few noted the use of peer educators for health education purposes on historically black college campuses.

Key Finding 7: The benefits of reducing the transmission of HPV among a group considered to be at higher-risk, those aged 18-26, are numerous and extend beyond the vaccines efficacy and protection benefit to the individual. The fiscal, personal and societal cost savings associated with vaccinating this population are equally significant.

Measures to protect against cancer and sexually transmitted diseases, both threats to the health of communities of color, are necessary and should be widely supported.

Vaccination against four HPV types 6-11-16-18 that cause the majority of genital warts and 70% of cervical cancers has shown to be 100% effective. The ACIP recommendation allows for vaccination of girls beginning at nine years old, as well as vaccination of girls and women 13-26 years old, with the routine vaccination of 11-12 year olds. The vaccine is given in a series of three injections over a six-month period, and ideally it should occur prior to the onset of sexual activity before exposure to the virus, HPV. Several respondents felt inclusion of the statement regarding sexual activity actually dissuades many young adult women and healthcare providers from considering the advantages of vaccination for this group. A physician shares her thoughts on this particular issue:

It's really a shame because there are many, many women in that age range who would very much benefit from the vaccine who, either their physicians are unwilling to give it or don't feel that it is a priority to give them the vaccine, or the women themselves just don't hear the message because what they hear is, I should have gotten it when I was 12 and it's too late for me.(Healthcare Professional)

Although a woman may be sexually active, significant protection benefit from vaccination can still be derived. According to an industry official, approximately 97% of women participating in the Gardasil® clinical trials were sexually active 18-26 year olds; the efficacy data is in fact based upon those in the “catch-up” group.

I think that certainly the way in which the literature is written to explain that the vaccine efficacy is 100%, certainly for everybody through the age of 26, and when you actually broke it down by age group, which is never published, you saw that the efficacy was actually higher

in our 24 to 26-year-old women than it was in our 15 to 16-year-old women. (Public Interest Group- Pharmaceutical Industry)

Several respondents believed there was a bias against recommending and offering the vaccine to women who were ‘assumed’ to be sexually active, based solely upon their age. Healthcare providers acknowledged that among this age group, there are those who have had minimal exposure to HPV. Some interview participants were of the opinion that, in many ways, the ACIP recommendation makes it sound as if the upper age limit is a second class group; however, it is just as important for them to be vaccinated as it is for the 11-12 year old target group, given the evidence supporting effectiveness of the vaccine. Despite the fact that it is highly unlikely that young adult females have been infected with all HPV types, this finding illustrates the value judgments shared by many about a woman’s worthiness to receive the HPV vaccine after she has become sexually active.

The prevention of cervical cancer and genital warts was by far the most acknowledged public health benefit of vaccinating young African-American women, aged 18-26 against HPV. Quite a few informants emphatically stated that prevention of any type is always going to be a benefit to the public’s health. A variety of explanations were given, including: a reduction in the number of Pap tests and diagnostic procedures; decreases in morbidity and deaths; lessening the burden of disease in a population at higher-risk; and reducing the strain on an already fragile healthcare system. The advantage of population-based HPV vaccination over that of a high-risk strategy is evidenced by higher rates of immunization coverage of women, which has direct benefits to men in terms of decreased transmission of the virus, according to public health experts.

Particularly among young adult African-American women, higher rates of HPV infection, late stage diagnosis, and cervical cancer deaths were confirmed as a factor in

directing immunization efforts towards this group. A compelling argument raised by one subject implied that an inadequate healthcare system contributed to disparities in diagnosis and treatment of cervical cancer, and perhaps vaccination against HPV was one means of rectifying this.

African-American women, have high rates of Pap testing, however they are still diagnosed at more advanced stages of the disease and have worse prognosis which kind of indicates something to do with the healthcare system and the quality of care they are getting. So, I think if we recognize that, then the vaccine is actually one way to sort of get around some of the issues that might come with screening and treatment, because the treatment isn't really adequate or not up to par maybe. (Government Official)

Quite a few respondents mention lack of access to routine healthcare among young adults as a key consideration for encouraging vaccination; as it is assumed that at some point among a vaccinated population, cervical cancer screening intervals would likely be increased. Another informant suggested that this was an equity issue providing quality healthcare to those in greatest need rather than just to those who can afford it.

Colleges and universities were referenced by several informants, as high risk environments for women to start becoming sexually active; this cohort of females was mentioned as ideal candidates for HPV vaccination upon entry onto campus. Two informants commented that education and appropriate counseling about HPV related disease would increase as a result of vaccination, and considered this advantageous.

Many respondents noted the suffering and considerable costs- personal, emotional, social, and financial- attributable to HPV related disease that could be lessened to a great extent. An unexpected finding suggested a correlation between HPV vaccination and a woman's reproductive health; as vaccination against HPV increases, pre-cancerous cervical lesions and rates of hysterectomy among African-American women will decrease. While the evidence confirms other conditions more commonly associated with hysterectomy among African-American women, the notion that rates of hysterectomy might be diminished as a

result of vaccination may encourage its use. Additionally, three informants specifically mentioned a possible connection between childbearing (e.g. cesarean births and adverse pregnancy outcomes) as a result of weakened/ incompetent cervixes.

The healthcare dollars tied into treating patients that have genital warts, pre-cancers and cervical cancer is sizeable. Several informants felt that the reduction in diagnostic procedures due to abnormal cervical screenings could save upwards of \$3-4 billion in direct costs per year. An OB/GYN and leading expert in cervical cancer prevention went on further to quantify the cost savings:

When you consider the anxiety, and the pain, and all of the secondary costs that are associated with this, I think that's really considerable, ...it may triple or quadruple in value. So you know we may be saving \$16-\$20 billion which could be spent on primary preventatives, like vaccines. (Government Official)

On a societal level, the cumulative benefits that accrue to the individual would be applied broadly. Two informants commented on the reduction of societal costs; for example deaths, loss productivity in the older age group, and transmission of the virus associated with vaccination of HPV. From a public health perspective, the population-based approach was believed to be less resource intensive on physicians and the healthcare system in general.

Evidence is needed to aide policy makers in evaluating the benefits and costs of healthcare innovations for decision-making. These findings suggest there are numerous criteria that may be considered for the adoption of HPV vaccination among young adult women. Furthermore, they reveal the importance of societal values, fiscal, political, and ethical issues in the equation.

Key Finding 8: There are varying opinions about who the priority population(s) for HPV vaccination should be. Differences in recommendation of the HPV vaccine and who it is given to are influenced by the providers interpretation of the vaccination guidelines.

The effectiveness of prophylactic HPV vaccination is maximized when exposure to the virus is minimal, generally during childhood or adolescence before initiation of sexual activity. Therefore the routine recommendation is for young girls, 11-12 years of age, when exposure to the virus is minimal. Distinguishing the priority populations for HPV vaccination was a source of contention among several respondents as the findings below illustrate a divergence from the vaccination guidelines.

More than half of the informants were asked about their level of understanding concerning human papillomavirus and the vaccine to prevent infection of HPV. Overall, respondents were moderately to very familiar with HPV and associated the virus as having a causal link to cervical cancer. This was not unexpected, given that informants were identified because of their involvement in cervical cancer prevention and control.

Responses pertaining to specific aspects of the HPV vaccine- priority for vaccination, protection, and vaccination guidelines- were mixed. While all were aware that the vaccine protected against the HPV types that cause cervical cancer, not everyone was familiar with its protection against genital warts. When asked about the priority populations for vaccination, most offered the recommendation of females, aged 9 to 26. Those very familiar with the vaccination guidelines were specific in stating that priority be given to 11 and 12 year old girls or adolescents prior to sexual debut. One healthcare provider expressed a criticism of the ACIP's recommendation- coupling the HPV vaccine with the adolescent health visit, "*HPV vaccine development happened to coincide with this push to get young*

adolescents in for a pediatric visit. So, in many ways, the HPV vaccine has become co-opted into an 11 and 12-year-old vaccine because the intended purpose is to increase the number of pediatric visits so that those very important preventative healthcare discussions can occur.”

Several respondents conveyed their preference of providing the HPV vaccine to females in the ‘catch-up’ population, particularly those who are most likely to get HPV. Females entering into early adulthood- college students and 18 to 22 year-olds who are becoming independent and starting to live on their own were identified by several respondents as a priority population. This was thought to be a time in a young woman’s life in which she should be responsible for making decisions about her health and sexual partners; vaccination against HPV was perceived to be a key consideration in that decision-making. A public interest group stakeholder expressed dissent, emphasizing that those who could afford the vaccine were the ‘real’ priority population; that the vaccine was out of reach to those who would likely benefit most, minorities, low-income, uninsured, and underinsured girls and young women.

Furthermore, there was variation in familiarity with the various vaccination guidelines across respondents and perceived differences in understanding in general. Respondents suggest that a misunderstanding of eligibility for vaccination and a narrow interpretation of the HPV vaccination guidelines appear to have resulted in variation in the usage of the vaccine by healthcare providers. Physicians considered the least knowledgeable about HPV disease and vaccination, are more stringent in *only* recommending and administering the vaccine to those fitting the criteria for routine vaccination; girls prior to the onset of sexual debut.

So I think there's a tremendous amount of misunderstanding about the use of the vaccine on the providers' interpretation of what the ACIP and the CDC have written for guidelines. Some of my colleagues feel the guidelines have been written so strongly that it should be given only to 11 and 12-year-olds.....they are very influenced by the statement that says the vaccine must be given prior to the onset of sexual activity. (Healthcare Provider)

To illustrate, one informant described instances where providers refused to administer the second and third doses of vaccine if a young woman admitted to becoming sexually active after receipt of the first dose. Such a strict interpretation of the guidelines raises concerns because it imposes a systematic barrier to accessing the vaccine intended for women up to age 26, including those who are sexually active. Another healthcare professional raised concerns that the ACIP HPV vaccine recommendation as currently written is not comprehensive enough, that it is too brief.

The above mentioned findings demonstrate that policies and knowledge about HPV vaccine dissemination may not be universally known or widely accepted, suggesting the need to further address some of these misunderstood issues. Due to the high prevalence of HPV infection among sexually experienced individuals, priority for vaccination to pre-adolescent and adolescent girls is expected to achieve the greatest reduction in cervical cancer incidence over time. Until vaccination coverage levels of this cohort become high, “catch-up” vaccination of young adult females may be advantageous. Because several studies have confirmed that African-Americans are more accepting of HPV vaccination for teens and young adult women, perhaps directing initial HPV vaccine program efforts toward these groups may foster acceptance of immunization for the 11-12 year old target population.

Key Finding 9: Provider knowledge, personal beliefs, and experiences with HPV are decisive factors associated with their acceptance and recommendation of the HPV vaccine. Numerous obstacles faced by healthcare providers related to administration of the vaccine pose challenges to increased uptake of the vaccine.

Interviews with a number of respondents reinforced the notion that provider recommendation of preventive health services, such as screenings and immunizations is a critical determining factor in the use of such services. A strong recommendation from the provider increases the likelihood that women will accept vaccination. Several informants noted that patients are generally uninformed about HPV and strategies to prevent acquiring the virus; consequently they rely on the healthcare provider's knowledge and experience to help them determine their individual risk of acquiring HPV infection and the pros and cons of vaccination. Furthermore, several subjects stated acceptance of HPV vaccination by African-American women has shown to increase with education and recommendation from a provider of the same racial background.

I found that who the messenger is, is really important, and I feel that, if they have, physicians of color who believe in the vaccine and talk about it and go over the safety and explain things like, and answer questions, then you can get some buy-in. (Healthcare Professional)

One informant observed that many African-American physicians remain very questioning of the HPV vaccine and have not necessarily been strong advocates. As with patients, a healthcare providers own personal and cultural beliefs are both powerful dynamics when it comes to the delivery of healthcare. Given the burden of disease in this population, hesitancy on the part of providers to recommend the vaccine is certainly an obstacle that must be overcome.

If black doctors don't take up the charge and are kind of lukewarm about the vaccine, we are going to widen the gap between the majority population cervical cancer rate and the black and brown women cervical cancer rate. And we are going to do it to ourselves. (Public Interest Group- Pharmaceutical Industry)

Several factors were noted as influencing the provider's belief in HPV vaccination: 1) time-provider buy-in would likely come about over time, 2) a reduction in cost of the vaccine, and 3) confidence in its safety.

Among the healthcare professionals interviewed, there were a variety of provider office settings represented including the health department, family planning and hospital indigent care clinics, private practices, and a nonprofit healthcare organization whose services are aimed at reaching African-American women. A vast majority of patients seen in these settings included women from the population of focus- African-Americans, aged 18-26. A high percentage of women were described as low-income and/or uninsured, some of which were identified as college students.

All provider respondents were knowledgeable of the HPV vaccine and routinely recommended it in accordance with the ACIP guidelines. Additionally, several informants indicated following the immunization practices established by their respective professional societies, for example American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG). This suggests that provider buy-in of HPV vaccination is strengthened when there is support amongst one's colleagues. One informant suggested that the HPV vaccine is broadly accepted in the medical community; at the same time, interpretation of the guidelines for immunization usage and to whom it should be given differs significantly among providers depending upon their level of knowledge and understanding.

It's good that just about every single healthcare segment of our society is behind the vaccines, but I think what's not good is that there is a blind acceptance of that. There is an unwillingness to discuss taking the vaccine outside of the 12-year-old age range, that we need to encourage them to say the vaccine is as good in the 18 to 26-year-old range, that this is important, that we need to encourage them to admit that. (Healthcare Professional)

Overall, informants characterized their experience with HPV vaccination as positive. Interviews with a number of respondents uncovered feelings of skepticism associated with the vaccine, most common among African-American patients in comparison to others. Among this group, some are less educated about HPV and/or misinformed about the pros and

cons of vaccination, citing concerns about safety and its effectiveness. Several informants noted that a variety of women: sexually active young adults, those with previous HPV infection, and women beyond the recommended age for immunization are requesting the vaccine. This appears to be occurring across age groups, among multiple ethnicities and educational backgrounds.

Other issues revealed by respondents were some of the challenges faced by healthcare providers in administering the HPV vaccine. They registered concerns related to the high cost of the vaccine, the support systems and infrastructure needed to stock vaccines, and the low reimbursement rates by insurers. In addition, one provider responded that there was not enough time to educate women about the vaccine and that there were more pressing priorities to be addressed such as teen pregnancy.

Many stated that because the HPV vaccine is priced so high, there's no ability to have any overhead coverage, nor profit in administering the vaccine. This particular finding may have implications for access to the vaccine by low-income individuals and among communities of color wherein providers have chosen not to make the vaccine available. According to several informants, vaccine administration can be intimidating and cumbersome, especially to some specialty groups that are not accustomed to providing that service. In addition to pediatricians, family physicians, and nurse practitioners were most likely to be familiar with administering vaccines, while OB/GYN providers and general internists were described as least likely. In support of reaching 18-26 year old adults for vaccination, respondents recommended targeting pediatricians, family physicians, and OB/GYNs.

Respondents noted that on average healthcare providers were ill-equipped with the knowledge and tools necessary to communicate HPV and immunization information

effectively. In spite of the need, several providers stated that the time required to properly educate and counsel patients about HPV and their options for vaccination is very limited. Two physicians suggested that patient education is a very important element in the patient encounter and delivery of healthcare and regarded it as a reimbursable service, which it is currently not. Finally, the vast majority of respondents also referred to the requirement of three doses of vaccine as a significant challenge to successfully administering the HPV vaccine. Compliance with the three doses of the vaccine was also considered a challenge to providers; however, several respondents agreed that women who are highly motivated are more likely than those less motivated to be compliant with the 3-dose requirement.

Key Finding #10: Social determinants contribute to the disparities in cervical cancer among African-Americans. Similar disparities will persist in HPV immunization rates due to racism and inequities created by unjust social conditions and policies, increasing the burden of negative health outcomes.

Respondents offered a range of explanations for disparities in HPV infection and cervical cancer diagnosis and death rates, some of which included: less access to care, inequities in education and income, and racism, among others. For example, young adult AA women are likely to be low-income and uninsured restricting access to both primary and secondary cervical cancer prevention methods. These factors, commonly known as social determinants of health, are beyond the realm of the healthcare system and speak to broader issues of equity and social justice.

One question posed to respondents asked, *“What steps can be taken to ensure that the inequities that currently exist in cervical screening will not worsen with the introduction of the HPV vaccine?”* While a myriad of answers were given, still the overall consensus was

that those same women who don't participate in routine Pap testing are likely the same ones who will not have access to the HPV vaccine. Several informants expressed great dissatisfaction at the challenges faced by women who are unable to obtain vaccination because of cost; presently only those who can afford to pay or have some form of insurance coverage will get the vaccine. As one respondent explains, even with insurance coverage of some vaccines, there are differences in availability as providers are known to accept one type of insurance over another; for example, private pay over Medicaid, due to variations in reimbursement rates. This in and of itself creates inequities in access particularly to populations that are already vulnerable.

Racism, discrimination, and the destructive history between African-Americans and the healthcare system were identified as contributing factors to health disparities. The relationship between racism and inequalities in health status is demonstrated by persistently higher mortality rates of cervical cancer and other diseases among blacks and other people of color. Several informants raised as an issue, the importance of understanding the relationship between the African-American community and medical establishment; the way it impacts how they think about, feel about and utilize healthcare resources.

I see a lot of women who are turned off from the medical system in general because they are not well treated. They are not well respected. (Public Interest Group- AA Sorority)

Political power and institutional policies based on the premise of the inferiority of blacks have created the conditions that affect health and the receipt of healthcare services.

One informant suggested a comprehensive approach to addressing inequities in HPV vaccination needs to focus on reaching specific at-risk populations. Efforts should be led by the communities themselves and supported by government; with an emphasis on changing policies that impose systematic barriers. Coupled with these, addressing the root causes of

these disparities will require investments in social spending such as public health, education, and job creation among less advantaged groups.

These findings illustrate the manner in which socioeconomic conditions and social position are implicated in producing health outcomes; those with socioeconomic disadvantage are more likely to be susceptible to preventable disease, early death, and inequities in health status. Understanding the complex array of socio-demographic, behavioral, and attitudinal dynamics associated with health practices among African-American women will be important to assessing interest in vaccination and ensuring the benefits of immunization are shared by all.

Key Finding# 11: A comprehensive strategy for successful introduction of HPV vaccination to communities, especially communities of color, must be coordinated at multiple levels focusing on effective implementation strategies and vaccine policies to ensure program performance

Policies

The literature points to the utility of public policy in promoting primary prevention efforts to influence health outcomes. Policies affect large numbers of people as well as social norms and have tremendous potential for preventing needless suffering, injuries and deaths. In order to assess policies in relation to HPV vaccination, study participants were asked what factors should be considered when recommending policies for HPV vaccine introduction. Table 4.6 lists these factors for consideration.

Table 4.6: Factors to consider for HPV vaccine policy recommendations

FACTOR	INFORMANT RESPONSES
ISSUE	<ul style="list-style-type: none"> ▪ HPV vaccination is not a substitute for cervical cancer screening ▪ Address burden of disease & disparities in cervical cancer/ STI rates among population ▪ Understand SES factors impacting poor health outcomes (i.e. education, income, policies and practices)
EDUCATION	<ul style="list-style-type: none"> ▪ Policymakers need to understand this as an issue on three fronts (public health, women's health, minority health) ▪ Support strategic plan for comprehensive education and outreach to communities aimed at increasing understanding, acceptability, and improving communication ▪ Proactive in addressing safety concerns
ACCESS	<ul style="list-style-type: none"> ▪ Allocate funding for vaccine (ensure low cost ways to get vaccine, availability and equal access) ▪ Fund entities and build infrastructure to design effective mechanisms to provide vaccine within existing systems, without posing an additional burden ▪ Mandates associated with HPV vaccination should be used judiciously
PARTNERS/STAKEHOLDERS	<ul style="list-style-type: none"> ▪ Engagement of a variety of stakeholders <ul style="list-style-type: none"> ○ Intended Audience ○ Decision-makers (Legislative & Policymakers) ○ Medical Community ○ Industry (Pharmaceutical, Insurance, Business) ○ Colleges & Universities ○ Advocacy & Policy Groups/Organizations ○ Media

Consideration of disparities in HPV related disease and addressing them through policy intervention was prominent among respondents. One respondent stated:

Understanding African-American health issues and those that impact disparities in health outcomes is essential when recommending policies for HPV vaccine introduction. That the disparities are always related to education, income, those kinds of things, but it may be the policies themselves or practices in the healthcare environment. (Public Interest Group- Health Education nonprofit)

Respondents commonly identified the establishment of policies that would have an impact on the fiscal aspects of enhancing access to HPV vaccination. A government official suggested

delivery methods of vaccine could be greatly enhanced through the political process, “*That would mean that you fund entities to build infrastructure to provide the vaccines in systems that would not put great financial burden on the healthcare system as it exists. An effective mechanism where you know that you’re going to need x number of doses at a specific time would be more efficient.*” Certainly, reducing the cost of the vaccine is vital to expanding its use to communities at highest risk.

Policies should ensure that there are low cost ways in which to get the vaccine; so that we can ensure equal access to the vaccine. (Public Interest Group- AA Health nonprofit)

The importance of education was a prevailing issue. Quite often respondents pointed out the necessity of understanding the complexities of HPV and vaccination and communicating information about the subject to a multiplicity of audiences as an emerging health concern

From a policy standpoint, working with state health departments or local health departments and implementing policies that support education of young women about vaccines such as the HPV vaccine and the role that it can play in staying healthy. (Public Interest Group- Legislative policy nonprofit)

Certainly by passing laws that encourage the development of community competent educational methods that are well understood and accepted, and again dispelling the mistrust that can often be associated with having something come to minority groups from a political entity that they often fear or are suspicious of, I think is extremely important. (Government Official)

Additionally, collaboration amongst a diverse group of stakeholders facilitates a dialogue in hopes of bringing forth the needs and concerns of the community while being a catalyst for broad-scale change.

Implementation Strategies

Sustainable health behavior change can be facilitated through a variety of means. Achieving or maintaining high levels of vaccination coverage can be accomplished by implementing effective population-based strategies. The methods for reaching individuals, communities, or the public can vary. According to the Task Force for Community Preventive Services, demonstrated strategies for increasing immunization rates include: 1) increasing community demand, 2) enhancing access to vaccination services, and 3) provider based interventions.⁸⁸ In order to more fully understand factors that might hinder or enhance use of the HPV vaccine among young adult African-American women, a population regarded to be at higher-risk for HPV-related disease, participants were asked to identify effective strategies and program attributes for successful vaccine implementation. Table 4.7 lists the strategies that participants considered most useful.

Many of the proposed strategies are aligned with those presented in the Guide to Community Preventive Services (The Community Guide) recommendations to improve targeted vaccination coverage among high-risk adults. Additional proposed strategies are based on the respondents experience supporting HPV vaccination efforts. As stated previously, the implementation recommendations generally fell into the three intervention strategy categories with a fourth category '*Other*' included for additional approaches for successful execution of HPV vaccination programs.

Table 4.7: Strategies for Effective HPV Vaccine Implementation, 18-26 Year Olds

COMMUNITY GUIDE INTERVENTION STRATEGIES	KEY INFORMANT HPV VACCINE IMPLEMENTATION RECOMMENDATIONS
<p>Increasing Community Demand for Vaccinations</p> <ul style="list-style-type: none"> ◦ Client reminder/recall ◦ Multicomponent interventions including education ◦ Vaccination requirements for childcare, school and college attendance ◦ Community-wide education-only interventions ◦ Clinic-based education-only interventions ◦ Client or family incentives ◦ Client-held medical records 	<p>Improve health literacy (patients, providers, public)</p> <p>Social Marketing Education Campaign-(What's Available, Why Important, Where, Costs)</p> <p>Ensure messages are framed appropriately</p> <ul style="list-style-type: none"> ◦ Combine w/ women's and sexual health education ◦ Culturally/literacy appropriate <p>Engage Community (Intended audience)</p> <ul style="list-style-type: none"> ◦ Community empowerment (demand vaccine) ◦ Drive education efforts ◦ Gain buy-in <p>Intergenerational Approach</p> <ul style="list-style-type: none"> ◦ Education and screening ◦ Involve grandmothers, mothers, daughters ◦ Gain buy-in
<p>Enhancing Access to Vaccination Services</p> <ul style="list-style-type: none"> ◦ Reducing out-of-pocket costs ◦ Expanding access in health care settings ◦ Vaccination programs in women, infants and children settings ◦ Home visits ◦ Vaccination programs in schools ◦ Vaccination program in childcare centers 	<p>Enhance Access to Vaccine</p> <ul style="list-style-type: none"> ◦ Ensure affordability (i.e, cost-sharing or free) ◦ Vaccine readily available in non-traditional community settings ◦ Pharmacies ◦ Beauty salons ◦ Churches <p>Integrate into Existing Programs</p> <p>Cervical Cancer Screening Programs</p> <ul style="list-style-type: none"> ◦ Pap test and vaccination same visit ◦ Education ◦ Infrastructure ◦ Support to community <p>NBCCEDP screening sites</p> <ul style="list-style-type: none"> ◦ University/college student health services ◦ Family Planning/Planned Parenthood ◦ Utilize existing models i.e. HIV Model/ REACH
<p>Provider-Based Interventions</p> <ul style="list-style-type: none"> ◦ Provider reminder/recall ◦ Standing orders ◦ Provider education only ◦ Assessment and feedback for vaccination providers 	<p>Standing Orders</p> <p>Decrease Missed Opportunities</p> <p>Provider reminder systems</p> <ul style="list-style-type: none"> ◦ Tickler systems ◦ Scheduling appt in advance
<p>Other Interventions (** not Community Guide)</p>	<p>Patient Compliance (3 Doses)</p> <ul style="list-style-type: none"> ◦ Message of compliance thru multiple channels ◦ Use of technology (text message/email reminders) ◦ MERCKs '3 is Key' reminder (thru doctors office) ◦ Financial incentives ◦ Expedited vaccine schedule

	<ul style="list-style-type: none"> ◦ Vaccine registry w/ call back system ◦ Reveal consequences of disease <p>Partnerships & Collaborations</p> <ul style="list-style-type: none"> ◦ Foster coalitions and networks (community, government, industry, academia, health sector) <p>Monitoring & Evaluation</p> <ul style="list-style-type: none"> ◦ Vaccine uptake ◦ Collect data ◦ Document programmatic effectiveness ◦ Modify efforts based on data <p>Involvement of Males</p> <ul style="list-style-type: none"> ◦ Education and messengers ◦ Partners of women
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Source: Adapted from Task Force for Community Preventive Services

The analysis of effective strategies and program attributes revealed several main ideas: 1) characteristics of the program must improve access and entail a comprehensive education plan, 2) role of the community is critical, 3) integration of vaccination into existing health services, with an emphasis on cervical cancer screening programs, and 4) the importance of patient compliance. A successful HPV vaccination program would require considerable investment in educating a range of audiences. Additionally, a reduction in the vaccine’s cost to females and providers would be necessary to expand access and availability. Incorporating HPV immunization into existing cervical cancer screening programs, across a variety of health settings, surfaced as the least complicated option for young adult females to gain access to the vaccine.

Areas for Further Exploration

There were a number of other issues that surfaced during the interviews. Several respondents introduced the issue of males and their role or involvement in the great HPV debate. Respondents were committed to the idea that males should be educated about HPV, the risks and benefits of vaccination, and share in decision-making with their partners, while taking an active role as a messenger of HPV information. Currently, there are a number of

studies underway exploring vaccination of males. The verdict is still out; however, the need to expand coverage of the vaccine to include young males was perceived by some as ‘the missing link’ in reducing the cycle of HPV transmission.

Community mobilization and empowerment was addressed repeatedly. Respondents agreed that getting African-American communities to understand that HPV isn’t about good or bad, but rather about an issue that can be dealt with; and HPV vaccination is a prevention tool to keep ‘us’ healthy came across from several respondents. More than that, it involves the community taking ownership of an issue and thinking through how best to handle; it’s having the resources within the community, not only to provide the medical service, or information and education, but to be a conduit between the two. One respondent noted the role of African-American women as decision-makers in their families, communities, churches, etc., recognizing that this was something to be embraced. They went on to say, by respectfully reaching out to grandmothers, mothers, aunts, we are empowering women to want better healthcare for themselves, their daughters, their loved ones. While this study addresses the needs of young adult African-American women, there are several issues that pertain to girls and women of other racial/ethnic groups.

Variation in Key Informant Responses

The possibility of preventing HPV-related cervical cancer and other conditions through vaccination has kindled broad interest from a diverse group of audiences; key informants contributing to this study are representative of some of these factions. As illustrated in these findings, the responses were mixed and as diverse as the participants themselves; differences between and within interest groups were noted across several topics. For example, sharing information about health disparities in the African-American

community was perceived as both a barrier and facilitator to uptake of the vaccine.

Participants representing public interest groups were more likely to indicate that statistics highlighting negative outcomes were a hindrance, deepening opinions of information bias and mistrust. In addition, there was no consensus reached regarding cervical cancer as a priority among African-American women. However, it should be noted, across informants, African-American respondents were least likely to consider prevention of cervical cancer a primary concern in comparison to other health conditions afflicting this community. While the benefits of vaccination to those aged 18-26 were consistently acknowledged across respondents, there were differences in opinion about classifying African-Americans in this age range as priority for HPV vaccination. Government officials, with one exception, explicitly stated that 11 and 12 year olds were the target group; while stakeholders from public interest groups and healthcare professionals favored immunizing the ‘catch-up’ population. The range of views reported in these findings raise a number of questions that are certain to have implications for HPV vaccine introduction and public policy.

CHAPTER V: POLICY ANALYSIS

This chapter describes the results and analysis of policy considerations to increase acceptance and use of the HPV for use in the development of an advocacy plan. The findings are presented and answer the study's research Aim 4.

Aim 4: Use the data collected to recommend policy considerations for enhancing acceptance of the HPV vaccine among young adult African-American women.

A review and interpretation of relevant literature was conducted associated with vaccine policy, diffusion of medical innovations, and the adoption of policies. Policy interventions will focus on both clinical practice-based and public health initiatives. Relevant findings from analysis of the immunization literature are discussed below.

Immunization

Historically, vaccination laws were enacted to control epidemic diseases; currently these laws are used to protect the public's health by increasing vaccination coverage, even in the absence of epidemics. Public health officials confirm that wide use of vaccinations encourages what is known as "herd immunity." Herd immunity is achieved when a high proportion of the population is immunized to stop the spread of disease.

Vaccines are delivered to hundreds of thousands of children and adults in the United States annually. The delivery of immunizations occurs through a network of public- and private partnership activities, with a large fraction occurring in the private sector. At one time, the provision of those services for less advantaged groups occurred primarily through

the public health departments and clinics. As a result of changes in Medicaid policies, and creation of programs such as Vaccine for Children (VFC), and the State Children's Health Insurance Program (SCHIP), a shifting of resources has emerged, removing coverage from many low-income, uninsured and underinsured individuals and families who were once served by the traditional public health system.^{89, 90}

One of the great successes of public health are vaccines, as evidenced by their ability to prevent disease and reduce healthcare costs. The effectiveness of preventing disease through universally recommended vaccination is well-documented. While childhood vaccination programs have achieved great success with coverage levels exceeding 95% for some vaccines, the same does not hold true for adults, as universally recommended vaccines among this group are underused.^{88, 91} Consequently, disparities in access to vaccines, due to socioeconomic factors (i.e. differences in geography and economics), have led to reduced levels of immunization coverage among certain populations.^{88, 90, 91}

Whereas access to immunization is known to be a contributing factor to increasing vaccine coverage rates, the evidence reports a mixture of methods that can be utilized. The Task Force on Community Preventive Services conducted a systematic review of population-based interventions to improve vaccination coverage. A summary of recommendations on the use of interventions to improve vaccination levels across the lifespan (children, adolescents, and adults) is presented in Table 5.1 below.⁸⁸

Table 5.1: Recommendations Regarding Interventions to Improve Vaccination Coverage

INCREASING COMMUNITY DEMAND FOR VACCINATIONS	ENHANCING ACCESS TO VACCINATION SERVICES	PROVIDER-BASED INTERVENTIONS
Client reminder/recall	Reducing out-of-pocket costs	Provider reminder/recall
Multi-component interventions that include education	Expanding access in health care settings	Standing orders
Vaccination requirements for childcare, school and college attendance	Vaccination programs in women, infants and children settings	Provider education only
Community-wide education-only interventions	Home visits	Assessment and feedback for vaccination providers
Clinic-based education-only interventions	Vaccinations programs in schools	
Client or family incentives	Vaccination programs in childcare centers	
Client-held medical records		

Source: Task Force on Community Preventive Services

Many groups have a stake in vaccine-related issues. Federal, state, and local health agencies jointly support the roles of the national immunization system (See Figure 5.1 below), while collaborating with other public and private partners. The six fundamental functions of the national immunization system, as described below, are to ⁸⁹:

- Assure the purchase of recommended vaccines for the total population of U.S. children and adults, with particular emphasis on the protection of vulnerable groups
- Assure access to such vaccines within the public sector when private health care services are not adequate to meet local needs
- Control and prevent infectious disease
- Conduct population wide surveillance of immunization coverage levels, including the identification of significant disparities, gaps, and vaccine safety concerns
- Sustain and improve immunization coverage levels within child and adult populations, especially in vulnerable communities
- Use primary care and public health resources efficiently in achieving national immunization goals

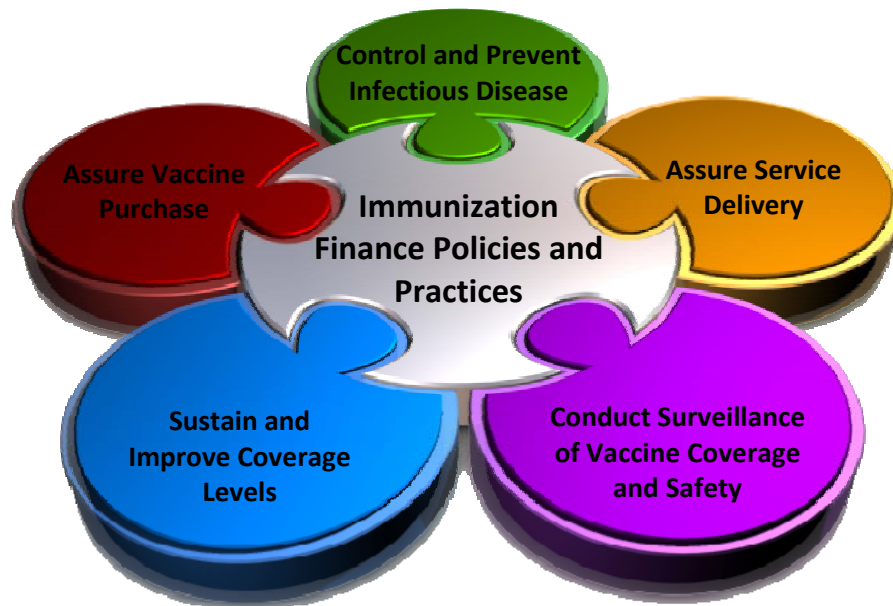


Figure 5.1: Functions of National Immunization System ⁸⁹

The federal government and its respective agencies share responsibilities related to research and development, licensing, protecting health and the safety of populations, surveillance and monitoring of adverse reactions, provision of health services, trade and homeland security. State and local governments primarily conduct vaccine activities as part of their public health role; through administering vaccines and maintaining immunization registries and establishing and enforcing requirements for school attendance. Organizations and interested parties outside of government also play a key role. They include consumers, employers who provide health benefits and insurers, professional healthcare associations, the pharmaceutical industry, and an array of public interest groups. ^{89, 92}

Vaccine Policy Issues

Public policy is a strong tool for primary prevention because policy shapes the environment in which we live, work and play. While there are a number of players involved in vaccine-related issues, there is no one central authority for vaccine policy within the federal government. A multi-disciplinary, multi-level approach is required to address the complex nature of policy adoption across states and among varying populations, all of whom have their own unique needs and challenges. For the most part, legislative issues pertaining to vaccines that political bodies/state legislatures consider usually fall into 3 categories: a) availability, b) safety, and effectiveness and c) access^{89, 92} as detailed in Table 5.2 below.

Table 5.2: Vaccine Policy Issues

ISSUE	PROBLEM	SOLUTION
Availability	Production Costs	Financial incentives
	Production Failures	Liability
	Liability	Partnerships
	Market	Improved Coordination
	Planning	Alternatives to Safety Documentation
Safety and Effectiveness	Side Effects	Improving Post Licensure Adverse Event Surveillance
	Insufficient knowledge and inadequate risk communication	Education and Risk Communication
	Assessment of competing products	Studies in Pharmacoepidemiology and Pharmacoeconomics
	Production of Generic Biologics	Compensation
Access	Completion of Vaccination Schedule	Global Health
	Regional and Economic Disparities	Coordination of Government Financing Programs
	Varying Health Benefit Coverage	Payment for Vaccination and Follow-up Care

Source: Adapted from Congressional Research Service-Library of Congress

Vaccine Financing Mechanisms

Vaccine programs are funded through a mix of federal and state resources. Federal funding for immunizations programs subsidizes state costs for vaccine purchases and infrastructure support. Two vaccine-financing mechanisms were established by the federal government to aid in increasing immunization coverage rates in the U.S. The Vaccines for Children (VFC), is a federal entitlement program, the Section 317 Immunization Program, is a federal grants program that receives an annual appropriation from Congress which is subject to change from year to year. In addition, states invest funds in immunization programs through direct or in-kind support.⁸⁹

The federal VFC provides free immunization to uninsured children and children on Medicaid at their regular healthcare provider. VFC provides vaccines for qualified children to private providers, and free vaccines to children at Federally Qualified Health Centers (FQC) and Rural Health Clinics (RHC). Children 18 years of age or younger who are either uninsured, Medicaid eligible, or of Alaska Native/American Indian descent are eligible to receive VFC vaccine. Additionally, underinsured children 18 years of age or younger who receive care through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) are VFC eligible. The CDC negotiates federal contracts with vaccine manufacturers for VFC vaccines, as recommended by the ACIP, and states distribute and administer the vaccines through public health clinics and private providers.^{17, 89, 90, 92}

The Section 317 program was authorized through the Public Health Service Act to support vaccination infrastructure and direct service delivery. CDC provides grants to state and local (jurisdictional) health departments (immunization programs) to vaccinate children, adolescents and adults who have no means to pay for vaccines and are not eligible for other

government programs which provide vaccines. With reductions in funding and the increased need for services, Section 317 program funds have focused on conducting routine vaccination of children. As the costs of vaccinating uninsured and underinsured children grow and expensive vaccines are added to the immunization schedule, states face the challenge of contributing more toward financing immunization programs.⁸⁹ Because the Section 317 grants program does not require a state match, fiscal incentives for states to share the costs do not exist. Despite the need, vaccines to adolescents and adults who are largely underserved, and racial and ethnic disparities persist.^{88, 91}

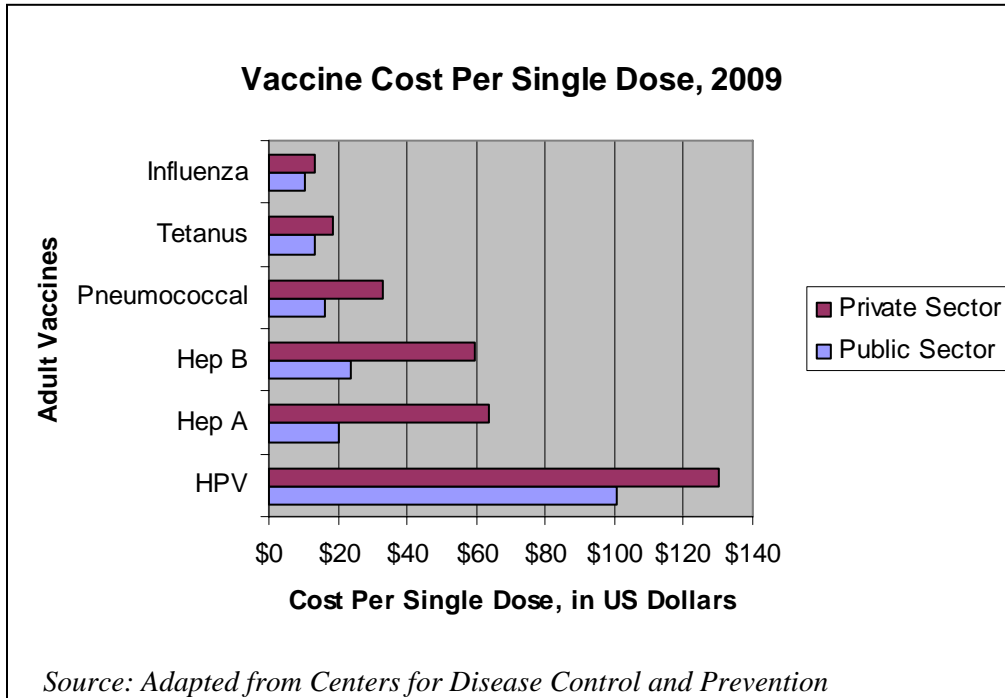
Private vaccine financing is another method through which immunization services are purchased. Private funding generally occurs as an out-of-pocket expense by the individual, through some type of insurance benefit coverage or a combination of both. Approximately three-fourths of those with private health insurance obtain it through employer-sponsored health plans. Among employer-sponsored health benefit plans coverage of childhood immunizations is common. Many states have passed legislation to require insurance companies to cover immunization services.⁸⁹

HPV Vaccine: Costs v. Benefits

As new vaccines are introduced and recommendations are made for their use; federal, state and private entities have had to respond accordingly. Based upon the CDC Vaccine 2009 Price List, the cost of the HPV vaccine is considerably higher than other adult recommended vaccines.^{17, 90} Table 5.3 illustrates the cost differential between the HPV vaccine and other recommended vaccines. As shown, private sector and CDC cost of the HPV vaccine per dose ranges from \$70 to \$76 more than other vaccines. While it is true that

the price of the vaccine is costly, the actual expense of delivering the vaccine includes education, counseling and delivery mechanisms; the costs of which are yet to be determined.

Table 5.3: Vaccine Cost per Single Dose, 2009



The burden of HPV-associated disease and cancers is considerable and has substantial direct and indirect costs; both to the individual and society. Costs attributable to cervical screening, diagnosis, management, and treatment of cervical abnormalities are in the billions of dollars.⁹³ Premature death, disability, medical costs, and loss productivity pose a societal burden and adversely affect the health of our nation.⁹⁴ Ekwueme et al, estimated mortality costs (years of potential life lost-YPLL and productivity costs) from HPV-associated cancer deaths in 2003, accounted for approximately 3% of the mortality costs of all malignant cancers. These costs ranged from \$2.9 billion to \$5.3 billion; with cervical cancer having the highest estimated cost of \$1.8 billion among women.

When evaluating policy considerations for introduction of HPV vaccination programs, both the health and economic implications must be considered. Several published studies have conducted analyses assessing the cost-effectiveness of vaccinating young girls- 11 and 12 year olds, those in the catch-up age range- 13 to 26, and most recently boys. Studies have used numerous mathematical models, based on a variety of assumptions, to estimate the cost-effectiveness of prophylactic vaccination of HPV types 6-11-16 and 18. In general, HPV vaccination is most cost-effective among young adolescent girls, with the cost of extending vaccination to girls and women to age 26 years becoming less cost effective as the cut-off age of vaccination increases. However, as the potential benefits of preventing non-cervical HPV associated cancers increases, the cost-benefit of extending vaccination up to 21 years of age becomes more favorable.^{95, 96} According to Kim & Goldie, the cost-effectiveness of vaccination will be optimized by attaining high rates of coverage among preadolescent girls, targeting initial catch-up efforts to girls and women younger than 21 years of age and revising screening policies.⁹⁵⁻⁹⁸

Through effectively integrating primary and secondary cervical cancer prevention strategies, reductions in morbidity, premature death, and the economic burden associated with HPV-related cancers can be achieved. If one weighs the costs of a \$500 vaccine versus the tens of thousands of dollars it takes to treat a case of cervical cancer, the millions of dollars spent on the follow-up of abnormal Pap test results', and the mortality costs of HPV-associated cancers, the economic benefits to individuals and society are apparent.

Equally important in determining public health policy are aspects beyond the cost-effectiveness of a new technology or medical intervention. Concerning HPV vaccination, inclusion of issues such as socioeconomic status, acceptance of the vaccine among certain racial/ethnic groups, and the current disparities in HPV-related disease, enhance decision-

making regarding prevention efforts. For example, among African-Americans, acceptance of the vaccine increases with age of child; parents are less accepting of the vaccine for their daughters under age seventeen. Differential uptake and utilization of HPV vaccination will have both positive and negative consequences for cervical cancer prevention. Therefore, careful deliberation must be undertaken.

Policy Goal

Disparities in health among some income, racial, and ethnic groups in the U.S. are significant and, by many measures, expanding. Communities of color and those of low socioeconomic status disproportionately experience worse health and safety outcomes across a broad spectrum of illnesses and treatments. Cervical cancer is no exception, as minority women bear an unequal share of the disease burden.

For the purposes of this analysis, the public health goal is to reduce the burden of cervical cancer and HPV-related disease among all women, through use of the HPV vaccine; with an emphasis on the disparities that exist among African-Americans who are markedly impacted by its negative health consequences. The ACIP recommends routine vaccination for 11-12 year old girls prior to sexual debut, with a “catch-up” vaccination for females ages 13-26 years.^{8, 28} While the evidence suggests that those not previously exposed to HPV can more fully benefit from vaccination, there are advantages to vaccinating young adult women that are sexually experienced who too will derive some benefit from vaccination.^{17, 28}

The key to successful implementation of the HPV vaccine will be in how key stakeholders, from policymakers and healthcare providers, to parents, women and girls, respond to ensure that all those who can benefit have access to it. There are a variety of comprehensive and incremental approaches that could be taken together or separately to move towards achievement of this goal.

A. Diffusion of Innovations

An innovation may be a product, service, a process, system, a structure that is new to an organization.⁹⁹ The process by which individuals and social groups adopt innovations to improve health care delivery is a composite process. Everett Rogers describes the diffusion of innovation as “a process by which (1) an innovation (2) is communicated through certain channels (3) over time (4) among the members of a social system.”^{100, 101} For the purpose of this study, the general Diffusion of Innovations theory will be discussed to facilitate decision-making as it relates to the adoption of the HPV vaccine.

The process of innovation of diffusion describes the existence of five distinct population sub-groups; the *innovators*, *early adopters*, *early majority*, *late majority*, and the *laggards*. The innovators are the first to adopt an innovation. The second sub-group to adopt innovation are the early adopters, comprised of a large concentration of opinion leaders. Members of the early majority utilize their interpersonal connections as a catalyst for change. The late adopters are very cautious and skeptical, and are generally obliged to adopt an innovation due to peer pressure.^{100, 101} According to Rogers, the last to adopt an innovation are the laggards who are typically suspicious and retain the least power and influence as a result of their socio-economic standing.

The speed at which an innovation is adopted is determined by the members of the social system, as described above. Several attributes act as independent variables to rate of adoption including: relative advantage, compatibility, trialability, and observability.^{100, 101} Relative advantage refers to the cost-benefit of the innovation over the current method, for example HPV vaccination versus other methods of cervical cancer prevention- screening. Decision-makers often seek an innovation that will yield tangible benefits in the form of cost savings; this does not negate the intangible benefits that are similarly valuable. The

opportunity costs of adopting the innovation the potential return on investment are also measured. The relative advantage of preventive innovations is difficult to demonstrate and can be uncertain, as the advantages of the innovation occur at some future point in time.¹⁰¹ Innovations associated with a perceived high degree of risk or uncertainty have a lower likelihood of adoption.⁹⁹

In adopting an innovation, decision-makers want to be clear about what will be gained and its capacity to further the goals. Compatibility relates to the innovation's alignment with the group's socio-cultural values, beliefs, and previously held ideas. A high degree of compatibility between an innovation and the adopters increases the rate and success of adoption.⁹⁹

The ability to try an innovation on a limited basis is important to innovators and early adopters. Trialability provides decision-makers an opportunity to see if the innovation addresses a particular need in a beneficial manner on a non-committal basis. Oftentimes, an organization will conduct a pilot study of an innovation to determine its acceptability and assess whether the innovation needs to be adapted. An incremental, phased approach can also be used to build support and promote success of the innovation. Trialability is associated with higher rates of adoption and assimilation.^{99, 101} Policymakers and states follow this pattern of diffusion by watching the actions and results of policy adoption of others to similar issues and then either adopt or reject the policy.¹⁰⁰ As a final point, Rogers describes observability as the degree to which the results of an innovation are visible to others. Innovations that have observability are more likely to have a high rate of adoption.^{100, 101}

Two essential elements absent from Rogers theory are the importance of readiness for change and feasibility. Successful adoption of an innovation is greatly enhanced when there is a perceived need for change, at all levels. Ensuring that all stakeholders- patients and

families, community organizations and others- have a positive attitude toward the innovation can be critical to its success.⁹⁹ As with all innovations, some degree of change is required; policy-makers must also assess whether adoption of a particular innovation is feasible. A state's passage of a school mandate, requiring HPV vaccination and its associated costs (economic, parental rights), illustrate the significance of these aspects of adopting innovation.

Diffusion of HPV Vaccination

HPV vaccine is a preventive innovation, in that it was created to address the looming risk of cervical cancer, genital warts, and their associated costs; these include economic, social, and personal costs.¹⁰⁰ The introduction of emerging technologies, such as vaccines to reduce the spread of preventable diseases, have far exceeded federal, state and private-sector investments in these innovations. Significant policy implications come along with the introduction of an innovation, as decision-makers consider laws and policy to further implementation and uptake of the vaccine.

Employing the Diffusion of Innovation theory, the rate of adoption of Gardasil®, the HPV vaccine, has faced challenges as a result of its low relative advantage, incompatibility with some beliefs, lack of trialability, and lack of observability. For these reasons, the vaccine has experienced difficulty integrating easily into the population and states as an adoptable innovation.¹⁰¹ Prevention innovations are generally slow to implement.

Additionally, the HPV vaccine has only been on the market for about three years. Its novelty alone has contributed to slow policy adoption, as the information available early on to help policymakers reduce uncertainty in decision making was somewhat limited and obscure. As more information beyond the vaccine's efficacy becomes available, such as its cost-effectiveness, policymakers will be in a better position to assess the economic feasibility of

adopting policies.^{100, 101} Over time, acceptance of HPV policy options will likely increase as policy options diffuse through states.

Kingdon's- Three Streams Framework

The policy formulation process is wrought with ambiguity. Many attempts have been made to explain why some policy agenda items are prominent while others are abandoned. Kingdon suggests that policy alternatives occur across three independent streams- *problems, policies and politics*- in which different stakeholders each play a role.⁸⁵ The likelihood that an issue will receive serious policy-maker attention is enhanced at the point in which the three policy streams converge, creating a window of opportunity. This coupling is known as the “*policy window*,” a fleeting moment in time, by which heightened attention to and action on a specified agenda are most likely to occur. A favorable environment for any form of health policy is dependent upon a number of actors and requires a number of elements that are aligned accordingly.⁸⁵ A clear understanding of the policy environment, stakeholder perceptions of that environment, as well as perceived roles and relations among the various actors, is increasingly relevant in achieving health policy outcomes as evidenced in formulation of HPV vaccine policy options.

The streams flowing through the policy system are independent. Kingdon's problem stream includes concerns that individual citizens and policymakers have. Some indicators provide evidence to focus attention on the magnitude of a particular issue; the indicator alone is not sufficient to define the issue as a problem until a disaster event occurs.^{85, 102} The burden of cervical cancer caused by persistent infection with high-risk ‘oncogenic’ types of HPV in the United States and globally, has been well-documented. Even more alarming are the proliferation of disparities among certain groups based on income, race/ethnicity,

geography, and other factors. The escalation in healthcare expenditures and continuous decline in health outcomes has been described as a “crisis” by many who are advocating for reforms in the U.S. healthcare system. The reallocation of resources toward preventive care rather than the treatment of illness has been identified as a potential solution.

The policy stream, according to Kingdon, is represented by a collective of ideas, of which only a few are given serious consideration. This consideration is demonstrated in various forms such as resource investments, hearings and white papers, among other products.^{85, 102} Of those given consideration, certain characteristics enhance their odds of moving forward; technical feasibility, value acceptability among policy-makers, cost, public acquiescence, and receptivity among elected officials and decision-makers. Within this stream, political actors representing the wishes and demands of their constituencies, share a common concern for a single issue and select the means by which it should be attended to.¹⁰² Relative to the HPV vaccine, multiple monographs and numerous studies, and financial investments in the form of funding through VFC, and routine ACIP meetings indicate its significance within certain policy networks.

Kingdon’s third stream is politics, representative of the various political forces: national mood, organized interests, the political ideology of elected officials and legislative turnover.^{85, 102} In the 2008 Presidential election, a sweeping shift in the national mood was conveyed by the election of President Barack Obama, a Democrat whose political orientation is in stark contrast to that of his predecessor; furthermore, majority and minority makeup of Congress shifted, altering the ownership of power. The political stream plays a critical role in promoting or inhibiting the rise or fall of an issue on the policy agenda.

The point at which the three streams converge is known as the policy window; the “fleeting moment in time” in which a policy option is likely to receive traction and be

adopted by policy makers. Immediate action is taken on the part of policy entrepreneurs to seize the moment.^{85, 102} Policy entrepreneurs are those advocates that are willing to invest resources- time, energy, reputation, and money- in hopes of a future return on their investment. The success of a policy entrepreneur lies in their ability to manipulate the coupling of the policy streams, access policy makers and devote substantial resources. MERCK actively participated as a policy entrepreneur in promoting the acceptability and use of Gardasil®. The pharmaceutical company invested resources to increase awareness of HPV and the vaccine that protects against the virus; and were successful in gaining access to state legislators and policy-makers through the organization Women in Government (WIG), a national bi-partisan organization of women state legislators, initiating a momentous degree of highly charged political engagement in the prevention of cervical cancer, across the nation, within state and local governments.

The current favor toward a domestic policy agenda in which an overhaul of our systems of healthcare, education, and energy are being aggressively championed, as demonstrated by the participation of various political actors, exemplifies a potential '*window of opportunity*.' By extension, the HPV vaccine debate is likely to gain policy traction because of its role in supporting prevention and wellness that may have been previously limited.

Status of Existing HPV Related Policy Options

While adoption of HPV related policy has been deliberate, it has not slowed the flurry of debate that has occurred since the FDA's approval and ACIP's recommendation of the vaccine to protect against human papillomavirus. Discourse taking place around HPV and the vaccine has centered around three major issues: 1) mandated school vaccine requirements, 2) education and awareness about HPV and cervical cancer, and 3) improving access.^{103, 104}

Table 5.4 from the State Cancer Legislative Database (SCLD) shows cervical and HPV-related state legislation, dating back from 1977 thru 2008.

State Cervical Cancer- and HPV-Related Legislation Over Time

Source: National Cancer Institute's State Cancer Legislative Database

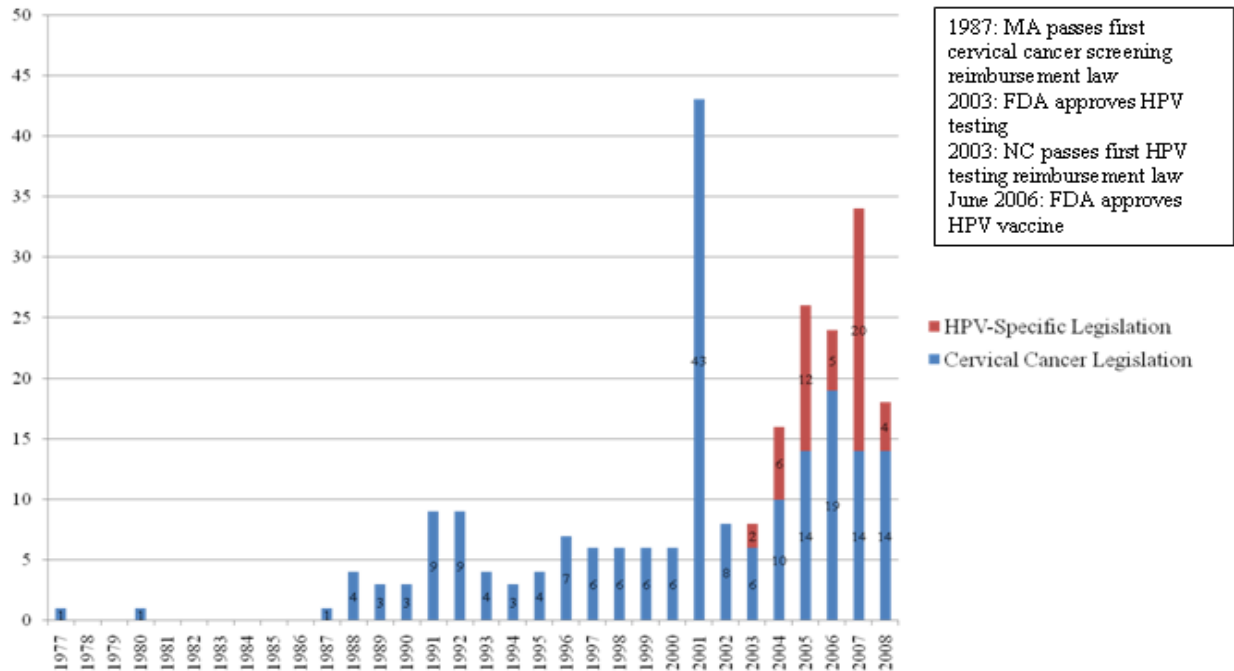


Table 5.4: State HPV-Related Legislation (1977-2008)

Policymakers across the country have taken varied approaches to addressing cervical cancer prevention. Several states have introduced and enacted legislation aimed at increasing awareness and education about cervical cancer, and the virus that causes it, HPV. Other states have sought to improve access to new screening and preventive technologies by requiring insurers and public programs to offer advanced services, such as the HPV test. Some of these approaches, examined here, are summarized below in Table 5.5.^{103, 104}

Table 5.5: Proposed/Enacted HPV-Related Legislation by Type

TYPE OF STATE LEGISLATION	DESCRIPTION OF HPV RELATED LEGISLATIVE ACTIVITY	# OF STATES PROPOSED/ ENACTED LEGISLATION
1. Cervical Cancer Task Force	State law or resolution designating creation of task force or commission to study and make policy recommendations around cervical cancer prevention	24
2. Education and Awareness	State laws aimed at educating the public, parents, and students about HPV and cervical cancer	15
3. Mandated School Requirements	State laws requiring HPV vaccination requirements for school attendance	2
4. Funding for Vaccination	State laws aimed at allocating funds to pay for the HPV vaccine for females 9-26 years of age	1
5. Mandated Insurance Coverage	State laws aimed at requiring third party insurers to provide coverage for cervical cancer screening, HPV screening and the HPV vaccine	29
Total		71

Sources: National Conference of State Legislatures/NCI: State Cancer Legislative Database

Policy Evaluation Criteria

In an effort to gauge ease of implementation of the policies, a review of the policy options was conducted, examining the following three criteria—political feasibility, degree of health protection, and cost.^{85, 102} Each of these different options for improving acceptability and use of the HPV vaccine to reduce the burden of HPV related disease varies in terms of the degree of political feasibility, offers different degrees of health protection, and is associated with different types and amounts of economic costs. Political feasibility is a combination of factors such as public acceptance of the idea, acceptance by policymakers and key stakeholders, and timing relative to other legislative considerations. Feasibility is an important measurement tool because it predicts the likelihood of enactment of the policy option by state governments.

The degree of health protection offered by each policy option is important because the ultimate goal is to more adequately protect the health of the greatest number of women, who are likely to benefit most from HPV vaccination. A policy option that does not protect the most people would not be considered a viable policy option unless it offered some external tradeoff that ultimately would produce greater health benefits or accomplish some other related policy goal. Economic costs are a third and final important consideration for deciding among the policy options described in this paper because costs to the State are generally undesirable. However, some social or economic costs could be considered acceptable either by policy makers or the public if there are substantial social and health benefits.

Policy Option #1: Establish Cervical Cancer Task Forces

Approximately twenty-four states have established Cervical Cancer Elimination Task Forces or some accountable entity, providing the infrastructure needed to support and monitor progress of cervical cancer prevention efforts. Their ultimate goal is the elimination of cervical cancer through policy initiatives. In addition, they provide leadership in the development of cervical cancer-related laws and regulations and identify gaps in policy, programs, and services that can be dealt with through legislative means.¹⁰⁵ For example, some have devised recommendations on steps to improve how low-income and uninsured women are screened for policymakers and health agency officials. An overarching priority of the task forces is improving education about cervical disease and its cause, HPV, while addressing health disparities in vaccination, screening and treatment.

A central aim of the task force is to complement and build upon existing activities that may be performing similar tasks; therefore, a number of these groups work in

collaboration with state Breast and Cervical Cancer Early Detection and Comprehensive Cancer Control Programs.¹⁰⁵ They have been successful in bringing together lawmakers, public health and medical professionals, insurance industry officials, communications experts and women's health groups in the development of statewide cervical cancer prevention initiatives. The following is an example of how the state of Maryland's Cervical Cancer Task Force (*the task force*) worked collaboratively to integrate efforts:

House Bill 1049, introduced by *the task force*, established the HPV Vaccine Subcommittee, through the Maryland Comprehensive Cancer Control Plan- Cervical Cancer Committee. The HPV Vaccine Subcommittee is charged with increasing awareness and education about HPV; evaluating the availability and affordability of the HPV vaccine and identifying barriers to its administration; identifying resources to cover the costs of the vaccine and evaluating mechanisms to increase access.¹⁰³

This illustrates the utility of the cervical cancer task forces and the critical role that they can play in introducing and adopting state policy for increasing acceptance of and access to the HPV vaccine. Task forces are an opportunity to both inform policymakers and gather credible evidence.

Cervical Cancer Task Force membership is composed primarily of Women in Government (WIG) members. Women in Government (WIG), a non-profit, national bipartisan organization of women state legislators has been very instrumental in the creation of these task forces across the country, through their *Challenge to Eliminate Cervical Cancer Campaign*, launched in 2004.¹⁰⁵ Collectively, they have been particularly influential in identifying opportunities to expand or improve current mechanisms to ensure that women have access to routine and appropriate cervical cancer screening. Furthermore, as part of their campaign platform, WIG and the task forces are actively engaged in efforts to implement the

HPV vaccine to all age-appropriate girls and women- regardless of their socioeconomic status.^{105, 106} Uniting of the cervical cancer task forces and WIG, a visible and vocal group of female policymakers, is extremely valuable as they are in a position to educate their fellow legislators about the HPV vaccine and advocate for a more comprehensive cervical cancer prevention agenda.

Policy Option #2: Educate Public, Parents, and Students about HPV and Cervical Cancer

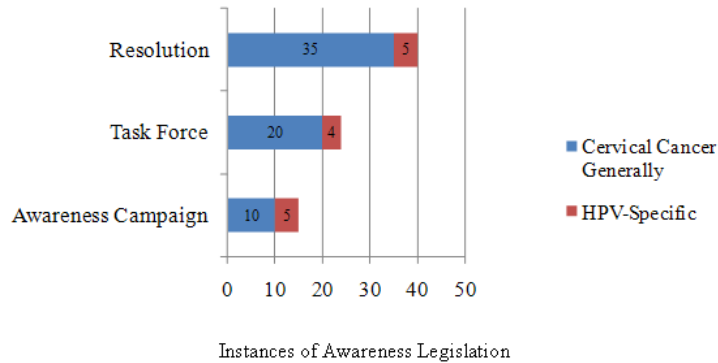
Numerous states have proposed or enacted some form of legislation aimed at expanding cervical cancer and/or HPV awareness and identifying innovative ways to better disseminate the information.¹⁰³ Types of legislation addressing one or more of these issues are displayed in Table 5.6 below. Strategies for increasing awareness are generally aimed at a one or more audiences including: the general public, students in grades 6-12, and in some instances public versus private schools are stipulated, as well as parents of students and those considering vaccination. Examples of those entities responsible for carrying out and enforcing the legislation represent health departments and schools, among others.

Table 5.6: Education & Awareness Legislation by Type

Legislation that Addresses Cervical Cancer and HPV Awareness*

(As of December 31, 2008)

Source: National Cancer Institute's State Cancer Legislative Database



*Data are not Mutually Exclusive

The approaches to increasing knowledge about HPV/HPV vaccination and cervical cancer are broad and diverse, ranging from requiring schools in Louisiana to provide HPV information and vaccines under certain circumstances, to the mailing of age-appropriate written materials to parents of female students via direct mail in Missouri. During the current legislative period (2009-2010), New York introduced [A3202/S1983](#) which would require:

Parents and guardians of a child in New York State be encouraged, through written educational materials and consultation, to be vaccinated against human papillomavirus; The measure also encourages voluntary, informed vaccination against human papillomavirus (HPV) for adults. *The bill is currently in committee.*¹⁰³

In reviewing this particular legislation and others, it is apparent that policies centered on heightening awareness do not necessarily expand the breadth of ones knowledge.

Information sharing and distributing educational materials about HPV is a necessary step toward reaching that goal. Nevertheless, providing information about an issue as complex as

HPV must be coupled with a mechanism to ensure that the information is being interpreted appropriately and that any uncertainties are responded to in an appropriate manner.

Health policies designed to increase awareness do not necessarily ensure the public's understanding of or their ability to adhere to recommended preventive services. This finding suggests the need for policies that encourage comprehensive and integrated approaches to education, such that truly informed decisions can be made about one's health at the appropriate time. Existing statewide entities focused on cancer prevention and/or health should take the lead with like-minded organizations and execute programs to educate and involve stakeholders (e.g., policymakers, providers, parents, men, women, school administrators, advocacy groups, etc.) about cervical cancer, HPV, and the role of available preventive technologies.

Policy Option # 3: Mandate HPV Vaccination Requirement in Schools

The addition of the HPV vaccine to the school-based immunization requirement is a highly effective way of ensuring its rapid and widespread use, as has been the case for vaccines for meningococcal disease, pertussis (whooping cough) and Hepatitis B.⁸⁹ A number of laws have been proposed mandating HPV vaccination as a prerequisite for school attendance. Currently one state and the District of Columbia have an HPV requirement. In general, legislation would establish requirements for immunization against HPV for 11 and 12 year old girls entering into the sixth grade or in accordance with the ACIP immunization schedule.^{103, 104} Even after recommendations by the ACIP, school vaccination requirements are decided mostly by state legislatures.

Many who support availability of the vaccine do not support a school mandate. Proposed mandates requiring vaccination of school-aged girls for HPV have met with great

opposition. Critics have cited concerns about the drug's cost, safety, and parents' rights to refuse. One of the strongest arguments against having a law requiring the HPV vaccine relates to how HPV is transmitted, through sexual contact. The influence of religion and moral values has played a significant role in this issue. Parents oppose a mandatory requirement and instead prefer a policy that provides for voluntary use of the vaccine; they also believe that the decision to be vaccinated should be in consultation with their doctor.

There is strong sentiment that the legislature should be used to inform the public and especially parents so that they can make their own decisions. Those in favor of individual rights and the right to choose also oppose mandatory requirements. In addition, anti-vaccine groups who are concerned about the safety and efficacy of such a new vaccine have already voiced their disapproval.

It is likely that the measure would add millions of dollars in health insurance costs to state and local government childhood immunization programs. Girls with access to the vaccine through private insurance will incur a co-payment or insurance deductible, administrative costs each time a dose of the vaccine is administered. Likewise, the costs incurred by private insurers will likely be passed on to employers and employees in the form of higher premiums. Augmenting the current schedule of vaccines for school attendance to include Gardasil® would be rather easy to do.

Policy Option # 4: Expand Coverage/Access to Uninsured Adult Women, 19-26 for vaccination of HPV

Very few states allocate funds to pay for the HPV vaccine for females 18 years and younger. Some states have proposed and/or enacted legislation to require vaccination of girls entering the sixth grade. One state has put forth/enacted legislation recommending that the state pay for the vaccine for adult women 19 to 26 years of age.

Disparities in cancer burden (incidence, mortality and survival) are highly correlated to race/ethnicity and socioeconomic status. Uninsured and/or underinsured women between the ages of 19-26 will not have access to the HPV vaccine, as there are no public programs to cover adult immunizations with the exception of Medicare and Medicaid (for adults who qualify).

Existing public health programs, screening and vaccination, should be adequately funded and utilized to ensure that uninsured or underinsured females have access to HPV vaccination and cervical cancer screening. Potential resources in the form of direct or in-kind support might include: Medicaid/SCHIP, Section 317 Grants Program or MERCK's Vaccine Patient Assistance Program. By extending Medicaid or SCHIP eligibility to age 24, more low-income young adults would qualify for public coverage through their college years or first years in the job market. The inclusion of \$300 million for the Section 317 Grants Program was authorized and signed into law by President Obama, as part of the American Recovery and Reinvestment Act of 2009. A greater proportion of a state's/jurisdiction's Section 317 funds should be dedicated for vaccine purchases of recommended adult immunizations.

Additionally, MERCK the manufacturer of Gardasil® established the Vaccine Patient Assistance Program (VPAP) to provide MERCK vaccines free of charge to eligible

individuals, primarily the uninsured whom would not have access to them otherwise. All of Merck's vaccines for adults are available through the program; however, the program is targeted toward women aged 19-26 who have no other source of payment for Gardasil®.¹⁰⁷ VPAP is operated through private provider offices as a vaccine dose replacement program; most recently the MERCK VPAP Public Sector program was implemented to extend participation to health departments and public health clinics.

Federal, state, and private-sector investments in vaccine purchases and immunization programs are critical, given the complexity of our fragmented vaccine delivery system. Policy makers should seek opportunities to collaborate with industry, as demonstrated above, to maximize resources. Extending access to uninsured women thru existing public health programs (immunization or STD clinics, family planning clinics, and breast and cervical screening programs) would be advantageous to women and the state. A large percentage of the uninsured utilize hospital emergency rooms more frequently, presenting at acute stages of illness, which poses an additional burden to an already strained health system. Expenditures related to indigent care have sky-rocketed; the monetary costs associated with needless follow-up and treatment due to HPV related disease can be reduced considerably when one gains access to primary prevention services.

Policy Option # 5: Mandate Coverage of the HPV Vaccine by Insurers

The more costly immunizations become, the less incentive exists for insurers to offer them as a benefit. Many believe vaccines, once they have been recommended for widespread use, should not be an *optional* benefit of health plans, as is the current practice. Vaccines should be integrated as part of a plans basic healthcare package. Several states, approximately twenty-nine, have passed laws requiring third-party reimbursement for

cervical cancer screening, HPV screening and/or the HPV vaccine. In general, those laws addressing immunization against HPV specify that health benefit plans cover the costs of the HPV vaccine for female beneficiaries.

Despite lawmakers best efforts, insurance mandates would not apply to self-insured employer-sponsored health plans as they are governed by the Employee Retirement Income Security Act of 1974 (ERISA) and are not subject to individual state laws. In 2003 the *IOM Committee on the Evaluation of Vaccine Purchase Financing in the United States* made a recommendation that included a combined mandate, subsidy, and voucher plan to improve access and availability of vaccines. The recommendation has not been implemented; however, if executed it would require coverage of vaccines endorsed by the ACIP in all private and public insurance plans.⁸⁹ Federal intervention mandating insurance coverage may be necessary to reduce the inconsistencies between public and private health plan benefits. Insurance mandates remove a barrier to accessing preventive health and primary care services and are relatively easy to implement in comparison to some other policy options.

B. Analysis of Options

Several states have proposed or enacted legislation/policies in support of eliminating cervical cancer. There are arguments in support of and against each of the policy options described. Using the three criteria- political feasibility, degree of health protection, and cost-for analysis, four of the five policy options examined are expected to have the most influence achieving higher levels of acceptability and uptake of the HPV vaccine. In terms of health, extending insurance coverage/access to uninsured individuals, including young adult women ages 19-26, offers the most protection to the greatest number of people. Mandating

reimbursement of the vaccine by third-party insurers would be an effective means for protecting health by improving access to a select group of insured individual's, however it would likely have minimal impact on young adults who are most likely to be uninsured. Establishing cervical cancer task forces or coalitions who can yield some political clout offers a moderate degree of protection; as does implementing an educational campaign to increase knowledge and awareness about HPV and cervical cancer. However, the potential for these two options to extend the health protection benefits to a larger number of people increases over the long-term.

Launching a cervical cancer task force or coalition of some sort is likely to be among the more politically feasible options. The National Comprehensive Cancer Control Program (NCCCP) provides funding to all 50 states, several tribes, and territories in support of comprehensive cancer control (CCC) coalitions to address cancer prevention and control initiatives. By identifying cervical cancer as an issue of significance, it is likely to become a priority to be addressed by the coalition within the context of the cancer plan. The CCC plan provides a blueprint for coordinating the actions of coalition partners and stakeholders; ensuring the efficient use of resources and that objectives are met. This approach to addressing HPV, vaccination and cervical cancer through established networks is likely to be more acceptable, as it lessens the burden for those involved. Likewise, any and all efforts to increase knowledge and understanding about HPV related disease and acceptability of HPV vaccine across stakeholder groups, the public and policymakers is also likely to be among the most politically feasible options. Developing an educational campaign and providing resources can be done in collaboration with the work of the cervical cancer task force or coalitions.

Mandating coverage by insurers has a moderate level of political feasibility. The majority of health insurance plans include coverage of most or all of the ACIP recommended immunizations in their benefits for children, adolescents and adults; however, given the high cost of the HPV vaccine and its requirement of three doses, there may be some resistance to covering this particular vaccine. The degree of political engagement by insurance interest groups in particular regions, may be an inhibiting factor. While the policy option expanding public health insurance benefit programs to an additional category of uninsured seems to have a low level of political feasibility. It is more likely that some sort of incremental change will need to occur first in order for legislators and the public to accept comprehensive change. The alternative strategy of increasing access include participation in MERCK's VPAP, which will minimize costs to state governments, is politically more favorable than expanding public health benefits.

Cost of two of the four options- cervical cancer coalitions and education programs is relatively low. Covering the expense for uninsured women is likely to be a high cost option for policy makers, unless some form of cost-sharing mechanism is enacted; for example, public-private partnerships such as MERCKs VPAP or perhaps requirement of a fee to individuals on a sliding scale. Similarly, the costs of requiring coverage of the HPV vaccine by insurers is also a relatively low cost option to policy makers; however there may be political costs and the costs to insurers are assumed to be relatively high.

Table 5.7: Evaluation of Policy Options for Improving Cervical Cancer Prevention

	ESTABLISH CERVICAL CANCER TASK FORCES	EDUCATION & AWARENESS	MANDATE SCHOOL REQUIREMENTS	EXPAND COVERAGE/ACCESS TO UNINSURED WOMEN	MANDATE COVERAGE BY INSURERS
HEALTH PROTECTION	Moderate	Moderate	Moderate Immediate; High Potential	Moderate Immediate; High Potential	High: Insured Low: Uninsured
POLITICAL FEASIBILITY	High	High	Low	Low; Moderate Potential	Moderate
ECONOMIC COST	Low	Low	Individual: Moderate Insurers: Moderate State: High	Moderate to High	Individual: Low Insurers: High State: Low

When all of the policy options are examined using the criteria, some options are less desirable than others, but each would achieve some component of the goal to reduce the burden of cervical cancer and HPV-related disease among young adult African-American women, aged 18-26. Four of the five options summarized in Table 5.7 above— establishment of a cervical cancer task forces, executing an educational campaign, expanding coverage/access to uninsured, and mandating third-party insurance coverage- could be pursued simultaneously or independently of one another. Based on the experiences of some states it might be most effective to first invest advocacy efforts into the establishment of cervical cancer task forces or coalitions in conjunction with a broad-based education and awareness social marketing campaign. Next steps would include pursuit of mandates requiring coverage of the vaccine by third-party insurers, followed by expansion of insurance coverage to comprehensive preventive health services for low-income uninsured individuals. However, enhancing access to the vaccine through alternative funding mechanisms should be pursued. The policy mandating school requirements will have the least impact on this population and therefore is not considered a viable option.

The following policy options will be pursued and an advocacy strategy and implementation plan will be described in *Chapter 6*.

Strategy #1- Educate Public, Parents, and Students about HPV and Cervical Cancer

In collaboration with Academy for Educational Development (AED), the *Women ROCC!* (Women Reaching Out Against Cervical Cancer) social marketing educational campaign, will be expanded to two historically black colleges and universities (HBCUs) in states with high cervical cancer rates (Southeast region of the United States). The curriculum utilizes a peer education model to conduct trainings, presentations and disseminate information.

Strategy #2- Expand coverage/access to Uninsured Adult Women, 19-26 for vaccination of HPV

Through the National Cancer Prevention and Control Programs, an assessment will be conducted to determine the potential for integrating HPV vaccination into existing programs of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

These combined efforts seek to expand access to vaccination among, 19-26 year olds. Additional information regarding plans for implementation will be further described in *Chapter 6: Implementation Plan*.

CHAPTER VI: IMPLEMENTATION PLAN

As the findings of this study- the literature review, key informant interviews and policy analysis- suggest implementing HPV vaccination among African-American women requires that a comprehensive, multi-phased approach be employed. There are arguments in support of and against each of the policy options described in Table 5.7 (See page 127). For the purposes of this paper, the choice of policy options to further support implementation of HPV vaccination among the upper age limit of the ‘catch-up’ group will address the gaps in knowledge of HPV and cervical cancer and access to vaccination, that currently exist.

As outlined earlier, education and information about HPV and cervical cancer is necessary for making informed decisions; conveying information and communicating messages about HPV are critical to increasing acceptance and uptake of the vaccine. Furthermore, cost and availability collectively pose barriers to entry into vaccination among this population- low-income and uninsured young adults. Access to immunization against HPV types can be facilitated by identifying alternative sources of funding and expanding the number of venues that offer vaccination.

The purpose of this plan for change, then, is to take an incremental and targeted approach to addressing the burden of HPV-related disease among young adult African-American women. This twofold strategy is intended to serve as a guide to expanding vaccine coverage and participation in HPV vaccination catch up programs, specifically designed for African-American women, aged 18-26. Discussion of the elements of the implementation

plan follow; however the actual plan would be developed by the target audience and multiple stakeholders.

- Adapt and implement Women ROCC! and the *Women Reaching Out Against Cervical Cancer (ROCC): A Guide for successful HPV and cervical cancer prevention* toolkit at two Historically Black Colleges and Universities (HBCUs).
- Conduct an assessment to determine the potential for integrating HPV vaccination into existing programs of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

Implementation Strategy #1

Adaptation of Cervical Cancer Prevention Social Marketing Campaign

The Academy for Educational Development (AED) through its partnership with the National Education Association-Health Information Network (NEA-HIN) designed a cervical cancer prevention campaign focusing on colleges and universities. Colleges and universities historically have utilized peer educators to conduct intervention activities on campus and within the community; this model is known to be effective in a campus setting. The Women ROCC program is designed to:¹⁰⁸

- 1) Engage young adults 18-25 in cervical cancer prevention activities in the campus environment
- 2) Increase knowledge about cervical cancer, HPV and screening
- 3) Assist students in identifying cervical screening resources on campus or in the community
- 4) Develop student peer educators to speak about cervical cancer prevention, while encouraging broader student participation, and
- 5) Build sustainability of the program on campus/community

The curriculum development was guided by the Task for Community Preventive Services guidelines for cervical cancer prevention strategies;¹⁰⁸ HPV and cervical cancer prevention were addressed in an interactive format through the integration of one-on-one education, small media and multi-component interventions. The content and materials were developed through coordination with HBCUs and Hispanic-Serving Institutions (HSIs). In addition, the program will be adapted to also address vaccination against HPV and related issues (i.e. risk/benefits of vaccination, safety and efficacy concerns and potential resources for vaccination). Below Table 6.1 describes the Women ROCC! core elements adapted to include the HPV vaccine.

Table 6.1: Women ROCC! Core Elements adapted to include HPV Vaccination

DISSEMINATION OF 4 KEY MESSAGES	DELIVERY OF EDUCATION PRESENTATION
<ul style="list-style-type: none"> • HPV is an STI that is linked to cervical cancer and genital warts • Cervical cancer is preventable • HPV vaccination and regular Pap tests are tools available to you to protect your health • Schedule an appointment to discuss your options with a healthcare provider 	<ul style="list-style-type: none"> • HPV and it's link to cervical cancer • What is a Pap test? • What is the HPV vaccine? • Importance of prevention • Inclusion of at least one Guide activity (e.g. game)
RESOURCES FOR HPV VACCINATION AND CERVICAL CANCER SCREENING	HPV AND CERVICAL CANCER FACT SHEET
<ul style="list-style-type: none"> • Provide list of locations that provide quality and accessible services • Business card format for something portable 	<ul style="list-style-type: none"> • Organization mission & role in Women ROCC! • 4 key messages • Burden of HPV-related disease statistics • Healthcare provider resource list • Organization contact information

Source: Academy for Educational Development

Women ROCC!

The AED has made a guide and CD-ROM available which includes a variety of tools, templates, and materials that are easily customizable to those interested in adapting the program to their campus. The materials fall into three categories: 1) planning and promotion materials, 2) education materials, and 3) assessment and evaluation materials. The materials are posted on the Women ROCC! website, www.GetThePap.org.¹⁰⁸

Step 1: Identification of HBCUs

Selection of universities to implement Women ROCC will be primarily based on their location in states with higher than average cervical cancer mortality rates among African-American women. Furthermore, HBCUs should be given particular consideration based on their capacity to execute the campaign and ability to complete program requirements.

Step 2: Establish a core Women ROCC! team on campus

The core team should be composed of key stakeholders who have a role or interest in addressing the preventive health needs of college students, with an emphasis on cervical cancer prevention, HPV education and improving safe-sex behaviors. Members of the team should be specific to the community/environment; however, recruitment should include faculty, staff and students; examples include student health, colleges/schools representing public health, allied health sciences (nursing) and social work, Greek fraternal organizations, etc. One essential member of the core team should be a healthcare professional who is knowledgeable about the HPV vaccine, and is able to communicate to students in a meaningful way, addressing any concerns. A staff/faculty member(s) champion and student

representative will co-manage the program and a campus *'home'* for the campaign should be designated for organizational purposes, to provide structure and the necessary administrative support.

The goals of the team should be to: educate and engage the university (students, staff, faculty) and surrounding community in dialogue and frank discussions about health and healthy lifestyles, for positive health outcomes; support campus program efforts to increase peer educator knowledge and awareness of HPV and cervical cancer and primary and secondary prevention strategies (vaccination and screening); increase behavioral intention of young adult women to participate in HPV vaccination and cervical cancer screening, as appropriate; identify benchmarks against which to measure program outcomes; monitor and report on the progress of meeting established targets through use of process and outcome evaluations; and engage additional partners within and outside of the university community to leverage resources, sustain and enhance program goals.

Step 3: Identify target audience

While Women ROCC! is designed to be implemented campus-wide, the target audience for this campaign should be incoming freshmen. Incoming freshmen will be required to participate in specific program events. Additionally, they will be asked to complete routine online evaluations to assess current prevention (i.e. screening and vaccination) and lifestyle practices. The freshmen activities should be coordinated through the universities' Student Health Services and Residence Life in collaboration with the core Women ROCC! team.

Step 4: Obtain and allocate appropriate resources necessary to plan, implement and maintain program

Based on the scope of the program an array of resources will be required for its successful development and execution. An overall budget should be established with set parameters for program needs (space, equipment, refreshments, photography/ videography, materials, etc). It is assumed that minimal financial resources will be necessary. To begin determine the number of people available to help plan, promote and staff particular events. A fair amount of human capital and effort will likely be required.

Given the nature of university culture, the scope of program activities, time constraints, and competing priorities should be taken into consideration when allocating resources.

Step 5: Recruit and train a cadre of peer educators

Peer education implies a role model-method of education in which trained, self-identified members provide education sessions to their peers;¹⁰⁸ in this case HPV and cervical cancer education. Peers generally share an identity with the intended audience and speak a common ‘language.’ Due to their familiarity with the group’s cultural nuances (based on race, age, gender, student status, etc), they are able to convey certain norms and values; while serving as a liaison between the university and student/community group(s) in an advocacy role.¹⁰⁸

The core Women ROCC! team should recruit at least 15-20 volunteers to serve as peer educators; they should represent a variety of class years and academic disciplines. An initial kick-off training should be held at each school, in which the program and toolkit will be rolled-out and students will be trained to be peer spokespersons using the AED curriculum. Volunteers will participate in a training to increase their basic knowledge about cervical cancer and HPV, the importance of prevention and increase attendees’ capacity to conduct formal presentations and engage in informal discussions about HPV-related disease

and prevention. A pre/post survey will be administered at each training to assess the peer educator's knowledge around the topic and prevention program.

Peer educators should commit to the following responsibilities: 1) attend program trainings, 2) conduct education presentations to peers about cervical health in an interactive and engaging forum, 3) plan and conduct outreach to community through program events and activities, and 4) collaborate with partners.

Step 6: Adapt Women ROCC! program

The AED has made a guide available at www.GetThePap.org to be used in the adaptation and design of a Women ROCC! program for college/university settings. However, tailoring the guide to meet the organizations need is encouraged. Internal and external partners should be integrally involved in this stage of program development. Additionally, the core elements of Women ROCC! (See Table 6.1- page 126) should be maintained to ensure success of the program.

Step 7: Implement Women ROCC! on campus

Peer spokespersons should implement a variety of programmatic activities on campus and surrounding community (where appropriate) over a given time frame (i.e. semester/school-year). Ideally, the program would begin in the fall and be implemented over the course of two semesters. Student outreach, communications, and health education activities should be coordinated and closely monitored. Using the materials provided in the toolkit, it is suggested that each peer educator at minimum be required to:

- Deliver Women ROCC! education presentation in a formal setting to at least 25 students(each),

- Engage in informal dialogues reaching a minimum of 40 students,
- Partake in campus or community outreach activities individually and in small groups (i.e. media outreach, partner activities and high-profile campus events)

Step 8: Evaluation and Monitoring of Program Activities

Both process and outcome evaluations could be carried out to assess the effectiveness of implementing the Women ROCC! campaign and identify lessons learned. The overarching goal of increasing the number of college women (age 18-25) attending HBCUs who are knowledgeable about HPV, cervical cancer, primary and secondary prevention strategies should be measured. The evaluations should be conducted by the faculty/staff advisor and student co-managers in collaboration with AED.

Process Evaluation

The process evaluation is designed to assess the process of recruiting and training peer educators and tracking of volunteer spokespersons activities. Peer educators should track activities using a variety of mechanisms and tools to attain feedback from students they've interacted with on behalf of the Women ROCC! program. The following can be used to gather feedback: peer educator training pre/post survey, sign-in sheets, student feedback forms, monthly logs of outreach activities and other tracking methods.¹⁰⁸

Outcome Evaluation

Utilizing the results from the behavioral assessment of prevention and lifestyle practices conducted with freshmen students, several quantitative measures might be used to assess the effects of the cervical health program; for example numbers of students seeking

HPV vaccination and/or cervical cancer screening, health behaviors, increased sharing of information.

Local Implementation of Women ROCC!

For the purposes of this study, consideration should be given to implementing the Women ROCC! program or some adapted version at two HBCU's- Clark Atlanta University and Spelman College- in Atlanta, GA.

Implementation Strategy #2:

Assessing Potential Implications for Integration of HPV Vaccination within NBCCEDP

In developed nations, the U.S. being no exception, cytology screening has been a public health success in cancer control. Many of these countries mobilize substantial resources toward screening whether it is through organized screening programs or opportunistic screening. Even with the introduction of the HPV vaccine as a primary prevention tool, cervical cancer screening will have to continue.^{93, 109-111} The adoption of HPV vaccination represents an opportunity to consider what to do with existing screening programs, and how synergy can be achieved between vaccination and screening.

In 1990 Public Law 101-354 established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). Through the NBCCEDP, the Centers for Disease Control and Prevention (CDC) provides low-income, uninsured, and underserved women access to timely, high-quality screening and diagnostic services, to detect breast and cervical cancer. The NBCCEDP provides screening support in all 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian/Alaska Native tribes or tribal organizations. A network of providers in the program work collaboratively to provide breast and cervical cancer screening, diagnostic evaluation, and treatment referrals (where appropriate). An

estimated 8–11% of U.S. women of screening age are eligible to receive services through the NBCCEDP. Federal guidelines establish an eligibility baseline to uninsured and underinsured women at or below 250% of federal poverty level; ages 18–64 for cervical screening; ages 40–64 for breast screening.

The NBCCEDP proactively recruits high risk women for screening. CDC's goal is to facilitate access to screening for women and in support of this goal makes use of a strong public health infrastructure. The NBCCEDP is a one-of-a-kind program which employs a public health approach for the delivery of breast and cervical cancer screening services across the nation to low income, under and uninsured women; the program's success can be attributed in part to its comprehensive model. This model not only includes the reimbursement of clinical screening services, but also outreach to rarely and never screened women, case management, public awareness and education, professional education and quality assurance, tracking and surveillance, and, program assessment/evaluation.

While the majority of women screened through the NBCCEDP are aged 40 to 64 years, there is a small proportion of women under the age of 30 who receive cervical screening services. Of the sixty-eight funded NBCCEDP grantees, approximately one-third provide cervical screening and/or diagnostics services to young women <30 years of age. Among this group of women, a considerable number of abnormal Pap tests occur within the NBCCEDP.¹¹² Recognizing the vast resources and expenditures associated with the management of abnormal cytology, facilitating vaccination of young women who are also NBCCEDP-eligible could potentially yield great benefits. Figure 6.1 below illustrates the potential opportunity for conducting both cervical screening and HPV vaccination among a group of age-eligible women. As was evident in the key informant interviews and policy analysis, an integrated approach to HPV immunization and cervical screening delivery would

likely enhance vaccine uptake while supporting continued Pap testing among young adult AA women, who have less access and limited resources.

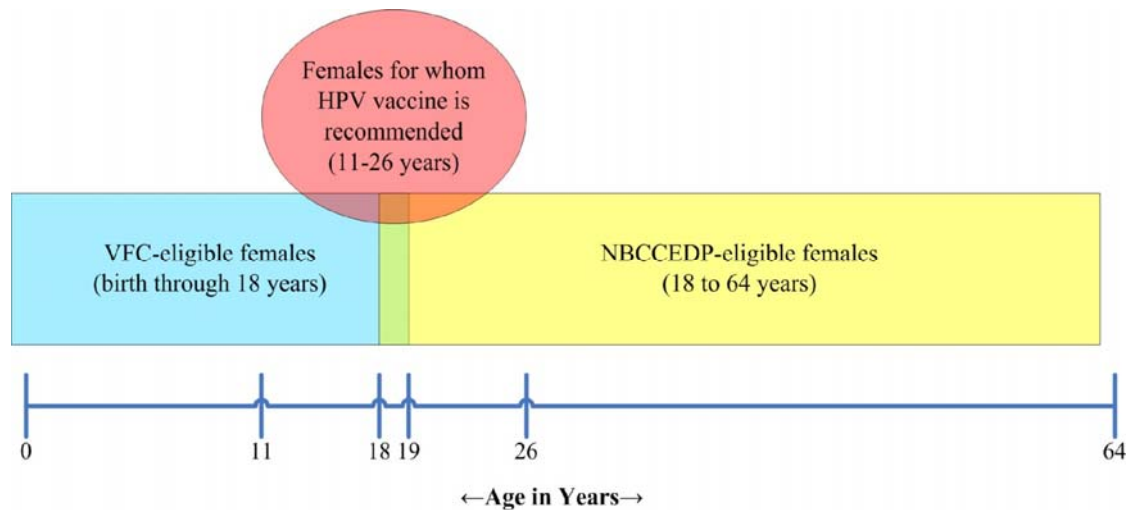


Figure 6.1: Age-eligibility requirements for NBCCEDP, VFC and the 2006 ACIP HPV Vaccine Recommendations¹¹²

Proposed Evaluation Plan

Given that there is so much influx with respect to implementing HPV vaccination, the current cervical cancer prevention policy environment suggests it is an ideal time to examine the capacity of the NBCCEDP to engage in immunization of a select group of clients/women and examine models of integrated vaccination/screening to better understand the benefits and drawbacks of each on the NBCCEDP. The researcher will conduct an assessment, resulting in the development of a White Paper that explores NBCCEDP in the context of HPV vaccination and identify any pressing programmatic and policy issues. This assessment will help the NBCCEDP take stock of the emerging issues that will be of interest.

The primary objective would be to understand the implications for the NBCCEDP in the realm of HPV vaccine delivery and/or reimbursement and identify potential opportunities and barriers to advancing policies to promote cervical cancer prevention (primary and secondary) for uninsured, low-income women.

Specific Objectives:

- The primary objective of this assessment is to determine the capacity for integration of HPV vaccination within the NBCCEDP.
- To assist the NBCCEDP in establishing its role in primary prevention efforts as it relates to cervical cancer.

A preliminary list of evaluation questions regarding the integration of HPV vaccination into the NBCCEDP are presented in Table 6.2 below.

Table 6.2: Integration Evaluation Questions

1. Is there an interest in providing HPV vaccination through the NBCCEDP to eligible clients? (Interest assessed at the national and grantee levels)
2. Are NBCCEDP programs currently involved in HPV vaccination endeavors? If so, in what ways and to what extent?
3. What are some ways in which the NBCCEDP can become actively engaged in HPV immunization practice or policy issues?
4. What would encourage or discourage the participation/ integration of vaccination and cervical cancer screening via the NBCCEDP?
5. What lessons can be learned from integrated cervical cancer prevention programs already implemented (e.g. New York)?
6. Should incorporating immunization into an existing cervical screening program be encouraged, how will issues such as vaccine supply, reimbursement and administration of vaccine be addressed?
7. What other considerations (e.g., provider adequacy, vaccine availability, compliance with 3 dose immunization schedule) might need to be addressed?
8. How would low-income, uninsured women served by the NBCCEDP fare? (Consideration should also be given to provider network)?
9. What ways can other CDC cancer programs; specifically the National Comprehensive Cancer Control Program (NCCCP) and the National Program of Cancer Registries (NPCR) support/ encourage integration of HPV vaccination into existing cervical screening programs?
10. How can public-private partnerships be used to support this effort (e.g. MERCK's Vaccine Patient Assistance Program (VPAP) designed to provide access to low-income, uninsured women, aged 19-26)?
11. What would be the implications for the NBCCEDP in general and CDC?
12. What policy questions should the Division of Cancer Prevention and Control seek to try to address as a way to inform decision-makers?

Since the program's inception, research and scientific advances in new technologies have required CDC to make determinations about the implementation and reimbursement of emerging technologies in the NBCCEDP. CDC considers a wide range of factors and strategically and systematically develops programmatic and reimbursement policies for new technologies. Given the stipulations placed on the program by PL 101-354, this is not meant to be a document advocating for changes to the law; but rather an assessment of the role of the NBCCEDP in furthering cervical cancer prevention efforts.

CDC's DCPC should conduct an assessment and develop a white paper to be delivered to address the above mentioned evaluation questions as it relates to screening and vaccination in the NBCCEDP. Although the paper might be empirically based, it would be more of a thought piece designed to identify emerging issues of potential interest. The goal would be to shape recommendations that are useful in determining how immunization delivery and screening service delivery might be strengthened through the NBCCEDP. Additionally, an assessment of this nature may also help inform the larger issue of combining HPV vaccination and cervical cancer screening for all women.

The evaluation will position CDC/NBCCEDP to proactively determine and lead action steps based on sound evidence and research findings. The results will serve to guide the development of recommendations that can be used to inform policies and decision-making. Findings from this project will be shared with a variety of stakeholders who have an interest in achieving reductions in cervical cancer incidence, morbidity and mortality. The findings could also be disseminated via reports, publications in peer-reviewed journals, and via presentations at professional meetings and conferences.

CHAPTER VII: DISCUSSION

In an effort to more fully understand the issue of HPV vaccination acceptance and use among African-American women, this study examined two key questions:

1. What are the attitudes, practices and beliefs about human papillomavirus among young adult African-American women?
2. What factors would be likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction among young adult African-American women, aged 18-26?

Through all phases of the study- review of the literature, key informant interviews and the policy analysis- insights were gleaned to address the research questions. The literature review sought to describe knowledge and attitudes of young adult women as it relates to HPV vaccination; illuminate factors that may influence and/or deter young adult women from receiving the HPV vaccine; and evaluate the multiple frameworks utilized to analyze and develop policy for bringing about change. Through the process of interviewing key informants, the goal was to further explore the determinants of HPV vaccine use among a specific population, African-American women aged 18-26; and to identify factors that may hinder or facilitate acceptance of the HPV vaccine to inform policy considerations for increasing use and widespread implementation of the vaccine. The key informant interviews explored the perceptions and beliefs of respondents; building upon the findings of the literature review regarding- cervical cancer prevention, health practices and beliefs, and HPV vaccine acceptance and use. During the final phase of the study, an analysis and

interpretation of the relevant policy and vaccine literature was conducted; policy options for improving vaccine use were examined; and policy considerations and implementation strategies informed by the literature and key informants were evaluated. The findings of all three study phases- the literature review, key informant interviews and policy analysis and interpretation- are synthesized along those lines. The results can be summarized as follows:

1. Social inequities persist along the cervical cancer continuum across several social domains, particularly among communities of color. These factors, commonly known as social determinants of health, are beyond the realm of the healthcare system and speak to broader issues of equity and social justice.
2. Facilitators of HPV vaccination acceptance and uptake, among young adult African-American women, are represented within the social, cultural, and political context of health. Broadly, these factors are associated with education, personal beliefs, access, social support and trust in the medical establishment.
3. Public policy can play a role in the effective implementation of strategies to reduce the burden of HPV-related disease, including cervical cancer. Addressing this challenge will require response from a “*diversity of actors, interests, norms, processes, initiatives, and funding streams.*”¹¹³

In the United States, and particularly across communities of color, there is a crisis in health. Despite the trillions of dollars spent annually on diagnosis and treatment of illness, disparities across disease conditions remain. Much of the pain and suffering and countless deaths that occur can be attributed to preventable causes; unfortunately, low-income and minority populations bear a disproportionate share of the burden. Among African-American women, disparities in cervical cancer morbidity and mortality persist. In addition, the rates of sexually transmitted infection, including HPV are higher among this population.

A range of explanations associated with disparities in HPV infection and cervical cancer diagnosis and deaths can be offered. Race and ethnicity, racism, socioeconomic position (income), insurance status, and access to care; their relation to screening, diagnosis, treatment, and survival are frequently acknowledged as contributors to the persistent inequalities that exist. Just as significant among these are the disparities that encompass gender, age, language, literacy, immigrant status and geography.^{114, 115} Furthermore, an under-representation of African-Americans participating in clinical studies contribute to ongoing disparities. Clinical studies are crucial to the development of effective prevention and treatment methods for cancer and other diseases. The relevance and application of clinical trial results into practice is directly related to the type and number of participants enrolled. Fostering greater diversity in clinical research is necessary for lessening differences in negative health outcomes.

Overall, African-American women have high rates of participation in cervical cancer screening, which illustrates prevention of cervical cancer as a concern among this group. Additionally, screening rates among women of reproductive age have shown to be higher, when compared to older women.¹¹⁵ Conversely, while African-American women are reported to have higher rates of screening for cervical cancer as compared to White women, the incidence and mortality rates of cervical cancer are two-fold higher among African-American women. This reinforces the idea that there are inherent differences in how and when African-American women are diagnosed and treated.^{114, 115}

The association between preventive health practices of African-American women and cervical cancer reduction were examined. Results of this dissertation acknowledge that cervical cancer prevention is an issue of importance, in addition to other priorities, among African-American women. Current health practices of young adult AA women- cervical

screening, an abnormal Pap test, previous history of STI, condom use and routine check-ups correlate to her intent to be immunized. As a group, 18-26 year olds are generally healthy, utilize the healthcare system less frequently, and are also more likely to be low-income and uninsured. One can infer having health insurance or coverage of preventive services among this population is likely to positively influence use of cervical cancer prevention approaches, such as vaccination and screening.

Attitudes and beliefs about health as well as individual health practices and behaviors are influenced at multiple levels- individual, relationship, community, and societal. For the purposes of this dissertation, a socio-ecologic framework was employed to guide exploration into those factors that might hamper or facilitate acceptance and/or use of immunization against HPV, among young adult African-American women. The results of this dissertation offer an array of explanations into the dynamics and complexities associated with the determinants of health behavior and decision-making, within the context of HPV vaccination. The research revealed the following- education, personal beliefs, access, social support, and trust- to be variables in this process.

The value and importance of education and information are essential for prevention efforts to be effective and equally important to personal decision-making. Currently, there is a deficit in literacy as it pertains to health. Several studies have linked literacy as an important predictor of health behavior. Consistent with others, the findings of this research revealed variations in access to health information about HPV and cervical cancer prevention among African-American women. Newmann and Garner, explored the relationship between health behavior and health literacy and found that patients most at risk for non-screening behavior have limited access to cervical cancer education materials; and those information resources that are available are written at inadequate literacy levels.¹¹⁵ Access to information

is an essential element in reducing barriers and decreasing disparities in HPV infection and HPV-related disease.^{116, 117}

More recently there has been considerable attention given to HPV and cervical cancer, with the introduction of the vaccine to prevent against four HPV-types. Given the surge in media coverage and advertising for the HPV vaccine, one might assume that knowledge and understanding of the virus and related diseases have improved as a consequence. However, awareness does not necessarily correlate to accurate knowledge, particularly among certain racial/ethnic minorities and low socioeconomic groups.^{116, 117} Studies assessing awareness and knowledge of infection with human papillomavirus and its link to cervical cancer show that African-American women appear to be less informed.¹¹⁶ Conclusions from this study regarding African-American women and their understanding of HPV are comparable to the results of similar analyses. Although much confusion remains around HPV and its link to cervical cancer, it was generally reported that African-American women show a high level of interest in being educated about HPV. Similarly, the results of this research reinforced the association between enhanced knowledge and awareness of HPV and increased vaccination uptake.

Opportunities to increase knowledge of HPV and cervical cancer prevention should engage young women and communities. Educational efforts must be comprehensive, personalized to the intended audience- the public, patients, and healthcare providers and enlist a tailored approach. Specifically, study findings identified physicians of color as priority for targeted educational efforts aimed at influencing their knowledge and beliefs about HPV and the vaccine; likewise this approach was described as an opportunity to encourage providers to become champions of HPV vaccination within the African-American community.

Communications and messaging to further advance HPV education and encourage uptake of the vaccine cannot be undervalued. The importance of education for increasing acceptance and uptake of the HPV vaccine, the types of messages, how they are disseminated, and to whom, is a piece of the puzzle with which many practitioners struggle. When attempting to reach minority communities regarding health matters, a multi-faceted approach should be utilized. Educational materials and information must be transparent, culturally and literacy appropriate; furthermore the information must be perceived as nonbiased. Where possible, young women, the intended audience, and community members, should be engaged in all aspects of dialogue and the exchange of ideas.

Exploring effective ways that are comprehensive in scope to improve knowledge about the disease and risk factors will be advantageous to the utilization of cervical cancer prevention methods. For African-American women, an understanding of personal risk should be included as a part of communications related to HPV and cervical cancer prevention. Given the sensitive nature of HPV as a sexually transmitted infection, the way in which education and information about the disease and vaccination are framed is central to understanding the issue. Acceptance of the HPV vaccine and intent to be vaccinated are also shown to be influenced by message framing. In a study conducted by Leader et al, intentions to vaccinate were significantly higher when information about the vaccine was presented as protecting against cervical cancer and there were little or no costs to the individual or family members.¹¹⁸

Depicting HPV as an STI has a negative connotation and carries with it a social stigma associated with feelings of shame and promiscuity. Results of this study further support previous research findings, which suggest that the stigma associated with an STI such as HPV may pose barriers to participation in vaccination programs among young adult

African-American women.¹¹⁸ Therefore, the principal message to the public and patients regarding HPV and vaccination should highlight the virus' link to cervical cancer and the benefits of immunization against HPV as a tool to prevent cervical cancer. In addition to its protection benefits, thoughtful consideration should be given to highlighting the safety and effectiveness of the HPV vaccine and potential side effects. Thus, the way in which information is framed, has the potential to either hinder or facilitate health behaviors and decision making.

Equally important to the information being shared is the source of information and mode of delivery. Multiple information channels and communication types are used within communities of color. For younger women, technology and electronic media are customarily used for the exchange of information and an effective means of reaching this audience on an array of matters including health messages. Due to the internet's influence and broad reach among this age group, accurate and accessible information on the world-wide- web from credible sources is needed. Regarding African-American women, perhaps the most significant attributes of those supplying information about HPV, are trust, credibility, and same race. Healthcare providers are commonly perceived as highly credible sources of information; however, among some communities of color this is not the case. With respect to healthcare professionals, similar race of the provider was highly correlated with increased acceptance of HPV information and the vaccine. Results of this dissertation recognized peer groups and social networks as being vitally important communicators of messages and information in minority communities; the use of peer educators, commonly used at HBCU's for health education purposes, was advocated as an effective vehicle for increasing knowledge about the disease and support of the vaccine.

Among young adult African-American women, attitudes about HPV and the vaccine were influenced by factors that were similar to AA women of all ages; perceived risk of infection, stigma associated with an STI, and concerns about the vaccine were foremost. Perceived risk or susceptibility can be defined as one's belief about the likelihood of harm.^{71, 75, 119} Consistent with other findings, knowledge of personal risk of acquiring HPV and developing cancer are generally low; as is knowledge of the link between HPV and cervical cancer among this group. One can assume that an insufficient understanding of HPV and HPV-related disease has some bearing on African-American women's perception of risk of exposure to HPV and susceptibility to cervical cancer. Although statistics confirm disparities in cervical cancer and STI rates, the findings reported lower levels of perceived risk of acquiring HPV among African-American women. As evidenced in this study's results and the literature, an African-American woman's opinion of her risk positively correlates to decision making to participate in primary and secondary cervical cancer prevention efforts.

One's ability to accurately assess disease risk relies heavily on knowing about HPV, in particular how it is acquired, and the disease process; furthermore, it requires consideration of participation in cervical cancer risk behaviors. Both sexual activity and screening practices are behaviors/practices that contribute to a woman's perceived risk. Sexual activity is significantly associated with age; young women, aged 16-24 years, are likely to have had more partners or concurrent sexual relationships compared to older women,^{71, 119, 120} therefore, risk of acquiring HPV is higher among this group. Due to HPV's sexually transmitted nature, steps must be taken to limit any unnecessary anxiety or negative feelings. Women must be encouraged to engage in positive health practices and be reassured that there are options for controlling some risk behaviors. Further exploration into those

factors that contribute to the beliefs and health behaviors of African-American women as it relates to cervical cancer reduction is needed.

Routine funding for adult immunization is limited at best and in some cases non-existent. Improving affordability and access to the vaccine is influenced by factors such as cost, insurance and availability of the vaccine. The results from this study are consistent with other studies which confirm differences in cervical cancer morbidity and mortality experienced by certain groups- specifically minority women and those of low socioeconomic status; African-American women are no exception. For this reason, young adult AA women who are more frequently low-income and uninsured, will likely have restricted access to both primary and secondary cervical cancer prevention methods. Successfully advocating in support of a reduction in the cost of the vaccine is expected to improve access and availability, on many fronts.

While the HPV vaccine appears to be regarded as beneficial by the provider community at large, variations in its use are wide across medical disciplines, engendering the potential for inequalities in access to and availability of immunization services. The ACIP recommendation allows for vaccination of girls beginning at nine years old as well as vaccination of girls and women 13-26 years old, with the routine vaccination of 11-12 year olds prior to the onset of sexual activity. One significant study finding revealed a perceived or real bias against vaccinating those in the 'catch-up' population, particularly those who are sexually active, by many in the medical community. Physicians considered the least knowledgeable about HPV disease and vaccination, appear to be more stringent in *only* recommending and administering the vaccine to those fitting the criteria for routine vaccination; girls prior to the onset of sexual debut. Such a strict interpretation of the guidelines raises concerns, as it may impose a systematic barrier to accessing the vaccine

intended for women up to age 26, including those who are sexually active, for which protection benefit and efficacy have been shown. These findings illustrate the value judgments shared by many about a woman's worthiness to receive the HPV vaccine after she has become sexually active. It further demonstrates that policies and knowledge about HPV vaccine delivery may not be universally known or widely accepted.

Moreover some providers face challenges in dispensing the HPV vaccine due to its high cost and lower reimbursement rates, inadequate vaccine supply, burdensome administrative requirements and patient compliance with the immunization schedule. This particular study finding may have implications on access to the vaccine by low-income individuals and among communities of color wherein providers have chosen *not* to make the vaccine available. Given the burden of disease in this population, hesitancy on the part of providers to recommend the vaccine is certainly an obstacle that must be overcome. Inequities in access to and the availability of HPV vaccination will further expand the health gap between those that have and those that have not.

Another finding from this study confirms the importance of support from one's partner, family, and community in influencing health beliefs and behaviors. Results of this research revealed that the benefits of vaccination were perceived as favorable in relation to the protection of oneself and one's partner. It was further reported that the belief that influential people in one's life would approve of vaccination, was deemed to encourage immunization. Young adult women can be very persuasive within their peer group; they are trusting of one another and enthusiastically accepting of information and recommendations from each other. In the same way that peer groups and social networks disseminate information, they also shape beliefs and influence acceptance and understanding of health practices among African-Americans. Because of the significant influence these networks

have, communities themselves need to become better informed and educated; grandmothers, mothers, daughters, opinion leaders and in fact the male partners of these women.

As with previous studies, provider knowledge and attitudes of HPV, cervical cancer, the vaccine and recommendation to be vaccinated by a healthcare professional can be powerful motivators for or against receiving immunization against HPV. Providers have a particularly influential role, which is shaped by a composite of dynamics; personal beliefs, education and professional opinions, experience with HPV and vaccination, as well as policies and their interpretation. Additionally, provider buy-in of HPV vaccination is strengthened when there is support amongst one's colleagues

Yet another finding of this study revealed the significance of mistrust and the role that it plays in the decision to participate in HPV vaccination within the African-American community. Dating back to slavery, African-Americans have been discriminated against in several areas: education, employment, and unfortunately health services research. Feelings of mistrust and skepticism have positioned themselves staunchly in the midst of the multitude of problems that plague the African-American community, including health. Negative views of these institutions- government, the medical establishment, and industry- have been fashioned for generations of people of color, in response to a history of racism and discrimination. Trust in this country's systems of health care (public and private), healthcare practices, providers, and health information has been broken for many minority communities.

The results of this research confirm a veil of suspicion of public health and government agencies that is significant even today, which leads one to conclude that vaccine acceptance and use may be negatively impacted. This study's findings also suggest that efforts to overcome trust as a barrier must start from *within* communities of color. Health, government, and industry officials must successfully engage minority communities as

collaborators, supplying them with the necessary tools to comprehend HPV-related information and apply that knowledge, assess the risks and benefits of vaccination, and translate that information into decision-making. Only then can individuals and communities of color be empowered to want better health for themselves and take action to improve health status.

Sustainable health behavior change can be facilitated through a variety of means. Both legislative and policy domains represent opportunities for broadly addressing improvements in health. Policies affect large numbers of people as well as social norms and have tremendous potential for preventing needless suffering, injuries, and deaths.¹²¹ Arguments driving public health policy should take action toward- improving population health, reducing health inequalities and sustainable public health solutions. Harnessing the energy of stakeholders and coordinating their activities is essential for a healthy society. Beyond that of government, stakeholders possessing the power to influence health include business, employers, academia, foundations, the media, civil society, and most importantly communities themselves. An effective response to disparities in HPV-related disease requires that stakeholders share responsibility for key dimensions of the problem within appropriate ‘policy channels’ or policy streams.^{113, 122}

Results of this dissertation suggest that the capacity of different stakeholders to respond and address the challenges of implementing effective HPV vaccination programs will require considerable collaboration and coordination, employing a variety of strategies- programmatic, legal, political and economic.^{113, 122} Furthermore, achieving and maintaining high levels of HPV vaccination coverage are associated with successfully implementing population-based approaches and effective strategies. This study’s analysis of effective strategies and program attributes for HPV vaccine implementation revealed several main

ideas: 1) characteristics of a program must improve access and entail a comprehensive education plan, 2) role of the community is central and engagement of community members should be at the core of all activities, 3) integration of vaccination into existing health services is likely to be the most effective strategy for reaching this population, young adults, aged 18-26, with an emphasis on cervical cancer screening programs, and 4) the importance of patient compliance in vaccination and continued cervical screening. A successful HPV vaccination program would require considerable investment in educating a range of audiences. Additionally, a reduction in the vaccine's cost to females and providers would be necessary to expand access and availability; while incorporating HPV immunization into existing cervical cancer screening programs. Findings from this study reinforce the strategies for increasing immunization rates as described by the Task Force for Community Preventive Services.

A. Conclusion

Cervical cytology and advances in cancer screening tools and methods have contributed significantly to the decline in rates of cervical cancer over the past several decades. Despite these advances, social inequities persist along the cervical cancer continuum across several social domains. Commonly referred to as social determinants of health, these factors are beyond the realm of the healthcare system and speak to broader issues of equity and social justice. In the United States, disparities in cervical cancer and STIs are public health problems that reflect cracks in society that follow place, class and race. An effective approach to prevention acknowledges the underlying factors- risk and protective- that influence the burden of disease.¹²¹

Measures to protect against cancer and sexually transmitted diseases, both threats to the health of communities of color, are necessary and should be widely supported.

Vaccination against four HPV types 6-11-16-18 that cause the majority of genital warts and 70% of cervical cancers has shown to be 100% effective. However in some ways, the ACIP recommendation inadvertently differentiates the upper age limit as a second class group despite the fact that it is highly unlikely that young adult females have been infected with all HPV types. Given the evidence supporting effectiveness of the HPV vaccine, it is important for young adult African-American women, aged 18-26 to be vaccinated. From a public health perspective, a population-based approach to HPV vaccination is evidenced by higher rates of immunization coverage of women, which has direct benefits to men in terms of decreased transmission of the virus. Furthermore, a population approach to vaccination is considered to be less resource intensive on physicians and the healthcare system in general. The advantages to the individual and society are many, and will have a significant impact on the disproportionate rates of HPV and cervical cancer disease among African-American women as well as other racial and ethnic minority groups. Conversely, there are some drawbacks to vaccinating a group with a high prevalence of HPV, as the maximum protection benefit is derived before the initiation of sexual intercourse. Furthermore, studies have confirmed that the vaccines efficacy diminishes among females infected or previously infected with certain HPV types. Table 7.1 presents additional benefits and drawbacks to vaccination of African-American women, aged 18-26.

Table 7.1. Advantages/Drawbacks to HPV Vaccination of African-American females, age 18-26

	BENEFITS	DRAWBACKS
Scientific/ Public Health Aspects	<ul style="list-style-type: none"> • Protection benefit derived from vaccination (full or partial prevention of HPV 16/18) • Reduced transmission of disease • Cross protection against infection with non-vaccine HPV types • Effects of reduced HPV disease may be realized sooner among 'catch-up' population • Duration of protection extended during sexually active years without booster • Disparities in burden of disease among AA may improve with vaccination • Protection against genital warts • Vaccination may benefit those who have less access to routine healthcare (Pap tests) • Reduction in costs- personal, emotional, social and financial • Easily integrated into cervical cancer screening 	<ul style="list-style-type: none"> • High prevalence of HPV among this age group (18-26 years) • Vaccine efficacy diminishes among females currently infected or previously infected with HPV types • Lower immune response for older women compared to younger • Provision of low cost vaccine limited for 'catch-up' population (eg. Section 317 programs)
Behavioral Aspects	<ul style="list-style-type: none"> • Acceptance of vaccination increases when administered to aged 17 or older • Lower perceived risk of infection 	<ul style="list-style-type: none"> • Stigma associated with receipt of vaccine against STI • Mistrust of government, healthcare system, new technologies among communities of color • Concern about reproductive health and pregnancy • Decreased belief in importance of cervical cancer screening

A noteworthy study finding indicated that African-American women are likely to have a more holistic view of health and wellness. In recent years heightened awareness and attention have been given to other chronic disease conditions, such as obesity, cardiovascular disease, hypertension, and their root causes- for example poor nutrition and physical activity patterns and tobacco use- all of which significantly impact the health status of African-American women. These co-factors are also shown to contribute significantly to cancer. Whereas, vaccination, improving diet and increasing exercise are considered primary prevention strategies to combating disease before poor health occurs none of them can be done in isolation. Efforts utilizing a disease-specific approach to prevention may inadvertently contribute to disparities, as the causes that contribute to one disease are

multiple and manifest themselves across medical conditions. Primary prevention must occur at the individual and community level through a combination of education, advocacy and policy to effect change.¹²¹ Strengthening individual knowledge and skills as well as promoting community education by providing information and resources to promote health and safety are critical; and in communities of color, social networks are a valuable source for education and programmatic efforts meant to enhance participation in vaccination. The utility of public policy in promoting primary prevention efforts to influence health outcomes is evidenced in practice today.

Moving forward, action must be taken at multiple levels to address the societal and structural determinants of STIs and cervical cancer; a matter of importance that has too long been neglected. It is the view of this researcher that the foundations of public health are built upon the values of equity, unity, justice and accountability. Let us be reminded that public health and health inequities are –and must remain- societal matters for which we are all responsible.

B. Limitations of the Research Study

The three phases of this study allowed for a better understanding of those factors that might hinder or facilitate acceptance and use of the HPV vaccine. The data collected provided a basis to answer all the research aims, however there were limitations to this study.

First, the study did not assess the perceptions and opinions of African-American women, aged 18-26, the target population for this research. While the literature review and participation by key informants representing the views of young adult African-American women provided an understanding of women's barriers and facilitators to HPV vaccination and strategies for implementing effective immunization policies, the lack of consumer input

is a study gap. Young adult African-American women should participate in future efforts to effect widespread use and implementation of the HPV vaccine.

A second limitation of this study is related to the key informant interviews. Since all of the interviews were conducted by one researcher, bias may have been introduced into the results of the key informant interviews. The relatively small sample size, the sampling methodology and participation may have introduced selection bias. This limitation was partially addressed through purposeful inclusion of representatives in each of the sampling categories through maximum variation as described in the study's Methods section (*Chapter 3*).

General limitations of the key informant interviews include heavy reliance on the knowledge and expertise of the key informants interviewed. Key informants undoubtedly injected bias into their responses and there was variability in the respondents' abilities to perceive the full extent and intention of the question(s), and to effectively communicate all of the information requested by the researcher. Study limitations were primarily addressed through validation techniques, such as triangulation of data sources.

Implications for Further Study

In order to gain a better understanding of the issues surrounding HPV vaccine decision making among African-American women findings from this dissertation suggest at least four avenues for next steps or further study:

- 1) *Recruitment of racially diverse participants in studies.* Racial and ethnic minorities as well as those of low-socioeconomic status should be included in research. Enhanced collaboration with African-American investigators, HBCU's, community members

and physicians is likely to improve representation of this population in medical research.

- 2) *Integration of vaccination and screening for cervical cancer reduction.* An assessment of opportunities to combine HPV vaccination into existing cervical cancer screening programs should be conducted and implemented where appropriate.
- 3) *Employ novel health communication strategies.* Development and dissemination of tailored HPV health messages through a variety of approaches such as risk-based education.
- 4) *Consideration of viable policy options.* Legislative and policy options that have the capacity to expand access to the HPV vaccine to all segments of the population should be explored. These might include consideration of extending Medicaid or State Children's Health Insurance Program coverage, the Vaccine for Children's Program, or the Section 317 Program to include primary and secondary cervical cancer prevention services for low-income women who have no other resources for accessing preventive health services. More could be done to expand the services that are reimbursed by insurers as it relates to education and counseling of patients. While providers have an interest in providing learning opportunities to patients, the investment of time required addressing the complexities of HPV and vaccination is sizeable. Preventive measures are more likely to be offered and fully utilized by healthcare providers as reimbursement for these types of services are augmented.

C. Final Word

“Democracy is only possible if equality, participation, and mutual respect are part of society’s major institutions.”¹²³

Health is produced by the conditions under which people live, and the roots of inequalities in health lie in social and economic disparities; they result from preventable, avoidable conditions and policies.¹²³ Addressing disparities in cervical cancer and other disease conditions will require that public health take risks and assume a greater leadership role in decision-making and public policy. Public health leaders must ignite concern about the link between social and economic equality and the health of this nation. Our democracy is dependent upon the willingness of ordinary people to participate in “social movements aimed at the collective empowerment of *all people*.”¹²³

APPENDIX A

Literature Review Keywords/Search Terms

Search Terms-The databases were searched using a combination of terms and keywords as outlined in the table below:

Human Papillomavirus	AND	Cervical Cancer	AND	Knowledge	AND	Young Adult Women
HPV	AND	Cervical Cancer	AND	Knowledge	AND	Women
HPV	AND	Cervical Cancer	AND	Knowledge	AND	Adolescents and Young Adult Women
Human Papillomavirus	AND	Vaccine	AND	Attitude(s)	AND	Young Women
HPV	AND	Vaccination	AND	Attitude(s)	AND	Adolescent and Young Adult Women
Human Papillomavirus	AND	Immunization	AND	Acceptability	AND	Women

Literature Review Criteria for Inclusion/Exclusion:

The inclusion criteria used for this review were limited to those that focused on knowledge and/or attitudes of young adult women and the relationship to the human papillomavirus, cervical cancer, and the human papillomavirus vaccination. Articles were included if they were produced from credible sources such as peer reviewed journals, health organizations, news journals, etc. and contained supporting arguments for the relationship mentioned above. In addition, availability of articles in English and availability of full text of the article were also criteria for inclusion. Full text was preferred due to time limitations of the reviewer. While, no date limits were placed on the search, it should be noted that most of the literature on the HPV vaccine is very recent, within the last 2-4 years.

Exclusion criteria included those articles focusing on knowledge and/or attitudes of adolescents only, parents, or providers and the relationship to the human papillomavirus, cervical cancer and the human papillomavirus vaccination. In addition, articles in languages other than English were also excluded.

APPENDIX B
Level of Influence Factors
Associated with Acceptance of
An HPV Vaccine

Intrapersonal (Individual) Factors:

Acceptance of the HPV vaccine involves the attitudes, behaviors, knowledge and beliefs of individuals. Understanding and dispelling personal fears and anxieties one may have is key. Perceived risk of HPV and cervical cancer, including beliefs about sexual activity and contraceptive use; an individual's commitment to personal health; and understanding the benefits of vaccine and its efficacy are constructs of the Health Belief Model which facilitate health behaviors.

Intrapersonal (Relationship) Factors:

Involves social support and social networks, including family, friends, peers, and sexual partners influencing a woman's decision-making. Both formal and informal support systems: Does she rely on their guidance and opinions?(i.e. family values and rules) Does the individual have a relationship with a healthcare provider that might serve as a barrier or facilitator?

Community/Organizational Factors:

Includes rules, cultural and social norms and organizational attributes. Is the university promoting safe and healthy sexual practices through education/ awareness campaigns? What is the role of the university's student health services center as it pertains to provision of vaccine, screening (Pap tests), physician referral and education? Issues related to accessibility to transportation, locale of nearest healthcare facilities are identified within a community/ neighborhood.

Societal Factors:

Includes local state and federal laws, policies and regulations that support the distribution, control and management of the HPV vaccine to appropriate groups. Media and

communication channels play a major role in an individual's health behaviors and lifestyle choices, politics, and societal acceptance of the HPV vaccine.

APPENDIX C

Recruitment Script

IRB Study # 08-1601

Dear XXX,

Hello. My name is Chastity Walker and I am a doctoral student from the University of North Carolina at Chapel Hill in the School of Public Health, Department of Health Policy and Management. I am conducting research on factors that may help inform the development of effective policies for use of the HPV vaccine among young African-American women. I'd like to give you a bit of background on my project and invite your participation.

The purpose of the study is to identify factors that are likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction. My hope is that the information gained will be useful in contributing to the development of policies concerning the use and acceptance of the HPV vaccine among young adult African-American women.

Given your knowledge of cervical cancer prevention and control, your insights would be particularly helpful to me. With your permission, I would like to conduct an interview with you. The interview will last approximately 60 minutes and will be scheduled at your convenience; interviews can be conducted in person or by phone. If you live in Atlanta, I can come to your office or preferred location. Alternatively, we can conduct the interview by phone. Interviews will be audio-recorded and transcribed for analysis. All the information I receive from you, including your name and any other identifying information, will be strictly confidential and will be destroyed upon completion of my dissertation. Written work resulting from my project will contain no information that could identify individual participants. Upon completion of the project, participants will receive a \$25 gift card to use as they see fit.

As I noted above, I am conducting this study as part of my doctoral program in public health. My research is being supervised by Dr. Suzanne Havalala Hobbs, and she can be reached at 919-843-4621 for additional questions about the study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. Human subjects review approvals have been received from the UNC institutional review board for this study.

I'll follow up with you shortly by email to confirm your interest. Thank you very much for considering this request.

Sincerely,

Chastity L. Walker, MPH

APPENDIX D

University of North Carolina-Chapel Hill

Consent to Participate in a Research Study

Adult Participants

Social Behavioral Form

IRB Study # 08-1601

Consent Form Version Date: 10/17/08

Title of Study: Attitudes, Practices and Beliefs about HPV Vaccine Among Young Adult African-American Women: Implications for Effective Implementation

Principal Investigator: Chastity L. Walker, MPH

UNC-Chapel Hill Department: Department of Health Policy and Management

UNC-Chapel Hill Phone number:

Email Address: *wchastit@email.unc.edu*

Faculty Advisor: Suzanne Havala-Hobbs DrPH, MS, RD, Clinical Assistant Professor, Department of Health Policy and Administration, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

Funding Source and/or Sponsor: Not funded

Study Contact telephone number: 404-317-7908

Study Contact email: *cwalker@cdc.gov*

What are some general things you should know about research studies?

You are being asked to take part in a research study. Participation in this study is entirely voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to generate knowledge and identify factors that are likely to hinder or enhance the effectiveness of policies aimed at increasing use of the HPV vaccine for cervical cancer risk reduction among young adult African-American women. The

information will be used to explore policy options for widespread implementation and/or uptake of the vaccine and determine the best strategy to increase use and acceptance of the HPV vaccine among young adult African-American women.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 25 participants. The research involves approximately 25 individual interviews with key stakeholders who have knowledge and expertise in cervical cancer prevention and control.

How long will your part in this study last?

Interviews are an extremely important data source, in part because they provide such rich data. All interviews will be conducted at your convenience and should not last more than 60 minutes. In addition to the actual interview, you should plan for approximately 15 minutes to review the informed consent form and allow for any follow-up questions and answers related to the study immediately after the interview.

What will happen if you take part in the study?

- *The research involves approximately 25 individual interviews with key stakeholders who can provide insight into the development of effective policies for use of the HPV vaccine among young adult African-American women.*
- *You have been selected to participate in a 60 minute interview. The interview is a one-time event, although the researcher may contact you again for clarification of comments made during the interview.*
- *The interview will be conducted in person or by phone at your convenience.*
- *The interview will be audio-recorded. You may refuse to answer any question and ask to turn off the tape recorder at any time.*
- *Upon completion of the interview, you will receive a \$25 gift card to use as you see fit.*
- *All information received from you, including your name and any other identifying information, will be strictly confidential and will be destroyed upon completion of the research study.*

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. While you may not benefit personally by participating in this research study, your participation will contribute to the public's health to the extent that the knowledge gained will provide specific recommendations for widespread vaccination. In addition, the knowledge gained will inform researchers and practitioners of the facilitators to successful administration of the HPV vaccine to priority populations.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher. The proposed research study poses no more than minimal risk to you as a participant. The primary risk to subjects participating in this study is a breach of confidentiality. The risk of such a breach is minimized by the principal investigator's

training in human-subjects protection. Assurances of confidentiality will be maintained throughout the research study.

How will your privacy be protected?

Participants *will not* be identified in any report or publication about this study. The PI will not divulge, publish, or otherwise make known to unauthorized persons or to the public any information obtained in the course of the study that could identify the persons who participated in the study. The interviews will be conducted privately. None of the questions asked are very personal or of a sensitive nature, however there is a chance you may feel uncomfortable answering them. You may refuse to answer any question that you don't want to for any reason. You may also request that audio recordings be turned off and stop the interview at anytime.

Audio-recordings will be erased upon completion of the study. Electronic and hard copies of interview notes and other data will be stored without personal identifiers on a password-protected laptop kept in a secure location. While each study participant will be assigned a unique identification number, the master list linking names and identification numbers will be stored separately from project data. Only the PI will possess the master list. Access to electronic and hard copies of notes will be restricted to the PI and dissertation committee only. Any oral presentations and written reports on the data will contain no identifying information linking individuals with specific comments.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Check the line that best matches your choice:

OK to record me during the study

Not OK to record me during the study

Will you receive anything for being in this study?

You will be offered an incentive, not to exceed \$25, for taking part in this study. The incentive will be in the form of a VISA gift card. If you withdraw from the study prior to completion of the interview, you will not receive any incentive.

Will it cost you anything to be in this study?

There will be no monetary costs for being in the study. The only cost of participation is your time.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Title of Study: Attitudes, Practices and Beliefs about HPV Vaccine Among Young Adult African-American Women: Implications for Effective Implementation

Principal Investigator: Chastity L. Walker, MPH

Participant’s Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

APPENDIX E

Interview Guide- Government Officials

Introduction

The purpose of the interview is to learn more about the determinants of HPV vaccine use among African-American women aged 18-26, and to identify factors that may hinder or facilitate acceptance of the HPV vaccine. Twenty to twenty-five stakeholders who have an interest in cervical cancer prevention will participate in the interviews. It is anticipated that the interview should take about 60 minutes. The interviews will be strictly confidential. The themes that emerge from the interviews will be used to inform policy considerations for increasing use and widespread implementation of the vaccine. The comments and answers you provide will not be linked to your identity. This interview session will be recorded with your consent. Tape recordings and transcribed notes will be stored in a secure location and destroyed upon completion of this study.

- ♦ At this time, do you have questions about the study or the interview session?
- ♦ Do I have your permission to record the interview?

Education/Communications

1. What measures should be taken to improve health literacy about HPV and cervical cancer prevention?
2. What is the best way to ensure that women have enough information to make informed decisions about HPV vaccination and cervical cancer prevention?

Fiscal

3. What are the key influences associated with the costs and benefits of HPV vaccination?

4. Given the high cost of the HPV vaccine, what fiscal considerations should be allowed to ensure affordability and cost-effectiveness of the vaccine to young adult African-American women?

[Probe] How might use of state 317 Program funds be used to support vaccination of underserved women?

5. What are the potential public health benefits of investing public funds for HPV vaccination of young adult African-American women?
6. How might the economic investment case for HPV vaccines best be made for national-level decision makers? (i.e. governments, insurers, professional organizations)

Implementation Strategies

7. What are the benefits to vaccinating the catch-up population, those aged 18-26?
8. What is the benefit of HPV vaccination programs from a population-based public health perspective?

[Probe] Are there any potential negative effects of HPV vaccination programs?

9. What factors should be considered when recommending policies for HPV vaccine introduction among African-American women?

[Probe] Which vaccination guidelines should be considered (i.e. ACIP versus ACS)

10. How can an integrated service delivery approach to prevention be utilized to reduce the burden of cervical cancer?

[Probe] What form might it take?

11. What specific program attributes can contribute to the successful implementation of vaccine policies and program performance?

12. How will cervical cancer screening policies change among vaccinated populations?

Barriers and Facilitators

13. What do you perceive to be barriers to HPV vaccination among African-American women?
14. What actions can be taken to support African-American women in overcoming barriers associated with HPV and HPV vaccination?
[Probe] What can be done to address a woman's fears and anxieties?
[Probe] What can be done to address a woman's concerns regarding efficacy and safety issues?
15. Given the mistrust issues in the African-American community, how important do you think it is to focus on African-American women, aged 18-26?

Advocacy

16. What role can government play to support acceptance and use of the HPV vaccine among at risk groups?
17. How can political support for HPV vaccines be created?
18. What steps can be taken to ensure that the inequities that currently exist in cervical screening will not worsen with the introduction of the HPV vaccine?
19. How can we ensure that women will still get the message to continue screening

Closing

Thank you for your time. What additional comments about the determinants of HPV vaccine use and acceptance among African-American women do you have?
Have we covered everything that you think is important?

APPENDIX F

Interview Guide- Healthcare Professionals

Introduction

The purpose of the interview is to learn more about the determinants of HPV vaccine use among African-American women aged 18-26, and to identify factors that may hinder or facilitate acceptance of the HPV vaccine. Twenty to twenty-five stakeholders who have an interest in cervical cancer prevention will participate in the interviews. It is anticipated that the interview should take about 60 minutes. The interviews will be strictly confidential. The themes that emerge from the interviews will be used to inform policy considerations for increasing use and widespread implementation of the vaccine. The comments and answers you provide will not be linked to your identity. This interview session will be recorded with your consent. Tape recordings and transcribed notes will be stored in a secure location and destroyed upon completion of this study.

- ♦ At this time, do you have questions about the study or the interview session?
- ♦ Do I have your permission to record the interview?

Knowledge of Human Papillomavirus (HPV)

1. How common is human papillomavirus (HPV)?

[Probe] How easy is it to clear?

2. How familiar are you with the vaccine to prevent infection of HPV?

[Probe] Who are the priority populations for vaccination?

[Probe] What does the vaccine protect against?

[Probe] How familiar are you with the various vaccination guidelines (ACIP vs. ACS)?

Provider Experience with the HPV Vaccine

3. What types of patients do you see in your clinic/office?
4. What has been your experience with the HPV vaccine?
5. Do you recommend the HPV vaccine to your patients?
[Probe] If yes, for what age group(s)?
6. Do you administer the HPV vaccine?
[Probe] If yes, for what age group(s)?
7. What has been your experience with those who get the vaccine in your practice?
8. Which groups are requesting the HPV vaccine in your practice?
[Probe] What age and racial/ethnic groups?
[Probe] Are women with abnormal Pap results requesting the vaccine?
9. What are some of the issues associated with getting the vaccine for girls or women who want it?
[Probe] What group(s) of women are having issues?

Preventive Health

10. How much of a priority is cervical cancer risk reduction for preventive health among African-American women?
[Probe] How does this fit within the/their cultural values and understandings of health and wellness?
11. What measures should be taken to address cervical cancer risk behavior among at-risk populations, such as African-American women?

Education/Communications

12. Where do African-American women generally get information about HPV?
13. What measures should be taken to improve health literacy about HPV and cervical cancer prevention?

14. What is the best way to ensure that women have enough information to make informed decisions about HPV vaccination and cervical cancer prevention?
15. What types of educational materials are needed to inform patients about HPV and cervical cancer prevention?
[Probe] What groups/organizations should be involved in the development of these educational materials?

Implementation Strategies

16. What are the benefits to vaccinating the catch-up population, those aged 18-26?
17. What is the benefit of HPV vaccination programs from a population-based public health perspective?
[Probe] Are there any potential negative effects of HPV vaccination programs?
18. How can cervical cancer screening programs support vaccination?
19. What kind of systematic interventions would be helpful for encouraging full compliance of the three doses of vaccine among 18-26 year olds?
20. How will cervical cancer screening policies change among vaccinated populations?
[Probe] Should there be differences between those vaccinated pre-sexual debut versus those vaccinated post-sexual debut?

Barriers and Facilitators

21. What do you perceive to be barriers to HPV vaccination among African-American women?
22. What actions can be taken to support African-American women in overcoming barriers associated with HPV and HPV vaccination?
[Probe] What can be done to address a woman's fears and anxieties?
[Probe] What can be done to address a woman's concerns regarding efficacy and safety issues?
23. Given the mistrust issues in the African-American community, how important do you think it is to focus on African-American women, aged 18-26?
24. What challenges do health care providers (public/private) face with regard to incorporating HPV vaccination into existing preventive health services?

Advocacy

25. What role can the healthcare sector play to support acceptance and use of the HPV vaccine among African-American women?
26. How can we ensure that women will still get the message to continue cervical cancer screening?

Closing

Thank you for your time. What additional comments about the determinants of HPV vaccine use and acceptance among African-American women do you have?

Have we covered everything that you think is important?

APPENDIX G

Interview Guide- Public Interest Groups

Introduction

The purpose of the interview is to learn more about the determinants of HPV vaccine use among African-American women aged 18-26, and to identify factors that may hinder or facilitate acceptance of the HPV vaccine. Twenty to twenty-five stakeholders who have an interest in cervical cancer prevention will participate in the interviews. It is anticipated that the interview should take about 60 minutes. The interviews will be strictly confidential. The themes that emerge from the interviews will be used to inform policy considerations for increasing use and widespread implementation of the vaccine. The comments and answers you provide will not be linked to your identity. This interview session will be recorded with your consent. Tape recordings and transcribed notes will be stored in a secure location and destroyed upon completion of this study.

- ♦ At this time, do you have questions about the study or the interview session?
- ♦ Do I have your permission to record the interview?

Knowledge of Human Papillomavirus (HPV)

1. How common is human papillomavirus (HPV)?

[Probe] How easy is it to clear?

2. How familiar are you with the vaccine to prevent infection of HPV?

[Probe] Who are the priority populations for vaccination?

[Probe] What does the vaccine protect against?

[Probe] How familiar are you with the various vaccination guidelines (ACIP vs. ACS)?

Preventive Health

3. How much of a priority is cervical cancer reduction for preventive health among African-American women?

[Probe] How does this fit within the/their cultural values and understandings of health and wellness?

4. What measures should be taken to address cervical cancer risk behavior among African-American women, aged 18-26?

Education/Communications

5. Where do African American women generally get information about HPV?
6. What measures should be taken to improve health literacy about HPV and cervical cancer prevention?
7. What is the best way to ensure that women have enough information to make informed decisions about HPV vaccination and cervical cancer prevention?
8. How can cervical cancer prevention educational campaigns be tailored to meet individual/cultural needs of African-American women?

[Probe] What specific messages should be communicated about HPV for African-American women?

9. Who is best to communicate these messages?

Fiscal

10. What are the key influences associated with the costs and benefits of HPV vaccination?
11. Given the high cost of the HPV vaccine, what fiscal issues should be considered to ensure affordability and cost-effectiveness of the vaccine to young adult African-American women?

[Probe] How might use of state 317 Program funds be used to support vaccination of underserved women?

12. What are the potential public health benefits of investing public funds for HPV vaccination of young adult African-American women?
13. How might the economic investment case for HPV vaccines best be made for national-level decision makers? (i.e. governments, insurers, professional organizations)

Implementation Strategies

14. What are the benefits to vaccinating the catch-up population, those aged 18-26?
15. What factors should be considered when recommending policies for HPV vaccine introduction among at-risk population groups?
16. How can an integrated service delivery approach to prevention be utilized to reduce the burden of cervical cancer?
[Probe] What form might it take?
17. How can cervical cancer screening programs support vaccination?
18. What specific program attributes can contribute to the successful implementation of vaccine policies and program performance?
[Probe] What kind of systematic interventions would be helpful for encouraging full compliance of the three doses of vaccine among 18-26 year olds?
19. How will cervical cancer screening policies change among vaccinated populations?

Barriers and Facilitators

20. What do you perceive to be barriers to HPV vaccination among African-American women?
21. What actions can be taken to support African-American women in overcoming barriers associated with HPV and HPV vaccination?
[Probe] What can be done to address a woman's fears and anxieties?
[Probe] What can be done to address a woman's concerns regarding efficacy and safety issues?
22. Given the mistrust issues in the African-American community, do you think it is more important to focus on African-American women, aged 18-26?

23. What challenges do health care providers (public/private) face with regard to incorporating HPV vaccination into existing preventive health services?

Advocacy

24. In what ways can communities be mobilized to increase awareness about HPV and acceptance of the HPV vaccine?

25. What role can advocacy groups play to support acceptance and use of the HPV vaccine among at risk groups?

26. How can political support for HPV vaccines be created?

27. What steps can be taken to ensure that the inequities that currently exist in cervical screening will not worsen with the introduction of the HPV vaccine?

28. How can we ensure that women will still get the message to continue screening

Closing

Thank you for your time. What additional comments about the determinants of HPV vaccine use and acceptance among African-American women do you have?

Have we covered everything that you think is important?

APPENDIX H

HPV VACCINE STAKEHOLDER INTERVIEWS CODING MANUAL/ DEFINITIONS

HPV Vaccine Issues

Operational definition: This code refers to the human papillomavirus (HPV) vaccine, Gardasil® (developed by MERCK), the first vaccine developed to prevent cervical cancer, precancerous genital lesions, and genital warts due to HPV. Another HPV vaccine (being developed by GlaxoSmithKline) is in the final stages of clinical testing, but it is not yet licensed. Issues surrounding the vaccine include its novelty (new technology), safety, efficacy, duration of protection, and understanding of what the vaccine protects against.

Priority Populations

Operational definition: This code refers to the group(s) recommended to receive priority for HPV vaccination.

Vaccination Guidelines/Recommendations

Operational definition: This code refers to the written recommendations for the routine administration of vaccines, specifically the HPV vaccine, to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications.

Cervical Cancer and HPV

Operational definition: This code refers to genital human papillomavirus (HPV) infection and cervical cancer, an HPV related disease. Genital HPV infection is a sexually transmitted disease (STD) that is caused by human papillomavirus (HPV). There are approximately 40 types of genital HPV. Some types can cause cervical cancer in women and can also cause other kinds of cancer in both men and women. Other types of HPV can cause genital warts in both males and females. Cervical cancer is a gynecologic cancer that affects a woman's reproductive organs. Cervical cancer begins in the cervix, which is the lower, narrow end of the uterus. (The uterus is also called the womb.) The human papillomavirus is the main cause of cervical cancer.

Providers/Provider Experience

Operational definition: This code refers to health care providers and their experience as a health care provider with HPV and the HPV vaccine. A provider is a health professional in an organization or person who delivers health care to an individual(s) in need of health care services. Provider experience encompasses: knowledge and beliefs about HPV, the HPV vaccine, recommendation of the HPV vaccine to patients, and the purchase and administration of the vaccine to patients.

Patient(s)

Operational definition: This code refers to an individual(s) who receives medical attention, care or treatment from a physician or other health professional.

Preventive Health

Operational definition: This code refers to an action(s) which can reduce the burden of mortality or morbidity from negative health affects and disease. Preventive health measures occur at primary (vaccination), secondary (screenings) and tertiary (treatment) prevention levels.

HEALTH BELIEFS

Perceived Risk/Susceptibility

Operational definition: This code refers to ones perception of his/her own risk of contracting a sexually transmitted infection (HPV), transmitting HPV and/or developing cervical cancer.

Vaccination Beliefs

Operational definition: This code refers to any personal or higher level belief (African-American community) regarding vaccinations.

Social Norm/Peer Influence

Operational definition: This code refers to the shared expectation by and/or influence of peers to engage/not engage in preventive health measures such as vaccination (HPV vaccination) and routine screenings (Pap tests), or to change/improve health practices when he/she may not normally engage in these behaviors.

Perceived Social Support/Lack of Social Support

Operational definition: This code refers to emotional support or comfort, or a favorable attitude given by ones family, spouse/partner, friends, and others toward health related behaviors (HPV vaccination, cervical cancer screening, condom use).

Cultural/Religious Beliefs

Operational definition: This code refers to the cultural and/or religious beliefs of an individual(s), community, society as it relates to HPV (a STI), HPV vaccination and cervical cancer.

HPV Knowledge & Awareness

Operational definition: This code refers to one's awareness and understanding of HPV, the HPV vaccine, cervical cancer and the relationship between the two.

Education/Information

Operational definition: This code refers to the ways in which an individual(s) can learn specific knowledge, information and skills through instruction, teaching, training and experiences. More specifically, this code refers to knowledge pertaining to HPV, HPV vaccination and cervical cancer.

Messages

Operational definition: This code refers to a thought, idea or concept expressed to communicate knowledge or information. Messages can be verbal (exchange of information using words) or nonverbal (exchange of information through actions or behaviors rather than words).

Benefits 18-26/Public Health

Operational definition: This code refers to the actual or perceived benefits of HPV vaccination. At the individual level HPV vaccination directly benefits the woman, ages 18-26 years. From a population-based public health perspective, public health activities aim to improve health status and reduce the burden of disease in communities or populations.

Three (3) Dose Compliance

Operational definition: This code refers to patient compliance regarding completion of the three dose series required for administration of the HPV vaccination. The HPV vaccine is given in a series of three injections over a six-month period. The second and third doses should be given two and six months (respectively) after the first dose.

Cervical Cancer Screening (Pap Test) Programs

Operational definition: This code refers to the Pap test (or Pap smear) which looks for precancers, cell changes on the cervix that might become cervical cancer if they are not treated appropriately. Pap tests are a secondary prevention (screening) strategy for the prevention and early detection of cervical cancer. Health professionals in a variety of clinical settings provide cervical cancer screening services. Routine cervical cancer screening is recommended for all women.

Continue Cervical Screening (Pap Test)

Operational definition: This code refers to girls/women participating in cervical cancer screening (Pap tests) after being vaccinated against HPV, the virus that causes cervical cancer. The Pap test can prevent cervical cancer by finding precancers, cell changes on the cervix that might become cervical cancer if they are not treated appropriately.

Facilitator

Operational definition: This code refers to anything, either real or perceived, that facilitates ones acceptance and/or use of the HPV vaccine.

Barriers

Operational definition: This code refers to anything, either real or perceived, that serves as a barrier to ones acceptance and/or use of the HPV vaccine.

Overcome Barriers

Operational definition: This code refers to anything/actions, either real or perceived, that may aide in reducing or eliminating a barrier(s) (as described above) to ones acceptance and/or use of the HPV vaccine.

Mistrust

Operational definition: This code refers to a lack of trust by some minority populations of governmental agencies and the healthcare system/medical establishment in the United States. More specifically, mistrust in this context refers to the African-American community which has suffered

needlessly as a result of discrimination and various injustices inflicted upon them by the U.S. government in education, employment and health services research, dating back to slavery.

Implementation Strategies/Program Attributes

Operational definition: This code refers to factors that might be considered for developing and introducing HPV vaccination programs into various settings. In addition, specific attributes that may contribute to successful implementation of HPV vaccine program performance are included.

Fiscal Considerations

Operational definition: This code refers to factors that should be considered to ensure affordability and cost-effectiveness of HPV vaccination.

Policies

Operational definition: This code refers to factors that might/should be considered when recommending policies for HPV vaccine introduction to multiple audiences across various settings.

Cost/Benefit (Economic Investment)

Operational definition: This code refers to important factors associated with the costs and benefits of HPV vaccination, specifically at the individual level and more broadly at the population level.

Community Mobilization

Operational definition: This code refers to opportunities for communities to come together, specifically the African-American community, in support of efforts to reduce the burden of HPV infection and HPV related disease. Community members lead efforts to create sustainable change while ensuring that prevention efforts are culturally appropriate and effective.

Advocacy Efforts

Operational definition: This code refers to opportunities for organizations and/or groups (i.e. healthcare providers, governmental agencies and interest groups) to support actions that work toward reducing the burden of HPV infection and HPV related disease (i.e. cervical cancer and genital warts).

Health Disparities

Operational definition: This code refers to factors associated with disparities in HPV infection and cervical cancer rates among certain populations (in this case African-Americans) and steps that can be taken to ensure that similar inequities do not arise with the introduction of the HPV vaccine. Cancer health disparities can be defined as "differences in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific populations groups in the United States (National Cancer Institute, 2008).

Additional Codes

Males

Operational definition: This code refers to the role of males in the transmission of HPV, HPV vaccination of males, and efforts to support increased acceptance and/or use of the HPV vaccine among men and women.

Empowerment/ Self-efficacy

Operational definition: This code refers to an attitudinal, structural, and cultural process whereby individual's/community's gain the ability, authority, and agency to make decisions and implement change in support of improving their own lives, which includes health status, and the lives of other people. Empowerment is associated with self-efficacy, ones perception of his/her own skills and the ability to use those skills effectively to change or improve ones health status.

Motivation

Operational definition: This code refers to ones motivation as a factor in improving or attempting to improve ones health status by taking preventive health measures. It is also associated with an individuals acceptability of the HPV vaccine and willingness to be immunized.

Health Equity & Social Justice

Operational definition: This code refers to the fair distribution of society's resources, benefits, responsibilities and their consequences. The relative position of one social group in relationship to others in society, and the root causes of disparities influence health status. Social justice assumes that in order to ensure health equity and advance human well-being, improving health must address meeting the needs of the most disadvantaged. (Center for Health Equity, 2008)

Other

Operational definition: Miscellaneous

Slam Dunk

Operational definition: This code refers to "words from the field" or quotations that support the themes identified.

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Center for Health Equity- Louisville Metro Department of Public Health and Wellness, <http://www.louisvilleky.gov/Health/equity/> Accessed February 2009

Definition of Cancer Health Disparities www.cancer.gov/cancertopics/types/disparities, National Cancer Institute, Accessed February 2009

Definition of Empowerment. www.wikipedia.org Accessed February 2009

APPENDIX I

Immunization Policy Analysis Description of Sources

CDC-National Center for Infectious and Respiratory Diseases

The Centers for Disease Control and Prevention (CDC), National Center for Infectious and Respiratory Diseases (NCIRD) is the federal governments leading public health entity whose primary mission is the prevention of disease, disability, and death through immunization and by control of respiratory and related diseases. Through the work of its Immunization Services Division (ISD), individuals and communities are protected from vaccine-preventable diseases. ISD activities involve: measuring vaccination coverage, provider and public education, research and evaluation to identify methods to improve immunization service delivery, development of immunization information and surveillance systems, and administration of the Vaccines For Children (VFC) and Section 317 grant program. The vaccines and immunizations website provides a wide array of resources for the public and health professionals alike related to immunization schedules, vaccination guidelines, vaccine safety, state immunization laws and requirements, publications and training resources.

Immunization Action Coalition

The Immunization Action Coalition (IAC), which began as a nonprofit grassroots coalition, has established itself as one of the leading clearinghouses of childhood, adolescent, and adult immunization information for healthcare professionals. The central aim of IAC is to increase immunization rates, enhance the delivery of safe and effective immunization services, and facilitate dialogue across the immunization spectrum of stakeholders. IAC works in partnership with the CDC to create and distribute educational materials for providers and the public, educate health professionals about U.S. vaccine recommendations, improve immunization practices, and provide disease/vaccine specific information. The Vaccine Policy and Licensing (VPL) site was created by IAC as an official one-stop shop vaccine policy resource. The VPL website hosts a variety documents concerning science and financing policy including: recommendations for vaccine use, product approvals, journal

publications, video podcasts, policy statements and position papers indexed by date, vaccine, and topics of interest.

NCI State Cancer Legislative Database

The National Cancer Institute's (NCI) State Cancer Legislative Database (SCLD) serves as resource for federal and state agencies, Congress, health departments, academia, professional organizations, and the public for research and analysis of cancer-related health policy. The SCLD monitors cancer-related state legislation around select topics such as cervical cancer and health disparities; while supporting evaluation of the impact of state legislative activities on public health and cancer control, and monitoring legislative trends that may reflect shifts in attitudes and practices toward cancer prevention and control. The SCLD Program website houses publications and conference presentations, quarterly newsletters containing reviews of is a resource state cancer-related legislation enacted each quarter and an inquiry response system for customized searches of the database for specific inquiries about the status of state laws and cancer-related legislation.

Other Documents & Sources

Several other documents and sources were included from the following websites and organizations: Congressional Research Service, Guide to Community Preventive Services, Henry J. Kaiser Family Foundation, Institute of Medicine (IOM) Committee on Immunization Finance Policies and Practices, National Conference of State Legislatures, Women in Government, and the Global Alliance for Vaccines and Immunization.

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