THE HPV CONNECTION PROJECT:

INCREASING AWARENESS OF THE ASSOCIATION BETWEEN ORAL CANCER AND HPV

by

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University of Pittsburgh, 2013

ABSTRACT

Description of the Problem

Human Papilloma Virus (HPV) is confirmed to be a risk factor for oral cancer. Recent studies on oral infections show HPV as a cause of oropharyngeal cancer, which affects the throat, tongue, soft palate, and tonsils. HPV has become increasingly more common among men than women in the U.S. with risk factors that include certain sexual behaviors.

The goal of "HPV Connection Project" is to disseminate information on HPV, its causes, populations at risk, its consequences and to increase awareness of behaviors that lead to risk of HPV infection. Awareness includes increasing knowledge regarding sources of risk, safer behaviors, and prevention approaches available.

Approach

The aim of this document is to outline an intervention to:

- Increase awareness of risks and prevention approaches in populations most at risk through linguistically and culturally appropriate multi-modal information delivery mechanisms.
- 2. Increase community engagement by facilitating access to and utilization of reliable information among teenagers, parents, health providers and the general population.
- 3. Raise public awareness about the relationship between HIV and the risk of oral cancer.

4. Train dental health professionals on early identification of HPV and how to be authoritative information multipliers.

Methods

The "HPV Connection Project" focuses on the development of educational tools on HPV screening, prevention and treatment, including dissemination of information through social media such as Facebook, Twitter, LinkedIn and YouTube to the target populations. It also includes presentations and webinars oriented to train dentists, dental hygienists and dental assistants on HPV and related dental issues.

In order to leverage the reach of existing organizations, the project seeks to create partnerships with existing educational projects in health promotion and training including the Pennsylvania/ MidAtlantic Aids Education and Training Center (PAMA AETC), the Telehealth AETC Appalachia Project (TAAP), the Graduate School of Public Health at the University of Pittsburgh, dental health organizations and societies, the public health system, and the education system.

The HPV Connection Project will also seek to develop relationships with other relevant public health organizations, and collaborate with high school superintendents, health educators, and nurses to engage them in discussions and distribute educational information. It will be a pilot dissemination model in one school district in Allegheny County, PA to provide current CDC guidelines for use of HPV vaccine by school health professionals.

Anticipated Results and Outcomes

Increase in the use of the HPV vaccine provided to young women and men (aged 11 to
 as recommended by CDC.

- 2. Improve the early identification of existing HPV infection by dental providers through oral examination.
- 3. Refer youth who have oral manifestations of HPV to dental care and medical treatment.
- 4. Become a recognized web source for information about HPV prevention, access to information on vaccination and treatment for parents, schools, dental and other dental health practitioners.
- 5. Integration of HPV information into the health programs within one secondary school.
- 6. Suggest policy changes for consideration by school districts to require HPV vaccination for students aged 11 to 18.

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PREFACE

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To Juan Diego, my miracle of love: It's for you!

NOMENCLATURE

AAP American Academic of Pediatric

ACIP Advisory Committee on Immunization Practices

ACS American Cancer Society

AETC AIDS Education and Training Center

CDC Centers for Disease Control and Prevention

CTCA Cancer Treatment Center of American

DMD's Doctors of Dental Medicine

DDS's Doctor of Dental Surgery

FDA Food and Drug Administration

HNSCCs Head and neck Squamous Cell Carcinomas

HIV Human Immunodeficiency Virus

HSV Herpes Simplex Virus

HPV Human Papilloma Virus

K-12 Designation for the sum of primary and secondary education used in the United

States

LEEP Loop Electrosurgical Excision Procedure

LGBT Lesbian Gays Bisexual and Transgender

MEC Mobile Examination Center

NAACCR North American Association of Central Cancer Register

NCI National Cancer Institute

NHANES National Health and Nutrition Examination

NIS National Immunization Survey

Pap Papanicolau Test

SCCs Squamous Cell Carcinomas

SES Socioeconomic Status

STD's Sexual Transmitted Infections

TAAP the Telehealth AETC Appalachian Project

TTM TransTheorical Model

USPSTF the U.S. Preventive Services Task Force

VFC The Vaccines for Children program

VLP's Virus Like Particles

1.0. INTRODUCTION

The incidence of oropharyngeal carcinoma related to human papillomavirus (HPV) has been increasing in recent years. According to the American Cancer Society, 2013 estimates indicate that in the United States about 36,000 people will get oral cavity or oropharyngeal cancer and an estimated 6,850 people will die of these cancers. The number of oropharyngeal cancers linked to HPV has risen dramatically over the past few decades. HPV is now found in about two out of three oropharyngeal cancers (American Cancer Society [ACS], 2013). This increase in the incidence of HPV-related oropharyngeal cancer has important public health implications.

HPV is the most commonly diagnosed sexually transmitted infection in the US. Some individual sexual behaviors that lead to risk of HPV infection including multiple sex partners, oral sex, and sex between heterosexual as well as same sex partners. In addition, tobacco smoking and alcohol use are considered major risk factors associated with development of oral cancer (Dietz & Nyberg, 2011).

There are significant costs associated with the management and treatment of HPV related diseases. In 2010, the overall annual direct medical cost burden of preventing and treating HPV associated diseases in the U.S. was estimated to be \$8B, of which \$6.6B (82.3%) was for routine cervical cancer screening and follow-up, \$1B (12.0%) for cancer, including \$.4 B for cervical cancer and \$.3 B for oropharyngeal cancer, \$.3 B(3.6%) for genital warts, and \$0.2 B(2.1%) for recurrent respiratory papillomatosis (Chesson et al., 2012).

The most common symptoms of HPV positive oropharyngeal cancer are sores or ulcers in the mouth, warts, lumps, squamous intraepithelial lesions, white or red patches on the mouth, tongue and throat, and difficulty swallowing. Most people with HPV do not develop symptoms or health problems. In 90% of cases, the body's immune system appears to clear HPV naturally within two years. But it is impossible to know which people who are infected with HPV will go on to develop cancer or other health problems. HPV infections can be detected only by clinical inspection and annual screening by dentists, physicians or other primary care practitioners such as nurse practitioners and physician assistants. Early detection facilitates linkage to care and control of the disease progression. The U.S. Healthy People 2020 effort aims to reduce HPV spread among teenagers with education and promotion of HPV vaccination; these are proven to be the most effective prevention approaches against HPV (United States Department of Health and Human Services [HHS], Healthy People 2020, 2012).

The HPV Connection Project is intended to reduce the burden of oropharyngeal cancer and HPV through education. It addresses a critical issue in public health that impacts the health of individuals and communities that requires a preventive approach to identification and control. In addition, the project seeks to engage dentists into prevention and management of HPV and oral cancer and provide patients with credible and accurate information about the risk of disease and performing early detection and treatment.

The HPV Connection Project seeks to increase awareness of risk and of means of prevention in populations most at risk. The project focuses primarily on youth, parents, guardians, school leadership, nurses and health educators, and dental professionals through linguistically and culturally appropriate multimodal information delivery mechanisms. The HPV

Connection Project identifies individual, and interpersonal, social, structural and systemic factors that need to be addressed to influence individual behavior and decision making related to prevention of HPV diseases.

The HPV Connection Project utilizes the TransTheorical Model (TTM), also called "Stages of Changes Theory" as a framework to develop mechanisms and interventions that can assist young men and women to change sexual behavior and increase utilization of the HPV vaccine.

The HPV Connection Project is intended to distribute information using constructs of the Social Communication Theory to reach teens and their parents through health communication campaigns combined with the distribution of free health related products. The HPV Connection Project has two phases:

Phase 1:

This phase is aimed at utilizing a web site designed to provide information on HPV, related diseases, prevention methods and educational material as a direct channel to reach targeted population. The project will have a socially enabled web site under the domain <HPV Connection.org>. It will be designed to maximize the distribution of information and increase awareness through mass media, small media and interpersonal communication providing ample opportunities for exposure and distribution of information materials through social media. Material on topics of specific interest will be designed to be culturally and linguistically tuned for the target audience. Three key messages are included in the initial campaign and are part of the identity of the HPV Connection Project:

- 1. Spread the word NOT the disease;
- 2. Speak with your dentist and physician; and

3. Get the vaccine.

In addition, the messages are designed in English, Spanish and Portuguese to reach out to Spanish and Portuguese speakers in the pilot location in Pittsburgh, PA. This essay mainly focuses on the Phase 1 of the HPV Connection Project.

Phase 2

This phase of the pilot project focuses on face-to-face education and training of health care professionals. The HPV Connection Project phase 2 seeks to establish partnerships with organizations that have compatible missions. The activities of the HPV Connection Project and its partners will include design and delivery of web based educational training in HPV basic, HPV/HIV, HPV associated diseases, and prevention methods targeted to health care professionals.

Another component of Phase 2 includes reaching out to one secondary school in one school district to introduce a health education program focused on HPV prevention. Health educators and school nurses would be engaged to deliver information about sexual behavior and prevention of HPV and other sexually transmitted infections (STIs) in middle and high school courses.

The HPV Connection Project will use diverse methods for process evaluation through web analytics services for its website, tracking attendance at events and monitoring comments and requests for information. Additional methods will include audience satisfaction surveys to assess the quality and number of seminars delivered by partnerships, nurses and health educators.

The HPV Connection Project aims to disseminate information about HPV prevention, promote vaccination and facilitate access to it through integration of HPV information into the health programs within school districts. The goal is to increase the use of the HPV vaccine among boys and girls aged 11 to 26 as recommended by the Centers for Disease Control and Prevention (CDC). A parallel effort intends to increase identification of existing HPV infection by dental providers and help link patients to dental and medical care. The ideal would be to develop support of enough people to spark policy changes leading to mandatory HPV vaccination for students for students aged 11 to 19.

2.0. LITERATURE REVIEW

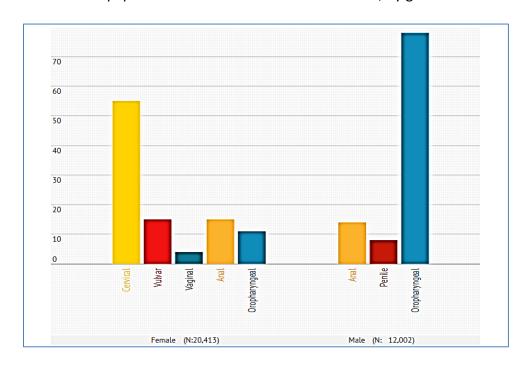
2.1. PREVALENCE OF HPV INFECTION IN THE UNITED STATES

Approximately 20 million people in the U. S. are infected with the Human Papilloma Virus (HPV). It is the most common sexually transmitted disease in the U.S. among the young and sexually active population. Approximately 6.2 million people become infected each year. At least 50% of sexually active men and women get HPV, and up to 75% of sexually active adults will become infected in their lifetime. High prevalence occurs in youth between the age 22 and 25 (CDC, 2011).

For most individuals, HPV remains asymptomatic after acquiring the infection; however, a small portion of individuals will develop clinically or histologically recognizable HPV lesions (Watson, 2005). Certain types of the virus can evolve into cancer. HPV is linked to various types of cancer, including cervical and anal, it is also significantly linked to squamous cell carcinoma, which occurs in the oral cavity, oropharynx, hypopharynx and larynx (Ha & Califano, 2004). Each year in the U.S. about 12,170 women get cervical cancer; some of those cancers are associated with HPV. Also, an estimated 2,700 women and 1,500 men get HPV associated anal cancer. About 400 men get HPV associated penile cancer, 1,500 women get HPV-associated vulvar cancer, and 1,500 women and 5,600 men get HPV-associated oropharyngeal cancers (CDC, 2012).

2.2. HPV LINKED CANCERS ON THE RISE

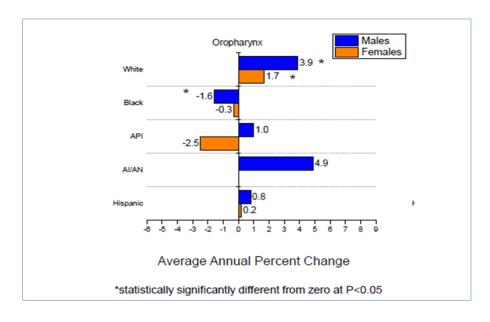
The Annual Report to the Nation on the Status of Cancer (1975 -2009), by researchers from the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the North American Association of Central Cancer Registries (NAACCR), includes a special feature section and evaluation of the burden and trends of HPV associated cancer and the HPV vaccination coverage level in the United States. The report shows that cancer deaths overall continue to decline. However, there is growing concern about an increase in cancer linked to HPV, particularly of the throat. Figure 2 below shows the number of new human papilloma virus associated cancers overall, by gender in the U.S.



Source: Jemal A et al. J Natl Cancer Inst 2013;105:175-201 * Total N: 32,415

Figure 1. Number of New Human Papillomavirus (HPV) - associated cancers overall, by sex in the United States

Figure 3 shows an analysis of data collected from 2000 to 2009. It indicates that the percentage change for HPV associated oropharyngeal cancer increased among white men and women.



API: Asian/Pacific Islander AI/AN: American Indian/Alaskan Native Source: CDC,2012 Figure 2. Trends in Oropharyngeal cancer-HPV associated by sex, race and ethnicity

2.3. HPV AND RELATED CANCERS

Human Papilloma Virus is a ~8kbp, non-enveloped, double strained, circular DNA tumor virus from the family of Papovaviridae (Stoler, 2003). More than 150 types of HPV have been fully identified and classified according to the type of cell infected and the ability to affect cellular transformation. Differences in genetic structure determine the location and type of lesions that can be caused on the skin and other parts of the body.

HPV types can be divided into two broad groups, low risk and high risk types, depending upon their association or lack of association with cancer of the lower genital tract (Ragin et al., 2006).

Low risk types (6, 11, 42, 43, 44, 54, 61, 70, 72, and 81) are called non carcinogenic HPV and are associated with benign lesions such as warts on the hands, legs, arms and another areas on the skin. The high risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82) are considered oncogenic or carconogenic, and have been identified in the cervix, vagina, vulva, penile, anus, oropharinx, neck and head cancer (Ha & Califano, 2004). This paper focuses on the implication of HPV high risk types 16 and 18, which are responsible for aproximately 70 percent of HPV cervical cancers (Schiffman, Castle, Jeronimo, Rodriguez, & Wacholder, 2007).

In the U.S., more than half of the cancers diagnosed in the oropharynx are linked to HPV-16, Figure 1 shows the percentage of HPV 16 detected in cancer specimens in 2008. Recent studies show that HPV 16 is linked to 85 to 95 percent of HPV positive oropharyngeal cancers (Cleveland et al., 2011). In 2011, a study by Chaturverdi et al., reported the incidence of HPV cancer has increased in the past 20 years and is expected to surpass the annual number of cervical cancers by the year 2020, especially among men in the U.S. (Chaturvedi et al., 2011)

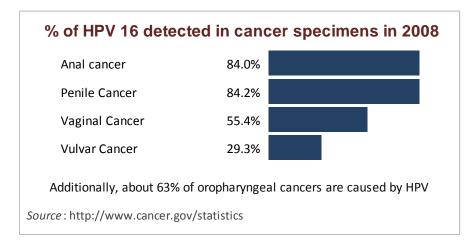


Figure 3. Percentage of HPV 16 detected in cancer specimens in 2008

A cross sectional study to determine the prevalence of oral HPV infection in the U.S. was conducted using the National Health and Nutrition Examination Survey (NHANES) in 2009-2010. The study included a representative sample of civilian non-institutionalized U.S. population of 5,579 participants, men and woman aged 14 to 69 years. Demographic data were obtained by in-home survey, and behavioral data were obtained by audio, computer assisted self-interview at the Mobile Examination Center (MEC). Individuals were examined for HPV using DNA purified from oral exfoliated cells and evaluated by polymerase chain reaction and type specific hybridization (Gillison, Broutian, et al., 2012).

Results from the NHANES 2009-2010 survey show that the overall prevalence of HPV infection among men and women aged 14 to 69 years was 6.9 percent, and the prevalence was higher among men (10.1 percent) than women (3.6 percent), even after accounting for differences in sexual behavior variables. The prevalence of high risk HPV infections was 3.7 percent and for low risk HPV infections was 3.1 percent. The most prevalent HPV type detected in the study was HPV 16 (Gillison, Broutian, et al., 2012).

Data from the NHANES 2009-2010 study provided evidence that oral HPV infection is predominantly sexually transmitted, is higher among sexually experienced individuals and increased significantly with number of sexual partners. It is rare or uncommon among sexually inexperienced individuals (CDC, 2012). Also, the study shows a positive association between oral sexual behaviors, HPV infection and oropharyngeal cancer. Previous studies by Gillison, et al. (2008), D'Souza, et al. (2007) and Schwartz, et al. (1998) have shown this association as well with transmission of other viral infections like Herpes Simplex Virus (HSV).

A new survey of young people's sexual habits in the U.S. found that about one-quarter of young people engage in oral sex before they engage in intercourse and two-thirds of Americans aged 15 to 24 have engaged in oral sex (CDC, 2012). These data showed that

Among adults aged 25–44, about 98% of women and 97% of men ever had vaginal intercourse, 89% of women and 90% of men ever had oral sex with an opposite-sex partner, and 36% of women and 44% of men ever had anal sex with an opposite-sex partner. Twice as many women aged 25–44 (12%) reported any same-sex contact in their lifetimes compared with men (5.8%). Among teenagers aged 15–19, 7% of females and 9% of males have had oral sex with an opposite-sex partner, but no vaginal intercourse.¹

In 2007, D'Souza, et al. reported an association between open mouth kissing and oral HPV, among individuals without a history of performing oral sex but with a high number of open mouth kissing partners. Open mouth kissing, also called "French kissing," is defined as "a kiss involving insertion of the tongue into the partner's mouth"². The number of new reported HPV cases was fully associated with open mouth kissing or oral sex partners and remained after vaginal intercourse was statistically controlled (D'Souza et al., 2007). Open mouth kissing appears to be a common practice that contributes to the spread of HPV among individuals.

2.4. HPV REPLACES TOBACCO AND ALCOHOL AS A MAJOR RISK FACTOR FOR ORAL CANCERS

Tobacco smoking and alcohol use are major risk factors associated with development of oral cancer (Petersen, 2009). Several studies about risk factors for head and neck squamous cell carcinomas (HNSCCs) have observed that HPV infection and smoking are not mutually exclusive.

¹ http://www.cdc.gov/nchs/data/nhsr/nhsr036.pdf

² http://dictionary.reference.com/browse/french+kiss

HNSCCs from smokers may contain transcriptionally active HPV (Ragin et al., 2006). Tobacco use was associated with prevalence of oral HPV infection, and cumulative tobacco exposure was not associated with the risk of HPV (D'Souza et al., 2007). Studies have showed that HPV positive tumors tend to be located in the oropharynx (floor of the mouth, tonsil and larynx) and are more likely to occur in non-smokers (Ragin et al., 2009). However, the degree to which oral HPV infection may combine with tobacco and/or alcohol use to increase the risk of cancer is not yet clear. A controversial case-control study to determine whether the risk of this cancer is related to HPV infection and sexual history factors suggested that HPV type 16 infections may contribute to the development of a small proportion of oral SCCs in this population, most likely in combination with cigarette smoking (Schwartz et al., 1998).

According to the Cancer Treatment Center of America (CTCA), people with oral cancers linked to HPV usually have good prognosis as they tend to be non-smokers and non-drinkers. There is, however, a strong association between smoking and/or alcohol consumption and oropharyngeal cancer, oral cavity, and neck and head cancer. In addition, marijuana smoking is strongly associated with risk of developing HPV-16–positive HNSCC. A hospital based case-control study of HNSCC from the Johns Hopkins Medical Institution compared the risk factor profiles for HPV-16–positive and HPV-16–negative HNSCCs. It was the first study to connect marijuana use with the development of HPV oral cancer. Head and neck tumors caused by the human papillomavirus (HPV) demonstrated that it is most often linked to certain sexual behaviors and marijuana use rather than tobacco and alcohol use. The study also determined the link between the cannabis found in the marijuana with suppression of the immune system. It showed as well that younger people are at higher risk (Gillison, Alemany, et al., 2012).

2.5. HPV A SILENT ENEMY

There is no cure for the HPV infection. HPV infections can cause genital warts which appear sometimes between weeks or months after sexual contact with an infected partner. HPV-16 and HPV-18, which are sexually transmitted, cause up to 95% of cervical cancers. HPV-31 and HPV-45 are cancer-causing HPV types associated with dysplasia. Dysplasia is the occurrence of tissue changes seen prior to malignancy. Dysplasia can be detected on the female cervix through a Pap smear test (NCI, 2012). Among men who have sex with men (MSM), the incidence of anal cancer is significantly more prevalent and increasing annually. Anal cancer is caused by the same strains of HPV that cause cervical cancer in women. The anus and the cervix are biologically similar, and both are orifices that serve as sites of HPV infection. The same screening methodology (pap smear) can be used to test the anus for cancer and pre-cancerous cell changes (Dietz & Nyberg, 2011).

Cancer of the oropharynx is a major cause of cancer-related death in the U.S., exceeding the annual death rates for cervical cancer and malignant melanoma (NCI, 2010). The most common symptoms of oropharyngeal cancer are sores in the mouth that do not heal and/or mouth pain. Other possible signs and symptoms include a white or red patch on the gums, tongue, tonsil, or lining of the mouth, a lump in the cheek, sore throat, difficulty swallowing or hoarse voice changes. Oral cavity and oropharyngeal cancer can be detected early through regular routine examinations by dentist, doctor, nurse practitioner, physician assistant, or dental hygienist, and by individual self-examination. The American Cancer Society also

recommends that doctors examine the mouth and throat as part of routine cancer related checkups (ACS, 2011).

HPV infections can be detected by testing a sample of cells to see if they contain viral DNA or RNA. The HPV tests on the market are used only to help screen women 30 to 65 years of age as part of regular screening, with a Papanicolau Test, also known as Pap test, or age 21 or older for follow-up. An abnormal Pap test result means that cell changes were found on the cervix, but it does not mean that the patient has cervical cancer. There is no general test for men or women to check one's overall "HPV status," nor is there an approved test to find HPV on the genitals or in the mouth or throat (CDC, 2012).

2.6. HPV PREVENTION AND VACCINE

HPV is found aproximately of 99% of cervical cancers and cervical cancer is the second most common cancer in women worldwide³. Actual rates of cervical cancers in the U.S. have declined among all women except American Indians and Alaska Natives and women living in low socioeconomic areas. The decline has been aproximately 2% primarily due to the widespread use of Pap test for early detection of cervical abnormalities and dysplasia (Jemal et al., 2013). Recently updated guidelines now recommend that women begin having Pap tests at age 21 (CDC, 2012). The Pap test is recommended for all women between the ages of 21 and 65 years old, and can be done in a doctor's office or clinic (USPSTF, 2012). The same screening

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³ http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf

methodology (pap smear) can be used to test the anus for cancer and pre-cancerous cell changes (Dietz & Nyberg, 2011). Moreover, effective screening procedures for other HPV related cancers, such as penil and oral are not available. Due to these limitations the HPV vaccine is the most effective strategy to reduce HPV related cancers in men and women.

In 2006, The U.S. Food and Drug Administration aprroved Gardasil®™ The Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant by Merck & Co., Inc. Gardasil®™ protects females nine through 26 years of age against HPV 6 and 11, which cause 90% of genital warts, and HPV 16 and 18, which cause 70% of cervical cancers. Vaccination is recommended for males nine through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11 (ACIP, 2009). Vaccination in both boys and girls ages nine through 26 years is recommended for the prevention of anal cancer and associated precancerous lesions due to HPV types 6, 11, 16, and 18. (FDA, 2009)

In 2011, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of Gardasil®™ quadrivalent human papillomavirus (HPV) vaccine in males aged 11 or 12 years. These recommendation replaced the ACIP guidelines made in 2009 (CDC, 2012). Gardasil®™ has been shown to be 100% efficacious in preventing persistent HPV infections from types 6, 11, 16, and 18. The two vaccines are licensed, safe and recommended by the FDA and the CDC.

In 2009, the FDA approved Cervarix^{®™} the Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant by GlaxoSmithKline. Cervarix^{®™} is indicated for the prevention of cervical cancers caused by oncogenic HPV types 16 and 18. Vaccination with Cervarix^{®™} is

approved for use only in females nine through 25 years of age (FDA,2012). Table 1 below shows the HPV vaccines licensed by FDA and recommended by the CDC (CDC, 2013).

Table 1. HPV Vaccines Licensed by FDA

	Quadrivalent (Gardasil®)	Bivalent (Cervarix®)
Manufacturer	Merck	GlaxoSmithKline
VLP types	6, 11, 16, 18	16, 18
Licensed in US	Females -2006 Males -2009	Females - 2009
chedule in months om first vaccination	0, 1-2, 6	0, 1-2, 6

Both vaccines are derived from inactive virus-like particles (VLPs) which are known to be one of the safest methods of vaccination currently available. Vaccinations do carry possible injection side effects, most commonly manifested as redness, pain, and swelling, self-resolving fevers and gastrointestinal complaints.

The CDC recommends HPV vaccination in a series of three injections. All those being vaccinated should receive all three intramuscular doses. The second and third doses should be administered between two and six months after the first dose. The HPV vaccine provides the most protection when all three doses are given before sexual activity begins. If a pre-teen (age 11 or 12) was not vaccinated against HPV, the vaccines can be given later in the teen years. However, studies show that 11 to 12 years is the ideal age to acquire maximum protection from HPV vaccines (CDC, 2012). The vaccine prevents HPV infection in persons who have not previously been infected with one or more HPV types. It does not work as effectively for those who were already exposed to the virus before getting the vaccine (CDC, 2012).

The NIS – Teen 2011 reports shows that in 2010, about 48.7% of girls aged 13 through 17 had received at least one dose of HPV vaccine, compared with only 32 % of girls aged 13 through 17 who had received all three shots. The report also shows lower coverage rate among girls living below the poverty line, and among Hispanics. HPV vaccination coverage rate for boys who received at least one dose was 1.4% in 2010 and 8.3% in 2011. But only 1% had received all three recommended doses. Figure 4 below shows that HPV vaccine coverage rates are lower for younger girls (CDC, 2013).

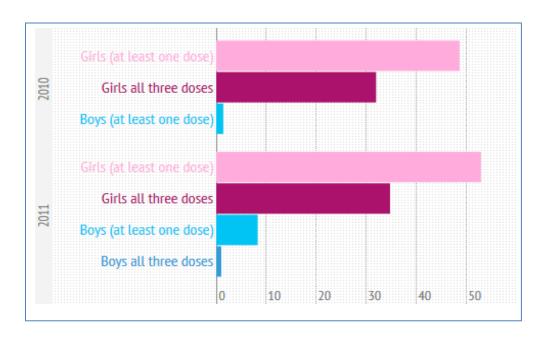


Figure 4. Compared percentage of people aged 13 to 17 years old vaccinated in 2010-2011.

2.7. HPV VACCINE CONTROVERSY

HPV vaccination in the U.S. is one of the most controversial topics in health care. The CDC, ACS and the American Academy of Pediatrics (AAP), among other medical societies support the vaccine to protect girls and boys from diseases causes by HPV.

The controversy focuses on mandatory HPV vaccine for teen girls (Allen et al., 2010). A main focus of the controversy is that parents or custodians of minors currently have the right to refuse giving a child the vaccine. Some conservative religious groups have been very vocal against the HPV vaccine prevention policy, arguing that the vaccine will result in an increase of early sexual activity in teens and/or would lead to an increase in risky sexual behavior in girls (Vamos, McDermott, & Daley, 2008). A recent study published in *the Journal American*Academy of Pediatrics about sexual activity related outcomes after HPV vaccination of 11 to 12 year olds shows that vaccination in the recommended ages is not associated with increase in sexual activity (Bednarczyk, Davis, Ault, Orenstein, & Omer, 2012).

From the introduction of HPV vaccine in 2006, prevention and recommendations policies were focused only in girls and young women to protect them from HPV. For many years, boys were excluded from research about HPV vaccine and the connection between HPV and other associated cancers including cervical, vulvar, vaginal, anal, penile and oropharyngeal cancers. In 2011, CDC issued an official recommendation for boys to receive the HPV vaccine.

Another important concern is the cost of the HPV vaccine. The retail price for HPV vaccines is \$130 per shot for people not covered by a health insurance plan. Thus, the cost for the three shots could be approximately \$500. Given that most people who have no health

coverage are low income, this can lead to social disparities regarding access to the vaccine and associated preventative care (Chesson et al., 2012). Table 2, below, shows the annual cost of HPV- associated disease in U.S. dollars in 2010.

Individual or group insurance plans are subject to state laws. These laws generally establish whether insurers should cover the cost of vaccination based on recommendations from the ACIP (NCI, 2012). The good news for parents who are not able to afford the vaccine is that HPV vaccine is available through the Vaccine for Children (VFC), a federal program that provides free vaccines to children and teens younger than 19 years of age who are either Medicaid-eligible, American Indian, Alaska Native, or uninsured⁴.

Table 2. Annual Cost of HPV-Associated Disease, In 2010 U.S. Dollars

billions)
6.6
0.4
0.2
0.3
0.3
0.2
8.0

^{*}Cervical cancer screening costs: ~ 80% routine screening, ~20% follow-up **RRP costs: ~ 70% juvenile-onset, ~ 30% adult-onset. Source: Chesson H et al. Vaccine 2012;30: 6016-19

 $^{^4\} http://www.nal.usda.gov/wicworks/Learning_Center/mailing/FinalParentsGuideEnglish.pdf$

Another significant controversy about HPV vaccinate regards equal protection for boys against HPV and others associated cancers. About 1% of sexually active men in the U.S. have genital warts at any one time. Some types of HPV can cause cancer in the penis, anus, or oropharynx (back of the throat, including base of the tongue and tonsils). In the U.S. each year, aproximately 400 men get HPV related cancer of the penis, 1,500 men get HPV related cancer of the anus, and 5,600 men get cancers of the oropharynx. Men are three times more likely to get HPV oral cancer than women. Gay and bisexual men are about 17 times more likely to develop anal cancer than men who only have sex with women (CDC, 2012).

Despite the controversy about HPV vaccination for boys, the FDA approved Gardasil®™ for males, and the CDC, as well as the American Academy of Pediatrics, now recommend vaccination of males aged 11-12, with catchup vaccination for boys ages 13-21, and up to 26 years for men who have sex with men (AAP, 2012). Additionally, vaccination for males should increase protection against cervical cancer and reduce the risk of other associated cancers for females.

2.8. HEALTH COMMUNICATION AND PREVENTION CAMPAIGNS

The Healthy People 2020 recognizes that innovative communication strategies are critical for addressing issues of health disparities (HP2020, 2012). Communication strategies facilitates HPV vaccine uptake and help normalize perceptions of sexual health and STD prevention. The CDC is leading efforts to develop research, use data and update information on HPV and associated cancers to the general public. It increases awareness through educational campaigns

and offers national programs such as cervical cancer screening (Pap test), HPV tests, and vaccine campaigns aimed at preteens in the U.S. (CDC, 2012). In addition, the American Cancer Society has increased efforts to conduct research, inform the general population and promote vaccination for the prevention of HPV for cervical and other associated cancers (ACS, 2012).

Regarding preventive measures for HPV and oral related issues, the available early detection methods include clinical inspection and annual screening by dentists or physicians. Dentists are trained for a screening that involves visual examination of the oral cavity including all tissues in the mouth, floor and back of the throat, nasopharynx and larynx. The procedure involves manually feeling the neck for swollen lymph nodes and hardened masses. The examination also includes a check of the mouth for white or red patches, ulcerations, lumps, loose teeth, and review dental x-rays for abnormalities.

A prevention method that has shown to help reduce the risk of genital HPV and associated infections is the consistent and correct use of latex condoms. However, condoms are not 100% effective because HPV can infect areas that are not covered by a condom (CDC, 2012). Therefore, communication campaigns must emphasize that the best prevention is limiting the number of sexual partners and choosing partners who do the same or are in mutually monogamous relationship. Communications and prevention campaigns need to clearly transmit the message that the best way to protect from HPV is to take advantage of the options available: HPV vaccination for both boys and girls starting at nine years of age, Pap tests for young women to detect HPV viruses or sexually transmitted diseases, and healthy sexual behaviors.

3.0. THE HPV CONNECTION PROJECT

Oral cancer and HPV are critical issues in public health that impact the health of individuals and communities and require a preventive perspective. Prevention explores factors that are more likely to influence individual behavior and decision making on aspects related to health.

Social communication and health information strategies among individuals have demonstrated efficacy in generating a positive impact on health, health care and health equality (HP2020). Working along these lines, the HPV Connection Project aims to provide information on HPV and oral cancer to targeted populations using on-line and off-line mechanisms. On-line mechanisms use social media and off-line mechanisms use printed materials and face-to-face training.

3.1. DENTAL MEDICINE AND PUBLIC HEALTH

The HPV Connection Project was born in the spring of 2012 as an informative blog and multimedia website. It is intended to be a resource for information on HPV, its prevention, treatment, research, and news. At the same time, it intends to be a multiplier to help spread the word and create awareness about HPV Oral Cancer. The idea of the HPV Connection Project is to use the internet and social media to reach out to teens and their parents, and the general population in simple targeted messages with the goal of making them aware about HPV diseases, risky behaviors and prevention mechanisms. It incorporates education, promotion and prevention related to oral health.

Given the documented increase in the incidence of HPV related oropharyngeal cancers, a first channel to provide patients with credible and accurate information is through dental providers. They can start providing information about the risk of the disease and performing early detection and treatment.

The HPV Connection Project seeks to engage dentists and dental health practitioners including dental hygienists and dental assistants, through a series of short targeted training sessions and information made available in brochures designed in several languages so they can be distributed to patients during routine dental checkups. In addition, the HPV Connection web site offers tools like videos and targeted educational material about HPV and related diseases.

3.2. PROJECT GOALS

The HPV Connection Project seeks to increase awareness of risks and prevention mechanisms in populations most at risk through linguistically and culturally appropriate multi-modal information delivery mechanisms.

The project intends to increase community engagement by facilitating access to and utilization of reliable information among teenagers, parents, health providers and the general population. The main goal is to raise public awareness of the risk of oral cancer and HPV and the connection between them, i.e. sources of risk, safe behaviors, protection mechanisms and available support networks.

This would be achieved through the dissemination of educational materials via the internet, social media, targeted brochures and seminars, and training of dental health professionals on early identification of HPV and as authoritative information multipliers.

3.3. TARGET POPULATIONS

Youth

The HPV Connection Project is focusing primarily on youth, sexually active adolescents ages 15 to 19 and young adults aged 20 to 24 who are at higher risk of getting STDs compared to older adults. However, the project seeks to reach out to all genders independent of social, economic and behavior factors. The reasons for the focus on youth include the following:

- The incidence of HPV related oral squamous cell carcinoma (SCC) has increased significantly among younger populations.
- Vaccination as preventive measure is most effective for people aged nine to 18 and 18 to
 26 years.
- HPV communication and vaccination campaigns have been focused on females.
- There has been a substantial increase in new cases of oral, throat, neck and anal cancer among young men.
- Current messages in communication campaigns suggest that HPV is exclusively a heterosexual concern, but HPV affects the LGBT population as well.

Parents and Guardians

Parents and guardians are key target audiences for information because they are decision makers for their minor children's health care. Providing them with clear information on HPV vaccination is critical to inform and support their decision process regarding their children's health.

Parents' decisions to have their children vaccinated are influenced by multiple factors mentioned before. Parental beliefs about the appropriateness of pre-adolescent immunization can limit the use of HPV vaccines among pre-teens. Thus, efforts to provide information to parents can impact acceptance and uptake of HPV vaccination and improve communication with their children on risk behaviors.

School Leadership, Nurses and Health Educators

Natural multiplier groups include K-12 school leaders, nurses and health educators. Thus material needs to be designed to provide them with information about the HPV vaccine and to be able to help educate K-12 students on the matter. To engage this group, lectures, discussion groups, webinars and educational materials should be made available to middle school and high school personnel.

Dentists, Dental Hygienists and Dental Assistants

Dentists, dental hygienists and dental assistants should be included in the initiative to increase awareness and immunization. They are an essential group that can be leveraged to provide information regarding vaccine recommendation and safety to the community through their

position as authorities on dental health issues. In case of positive HPV oral cancer patients, dentists are able to link patients to treatment and care for HPV and other clinical and support services (HHS, 2013).

3.4. SOCIAL ECOLOGICAL PERSPECTIVE

The social ecological perspective asserts that health is a complex phenomenon that cannot be understood from a single level of influence. The social ecological model is a framework of determinants of health across multiple levels of influence. In the social ecological model, environments influence individuals, and individuals influence their environments. Determinants may include risk factors, which place an individual at increased risk for a negative health outcome, and protective factors, which decrease the likelihood of negative consequences from exposure to risk (Glanz, Rimer & Lewis, 2002). Figure 6 below illustrates the main elements of the social ecological perspective and the relationship among them. The rest of this section discusses some of the social framework levels that need to be addressed in relation to the HPV Connection project.

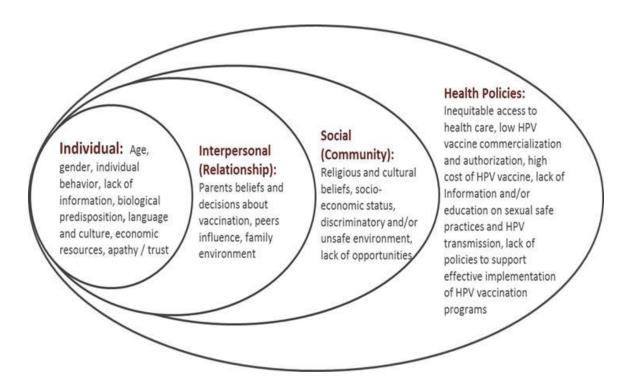


Figure 5. Social ecological perspectives of the HPV Connection Project

Source: Adapted from (McLeroy, Steckler, Bibeau and Glanz, 1988)

3.4.1. Individual Factors

Individual behavior

One of the factors associated with oral HPV spread is sexual activity. Sexually active individuals with a high number of lifetime partners are at high risk of developing HPV-positive oral cancer (CDC, 2012).

Lack of information

Many people lack information and/or education on safer sex practices and HPV transmission.

Specifically, there is lack of information about HPV transmission through genital, anal and oral

sex. In addition, HPV is transmitted by skin-to-skin contact and not penetrative sex like Human Immunodeficiency Virus (HIV). Most cases of oral HPV are associated with oral sex (CDC, 2012).

Biological predisposition

According to studies about the prevalence of oral HPV from the CDC, men are three times more likely than women to have HPV in their oral cavity (CDC-STD's, 2012). Thus, men are at higher risk of developing oral HPV cancer.

3.4.2. Interpersonal Factors

Parents' decision making and beliefs about vaccination

Many parents decide to delay their children's vaccination until the onset of sexual behavior.

Other parents have the perception that vaccines cause secondary effects, or in some cases their belief is that children are too young to receive the HPV vaccine. It appears that many parents reject the vaccine because they believe that their children's safe behavior is adequate protection against STDs (Gamble, Klosky, Parra, & Randolph, 2010).

Peer influence

Some teenagers have peers with the ability to influence and engage in oral sex because they believe that by doing so they do not have to worry about pregnancy. This practice is often mistakenly considered by many teenagers as a safe alternative to sexual intercourse. However, most cases of oral HPV are associated with oral sex (CDC, 2012).

Relationship with a family member

Teenagers can repeat behaviors modeled by family members and begin sexual activity early with the belief that what they are doing is normal. Close family members who consume alcohol, smoke, and/or exhibit unsafe sexual behavior tend to be an example for teenagers, therefore greatly increasing their risk for HPV and other STDs (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012).

3.4.3. Structural and Systematic Factors

Three of the most important fundamental structural and systemic factors that contribute significantly to the increase of cases of HPV associated cancers of the oral cavity and oropharynx amongst women and men in the United States are:

Inequitable access to health care

Socio-economical marginalization limits access to health care. The most vulnerable are women who live in poverty, lack adequate health insurance, may have linguistic barriers, have insufficient knowledge and/or trust in health services and who might feel ashamed or fearful of gynecological examinations (Downs, Scarinci, Einstein, Collins, & Flowers, 2010).

HPV vaccine: Authorization and commercialization

The authorization for commercialization of the HPV vaccine has been slow. In addition, the high cost of the vaccine is a barrier for girls and boys, and vulnerable population that have no health coverage (Ma, Roden, & Wu, 2010).

Inaccurate or non-properly targeted messages

Another factor hindering the acceptance of HPV vaccine has been the focus of advertising messages on HPV immunization for girls to ensure herd immunity, which focus solely on cervical cancer. So far, marketing messages have excluded oral throat, anal, and penile cancer (Graham & Mishra, 2011). The content of messages suggests that HPV is exclusively a heterosexual concern and ignores that HPV is an infectious disease risk for lesbians, gays, bisexuals and transgender individuals (LGBT).

3.4.4. Religion and cultural belief

Many beliefs in communities are strongly attached to religion and church guidance (Gerend & Magloire, 2008). Some religious leaders have argued that the vaccine will promote and/or encourage young people to engage in early sexual activities with multiple partners. This may contribute to parental fears that having their children vaccinated will condone such early sexual activities. At the same time those beliefs spread out through second-hand information with an ever growing distorted message (Davis, Dickman, Ferris, & Dias, 2004).

3.5. IMPLEMENTATION OF THE TRANSTHEORETICAL MODEL

The HPV Connection Project uses the TransTheorical Model (TTM), also called Stages of Change Theory. The basic premises of TTM are that behavior change is a process where individuals differ in their readiness to change and that change is gradual. Therefore, intervention strategies must be tailored for each stage of readiness to change. The model consists of five stages: (1) **Pre-contemplation**, no intention to act; (2) **Contemplation**, intention to act sometime in the future; (3) **Preparation**, intention to act in the near future with some steps towards action; (4) **Action**, behavior change for less than six months; (5) **Maintenance**, behavior change for more than six months (Glanz, Rimer & Lewis, 2002).

During Phases 1 and 2, the HPV Connection Project focuses on individual readiness to change as a determinant of behavior. Each individual differs in the readiness to change, and intervention strategies must be tailored for each stage of readiness to change. The HPV Connection Project uses TTM as a model to develop mechanisms that can help encourage young men and women to change their individual sexual behavior and increase uptake of the HPV vaccine. The TTM model for the HPV Connection Project considers opportunities for intervention in five stages:

Pre-contemplation

During initial stage, individuals who are not even considering changing their behavior, as well as those who are consciously intending not to change receive information about HPV and factors associated with high risk of developing oral cancer. Information will be provided through

websites and health professionals with the goal of increasing awareness of the risks, provide statistics about how prevalent HPV is, encourage safe sexual practices, and to increase use of HPV vaccine among youth. The main goals are to make individuals aware of the risks associated with their behavior and the benefits of safer sexual practices and vaccination.

Contemplation

In this stage, individuals are considering making changes based on the information received.

Nurses and health educators are reliable professionals to influence individual decision making on health topics. Clinicians should share information about the HPV vaccine: side effects, vulnerability and susceptibility, the infection itself, and the efficacy of the vaccination.

Continued engagement could include video assessments from the website to educate and talk with individuals. They could also be engaged in conversations and discussions about HPV that clarify the benefits and deficits of getting vaccinated.

Preparation

Dentists and physicians should encourage patients to schedule appointments for their child's HPV vaccination. Dental professionals should inform youth, and their parents or guardians about the two HPV vaccines available for prevention of HPV oropharyngeal cancers and other associated related cancers. Distribution of educational material to the targeted group and information about vaccine locations will benefit in two ways: increase patient's knowledge and improve provider-patient relationship. Preparation could include making the vaccine accessible to individuals.

Action

The Action phase of TTM may include an individual actually contacting or scheduling an appointment to obtain the vaccine. Parents, in collaboration with health professionals, provide direction for their children to receive the first dose of HPV vaccination for females between 11 to 26 years and males between 11 to 21 years. The impact of this intervention could be evaluated by 1). keeping appointments for vaccination; 2). number of appointments kept to obtain full course of vaccine; 3). adoption or reinforcement of safer sexual behavior.

Maintenance

During the maintenance phase of the TTM, parents would follow recommendations for routine HPV vaccination for their child and follow-up with screening for oral cancer every three years. At the same time, parents and individuals should continue receiving information about safer sex guidelines from pediatricians and other healthcare professionals including dentists. At this stage is important that health care professionals continue providing support and information on the need of getting all three of the shots within a six month period. The impact of this intervention should be reflected on the local Health Department immunization statistic report.

3.6. COMMUNICATION THEORY

3.6.1. Implementation of the Communication Theory

Communication Theory focuses on the production and exchange of information as a determinant of health. Communication theory uses media and communications to provide information, influence behavior change, and influence what individuals are concerned about. The most common forms of communication in public health are interpersonal and mass communication. The processes involved in communication include encoding, transmission, reception (decoding) and synthesis of information and meaning. A number of factors can affect the communication process including: (1) context of the communication; (2) relationship between sender and receiver; (3) meaning attached to the channel (i.e., radio, TV, interpersonal communication); and (4) process of encoding and decoding. Communication theory is an important tool for addressing health literacy, cultural competency, and limited English proficiency in populations. New communication strategies include internet-based health information, online support groups, telephone-delivered interventions, and interactive health games (Glanz, Rimer & Lewis, 2002).

Based on strong evidence of effectiveness for producing intended behavior changes, the U.S. Community for Preventive Services Task Force (UPSTF) appointed by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality recommends that health communication campaigns use multiple channels, one of which must be mass media, combined with the distribution of free or reduced-price health-related products (NHS, 2012).

USPSTF was created in 1984 as an independent group of national experts in prevention and evidence-based medicine. Its goal is to improve the health of all individuals by making recommendations about clinical preventive services based on evidence. Those recommendations include topics like screenings, counseling services, or preventive medications.

The HPV Connection Project will use the World Wide Web as a communication channel to distribute information on HPV prevention. The project will have a socially enabled site <HPVconnectionproject.com> designed to maximize the distribution of information and increase awareness about HPV and health related outcomes. The web site content will be designed to target several segments of the population including teenagers, parents, young adults, educators and health professionals. Although the last category will focus mainly on DMDs, it would be as well a source for other professionals like pediatricians and family physicians.

Specific health web content will include videos, educational articles, research papers, and educational material for health professionals. Content will be distributed through email and social media sites like Facebook, Twitter, Google+, Pinterest, Y!mail, LinkedIn, Wordpress and/ or other social media like YouTube. They are the most used channels of communication among young people and have the potential to reach vast populations with targeted messages in a short time with minimal resources (Casillas et al., 2011). This approach would be especially effective to reach teenagers, who are the most comfortable with consuming and spreading information through web social media. The graphic 6 and tables 3 and 4 below provide summary information on the use of social media by age group.

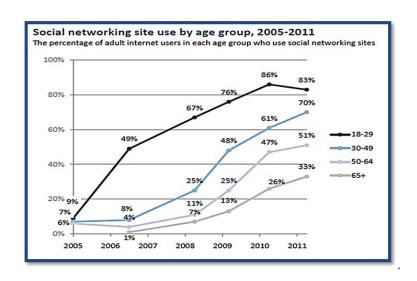


Figure 6. Social networking site used by age group, 2005-2001.

Source: Pew Research Center's internet and American Life Project Survey: February 2005, August 2006, May 2008, April 2009, may 2010 and May 2011

Table 3. Top 10 Social Media Websites. Week ending February 16, 2013.

Websites	Total Visits	Visits Share	Rank 02/09	Rank 02/02	Rank 01/26
Facebook	1,948,311,414	60.66%	1	1	1
YouTube	732,012,688	22.79%	2	2	2
Twitter	58,858,869	1.83%	3	3	3
Pinterest	36,756,784	1.14%	4	4	4
Yahoo! Answers	31,057,900	0.97%	5	5	5
LinkedIn	26,115,913	0.81%	6	6	6
Google+	25,282,669	0.79%	7	7	7
Tagged	17,900,658	0.56%	8	8	8
Yelp	10,069,126	0.31%	10	10	11
Tumblr	9,966,826	0.31%	9	9	10

Source: Experian Hitwise US. Retrieved from: http://www.experian.com/hitwise/online-trends-social-media.html

Table 4. Who use social networking site. Spring tracking survey

All internet users	65%	
Gender		
Men	60	
Women	69*	
Age		
18-29	83***	
30-49	70**	
50-64	51*	
65+	33	
Race/Ethnicity		
White, non-Hispanic	63	
Black, non-Hispanic	69	
Hispanic (English- and Spanish-speaking)	66	
Household Income		
Less than \$30,000	68	
\$30,000-\$49,999	70	
\$50,000-\$74,999	63	
\$75,000+	68	
Education level		
Less than high school	68	
High school grad	61	
Some college	65	
College+	67	
Geographic location		
Urban	67	
Suburban	65	
Rural	61	

April 26 - May 22 2011. Spring tracking survey. N=2.277 adults internet users age 18 and orders, including 755 cell phone interview. Interviews were conducted in English and Spanish. Source: Pew Research Center's internet and American Life Project Survey.

The HPV Connection Project will have a socially media enabled website <HPV

Connectionproject.com>. Boyd and Ellison defined social network sites as web-based services that allow individuals to construct a public or semi-public profile within a bounded system.

Within the system, users can select other users with whom they want to share a connection, and view their list of connections and those made by others within the system and share their information (Boyd & Ellison, 2007). The HPV Connection Project website is reachable with a

linked barcode (Figure 7) available in posters, brochures and printed material. That way, people with smart phones can scan the barcode and immediately reach the site.



Figure 7. 2D Code/ QR Code for HPV Connection Project

3.7. MESSAGES AND MATERIAL DEVELOPMENT

Efficacy messages

As a part of the identity of the HPV Connection Project, three key messages in the form of slogans are included in the initial campaign:

Message 1: "Spread the word, not the disease"

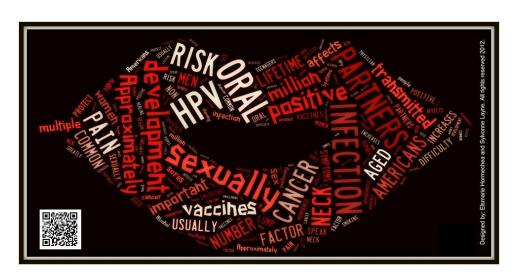
The word "spread" means "to cause to become widely seen or known; scatter or disseminate".
In the context of use the word spread in the message relates to dissemination, as of news and diffusion of information about HPV as opposed to the spread of HPV infection. This simple message helps reinforce the public mindset to get information, learn and share knowledge among friends, family and partners as a method to educate and learn about HPV disease.

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⁵ http://www.thefreedictionary.com/spread

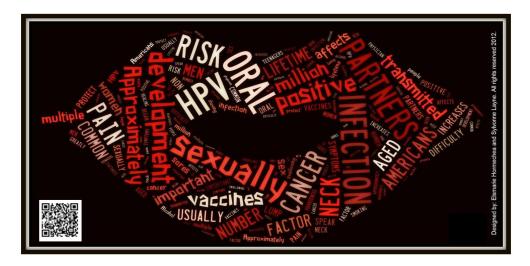
In order to help overcome language barriers, the slogan is initially translated into Spanish and Portuguese languages as a part the pilot project and could be translated into other languages. When accompanied with logos the message is particularly easy to understand.

The HPV Connection Project logo is represented by lips (Figures 8, 9 and 10). It generates an intuitive association between HPV, oral transmission and where the disease produces consequences (oral cavity). Inside the diagram some key words are placed such as sexually, risk, cancer, oral, infection, and vaccines among other. The goal of the logo is to spark people's interest and generate in them several questions associated with the perception of the disease, and promoting "curiosity" to discover what is beyond this word and the implications.



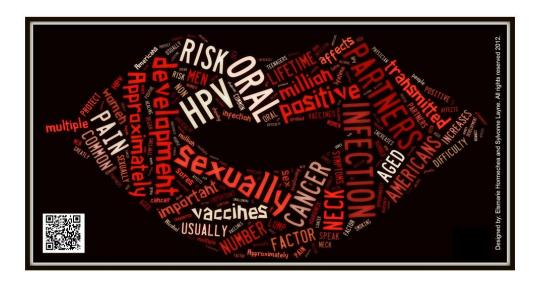
Spread the word, not the disease

Figure 8. English Version of the HPV Connection Project Logo with CR code English video clip



Corre la voz, no la enfermedad

Figure 9. Spanish Version of the HPV Connection Project Logo with CR code Spanish video clip



Disperse a palavra, não a doença

Figure 10. Portuguese version of the HPV Connection Project logo with CR code Portuguese video clip

Message 2: "Speak with your dentist and physician"

The first message attempts to motivate individuals to seek information and change attitude.

The second message tries to encourage individuals to talk with health professionals (dentists and/or physicians). They are the individuals from whom to obtain accurate and reliable information about HPV, mode of transmission, diseases linked to HPV, methods of prevention, and/or early treatment.

Message 3: "Get the vaccine"

Finally, the closing message "get the vaccine" is aimed at promoting the most effective strategy to prevent transmitting HPV among the target group. By doing so, it has the potential to play a role in the reduction of incidence of HPV, related oropharyngeal cancer and other associated cancers. The perception of individuals about HPV threat depends upon beliefs regarding their perceived susceptibility to HPV and belief that the disease has potentially serious consequences versus the benefits of getting the vaccine.

The three messages included in the first 2012 campaign are intended to form a sequence (Figure 11). Educational materials which include the three messages are available for distribution and pretexting.



Figure 11. Sequence message process. Attitude /belief change/ skill changes

2013 Campaign:

Efficacy messages: "3 for me"

After one year of the recommendation of HPV vaccine Gardasil®™, and in girls continues to increase but for both genders the progress is slow. The substantial burden of HPV associated disease can be reduced by the use of two available safe and effective prophylactic HPV vaccines. For instance, according to the Centers for Disease Control and Prevention, only 1.4 percent of boys in the U.S. were vaccinated during 2010 (CDC, 2012).

The "3 for me" campaign aims to convey the message that three shots of HPV vaccine are required and to assists youth to think about the risks of being unprotected from HPV transmission. This campaign also seeks to increase knowledge and information among teens and encourage self- decision making. This message is also aimed at engaging parents about the benefits of vaccination with the goal of reducing barriers such as the concern for the cost of the vaccination and disease treatment.

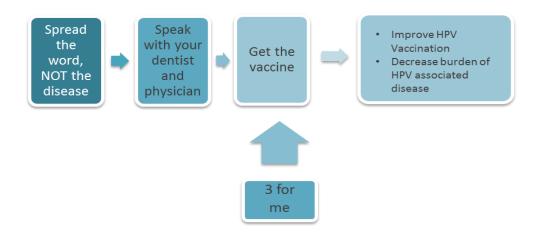


Figure 12. Attitude /belief change/ skill changes. Sequence 2013 messages campaign

4.0 DEVELOPMENT OF EDUCATIONAL TOOLS

4.1 THE HPV CONNECTION PROJECT PHASE 1

Description of Planned Website

The HPV Connection Project mission is to provide the public with accurate and up-to-date information and increase awareness about oral cancer and HPV. The target audiences are youth aged 13-26, parents, and dental health professionals.

The project acquired the web domain < hpvconnection.org >. An early prototype version of the site is currently in wordpress.com (Figure 13 below) under the URL:

http://hpvconnectionproject.wordpress.com/. A YouTube Channel will be incorporated on the main project website to maintain and distribute training material, webinars and promotional video clips and outreach youth communities around the world. The website and web pages are multilingual and initially the site will be in English, Spanish and Portuguese.



Figure 13. Provisional HPV Connection Website

URL: http://hpvconnectionproject.wordpress.com/

The HPV Connection Project website will contain free information on HPV and oral cancer topics in a variety of formats as well as topics of specific interest to target audiences. The website will provide information about HPV issues that include HPV basic knowledge of the disease, modes of transmission, risk behaviors, related HPV diseases and prevention methods available.

Use of social media in the HPV Connection Project domain initially includes: Twitter, an online social networking service and micro blogging service that enable its users to send and read text-based messages of up to 140 characters, known as "tweets". Under the username **@hpvconnection** unregistered users can read tweets, while registered users or followers to @hpvconnection can re- tweet through the website interface, short messages services (SMS),

or a range of apps for mobile devices. Figures 14 and 15 below show the HPV Connection Project webpage on Facebook and Twitter.



Figure 14. HPVconnection project Facebook webpage



Figure 15. @hpvconnectionproject twitter web page.

The production version of the site will include elements specialized on dissemination and sharing of information including:

- RSS Feeds to provide syndicated content to partner sites, organizations and information for health professionals;
- LinkedIn account to support professional networking and discussions groups. LinkedIn is the largest online professional network which makes it a natural tool for outreach proposes;
- Newsletters and E-Alerts;
- Feedback survey to visitors to evaluate and make suggestions; and
- Discussion forums.

4.2. MULTICULTURAL PERSPECTIVE AND PREVENTION

The HPV Connection Project is based on multi-modal communication and training campaigns that are designed to be culturally and linguistically in tune with the target audiences.

Responding to the demographic changes, the initial campaign "spread the word, NOT the disease 2012" was designed in English, Spanish and Portuguese languages. The messages are intended to help reaching first and second generation of Latino/ Hispanic population who are Spanish and Portuguese speakers in the pilot location in Pittsburgh PA. Therefore, the HPV Connection Project has the potential to help increase access to services to the whole population and to help reduce health disparities.

The website contains video clips and bilingual videos on HPV screening, prevention and treatment. The first steps were a series of video clips targeted to the general public with photos and broadcasts in English, Spanish and Portuguese. These video clips explain HPV and provide information on transmission, etiology, consequences, screening, early diagnosis, treatment, and prevention methods.

An initial poster and post-cards with information on HPV prevention were designed. They are intended to be shared through social media and reach out to heterosexual and LGBT couples. They have the same trilingual format used in other messages. Figure 16, 17, 18 and 19 are examples of a poster and e-cards to be distributed on social media.

The poster, video clips and postcards were designed in collaboration with Sylvonne Layne as a part of the final project for IDM 2038 Prevention, Treatment, and Control of Global Infectious Diseases.

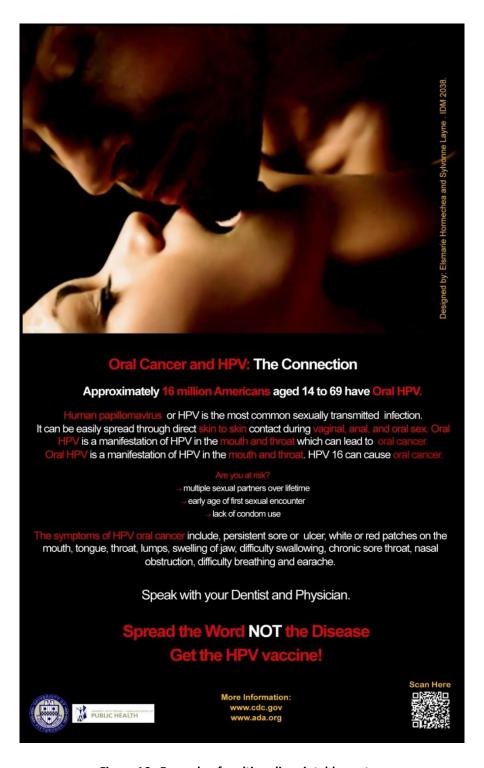
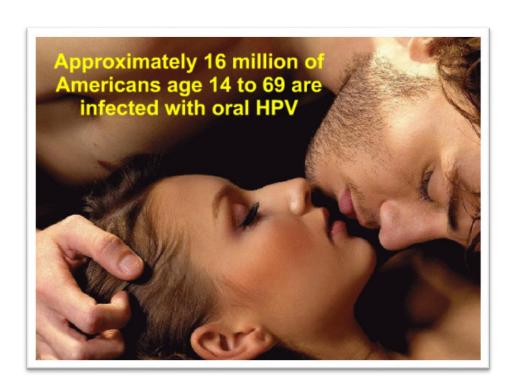


Figure 16. Example of multimedia printable poster.



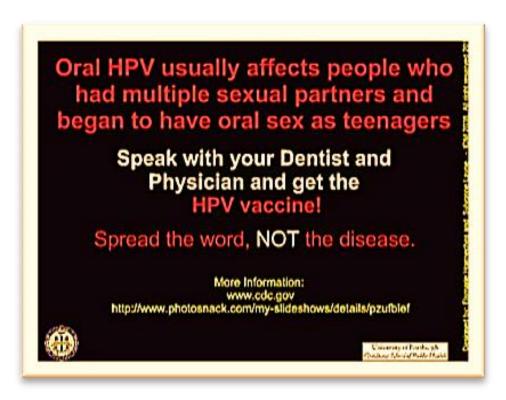


Figure 17. Example of e-cards English language





Figure 18. Example of e -cards Portuguese language

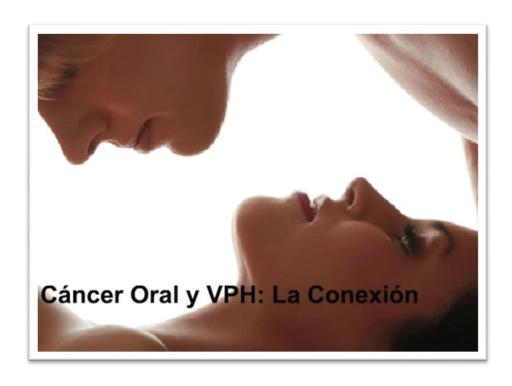




Figure 19. Example of e-card Spanish language

Initial videos targeted to teens are titled "Teen: What do you know about HPV?" The video is complemented with a printable brochure that explains in simple and clear language what HPV is, the relationship between HPV and oral health, symptoms, prevention and the need and benefits of vaccination. Figures 20 and 21 below show the videos posted on the HPV Connection Project website and posted on the YouTube channel. These educational products could be used in diverse venues, e. g. dental professionals during a dental checkup. The video in Figure 20 was designed in collaboration with Nick Celender as a part of the final project for PUBHLT 2016 Public Health Biology.



Figure 20. Example of video targeting Youth.

URL: http://hpvconnectionproject.wordpress.com/2013/03/01/hpv-what-teens-what-do-you-know-about-hpv/

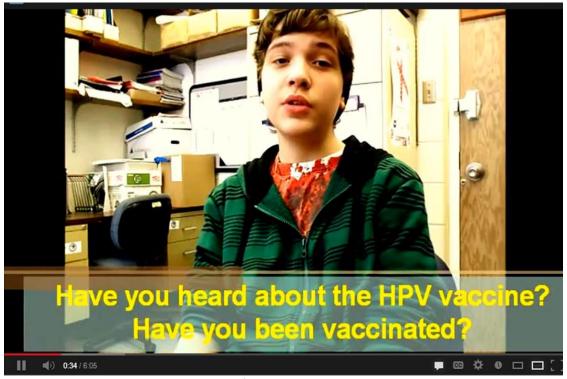


Figure 21. Example of video targeting Teen Boys

The HPV Connection Project will provide webinar series intended for dentists, dental hygienist and assistants and featuring special topics on dental health issues related to HPV. Each webinar would feature one or more speakers who are experts in the field. Webinars would be conducted by the HPV Connection Project partnerships and funded by future grants.

4.3 PRIVACY AND LEGAL ISSUES ON THE WEBSITE

The website will have a prominent disclaimer that information being provided is (1) of a general nature; (2) does not represent medical or dental advice; and (3) should not be used as a substitute for consultation with qualified health professionals.

All original content that is posted and contained on the HPV Connection Project website, including text, graphics, logos, button icons, images, videos and audio clips will be copyrighted

and considered property of the HPV Connection Project and its partnerships, and may not be copied, reproduced, transmitted, displayed, performed, distributed, sublicensed, altered, stored for subsequent use or otherwise used in whole or in part in any manner without the HPV Connection Project prior written consent. It may be used by the website visitor for personal and noncommercial uses that do not harm the reputation of the project, provided that the user does not remove any trademarks, copyright, or any other notice contained in such content. This policy and reservation of rights will be prominently displayed on the website as well.

4.4. THE HPV CONNECTION PROJECT PHASE 2

4.4.1 Partnership and Community Building Resources

Partnership with existing educational project in health promotion and training

During Phase 2, the HPV Connection Project will seek to establish partnerships with

organizations that have compatible missions. Some of these organizations might include the

AIDS Education and Training Center (PA/MA AETC) Program of the Ryan White HIV/AIDS

Program. It currently supports a network of 11 regional centers and more than 130 local

performance sites. These sites conduct targeted, multi-disciplinary education and training

programs for healthcare providers treating persons with HIV/AIDS and STDs related issues; the

Pennsylvania Mid/Atlantic AIDS Education and Training Center (PA/MA AETC)⁶ is part of AETC

⁶ http://www.pamaaetc.org/

program and serves Delaware, District of Columbia, Maryland, Ohio, Pennsylvania, Virginia, and West Virginia.

Another potential partner is the Telehealth AETC Appalachia Project (TAAP). Its aim is to increase HIV clinical capacity to rural Appalachian community health centers through distance based clinical consultation, education and technical assistance The headquarters of PA/MA AETC and TAAP are located at the University of Pittsburgh, Graduate School of Public Health in Pittsburgh, Pennsylvania, with offices throughout the region, and the Department of Infectious Diseases and Microbiology at University of Pittsburgh Graduate School of Public Health. These organizations have infrastructure in place, access to most professionals with medical training in STDs prevention and resources to reach out to related institutions and many communities.

The PA/MA AETC and TAAP consortiums partners have been providing clinically focused education, training, consultation, and technical assistance to health professionals, agencies and programs in the HIV/AIDS service delivery system. The introduction of the HPV Connection Project will add design and delivery of web based educational training in HPV basics, HPV and HIV, and HPV associated diseases. It would also add training on prevention methods for physicians, dentists, dental assistants, nurses, nurse practitioners, physician assistants, pharmacists and other members of health care professional teams. Formal written agreements will need to be made with the Project's various collaborators covering details on rights, duties and obligations. Provisions will need to be made to limit the respective liabilities of the parties, and protocols will need to be established to ensure that the various regulatory and reporting requirements of the parties are met. As most collaborators are non-profit institutions, care must be taken to ensure that participation does not jeopardize tax status or funding.

Secondary schools and school districts

Phase 2 includes a pilot project to reach out to one secondary school in one school district in Allegheny County to introduce a health educational program focused on disease prevention and health promotion targeting K6-12 students. In preparation for this phase, the project would study the selected school, SES of students and their families, involve stakeholders and obtain parental consent to administer surveys, make presentation, offer training, and evaluate the study.

Health educators and school nurses would deliver information about sexual behavior and prevention of HPV and other STDs in middle and high school courses. The curriculum that include information about HPV, Prevention of Sexually Transmitted Infections (STI's), HPV and associated cancers, HPV and oral cancer, HPV Prevention and Vaccine among others. The curriculum should be designed by health educators and with the previous agreement from board school and sciences professors. It would be designed to promote interaction between students and trainers, trainers and parents, and students and parents. Students would be able to use the HPV Connection Project website for further training and sharing with peers, designing and creating educational materials, applying their knowledge to themselves and share experiences with their social network. Students will become "peer promoters", influencing peers' behavior as well as providing project information to other students and students' parents. As a mechanism to reward students' contributions, the website would provide a space where they can share their related projects and experiences. That way, the HPV

Connection Project will start to become a social media platform to spread the word amongst young people.

Collaboration with Dental Health Schools and Organizations

After the project establishes itself as a trustworthy presence in the communities where it intervenes, options might develop to partner with dental and public health schools and organizations that might be interested in training and dissemination information on HPV and Oral Cancer. The prospective partnership: PA/MA AETC would include the production of webinar series about HPV and oral implications, inclusion on HPV vaccination recommendations lead by health professional experts in infectious diseases and clinical management.

4.5. DISSEMINATION

In Phase 1, the project will use a web-based site as a principal way to spread information and messages to increase awareness through information delivered across multiple channels one of which is social media. Educational material posted on the website will be distributed through social media such as Facebook, Twitter, Google+, Pinterest, LinkedIn and YouTube among others to share and distribute between targeted populations. Following the concepts from social marketing, the HPV Connection Project Phase 1 health communication campaigns can be combined with other activities like the distribution of small media products, including brochures and posters that promote the adoption and/ or maintenance of healthy behaviors as protection against HPV related diseases.

Seven states (WA, LA, NC, MI, IA, TX, IN) have education requirements on HPV and sexual behavior, and two other jurisdictions (DC, VA) have HPV vaccination requirements in middle schools (CDC, 2012). Thus, during Phase 2, the HPV Connection Project would begin a process to help advance policies in support of adolescent HPV immunization with the utilization of schools as alternative immunization sites and the creation of education and school requirements related to HPV.

4.6. MEASUREMENT AND EVALUATION

The HPV Connection Project is based on a health communications strategy that leverages factors that are more likely to influence individual behavior and decision making on aspects related to health. In order to measure the success of the project and receive feedback to enable fine tuning or changes there will be measures associated with each phase.

PHASE 1

This phase involves mostly development of an on-line presence an outreach through social media. The best methods to measure the impact and perceived usefulness and quality of the project are on-line satisfaction surveys, direct feedback received through the site comments and web analytics. The satisfaction surveys will be designed and the project will utilize the expertise of the PA/MA AETC. The survey will include questions in Likert scale associated with the level of satisfaction that users have with the HPV Connection Project site. Surveys and the site itself will provide mechanism for people to submit suggestions and feedback.

There are affordable web analytics services available with the most known perhaps being Google Analytics. Initial services acquired would be basic and help to track how users visit and share the site. This information will enable its continuous improvement. As the site's presence grows in the social media, and people start to add comments and share project documents and videos in those sites, the available options in web analytics nowadays include sentiment analysis. It is a rapidly growing field that leverages the comments that people enter in social media sites to gauge their opinion on target topics. Thus, it will permit assessment of the perception that visitors and users have of the HPV Connection Project.

Finally, the ultimate evaluation of a web site's success is its ranking on web searches.

Thus, the goal would be for the site to appear in the first page of results in the top search engines (Google and Bing) within the first year of its release when the search string includes the words HPV or Human Papilloma Virus.

PHASE 2

In this phase, the HPV Connection Project will add mechanisms to assess its ability to deliver services as well as the mutual benefits brought by the proposed partnerships. This will include assessments of participation rate of target populations, the amount of training delivered, and post intervention surveys. Participants in the assessment will be professionals who received training and delivered information to target audiences including dentists, dental health professionals, school nurses and health educators at the pilot school.

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⁷ Sentiment Analysis and Opinion Bing Liu, 2012 http://www.morganclaypool.com/doi/abs/10.2200/S00416ED1V01Y201204HLT016

Under a common agreement the HPV Connection Project would use the PA/MA AETC surveys and standardized forms to receive feedback as well as satisfaction surveys from participants after trainings or presentations. In addition, post-intervention surveys will be designed and used to assess modifications to dental clinical practices after receiving training and information on HPV. Although the survey's design might require professional assistance, it can be assumed that it would include questions to identify behavior changes, recommendations and information received by providers on targeted population, and gauge acceptability of HPV vaccination and follow-through with the treatment.

4.7 RESULTS AND OUTCOMES

The main outcome of Phase 1 will be the design and implementation of a social media enabled website to disseminate information about HPV prevention, access to information on vaccination and treatment for youth, parents, schools, dental and other dental health practitioners.

During Phase 2 a pilot campaign will be performed at a high school involving training of nurses and health instructors as well as engagement with parents and students. Phase 2 will also start training of dentists as health professionals on HPV with the goal of motivating them to modify their practices and serve as multipliers of information.

At this stage the main outcomes will be: first, an increase in the use of the HPV vaccine among girls and boys in the targeted population as recommended by the Center for Disease Control and Prevention CDC, ages 11 to 26; second integration of HPV information into the

health programs within the pilot school; third, early identification of existing HPV infection cases during dental examination, and linking of those cases to dental care and medical treatment.

The HPV Connection Project seeks to reach a position where it can support policy changes in school districts to require HPV vaccination for students aged 11 to 19 within five years of the starting of it operation.

5.0. CONCLUSION

Despite the recommendations of health agencies for an increase in HPV vaccination and numerous promotional campaigns funded by state and the federal governments, low HPV vaccination rates suggest that new approaches are required. With that goal in mind, the HPV Connection Project seeks to increase awareness about HPV and oral cancer in high risk segments of the population as well as risk behaviors associated with them. It will strongly support the current recommendation by the CDC and the National Cancer Institute for the need for young teenagers to receive the HPV vaccine. Thus, its ultimate goal through the two planned phases is to increase the prevalence of HPV vaccinated teenagers.

Services

The HPV Connection Project will provide free educational services to help increase access to and utilization of about HPV and oral cancer among teenagers and their parents. To that end, the project has been designed to increase awareness about HPV and encourage teenagers to get the vaccine in order to prevent HPV infection and related diseases. This is in alignment with the Centers for Disease Control and Prevention, which recommends three vaccinations for preteens and teenagers (CDC, 2011).

The HPV Connection Project is designed to promote and educate on safer sexual behaviors, risks of acquiring HPV and prevention of HPV and oral cancer. The main tool is a social media enabled web site that provides free access to educational material and information for teenagers and parents. It also provides material for dental practitioners and

other health professionals to help them modify clinical practice and serve as multipliers for the dissemination of information. The web presence will be accompanied with a training campaign.

The potential impact of the HPV Connection Project would be a reduction in morbidity and mortality related to HPV and a significant reduction in health disparity. This is in alignment with the approach and goals included in the Healthy People 2020 objectives.

Training

The project will provide free training to help increase the ability of dental and health care practitioners to perform early detection of oral cancer related HPV detection and address associated risk factors.

The HPV Connection Project seeks to help parents make informed decisions regarding the authorization for their children to get vaccinated. To that end, there will be a campaign in high schools starting with a pilot program. Information on HPV will be incorporated into health classes, community education programs and educational programs involving parents and students. School nurses and selected health professionals will receive training through the HPV Connection Project and its partners.

Research

There are open questions regarding the ethical and legal issues. Mandatory vaccination is controversial. It poses political, legal and ethical questions regarding patient autonomy, parental authority, and the role of the state and federal governments in individual public health matters. Nationwide, there is significant controversy about the limits of mandatory public

health measures and conflicts with religious and political beliefs. These issues are particularly sensitive when dealing with minors.

Dealing with minors requires prudence as any involvement with them demands the approval of their parents or guardians. Parents are often very protective of their children and fear the interference of others in their parenting. This is especially so in dealing with issues regarding sexual behavior and medical care. It is one of the reasons that the HPV Connection Project and partnerships will train health professionals in all aspect of HPV issues including legal issues and cultural beliefs.

The use of social media for health purposes poses challenges of misuse by consumers and privacy concerns. Once again, these concerns are increased by the presence of minors.

The Project recognizes that matters concerning the sexual behavior of teens and young adults are sensitive areas, and will monitor its web site and procedures to ensure that inappropriate content is not posted or shared.

Policy

The goals of the HPV Connection Project include helping raise public awareness of the risk of HPV and Oral Cancer and the connection between them. To that end it will support the development of policies to make HPV vaccination mandatory. School nurses and local health providers trained on HPV along with well-informed parents and teenagers could help recommend and promote policy changes for children in school districts. This could results in changes in laws and policies leading to mandatory vaccination as a part of requirement to middle school and high school. This will be in alignment with the ultimate goal of increasing the

utilization of HPV vaccine as the most effective mechanism to reduce HPV infection and its adverse effects.

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