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An Evidence-Based Toolkit for Human Papillomavirus Vaccine Education of Female Adolescents in the School Setting

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Running head: HPV Toolkit

An Evidence-Based Toolkit for Human Papillomavirus Vaccine Education of
Female Adolescents in the School Setting

Final Technical Report

A paper submitted in partial fulfillment of the requirements for the degree of
Doctor in Nursing Practice at the University of Kentucky

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Table of Contents

I.	Abstract.....	4
II.	Executive Summary.....	5
III.	Introduction to the Project.....	7
IV.	Description of the Problem.....	7
V.	Review of Literature.....	8
	Cervical Cancer.....	8
	Human Papillomavirus.....	9
	HPV Vaccine.....	12
	HPV Vaccine Uptake.....	13
	Adolescents—The Vulnerable Population.....	14
	School Nursing.....	16
	HPV Programming in Schools.....	17
V.	Settings and Stakeholders.....	20
VI.	Creative Approach.....	22
	Project Mission, Goals and Objectives.....	22
	A Conceptual Model for the Project.....	23
	Methods, Data Collection and Use of Consultants.....	31
	Evaluation of Issues R/T Changing Systems/Attitudes/Values/Beliefs....	35
	Analysis of Impact on Other Populations within the HCDS.....	37
	Impact of Technology on the Problem Being Addresses.....	39
	Analysis of the Fiscal and Systems Impact of the Project.....	43
VII.	Findings, Outcomes and Evaluation.....	45

	Focus Group Findings and Analysis.....	45
	Discussion.....	48
	Outcomes.....	50
	Evaluation.....	51
	Reflections on the Process.....	52
VIII.	Conclusions.....	53
IX.	References.....	55
X.	Acknowledgements.....	68
XI.	Tables.....	69

Abstract

A new vaccine to prevent human papillomavirus infection was approved in 2006 in the United States (U.S.). Uptake of the vaccine has been less than optimal (CDC, 2010c). New venues for promoting vaccine acceptance are needed (Middleman & Tung, 2010). The goal of this capstone clinical project is to create an evidence based toolkit for use by school nurses in educating female adolescents, parents, communities and other healthcare providers about the HPV vaccine.

School nurses have daily access to young people in the target group for HPV immunization. A vital component of vaccine acceptance is education of those who are involved in making decisions for vaccine recipients (Cates et al, 2010). School nurses are in a prime position to educate due to their exposure to students and others. Students, teachers and parents value their opinions (NASN, 2010b).

A Clinical Practice Model for HPV Vaccine Programming guided the development of a toolkit for school nurses to use in educating individuals and groups about the HPV vaccine. A survey was posted on a school nurse list-serve to gather recommendations for the toolkit contents. Influenced by the Health Belief Model, the toolkit was assembled to contain information in various formats to answer questions which adolescents, parents, communities and health care providers have about HPV and the vaccine. After the toolkit prototype was complete, a focus group of school nurses formatively evaluated it by examining and discussing its contents.

Executive Summary

Human Papillomavirus (HPV)-related disease, including cancer of the cervix, affects many women in the United States and worldwide. Leading professional health organizations approved the 2006 recommendation of the Advisory Committee on Immunization Practice (ACIP) to administer the HPV vaccine to females aged 9 to 26 (CDC, 2010; ACOG, 2009; AWHONN, 2009; AAP, 2010). The first HPV vaccine became available and was approved by the U.S. Food and Drug Administration (FDA) also in 2006. The ACIP recommends the target age for vaccinating females as 11-12 years.

HPV infection is responsible for nearly 100% of cervical cancer cases (CDC, 2010a). In the U.S. in 2009, more than 11,000 women were newly diagnosed with cervical cancer and more than 4000 women succumbed to the disease (NCI, 2010). Worldwide, cervical cancer is the 2nd most common cancer in women. Around the globe, nearly 300,000 women die each year from cancer of the cervix with 80% of the deaths occurring in developing countries (WHO, 2010).

Introduction of a quadrivalent vaccine in 2006 and a bivalent vaccine in 2009 were welcomed joyfully by the public health community as a long-awaited piece of the solution for eradicating HPV-related disease. Unfortunately, issues such as lack of knowledge, opposing beliefs/values and the high cost of required injections have influenced its less than enthusiastic reception by the potential recipients and their communities of interest.

Adolescent vaccine uptake has been significantly improved in the past by bringing vaccine education and administration to the school setting (Dilraj et al, 2003; Brabin et al., 2008; Watson et al., 2009; Ogilvie et al, 2010). Scarcity of compliance with preventative visits in the adolescent years and convenience for parents of school-based immunization has contributed to this finding (Humiston & Rosenthal, 2005).

Of concern is the occurrence of racial discrepancies in completion of the 3 dose series required for full vaccine coverage. Black adolescents are less likely to finish the series than are white adolescents (Widdice et al., 2010). Not completing the vaccine can be expected to lower vaccine efficacy which could exacerbate cervical cancer disparities in the U.S. This problem could be duplicated in any racial or geographic group who fails to complete the 3 dose regime.

Improvements in vaccine initiation and completion are dependent upon educating potential vaccine recipients and those who influence them about the disease and the vaccine. School nurses are an excellent resource for this education. The goal of this project was to help school nurses with HPV education by developing a toolkit for them to use. By surveying school nurses prior to toolkit development and evaluating the toolkit formatively through a school nurse focus group, user input was solicited. The resulting user-friendly product can be utilized to educate various groups, promote HPV awareness and vaccine acceptance.

The evidence is plentiful that the HPV vaccine is both safe and effective (Markowitz et al, 2007). If healthcare providers support and recommend the vaccine to their patients, it will help to put aside concerns (Brewer & Fazekas, 2007; Dempsey et al., 2009; Reiter et al., 2009; Gamble et al., 2010). The influence school nurses can have as health educators and vaccine champions has great potential to positively impact vaccine uptake.

Introduction to the Project

The most common sexually transmitted infection is caused by the human papillomavirus. There are many types of HPV, but the types most frequently implicated in genital warts and cervical cancer are types 6, 11, 16 and 18. Types 16 and 18 are most frequently the cause of cervical cancer. Genital warts caused by types 6 and 11 plague men and women alike (ACS, 2010; CDC, 2010a).

Two vaccines have been approved to prevent HPV infection. Uptake of these vaccines has been less than optimal (FUTURES II, 2007; Paavonen et al., 2007). Lack of knowledge, along with negative beliefs and values about the vaccine may discourage vaccine initiation by the target population of females aged 11-12 and the people who make decisions for them (Rosenthal et al, 2008).

By educating adolescent females, parents, communities and healthcare providers about HPV disease and the vaccine that can prevent it, there is the potential to significantly decrease or eradicate HPV-related disease in the next generation. School nurses can impact this amazing possibility.

Description of the Problem

Acceptance of the HPV vaccine is needed in order to positively impact its uptake and future cervical cancer reduction. Because the ideal time for administration of HPV vaccine is prior to sexual involvement (Pederson et al., 2007), vaccine programs target females at ages where parental consent is required. For widespread vaccine uptake to become a reality, parental acceptance is a crucial issue (Kahn & Hillard, 2006). While there will always be groups who voice opposition to the HPV vaccine, studies support acceptance of the vaccine by many health care providers, parents and adolescents (Brabin et al., 2006; Constantine & Jerman, 2007;

Dempsey et al., 2006; Kahn et al., 2005; Lazcano-Ponce et al., 2001; Mays et al., 2004; Noakes et al., 2006; Olshen et al., 2005; Sturm et al., 2005; Zimet et al., 2005a; Zimet, 2005; Zimet et al., 2000a; Zimet et al., 2005b). Of course, accepting the vaccine and actually making sure adolescent females get 3 doses of the vaccine are two separate issues.

One way to increase vaccine uptake is to provide immunization clinics at schools. In the past, improved uptake of vaccines has been achieved through school vaccine programs, but even better uptake occurred when recommended vaccines were mandated for school attendance. While numerous states have HPV vaccine school mandates under consideration, only a few have actually succeeded at mandate passage (Dempsey & Mendez, 2010). As of December, 2010 Virginia and the District of Columbia are the only States where HPV vaccine is required to attend school. There is always the option for parents to refuse having their children receive the vaccine (NCSL, 2010).

Since HPV vaccine is recommended for girls aged 9-26 and targeted for 11-12 year old girls, the challenge of dealing with an adolescent population exists. Adolescence is a time of transition between childhood and adulthood. While striving for increased independence, adolescents especially in the earlier years often seek advice from parents regarding healthcare decisions such as vaccination (Rice & Dolgin, 2008). Since most adolescents are relatively healthy, they are less likely to see healthcare providers for episodic or preventive visits. A large proportion of most adolescents' time is spent in school and families are increasingly busy. Therefore, school-based vaccination programs in middle- and high-schools are a viable alternative (Humiston et al., 2005; Zimet, 2009; Dempsey & Freed, 2010).

Review of Literature

Cervical Cancer

An alarming number of women suffer the effects of cancer of the cervix and external female genital organs. For 2010, it is estimated that 12,200 new cases of cervical cancer will be diagnosed in the United States (U.S.) and 4,210 women will die from the disease (National Cancer Institute, 2010). Each year more than 17,300 HPV cancers occur in women and almost 7,600 occur in men. The cervix is the most frequent site of HPV-associated cancer in females while the oral cavity and oropharynx are most frequently affected in males (NCI, 2010).

Worldwide, cervical cancer is responsible for 510,000 new diagnoses and 288,000 deaths annually and ranks as the 2nd most commonly diagnosed cancer in women. More than 80% of deaths due to cervical cancer occur in developing parts of the world (World Health Organization, 2010). African American women are disproportionately affected in the U.S. with cervical cancer occurring >2 times more than in white women. This cancer is also more prevalent in Hispanic women than in non-Hispanic white women (NCI, 2010). Disparities in mortality also exist in relation to socioeconomic and geography.

Women living in rural areas, especially in Appalachia, the central valley of California, the rural South and the Texas/Mexico border have consistently had higher rates of cervical cancer mortality than women in other areas of the U.S. during the last several decades. It has been postulated that this disparity may be due in large part to limited access to health care and cervical cancer screening (Yabroff et al., 2005).

Human Papillomavirus

Human papillomavirus is responsible for nearly 100% of cancers of the cervix, 85% of anal cancers, 70% of vaginal cancers, 40% of vulvar and penile cancers, 25% of mouth cancers

and 35% of cancers affecting the throat (Center for Disease Control, 2010a). There are over 100 types of HPV that can infect humans. Four types of HPV (16, 18, 6 & 11) have been implicated in causing the vast majority of cervical cell changes and cancer of the cervix. Of those four types of HPV infection, two of the types (16 & 18) have been found to be responsible for more than 70 percent of cervical cancer (American Cancer Society, 2010). This means that the other 30% of cervical cancers are caused by HPV types other than 16 and 18.

Human papillomavirus affecting the anogenital region is the most common sexually transmitted infection in the United States. It is estimated that 6.2 million people in the U.S. alone are newly infected each year. The majority of infections produce no symptoms and appear to resolve in a short period of time, often within 6 months to 2 years (CDC, 2010).

Transmission is primarily by direct genital contact during sexual intercourse. Between half and three-fourths of all people who have sex will, sometime in their life, be infected with HPV. Over half of people currently infected with HPV are between 15 and 25 years of age (ACS, 2010).

An estimated 4 billion dollars per year is spent in the U.S. toward direct costs related to anogenital warts and cervical HPV-related disease. Of this amount, \$300 to \$400 million goes to treatment of invasive cervical cancer, \$200 million to management of genital warts and the rest goes to cervical cancer screening and follow-up of abnormal Pap tests and pre-invasive cervical cancer (Markowitz, 2007).

While women in their third and fourth decade of life are those most affected by cervical cancer, the evidence of HPV infection becomes evident at a much earlier time. Venereal warts and changes detected on Pap testing are two of the most common problems women affected by HPV infection face in their teens or twenties. As a result of abnormal Pap smear

reports, many young women experience more frequent gynecological exams, colposcopy, cryosurgery and other more invasive remedies for genital organ HPV infection (CDC, 2010a). In addition, they are exposed to the embarrassment and anxiety created by such a diagnosis. Treatment of cervical abnormalities can also leave a young woman with difficulties in carrying a pregnancy to term.

Some, but not all, of the Healthy People 2010 (HP2010) goals relating to adolescent preventative care, immunization and prevention of STD's have been met. HP2010 Objective 14-29 was to achieve 90% vaccination coverage among 13-15 year-olds for HepB, MMR, Td and varicella (HP, 2010). The overall estimates of those diseases in 13-17 year-olds on the National Immunization Survey done in 2009 were 89.9%, 89.1%, 76.2% and 87% respectively. HPV vaccine was only released in 2006, so was not specifically addressed in the HP2010 objectives. It could fall under "prevention of STD's", however, and the reported 26.7% coverage with the 3 dose regime in 2009 does not fare well toward meeting that HP2010 goal.

Healthy People 2020, Objective STD-9 (Developmental) is to reduce the proportion of females with HPV infection. A second objective relating to this topic, IID-11 is to increase routine vaccination coverage levels for adolescents including three doses of HPV vaccine for females by age 13 to 15 (HP, 2020). Other objectives relating to reducing the numbers of adolescents who have had sex and increasing the number who have had reproductive health education are important in achieving reduction in HPV infection as well. These HP2020 objectives give focus and direction to the challenges of HPV education and vaccination for the coming decade. The work is cut out for us.

The next section will discuss the vaccines available to assist in meeting these 2020 objectives. For the vaccines to reach their potential, however, adolescents and their parents need

education about their benefits, side effects and safety, preferably within the context of reproductive health education in the classroom and nurse-led health education in the school health office. Reducing numbers of adolescents having sex is an admirable objective, but HPV vaccine uptake in adolescence is the key to reducing HPV-related cancers (Lugo, 2009).

HPV Vaccine

On June 8, 2006, the Food and Drug Administration licensed the first vaccine for HPV, Gardasil, which protects against HPV types 6, 11, 16 and 18 (CDC, 2010a). A second vaccine, Cervarix, was licensed by the FDA in 2009 and protects against HPV types 16 and 18. Studies have shown the efficacy of both Gardasil and Cervarix against cervical disease to be nearly 100% and the safety of both vaccines to be extremely high (FUTURES II, 2007; Paavananen et al., 2007).

The vaccination process requires a series of three injections over a six-month period. The cost is approximately \$130 per dose. The Advisory Committee on Immunization Practices has recommended that a series of one of these vaccines be administered to females, 9 to 26 years of age (CDC, 2010a), with the target age for both being the 11-12 year old female.

The intention of targeting 11-12 year old girls is to, hopefully, administering the vaccine prior to initiation of sexual activity. While sexually active females may also benefit from receiving the vaccine, they would only get protection from HPV types not previously acquired. Safety of the vaccine has been tested on girls as young as age nine. Girls aged 13 to 26 who have not received the vaccine or completed the series are also recommended to be vaccinated. In 2010 the ACIP approved Gardasil has also been approved for use in male aged 9 to 26 to reduce their likelihood of acquiring genital warts. Use of the Gardasil vaccine in women older than 26 is being studied (CDC, 2010a). The cost of HPV vaccine is covered by many insurance companies. For those who do not have insurance or whose policies do not cover the vaccine, many are able

to receive the vaccine through the national Vaccines for Children (VFC) program.

The Vaccine Adverse Reporting System (VAERS) received 12,424 reports of adverse events following immunization from June 1, 2006 through December 31, 2008. The events reported were divided into serious and non-serious. Of adverse events reported, 6.2% were considered to be serious. No common pattern was found among the serious events suggesting causation by the vaccine. The most common event, syncope, lead to a recommendation that vaccine recipients be observed for 15 minutes after the injection (Slade, 2009). Data regarding adverse events continue to be collected and analyzed (CDC, 2010a).

Forty-one states have introduced legislation to require, fund or educate the public about the HPV vaccine since September, 2006. As of December, 2010, 19 states have enacted legislation regarding the vaccine, with only Virginia and the District of Columbia requiring the vaccine for school attendance while allowing an opt-out clause for parents who object.

HPV Vaccine Uptake

Many studies have been done regarding HPV vaccine acceptance. Study populations vary in their acceptance of the vaccines (Dempsey et al., 2010) and the number of parents accepting vaccination for 11-12 year old females has been especially low (Askelson et al., 2010; Rosenthal et al., 2008). Racial disparities in vaccine acceptance have been found to exist.

Latinos, the fastest growing ethnic group in the U.S., have twice the rate of cervical cancer as do non-hispanic white women and are, as a group, more supportive of HPV vaccine mandates (Yeganeh et al, 2010) and school-based immunization programs (Middleman & Tung, 2010). Mortality from cervical cancer in the U.S. is twice as high for African American women as for white women and HPV awareness is sometimes less in Blacks (Hughes et al., 2009).

Rural populations in parts of the U.S. have higher cervical cancer morbidity and mortality than do urban areas and may need different communication interventions (Cates et al., 2009). Lower socioeconomic status is associated with disparities in awareness, screening, diagnosis, and treatment and greater attention to HPV education in the schools would benefit people in this group (Cates et al., 2010). Unfortunately, there has been significantly less HPV education in middle schools than in high schools (Dempsey & Schaffer, 2010) in spite of the recommended age of vaccination being 11-12 years.

Recommendation of the HPV vaccine by trusted health care providers has been shown to be most useful for increasing vaccine utilization (Brewer & Fazekas, 2007; Dempsey et al., 2009; Reiter et al., 2009; Gamble et al., 2010). The HPV vaccine is often marketed as a cancer preventative (Habel et al., 2009), which has under certain conditions improved its appeal to women (Leader et al. 2009). Measures for improving HPV and other adolescent vaccine completion rates include use of patient reminder systems, utilization of every patient encounter for administration of recommended vaccines, and school-based vaccination programs with all recommended adolescent vaccines available (Jacobson & Szilagyi, 2005; Neubrand et al., 2009; Reiter et al., 2010).

Adolescents—The Vulnerable Population

Most adolescents are developing their ability to think abstractly, ponder the long-term consequences of their actions, recognize personal risk and evaluate information (Rice & Dolgin, 2008). They may not see the need to be vaccinated against a disease that probably won't affect their health until they are much older.

A study of pediatricians and family physicians revealed significant agreement among providers regarding barriers to immunizing adolescents. Barriers included rarely seeing

adolescents for preventive health visits, lack of knowledge about need for immunizations, parents and adolescents underestimating the risk of disease, poor compliance with multiple-dose vaccines, lack of immunization records and adolescents choosing to seek care from facilities other than physicians' offices (Oster et al., 2005).

The majority of adolescents who have sex will be infected with the HPV virus soon after sexual debut. Most HPV infections will clear the adolescent's body due to the effects of a strong immune system. Those infections which do not clear the body can go on to cause genital lesions or precancerous lesions of the cervix. Although cervical cancer is most often diagnosed during the 3rd and 4th decades of life, its precursor, HPV is often contracted in adolescence and the twenties (CDC, 2010a).

A national survey found that of those questioned, 57% of females aged 14-19 years were sexually active and that 40% of those females who had sex tested positive for HPV infection. In females aged 20-24 years, 97% were sexually active and 50% of those were HPV positive (CDC, 2010b).

According to a recent report on vaccination coverage among adolescents aged 13-17, HPV immunization with 1 or 2 doses of the vaccine increased from 37.2% to 44.3% between the 2008 to 2009 surveys. Those adolescents having 3 doses increased from 17.9% to 26.7% in the same time period. In Kentucky, 31% of those surveyed received 1 or more doses of HPV on the 2009 survey (CDC, 2010c). These statistics for vaccine uptake are less than optimal, since at least 90% uptake of recommended doses of vaccine are needed to approach herd immunity---the reduced probability of infection achieved when susceptible individuals are few enough to make transmission unlikely.

Since the majority of HPV infections clear spontaneously and worsen slowly if they do

progress, The American College of Obstetricians and Gynecologists recently endorsed the recommendation that females begin having Pap testing at age 21, regardless of when they become sexually active. The thought behind this recommendation was that since the healthy immune system of most adolescents will clear an HPV infection, it is safe and cost effective to delay the start of screening for cervical cancer until age 21. In addition, exposure of adolescents to multiple procedures to treat an infection that will most times clear on its own is thought to be unnecessary (ACOG, 2009).

School Nursing

Increasing immunization rates for adolescents, especially when vaccines are recommended but not mandated, is dependent on healthcare providers, including school nurses sharing knowledge about the safety, effectiveness and availability of vaccines (NASN, 2010a). School nurses have knowledge of vaccine-preventable diseases and the dangers they present. They are in an excellent setting to educate parents and staff about vaccines, their indications, contraindications and ability to help the body defend itself against vaccine-preventable diseases. Schools with nurses have increasing immunization rates. One reason may be that parents are less likely to ask for immunization exemption from nurses than from school employees without health training (Kinne & Bobo, 2010).

Having a healthcare provider who can be trusted and is able to be accessed where adolescents spend much of their time is one important solution to increasing vaccine uptake. Currently in the U.S., there is a grassroots effort to expand numbers of school nurses. Registered nurses or nurse practitioners in school systems can provide health education and immunization on-site, in addition to numerous other health benefits (NASN, 2010b).

Presently, only half of school children in the U.S. have access to a school nurse. The

National Association of School Nurses has recommended a 1:750 nurse to student ratio. A few states have reached or exceeded this ratio, but many more have not. In Kentucky, the ratio of school nurses to students is currently 1: >1500 (NASN, 2010b).

In adolescence especially, the school nurse is, in some cases, the only interface with the health care system. For this reason, the school nurse was chosen for this project as an excellent resource for providing HPV education and vaccination.

HPV Programming in Schools

Since the HPV vaccine has only been available since 2006, evaluation of vaccine programs for HPV are limited. A gap in the literature exists relating to availability of HPV programming for adolescents in school settings. A precedent has been set, however, in programs with other vaccines for adolescents such as measles, mumps, rubella (MMR), human immunodeficiency virus (HIV), and hepatitis-B (HepB).

Because HepB vaccine programs have great similarities to HPV vaccine programs, a search of the literature was done on HepB vaccine programming in schools. Both HepB and HPV vaccines protect against viruses that can be transmitted through sexual activity. Both vaccines are administered in a 3 dose series. Both are recommended for groups of pre-adolescents and adolescents who require parental approval and consent. Therefore, lessons learned from HepB vaccine programming in schools may be applicable to HPV programs.

Challenges addressed by school-based HepB immunization programs included providing an infrastructure for adolescents to receive vaccination, facilitating vaccine administration before students engaged in high-risk behaviors and improving chances for vaccine completion (Goldstein et al., 2001). Linking evidence to action, HepB vaccine programs: 1) demonstrated benefits of carefully planning ahead and having contingency plans for immunization days

(Wilson, 2001), 2) enlisted stakeholder support and facilitation of parental consent (Boyer-Chuanroong et al., 1997), 3) involved as many staff and volunteers as possible and educated everyone (Harris et al., 1997) and 4) used media for advertising and developed a variety of educational interventions for use with high risk groups to maximize vaccine uptake (Dilraj et al., 2003). While numerous examples of programs for the HepB vaccine exist, it has taken nearly 30 years, since its introduction, for coverage to be achieved of the 90% of target aged youths needed for herd immunity (CDC, 2010c).

Although the relationship between cervical cancer and HPV has been well established, as has the advisability of immunizing young females before the age of first sexual experience (Pedersen et al, 2007), reports on school-based HPV vaccine programs in the U.S. were not found in the literature. While much research has been done on possible barriers to HPV vaccine uptake such as attitudes and knowledge of adolescents, parents and providers (Zimet et al., 2005; Wetzel et al., 2007; Zimet et al., 2005a; Sturm et al., 2005; Dempsey et al., 2006; Mays et al., 2004; Zimet et al., 2006; Hopenhayn et al., 2007; Tissot et al., 2007; Mays & Zimet, 2004; Kahn et al., 2005; Jacobsen & Szilagyi, 2005; Schwartz et al., 2007; Zimet et al., 2000a), reports of implementation projects in the literature have come mostly from Australia, British Columbia and the United Kingdom.

Starting in April, 2007, Australia began a national school-based HPV vaccination program, providing publicly funded vaccine to all girls in the first year of high school (ages approximately 12-13 years) and free catch-up vaccination of 12-26 year-olds for the first 2 years after initial implementation of the program (Watson et al., 2009). In September, 2008, programs delivering HPV vaccine to schoolgirls were begun in the United Kingdom (Brabin et al., 2008) and British Columbia (Ogilvie et al., 2010).

In Australia, the program was challenged by having only 5 months to plan between initial announcement of the program and its implementation for girls in school Years 8-12. Some students did not have access to the program if their school was not supportive of it. Much negative media occurred and it was hoped that this would not adversely affect the value placed by the public on other vaccine programs (Watson et al., 2009). Uptake was less than expected. Dose 1 coverage was highest in Year 8 (83%) and lowest in Year 11 (64%). Dose 3 coverage was highest in Year 8 (77%) and lowest in Year 11 (55%).

As a prelude to the 2008 program offering HPV vaccine to schoolgirls aged 12-13 in the United Kingdom, a prospective cohort study was done involving two primary care trusts. Good uptake of HPV vaccine dose one (70.6%) and two (68.5%) was reported, but data on coverage for the 3rd dose were not available and was hoped to be commensurately high in order to secure success of the program. Parental concerns related to vaccine refusal included fear of adverse events and lack of familiarity with the vaccine (Brabin et al., 2008).

The program in British Columbia, publicly funded and school-based, was reported to be better received by parents with less education than those with more education. Hesitancy to have daughters vaccinated was based on safety concerns, preferring to wait and not having enough information to decide. Parents interviewed via survey reported that 65.1% of their daughters received dose 1 of the HPV vaccine while 88.4% and 86.5% gave consent for the HepB and Meningitis vaccine, respectively. Reasons for consenting to the vaccine included vaccine effectiveness, endorsement of the vaccine by a healthcare provider and concern about the daughter's health. Low uptake of HPV vaccine in this study occurred even in the absence of financial and healthcare barriers, seemingly due to issues of parental concern (Ogilvie et al., 2010).

There is a great potential for developing and implementing evidence-based programs for HPV vaccination of adolescent females in the U.S. Based on experiences in other countries, if the HPV vaccine can be cost-neutral to the consumer, school-based HPV education and vaccine administration can provide an important avenue for improving vaccine uptake. In learning from the lessons of other vaccines for STDs given to adolescents, perhaps herd immunity can be reached within a more reasonable time-frame.

Setting and Stakeholders

While cervical cancer is problematic throughout the world, its incidence is much higher in developing countries and poorer areas. In the U.S., one of the areas with the highest incidence of cervical cancer mortality is Appalachia. In a study of cervical cancer rates in 5 states with areas in Appalachia, including Kentucky, West Virginia, Alabama, Ohio and Pennsylvania, substantially higher rates of invasive cervical cancer (ICC) were found in Kentucky and West Virginia (Yabroff et al., 2005).

Within Kentucky, the rate of ICC was found to be 25% higher in Appalachian Kentucky than in the rest of the state. Higher variations of ICC in the Appalachian counties of these 5 states were thought to be related to higher poverty rates and lower education of the population which incidentally also had higher rates of smoking, which is a cervical cancer risk factor, and less utilization of Pap testing (Hopenhayn et al., 2008).

The author resides and is a healthcare provider in Appalachian Kentucky. Since she performs female cancer screening exams through a local health department and works with adolescents in a rural high school in Appalachian Kentucky, this geographic area was chosen for her clinical project.

One challenging aspect of a successful project plan is utilizing the human resources

which are available (Baca, 2007). The author identified sponsors, stakeholders and team members who were important to implementation of the clinical intervention. The project sponsor provides financial support, advice and resources important to accomplishment of the undertaking. A stakeholder is anyone interested in or affected by the project. Team members provide expertise to the project and are involved in seeing that the work of the project is realized.

Academic sponsors for the project identified by the author were her doctoral committee members and the financial sponsor was the organization granting funding for the project, Nurse Practitioner Healthcare Foundation (NPHF). The academic sponsors included the author's advisor, a mentor who was a content expert for the project, and an additional faculty person who served as reader. The committee was important to the completion of the project because they gave guidance and direction to the author. The NPHF provided a small grant to the author for use in developing the toolkit and other expense incurred during the project. The grant was very helpful in allowing the author freedom to spend money on quality materials and partially funding her trip to a national conference for poster presentation of the project.

The stakeholders included female adolescents eligible to receive the vaccine; parents of potential vaccine recipients; school faculty, staff, administration and school board; local church leaders; local providers of healthcare to adolescents; local health department and school nurses in Kentucky. Of these the school nurses in Kentucky were instrumental in participation in a survey and focus group, while the health department provided a private meeting place for the focus group. The other stakeholders mentioned above were those for whom the educational contents of the toolkit were developed. All of these stakeholders gave focus to the project development.

Additional stakeholders identified were the U.S. Center for Disease Control and Prevention, the vaccine manufacturers and the National Association of School Nurses. These

were groups identified by the author as potentially having interest in the final toolkit.

During the development and evaluation phases of the project, various team members were consulted for their expertise. These included school nurses with whom the author works, the local health department director and administrative assistant, and specialists in instructional technology, arts and graphics and administrative support. Each of these team members provided knowledge and help crucial to project completion.

Creative Approach

Project Mission, Goals and Objectives

One of the most important aspects of a successful project is the planning stage. A definition of what the project planner hopes to accomplish as well as the steps to accomplish it are basic

to successful project planning (Kemp, 2004). The mission of the project is an overall statement of aim or what the project planner hopes to accomplished. The project goal is a more specific statement of how the mission will be reached. The objectives which follow the goal should be specific, measurable, attainable, realistic and time-constrained (Hampton, 2008). Following are the mission, goals and objectives of this project:

Mission.

Equip school nurses with evidence-based methods for HPV education to promote vaccine acceptance, increase uptake and influence reduction in HPV disease and cervical cancer.

Goal.

Create an evidence-based toolkit to be used by school nurses for educating female adolescents, parents, healthcare providers, and communities about the HPV vaccination.

Objectives.

1. Obtain IRB approval.

2. Survey school nurses using state school nurse association list-serve about ideas of what toolkit should contain.
3. Create toolkit based on survey results and review of the literature.
4. Provide for focus group of school nurses to give feedback on toolkit prototype.
5. Evaluate focus group data.
6. Present poster about project at a national school nurse conference
7. Co-author manuscript with mentor for journal submission.

Because the process of vaccine acceptance not only involves education of the vaccine recipient, but also parental consent and the influences of school, church, and healthcare providers, a search for a model to define this process was begun.

A Conceptual Model for the Project

Models are used to “observe, order, clarify and analyze events” (Bush, 1979). “As research and practice related to behavior and behavior change grow, models have evolved that attempt to account for the various elements that predict behavior” (Glanz, Rimer & Lewis, 2002). An adequate model is one which is tied to the empirical world by being descriptive and explanatory. Such a model must also be built upon concepts and relationships, be logical, generalizable and parsimonious (Omery, 2007).

Therefore, a clinical practice model is provided as a framework from which vaccine uptake programs can be developed to increase the number of adolescent females receiving HPV vaccine, and by so doing decrease the incidence of cervical cancer in the future. While the model is used for HPV vaccine uptake in this paper, it is hoped that this model could also be used with other sexually transmitted disease STD vaccines targeted for the adolescent population.

Description of the model.

Ideas for the development of this model came from several sources. In thinking about what kind of framework would best fit providing a potentially controversial immunization to a young adolescent population, the author discussed with a nurse expert a framework, *Psychosocial/Behavioral Factors and STD Vaccine Acceptance* used by a mid-western university research group, whose work dealt with acceptance of STD vaccines for adolescents. (Mays, 2007).

In 1999, other STD vaccines, such as HIV and were being worked on and several were very near release. At the above noted university, the members of an interdisciplinary seminar group considered the following:

We believe that the time has come to develop a research agenda for psychosocial and behavioral issues that anticipates the arrival of new STD vaccines. It is not too early to begin laying the groundwork for the use of these vaccines to ensure their long-term effectiveness in STD prevention and control. (Zimet et al., 2000b).

From those ideas grew cooperative research between disciplines on factors affecting vaccine acceptance.

The groups thinking proceeded in the following way: If in the ideal traditional model applied to acceptance of vaccination, the vaccine is developed, made available, accepted and disease incidence is decreased, a new way of visualizing was needed for STD vaccine acceptance for adolescents. If the psychosocial factors relating to acceptance of an STD preventing vaccine (*individual, family/parent, cultural and provider issues and vaccine characteristics*) are all addressed, the vaccine is more likely to be accepted (Mays, 2007).

This new model was based on the Health Belief Model (HBM) which served as a broad, guiding thought process for the research group. They adapted it to explore sexual risk behaviors and transmission of STD's (Mays, 2007). By focusing on the attitudes and beliefs of individuals,

the HBM attempts to explain and predict health behaviors (Becker, 1974). According to the HBM, which includes the concepts perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy, a person will take a health-related action, such as taking the HPV vaccine if that person: (a) feels that a negative health condition (i.e. cervical cancer) can be avoided; (b) has a positive expectation that by taking a recommended action, he/she will avoid a negative health condition (ie. taking HPV vaccine will prevent cervical cancer); and (c) believes that he/she can successfully take a recommended health action (ie. taking HPV vaccine will be safe and effective) (Glanz et al., 2002).

The HBM thereby frames an explanation of why people take positive actions to avoid negative consequences (Hochbaum, 1958; Rosenstock, 1960; Stretcher & Rosenstock, 1997). Application of the HBM to this clinical project gives reason for action to be taken to accept HPV immunization in order to reduce the chance of infection with a sexually transmitted disease which could lead to cervical cancer. For instance, perceived likelihood of exposure to HPV has lead to higher acceptability (Olshen et al., 2005; Salz, 2010), perceived severity has influenced parents to have their children immunized (Zimet et al., 2005), perceived effectiveness has facilitated greater intent to obtain HPV vaccine in parents of adolescents (Dempsey et al., 2006; Zimet et al., 2000) , perceived barriers of cost (Zimet et al., 2000) and anticipated discomfort (Dempsey et al., 2006) were related to low acceptance, and health provider endorsement was a cue to action (Dempsey et al, 2006; Olshen et al., 2005).

Elements from another model influenced the author's thinking as well. The *Clinical Practice Model for Immunization Programming in Vaccine-Preventable Diseases* (Butler, 2007) was used for the development of an evidence-based toolkit to prevent meningococcal disease in college students. Butler's model was based on a logic framework depicting the conceptual

approach used to improve vaccination coverage in children, adolescents, and adults (Briss et al., 2000). Her population was college students who are at risk for meningococcal meningitis. Four concepts in Butler's model from which she developed interventions were increased community demand for immunizations, increased access to immunizations, provider-focused interventions, and environmental influences. If programs were planned using these concepts, it was postulated that increased vaccine coverage and decreased incidence of disease would be the outcome.

The model in Figure 1 depicts an overlapping of ideas from the research group's model and Butler's model to create a model for use with adolescent females/ HPV vaccine acceptance

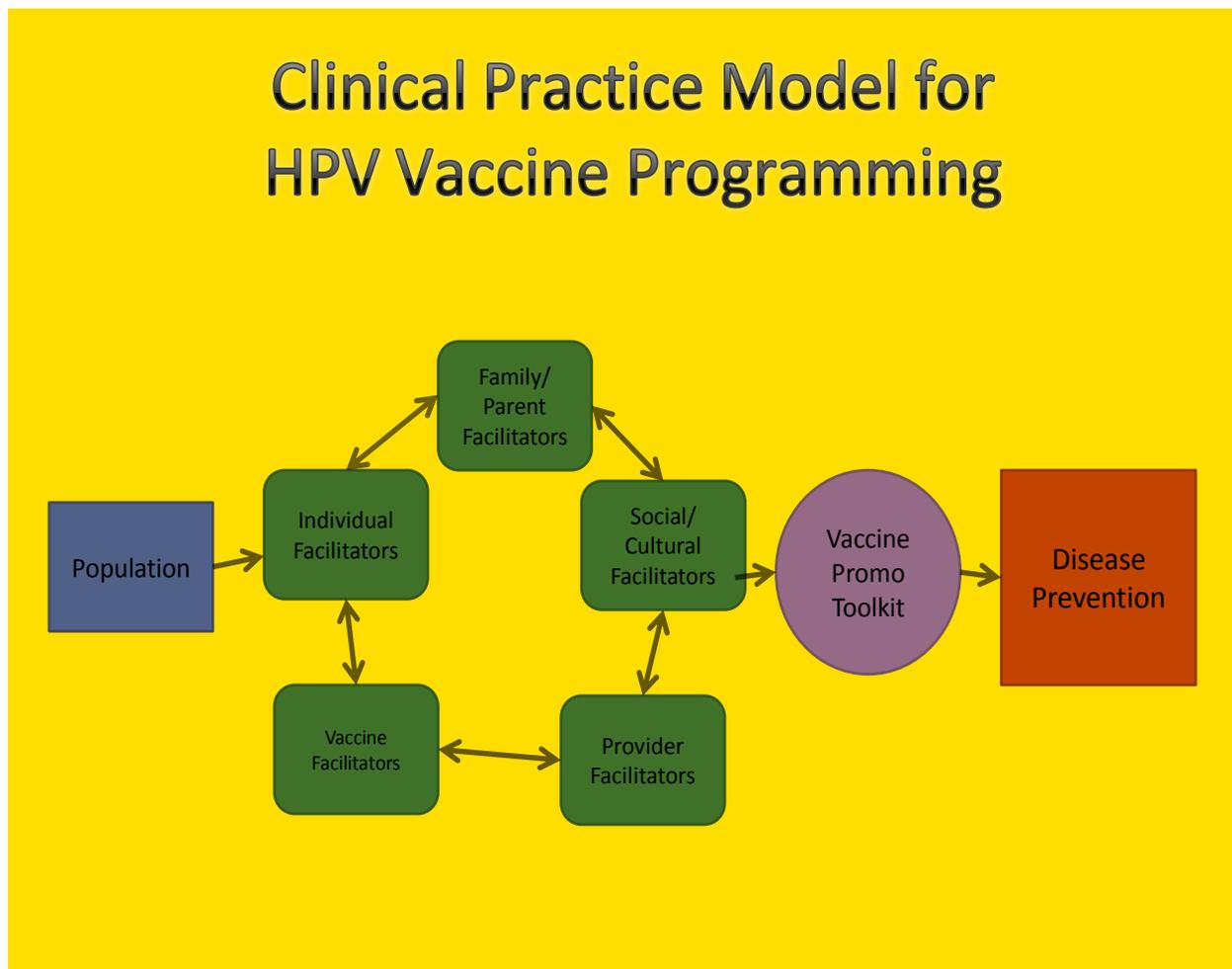


Figure 1

Concepts and relationships.

The key concepts of the *Clinical Practice Model for HPV Vaccine Programming* consist of the population, followed by 5 interrelated, action-focused, research-based concepts which impact the population, and then 2 desired outcomes of the action-focused concepts on the population.

The concept *population* signifies those in the age-group recommended to receive the vaccine, in this case adolescent females in middle and high school. A one-way arrow depicts the relationship of the population attempting to reach the outcomes while addressing the 5 concepts along the way. These concepts, arranged in a circle to show equal relevance, are *individual facilitators, family/parent facilitators, social/cultural facilitators, provider facilitators and vaccine facilitators*. The term *issues* from the research groups' model have been changed to *facilitators* because the author sees facilitation to be more action oriented. A successful vaccination program would do well to include interventions addressing all five of these areas (Zimet et al., 2000b). The relationship between these concepts is depicted by 2-way arrows showing equal involvement and importance of all five concepts.

One-way arrows are used to show that after the five concepts in a circle are addressed in a comprehensive vaccine program, the outcomes can be reached in successive order. The short-term outcome is *vaccine coverage* of the target population. The long-term outcome is *decreased incidence of disease*.

Evidence that supports the model.

A great deal of evidence was gathered in the years prior to the introduction of the HPV vaccine. This was done because there was concern over acceptance of the vaccine for the target population. Since the vaccine is licensed for use in females aged 9 to 26 years and

recommended to target 11 and 12 year old females, it was recognized that there would be controversy regarding its utilization. The evidence existed for health risks posed by HPV infection and the potential for development of cervical cancer (Dunne et al. 2007; Freedman 1998; Kahn 2005; Moscicki 2005). Adolescent females as an at-risk population was well supported. However, it was postulated that concerns would be raised by parents, healthcare providers and communities about the wisdom of vaccinating ones so young, safety of the vaccine, cost, moral issues and long term efficacy of the vaccine. Thus, research supporting the five concepts presented in the *Clinical Practice Model for HPV Vaccine Programming* had already begun.

Evidence for the concept of individual facilitators is plentiful. Adolescents often see themselves as immune to risk of harm or death. Education is, therefore, an important undertaking with the adolescent population so that they will recognize their susceptibility and need for immunization (Zimet et al., 2005b). Research also supports that those adolescents at greatest risk for STD's are those who are the most difficult to access for prevention services (Wetzel et al, 2007). This may be because those adolescents are in situations where they or their parents do not seek regular medical care due to cost, transportation or medical home issues. They also may have dropped out of school and are therefore not prompted by school nurses or others to access recommended vaccinations.

The concept of family/parent facilitators has received the greatest amount of attention from researchers; the attitudes and willingness of parents to accept immunization for their child against a disease spread through sexual activity. Because of the target recipient's age, parental consent must be obtained. Research reveals that families are interested in protecting their youngsters from disease, regardless of its etiology, especially when trusted institutions and

providers are recommending them to do so (Dempsey et al., 2009; Zimet, 2005; Zimet et al., 2005a; Sturm et al., 2005; Dempsey et al., 2006; Mays et al., 2004). Some parents worry about discussing sexual issues with their children. They look for help from schools, medical homes and healthcare personnel to assist them with this task.

Next, the concept of social/cultural facilitators speaks to those community, society and religious influences that affect attitudes and behaviors of individuals and families regarding their health decisions. Support for the HPV vaccine as a valuable tool against cervical cancer has come even from conservative groups as long as parents still have the authority to decide who receives it (Zimet et al., 2006; Hopenhayn et al., 2007; Tissot et al., 2007). Some parents have even accepted the idea of schools requiring adolescent vaccines as long as opt-out clauses exist (Schwartz, 2007). While many opposed the vaccine in 2006 when multiple states submitted bills for school mandates, the use of patience, education and further evidence of vaccine safety is hoped to undo the harm done in the early phases of state legislative initiatives.

The fourth concept, provider facilitators, is equally as important as the other concepts, but often more difficult to approach. Healthcare providers, such as physicians, nurse practitioners, nurses, etc. are often set in their ways. They are either hearty proponents or very verbal opponents of HPV vaccination. Some of this comes from personal attitudes about adolescent sexuality, whereas others are unwilling or uncomfortable to discuss this vaccine with parents and adolescents. Still others providers fear that the vaccine is still too new and untested by time and large cohorts of recipients (Mays & Zimet, 2004; Kahn et al., 2005; Jacobsen & Szilagyi, 2005).

Finally the last concept, vaccine facilitators, consists of issues which still need time and work. In looking historically at vaccines which have gone through the acceptance and assimilation process, time has been required for things to work themselves out (Schwartz et al.,

2007). One issue that takes time is getting the vaccine to be affordable to everyone in the target group (Zimet et al., 2000a). At the present time, Medicaid, the Vaccine for Children's program, drug assistance programs, or private insurance are available to pay for most, but not all vaccine needed for the targeted population. The HPV vaccine is especially expensive at approximately \$130 dollars/dose for a 3 dose regime. In addition, there are those who refuse to accept the vaccine until it has been around longer and shown to be free of unacceptable side effects. Others are waiting to see what the data will show about efficacy of the vaccine over time and whether or not booster doses will be required (Zimet et al., 2000a). Vaccine availability is also a potential roadblock as demands on vaccine supply created by mandating the vaccine have not yet been a problem, due to scarcity of mandate passage.

Strategy for model implementation.

After developing the *Clinical Practice Model for HPV Vaccine Programming*, plans were made to develop an HPV vaccine education toolkit for school nurses to use in middle and high school settings. Keeping in mind that information about HPV which is user-friendly and accessible is crucial for successful HPV vaccine program (Low et al., 2006), a toolkit was created including posters, pamphlets, brochures, a flip-chart, letters to various stakeholders, a scripted radio announcement and peer-reviewed articles. In addition, a power-point presentation which can be adapted to various groups was included.

The toolkit consisted of materials geared toward education of each of the five model concept facilitators: individual, family/parent, social/cultural, provider and vaccine. Following are examples of possible interventions with the toolkit contents:

Individual

- Be available for speaking in the classroom setting about the cancer/HPV connection.

- Use visual prompts in the school clinic to facilitate students asking about HPV.

Family/parent

- Send letters home to parents about HPV vaccine availability and recommendation.
- Provide for consent forms to be returned by students or through mail.
- Advertise availability of supplemental information on HPV for those with concerns.

Social/cultural

- Utilize mass media to encourage vaccination and use of school program.
- Facilitate community-wide education via posters, brochures and letters to clergy and school administrators.

Provider

- Share CD and expert information with healthcare providers.
- Provide reminder and recall system for their patients.
- Encourage providers to use HPV brochures in their offices.
- Request provider support for school vaccine programming.

Vaccine

- Provide vaccine safety, cost, and efficacy information to all groups.
- Pursue ability to provide vaccine to all recipients at little or no personal cost.
- Obtain sufficient vaccine for all who express interest.

Methods, Data Collection and Use of Consultants

Funding for the project was requested from the Nurse Practitioner Healthcare Foundation and a \$3,500 Sanofi-Pasteur “Health Through Immunizations” award was received from that organization in 2007. The money was spent on toolkit development and attendance for poster presentation at a National School Nurse Association conference in 2010.

Upon receiving approval from the Institutional Review Board, a one-time email survey was sent to a school nurse list-serve in Kentucky prior to toolkit development. (Table 1).

A survey is a type of qualitative research method used for exploration and collecting of data to make plans for improving health care (LoBiondo-Wood & Haber, 2002). It was chosen for use in this project to collect opinions of the intended audience related to HPV education in the schools.

Twenty-four school nurses responded to the survey. The number of nurses belonging to the list-serve was unknown. Participation in the survey was on a voluntary basis using the Survey Monkey website. Names, ages, ethnicity and gender of the participants were unknown to the author. Introductory remarks at the beginning of the survey asked that only school nurses who worked with middle-school and high-school students respond. Those serving only elementary-school students were asked to refrain from participating. Questions dealt with previous use of toolkits, what would be helpful to include, kinds of educational programming preferred, toolkit format and inquiry about toolkit utilization, distribution and implementation.

Survey results.

A total of 24 responses to the survey were received by Survey Monkey. Nineteen respondents (79%) stated they had previously used toolkits in their practices. All 24 wanted the toolkit to provide information about HPV, including statistics on incidence, symptoms, recommendations, treatments and pictures of damage caused by the virus. They also asked for provider-based information on the HPV vaccine, risks, benefits and side effects. Several also wanted information on condom use and abstinence.

Eighteen respondents (75%) asked for printed materials when questioned about types of educational programming preferred. Eight (33%) stated that they liked PowerPoint presentations

and eight (33%) listed face-to-face as their preference. Regarding toolkit format preference, 18 (75%) participants indicated brochures, 15 (63%) posters, 16 (66%) DVD's and 10 (42%) letters. Many respondents listed multiple preferences.

When asked about how they saw the toolkit contents being most utilized, answers were numerous. Only one respondent answered "not sure" to the question. Others responded with one or more of the following: one-on-one in the health office, in health and parenting classes, on the mobile unit, in mailings to parents, posters displayed in nurse's office, at orientation and health fairs, for STD counseling and presentations, at parent conferences, in the school newsletter, to send home to parents and to hand out with 6th grade physicals.

Suggestions for how best to distribute the toolkit were varied. Several mentioned that state school nurse conferences would be a good place. Others suggested distribution through school nurse consultants in either the State Department of Education or Department of Health, mandatory meetings for school nurses, by request through the state school-nurse list-serve, through local health departments or through a continuing education program offering. Still others wanted the toolkit sent directly to them.

The last question was worded too similarly to the question on utilization of the toolkit, because many participants gave the same answers as they had given to the utilization question. This final question dealt with the perceived best way to implement use of the toolkit. Answers which differed from those on the utilization question included: implement it by educating the healthcare providers, school administrators and parents, incorporate it into the health class curriculum as part of sex education material, give statewide training in which use of the toolkit is discussed and send an information letter about the vaccine to parents.

The toolkit.

Based on survey results and review of the literature, a prototype of the HPV education toolkit was developed for school nurses to use in educating students, parents, community members and healthcare professionals. Pamphlet, brochures and posters were accessed from reputable, non-biased sites which informed in non-medical jargon about HPV, its connection to cervical cancer and the HPV vaccine. A compact disc (CD) containing a PowerPoint presentation from which slides could be used by the school nurse was made for presentations to various groups of students, parents, school personnel or community members. A flip-chart was designed for the school nurse's office to stimulate interest in and conversation about HPV. Informational booklets were adapted from technical to non-technical wording to make them easier to understand. Also, original journal articles were included for health professionals to address issues such as safety and efficacy. The toolkit was divided into sections appropriate for each of the group: students, parents, community and healthcare providers.

Focus group.

When the toolkit prototype was ready, a focus group of school nurses was asked to formatively evaluate it. Participants were contacted in person by the author and asked to volunteer.

There were 6 female school nurses from Eastern Kentucky, the part of Kentucky which rests in the Appalachian mountains, who volunteered for the focus group. They were all Caucasian and ranged in age from 26 to 52. All 6 of the participants worked with students of middle-school and high-school ages.

The focus group meeting was held at a private conference room attached to a local health department administration complex. Group members were allowed time to examine the toolkit

contents and then participated in an hour-long session of questions and responses which were audio-recorded. The participants were identified only by number and not by name for confidentiality purposes. Focus group findings will be discussed in a later section.

Content expert, consultant and mentor for this project was Rose Mays RN, PhD, Professor Emeritus from Indiana University School of Nursing in Indianapolis, Indiana. Dr. Mays has done extensive research on acceptance of vaccines for sexually transmitted infections in the adolescent population and her writing is often referenced in peer-reviewed publications.

Evaluation of Issues Related to Changing Systems, Attitudes, Values and Beliefs

In looking at adoption of the toolkit for HPV vaccine promotion, use of a change process to facilitate acceptance of the offered information was helpful. Whether it is planned or unplanned, change can result in disaster. With careful planning, however, the possibility of a productive outcome is greatly enhanced (Tiffany & Lutjens, 1998).

In his book, *Surviving Change: A Survey of Educational Change Models*, J.B. Ellsworth describes the Change Communication Model pictured below:

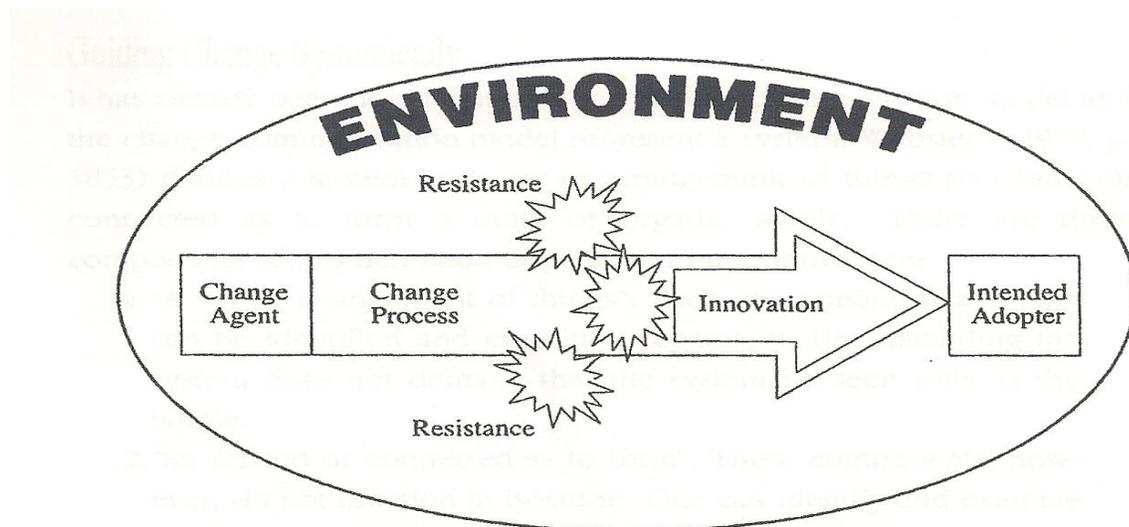


Figure 2. The Change Communication Model

This model depicts a change agent desiring to communicate an innovation to an intended adopter. “This is accomplished using a change process to establish a channel through the change environment between the two communicants. However, this environment also contains resistance that can disrupt the change process or distort how the innovation appears to the intended adopter.” Communication is described in this model as a two-way process which flows in both directions. Two-way communication is important to avoid perceptions of paternalism or manipulation (Ellsworth, 2000).

In the clinical project described in this paper, the change agent was the author, who wanted to facilitate uptake of the HPV vaccine by female adolescents in the middle and high school setting. The intended adopters were the school nurses who would ideally accept, receive and agree to utilize the innovation. The innovation was the toolkit developed for use by the school nurses. The change process was the planning and developing of the toolkit for use in the school setting. The resistance was the potential roadblocks raised because of individual, parent-family, socio-cultural, healthcare provider and vaccine cost-safety concerns or knowledge deficits. These resistance factors needed to be dealt with successfully for the innovation to be accepted.

This change model seemed applicable to the environment where the innovation was to be utilized. The HPV vaccine has been met by resistance in many situations already discussed. Several states have attempted to legislate mandating the vaccine as a requirement for school attendance. This has met with opposition for a variety of reasons. One reason was that at the time many state mandates were brought forward, the vaccine had not been on the market long enough for many to feel comfortable about its safety. There have been issues of cost creating the perception that all adolescents do not have the same access to the vaccine. Religious groups

have taken the position that an STD preventative vaccine should not be mandated for adolescents to attend school, since there is minimal risk of spreading the STD at school. Some parents have felt this is a family decision and should not be made a condition of school attendance. Not all healthcare providers are comfortable discussing or recommending the vaccine. Many adolescents do not have enough information to make an informed decision about vaccine acceptance.

Planning and developing the toolkit was done with potential barriers to acceptance of the vaccine kept in mind. In order to maximize its chance for success in the school setting, the toolkit had to address and navigate the shark-infested waters of resistance. When it comes to accepting a vaccine which protects adolescents from a sexually transmitted infection, the potential for controversy exists. But this vaccine protects females from HPV infection and cervical cancer. This is the message which needs to be communicated.

Change, in this situation, has the best chance for success if the message of HPV vaccine preventing cervical cancer is kept at the forefront. While other concerns need to be addressed, they must be dealt with in a positive, non-confrontational manner to keep the cancer prevention message from being blurred by negative emotion. Learning how to educate and persuade without alienating is the key.

Analysis of the Actual or Potential Impact of the Project on Other Populations Within the Healthcare Delivery System

In 2010, one of the HPV vaccines, Gardasil, was licensed by the FDA for use in males aged 9 through 26 to decrease their likelihood of acquiring genital warts caused by HPV types 6 and 11. While Gardasil is approved for males in this age-group, the ACIP does not as yet recommend it to be routinely given to males. Although nearly 90% of genital warts and many cases of anogenital cancer in males can be attributed to HPV, the health burden of HPV is

higher in females and it is thought to be more cost-effective to spend limited public health dollars on improving coverage to females aged 11-12 (CDC Control & Prevention, 2010a).

Some believe that there would be great economic and health benefit in including males in HPV vaccine programs which are currently focused primarily only on females (Garland, 2010). HPV is associated not only with genital warts in males, but also in cancer of the anus and penis. A proportion of cancers of the oropharynx are also attributed to HPV in both males and females. While cancers of these areas are less common than cervical cancer, using the HPV vaccine for prevention in males would be a welcomed public health benefit. At present, 90% of anal cancers, 40% of penile cancers and 12% of oropharyngeal cancers have been linked to HPV (CDC, 2010a). Also, most HPV infections in females have been transmitted by infected males. While there is certainly value in the inclusion of males receiving the HPV vaccine, studies are on-going to evaluate the cost-benefit of provision to this additional population (Garland, 2010).

The HPV toolkit already includes information which is geared to both male and female adolescents. Since it is presently focused on the prevention of cervical cancer, education regarding the link between HPV and anal, penile and oropharyngeal cancers could easily be included to widen its audience. This would broaden the ability to portray a more comprehensive picture of what HPV can do and why its potential effects should be prevented. Also, the stigma of HPV is currently born primarily by females because they are the ones who get cervical cancer. However, in reality, HPV is contracted by both males and females at similar rates and should be treated as equally harmful to both.

Similarly, the toolkit sections providing information to parents, school personnel, community members and other healthcare providers could likewise be fortified to examine the effects of HPV on young males as well. Many more people would be likely to take interest and

be educated if information about how not only cervical, but anal, penile and oropharyngeal cancers and genital warts are caused by HPV and could be prevented with a vaccine which is currently available.

While the cost is high for the recommended series of three doses of HPV vaccine, alerting parents and community members to the value of preventing HPV effects in all young people would certainly help the cause. Parents, grandparents, aunts and uncles could all appreciate this valuable service for the young people in their lives.

Having more people on the bandwagon could help propel the cause of HPV prevention for youth to affect policy making such as mandating HPV for school attendance. In this way, the cost of the vaccine could fall not to the individual, but to the government and the states initiating mandates. Even with provision for parents opting out of their children receiving the vaccine, taking away the financial burden would encourage much greater vaccine uptake. Greater demand for the vaccine would have the potential to bring down the cost as well, as has been the case with other vaccines in high demand due to state mandating (Dempsey & Mendez, 2010).

Impact of Technology on the Problem Being Addressed

Since the licensing of the first HPV vaccine in 2006, a limited number of studies have looked at the use of various technologies to improve vaccine acceptance. One U.S. study (Wetzel et al., 2007) involved the use of a two-booklet set in which one booklet contained key phrases, pictures and diagrams for the patients in an urban, hospital-based adolescent health center. The second booklet was a script for the educator to use. The study involved 252 adolescent boys and girls in three phases of the study. Phase 1 was development of the protocol by the teens and investigators. In phase 2 the teens quantitatively evaluated the effectiveness of the protocol at increasing HPV knowledge. Based on the adolescents' comments, the protocol

was then revised. The protocol was used in phase 3 to evaluate its effectiveness with an additional adolescent sample. A 10 or 11-item scale was administered to measure pre and post-protocol knowledge. It was found that despite risk behaviors and socioeconomic characteristics, the protocol significantly increased knowledge scores in the study population.

Feedback from participants included the suggestion that more pictures would help to teach adolescents of the seriousness of HPV infection. Use of the one-on-one educational approach with the adolescents was thought to be a way of promoting healthy sexual behaviors and regular Pap screening. This type of individual interaction was thought to be beneficial to those who may have trouble reading or lack access to the internet. Since its development this protocol has been successfully used in middle and high schools to educate about HPV prevention and infection.

In another study (Vallely et al., 2008) done in the United Kingdom a filmstrip about HPV and cervical cancer prevention was shown to school children with consent from their parents. The children targeted were 11 and 12 year olds in three schools who were to be offered the HPV vaccine. Outcomes measured included knowledge gained and the number of children allowed by their parents to view the film. The film had 4 key messages including HPV causes cervical cancer, HPV is sexually transmitted, condoms may not fully protect against HPV and HPV vaccination protects against cervical cancer. Student groups of 12-15 year old boys and girls worked on the script, produced art materials and helped produce the 10 minute film. Six schools participated in the study.

It was proposed that offending religious and cultural values could be minimized by initially consulting with parents and teachers. Nurses felt the film augmented health promotion in the schools. The idea that HPV information should be given before and continue to be given

after vaccination as a way to develop knowledge incrementally was suggested by parents and school nurses. The study was concluded to demonstrate that education of 12 year olds about HPV and cervical cancer can occur without HPV stigmatization and controversy.

In a third study (Chapman et al., 2010) done in the U.S. participants took a survey addressing HPV knowledge and vaccine acceptability followed by viewing an 8-minute video and a post-video assessment. The video consisted of facts about HPV and its transmission, prevalence and incidence of HPV and information about the HPV vaccine. Significant increases were made from pre- to post video in several areas relating to HPV. Prior to seeing the video, 67% of study participants were willing to receive the vaccine for themselves or their children if the vaccine were free. After the video, these values increased to 78% and 87% respectively. Belief that the vaccine should be required was 55% pre-video and 73% post-video. Willingness to have their child vaccinated at school increased from 51% to 65%. Acceptability of vaccinating children ages 9 to 15 increased from 57% to 94%, while acceptability of vaccinating a child as young as age 9 increased from 13% before to 43% after viewing the video. The majority (62%) thought after seeing the video that administration of vaccine to young people would not promote increased sexual activity. Also after the intervention, 69% were in favor of giving the vaccine to both males and females.

In the preliminary survey, Hispanics, Blacks and those with combined income less than \$50,000 were those more likely to decline the vaccine. After the video, these groups were the most likely to accept the vaccine. In addition, 77% of those participating in the study said they would vaccinate their child if a doctor recommended it and 75% would have the vaccine themselves to protect a partner. Answers to these questions did not change significantly after viewing the video. One conclusion reached regarding this study was that this type of video-

based intervention may be useful with lower income and minority populations to effect positive attitudinal changes toward the HPV vaccine.

Social marketing is a strategy with real potential to increase rates of vaccination. With its roots in the Health Belief Model, the Exchange Theory, and the Theory of Planned Behavior, social marketing is a mechanism for effecting healthy behavior (Opel et al., 2009). Both the messenger and the presentation of the message are important, as is the ability to get the attention of the audience and engage their minds. Use of a compelling story to affect action by the listeners can be an effective persuasion tool (Opel et al., 2009). Social marketing has application to adolescents, who value private one-on-one interaction with a trusted health provider and attention to timeliness and confidentiality. Use of text messaging, e-mail, social media, and the Internet are also popular with adolescents, as are incentives to encourage preventive health services utilization (Coker et al., 2010).

In a study by Lariscy et al., 2010, using Primary Socialization Theory, 452 seventh graders in Georgia were surveyed regarding their sources of health learning. Primary Socialization Theory posits that the most important sources for adolescent health socialization are parents, peers and schools, with mass media holding secondary importance. The findings of this study revealed that the participants ranked their sources of media-provided health information as first, the television, followed by radio, print, Internet and social networking media. Black adolescents utilized TV, radio and Internet more frequently than did other races. Girls were more apt to listen to the radio, especially news and entertainment. Rural youths reported utilization of the Internet and online social media sources more than did urban youths. Studies like this one which deal with adolescents' preferred methods of obtaining health information can be very important to consider in planning communication with teens and pre-teens.

Analysis of the Fiscal and Systems Impact of the Project Itself

Each project has a life cycle of its own including various phases from start to finish. One explanation of this includes the phases of defining, planning, executing and delivering. (Omery, 2008). The defining stage includes conceptualizing the project, its scope, goals and objectives. Elements of the defining stage were covered earlier in this paper. The planning stage consists of developing the timeline for the project, its budget and risk management plan. According to Kemp (2004), listing the activities or tasks of a project precede the creation of a schedule.

Toolkit development schedule (Gantt Chart).

One way of visualizing the schedule is to make a Gantt chart which shows the timeline when tasks or activities are scheduled to occur in the course of project implementation. The Gantt chart can be used as the project progresses to show the difference between when activities were scheduled to occur and when they actually did occur. This provides a method for seeing if the project is progressing according to schedule. Gantt charts can be very simple or can be increasingly complex with the involvedness of the project. Two simple Gantt charts delineating proposed and actual timelines and milestones for the HPV toolkit project are located in Tables 2 and 3. There was great variation in the proposed timeline and the actual timeline. Factors affecting this discrepancy included the IRB process taking much longer than expected and the author's inability to complete tasks in the proposed time allowed due to personal circumstances of teaching, clinical practice and family issues.

Communication strategy.

Sharing of information and keeping the lines of communication open are invaluable to project success. While communication among members of the team is crucial, that which occurs

between team manager and customers, sponsors and other stakeholders can be equally as critical. Although communication with non-team members may occur less frequently, it is also important and requires careful attention.

During the course of this project, the author handled communication in the following way. Progress reports were made to appropriate stakeholders at necessary junctures in the project's implementation. For example, the grant-conferring foundation was communicated with regarding the extended timeline of the project. Immediate reporting of any problems or changes were made to team members, sponsors or selected stakeholders as necessary as the project progressed. And finally, informal communication with team members and stakeholders occurred as needed with special attention to avoiding negativity such as anger, blame and criticism.(Kemp, 2004). Included in such communication were emails regarding deadlines needing postponed and explanation to IRB of a protocol violation related to changes made in focus group questions.

Risk management plan.

While some risks are not important enough to worry about, others are potentially serious enough to require a plan for managing. The concepts of impact and probability are the cornerstones of developing a risk management plan. Impact is the amount of damage a project can incur should the risk, in fact, happen. Probability is the likelihood that an event will happen. Baca (2007) suggests forming a risk chart using a 1 to 5 scale for both impact and probability. A score of 5 for impact would mean that the risk would have the highest impact on the project. For probability, a score of 5 would mean the risk is most likely to happen. In responding to possible risk, Baca (2007) discusses four possible strategies: avoid, transfer, mitigate and accept. A risk identification/response plan chart for the HPV toolkit project is located in Table 4. Risks

anticipated included a vaccine being pulled from the market, support of a sponsor being withdrawn and support of the health department being withdrawn. Strategies to address potential risks included 1) use of the alternate HPV vaccine should one be withdrawn from the market 2) finding another funding source should one be lost and 3) enlisting the support of another health department should the first health department's support be withdrawn. None of the possible risks anticipated occurred and none of the potential responses were needed.

Budget.

The cost of the project drew from the schedule displayed on the Gantt chart and the toolkit development and distribution costs based on items included. The project budget included both payroll and non-payroll expenses. Payroll expenses are an estimate of the time it will take to complete the toolkit development phase of the project multiplied by the salaries of the team members involved. Non-payroll expenses are the purchasing cost of materials and services needed for project completion. The author did not include in the budget the indirect costs of computer, office space, furniture, maintenance, utilities, telephone and furniture as these were provided within the author's personal residence or place of employment. An itemized estimate of the project's cost is located in Table 5. The author provided the service of project management negating that cost. The other salary, materials and travel were covered by the grant money received.

Findings, Outcomes and Evaluation

Focus Group Findings and Analysis

A focus group can be useful to gather people's ideas and perspectives with the added complexity of group interaction and conversation through which all group members can hear and react (Krueger, 1998). The purpose of using a focus group to formatively evaluate the HPV

toolkit was 1) to elicit recommendations of the focus group members on the appropriateness of the toolkit's contents for cervical cancer, HPV and vaccine education and 2) to discover changes which would improve the toolkit.

The questions asked were developed prior to the meeting of the focus group (Table 6). After allowing time for group members to examine the toolkit contents, discussion was held to one hour and led by the author. Consent forms were completed by the group members prior to beginning and the focus group interaction was tape-recorded.

The "transcript-based analysis method" (Krueger, 1998) was used for analyzing the data. The transcript was transcribed word-for-word into a typed document. After repeated readings of the transcription, emergent themes were identified. The discussion was coded and text segments within previously defined themes were sub-coded and organized into a framework.

Four recurring themes were:

- The toolkit is user-friendly
- The toolkit is appropriate for different audiences
- The toolkit promotes HPV awareness
- The toolkit promotes HPV vaccine acceptance

The toolkit is user-friendly.

All of the participants found the toolkit to be user-friendly. Comments related to answers being easy to find, being able to respond quickly to questions and materials being covered in a way that was easy to understand.

A lot of grandparents and even parents don't know how to get on the internet or they don't have access to a computer, so this information would be easy for them to access. Well, I particularly like the flip chart that I could use in my office, to flip across to get their interest in it. And then that would open the door for discussion, about ways to, you know, why it's important to get it.

It's very compact and would be easy to transport. It's simple and easy to understand. You could go to the health classes and select slides from the CD at the appropriate level or to parent groups and present them with the information they need.

The toolkit is appropriate for different audiences.

Group members thought the toolkit was flexible to use with students, parents, community members and other healthcare providers. It was mentioned that different reading levels might be needed in the materials. They spoke of its usefulness in health education and thought it enhanced the role of school nurse as health educator.

If you want to just pull paper, then it might be helpful to have two different reading levels, one your regular and one a little bit lower.

The education needs to put in perspective that it [HPV infection] really can happen to anybody, that it can hit close to home. They say if you've slept with someone, you've slept with everyone that person has slept with.

We are so busy that time is always a factor. Information they can take with them would be a benefit. After they've read it at home, they can come back and ask any questions they have.

The toolkit promotes HPV awareness.

Risks and benefits as well as effectiveness of the HPV vaccine were discussed by the group. Promotion of the vaccine as a cancer preventative and it not promoting sexual activity were also mentioned by multiple participants. The necessity of administration prior to sexual debut for optimum immunogenicity, use of media to spread the word and maximizing every opportunity to increase series completion were all factors of vaccine awareness thought to have importance.

It's got all the information needed to make a decision. If parents think 'My child would never do that until they're married' or whatever, we need to have the information available to be able to talk to them about possible consequences. Some kids that age think they're invincible.

Some people still perceive it as we're just opening the door for our kids to have sex. So it does have to be presented that we're trying to prevent cancer and this is the optimal time

to give the vaccine to prevent that. We are not by any means condoning. We are not saying ‘OK, you’ve had this shot so now you can go out and have sex and not worry about anything’. And we are just going to have to keep emphasizing the cancer preventative aspect of it.

The ideal time is during their 6th grade physical. That’s when you can really talk to them about it and present the information. And I think being able to give it in the school is wonderful. That’s what we need to do, because that’s where we have the kids. And it’s convenient for the parents.

When I offer the HPV information, I’d always let them know that I do have a teenage daughter and I did give her the vaccine. And a lot of time that gives them assurance ‘Oh, a nurse gave her child the vaccination. Then alright, my child can have it’.

The toolkit promotes vaccine acceptance.

School nurses in the focus group discussed that getting the vaccine at a nominal cost or free of charge would be important and that being able to get the vaccine while at school would provide welcomed convenience for the parents. It was felt that if people understood the importance of the vaccine along with the cost and convenience factors being non-issues, it would be accepted and utilized.

I think a lot of the community doesn’t know anything about it. If it’s not required they don’t want to get it. You know the cost, and taking the time for three different shots--- they just don’t look at the benefits. So I think if the community was more educated and aware of it, it would be better.

Discussion

Many comments were made regarding the user-friendliness of the toolkit for the diverse groups it was designed to serve. The toolkit was referred to as “handy”, “time-saving” and “good for answering questions without needing to use the internet”. Participants described the toolkit as useful in providing the nurse with relevant and timely knowledge about HPV, thus enhancing her stature as the school health expert. Providing the vaccine free-of-charge and in a nasal administration option were also discussed as increasing attractiveness and marketability of the vaccine.

Regarding the appropriateness of the toolkit, the consensus was that it pertained to people of a variety of ages and reading levels. The majority thought that materials designed for youths could be utilized for parents as well, in cases where there was a problem with understanding the vocabulary. The ability to copy information from the toolkit to send home or for anyone requesting information was positively received.

It was suggested that more pictures of genital warts would be useful in presenting consequences of sexual activity for older adolescents, but that graphic photos would not be appropriate for younger audiences. It was also discussed that the toolkit would be helpful to use as part of a comprehensive sex education course for middle and high school youths.

Respondents suggested that the promotion of the HPV vaccine as a cancer deterrent and protection for the future would be the best approach for encouraging acceptance by diverse cultural and religious groups. Explaining vaccination of pre-teens before sexual debut as optimal for future vaccine effectiveness was encouraged. Not being perceived as condoning early sexual activity was also viewed as important.

Using the “Ask me about your CANCER shot” slogan was suggested as a good way to promote the vaccine. Offering the vaccine in conjunction with the 6th grade physical at school was thought to be important for the convenience of the parents as well as efficiency and greater vaccine uptake. The focus group nurses agreed that endorsement of the vaccine by healthcare providers, including themselves would be very productive.

The school nurses in the focus group welcomed the HPV toolkit as something that would enhance their practice and that they would be able to use in their daily routine to improve the health of their patients. All of the nurses interviewed agreed that directing their education efforts

to students, parents, communities and healthcare providers would optimize getting the word out and enhance vaccine uptake.

Feedback from focus group members confirmed past research that increasing knowledge, attention to values and beliefs, and cost-covering of vaccine would increase acceptance and uptake. Formative evaluation of the toolkit by additional focus groups of school nurses would give additional strength to these findings.

Phase 2 of this project has not been completed, but should include the incorporation of suggestions made by school nurses into the final version of the toolkit. Additional funding could be solicited to allow piloting of the toolkit in middle and high-schools in a select area. After piloting and subsequent summative evaluation, the author would like to offer the toolkit to an organization such as the National Association of School Nurses who could promote its wider distribution, use and evaluation.

Outcomes

Outcomes are results that can be affected by action as opposed to results that are beyond one's control (Omery, 2008). While clinical outcomes deal with the quality of the project, utilization outcomes deal with efficacy and financial outcomes deal with efficiency. Outcomes provide the metrics to determine the success of the project (Omery, 2008).

Clinical outcome.

An HPV vaccine toolkit will be made available to school nurses in Eastern Kentucky to use for educating adolescent females, parents, communities and healthcare providers.

Utilization outcome.

The HPV vaccine toolkit will be accepted and utilized by 5 school districts in Eastern

Kentucky resulting in the introduction of school-based HPV or adolescent vaccination programs in those districts.

Financial outcome.

The financial costs of the HPV vaccine toolkit will be neutral for the school health office.

Validation of the clinical outcome was begun, but will be completed in Phase 2 of the project by developing a list of middle-schools and high-schools in Eastern Kentucky which have school nurses and distributing a toolkit to each nurse interested in participating. The utilization outcome will be validated by comparing the number of toolkits distributed to the number of HPV programs actually begun. To validate measurement of the financial outcome, costs for vaccine promotion and administration at the participating school clinics before and after the advent of the HPV vaccine programming will be compared. Consideration will need to be given to any other possible unusual circumstances which could have a financial impact on the vaccine promotion and administration budget.

Evaluation

The goal and objectives of the project were met. Creation of the toolkit was completed as were all the steps included in making that a reality. A limitation of the study was that there was no opportunity to implement Phase 2 prior to the author's deadline for completing degree requirements. Phase 2 would be piloting of the toolkit in several school systems in Eastern Kentucky where HPV vaccine programs would be initiated by the nurses in those schools. Then summative evaluation of the toolkit in relation to success of the HPV vaccine programs, HPV vaccine uptake and cost of conducting the programs could be completed.

Another limitation of the project is that it would only involve school nurses and their schools in Eastern Kentucky. Its success or failure in this rural, geographically secluded, conservative area would not be generalizable to other areas of the state or country.

Qualitative research methods such as using a survey and focus group were appropriate to the task of determining the usefulness of the toolkit contents at effectively and persuasively communicating the intended messages. Focus groups can elicit richer data with the advantage of more in-depth discussion and consideration of the opinions of others. Seeking and incorporating input from school nurses who are part of the local culture and neighbors to its residents was an important factor in community acceptance of HPV vaccine programming.

One quality of a “Best Practice” in nursing is that it demonstrates professional development support for nurses (AACN, 2002). This project does that for school nurses. It equips them with new knowledge and confidence to become the health expert and champion on immunization. By having a toolkit to utilize and rely upon they are armed with information needed to be partners in advancing HPV-related disease prevention.

Once school nurses catch the excitement of impacting disease prevention in this way, they may decide to advocate for adolescent vaccine mandates. As mandating has helped reach herd immunity levels for immunizations in younger children, so it can for adolescents. Mandating does not need to be viewed negatively. As with younger children, parents can opt-out. However, the advantages of cost shifting to state and federal programs is immensely important in eliminating racial and economic disparities in obtaining recommended vaccination.

Reflections on the Process

Initiation of a project involving creation of an evidence-based product and planning a program for implementation were new and challenging activities for the author. The process was

certainly more complex than imagined and took longer than expected. Comprehensive literature reviews, navigating the IRB process, survey development and focus group planning were all very interesting, informative and sometimes problematic experiences. Much respect was gained for scientific inquiry and research.

Looking at all the things which needed consideration for a clinical project to be completed was enlightening and exhaustive. Involvement with the content expert/mentor enabled the author to complete her first experience with writing an article for publication. Due to the pleasure of that experience, the author will consider writing additional articles for publication in the future.

Completion of this project also introduced the author to other new experiences including 2 poster presentations at professional conferences and interaction with other nurses and healthcare professionals interested in the HPV vaccine and adolescent immunization. As expected, but never before fully appreciated, completing a doctor in nursing practice capstone project expanded the author's world and increased her love for the profession of nursing.

Conclusions

Most people would agree that if there were a vaccine to prevent cancer, this would be a desirable vaccine to use. The human papillomavirus is contracted by many females and males in their teens and twenties and can lead to the development of anogenital and oral cancers years after the initial exposure. In the process of getting the HPV vaccine to those who are susceptible, a healthcare provider may encounter pitfalls such as a parent not wanting to think about their child having sex. When emotion interferes with reason, it takes leadership to navigate the road to the best outcome for all involved. By educating with evidence, the school nurse is in a position to share with various stakeholders the information which can prevent several types of cancer.

In *The Fifth Discipline*, P.M. Senge (1990) states, “Only by changing how we interact can shared visions, shared understandings and new capacities for coordinated actions be established”. The purpose of this clinical project was to provide school nurses with the tools needed to promote the human papillomavirus vaccine to students, parents, community leaders and other healthcare providers. In order to achieve vaccine acceptance and uptake, the hurdles of educating about the relationship of HPV to cancer and the importance of vaccinating before sexual debut must be conquered. This is no small task. Education is crucial to vaccine acceptance. In a *Harvard Business Review* article, V.U. Druskat (2001) discusses the achievement of group emotional intelligence by confronting positively, caring genuinely, acknowledging negative emotions and creating an affirmative environment. These skills, along with evidence-based education will facilitate vaccine utilization and HPV cancer prevention. It is the responsibility of the school nurse and other adolescent healthcare providers to get the word and the vaccine out. The gift this vaccine imparts to public health is ours to carefully and caringly impart to others.

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Acknowledgements

Today, as I write this, I think about the youngest of my 3 daughters turning 21 this month---a milestone. She, unlike her mother, has grown up in an era when the pitfalls of sexual relationships have always made their way to the forefront of a growing girl's consciousness. I have spent many years of my life as a nurse practitioner working with young girls like her and wishing there was a way to prevent one of those pitfalls, cervical cancer. Now there is a vaccine to help with that prevention process and I believe in its value. So, my first thanks go to the researchers who have developed the vaccine and dedicated their lives to seeing that it became available.

My path to completing a doctoral degree has been long and sometimes arduous, but nevertheless, worthwhile and rewarding. I would not have persisted if not for the support of some very special people who helped me along the way. I would like to thank Dr. Pat Howard who has believed in me and encouraged me; Dr. Debra Anderson for her guidance and confidence that I would finish the work; Dr. Rose Mays for devoting her research to STD vaccine acceptance and facilitating my first publication effort, Dr. Sharon Lock for her calming way of sharing her expertise and friendship; the health department personnel and school nurses with whom I look forward to spending time each day in the clinical arena and last but certainly not least, my wonderful husband, Rev. Mark Kloha, and daughters Rachel, Rebecca and Ruth, who have given my life meaning and always told me "You can do it!".

Table 1

Electronic Mail Survey to Middle and High School Nurses

Dear Colleague,

My name is Nancy Kloha. I am School Nurse Practitioner in an Eastern Kentucky high school. I am also working on my Doctorate of Nursing Practice (DNP) degree through the University of Kentucky. As my DNP capstone project, I am developing an evidence-based toolkit for school nurses to use in educating adolescents, parents, teachers and communities about human papillomavirus (HPV), its relationship to cervical cancer and the HPV vaccine. This project is being financially supported by the Nurse Practitioner Healthcare Foundation/Sanofi- Pasteur "Health Through Immunizations" Award Program.

The purpose of this e-mail is to ask you to respond to the following short survey about the toolkit for HPV vaccination of female adolescents. Your participation is voluntary and there is no penalty for nonparticipation. All responses will be confidential. Your identity will be known only to me. When I receive your returned survey, I will copy and paste your responses into another document and delete your email.

HUMAN PAPILOMAVIRUS TOOLKIT SURVEY

A toolkit is a set of materials (brochures, letters, posters, PowerPoint presentations, etc.) that help to administer a particular program. Examples of items which may be included in a toolkit include, but are not limited to:

- Information about the at-risk population and problem
- National recommendations and guidelines
- Educational materials for health care providers
- Educational materials for adolescents, their parents, and teachers
- Educational materials for the community
- Vaccine information

Please enter your responses to the following questions by January 30, 2009.

1. How have toolkits helped your practice in the past?
2. What information would you find helpful to include in an HPV vaccine toolkit?
3. What kind of educational programming (i.e. printed materials, PowerPoint presentations, face-to-face discussion with audiovisual aids, etc.) do you prefer?
4. What kind of toolkit format (i.e. brochures, DVDs, letters, posters, etc.) would you find most useful?
5. In what way do you see the toolkit being most utilized?
6. What is the best way to distribute the toolkit?
7. Please describe the best way to implement use of the toolkit.

Thank you for taking the time to answer this survey. If you have questions about this project or your rights as a participant, please feel free to contact me.

If you do not wish to participate, please do not respond to this email.

Nancy Kloha RN, FNP-BC, DNP Student
UK College of Nursing: nrkloh0@uky.edu

Table 2

Proposed Timeline for HPV Project Completion

2008-2009 Academic Year

ACTIVITIES	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
IRB process												
Communicate with stakeholders												
Research toolkit contents												
Teamwork on toolkit contents												
Distribution of toolkits												
MILESTONES												
IRB Approval				X								
Prototype ready									X			
Toolkits delivered											X	

Table 3

Actual Timeline for HPV Project Completion

May, 2008 – December, 2010

ACTIVITIES	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D				
IRB process	█	█	█	█	█	█	█	█	█																											
Survey School nurses									█	█																										
Research toolkit contents											█	█	█																							
Work on toolkit contents																█	█	█																		
IRB Approval									█																											
Proto-type ready																					█															
Focus Group																						█														
Focus Group Analysis																										█	█									
Writing Report																																	█	█	█	█

Table 4

Risk/Response Chart

Number	Risk Description	Probability	Impact	Response
1.	Gardasil or Cevarix vaccine pulled from market	2	3	Avoid -other HPV vaccine is available if one is pulled.
2.	Loss of sponsor or team member	2	2	Mitigate -find other funding source.
3.	Support for project withdrawn by health department	3	2	Transfer - find another health department to support project

Table 5

HPV Toolkit Development and Distribution Budget

Item	Amount	Justification
Salaries		
1. Project Manager (120 hrs x \$30/hr)	\$3600*	8 hrs/wk for 15 weeks to work on development/implementation
2. Administrative Asst. (125 hrs x \$12/hr)	\$1500	Assistance with toolkit content development
Materials/Supplies/Services		
1. Toolkit containers, dividers, CDs document covers, paper, flip-charts	\$200	For toolkit construction
2. Brochures	No cost from CDC	For inclusion in toolkits, etc.
3. Posters	Free from CDC	
4. Breakfast for Focus Group	\$100	Refreshments due to travel time
5. Conference Expenses	\$1500	Poster presentation-Chicago
6. Remote Wireless Hook-up	\$150	For internet during development
7. Incidentals	\$50	Unrecorded
TOTAL	\$3500	

*done by author without payment

Table 6

Focus Group Questions

- Have you ever used a toolkit in the school setting to educate students, parents and the community?
 - Was it effective? Why or why not?
- Do you see this toolkit being helpful to you and your practice?
 - If so, in what ways do you see it being helpful?
 - If not, why would it not be helpful?
- Why will the information provided be perceived as needed or not needed?
 - Is there anything that you would like to see added to the toolkit from a school nurse perspective?
 - From a parent's perspective?
 - From a community member's perspective?
- What do you like/dislike about the toolkit?
 - How do you feel about the education level of the toolkit's contents? Is it understandable?
 - Is there anything about one of the existing pieces of the toolkit that you would like to change?
 - Do you feel like anything should be added or removed from the toolkit?
- How do you think the toolkit will be received by the school board and/or faculty members?
 - Is there anything in the toolkit that you feel is controversial?
- Please share your thoughts regarding the goals and intended outcomes of the HPV education program in schools.
 - Do you feel as if this toolkit is an effective way of approaching HPV vaccine acceptance in a school setting?
 - If there is anything that you would do differently, what would it be?
- What else would help to facilitate better uptake of the HPV vaccine?