HPV Vaccination Policy Mandate

Final Research Report

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Abstract

**Purpose:** To review the benefits and risks of vaccinations against the Human Papillomavirus (HPV) and examine whether policies mandating the HPV vaccine as a school entry requirement is prudent, ethical, and justifiable, considering as a raison d'être an ethical vaccine mandate affords a public health benefit which justifies overriding individual liberties and choice.

**Background:** The Human papillomavirus (HPVs) infects human epithelial cells of the skin and mucous membranes. HPVs have been implicated in genital warts and high-risk genital HPV infections, in an estimated 6.2 million people yearly in persons aged 14 to 44 years, and it has been linked to 70% of invasive cervical cancer cases globally. An estimated 20 million people in the United States are infected with the highest rates among young women 15 to 25 years. Two vaccines Gardasil (HPV4), and Cervarix (HPV2) have been developed to offer protection against and prevent the development of certain types of HPV associated diseases. States have proposed HPV related legislation mandating the administration of the vaccine.

**Methods:** A systematic review of published journal reports was performed to identify pertinent studies related to the value and risks of vaccinations against HPV as assessed against evidence from random controlled investigations.

**Results:** Evidence from 15 Randomized Control Trial investigations persuasively suggest a prophylactic vaccine against the most common HPV types could substantially reduce the burden of HPV-related cervical diseases. The two HPV vaccines, developed thus far, have been shown to be safe, and appear to be highly efficacious in preventing persistent infection and cervical diseases associated with vaccine HPV types among young female adults.

**Policy Implications:** As the HPV disease is a sexually transmitted infection, the simple act of mandating the HPV vaccine for all individuals at a specific chronological age—without consideration for their choice to abstain from sexual activity until marriage, appears illogical and antithetical to the principles of justice. While mandating vaccination for school entry for a disease which can be transmitted by the respiratory route or casual contact is logical, a mandate for vaccination against sexually transmitted infections for school entry is problematic and analogies cannot be supported between the HPV vaccine and routine childhood diseases which are transmitted by the airborne or casual contact route. To directly force individuals who exercise or plan a life of sexual abstinence, to receive the HPV vaccine is not only a violation of the principles of justice, but, also a violation of the principle of autonomy.

**Conclusions:** Given concerns for autonomy and justice, as not all persons are at risk for HPV, a State mandated HPV vaccination program and school-based HPV vaccine mandates are not the optimal legislative solution; and as a consequence, the HPV vaccine should not be mandated for school or college entry. It would seem much more prudent to take a deliberative approach and view routine, voluntary HPV vaccinations as part of a comprehensive package for preventing sexually transmitted infections and cervical cancer.
Purpose

To review the benefits and risks of vaccinations against the Human Papillomavirus (HPV) and examine whether policies mandating the HPV vaccine as a school entry requirement is prudent, ethical and justifiable, considering as a raison d'être an ethical vaccine mandate affords a public health benefit which justifies overriding individual liberties and choice.

Background

The Human papillomavirus (HPVs), is a double-stranded DNA virus of the Papovaviridae virus family with over 100 different types, many of which infect human epithelial cells of the skin and mucous membranes [1,2]. HPVs are characterized according to the anatomic areas they infect, and are generally numbered in order of discovery [1]. Ordinary skin warts (papillomas), which are common among the general population and frequently found in children, are caused by HPV1 and HPV2 [3]. HPV6 and 11 and HPV16, 18, 33, and 65 have been implicated in genital warts and high-risk genital HPV infections, respectively, in an estimated 6.2 million people yearly in persons aged 14 to 44 years, and 74 percent among individuals between 15 and 24 years [4]. Moreover, HPV 16 and 18 have been linked to 70% of invasive cervical cancer cases globally, with HPV 16 being the most common type detected in 55% of cases; followed by HPV 18, in 15% of cases [5,6].

The transmission of most HPV infections is characteristically horizontal via direct contact. Genital HPV is normally transmitted via penetrative (vaginal or anal) and non-penetrative (oral-genital and hand to genital) sexual intercourse [6]. While vertical transmission from mother to infant is somewhat atypical, evidence suggests it can contribute to considerable respiratory papillomatosis (laryngotracheal papillomatosis) related morbidity [7]. Worldwide, HPV is
believed to be the most common sexually transmitted infection [8]. Estimates suggest over 6 million people are infected with genital HPV each year in the United States, alone [4]. Three is evidence suggesting at least half of all sexually active men and women acquire HPV at some point in their lifetime, and about 80% of sexually active women will have become infected by age 50 [9].

Reports show an estimated 20 million people in the United States, approximately 15% of the population, are infected as detected by HPV DNA assays [10,11]. The highest infection rates are among young women 15 to 25 years, with point prevalence estimates in this age group ranging from 27% to 46% [12,13,14]. A U.S. Centers for Disease Control and prevention (CDC) report indicated nearly a quarter of females aged 15 to 19 years and 45 percent of those aged 20 to 24, had an HPV infection during 2003-2004 [15]. Among females aged 14 to 24, the overall prevalence of HPV was 34 percent, representing approximately 7.5 million females with HPV in the U.S., a statistic higher than the previous estimate of 4.6 million prevalent HPV infections among females 14 to 24 in the U.S. [16]. A 2009 New England Journal of Medicine report suggested sociological and biological factors predispose adolescents and young adults to a much greater risk of contracting HPV than any other segment of the population [17]. From a sociological perspective, adolescents and young adults are more likely to have unprotected sexual intercourse, to have multiple partners, to be infected with other Sexually Transmitted Infections, to engage in substance abuse, to use oral contraceptives, to have inadequate access to medical care, and to lack knowledge of safe sex practices [17]. In considering the biological contribution, Goldstein et al. (2009) posits, young women produce less cervical mucus, and are
much more inclined to endure local tissue tearing during intercourse than older women, both significant contributors which encourage the HPV infection [17].

HPV infection is often asymptomatic and transient--usually persisting between 4 and 20 months in healthy individuals [18]. HPV16 and 18, the high-risk HPVs which convey the greatest risk of persistent infection constitute the most important risk factor for invasive cervical cancer [5]. Cervical cancer, the second most common cancer in women worldwide, ranks seventh amongst the most common forms of cancer amid women living in developed countries [19,20]. In the United States, cervical cancer is not listed in the top ten of most common cancers among women [19,20]. It is noteworthy to mention, the cervical cancer morbidity and mortality for women in the U.S. is currently 8.9 per 100,000, and 2.7 per 100,000, respectively [19]. Estimates suggest each year in the United States, 10,800 new cases of HPV-associated cervical cancer are diagnosed and 4,100 women die from cervical cancer [21]. Semi-annual Pap tests for the papillomavirus, and subsequent follow up for abnormal findings are reputed to have reduced the burden of cervical cancer in developed countries [19].

Despite the success of regular screening, there are significant racial, ethnic, and geographical disparities in the morbidity and mortality of cervical cancer among American women [19]. The morbidity and mortality are significantly higher among African American and Hispanic women when compared to their white, non-Hispanic cohorts [19]. Cervical cancer is the eighth most common and tenth most deadly cancer among African American women, and the seventh most common and tenth most deadly cancer among Hispanic women in the United States [22]. In addition, cervical cancer mortality is apparently higher among women living in Southern States than those living in the Northeast [19]. According to Watson et al. (2008),
these disparities may be attributable to lower rates of Pap Smear screening and follow up for cervical lesions or abnormal test results. Although cervical cancer is the most common HPV-associated cancer, HPV can also cause cancer of the anus, vagina, vulva, penis, tongue, and throat [6]. There is evidence which suggests HPV is responsible for approximately 85% of anal cancers (incidence rate of < 2/100,000 people), 70% of vaginal cancers (vaginal cancers have an incidence of < 1/100,000 women), 40% of vulvar cancers (vulvar cancers have an incidence of < 2/100,000 women), and 40% of penile cancers (incidence of < 1/100,000 men) [21]. However, the incidences of these HPV-associated cancers are pale and insipid in stark comparison to the incidence of HPV related cervical cancers.

Two virus-like particle vaccines Gardasil (HPV4) (by Merck & Co., Inc.), and Cervarix (HPV2) (by GlaxoSmithKline Biologicals) have been developed to offer protection against and prevent the development of certain types of HPV associated diseases. These vaccines are particles which present themselves to the human immune system as being characteristically analogous to the real virus, but they do not contain the viral genome [23]. The HPV vaccine is a virus-like particle vaccine with the capacity to personate the constructed shape of the HPV capsid, which is formed by repeating units of L1--the capsid protein which encases the viral genome [23,24]. The Gardasil and Cervarix vaccines have been reported to be safe and effective [24], and they have both had few safety issues during any of the trials [25].

In 2007, Texas (by an Executive Order on 2 February) and Virginia (by Virginia State Legislature vaccine requirement) made quadrivalent HPV vaccine mandatory for girls entering the sixth grade [26]. However, on 8 May 2007, the Texas legislature voted to overturn the governor’s order and Virginia granted parents generous “opt-out” provisions [26]. In January
2012, the Virginia Legislature voted on the passage of a House Bill to eliminate the requirement for vaccination against human papillomavirus for female children [27]. The House Bill remains with the House Education and Health Committee for review and adjudication. As of January 2012, 8 States have proposed HPV related legislation for the 2011-2012 sessions [27].

While there are legal and legislative precedents for vaccine mandates and exemptions to these vaccine mandates, it is interesting to question whether these policy mandates are sound and ethical. Since HPV is a Sexually Transmitted Infection, habitually associated with lifestyle choices, scientific policy issues may differ from those for vaccines against diseases without a specific behavioral risk or those which are highly communicable by the respiratory route. Accordingly, this report sought to review the body of literature pertaining to the benefits and risks of vaccinations against the Human Papillomavirus (HPV) and provide an analysis of HPV vaccine policy issues. This paper posits HPV vaccine mandates may afford a public health benefit by advancing vaccine coverage, but it lacks evidence to justify overriding individual liberties and choice for the sake of public well-being, safety, and health security.

Methodology

Search Strategy

A computerized systematic review of published journal reports was performed to identify pertinent studies related to the value and risks of vaccinations against HPV as assessed against evidence from random controlled investigations. A database-specific Boolean query was constructed to examine the body of literature and determine what is known about this topic. The emphasis of the query was primarily on Randomized Controlled Trials and meta-analyses. A Medical Subject Heading (MeSH) terms keyword search was performed in
PUBMED—a U.S. National Institute of Health database, which affords access to and catalogs all MEDLINE records and abstracts, and provides various full-text documents; EMBASE; and Google Scholar. The database search was employed utilizing the MeSH key word terms “Human,” “Papillomavirus,” “Vaccine,” “Randomized,” “Controlled,” and “Trial.” The specific Boolean query procedure employed for this search was applied as follows:\(\text{Human Papillomavirus OR HPV} \land \text{Vaccine} \land (\text{randomized or controlled}) \land \text{trial}\).

**Study Selection**

Studies obtained from the computerized search of the literature were examined by title and citation. During the initial review phase, article titles were scanned for relevance and appropriateness. Articles which appeared relevant were nominated for the second phase of the review process. During the course of this phase, the abstract of the designated articles were analyzed to determine their level of significance and suitability. Relevant abstracts were subsequently selected for a full text examination and prospective data extraction. Articles were included in the selection for consideration, if they were: written in English; an original empirical Random Control Trial or meta-analysis; published in a peer-reviewed journal; comparing the effectiveness of the HPV vaccine among a placebo or a no HPV vaccination group; a study intervention which included any vaccine against HPV with a prophylactic intent; and an empirical study involving women, with no exclusion on the basis of age, or other demographic characteristic. Studies were not excluded on the basis of their dosage regimen. Trials reporting male vaccination or therapeutic vaccination were excluded. Reports identified as review articles, commentaries, and observational studies were excluded from selection. Studies not designed to address outcomes related to vaccine efficacy against HPV strains were also
excluded. In addition, study trials with a population sample size totaling less than five were also barred from qualification. No publication date restrictions were applied to the article search tactic.

Results

Four hundred fifty title citations from the initial electronic database search were identified for this review. Eighty five duplicate records were removed from the search results. An aggregate of 365 potentially relevant titles and abstracts were extracted from the electronic body of the on-line literature, for a detailed analysis. Of these, 165 articles were identified for full-text review on the basis of the inclusion criteria. During the full-text analysis of the 165 articles, 151 studies were excluded from the detailed review process. Sixty were omitted based on study design as they were review articles addressing HPV vaccines and clinical trials; 40 studies were excluded as they analyzed HPV infections; 15 examined the HPV vaccines for its use therapeutically; 30 were eliminated because they investigated HPV vaccine immunogenicity; and 6 were studies including men. The remaining 14 articles fulfilled the stated criteria.

Figure 1 provides and displays a graphic illustration of the number of publications subjected to the comprehensive analysis in the search and review of the body of literature for evidence pertinent to the value and risks of vaccinations against HPV. The result of the search and the data provided in the Randomized Control Trial studies formed the evidence demonstrating a strong relationship between the risks and benefits of vaccinations against HPV.

Evidence from the Randomized Control Trial investigations [28-41] persuasively suggest a prophylactic vaccine against the most common HPV types could substantially reduce the burden of HPV-related cervical diseases. The two different types of HPV vaccines, developed
thus far, have been shown to be safe, and appear to be highly efficacious in preventing
persistent infection and cervical diseases associated with vaccine HPV types among young
female adults. Vaccination appeared to be well tolerated \[28-41\] with an apparent effective
public health measure for the prevention of cervical diseases and cancer. Accordingly,
conclusions regarding the prevention of early events in the natural progression of HPV-related
disease are somewhat robust.

**Figure 1.** Search strategy and results.

**Discussion**
The Food and Drug Administration (FDA) licensed Gardasil (HPV4), in 2006, to protect girls and women ages 9 through 26 against angogenital warts and cancers (vulvar, vaginal, cervical, and anal) caused by HPV6, 11, 16, and 18 \[^{[42]}\]. According to the U. S. Centers for Disease Control and prevention (2007), each 0.5 mL dose contains 20 μg each of HPV 6 and HPV 18 L1 protein and 40 μg each of HPV 11 and HPV 16 L1 protein \[^{[42]}\]. It also contains 225 μg of adjuvant (amorphous aluminum hydroxyphosphate sulfate), sodium chloride, L-histidine, polysorbate 80, sodium borate, and water \[^{[42]}\].

In 2009, Gardasil was also approved for use in males aged 9–26 years for the prevention of anal cancer and genital warts \[^{[43]}\]. But, the Advisory Committee on Immunization Practices (ACIP) did not recommend routine vaccination in this population at that time \[^{[43]}\]. Last October however, ACIP recommended the routine use of Gardasil in males aged 11 or 12 years \[^{[44]}\]. It also suggested the HPV4 vaccine for males aged 13 through 21 years who have not previously been vaccinated or who have not completed the 3-dose series; and males aged 22 through 26 years \[^{[44]}\].

The bivalent vaccine, Cervarix (HPV2), was also licensed in 2009 by the FDA to protect girls and women age 10 through 25 against HPV 16 and 18 \[^{[24]}\]. Each dose of Cervarix is 0.5 mL and contains 20 μg each of HPV 16 and HPV 18 as well as 500 μg of adjuvant (aluminum hydroxide, 50 μg of 3-O-desacyl-4’monophosphoryl lipid A), sodium chloride, sodium dihydrogen phosphate dehydrate, and water \[^{[24]}\]. According to the U. S. Centers for Disease Control and prevention, both Gardasil and Cervarix are recommended in a three-dose series of intramuscular inoculations with the second and third dose administered 2 and 6 months after the first dose\[^{[24]}\]. Both vaccines are reputed to offer protect against 70 percent of HPV16 and
18 associated cancers, with Gardasil providing an additional protection against 80 to 90 percent of genital wart–causing HPV infections [24].

In addition to the aforementioned efficacy of the vaccines, both Gardasil and Cervarix have had few safety issues during any of the trials [25]. According to an investigation conducted by Villa et al, injection site adverse experiences were reported in 83% of the Gardasil recipients and in 73.4% of the placebo recipients who participated in the Phase IIb randomized controlled trial [25]. The most common injection site experiences were erythema, pain, and swelling, with severe intensity being reported more often in the vaccine recipients; and the most common systemic adverse experiences, which were reported by a similar proportion of vaccine and placebo recipients (69%), were fever, headache, and nausea [25]. Overall, 11.4% of the vaccine recipients and 9.6% of the placebo recipients had a temperature of ≥100°F (≥37.8°C) [25]. Higher temperatures of ≥102°F (≥38.9°C) were recorded in only 1.5% of the vaccine and in 1.1% of the placebo recipients [25]. There were no deaths in the trial considered to be secondary to vaccine or procedure. Five vaccine and two placebo recipients had serious vaccine-related experiences [25]. Vaccine-related serious adverse experiences included one case of bronchospasm and one case of gastroenteritis (possibly related to a study procedure), one case of headache with hypertension (definitely related), one case of injection site pain with injection site joint movement impairment (probably related), and one case of vaginal hemorrhage (probably related) [25]. The placebo serious adverse experiences included one case of hypersensitivity and one case of chills with headache and fever, and only 0.2% of the subjects discontinued due to an adverse experience in both vaccine and placebo groups [25].
Vaccination is among one the greatest achievements of modern medicine. Vaccines can prevent or ameliorate the effects of infection caused by many pathogens as evidenced by the eradication of smallpox; the elimination of poliomyelitis in the Western Hemisphere; and the dramatic reduction of morbidity and mortality from diseases like diphtheria, pertussis, tetanus, measles, mumps, rubella, and polio [45].

For more than a century, States have mandated the use of vaccines as a public health and safety protection measure [46]. Court decisions at the Federal and State levels of government have sustained the right of the State to require vaccinations [47]. Landmark court decisions regarding vaccine mandates include Jacobson v Massachusetts (1905)[48] and Zucht v King (1922) [49]. The Jacobson v Massachusetts Case established the power of the State to implement vaccine mandates and override the autonomy of the individual in order to benefit the community, fundamentally supporting Mill’s harm principle, which advocates for each citizen to exercise their own rights to the extent they do not infringe upon the rights of others or cause harm to others [50]. The Zucht v King Case extended the Jacobson decision to give the State the power to compel parents to have their children vaccinated in order to enter school [49].

Jacobson v Massachusetts was focused on the case of Henning Jacobson, a Swedish immigrant and Lutheran minister who lived in Cambridge Massachusetts, and refused to endure free vaccinations against smallpox, due to his belief God would protect him from the disease [48]. In addition to refusing to be vaccinated, Jacobson also refused to pay the $5.00 vaccine refusal fee assessed by the city of Boston. He was tried in the County District Court and found guilty, at which time Jacobson appealed to the County Superior Court, which affirmed the
lower court’s verdict [48]. Jacobson then took his case to the State Supreme Court, where his lawyer argued compelling Jacobson to undergo vaccination against his will, was a violation of his religious beliefs [48]. The State Supreme Court ruled in favor of the State and so Jacobson took his case to the US Supreme Court, where his lawyer argued compulsory vaccination was a violation of the Fourteenth Amendment, which “forbids states from denying any person ‘life, liberty or property, without due process of law’” [51]. After about two years of debate and deliberations, the court ruled States have a right to compel citizens to undergo vaccination. They concluded the States’ legal authority to require immunization rests on the States’ 10th amendment ‘police powers,’ and the inherent authority of a government to impose restrictions on private rights for the sake of public welfare, order, and security [47,52]. The constitutionality of police powers is based on evidence of four criteria: first, “there must be a public health necessity,” second, “there must be a reasonable relationship between the intervention and public health objective,” third, “the intervention must not be arbitrary or oppressive,” and four, “the intervention should not pose a health risk to its subject” [53]. Since Jacobson, States have mandated many vaccines based upon the police powers authority.

The role of public schools as an enforcement mechanism for vaccine mandates was challenged in 1922 when the Supreme Court decided Zucht v King [47,49]. A Texas ordinance required all school children to present a certificate of vaccination in order to enroll, and when the Zucht family refused to have their fifteen year old daughter Rosalyn vaccinated, her high school expelled her. Rosalyn’s parents sought legal recognition of their refusal to vaccinate their daughter, claiming her expulsion violated her constitutional rights, but the Court established “States may require parents to have their children vaccinated in order to promote
the best interests of the broader community”[47]. Although the United States Courts have upheld the authority of the States to mandate vaccinations, it is interesting to ponder the bioethical principles of beneficence, justice, and autonomy on a national policy mandate to vaccinate against HPV.

**Policy Implications and Ethical Considerations**

In considering the application of the principle of beneficence to the HPV policy mandate, the evidence is strong and plainspoken, as studies have shown the vaccine to be safe, and highly efficacious in preventing persistent infection and cervical diseases associated with vaccine HPV types among young female adults [28-41]. The principle of justice specifies equitable treatment [54]. Therefore, economic justice would warrant and dictate the vaccine to be available to all who need it. Accordingly, for the criteria of justice to be met, mandatory HPV vaccination policies would have to consider programs and statutes to guarantee coverage and availability of the vaccine to eligible age-appropriate individuals who are uninsured, underinsured, and those covered by Federal and State Medicare programs. Moreover, provisions would have to be made to require health insurance carriers to ensure coverage of the vaccine for eligible beneficiaries. Currently, policies and statues for these considerations are not emplaced, thus making the principle of justice unmet with existing HPV vaccination policy mandates. Furthermore, as the HPV disease is a sexually transmitted infection, the mere act of mandating the HPV vaccine for all individuals at a specific chronological age--without consideration for their choice to abstain from sexual activity until marriage, appears illogical and antithetical to the principles of justice. Correspondingly, to directly force individuals who
exercise or plan a life of sexual abstinence, to receive the HPV vaccine is not only a violation of the principles of justice, but, also a violation of the principle of autonomy.

The principles of autonomy suggest individuals should be able to make their own choices and decisions [54]. Innately, to be autonomous requires a person to have the capacity to deliberate a course of action free from the control of others, and to put their plan into some executable action [54]. Simply stated, individuals should have the authority for their own actions; and in the case of individuals under the legal age, their parents or legal guardian should be afforded the autonomy to make the appropriate decisions. Accordingly, freedom of choice should be considered and endorsed. This is especially significant in the HPV vaccine debate considering the potential vaccine recipient is primarily at greatest risk from lifestyle choices.

In the United States, individuals have an ostensible right to autonomy which should not be infringed upon without due cause or appropriate justification. Historically, the United States Courts have sustained and declared prima facie rights should only be overridden under circumstances which present unjustifiable harm to others [47,52]. A risk of unjustifiable harm to others may include exposure to those individuals who have not been vaccinated against infectious diseases which pose a threat to public health because they are casually communicable, highly infectious, and imminently dangerous. These include, but are not limited to, vaccine preventable diseases, such as, measles; mumps; rubella; diphtheria; tetanus; pertussis; Hib; and polio. Failure to inoculate a child against these highly infectious and imminently dangerous vaccine preventable diseases would constitute an unjustifiable risk of harm. For these vaccines, a public health necessity is present. Accordingly, the United States Courts have upheld it is thus justifiable to override parental autonomy by mandating these
vaccines to protect children and the public from serious infectious diseases. As the threat of these diseases constitute public health necessities, broad opt-outs considerations for these vaccines which would allow parents to refuse them for any reason, would not be appropriate and revoking the social right of attending a public school in those cases of non-compliance would certainly be justifiable.

There are at least two key characteristics of the HPV vaccine which make it significantly different from the other vaccines which have been mandated for children entering school in this country. First, HPV does not pose an imminent risk of danger, it protects against cancer which may or may not develop as a cancerous malady. And, second, the risk of developing cervical cancer, a substantial harm, from HPV infection is quite low. The chances of developing cervical cancer–if one contracts HPV, are smaller than the chances of developing the disease and sequelae if one contracts other infectious diseases, such as measles or pertussis, for which vaccine mandates are in place. Children should not be kept out of public school because of their HPV immunization status, since being unvaccinated against HPV does not pose any risk of imminent danger to other students.

The HPV vaccine does not present a risk of harm significant enough to justify overriding parental autonomy. For these reasons, HPV does not present a public health necessity and accordingly, States should not mandate the HPV vaccine.

**Conclusion**

HPV does not pose a public health threat which is as serious as measles or any of the other aforementioned casually communicable diseases. HPV is not a highly infectious airborne disease, which is the paradigm for the exercise of compulsory vaccination. There is no
immediate risk of rapid transmission of HPV in schools, as is the case, for example, with measles. HPV is primarily transmitted by sexual contact and lifestyle choices and behavioral decisions are often involved.

Unquestionably, public health functions include the control of sexually transmitted infections. While mandating vaccination for school entry for a disease which can be transmitted by the respiratory route or casual contact is logical, a mandate for vaccination against sexually transmitted infections for school entry is problematic and analogies cannot be supported between the HPV vaccine and routine childhood diseases which are transmitted by the airborne or casual contact route.

Given concerns for autonomy and justice, as not all persons are at risk, a State mandated HPV vaccination program and school-based HPV vaccine mandates are not the optimal legislative solution; and as a consequence, the HPV vaccine should not be mandated for school or college entry. Therefore, it would seem much more prudent to take a deliberative approach and view routine, voluntary HPV vaccinations as part of a comprehensive package for preventing sexually transmitted infections and cervical cancer. A systematic approach to prevention would include promoting reduced sexual activity and safe sex, cervical cancer screenings, and encouraging education about HPV and cervical cancer among schoolchildren and the general public. Interventions would be particularly important among the disenfranchised and those who have a disproportionate burden of cervical cancer.

The goal of public health policy is to improve the Nation’s health for the betterment of society. When considering mandatory public health interventions, bioethics should guide and
inform the decision-making process concerning the morality of proposed mandates which would override individual liberties and freedom of choice.

**Limitations and Bias Considerations**

The results of this qualitative analysis have a number of restrictions which require an examination of the findings with an understanding of these limitations. First, the external validity of the Randomized Control Trial investigations [28-41] relates to the women included in the studies, which were young (mostly 15–25 years of age), were mostly white, were frequently from developed nations and were mainly otherwise healthy. Undeniably, the subject participants were recruited primarily from colleges and universities. Thus, further research is needed to demonstrate efficacy in more representative populations of women. Second, the pooled efficacy results presented in the Randomized Control Trial investigations were most likely derived from susceptible young females with limited sexual exposure to HPV, therefore, they may not be applicable to more mature, sexually active female populations who may already have been exposed to one or more vaccine HPV types. Third, this analysis did not address males due to the paucity of vaccine efficacy data for male subjects. Fourth, this report also did not address cost effectiveness because research on the duration of immunity for the HPV vaccine is unknown, which could affect the need for booster doses, if any; and ultimately, cost effectiveness. Fifth, I employed established literature search methods developed for systematic reviews of qualitative studies, to maximize the prospect of identifying all relevant articles and reduce bias in the identification of these investigations. However, the strategy is not absolute and susceptible to imprecision. This inexactness is due in large part to the subjective nature of the methodology in identifying themes from titles and text descriptions,
and does not eliminate the potential for bias. Sixth, my analysis was based upon studies published in the English language only. Thus, relevant studies published in languages other than English and associated with vaccinating against HPV were not included in this review. In searching the literature, I did consider the significance of relevant operational research and its contribution to the formation of national policy in local languages. However, research funding and translation services were not readily available resources to support this qualitative review. Finally, the heterogeneity of the included investigations examined in this qualitative analysis makes it difficult to generalize findings.
References


