Ethical analysis of HPV vaccine policy options

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Received 22 December 2005; received in revised form 17 February 2006; accepted 3 March 2006
Available online 23 March 2006

Abstract

Vaccines against human papillomavirus (HPV) may soon be licensed. In contrast to most vaccine-preventable diseases, which are transmitted by air or casual contact, HPV is primarily transmitted by sexual contact. An analysis that applies ethical theories, such as utilitarianism, rule of double effect, and principlism, is needed for policy considerations. These analyses reveal that HPV vaccination can be recommended universally, including at ages 11–12 years. However, given concerns for autonomy, justice, as not all persons are at risk, and non-maleficence, HPV vaccine should not be mandated for school entry. Economic justice indicates a need to provide vaccination for the disadvantaged.

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Keywords: Ethical analysis; HPV; HPV vaccine

1. Introduction

Human papillomavirus (HPV), the primary cause of cervical cancer, is acquired primarily by sexual contact with an infected person and is the most prevalent sexually transmitted infection (STI) in the United States. Infection usually occurs years to decades before the appearance of cervical cancer. The public is largely unaware of HPV, its mode of transmission, its role in cervical cancer, or the coming HPV vaccine. HPV vaccine, which has been shown to be highly effective against serotype specific infection and cervical intraepithelial neoplasia, has undergone Phase III testing, and awaits approval from the FDA. Because HPV is an STI that is often associated with lifestyle choices, scientific policy issues may differ from those for vaccines against diseases without a specific behavioral risk or that are highly communicable by the respiratory route (e.g., measles). Among all of the infectious agents against which widely accepted childhood and adult vaccines are available, only one other, hepatitis B, is primarily transmitted through sexual contact. This paper is an ethical analysis of HPV vaccine policy issues specific to females.

2. Cervical cancer

The 2005 American Cancer Society estimate for the number of new cervical cancer cases is 10,370 and the number of deaths is 3710 [1]. African American women suffer nearly twice the number of deaths as whites, with 5.7 deaths per 100,000 women, than white women, with 3.4 deaths per 100,000 [2]. According to SEER data, incidence rates per 100,000 women for cervical cancer are 2.6 for whites, 5.6 for blacks, 3.6 for Latinos, 2.8 for Native Americans, and 2.8 for Asian Americans [1]. The estimated lifetime cervical cancer risk is 3.67% and lifetime cervical cancer mortality risk is 1.26%, with a peak incidence of 81/100,000 at age 50 years [3]. The main cause of cervical cancer is HPV. Molecular studies show HPV DNA in virtually all (i.e., 99.7%) cervical
10th graders, 50% for 11th graders, and 60% for 12th graders in 14–19-year olds. The percentage of females reporting ever 1 year and about 91% clear within 2 years [8,11], high-risk cancer. 2 or 3 cervical intraepithelial neoplasia (CIN) and cervical infection over a number of years to decades may lead to grade types are more persistent than low risk types. Persistent infection of other types of HPV, and increased rates of other STIs exposure by changes in sexual practices (e.g., life-long monogamy and use of condoms) and, starting perhaps in 2006, by vaccination. Secondary prevention efforts include cervical cytology screening for early stage detection, HPV screening, and removal of HPV-infected precancerous lesions by laser, cryosurgery, LEEP excision and cervical conization.

3. HPV epidemiology and natural history

HPV is a group of almost 200 viruses, 15 of which have been associated with cervical cancer, particularly types 16 and 18. The viral proteins that prolong cell replication (namely E6 and E7) promote genomic instability and progression to malignancy. Although cervical cancer is the primary malignancy from HPV, anal, vulvar, vaginal, penile and head and neck cancers are associated, albeit at lower levels, with HPV. Other types of mucosal and genital HPV, especially types 6 and 11, are associated with genital warts, low grade cervical disease, and laryngeal papillomas.

Exposure within a few years of sexual debut is common but not universal. In one study, 39% of female college students are infected with HPV by 24 months after sexual debut, rising to about 54% by 48 months [7]. The cumulative HPV incidence by type is 7–10.4% for type 16 and 4–4.1% for type 18 by 24 months among previously negative but sexually active college women [7,8]. The most common individual types for first HPV infection were 16, 56, and 6. Two other studies found a 43–44% cumulative HPV incidence by 36 months in women who were HPV-negative at baseline [8,9]. An estimated 80% of sexually active persons have been infected with at least one serotype by age 50 years. Non-penetrative sexual contact (e.g., finger-vulvar or oral-penile) is associated with an increased risk of HPV among virgins [7]. Smoking, oral contraceptive use, higher numbers of sexual partners, male partners with higher numbers of sexual partners, and knowing a partner for less than 8 months before intercourse are predictors of HPV infection [7]. HPV prevalence is highest in 14–19-year olds. The percentage of females reporting ever being sexually active by age are 29% for 9th graders, 39% for 10th graders, 50% for 11th graders, and 60% for 12th graders [10].

Most HPV infections are asymptomatic and transient. Although about 70% of new HPV infections clear within 1 year and about 91% clear within 2 years [8,11], high-risk types are more persistent than low risk types. Persistent infection over a number of years to decades may lead to grade 2 or 3 cervical intraepithelial neoplasia (CIN) and cervical cancer.

4. Human papilloma virus (HPV) vaccines

Development of immunogenicity to papillomavirus involves presentation of the L1 protein on the HPV viral capsid to the immune system. Empty viral capsids, called “virus-like particles” can be synthesized and are immunogenic. Two vaccine manufacturers have completed randomized controlled trials of their respective HPV vaccines. Both used a three-dose schedule of an initial dose, a 2nd dose 1 month later and a 3rd dose 6 months after the initial dose. The long-term (e.g., decade or more) protection afforded by vaccination is not yet known due to relatively recent development of the HPV vaccines.

The Merck, Inc. HPV-16 L1 virus-like vaccine was 100% efficacious with a 95% confidence interval of 90–100% among 2392 young women [12]. Vaccine side effects include pain at the injection site but no serious reactions have been found. Only 0.3% of both vaccine and placebo recipients discontinued the study due to an alleged vaccine side effect. The Merck, Inc. vaccine under review by the Food and Drug Administration contains antigens for types 16, 18, 6, and 11. A Phase II efficacy trial found that persistent infection or disease fell by 90% [13].

The GlaxoSmithKline HPV 16/18 vaccine is 95.1% efficacious against persistent infection and 92.9% efficacious against cytological abnormalities in a trial of 1113 women [14]. Vaccine side effects include pain at the injection site in 93% of vaccinees and 87% of placebo recipients but no difference in general symptoms (86% versus 86%) and no difference in serious reactions (4% versus 3.5%).

4.1. Benefits and potential harms of HPV vaccination

The benefits of vaccination include reduced HPV infection, reduced cervical cancer, possibly a reduced frequency for recommended cervical cytological testing, and, for the vaccine that contains antigens against HPV types 6 and 11, decreased genital warts. Other benefits are theoretical but include decreases in other cancers and, for the vaccine that contains antigens against HPV types 6 and 11, decreased laryngeal papillomas.

Potential harms include adverse reactions, hypothetical concerns about reductions in safer sex practices and screening for cervical cancer, and potential misconception that HPV vaccine would protect against other STIs. Although HPV vac-
cine has a low level of local reactions, widespread use might uncover a rare adverse reaction not previously seen. Due to perceived protection from vaccination, the potential exists for increased sexual activity among partners, increased numbers of partners, and decreased use of barrier protection methods. The possible results of such actions include increased unplanned pregnancies, increased abortions, increased rates of other types of HPV, and increased rates of other STIs including HIV. A modeling analysis by Blower and McLean based on data from San Francisco Young Mens Health Study about HIV vaccine use found that if risk behavior increases...
as the result of an HIV vaccination campaign, then “vaccination could result in a perverse outcome by increasing the severity of the epidemic” [15]. Of course, there are many differences between these HIV analyses in men and HPV in women and furthermore, the perception of HPV risk seems less likely to influence sexual behavior than the perception of HIV risk. Another concern is that some vaccines may mistakenly assume that HPV vaccine protects against other STIs. Such overgeneralization has been noted before by health services researchers for routine childhood vaccines: there is a tendency for some parents to lump, that is think of “shots” in general, instead of the particular antigens [16]. Given this research on the tendency to generalize, caution will be needed in advertising and education to stress that HPV vaccines do not protect against other STIs. Finally, a hypothetical harm of HPV vaccination is inappropriately decreased use of cytology screening for cervical cancer due to a mistaken belief that screening is no longer needed or due to confusion about screening schedules which may change after widespread use of the vaccine. HPV vaccines near licensure will not eliminate cervical cancer for several reasons: (1) some women are already infected with HPV types 16 and 18; (2) while highly efficacious, the vaccines are not 100% effective; (3) some oncogenic types are not included in the vaccines.

4.2. Vaccine policy options

Policy options for HPV vaccine include routine vaccination during the 11–12-year old visit, routine vaccination at another, older age(s), risk-based vaccination based on behavioral factors, permissive recommendations, or no recommendation. Catch-up vaccination can also be recommended with most of the above options. Age 11–12 years is an established immunization visit in the US Recommended Childhood Immunization Schedule.

5. Surveys about women’s beliefs about HPV and HPV vaccine

Knowledge about HPV is limited [17–23]. Among risks of sexual activity, 87% of women in one study rank AIDS as their number one concern and half (52%) rank cervical cancer as their second highest concern [18]. Other studies found that HIV was the STI about which university students most worry [21,24]. Although the majority in one study thought condoms would help prevent HPV transmission, 10% indicated that they were not interested in taking precautions to prevent the spread of HPV and 11% indicated that they would care about transmitting HPV only if they cared about their partner [21]. The majority reported that they would not be any more concerned about spreading HPV if it was a cause of cancer [21]. Many women do not understand the link between cervical cancer and HPV [19,21–24].

Factors associated with acceptance of vaccines against HPV and other STIs identified by these studies include facilitating factors such as cost [25,26], universal recommendations and school requirements [25,27]; attitudes such as beliefs about vaccination and lack of fear of vaccines [27]; social influences such as parents’ feelings [25], belief that others would approve [28], and doctor’s recommendation [26]; and perceived consequences such as safety [25], vaccine efficacy [25,26] and severity of infection [29]. Another factor related to acceptance is the number of sexual partners [25,28]. Parents reasons for acceptance or declination of vaccines against STIs include protection of their children, vaccine efficacy, concern about diseases/severity of infection, feeling vaccines are important, no fear of vaccines, previous experience with the infections, perception that their children were at low risk for infection and lack of concern about the diseases [20,27,29,30]. Cost would also be a factor in vaccination decisions [25,26].

In one survey of adolescents about HIV vaccine, 77% thought that peers “would increase HIV-related risk behavior (e.g., decreased use of condoms, more sexual partners, less care taken with partner selection) after getting immunized with a 90% efficacious vaccine” [31]. In another study, focus group participants predicted that most people would be less cautious about practicing safer sex if they were vaccinated against HIV, including “more promiscuous sex,” reduced or eliminated condom use, and more sexual experimentation [32]. Furthermore, participants estimated that 50–100% of their peer group might change their sexual and/or needle use behaviors after receiving an HIV vaccine, with greater increases in risk behavior associated with greater efficacies of HIV vaccines [32]. Key informants worried that increases in other STIs would occur with an HIV vaccine and pointed to increased risk behaviors since the advent of highly active antiretroviral therapy: “Pandora is out of the box” [32]. On the other hand, provision of emergency contraception to women in a randomized trial did not change the pregnancy rate, the frequency of unprotected intercourse, or the percentage with STIs [33]. While this gives no definitive information on the effects of HPV vaccination, it provides some hope that HPV vaccine would not decrease safer sex practices.

6. Evaluation of arguments by analogy

6.1. Is hepatitis B vaccine an appropriate analogy?

Hepatitis B vaccine is recommended universally for all children and for adults with high-risk indications. Factors involved in the policy decision for universal childhood vaccination include the substantial percentage of hepatitis B virus (HBV) cases for which no known transmission route was identified and the failure of strategies for vaccinating high-risk persons to make a substantial impact on the disease epidemiology. The question, then, arises whether HBV vaccine is a good analogy for HPV vaccine.

A number of similarities exist in risk factors for HBV and HPV. Like HPV, hepatitis B vaccine targets viruses that
are transmitted from person to person, mostly through sexual contact (although HBV also is commonly transmitted by exchange of blood products (e.g., sharing “dirty needles”). The behaviors associated with transmission are usually performed by adolescents and young adults and thus, the largest incidence of new infections occurs in these groups. High-risk groups for hepatitis B are IV drug users, men who have sex with men and sexually active individuals with multiple partners [34]. Uptake of hepatitis B vaccine among these groups has been low for several reasons including difficulty accessing these groups because of low contact with the health care system, missed opportunities [35], and the three-dose regimen required for full immunogenicity. Before routine vaccination, many persons were infected with HBV within the first few months of injection drug use and thus, were infected prior to arriving at high-risk vaccination programs.

Differences exist between the epidemiology of hepatitis B and HPV. Although most acute HBV infections in the United States occur in adulthood because of high-risk behaviors, 36% of all persons in the United States with chronic HBV infection contracted the infection during childhood, because progression to the chronic carrier state is more likely in children [36]. Up to 25% of individuals infected with HBV as infants will die of HBV-related chronic liver disease as adults. These cases arise from either perinatal transmission or from inapparent contamination of skin lesions or mucosal surfaces (HBsAg has been found in impetigo lesions and saliva of persons chronically infected with HBV, and on toothbrush racks and coffee cups in their homes) [37]. Furthermore, epidemiological studies show that HBV can be transmitted between preschool-aged children [38–40]. In summary, the analogy between HBV and HPV is imperfect for policy decisions.

6.2. Do analogies for state mandates for routine childhood vaccines apply?

Historically, United States courts have allowed mandatory vaccination against smallpox and measles to protect public health [41]. Contemporary laws vary by state but mandate vaccination for school entry, although most allow a philosophical or religious exemption. Contemporary laws do not apply to adults except for college entry laws and, in a handful of states, to health care workers. The historical examples of measles and smallpox, which were among the diseases that led to public health immunization laws, are diseases which can be transmitted by the airborne route; thus, other children would be at risk from an infected child merely by the infected child’s presence in the classroom. In contrast, HPV is primarily transmitted by sexual contact. Lifestyle choices and behavioral decisions are often involved. Of course, public health functions include control of STIs. Whereas mandating vaccination for school entry for a disease that can be transmitted by the respiratory route or casual contact is logical, a mandate for vaccination against STIs for school entry is problematic. Thus, analogies cannot be supported between HPV vaccine and routine childhood diseases that are transmitted by the airborne or casual contact route.

7. Analyses based on various ethical theories

Various ethical theories can be used to evaluate policy decisions. Common theories applied to science policy include utilitarianism, natural law theory via the Principle of Double Effect, and Principlism; due to the nature of the policy questions, brief discussions of Religious Ethics and other possible approaches are included.

7.1. Utilitarianism

Utilitarianism looks at the rightness or wrongness of a decision based on its consequences. When applied to vaccine policy, utilitarianism usually takes the form of either some type of cost-benefit or modeling analysis or a more subjective weighing of vaccine-induced protection versus adverse reactions. Several cost-effectiveness or cost-benefit models have been published [42–44]. One model suggests that vaccination at age 12 is better than vaccination at later ages [44], whereas another suggested that vaccination plus biennial screening delayed until age 24 had the most attractive cost-effectiveness ratio but that vaccination and annual screening beginning at age 18 had the largest cancer reduction [43]. Vaccination at age 12 with triennial cytologic screening beginning at age 25 had an incremental cost-effectiveness ratio of <$60,000 per quality-adjusted life year gained [44]. Modeling analyses can be quite useful in determining for which age groups vaccination is most beneficial and cost effective, given the changing disease incidence by age.

The subjective, utilitarian weighing of direct HPV vaccine benefits, which are considerable, against vaccine adverse reactions, which are minor, local reactions in trials to date, argues that universal vaccination is the appropriate policy. Furthermore, given that school entry laws are known to raise rates [45] and that compliance is higher earlier in life, then a policy of universal vaccination at age 11–12, when school laws could be more effective than at later ages, could be justified on utilitarian grounds.

Although utilitarianism was once highly popular, it is losing influence and has limitations. Recent decisions including the US recommendation for inactivated poliovirus vaccine to reduce the rare complication of vaccine-associated paralytic poliomyelitis (1 case in 2.4 million doses distributed) [46] and the US withdrawal of rhesus rotavirus vaccine due to rare cases of intussusception [47] suggest that vaccine policy makers do not hold a strict utilitarian calculation but a perspective that values protection of individuals. Utilitarianism was once highly popular in Western thought; however, it has lost popularity due to several weaknesses, including the infamous use of utilitarianism as a defense by Nazi physicians at the war crimes trials [48]. Other weaknesses include difficulty in predicting which choices produce the most happiness,
particularly in the long-term; the likelihood that utilitarianism requires injustices against innocent persons; concern that it compromises personal integrity; and lack of ability under this theory to show preferences for family members [49–51]. Concerns exist that utilitarianism tramples individual liberties and conscience (e.g., forced to choose the “lesser of evils”) [50,52], which is the type of charge made by vaccine critics about US vaccine policy [53,54] and allegedly leads to alienation [50]. Furthermore, utilitarianism can be used to justify harm to minorities, particularly minority groups of small size, in order to satisfy the preference of the majority [50]. In summary, utilitarian ethics support universal vaccination at age 11–12 but as a theory it has limitations that make it problematic for being the main theory on which one bases this public policy decision.

7.2. Principle of Double Effect from Natural Law Theory

The Principle of Double Effect is used to evaluate moral conflicts when an action could produce both good and bad effects. HPV vaccine should lead to a number of benefits including reduced cervical cancer and reduced genital warts. On the other hand, adverse effects need to be considered, including adverse vaccine reactions, the hypothetical possibilities of decreases in safer sex practices, increases in other STIs, and confusion about cervical cancer screening. The criteria for the Principle of Double Effect follow: (1) the action itself must be morally indifferent or good; (2) the bad effect must not be the means by which the good effect is achieved; (3) the motive must be the achievement of the good effect only; (4) the good effect must be at least equivalent in importance to the bad effect [55]. To apply these criteria to vaccination of a person today: (1) the act of vaccination is good, as it results preventing disease in the recipient and may contribute to herd immunity. (2) The theoretical possibility of decreased safer sex practices or confusion about cervical cancer screening is not the means by which HPV vaccine works. (3) The motive for vaccination is protection of the vaccinee and, secondarily, potential protection of their contacts and the community by herd immunity; thus, the motives are good. (4) If vaccine advertising and counseling are done in a manner that promotes sexual responsibility, then the good effect, in this circumstance, seems clearly greater than the bad effect. The decrease in cervical cancer and HPV transmission, given that HPV is the most common STI, is likely to outweigh the negatives and I believe that the criteria for the Principle of Double Effect will be met.

7.3. Principism

Emphasis on the cardinal principles of beneficence, nonmaleficence, justice, and autonomy have been popular in recent years in bioethics [55,56]. Application of beneficence, that is, doing good, is rather straightforward, as HPV reduces cervical cancer and, if serotypes 6 and 11 are included, reduces genital warts. Even if a female is abstinent until marriage and faithful within marriage, her partner may not have been and he may transmit HPV to her. The potential of rape and date rape are other risks to be considered in protecting an adolescent or adult woman. Given that many adolescents have been sexually active (e.g., 29% for 9th graders and 60% for 12th graders [10]) and that HPV acquisition occurs in about 43–44% after 3 years of sexual activity, protection in early adolescence makes sense, assuming this vaccine results, as expected, in long-term immunity.

On the other hand, there are potential, theoretical harms that fall under the non-maleficence category. The theoretical potential for decreases in safer sex practices, with resultant increases in STIs, unwanted pregnancy and abortion must be considered. Another hypothetical harm is inappropriately decreased use of cytology screening for cervical cancer due to confusion. It is impossible to know the future impact of these theoretical harms. Survey data, as previously reviewed, suggest that most do not know about HPV related to cervical cancer and thus it seems unlikely that substantial increases in STIs would occur due to introduction of HPV vaccine. However, given the overgeneralization seen for childhood vaccines [16], it is theoretically possible that some might believe that HPV vaccine protects against other STIs. Confusion over cervical cancer cytological screening is a real possibility that could lead to a lack of needed screening in some women. For these reasons, counseling and advertising will need to be responsibly conducted with messages to promote sexual responsibility and to encourage appropriate cytological screening as well as to promote vaccination.

The concept of justice indicates equitable treatment. Economic justice indicates that the vaccine should be available to all who need it. The Vaccines for Children (VFC) Program offers free vaccine to uninsured and Medicaid-insured children and, at certain sites, to underinsured children [57]. Thus, inclusion under VFC is necessary in order for the principle of justice to be met. A major concern in the area of justice is the number of uninsured adults and the number of adult insurance programs without vaccine coverage. A new program to address vaccinations for uninsured and underinsured adults is needed. Until then, the principle of justice suggests that recommendations for HPV vaccine should include ages that allow provision under VFC, namely for those younger than 19 years of age.

A second issue of justice is that those at risk for the disease itself are the ones placed at risk for the adverse reactions from the vaccine, however rare those reactions may be. Because HPV disease is an STI, it seems unreasonable to mandate that an adolescent or college student who plans lifelong abstinence for religious or other reasons be vaccinated. To force this, would violate the principles of justice (and autonomy).

Finally, the principle of autonomy indicates that persons should make their own choices and decisions. It reflects the concept of inherent worth of the individual and to violate it is in essence, to treat someone as less than a person [55].
Thus, freedom should be granted; this is particularly important in the discussion of school mandates when the potential vaccinee is at risk primarily from lifestyle choices, not from the person’s mere presence in a school classroom. Being in a classroom places the student at risk for aerosolized agents (e.g., measles) and from casual contact, which leads to a rationale for school mandates for vaccines to prevent diseases transmitted by these routes. This issue is real, as some have already spoken for mandatory HPV vaccination [58]. A recent article on a framework for ethics in public health noted that “Regulations and legislation, strictly speaking, are coercive . . . they pose risks to liberty . . . While any of these measures, such as reduced speed limits, child-proof bottles, and immunization, have demonstrated efficacy, they none-the-less are the most intrusive approach to public health” [59]. A related autonomy issue, for persons less than 18 years of age, is that their parent or guardian gives consent, unless they are an emancipated minor. Many 11–12-year olds might choose not to receive three injections against a disease of which most are unaware.

To summarize the Principilism approach to HPV vaccine policy, vaccination would clearly be recommended due to beneficence, including at age 11–12 years. However, vaccination would not be required for school or college entry due to autonomy, justice and hypothetical non-maleficence concerns. HPV vaccination should be covered under the VFC due to justice concerns and it is hoped that a new national program to provide underprivileged adults with vaccine will be instituted so that all adults could access vaccine when indicated under a catch-up program.

7.4. Religious and cultural ethics

A discussion of available religious ethical perspectives could fill a book and is beyond the scope of this paper. However, a few observations are in order. Most religious ethicists are not opposed to technology per se but wish to see it used to promote the best in humans; thus, they are concerned about moral and immoral uses of technology (e.g., nuclear weapons). Not surprisingly, some difference in views occurs among religious groups; they want to protect women but differ in emphasis and in how best to accomplish that goal. As of the prelicensure writing of this article, many religious and cultural groups have not released official statements about HPV vaccine and therefore cannot be cited.

Some groups, such as Focus on the Family Research Council, report strong support for HPV vaccine and also emphasize abstinence and monogamy as the best ways to prevent STIs [60–62]. They note the substantial benefits to women at large and some discuss the risk of HPV from rape or a partner who was previously infected [61]. For instance, the web site of one prominent religious, medical organization finds the following quote “the Christian Medical Association enthusiastically welcomes the HPV vaccine. Not only does the vaccine promise to save millions from contracting human papillomavirus; it also reinforces the abstinence message. The vaccine actually highlights the gap between objective medical evidence and “safe sex” hype . . . Candid and compassionate physicians will also advise their patients that abstinence until marriage and faithfulness within marriage remain the best bulwarks against sexually transmitted diseases” [60]. “Focus on the Family affirms – above any available health intervention – abstinence until marriage and faithfulness after marriage as the best and primary practice in preventing HPV and other STIs . . . supports and encourages the development of safe, effective and ethical vaccines against HPV, as well as other viruses . . . Therefore, Focus on the Family supports widespread (universal) availability of HPV vaccines but opposes mandatory HPV vaccinations for entry to public school. The decision of whether to vaccinate a minor against this or other sexually transmitted infections should remain with the child’s parent or guardian” [61]. A number of such organizations emphasize full disclosure of benefits and adverse reactions as well as parental choice [61,62]. The leaders of the Medical Institute have a similar position to the above groups: “Promote abstinence for unmarried persons as a primary method to prevent pregnancy [63,64], STIs including HIV, and the emotional consequences of sexual activity; promote monogamy as a primary method to prevent STIs including HIV [65]; support the development and use of vaccines against HPV and other STIs; recommend continued regular health screening and counseling including pelvic examinations, Pap tests and appropriate STI screening” [66].

Some give more mixed views: Ethicist Hal Wallace MD is quoted as saying: “We’re going to be sending a message to a lot of kids, I think, that you just take this shot and you can be as sexually promiscuous as you want and it’s not going to be a problem, and that’s just not true.” Wallis says the vaccine does hold wonderful promise for those who need it. “I do think that we need to be selectively offering this to patients who are at high-risk for HPV infections, but I’m not sure that we are at a point where we can justify universal applications.” [67,68] Regarding HPV vaccine, one researcher notes: “In some cultures this might prove unacceptable as it could be felt that a ‘good’ woman should have no need of such a thing” [69]. Another expert suggests that administration of HPV vaccine cannot be done at age 12–13 in India, due to “a different socio-cultural milieu, noting that age 18 may be more appropriate in that country” [70].

7.5. Other ethical approaches

A broad range of ethical approaches have been used historically including skepticism, virtue-based system, deontology, and feminist ethics, to name some [49]. For instance, some have suggested that “values” should not be applied to drugs and vaccines [71]; however, this view misses the fact that health, prevention of disease, freedom, and pluralism are all values. It is beyond the scope of this article to review the application of each ethical approach to HPV vaccine but a few comments are in order about feminist ethics given that this article addresses HPV for females. However, as a male,
I must write with caution in speculating about the potential positions of feminist ethicists on HPV vaccine. Given the concern by feminists about the health of women, I suspect that most would support vaccination. Indeed, online listings and blogs suggest this: “Feminists in the U.S. are fighting for the approval of this vaccine”[72]. Given the ethic of care[73] and concern for protection of women, I suspect that most would support vaccination at a young age, such as 11–12-year olds. Finally, given the concerns about economic justice, I believe that feminist ethicists would be concerned about the lack of coverage for adult vaccines in many insurance policies and concern about access due to the number of uninsured women; I share this concern.

8. Limitations

This analysis does not address males due to scope of a single paper and due to the lack of vaccine efficacy data for males (immunogenicity data are available). A lengthy analysis based on the any one of the aforementioned ethical theories could be conducted, which would be beyond the scope of a single paper. Many positions, including those of religious groups, ethnic groups, and feminists, may be published after HPV vaccine licensure and therefore are unavailable to me now; indeed, the amount of controversy over HPV vaccine might increase after licensure. Finally, the duration of immunity for HPV vaccine is unknown, which could affect recommendations, need for booster doses, if any, and cost-effectiveness.

9. Conclusions

Ethical analyses using utilitarianism, the rule of double effect, and principlism support universal vaccination, including at age 11–12 years when a routine vaccination visit is indicated in the United States Recommended Childhood Immunization Schedule. However, theoretical concerns about harms must be considered seriously. Although some survey data suggest a general lack of awareness of HPV and a greater fear of HIV, from which one gains confidence that HPV vaccination is unlikely to reduce safer sex practices, survey and focus group data about HIV vaccine indicate that safer sex precautions might decrease after HIV vaccination. This calls for responsible advertising for all vaccinations against STIs. Another theoretical concern is confusion over cervical cancer screening, which will still be needed due to women infected prior to vaccination and due to oncogenic types that are not in the vaccine, again demonstrating the need for responsible advertising. Given concerns for autonomy, justice, as not all persons are at risk, and non-maleficence, HPV vaccine should not be mandated for school or college entry. Economic justice indicates a need to provide vaccination for the disadvantaged, such as the uninsured.

Conflict of interest: The author has a research grant on pneumococcal polysaccharide vaccination through a non-profit foundation that was originally funded by Merck Inc.; a license for HPV vaccine has been submitted by Merck Inc.

References


