HUMAN PAPILLOMAVIRUS VACCINES: WHO WILL PAY, WHO WILL RECEIVE, WHEN TO ADMINISTER?

Debbie Saslow, PhD; Cosette M. Wheeler, PhD

The availability of a prophylactic human papillomavirus (HPV) vaccine for the prevention of cervical cancer and its precursors offers the potential to reduce cervical cancer incidence, mortality, and related morbidity. In addition, HPV vaccination has the potential to reduce existing cervical cancer disparities. Policy and implementation issues, including vaccine funding and identification of whom to vaccinate and when, will affect the success of HPV vaccination in achieving its potential. While many public and private programs are available to cover the costs of vaccination, each has challenges and limitations. The high cost of the HPV vaccine in particular will substantially add to the burden of vaccine financing and delivery. Even as HPV vaccination for the prevention of cervical cancer is introduced and promoted, it remains critical that women undergo regular screening regardless of whether they have been vaccinated. (*Ethn Dis*. 2007;17[suppl 2]:S2-8–S2-13)

Key Words: Human Papillomavirus (HPV), HPV Vaccine, Cervical Cancer, Genital Precancers, Vaccine Financing, Cancer Disparities

From the Cancer Control Science Department, American Cancer Society, Atlanta, Georgia (DS) and Departments of Molecular Genetics and Microbiology and Obstetrics and Gynecology, University of New Mexico Health Sciences Center, Albuquerque, New Mexico (CMW), USA.

Reprints will not be available from the authors. Address correspondence to: Debbie Saslow, PhD, American Cancer Society, 1599 Clifton Rd, Atlanta, GA 30329, USA; 404-982-3690; 404-982-3621 (fax); Debbie.saslow@cancer.org

INTRODUCTION

In 2007, an estimated 11,150 cases of invasive cervical cancer will be diagnosed in the United States, and an estimated 3679 women will die from this disease.[1] Virtually all cervical cancers are causally related to infections by human papillomavirus (HPV).[2] Approximately 70% of cervical cancers are caused by HPV types 16 or 18.[3] Approximately 500,000 precancerous lesions (cervical intraepithelial neoplasia grade 2 and 3) are diagnosed each year in the United States, and 50%–60% are attributable to HPV 16 and 18.[4] Vaccines that prevent HPV infection, and particularly infection with HPV types 16 and 18, could eventually eliminate most invasive cervical cancers and many precancerous lesions.

In the United States, each year an estimated 6 million people are infected with genital HPV.[5] An estimated 20 million people in the United States, ≈15% of the population, are currently infected, and almost half of the infections are in those between 15 and 25 years of age.[5,6] At least half of all sexually active men and women acquire HPV at some point in their lifetime, and modeling studies suggest that up to 80% of sexually active women will have become infected by age 50.[7]

Genital HPV is transmitted via skin-to-skin contact, usually during vaginal (or anal) intercourse. Infection is common within a few years after onset of intercourse.[8] Most HPV infections are typically transient and resolve or become undetectable within a year or two, sometimes causing mild cervical cell changes.[9,10] Some infections persist, and women with persistent carcinogenic HPV infections are at the greatest risk of developing precancerous lesions and then cancer.[11] Human papillomavirus (HPV) 16 is unique in that it is most likely to persist and is the most prevalent type in high-grade precancerous and cancerous lesions.[12] However, most persistent infections do not progress to precancerous (high-grade) lesions, and most high-grade lesions do not develop into cancer.[9] The longer an HPV infection persists, the less likely a patient is to clear her infection.[12]

Two prophylactic HPV vaccines have been developed. One of the vaccines protects against HPV types 6, 11, 16, and 18 (quadrivalent) and the other protects against types 16 and 18 (bivalent). If successful, prophylactic vaccination will reduce the incidence of cervical cancer and precancerous lesions and additionally will reduce the incidence of other HPV-related genital disease, including penile, vulvar, vaginal, and anal cancer and precancerous lesions. Additionally, reduction in the incidence of genital warts is expected for those receiving the quadrivalent vaccine. These vaccines will protect only against new infections of the HPV types in the vaccine; they will have no therapeutic benefit. The US Food and Drug Administration recently approved the quadrivalent vaccine for use in females ages 9 to 26 years; the manufacturer submitted for review and approval of the bivalent vaccine in early 2007.

Vaccines are one of the greatest public health achievements: they are extremely beneficial and cost-effective as a public health intervention and have reduced or eliminated many serious diseases in the United States, including polio, smallpox, typhoid, measles, mumps, tetanus, rubella, and diphtheria.[13] However, newer and more expensive vaccines, including those targeting meningococcal meningitis and HPV, have raised concerns about the ability of public and private programs to sustain the financing and delivery of vaccines at optimal levels.

Table 1. The role of programs in vaccination

Program	Target Population(s)	Principal Benefit(s)	Population Covered[14]
Vaccine for Children Program (VFC)	Medicaid-eligible children Uninsured children American Indians Alaska Natives Underinsured, ie, children with insurance that does not cover vaccines	Vaccines	40%
Section 317	Low-income children not eligible for VFC Underinsured children Children of working poor/with insurance deductibles or other costs that parents cannot cover	Vaccines and administration	8%
State programs	Varies by state: may include all or some children, all or some vaccines, regardless of insurance status	Vaccines and administration	7%
Medicaid	Low-income and disabled children (criteria vary by state)	Administration	
State Child Health Insurance Program	Low-income children up to 200% of federal poverty level (sometimes more, depending on state)	Vaccines and administration	
Private insurance		Vaccines and administration; may require copays, deductibles, or other cost sharing	45%

The availability of HPV vaccines is a promising major advance in public health and cancer control. Nevertheless it comes with many questions and issues that will need to be addressed. Important among them are who will pay for vaccinations, who will (or should) receive them, and when to administer? The answers to these questions depend in part on HPV epidemiology and natural history in addition to vaccine financing. While the Federal Advisory Committee on Immunization Practices (ACIP) has recommended routine vaccination of females at ages 11 and 12 and catch-up vaccination of females ages 13–26 years, most publicly financed vaccine programs provide coverage only through age 18 years. Recommendations should be based on the best available evidence regarding safety, efficacy, and feasibility as they relate to gender, age, risk, and cost.

WHO WILL PAY: SOURCES OF VACCINE FINANCING

Vaccines are funded by a patchwork of public and private sources. Most public funding is restricted to children and adolescents. Funding for approximately half of children in the United States is covered by private insurance and out-of-pocket spending. The main source of public funding for children under age 19 years is the Vaccine for Children Program (VFC), with a small proportion covered by state and local programs. Table 1 summarizes the role of programs in covering the costs of vaccines and related services.

The Vaccine for Children Act (VFC) was passed by Congress in 1993; it is a state-operated federal entitlement program that provides free ACIP-recommended vaccines to eligible children through age 18 years. Eligible children include those on Medicaid, without insurance, American Indians, and Alaska Natives. Children whose health insurance does not cover vaccines or particular ACIP-recommended vaccines may receive VFC-funded vaccination if they are referred to a federally qualified healthcare center or a rural health clinic. Approximately 40% of children in the United States are vaccinated through VFC.[14] A major limitation of VFC is that the program covers only the cost of vaccines and not administrative costs; the latter are covered mainly by state Medicaid programs. A second limitation is that underinsured children may not have access to a federally qualified healthcare center or a rural health clinic. Travel to these sites, for example, is often a barrier to vaccination, which is a particular problem for HPV vaccines, for which three doses are required.

Section 317 of the Public Health Service Act, the Vaccination Assistance Act, was introduced in 1962. This grant program helps states provide free vaccines to children who are not eligible for VFC and to adults. There are two forms of grants: direct assistance for vaccine purchase and financial assistance for state programmatic activities, eg, outreach, surveillance and outbreak control. Most children served by the Section 317 program are underinsured or their parents are working poor who cannot afford the high deductibles. Most 317 funds are used for children rather than adults. While VFC funding increases as more vaccines and more expensive vaccines are approved and

recommended, and has increased approximately 10-fold in the last decade, Section 317 funding has remained relatively flat.[15] Because Section 317 appropriations are discretionary, they vary from year to year depending on the federal budget and are also subject to budget cuts. Major limitations of the Section 317 program include inadequate funding and a lag when each new vaccine is added to the immunization schedule. The shortfall in funds to purchase recommended vaccines will continue to increase as new and more expensive vaccines, including those for HPV, are introduced.

State programs are another source of public funds to supplement federal VFC and Section 317 programs. Some states have universal purchase policies that supplement available 317 funds to cover vaccines needed by all children in the state ("Universal" states, $n=10$).[16] Other states have universal programs that provide most, but not all, vaccines for all children but may not cover selected vaccines, eg, ones that are expensive ("Universal Select" states, $n=4$). Some states provide all vaccines to all VFC-enrolled providers to cover all children, even those who are underinsured but not seen in federally qualified healthcare centers or rural health clinics ("VFC & Underinsured" states, $n=14$). Still other states provide some but not all vaccines for these subsets of children ("VFC & Underinsured Select" states, $n=6$). The remaining states provide vaccines to cover only VFC-eligible children ("VFC Only", $n=17$). As with Section 317 programs, limitations of state programs include fluctuation in funding levels depending on annual state budgets and lags in funding for new vaccines.

Medicaid-eligible children are automatically eligible for VFC. In addition, appropriate immunization is covered by Medicaid until age 21. While coverage is theoretically provided, not all children get all of the services to which they are entitled, and some services are subject to waivers and other policies that create barriers to immunization.

The State Child Health Insurance Program (SCHIP), created as part of the Balanced Budget Act of 1997, provides coverage for children whose families are not eligible for Medicaid but whose income is below 200% of the federal poverty level (or possibly more, depending on the state). SCHIP is funded jointly by federal and state governments and administered by states.

Many states mandate some level of immunization coverage for certain private health insurance policies. These mandates do not apply to self-funded employer health plans, which represent about half of enrollees in private insurance plans.[17] Within states that have such mandates, coverage varies considerably.[18] For example, many mandates do not apply beyond age 8, and only 6 states rely on ACIP as the standard for which vaccines are covered. No state covers all children up to age 18, using ACIP as the standard, and prohibits copayments and deductibles for vaccines and vaccine-related services. While most insurance companies cover, or are planning to cover, HPV vaccines, a significant minority of private plans don't cover adolescent vaccines or they require co-pays. According to the Institute of Medicine,[17] 10%-30% of adolescents and adults have insurance plans that do not cover vaccines. Approximately 45% of children in the United States receive vaccines through private insurance or out-of-pocket spending.[14]

The higher cost of new vaccines compared to older ones has been and will continue to be problematic for all vaccine programs and providers. For example, the burden will increase on state and local governments, which have limited budgets for public health and vaccines, which will then impede compliance with ACIP recommendations. This is especially true for Universal states, which consequently may convert to Universal Select status or even less comprehensive coverage. With additional expensive vaccines, including HPV, currently the highest priced vaccine in the United States at $360 for a three-dose series, states will need to either increase funding within their state appropriations or selectively offer vaccines; the latter would likely be based on cost. This has already occurred with pneumococcal conjugate (PCV-7).[19] Nineteen states do not offer PCV-7 under Section 317 grants which has led to two-tiered policies in which vaccines are available to uninsured children but not to underinsured children. Within the private sector, providers may be less likely to buy adequate supplies of HPV vaccines, as has already been the case with other vaccines, such as rotavirus. Providers face options such as asking parents to pay for vaccines that are not (fully) covered, referring patients to public clinics, and not offering certain vaccines.[20] Additional problems will arise as new and more expensive vaccines are available. Funding shortfalls will increase disparities in who gets vaccinated and who does not, and in the case of HPV vaccines may lead to even greater disparities in who gets cervical cancer and who does not.

WHO WILL RECEIVE HPV VACCINES AND WHEN?

The ACIP, provider groups including the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, and the American Cancer Society all recommend routine vaccination of girls at ages 11–12 years.[21] Vaccination may begin as early as age 9 years and is recommended by most groups for females 13–26 years of age to catch up missed vaccine or complete the vaccination series. Ideally vaccination should be completed before potential exposure to genital HPV through sexual intercourse. The potential benefit diminishes with increasing number of lifetime sexual partners.

Human papillomavirus (HPV) vaccines are not currently licensed for use in women over age 26 or of males at any age, and vaccination of these groups is not currently recommended.

The three most important factors to take into account when recommending whom to vaccinate and when are 1) duration of protection, 2) age for optimal efficacy, and 3) feasible plans for distribution.[21] Because HPV vaccines have only recently been developed, data on duration of protection are limited and based on phase II studies of up to only 3.5–5 years. Optimal efficacy will be achieved by vaccinating patients before the age at which exposure to HPV is likely to occur. The lower age limit is bound by the age of study participants, the youngest being age nine. The clinical studies of HPV vaccines, however, only evaluated safety and immunogenicity in younger females: the lower age limit for vaccine efficacy studies of the quadrivalent vaccine is 16 years and for the bivalent vaccine is 15 years. As the vaccines are prophylactic, risk of prior infection, which is best estimated by prior sexual activity, should be considered. In the United States, according to national survey data, 24% of females report being sexually active by age 15, 40% by age 16, and 70% by age 18.[22] Seven percent of high school students (male and female) reported having initiated intercourse before age 13, and 10% of sexually active ninth graders reported having had four or more lifetime sex partners.[23] HPV acquisition often occurs soon after sexual debut; in one study, 39% of college-aged women acquired HPV within 24 months of onset of sexual activity.[8] In a study of adolescents and young women aged 13–21 years, 70% had evidence of HPV infection within five to seven years of onset of sexual intercourse.[24] However, epidemiologic studies underestimate the true exposure to HPV since infections of very short duration will likely go undetected. From a public health perspective, routine vaccination prior to sexual debut or shortly thereafter is important to achieve optimal effectiveness, as many currently or previously sexually active females will have been exposed to HPV 16 and/or 18.[21]

The question of when to vaccinate against HPV also encompasses the need for three doses and thus potentially three healthcare visits. Current recommendations are for the second dose to be administered one to two months after the first, and the third dose to be administered six months after the first dose. This recommendation presents a major barrier to widespread adoption and adherence, particularly in an adolescent population. Vaccinating any child or adult presents immense barriers.[25] The most successful regimens are those required for infants.[26] In adolescence and beyond, the ability to immunize is limited by access.[27,28] Most adolescents do not receive annual health examinations.[29] Hence, immunization opportunities occur during non-routine visits. The experience with hepatitis B vaccines underscores the difficulty in immunizing adolescents. A report by the National Committee on Quality Assurance, for example, showed adolescent vaccine rates (eg, varicella and hepatitis B) in the 45%-50% range for managed care as well as Medicaid plans, compared to 80%-90% for hepatitis B vaccination by age two.[30]

A platform for adolescent immunization similar to that of infant immunizations is needed for the currently recommended vaccines. The ACIP, American Medical Association, American Academy of Pediatrics, American Academy of Family Practice, and Society of Adolescent Medicine recommend an early adolescent healthcare visit at age 11–12 years.[31,32] Vaccinations for tetanus/diphtheria/pertussis booster, hepatitis A and meningococcal meningitis are recommended at this age, and other vaccines (hepatitis B, polio, varicella, measles/mumps/rubella, pneumococcal pneumonia, influenza) are recommended as catch-up or for special risk groups.[32] This adolescent platform may increase the likelihood of HPV vaccination of girls 11–12 years of age. Other venues will be needed to get adequate coverage, including sport physicals, school programs, and acute care visits.

ANTICIPATED IMPACT OF HPV VACCINES

In the United States, successful implementation of cervical screening programs has led to substantially reduced rates of cervical cancer incidence and related mortality. Reductions in cervical cancer incidence and, ultimately, mortality will require women to receive both screening and vaccination, because the current HPV vaccines do not provide protection against a number of carcinogenic HPV types. Given the high rate of screening in this country, HPV vaccines may have little effect on the incidence of invasive cervical cancer. The benefits of HPV vaccines in the United States and other countries with successful screening programs could be primarily obtained through a reduction in morbidity and costs associated with diagnosing and treating genital precancers.

Desptie high screening rates, significant racial, ethnic, and socioeconomic disparities exist with regard to incidence, mortality, and survival associated with the diagnosis of cervical cancer in the United States.[33] The benefits of HPV vaccines could ultimately expand protection to the under-served, resulting in improved health outcomes and decreased disparities. In particular, provision of free HPV vaccines under the VFC program to all eligible girls through age 18 offers the potential to reach many medically under-served individuals who are least likely to receive regular screening as they get older. Similar racial and ethnic disparities in acute hepatitis B infections

among children under age 19 were virtually eliminated in this country between 1990 and 2004 following recommendation for universal hepatitis B vaccination.[34] Of major concern, however, is the challenge of vaccinating young immigrants such as those in border states who are ineligible for many public health programs. More than half of cervical cancer deaths in the United States have been reported to occur in foreign-born women.[35]

In any setting, women without access or resources for HPV vaccines will often be those who could have benefited most. Healthcare disparities result in lower rates for both vaccination and screening,[36–38] and the same at-risk individuals might fail to participate in or have access to both primary or secondary cervical cancer prevention programs. Reduction of cervical cancer incidence will ultimately be determined by several factors, including the level of vaccination coverage in the population, the number of carcinogenic HPV types included in the vaccines, the durability of vaccine protection, the adequacy of accompanying provider- and patient-education programs, whether recommended screening practices are maintained at high levels, and finally how well we address continuing healthcare disparities.

CONCLUSION

The patchwork nature of vaccine financing in the United States can limit access and create disparities, or in the case of HPV and cervical cancer, increase existing disparities. While various vaccine programs provide funding for a substantial number of children and adolescents, there are substantial gaps, and the increase in both number and cost of new vaccines is likely to deepen these gaps. The introduction of prophylactic HPV vaccines has the potential to greatly reduce the burden of HPV-related anogenital diseases. The promise of these vaccines from a broad public health perspective, however, can be realized only if vaccination is widespread among uninsured and underinsured populations, where the burden of cervical cancer is greatest. To achieve this, the challenges of financing and delivering HPV and other vaccines must be addressed.

AUTHOR CONTRIBUTIONS AND DISCLAIMER

Design concept of study: Saslow, Wheeler

Data analysis and interpretation: Saslow

Manuscript draft: Saslow, Wheeler

Administrative, technical, or material assistance: Saslow, Wheeler

Cosette M. Wheeler received research contracts from Merck and Co., Inc. and GlaxoSmithKline to conduct HPV vaccine studies.

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