Genital human papillomavirus (HPV) is the most commonly sexually transmitted infection in the United States with an estimated 6.2 million new cases each year. More than 80 percent of women have been infected with HPV by the time they turn 50. Because most infections are transient and asymptomatic, HPV often goes undetected. Its relative invisibility belies the potential seriousness of the infection, however, as HPV is the single most important risk factor for cervical cancer. High-risk HPV strains are detected in 99 percent of cervical cancers.

Worldwide, cervical cancer is the second most common cancer in women, accounting for 260,000 deaths each year. Although these numbers are much smaller in the United States—due mainly to the Papanicolaou, or Pap, test—cervical cancer continues to cause over 3,700 deaths a year. Notable disparities in incidence rates exist as well. The incidence of cervical cancer in black women is 1.5 times higher than that of white women. In addition, women of Hispanic, Vietnamese and Korean origin have higher incidence rates than white women. HPV can also cause genital warts and vaginal, vulvar and anal cancer.

In June of 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil, a new vaccine manufactured by Merck, which protects against four strains of HPV: 6, 11, 16 and 18. Although there are over 100 strains of HPV, certain types are particularly likely to be linked to cancer; strains 16 and 18 are associated with 70 percent of all cervical cancer cases in the U.S. Strains 6 and 11 are associated with 90 percent of genital warts. In clinical trials, the vaccine showed high efficacy in preventing persistent infection, pre-cancerous lesions and external genital lesions from the four strains among females who had not been previously infected. A subset of women from the trial have been followed for five years and have shown vaccine efficacy of 95.8 percent against persistent infection or disease and 100 percent efficacy against pre-cancerous and external lesions. Further follow-up studies are needed to determine the duration of protection, but research has demonstrated that younger adolescent females, ages 10-14, show a stronger immune response to the vaccine than females ages 15-24, suggesting that earlier vaccination may result in longer antibody persistence. Other recent research has shown that the vaccine also provides protection against vaginal and vulvar cancer. According to the Alan Guttmacher Institute, the HPV vaccine “is widely considered one of the greatest health care advances for women in recent years.”

The federal Advisory Committee on Immunization Practices (ACIP) recommends that girls receive the HPV vaccine at 11 or 12 years of age. This recommendation is based on several factors, including:

- studies suggesting that the HPV vaccine is safe and effective for adolescents;
- studies examining immunogenicity;
- data on HPV epidemiology and age of sexual debut in the United States; and,
- the high probability of HPV acquisition within several years of sexual debut.

ACIP also recommends catch-up vaccination for females aged 13-26 who have not previously been vaccinated or who have not have received the full series of three vaccinations. The American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists, and the Society for Adolescent Medicine all support ACIP’s recommendations. However, recent research has suggested the real world effectiveness of the vaccine will be significantly lower in sexually active women who are more likely to have already been exposed to various subtypes of the HPV.

Although the HPV vaccine is a significant medical breakthrough, it does not eliminate the need for cervical cancer screens. Screening is still critically important to protect women against cervical cancer caused by HPV types that are not included in the vaccine, and those already exposed to HPV or who do not receive the vaccine.

**Coverage & Funding**

The vaccine is administered in three doses over the course of six months, and each injection costs $120. With a total cost of $360, the vaccine is an expensive venture. Providers’ offices may charge...

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*FDA approval is expected by January of 2008 for the vaccine Cervarix, manufactured by GlaxoSmithKline, which protects against HPV strains 16 and 18.

**The HPV vaccine is not currently licensed for use in males in the U.S. There is data on safety and immunogenicity in males aged 9-15 years, but efficacy trials are still being conducted.
additional fees, and patients are reporting costs as high as $600 for the full series in physicians’ offices.19

Private insurers usually follow ACIP guidelines, and many plans already cover the vaccine. Reimbursement, however, is not always straightforward; issues such as whether the vaccine is covered by the medical or drug portion of the plan and confusing claim submission requirements may make the process more arduous.

The vaccine is covered by Vaccines for Children (VFC) at a reduced rate. VCF is a federally funded program that pays for vaccines approved by ACIP for children ages 18 and under who are either eligible for Medicaid, uninsured, underinsured, or of American Indian or Alaska Native descent. Children eligible for the State Children’s Health Insurance Program (SCHIP) are also covered as SCHIP programs must reimburse for vaccines recommended by ACIP. For states with universal vaccine programs such as North Carolina and Washington, the addition of the HPV vaccine will increase expenses considerably. As new vaccines are recommended and the cost of vaccines rises over time, dollars within the state universal vaccine programs will increasingly need to be stretched.20

Because no federal funding stream exists to support the purchase of vaccines for adults, women over the age of 18 who do not have private insurance may not have access to the HPV vaccine. For adults receiving Medicaid, vaccine coverage is an optional benefit and varies from state-to-state. One option for uninsured women is a vaccine assistance program funded by Merck. The program is available to uninsured women between the ages of 19 and 26, and requires care be provided by a private physician who already distributes other Merck products. Many uninsured women receive care in public clinics funded by Title X family planning programs*** or other publicly funded health centers and are thus ineligible for Merck’s program.21

Despite these financial constraints, a number of states are making concerted efforts to ensure accessibility of the vaccine. In 2006, New Hampshire announced a plan to provide the vaccine at no cost to girls under age 18. South Dakota also demonstrated a significant financial commitment by providing $9.2 million—$7.5 million in federal vaccine funds and $1.7 million from the state’s general fund—to the Department of Health to offer the HPV vaccine to girls aged 11 to 18. In many states, partnerships with insurers have been important to ensuring adequate funding for the HPV vaccine and other vaccines.

School Mandates

Twenty-six states and the District of Columbia introduced legislation to specifically mandate the HPV vaccine as a school entrance requirement, and controversy over school mandates has been seen nationwide. In a February 2007 policy statement, the American Academy of Family Physicians (AAFP) stated that it is “premature to consider school entry mandates for [HPV] vaccine until such time as the long term safety with widespread use, stability of supply and economic issues have been clarified.”

Among the concerns voiced by the AAFP are: the fact that HPV does not adhere to the public health model for control of infectious disease in a school setting; the sudden significant cost of the vaccine; and, concerns regarding the HPV supply for the increased demand and ability to administer it. During the 2006-2007 state legislative session, school mandates were defeated or vetoed in many states, but several states passed laws recommending voluntary vaccination of female adolescents or requiring the provision of information about the vaccine to parents of female adolescents.”

Added Benefits

According to national data, adolescents do not seek routine healthcare as often as other age groups.22 The need to receive vaccinations such as HPV, meningococcal, and tetanus, diphtheria and pertussis—all recommended at 11-12 years of age—may have the added benefit of improving adolescents’ awareness of and motivation to seek healthcare services. Expanding the platform of adolescent vaccinations may ultimately serve to draw adolescents in for routine healthcare on a more regular basis.23 According to the AAP, “Providing information to adolescents and their families about the health consequences of sexual activity, including sexually transmitted illnesses such as HPV and the benefits and limitations of the HPV vaccine, as part of a comprehensive approach to support health-promoting behaviors will help adolescents make healthy choices.”

A variety of adolescent vaccines have been introduced in recent years, with additional ones in the pipeline. Given that adolescents are less likely to seek preventive health care, adolescent vaccinations may provide a welcome platform for such care, as has been seen over the years with the development of well child care built around a variety of childhood vaccines. While reimbursement and other logistical issues will need to be addressed, the introduction of the HPV vaccine offers an opportunity to begin to address the more comprehensive health needs of adolescents. Maternal and child health programs can play an important role as a partner to these efforts.

***The Department of Health and Human Services Administration, Office of Family Planning administers the Title X program which provides public funding for family planning and preventive health screening services. Title X services include education, counseling, testing and referral with respect to sexually transmitted infections as well as education and counseling around contraception. Title X also provides preventive services, such as breast and cervical cancer screening, pregnancy tests, and breast and pelvic examinations. Title X is the only federal grant program dedicated solely to the provision of comprehensive family planning and preventive health services. For more information visit http://opa.osophs.dhhs.gov/titlex/ofp.html

****For more information about state laws related to the HPV vaccine, refer to the National Conference of State Legislators at http://www.ncsl.org/programs/health/HPVvaccine.htm#hpvlegis.


6. Ibid Kaiser Family Foundation


21. Ibid Kaiser Family Foundation


