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Achieving Universal Vaccination Against Cervical Cancer In the United States: The Need and the Means

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The advent of a vaccine against the types of human papillomavirus (HPV) linked to most cases of cervical cancer is widely considered one of the greatest health care advances for women in recent years. Experts believe that vaccination against HPV has the potential to dramatically reduce cervical cancer incidence and mortality, particularly in resource-poor developing countries where cervical cancer is most common and deadly. In the United States, the vaccine's potential is likely to be felt most acutely within low-income communities and communities of color, which disproportionately bear the burden of cervical cancer.

Because HPV is easily transmitted through sexual contact, the vaccine's full promise may only be realized through near-universal vaccination of girls and young women prior to sexual activity—a notion reflected in recently proposed federal guidelines. And history, as supported by a large body of scientific evidence, suggests that the most effective way to achieve universal vaccination is by requiring children to be inoculated prior to attending school. Yet the link between HPV and sexual activity—and the notion that HPV is different than other infectious diseases targeted by vaccine school entry requirements—tests the prevailing justification for such efforts. Meanwhile, any serious effort to achieve universal vaccination among young people with this relatively expensive vaccine will expose holes in the public health safety net that, if left unaddressed, have the potential to exacerbate longstanding disparities in cervical cancer rates among American women.

The Case for Universal Vaccination

Virtually all cases of cervical cancer are linked to HPV, an extremely common sexually transmitted infection (STI) that is typically asymptomatic and harmless; most people never know they are infected, and most cases resolve on their own. It is estimated that approximately three in four Americans contract HPV at some point in their lives, with most cases acquired relatively soon after individuals have sex for the first time. Of the approximately 30 known types of HPV that are sexually transmitted, more than 13 are associated with cervical cancer. Yet despite the prevalence of HPV, cervical cancer is relatively rare in the United States; it generally occurs only in the small proportion of cases where a persistent HPV infection goes undetected over many years. This is largely due to the widespread availability of Pap tests, which can detect precancerous changes of the cervix that can be treated before cancer sets in, as well as cervical cancer in its earliest stage, when it is easily treatable.

Still, the American Cancer Society estimates that in 2006, almost 10,000 cases of invasive cervical cancer will occur to American women, resulting in 3,700 deaths. Significantly, more than half of all U.S. women diagnosed with cervical cancer have not had a Pap test in the last three years. These women are disproportionately low income and women of color who lack access to affordable and culturally competent health services. As a result, the incidence of cervical cancer is approximately 1.5 times higher among African American and Latina women than among white women; women of color are considerably more likely than whites to die of the disease as well.

Two new HPV vaccines—Gardasil, manufactured by Merck & Company, and Cervarix, manufactured by GlaxoSmithKline—promise to transform this landscape. Both are virtually 100% effective in preventing the two types of HPV responsible for 70% of all cases of cervical cancer; Gardasil also protects against two other HPV types associated with 90% of all cases of genital warts. Gardasil was approved by the federal Food and Drug Administration (FDA) in June; GlaxoSmithKline is expected to apply for FDA approval of Cervarix by year's end.

Following FDA approval, Gardasil was endorsed by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), which is responsible for maintaining the nation's schedule of recommended vaccines. ACIP recommended that the vaccine be routinely administered to all girls ages 11–12, and as early as age nine at a doctor's discretion. Also, it recommended vaccination of all adolescents and young women ages 13–26 as part of a national "catch-up" campaign for those who have not already been vaccinated.

The ACIP recommendations, which are closely followed by health care professionals, reflect the notion that to eradicate cervical cancer, it will be necessary to achieve near-universal vaccination of girls and young women prior to sexual activity, when the vaccine is most effective. Experts believe that such an approach has the potential to significantly reduce cervical cancer deaths in this country and around the world. Also, high vaccination rates will significantly reduce the approximately 3.5 million abnormal Pap results experienced by American women each year, many of which are caused by transient or persistent HPV infections. These abnormal Pap results require millions of women to seek follow-up care, ranging from additional Pap tests to more invasive procedures such as colposcopies and biopsies. This additional care exacts a substantial emotional and even physical toll on women, and costs an estimated $6 billion in annual health care expenditures. Finally, widespread vaccination fosters "herd immunity," which is achieved when a sufficiently high proportion of individuals within a population are vaccinated that those who go unvaccinated—because the vaccine is contraindicated for them or because they are medically underserved, for example—are essentially protected.

The Role of School Entry Requirements

Achieving high vaccination levels among adolescents, however, can be a difficult proposition. Unlike infants and toddlers, who have frequent contact with health care providers in the context of well-child visits, adolescents often go for long stretches without contact with a health care professional. In addition, the HPV vaccine is likely to pose particular challenges, given that it must be administered three times over a six-month period to achieve maximum effectiveness.

A large body of evidence suggests that the most effective means to ensure rapid and widespread use of childhood or adolescent vaccines is through state laws or policies that require children to be vaccinated prior to enrollment in day care or school. These school-based immunization requirements, which exist in some form in all 50 states, are widely credited for the success of immunization programs in the United States. They have also played a key role in helping to close racial, ethnic and socioeconomic gaps in immunization rates, and have proven to be far more effective than guidelines recommending the vaccine for certain age-groups or high-risk populations. Although each state decides for itself whether a particular vaccine will be required for children to enroll in school, they typically rely on ACIP recommendations in making their decision.

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In recent months, some commentators have noted that as a sexually transmitted infection, HPV is "different" from other infectious diseases such as measles, mumps or whooping cough, which are easily transmitted in a school setting or threaten school attendance when an outbreak occurs. Some socially conservative advocacy groups accordingly argue that the HPV vaccine does not meet the historical criteria necessary for it to be required for children attending school; many of them also contend that abstinence outside of marriage is the real answer to HPV. They welcome the advent of the vaccine, they say, but will oppose strenuously any effort to require it for school enrollment.

This position reflects only a limited understanding of school-based vaccination requirements. These requirements do not exist solely to prevent the transmission of disease in school or during childhood. Instead, they further society's strong interest in ensuring that people are protected from disease throughout their lives and are a highly efficient means of eradicating disease in the larger community. For example, states routinely require school-age children to be vaccinated against rubella (commonly known as German measles), a typically mild illness in children, to protect pregnant women in the community from the devastating effects the disease can have on a developing fetus. Similarly, states currently require vaccination against certain diseases, such as tetanus, that are not "contagious" at all, but have very serious consequences for those affected. And almost all states require vaccination against Hepatitis B, a blood born disease which can be sexually transmitted.

Moreover, according to the National Conference of State Legislatures (NCSL), all 50 states allow parents to refuse to vaccinate their children on medical grounds, such as when a vaccine is contraindicated for a particular child due to allergy, compromised immunity or significant illness. All states except Mississippi and West Virginia allow parents to refuse to vaccinate their children on religious grounds. Additionally, 20 states go so far as to allow parents to refuse to vaccinate their children because of a personal, moral or other belief. Unlike a medical exemption, which requires a parent to provide documentation from a physician, the process for obtaining nonmedical exemptions can vary widely by state.

NCSL notes that, in recent years, almost a dozen states considered expanding their exemption policy. Even absent any significant policy change, the rate of parents seeking exemptions for nonmedical reasons is on the rise. This concerns public health experts. Research shows that in states where exemptions are easier to obtain, a higher proportion of parents refuse to vaccinate their children; research further shows that these states, in turn, are more likely to experience outbreaks of vaccine-preventable diseases, such as measles and whooping cough. Some vaccine program administrators fear that because of the social sensitivities surrounding the HPV vaccine, any effort to require the vaccine for school entry may prompt legislators to amend their laws to create nonmedical exemptions where they do not currently exist or to make existing exemptions easier to obtain. This has the potential not only to thwart the effort to stem the tide of cervical cancer, but to foster the spread of other vaccine-preventable diseases as well.

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Financing Challenges Laid Bare

Another barrier to achieving universal vaccination of girls and young women will be the high price of the vaccine. Gardasil is expensive by vaccine standards, costing approximately $360 for the three-part series of injections. Despite this high cost, ACIP's endorsement means that Gardasil will be covered by most private insurers; in fact, a number of large insurers have already announced they will cover the vaccine for girls and young women within the ACIP-recommended age range. Still, the Institute of Medicine estimates that approximately 11% of all American children have private insurance that does not

The Potential Role of Family Planning Clinics in an HPV Vaccine 'Catch-Up' Campaign

Family planning clinics, including those funded under Title X of the Public Health Service Act, have an important role to play in a national "catch-up" campaign to vaccinate young women against HPV. This is particularly true for women ages 19–26, who are too old to receive free vaccines through the federal Vaccines for Children program but still fall within the ACIP-recommended age range for the HPV vaccine.

Almost 4,600 Title X–funded family planning clinics provide subsidized family planning and related preventive health care to just over five million women nationwide. In theory, Title X clinics are well poised to offer the HPV vaccine, because they already are a major provider of STI services and cervical cancer screening, providing approximately six million STI (including HIV) tests and 2.7 million Pap tests in 2004 alone. Because Title X clients are disproportionately low income and women of color, they are at particular risk of developing cervical cancer later in life. Moreover, most Title X clients fall within the ACIP age recommendations of 26 and under for the HPV vaccine (59% are age 24 or younger, and 18% are ages 25–29); many of these women are uninsured and may not have an alternative source of health care.

Title X funds may be used to pay for vaccines linked to improved reproductive health outcomes, and some Title X clinics offer the Hepatitis B vaccine (which can be sexually transmitted). Although many family planning providers are expressing interest in incorporating the HPV vaccine into their package of services, its high cost—even at a discounted government purchase price—is likely to stand in the way. Clinics that receive Title X funds are required by law to charge women based on their ability to pay, with women under 100% of the federal poverty level (representing 68% of Title X clients) receiving services completely free of charge and those with incomes between 100–250% of poverty charged on a sliding scale. While Merck has expressed an interest in extending its patient assistance program to publicly funded family planning clinics, it makes no promises. In fact, a statement on the company's Web site says that "Due to the complexities associated with vaccine funding and distribution in the public sector, as well as the resource constraints that typically exist in public health settings, Merck is currently evaluating whether and how a vaccine assistance program could be implemented in the public sector."

cover immunization, and even those with insurance coverage may have to pay deductibles and copayments that create a barrier to care.

Those who do not have private insurance or who cannot afford the out-of-pocket costs associated with Gardasil will need to rely on a patchwork system of programs that exist to support the delivery of subsidized vaccines to low-income and uninsured individuals. In June, ACIP voted to include Gardasil in the federal Vaccines for Children program (VFC), which provides free vaccines largely to children and teenagers through age 18 who are uninsured or receive Medicaid. The program's reach is significant: In 2003, 43% of all childhood vaccine doses were distributed by the VFC program.

The HPV vaccine, however, is not just recommended for children and teenagers; it is also recommended for young adult women up through age 26. Vaccines are considered an "optional" benefit for adults under Medicaid, meaning that it is up to each individual state to decide whether or not to cover a given vaccine. Also, states can use their own funds and federal grants to support the delivery of subsidized vaccines to low-income or uninsured adults. Many states, however, have opted instead to channel these funds toward childhood-vaccination efforts, particularly as vaccine prices have grown in recent years. As a result, adult vaccination rates remain low and disparities exist across racial, ethnic and socioeconomic groups—mirroring the disparities that exist for cervical cancer.

In response to all this, Merck in May announced it would create a new "patient assistance program," designed to provide all its vaccines free to adults who are uninsured, unable to afford the vaccines

and have an annual household income below 200% of the federal poverty level ($19,600 for individuals and $26,400 for couples). To receive free vaccines, patients will need to complete and fax forms from participating doctors' offices for processing by Merck during the patients' visits. Many young uninsured women, however, do not seek their care in private doctors' offices, but instead rely on publicly funded family planning clinics for their care, suggesting the impact of this program may be limited (see box).

Thinking Ahead

Solutions to the various challenges presented by the HPV vaccine are likely to have relevance far beyond cervical cancer. In the coming years, scientific breakthroughs in the areas of immunology, molecular biology and genetics will eventually permit vaccination against a broader range of acute illnesses as well as chronic diseases. Currently, vaccines for other STIs such as chlamydia, herpes and HIV are in various stages of development. Also under study are vaccines for Alzheimer's disease, diabetes and a range of cancers. Vaccines for use among adolescents will also be increasingly common. A key question is, in the future, will individuals across the economic spectrum have access to these breakthrough medical advances or will disadvantaged individuals be left behind?

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When viewed in this broader context, the debate over whether the HPV vaccine should be required for school enrollment may prove to be a healthy one. If the HPV vaccine is indeed "the first of its kind," as some have characterized it, it has the potential to prompt communities across the nation to reconsider and perhaps reconceive the philosophical justification for school entry requirements. Because the U.S. health care system is fragmented, people have no guarantee of health insurance coverage or access to affordable care. School entry requirements might therefore provide an important opportunity to deliver public health interventions that, like the HPV vaccine, offer protections to individuals who have the potential to become disconnected from health care services later in life. Similar to the HPV vaccine's promise of cervical cancer prevention, these benefits may not be felt for many years, but nonetheless may be compelling from a societal standpoint. And bearing in mind that school dropout rates begin to climb as early as age 13, middle school might be appropriately viewed as the last public health gate that an entire age-group of individuals pass through together—regardless of race, ethnicity or socioeconomic status.

Meanwhile, the cost and affordability issues raised by the HPV vaccine may help draw attention to the need to reform the vaccine-financing system in this country. In 2003, the Institute of Medicine proposed a series of reforms designed to improve the way vaccines are financed and distributed. They included a national insurance benefit mandate that would apply to all public and private health care plans and vouchers for uninsured children and adults to receive immunizations through the provider of their choice. Legislation introduced by Rep. Henry Waxman (D-CA) and Sen. Edward Kennedy (D-MA), called the Vaccine Access and Supply Act, adopts a different approach. The bill would expand the Vaccines for Children program, create a comparable Vaccines for Adults program, strengthen the vaccine grant program to the states and prohibit Medicaid cost-sharing requirements for ACIP-recommended vaccines for adults.

Whether the HPV vaccine will in fact hasten reforms of any kind remains to be seen. But one thing is clear: If the benefits of this groundbreaking vaccine cannot be enjoyed by girls and women who are disadvantaged by poverty or insurance status, then it will only serve to perpetuate the disparities in cervical cancer rates that have persisted in this country for far too long.

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