

Challenges and Opportunities for U.S. Family Planning Clinics in Providing the HPV Vaccine

By Rachel Benson Gold

Like a modern-day Icarus, the newly introduced HPV vaccine in the United States soared high with the promise of preventing cervical cancer, but crashed back to earth as efforts to require it as a condition for girls' attendance of middle-school ignited a firestorm of controversy. With that fall, the focus of public health and vaccine advocates is necessarily shifting from advocacy around school mandates to finding more targeted ways of getting the vaccine to girls and young women, as well as information about the vaccine's importance and benefits to parents and the public.

This shift has moved the nation's clinic-based family planning service providers much closer to center stage in the vaccine introduction effort. Family planning clinics constitute a major source of health care information and services to low-income and minority women, precisely those women who are at highest risk for cervical cancer. Recasting family planning providers as sources of vaccine-related information and services poses myriad challenges, but if these challenges can be met, family planning clinics are uniquely positioned to play a central role in reducing long-standing disparities in cervical cancer incidence and deaths in the United States.

Off and Running...

For much of 2006, it appeared that the introduction of the HPV vaccine was on a fast track to being one of the great public health success stories of our time (related article, Fall 2006, page 12). Gardasil, developed by Merck, had been shown to be virtually 100% effective in preventing the strains of HPV responsible for 70% of cervical

cancer cases. Review of the vaccine (but not the research itself) was expedited by the federal Food and Drug Administration (FDA) under a priority process designed for products with potential to provide significant health benefits, and approval was granted in early June. (A second vaccine, Cervarix, was submitted to FDA in March of this year by GlaxoSmithKline. Although Cervarix is not being given expedited review, it could be approved as soon as early 2008.) In addition, Gardasil has been approved in 75 other countries around the world (related article, page 15).

Within weeks, Gardasil was endorsed by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP), which is responsible for maintaining the nation's schedule of recommended vaccines. Because Gardasil is most effective before HPV exposure (which, given current levels within the U.S. population, is essentially a marker for sexual activity), the 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. At the same time, the panel 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 recommendations of the ACIP are typically used as a guide to states in establishing the package of vaccines that will be required for school attendance. 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.

State legislators rushed to introduce school-mandate proposals as soon as the chambers opened for business in 2007. Although widely accepted initially as a critical step to ensuring near-universal coverage of the vaccine, these proposals instead became the focal point for multiple strains of concern, and opposition.

...But Opposition Mounts

Virtually as soon as Merck publicly announced the results of its long-term clinical trials in October 2005, conservative activists began suggesting that inoculating young adolescents against HPV would encourage teenage sexual promiscuity. The heads of various “family

values” groups publicly declared that they would not vaccinate their own children. Vaccination “sends the wrong message,” asserted Tony Perkins of the Family Research Council (FRC). “Our concern is that this vaccine will be marketed to a segment of the population that should be getting a message about abstinence.”

In response to public opinion, however, that hard-line argument was soon dropped. Within a few months, opposition to the vaccine itself morphed into opposition to school mandates, which according to Wendy Wright, president of Concerned Women for America, would be “an end-run around parental rights.” Although, according to the National Conference of State Legislatures, most states allow exemptions from mandates in the case of a medical condition or a religious objection, and nearly half allow exemptions for “philosophical” reasons, that was not enough to quell the opposition. “Parents know what’s best for their daughters.” Provisions

How Safe Is the HPV Vaccine?

Because the HPV vaccine is designed for a healthy, young population, ensuring its safety is critical. Prior to its approval by the FDA, the vaccine was tested on 11,778 individuals, whose experience was compared with that of 9,686 individuals who received a placebo. According to the CDC, these trials—comparable in size to those for other vaccines—found that the vaccine “does not appear to cause any serious side effects.” The side effects that arose were mild and similar to those often accompanying the administration of any vaccine: pain, redness, itching or swelling at the injection site and mild or moderate fever.

By definition, however, clinical trials inevitably involve a limited number of people using a drug for a limited

period of time, and rare but serious complications often cannot be seen until a drug is in widespread use for an extended period of time. For that reason the FDA and the CDC use the Vaccine Adverse Events Reporting System (VAERS) to monitor the safety of all vaccines following their approval.

As of early 2007, 3.2 million doses of the HPV vaccine have been administered, and since approval, there have been 1,763 reports to the VAERS system. According to the CDC, 95% of these reports involved minor reactions similar to those seen during the clinical trials. However, 94 of the reports are considered serious, including 13 unconfirmed reports of Guillain-Barre Syndrome, a neurological illness resulting in muscle weakness and sometime paralysis.

According to the CDC, “some cases of [the syndrome] will occur by coincidence following vaccination but not because of vaccination.” Investigators are trying to determine whether the incidence among recipients of the HPV vaccine is higher than that would otherwise be expected.

There have also been four deaths among vaccine recipients, but according to the CDC, none appears to be caused by the vaccination. Two involved cases of influenza infection and two involved blood clots in women who were also taking oral contraceptives. (Blood clots are a risk known to be associated with use of oral contraceptives.) The CDC is continuing to investigate all four of these occurrences.

allowing parents to opt out, says Wright, “puts the parents in a position where they have to justify themselves to government officials.”

In addition, the school-mandate effort was drawing fire from some consumer groups concerned about vaccine safety in general and publicly leery of the underlying motivations of the for-profit pharmaceutical industry. (Merck’s own Vioxx had been removed from the market in 2004 because of previously unknown or undisclosed safety risks.) Indeed, the speed with which Gardasil arrived on the scene exacerbated underlying public concerns and raised fundamental questions about whether the government’s review and approval process had been adequate to ensure the drug’s safety (see box, page 9).

Coming hard on the heels of the expedited FDA approval, the full-force drive for school mandates increasingly began to appear premature. Indeed, by the end of the first quarter of 2007, legislation to mandate HPV vaccination for middle school girls was pending in 25 states and Washington, DC. In contrast, it took three years for even a single state to mandate the chickenpox vaccine, and a full eight years for one state to do so in the case of the Hepatitis B vaccine, according to *Stateline.org*. A suspicion in the minds of some—that with a second vaccine moving through the FDA approval process, Merck might have been more interested in locking in market share than in ensuring the safety of its product—only deepened the distrust.

Communities of Color Weigh In

These concerns merged in some minority communities, notwithstanding the fact that these are the same communities that disproportionately bear the burden of cervical cancer in the United States. When, for example, a school mandate was proposed for the predominately black District of Columbia by two white members of the city council—albeit members with a long history of activism on public health issues—deep-seated concern was given powerful voice by *Washington Post* columnist Courtland Milloy. In a widely read column appearing in mid-January, Milloy opposed the mandate, saying “After all, your daughter is 11 and probably black, so the

assumption is she’ll be having unprotected sex in no time—but don’t take offense.” Milloy went on to echo concerns about whether the process had gone too far too fast, raising the question of whether enough care had been taken to explore potential adverse side effects before moving to mandate it for young black girls.

Finally, he reprised the well-documented history of medical and sexual abuse of communities of color, including research on poor black men conducted in the absence of adequate—or sometimes any—ethical safeguards, involuntary sterilization of young girls and efforts to entice women to accept long-acting birth control in lieu of serving jail time. Jill Morrison, senior counsel for the National Women’s Law Center who herself is black, commented on the concerns expressed at a community meeting in the District, saying “Because of history, anything new is going to be looked at skeptically.” And, in a reference to the widely discredited, federally funded study of the impact of untreated syphilis on poor black men in Alabama, she added “Then you add in the sex part and the presumption of promiscuity, and it’s Tuskegee all over again.”

Death of a Campaign

Within weeks of Milloy’s column, a serious misstep by Merck gave vaccine opponents even more ammunition: News broke that the company had been financially supporting efforts to lobby state legislators to support the school-mandate legislation. (As if this were not enough, it also turned out that the former chief of staff for Texas Gov. Rick Perry (R)—one of the most vocal supporters of the vaccine, who mandated it by executive order only to be overturned by the legislature—was now a lobbyist for Merck.) Merck quickly suspended its lobbying activities, but the damage was done.

Ultimately, the mainstream public health community joined the fray, and delivered the final blow. “For many of us in public health who have been involved in immunization and state laws, it’s been too quick,” said Neal Halsey, director of the Institute for Vaccine Safety at the Johns Hopkins Bloomberg School of Public Health.

“You want the demand to come from the public who realize the potential benefits from the vaccine, not to be imposed upon them,” he continued. For its part, while continuing to firmly support voluntary use of the vaccine, and including it in its schedule of vaccines to be routinely administered to adolescents, the American Academy of Pediatrics declined to support school mandates, promoting instead a “go-slow” approach focusing on public education and careful monitoring of the vaccine’s safety.

Opponents now comprised an unlikely combination of supporters of parental rights, opponents of vaccines in general, drug company critics, communities of color and public health advocates. The effort to require the vaccine for school entry was effectively over. By July, with all but nine state legislatures having adjourned for the year, Virginia was the only state to have adopted a mandate. Significantly, the Washington, DC, mandate was ultimately approved, but only after a provision was added to delay its implementation for a year to permit an aggressive public education effort designed to ensure that parents had adequate information on which to base a decision about whether to exercise their prerogative under the measure to opt out.

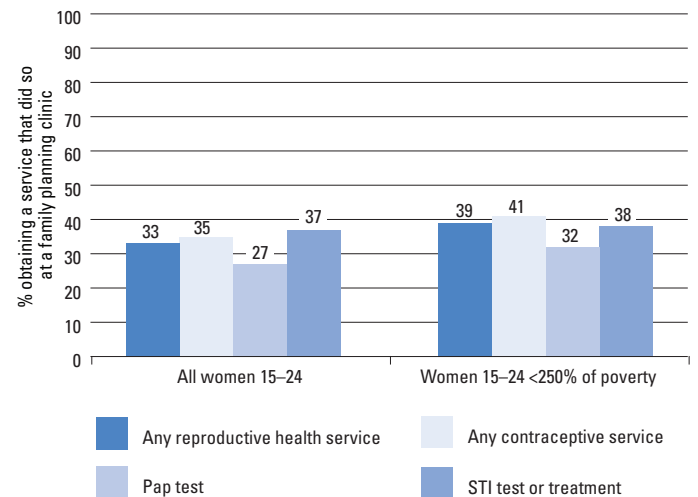
Family Planning Clinics to the Fore

The effective demise of the school-mandate campaign is reshaping the roll-out of the HPV vaccine in the United States. At a minimum, it puts increased focus on the importance of reaching out to the “catch up” population of young women above the primary vaccination target group of very young adolescents. Family planning providers are uniquely positioned to reach out to these women with information about the HPV vaccine and, potentially, the vaccine itself.

“The nationwide network of 7,500 family planning clinics,” says Dorothy Mann of the Family Planning Council in Philadelphia, “constitutes the front line when it comes to caring for this age-group.” Indeed, in 2002, one-third of all women 15–24 who obtained any reproductive health service at all did so at a family planning clinic (see chart). Among low-income women, nearly four in 10 who obtained a service did so at a

WHERE WOMEN GET CARE

Family planning clinics are a critical source of care for teenagers and young adults.



Source: Guttmacher Institute, 2007.

clinic. And family planning clinics are a major source of services related to sexually transmitted infections (STIs); nearly four in 10 women 15–24 receiving STI tests or treatment did so at a clinic. For many of these young women, a periodic family planning visit may be their only interaction with the health care system.

Moreover, family planning clinics are uniquely positioned to reach women at high risk of developing cervical cancer. Over one in four black women (28%) who received any reproductive health service and 40% of Hispanic women doing so looked to a family planning clinic for that care. Cervical cancer incidence among black women is nearly 1.5 times that among white women, and mortality is more than twice as high. Hispanic women have the highest levels of cervical cancer in the country.

Finally, as a trusted source of reliable health care information, and as a major provider of services to adult women and parents as well as young, unmarried women, family planning clinics can make a significant down payment toward the broad-based public education effort about cervical cancer and the importance of the HPV vaccine called for by the American Academy of

Pediatrics and others. Just over half of clinic clients are 25 or older, and nearly three in 10 are married; almost six in 10 (57%) are parents. By providing solid information to these women about cervical cancer, the importance of preventing HPV and the benefits of the HPV vaccine, family planning clinics have an important role to play in educating adults and, specifically, equipping parents to make well-informed decisions about vaccination of their children.

Covering the Cost

Perhaps the greatest challenge confronting family planning providers seeking to become actual providers of the HPV vaccine is finding a way to cover the cost. Doing so will be no small feat: Gardasil has the highest public sector cost of any vaccine listed on the CDC Vaccine Price List. Although approval by the ACIP admitted Gardasil into the funding streams usually used for vaccines, these programs have their own complicated requirements and restrictions, and in some cases are largely unfamiliar to the family planning provider community.

With 57% of the nation's family planning clinics recipients of funds under the Title X family planning program, it would be natural for clinics to look first to Title X. But Gardasil's steep cost—approximately \$300 for the three-shot regimen per client, even with the discount given to clinics—makes it highly unlikely that Title X could ever underwrite the expense on a large scale. (State laws requiring providers generally to obtain parental consent when administering vaccines to minors further complicate the situation, likely barring the use of Title X funds for the vaccine in many of those states.*) Another attractive but unlikely source of significant support over the long run is private philanthropy, although individual donor support has been received in a few cases.

*In general, according to Abigail English of the Center for Adolescent Health & the Law, providers must obtain parental consent before vaccinating a minor. However, all states have laws permitting at least some minors to consent to services related to STIs. Because the HPV vaccine is designed to prevent an STI, some of these laws are being interpreted as permitting minors to consent to the vaccine. According to the Office of Population Affairs, because all Title X services must be provided confidentially, grantees in states where parental consent is required for the HPV vaccine must ensure that activities related to the vaccine are outside of their Title X project.

An important potential funding source, however, is the Vaccines for Children (VFC) program, a massive federal program that covers more than four in 10 childhood vaccine doses given each year. The program provides free vaccines, including the HPV vaccine, to children through age 18 who are uninsured, underinsured (that is, covered by insurance that does not cover vaccines), eligible for Medicaid, native American or Alaskan natives. Family planning clinics must apply for enrollment with their state VFC program and meet a range of program requirements that vary from state to state.

In all states, Medicaid covers the vaccine for program recipients aged 19–20. But for women 21–26, each state program makes its own decision. According to Alexandra Stewart, who studies vaccine policy at George Washington University, 22 state Medicaid programs are covering the vaccine for individuals in this age range, and 22 are not. (The status of coverage in the remaining states was unknown as of April.)

Nine states, according to Stewart, have allocated state funds for the vaccine. New Hampshire, for example, plans to spend nearly \$5 million on Gardasil this year, more than a quarter of the state's entire budget for immunizations. Under the program, the vaccine will be given at no charge to 11–18-year-old girls. Similarly, the Washington legislature allocated \$12 million to provide the vaccine at no cost to girls 11–18; the state believes that this will cover the cost of vaccines for 94,000 girls over the next two years. And in South Dakota, the state program provided almost 20,000 doses between January and mid-May.

Private insurance generally will cover the cost for insured women up to age 26, the upper age limit approved by the ACIP. Merck estimates that 94% of individuals with private insurance coverage are in plans that cover the vaccine; three states—Colorado, Nevada and New Mexico—enacted laws this year mandating coverage in private plans. According to media reports, however, both public- and private-sector providers are becoming increasingly frustrated with the low levels of payment through insurance plans, especially given the high up-front cost of the vaccine to providers.

Finally, in mid-2006, Merck established a patient assistance program that will reimburse clinics and other providers for the cost of vaccines, including HPV, for uninsured, low-income adults. According to Merck, applications are processed quickly so that patients can apply and receive the vaccine during the same visit. On the other hand, because insurance status may change, a client must reapply for coverage for each of the three vaccine doses. While an increasingly important source of funding, program requirements make participation difficult, if not impossible, for some family planning clinics. Government entities, such as health department clinics, are not eligible to participate. Moreover, participating providers must pay for the vaccine up-front and then be reimbursed on a quarterly basis. As a result, some providers are able to participate only if they have another source of funding that can tide them over until their quarterly reimbursement arrives.

Forging Ahead

As daunting as the financial challenges are, they are by no means the only ones facing family planning providers seeking to make a direct contribution to the HPV vaccination effort. For a family planning clinic to recast itself as a vaccine provider, it must do everything from making fundamental decisions about the population to which the vaccine will be offered to arranging for staff training to designing specific protocols for counseling and service delivery. Although no systematic data are available on the number of family planning clinics engaged in these activities, some programs around the country are clearly stepping into the fray.

In designing their programs, these family planning clinics are grappling with the basic question of to whom to offer the vaccine. Some providers, such as the Family Planning Council in Philadelphia, are focusing their HPV vaccination efforts on their existing family planning clients, trying to make the vaccine one of the menu of services offered to these clients. Others, such as those funded through the Missouri Family Health Council, are serving vaccine-only clients who make an appointment specifically for the vaccine. In yet another approach, Tapestry Health in Western Massachusetts is also offering special,

freestanding vaccine-only clinics. Starting with one clinic site in Amherst in January, Tapestry has held special clinics at seven sites across western Massachusetts. The 2–3-hour sessions are generally held on weekdays in the late afternoon and early evening, although they are looking to expand to Saturdays.

Program decisions may intersect with decisions about funding sources, notably the VFC program. One issue that has arisen with family planning providers seeking to enroll with VFC is the package of vaccines that must be offered. In Utah, for example, family planning providers are required to offer the full range of vaccines required for adolescents and young adults as a condition of program participation. However, in Missouri, the program ultimately agreed to permit family planning clinics to offer only the HPV vaccine, as is the case in Massachusetts.

Having secured funding and decided to whom to offer the vaccine, a host of other service delivery challenges ensue. Working through them requires significant thought and effort since, as Karrie Galloway of Planned Parenthood of Utah frankly admits, delivering vaccines “isn’t in our traditional bag of skills.” To make programs work, clinics will often have to train a staff that is largely unfamiliar with procuring, administering or even storing vaccines. (The VFC program, for example, has special and costly requirements related to vaccine refrigeration.) Accordingly, Galloway brought representatives of Merck in to brief both the clinical and administrative staff, and then run a training program for the entire staff.

There are other service delivery challenges as well. For example, because of the unique three-shot regimen involved in the vaccine, clinics will need to develop service delivery protocols that include a system to ensure that women return for subsequent shots—a challenge as shots are not timed to coincide with regular clinic visits. Finally, there is the critical issue of counseling and education. Agencies such as the Family Planning Council in Philadelphia and Tapestry Health in Massachusetts have developed detailed policies and protocols designed to ensure that clients are given the full information they need to make an

informed choice—a necessity in any context, but one particularly relevant here as the controversy over the HPV vaccine has gained steam.

In theory, then, the national network of family planning clinics may constitute a near-perfect system to deliver the HPV vaccine—and information and education about the vaccine—to a population at high risk of cervical cancer for whom it has the promise of being highly effective. Making that theory a reality is no easy task, however, involving as it does a significant effort from a system already beset with serious challenges, including, but not limited to, a dearth of financing. But if those obstacles can be overcome, family planning clinics are poised to provide an additional, critical public health service to individuals in need and, by meeting that need, make major inroads in reducing disparities in cervical cancer that have long been a critical social and public health imperative. www.guttmacher.org

This article was made possible by a grant from the Ford Foundation. The conclusions and opinions expressed in this article, however, are those of the author and the Guttmacher Institute.