

# Rapid Public Health Policy Response Project



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## HPV Vaccination: Should it be Recommended or Required?

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### **About this Paper**

Legislation introduced by two members of the District of Columbia Council on January 9, 2007 would require all girls to be vaccinated against the human papillomavirus (HPV), the primary cause of cervical cancer, by the time they enter the sixth grade, unless a parent or guardian specifically “opts out” of the mandate. A similar bill was introduced last week in Virginia, and Maryland and West Virginia are poised to consider legislation. To place the proposals in a broader context, this paper reviews some of the scientific, legal, ethical and financial issues surrounding the HPV vaccine and compulsory vaccinations. The paper is being issued through the Jacobs Institute of Women’s Health, which is affiliated with the School of Public Health and Health Services.

### **For more information about the HPV vaccine:**

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### **About the Rapid Public Health Policy Response Project**

The Rapid Public Health Policy Response Project of the School of Public Health and Health Services at The George Washington University provides data and other background information on breaking public health stories. The goal is to educate the public, policymakers, legislators, health care providers, the media and others in order to promote informed decisionmaking. The Public Health and Policy Group of Pfizer, Inc. provides support for this project.

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In June 2006, the federal Food and Drug Administration (FDA) approved the first vaccine to protect females, ages 9-26, against four strains of the human papillomavirus (HPV). Two of these strains (strains 16 and 18) cause about 70% of all cases of cervical cancer; the other two (strains 6 and 11) cause 90% of all genital warts. The Advisory Committee on Immunization Practices (ACIP), a part of the Centers for Disease Control and Prevention, now recommends immunizing all girls and young women.

“Our challenge now is to determine how best to bring this tremendous medical breakthrough to the greatest number of people,” says Alexandra Stewart, JD, Assistant Research Professor in the Department of Health Policy at GW’s School of Public Health and Health Services. “In the past, policymakers have effectively used school mandates to achieve almost universal vaccination. That strategy is again being seriously considered.”

## The Problem

HPV infection is the most common sexually-transmitted disease in the United States, present in more than three-quarters of all women by age 50. There are more than 100 strains of the virus, about 30 of which cause some form of genital infection. While often asymptomatic, HPV was responsible for almost 500,000 new cases of cervical cancer and some 250,000 deaths around the world in 2005, mostly in developing countries, according to the World Health Organization.

Cervical cancer is less common in the United States, where Pap smears, which can detect pre-cancerous cell changes and early-stage disease, are routine. Nonetheless, about 10,000 new cases, and 3,700 deaths occur annually in this country, disproportionately affecting African-American and Hispanic women. Nationwide, 8.8 women per 100,000 are diagnosed with cervical cancer; in the District of Columbia, the incidence rate is 13.5 per 100,000. Death rates in the District are more than double national averages.<sup>1</sup>

## The Medical Advance

The HPV vaccine—called Gardasil and manufactured by Merck—is administered in three doses (dose one, followed in two months by dose two, and four months later by dose three)—and is safe and effective. The studies on which FDA approval was based identified only minor pain at the injection site as a common side effect. While it does nothing to treat existing infection, the vaccine confers almost 100% protection against new infections of the target HPV strains. Studies to date have shown immunization to be effective for five years; a booster shot may eventually be required to sustain protection. Because the vaccine does not target all cervical cancer-causing strains of HPV, Pap smears will continue to be recommended to sexually active females.<sup>2</sup>

The Advisory Committee on Immunization Practices now recommends that girls be routinely vaccinated against HPV at age 11 or 12 and that a catch-up vaccine be administered to females, ages 13 to 26, if they have not already been vaccinated. ACIP also

notes that the vaccine can be given to girls as young as 9. While its recommendations are not binding, they typically become the standard of care.<sup>3</sup>

### **Protecting the Target Audience**

Because HPV infection is a sexually transmitted disease, the use of the vaccine, and especially proposals to make its use mandatory, take on added complexity and controversy. Might parents hesitate to approve vaccinations for their children for fear of suggesting that it is acceptable to be sexually active? Might the stigma of sexually transmitted diseases lead women to avoid the vaccine? Will clinicians recommend it?

The research shows that young women are very interested in getting the HPV vaccine, and are particularly receptive when it has been recommended by their doctors.<sup>4</sup> Likewise, parents educated about its value are generally willing to have their children vaccinated. And clinicians are inclined to offer the HPV vaccine in their practices, especially where it has the support of their professional associations. Both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics endorse the use of the vaccine by their members.<sup>5</sup>

Experts emphasize the importance of creating immunization opportunities, especially given the challenge of reaching adolescents and the need to administer three doses within a short time period. Standards of preventive care are not well-established for this population and they tend to receive few well-child exams. Indeed, people in their teens and early 20s make fewer visits to physicians' offices than at any other time in their lives and currently fail to receive at least one of the other vaccines recommended for them.<sup>6,7</sup> Given the widespread prevalence of HPV, the goal of the vaccine is to confer immunity before a girl has initiated any sexual activity. With 26% of females having vaginal intercourse by age 15, and most becoming sexually active at some point in their teenage years, that means inoculating them young.<sup>8</sup>

### **Should the Vaccine be Mandatory?**

The HPV Vaccination Reporting Act of 2007, introduced to the D.C. Council on January 9<sup>th</sup>, would require certification that a girl has received the HPV vaccine prior to her enrollment in sixth grade.<sup>9</sup> Parents would be permitted to opt-out of the requirement on terms that have not yet been specified. California, Kentucky, Maryland, South Carolina, Virginia and West Virginia are also considering mandatory HPV vaccination. A similar proposal was defeated in Michigan last month.

Studies show that state laws requiring immunization as a condition of enrollment in school increase the use of vaccines, reduce disease, lessen racial disparities in coverage and increase available funding.<sup>10</sup> "Requiring HPV vaccination by law will almost certainly achieve more widespread protection against the disease than will policies that rely exclusively on persuasion and education," writes one commentator.<sup>11</sup> That does not mean there is a consensus that HPV vaccination should be mandatory.

**State Vaccine Mandates:** Vaccination requirements are established on a state-by-state basis; there are no federal mandates. The legal precedent for mandatory vaccinations is the 1907 decision in *Jacobsen v Massachusetts*, when the U.S. Supreme Court upheld a Massachusetts law requiring smallpox vaccinations for adults, declaring that “the police power of a State must be held to embrace, at least, such reasonable regulations... as will protect the public health and the public safety.”<sup>12</sup>

The diphtheria/pertussis/tetanus, measles/mumps/rubella and polio vaccines are almost universally required for children entering school; laws covering haemophilus influenzae Type B, hepatitis B, and varicella (chicken pox) vaccines vary.<sup>13</sup> Exemptions on medical grounds are permitted everywhere. Most states also allow religious exemptions, and 20 provide “personal-belief” exemptions, which vary in their flexibility. States that offer personal belief exemptions, and those that make any exemptions easy to get, have higher rates of unvaccinated children. They also have higher disease rates – for example, the incidence of pertussis (whooping cough) is twice as high in states that allow personal belief exemptions, compared to those that offer only religious exemptions.<sup>14</sup>

Despite the social movement of some force and visibility that has arisen in recent years to question the safety and value of vaccines, more than 95 percent of school-age American children ultimately receive the mandated immunizations.<sup>15</sup> Contagious diseases have dropped dramatically as a direct result. A single example: an average of 500,000 children contracted measles in the years shortly before the vaccine was introduced; in 2000, there were 81 cases of measles.<sup>16</sup>

The HPV Debate: The traditional basis for school immunization mandates is to protect school-age children and the community at large from communicable disease. Public health experts argue for requiring vaccinations because they provide protection not only to vaccinated individuals, but also to the community as a whole. “Herd immunity” occurs when enough people are protected against the disease to slow or halt person-to-person transmission, even to those who are not vaccinated because they slip through the cracks of the medical system or are exempt for medical, religious or personal reasons.

An additional argument for an HPV vaccine mandate tied to school enrollment is the absence of consistent venues for serving adolescents. In general, adolescents and young adults have poorer access to care than any other population in the United States. The National Adolescent Health Information Center says that “a significant minority [of adolescents]—including the uninsured, the poor, some racial/ethnic groups and adolescents with special risk factors—report having foregone needed care and having unmet health needs.”<sup>17</sup> If the HPV vaccine remains voluntary, adolescents in medically underserved communities are less likely to receive it, and another health disparity may well emerge between those who have ready access to medical care and those who do not.

But public health concerns must be weighed against bioethical considerations, which generally place paramount value on respect for individual liberties, autonomy and the need to obtain informed consent for medical treatment.

Where a disease is transmitted through casual contact or airborne droplets, and a third-party—such as a child who is medically ineligible for the measles vaccine—is placed at increased risk because someone else refuses vaccination, the public health advantage of mandatory vaccines has generally held sway. But because HPV infection is transmitted only through sexual contact, it provokes more scrutiny from bioethicists and others who want to limit the intrusion of government into the lives of its people. Towards that goal, some have argued that compulsory vaccination is “unacceptably paternalistic.”<sup>18</sup>

Other objections to an HPV mandate focus on parental rights and concerns about condoning sexual activity in adolescence.<sup>19</sup> There are also deep sensitivities in communities of color about stereotyping their sexual behavior. In a *Washington Post* opinion piece, Courtland Milloy writes that the DC proposal to vaccinate girls in school is built on this notion: “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.”<sup>20</sup> Milloy also raises the specter of the Tuskegee experiments, in which black men were deliberately left untreated for syphilis, as a reminder that when it comes to medical treatment, government intent has not always been benign.

### **Paying the Costs**

At a price of \$360 for the required three doses, the HPV vaccine is one of the most expensive on the market. Whether or not vaccination becomes mandatory around the country, cost issues will need to be addressed.

Private insurance companies are likely to pay for it, because they typically base reimbursement decisions on the guidelines of the Advisory Committee on Immunization. All Medicaid-eligible children under 21 are covered for all ACIP-approved vaccines, as are American Indian and Alaska Native teens under 18, and adolescents under 18 enrolled in the State Children’s Health Insurance Program. Federally funded community health centers, which charge for services on a sliding scale, may be another affordable source of coverage. Many states have additional mechanisms to vaccinate children, either through public clinics or by providing free supplies to private providers.<sup>21</sup>

Vaccine coverage for adults is more problematic. Under Medicaid, vaccines are an optional benefit determined at the state level. Some states choose to provide some or all adults with free or low-cost vaccines at public clinics and affordable coverage is sometimes available at community health centers. Additionally, Merck has said it will provide limited free HPV vaccine through its patient assistance program to women who meet eligibility requirements based on income.<sup>22</sup> Nonetheless, these piecemeal approaches will miss many women, leaving them either to pay for the vaccines themselves, or go without potentially lifesaving protection.

### **In Conclusion**

The approval of the HPV vaccine represents a significant breakthrough for women’s health. Now, the challenge is to find the best way to immunize as many girls and women as

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possible before they become infected with the virus that causes cervical cancer. That will require careful debate about the relative risks and benefits of policies that rely on voluntary compliance with public health recommendations, compared to policies that mandate vaccination as a condition of school enrollment.

### Notes on Sources

- <sup>1</sup> The incidence data on cervical cancer are drawn from multiple sources, including the Kaiser Family Foundation's background brief, "[HPV, Cervical Cancer and the New Vaccine](#)," which provides electronic links to additional data sources; the World Health Organization's [Comprehensive Cervical Cancer Control](#) (2006); the National Cancer Institute SEER Cancer Statistics; and the DC Department of Health's Division of Cancer Control, where a [chart](#) comparing DC and U.S. cervical cancer incidence and mortality rates among black and white women is available.
- <sup>2</sup> Information about approval of the HPV vaccine, the trials on which it was based, and safety and efficacy findings are available at the FDA's [Center for Biological Evaluation and Research](#) (CBER).
- <sup>3</sup> ACIP's recommended immunization schedule for children from birth to 18, including HPV, is published in [Morbidity and Mortality Weekly Report](#), January 5, 2007.
- <sup>4</sup> Two articles by Gregory D. Zimet review research on the attitudes of young women, parents and clinicians towards the HPV vaccine: "[Understanding and Overcoming Barriers to Human Papillomavirus Vaccine Acceptance](#)" (*Current Opinion in Obstetrics and Gynecology*, 2006) and "[Improving Adolescent Health: Focus on HPV Vaccine Acceptance](#)" (*Journal of Adolescent Health*, 2005).
- <sup>5</sup> The American College of Obstetricians and Gynecologists released its HPV vaccine recommendations for its members in an August 8, 2006 [press release](#). The American Academy of Pediatrics included the HPV vaccine in its recommended 2007 [immunization schedule](#), issued January 2, 2007.
- <sup>6</sup> See Sharon Humiston and Susan Rosenthal, "[Challenges to Vaccinating Adolescents: Vaccine Implementation Issues](#)," (*Pediatric Infectious Disease Journal*, June 2005).
- <sup>7</sup> "[Adolescent Vaccination: Bridging from a Strong Childhood to a Healthy Adulthood](#)," published in 2005 by the National Foundation for Infectious Diseases, describes current challenges to reaching adolescents with vaccines, and strategies for overcoming them.
- <sup>8</sup> Data on sexual activities were collected in the 2002 National Survey of Family Growth conducted by the CDC's National Center for Health Statistics and published in "[Sexual Behavior and Selected Health Measures: Men and Women 15–44 Years of Age, United States, 2002](#)," Advance Data from Vital and Health Statistics, No. 362, September 15, 2005.



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- <sup>9</sup> Bill B17-30 was introduced by Council members David A. Catania and Mary M. Cheh.
- <sup>10</sup> Walter Orenstein and Alan Hinman describe the “safety net” provided by school-based immunization in [“The Immunization System in the United States—the Role of School Immunization Laws.”](#) (*Vaccine*, 1999).
- <sup>11</sup> James Colgrove explores the debate in [“The Ethics and Politics of Compulsory HPV Vaccination”](#) (*New England Journal of Medicine*, December 7, 2006).
- <sup>12</sup> The Supreme Court established the right of states to mandate vaccinations in *Jacobsen v. Massachusetts* (197 U.S. 11, 25 S.Ct 358, 1905). Subsequent key decisions include *Zucht v. King* (260 US 174, 43 S.Ct. 24, 1922), which upheld the constitutionality of city ordinances excluding unvaccinated children from school and *Maricopa County Health Department v. Harmon* (156 Ariz. 161, 750 P.2nd 1364, 1987), which determined that an individual’s right to education did not trump the state’s right to require measles vaccination, even in the absence of an outbreak at a particular school.
- <sup>13</sup> James G. Hodge, Jr. reviews existing state laws concerning vaccinations in [“School Vaccination Requirements: Legal and Social Perspectives”](#) (National Conference of State Legislatures State Legislative Report, August 2002).
- <sup>14</sup> Saad Omer and colleagues review state exemption policies and their impact on vaccination rates in [“Nonmedical Exemptions to School Immunization Requirements”](#) (*Journal of the American Medical Association*, October 11, 2006). An international perspective is provided by Daniela Almon and colleagues in [“Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present and Future”](#) (*Lancet*, February 4, 2006). State-by-state descriptions of criteria for vaccine exemptions at the [Institute for Vaccine Safety](#).
- <sup>15</sup> In addition to noting the 95 percent vaccination rate, James G. Hodge, Jr. describes historic and contemporary objections to mandatory vaccination in [“School Vaccination Requirements: Legal and Social Perspectives”](#) (*National Conference of State Legislatures State Legislative Report*, August 2002).
- <sup>16</sup> A table comparing the average annual incidence, prior to the introduction of a vaccine, of 10 vaccine-preventable diseases with 2000 figures is available in Kevin M. Malone and Alan R. Hinman, [“Vaccine Mandates: The Public Health Imperative and Individual Rights,”](#) a chapter in *Law in Public Health Practice* (Oxford University Press, 2003).

- <sup>17</sup> Background about adolescent health care is available in an Adolescent and School Health [Fact Sheet](#), August 2005, prepared by the Association of State and Territorial Health Officials; at the [National Adolescent Health Information Center](#) at the University of California, San Francisco; and in the NAHIC publication [America's Adolescents: Are They Healthy?](#) ( 2003), which is the source of the quote.
- <sup>18</sup> James Colgrove, "[The Ethics and Politics of Compulsory HPV Vaccination](#)" (*New England Journal of Medicine*, December 7, 2006).
- <sup>19</sup> See, for example, the statement of the [Family Research Council](#) to the Advisory Committee on Immunization Practices, August 24, 2006.
- <sup>20</sup> Courtland Milloy, "[District's HPV Proposal Tinged With Ugly Assumptions](#)" (*Washington Post*, January 10, 2007).
- <sup>21</sup> For a detailed discussions of vaccine financing mechanisms, see Gary L. Freed, Sarah J. Clark and Anne E. Cowan, "[State-Level Perspectives on Immunization Policies, Practices, and Program Financing in the 1990s](#)" (*American Journal of Preventive Medicine*, 2000).
- <sup>22</sup> Information about Merck's patient assistance program is available [online](#) or by calling (800) 293-3881.