

# FAQs about Cervical Cancer / HPV Vaccine Access in the U.S.

## *Why do we need HPV vaccines?*

- Cervical cancer is the 11<sup>th</sup> most common cancer among women in the US; an estimated 9,710 new cases will occur in 2006 and about 3,700 women will die.<sup>1,2</sup>
- Cervical cancer is caused by genital human papillomavirus (HPV), a common sexually transmitted infection (6.2 million new cases each year).<sup>3</sup>
- Most sexually active adults (ages 15 to 49) will acquire HPV at some time in their lives and will never even know it. HPV usually has no symptoms and does not cause disease.
- Some types of HPV can infect a woman's cervix and cause the cells to change. Most of the time, HPV goes away on its own. When HPV is gone, the cervix cells go back to normal. But sometimes, HPV does not go away. Instead, it lingers (persists) and continues to change the cells on a woman's cervix. These cell changes can lead to cancer over time, if they are not treated.<sup>4</sup>
- Cervical cancer causes 240,000 deaths each year, worldwide, and is the leading cause of death from cancer among women in developing nations.<sup>5</sup> Widespread vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds.<sup>6</sup>
- HPV vaccines could reduce the psychosocial burden and health care costs associated with abnormal Pap and HPV tests, such as biopsies and invasive procedures.<sup>7</sup>

## *What HPV vaccines are in the pipeline?*

- Merck developed a 3-dose (0, 2 & 6 months) quadrivalent vaccine for men and women to be marketed under the name Gardasil.<sup>®</sup> The vaccine is close to 100% efficacious for prevention of persistent infection and clinical disease associated with HPV types 6 & 11 (subtypes associated with 90% of all genital warts) and types 16 & 18 (subtypes associated with 70% of all cervical cancers).<sup>8</sup>
- GlaxoSmithKline (GSK) developed a 3-dose (0, 1 & 6 months) bivalent vaccine for women that will be marketed under the name Cervarix.<sup>™</sup> It is also close to 100% efficacious for prevention of persistent infection and clinical disease associated with HPV 16 & 18 (associated with 70% of all cervical cancers).<sup>9</sup>
- The cost of the series of shots is not known. Economic studies have used costs ranging from \$300 to \$500 including administration.<sup>10</sup>
- Tested in thousands of people in many countries, both vaccines appear to be safe and well tolerated; the most common side effect has been soreness at the injection site.<sup>11</sup>
- A cost-benefit analysis **concluded that** vaccination of girls against high-risk HPV subtypes would be cost effective given certain parameters if all 12-year-old girls currently living in the United States were vaccinated, more than 1,300 deaths from cervical cancer could be prevented during their lifetimes.<sup>12</sup>
- Research is being done to evaluate Gardasil in men.

## *What is the process for vaccine recommendations and guidelines and/or mandating vaccine?*

- First, the FDA makes a licensing decision that includes an age and gender designation.<sup>13</sup>
- Next, the Advisory Committee on Immunization Practices (ACIP) meets to make written recommendations about who should receive it, the optimal age, how often, the appropriate dosage and applicable contraindications.<sup>14,15</sup> The ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases to the

Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC).<sup>16</sup>

- States decide whether or not to require vaccinations for enrollment in childcare or school attendance.<sup>17</sup> Although not binding, ACIP recommendations are followed closely by healthcare professionals and organizations; an ACIP recommendation usually determines whether a vaccine becomes the standard of care, whether an insurer will reimburse for it, and whether states will publicly fund it.<sup>18</sup>
- States can make school requirements by rules/regulations or by legislation or a combination of these (which include appropriations).

### *Will states make HPV- cervical cancer vaccines mandatory for school enrollment?*

- Fifty states will make this decision separately, so it is hard to know if vaccines will be mandatory.
- Because vaccine requirements were established to protect students against infectious diseases that are acquired in schools through casual contact (sneezing, touching), some experts believe it is unlikely that they will be mandatory in all states. Genital HPV is not transmitted through casual contact in schools.
- There is a positive correlation between school immunization requirements and reduction in diseases, help in eliminating racial disparities and influence in both private and public funding.

### *Can parents “opt out” of mandatory vaccine requirements?*

- According to the National Conference of State Legislatures, all fifty states permit parents to exempt children from vaccine requirements for medical reasons.
- Forty-eight states have provisions that permit exemption from vaccination if it contradicts sincere religious beliefs.
- Twenty states permit exemptions for philosophical reasons. These include, but go beyond, religious reasons. For example, Maine allows exemption for “moral, philosophical, or other personal beliefs.”

### *What is the current timeline?*

- HPV vaccines were on the agenda for the October 2005 and February 2006 ACIP meetings in Atlanta; meeting minutes for both are posted online at <http://www.cdc.gov/nip/ACIP/default.htm>. Another meeting is scheduled for June, 29 and 30, 2006; the meeting agenda has not been posted on the ACIP website (as of 5/19/06).<sup>19</sup>
- On February 7, 2006, the FDA accepted Merck’s Biologics License Application and announced that it will be given priority review (a priority designation is intended for products that address unmet medical needs).<sup>20</sup> The FDA is expected to announce its licensing decision by June 8, 2006.<sup>21</sup>
- GSK’s vaccine is currently in phase III (large-scale efficacy) trials. GSK anticipates submitting an FDA licensure application for Cervarix in late 2006.<sup>22,23</sup>

### *Who will pay for the vaccine?*

#### *Access through private insurance*

- State legislatures play a primary role under U.S. law in regulating health insurance and so immunization laws vary widely from state to state.<sup>24,25</sup>
- Individual or group insurance plans (which cover ~100 million non-elderly people) are subject to individual state laws that establish coverage floors based on recommendations from the ACIP.
- Self-insured employer-sponsored health plans are governed by The Employee Retirement Income Security Act of 1974 (ERISA) which is a federal law that sets minimum standards for most voluntarily established

pension and health plans in private industry to provide protection for individuals covered by these plans.  
<sup>26,27</sup> These plans are not subject to individual state laws.

- In a 2005 survey conducted by America's Health Insurance Plans (AHIP), the vast majority of health insurance plans reported including most or all of the ACIP recommended vaccines in their benefits for children, adolescents and adults. Most indicated an ability to act on new ACIP recommendations within three months of release with HMOs being able to reimburse more quickly than PPOs.<sup>28</sup>

### *Access through public insurance (The CDC's vaccine process/system is currently changing.)*

- Incomplete and unequal coverage of childhood vaccines led to the 1962 introduction of the Vaccination Assistance Act (section 317) of the Public Health Service Act to provide grants to state and local health departments for specific mass immunization efforts (rather than ongoing support). Through this mechanism, the federal government provides support of immunization services (vaccine delivery, administration, surveillance, communication and education) for children, adolescents and adults.<sup>29,30</sup>
- Since 1979, immunizations have been a mandatory service for children eligible for Medicaid. Amendments to the Medicaid law in 1989 specifically codified immunizations as a mandatory component of the Medicaid program for individuals under 21 and specified coverage in accordance with ACIP standards.<sup>31</sup>
- In 1993, Medicaid was further amended to include the Vaccines for Children Program (VFC) which is 100% federally financed. The program creates a federal entitlement to immunization services for children aged 18 and under who are 1) Medicaid eligible; 2) uninsured; 3) underinsured and receiving immunizations through a Federally Qualified Health Center or Rural Health Clinic; or, 4) Native American or Alaska Native.<sup>32,33</sup>
- The National Immunization Program (NIP) for the CDC administers the vaccine purchase program for the federal government based on state estimates of the vaccines needed for underserved children and adults.
- The VFC program requires HHS to negotiate vaccine purchase agreements with manufacturers.<sup>34</sup> Costs of administering vaccines are paid by other public funds [e.g., Medicaid and **The State Children's Health Insurance Program (SCHIP)**], by parents for children who are uninsured or absorbed as a loss by the providers.<sup>35</sup>
- **SCHIP** is Title XXI of the Social Security Act and is jointly financed by the Federal and State governments and administered by the States. Within broad Federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. When SCHIP is used to expand Medicaid coverage, enrolled children are considered VFC-eligible. When SCHIP is implemented via a separate program, Title XXI or state matching funds must be used to purchase vaccine for enrolled children. In either case, states must provide coverage for vaccinations under SCHIP based on the ACIP schedule.<sup>36</sup>
- States must cover the cost of ACIP-recommended vaccines for children enrolled in Medicaid 90 days after the ACIP recommendation/VFC resolution to add a vaccine to the schedule even if no CDC contract has been established. In the absence of a VFC contract, state Medicaid agencies must cover all ACIP-recommended vaccines directly as a basic Medicaid Early and Periodic Screening Diagnosis and Treatment program (EPSDT) service, paying commercial price for the vaccine and sharing the cost of purchase at the usual Medicaid matching rate.<sup>37</sup>

### *What is the most effective distribution method and age for administering the vaccine?*

- School-based immunization requirements will promote rapid, widespread, and equal distribution across SES levels.<sup>38</sup>
- Merck's trials found that a stronger immunological response occurred in females aged 10-15 years compared to females aged 16-23 years.<sup>39</sup>
- ACIP, the American Academy of Pediatrics, the American Association of Family Physicians and the American Medical Association in 1996 identified ages 11-12 as optimal for certain adolescent

immunizations; other immunizations are recommended at this time (meningococcal and a combined booster for tetanus, diphtheria and whooping cough).

### *What is known about HPV vaccine acceptance?*

- Most pediatricians say they would administer the vaccine.<sup>40</sup>
- More pediatricians support vaccination for older age groups (15+ years) compared to younger age groups (12 years).<sup>41</sup>
- Parental acceptance is also high; reservations are generally overcome when parents are educated about HPV, cervical cancer and the vaccine.<sup>42</sup>

### *What are the controversial/political issues?*

- HPV is a sexually transmitted infection.
- To be most effective, the vaccine needs to be administered before sexual debut. Teen sexuality has become a political issue in the US. Some groups may oppose vaccination (believing that it would encourage teenage sexual promiscuity).
- Some groups support the development of vaccines but may create barriers to access. For example, the Family Research Council says it “would oppose any measures to legally require vaccination or to coerce parents into authorizing it.”<sup>43</sup>

### *Will HPV/cervical cancer vaccines lead to increased or riskier sexual behavior among young people?*

- **Some organizations have expressed concern about “behavioral disinhibition,” the notion that HPV vaccines will convey a false sense of protection and result in risky sexual behavior among youth. CDC research found that it is unlikely that vaccines will lead to disinhibition because sexual risk among young people is influenced by many factors and “fear of an STD is not a major motivation for abstinence.”**<sup>44</sup>

### *What are some of the financing considerations?*

- Over time, the financial burden of vaccine provision has been shifting from private insurance coverage to public funding mechanisms that will stretch our already taxed public healthcare system<sup>45</sup>
- Some may resist using tax dollars to pay for a vaccine to protect against cancers caused by a STI.
- There is no federal funding stream to support the purchase of vaccines for adults. Women will want this vaccine even if they are post-sexual debut and so this may become a disparity issue if, for example, private insurance does cover the vaccine.
- New vaccines are costly because they are produced by technologically more sophisticated procedures.<sup>46</sup> Higher vaccine prices will exacerbate such problems as: demands on public and private health budgets; uneven distribution patterns; delays in the vaccine negotiation process for federal and state contracts; variation in vaccine benefits of public and private insurance plans; and, increased caseloads in public health clinics and other safety net organizations.<sup>47</sup>
- ACIP recommendations are made before the government negotiates a vaccine purchase price.<sup>48</sup>
- Increasing disparity exists in access to recommended vaccines within and across states. Some states assure access to all children, others do not. Low rates of immunization are particularly located in areas of poverty. Even those with insurance have to pay higher deductibles and co-payments for immunizations.<sup>49</sup>
- Vaccine coverage standards established under state law may be so vague as to not constitute a meaningful standard from a legal perspective.<sup>50</sup> When states are given the flexibility to do so, they tend to reduce coverage to that found in standard health insurance products, rather than covering at the level that has been the hallmark of Medicaid since the 1967 enactment of the Medicaid EPSDT.<sup>51</sup>

### *What else do we need to know?*

- HPV vaccines will not eliminate all HPV or cervical cancer. The vaccines prevent the HPV types that cause 70% of cervical cancer cases. But there are other types of HPV (not covered in the vaccine) that could cause

disease.

- HPV vaccines will not prevent infection with other STIs such as herpes (HSV) or HIV. So it will still be important for sexually active adults to take steps to reduce exposure to STIs.
- HPV vaccines will not eliminate the need for cervical cancer screening.

### *What remains unknown?*

- What is the potential impact for men, women who have had HPV, sexually active women?
- Can men benefit from receiving the vaccine?
- Will the professional organizations revise their recommendations regarding cervical cancer screening if HPV vaccinations become routine?
- Will individuals who are not eligible for VFC have access to this potentially expensive vaccine?
- What additional research is needed?
- What is needed to educate policy makers, the public, parents, patients, providers, and the press?
- How can we best manage expectations of the vaccine?

### **(Endnotes)**

<sup>1</sup> American Cancer Society [<http://www.cancer.org>].

<sup>2</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>3</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>4</sup> CDC Frequently Asked Questions – Human Papillomavirus (HPV) Vaccines.

<sup>5</sup> World Health Organization website: [www.who.int/vaccine\\_research/diseases/viral\\_cancers/en/index3.html](http://www.who.int/vaccine_research/diseases/viral_cancers/en/index3.html)

<sup>6</sup> Dailard, C. The Public health promise and potential pitfalls of the world's first cervical cancer vaccine. *Guttmacher Policy Review*, Winter 2006 (9)1: 6-9.

<sup>7</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>8</sup> Villa, L.L., Costa, R.L., Petta, C.A., et al. (2005) Prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in young women: a randomised double-blind placebo-controlled multicentre phase II efficacy trial. *Lancet Oncology* 6: 271-278.

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<sup>10</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>11</sup> ASHA unpublished document.

<sup>12</sup> Sanders GD, Taira AV. Cost-effectiveness of a potential vaccine for human papillomavirus. *Emerging Infectious Diseases*, 2003, 9:37-48.

<sup>13</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>14</sup> Dailard, C. The Public health promise and potential pitfalls of the world's first cervical cancer vaccine. *Guttmacher Policy Review*, Winter 2006 (9)1: 6-9.

<sup>15</sup> <http://www.cdc.gov/nip/ACIP/default.htm>

<sup>16</sup> <http://www.cdc.gov/nip/ACIP/default.htm>

<sup>17</sup> Calling the Shots. (Chapter 3: Financing Vaccine Purchase and Delivery).

<sup>18</sup> Dailard, C. The Public health promise and potential pitfalls of the world's first cervical cancer vaccine. *Guttmacher Policy Review*, Winter 2006 (9)1: 6-9.

<sup>19</sup> <http://www.cdc.gov/nip/ACIP/dates.htm>

<sup>20</sup> Dailard, C. The Public health promise and potential pitfalls of the world's first cervical cancer vaccine. *Guttmacher Policy Review*, Winter 2006 (9)1: 6-9.

<sup>21</sup> Steinbrook, R. The potential of human papillomavirus vaccines. *The New England Journal of Medicine*, March 21, 2006.

<sup>22</sup> GlaxoSmithKline 2005 Annual Report [<http://www.gsk.com/reportsandpublications.htm>].

<sup>23</sup> Dailard, C. The Public health promise and potential pitfalls of the world's first cervical cancer vaccine. *Guttmacher Policy Review*, Winter 2006 (9)1: 6-9.

<sup>24</sup> Rosenbaum S, Stewart A, Cox M, Mitchell S.

*The epidemiology of US immunization law: Mandated coverage of immunizations under state health insurance laws.*

<sup>25</sup> Rosenblatt R, Law S, Rosenbaum S. *Law and the American Health Care System* (Foundation Press, NY, NY, 1997) Ch. 2.

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- <sup>27</sup> <http://www.dol.gov/dol/topic/health-plans/erisa.htm>
- <sup>28</sup> AHIP survey
- <sup>29</sup> Hinman AR, Orenstein WA & Rodewald L. Financing immunizations in the United States. *CID*, 2004;38 1440-1446.
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- <sup>32</sup> Calling the Shots. (Chapter 3: Financing Vaccine Purchase and Delivery).
- <sup>33</sup> <http://www.cdc.gov/nip/vfc/>.
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- <sup>35</sup> Hinman AR, Orenstein WA & Rodewald L. Financing immunizations in the United States. *CID*, 2004;38 1440-1446.
- <sup>36</sup> Reference: CMS policy letter to State Medicaid Officials, dated May 11th, 1998.
- <sup>37</sup> Calling the Shots. (Chapter 3: Financing Vaccine Purchase and Delivery).
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- <sup>45</sup> Financing vaccines in the 21<sup>st</sup> century: assuring access and availability. Institute of Medicine report, August 2003. [<http://www.iom.edu/Object.File/Master/14/454/VaccFinancelayout.pdf>].
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