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## Frequently Asked Questions About Cervical Cancer / HPV Vaccine Access in the U.S.

HPV/cervical cancer vaccines have great potential as a public health tool. Read ASHA's FAQ to learn why these vaccines are so important, who will benefit, and what must be done to get the vaccines to those who need them most.

### *Why are HPV vaccines important?*

- 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>1</sup>
- Cervical cancer is caused by "high-risk" types of genital human papillomavirus (HPV), a common sexually transmitted infection (6.2 million new cases each year).<sup>2</sup>
- 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>3,4</sup>
- Widespread vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds.<sup>5</sup>
- HPV vaccines could reduce anxieties and health care costs associated with following up abnormal Pap and HPV tests, such as biopsies and invasive procedures.<sup>6</sup>

### *What HPV vaccines are available, and what's in the pipeline?*

- Merck developed a 3-dose (0, 2 & 6 months) quadrivalent vaccine to be marketed under the name Gardasil®. The vaccine is close to 100% efficacious for preventing persistent infection and clinical disease associated with HPV type 6 & 11 (subtypes associated with 90% of all genital warts) and types 16 & 18 (subtypes associated with 70% of all cervical cancers, and many vulvar and vaginal cancers).<sup>7</sup>
- In June of 2006 the Food and Drug Administration (FDA) licensed Gardasil for use with females ages 9-26 for the prevention of cervical pre-cancers and cancers, vulvar and vaginal pre-cancers, and genital warts.
- Following FDA approval, the Advisory Committee on Immunization Practices (ACIP) recommended Gardasil for routine use with females ages 11-12, with "catch up" immunization for women ages 13-26 who have not received the vaccine. Health care providers may administer the vaccine to girls as young as age 9 at their discretion. 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>8</sup>
- Merck has priced the series of shots at \$360 (\$120 per dose). Individual provider's offices may charge additional fees (e.g., for administration) and some individuals are reporting costs as high as \$600 for the full series in physician's offices. However, most insurance plans indicate they will

cover the vaccine when used for females within the recommended age range (see *Who pays for the vaccine?* Below).

- GlaxoSmithKline (GSK) is developing a 3-dose (0, 1 & 6 months) bivalent vaccine for women that will be marketed under the name Cervarix.™ 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>
- GSK's vaccine is currently in phase III (large-scale efficacy) trials. GSK anticipates submitting an FDA licensure application for Cervarix in April 2007.<sup>10, 11</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>12</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.<sup>13</sup>

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

- Each state decides whether or not to require vaccinations for enrollment in childcare or school attendance.<sup>14</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>15</sup>
- 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 most states. Genital HPV is not transmitted through casual contact in schools. School requirements correlate positively with reduction in diseases, help to eliminate racial disparities, and influence both private and public funding.
- Legislators in at least 37 states and D.C. have introduced legislation to require, fund or educate the public about the HPV Vaccine.
- On February 2, 2007, Texas became the first state to enact a mandate--by executive order from the governor--that all females entering the sixth grade receive the vaccine, with some exceptions. Legislators in Texas have introduced a bill to override the executive order, claiming the legislative process was circumvented.
- Virginia became the first state legislature to pass a school vaccine requirement, followed by New Mexico. Both bills need governor approval to become law. Although provisions vary, all bills permit parents to opt out for medical, religious, or philosophical reasons. In some states parents may opt out after education.

### ***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. In Michigan, for example, parents can elect not to have girls receive the vaccine if they object for "medical, religious, or philosophic reasons."

### ***Who pays 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>16, 17</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.

- The vast majority of health insurance plans report including most or all of the ACIP recommended vaccines in their benefits for children adolescents and adults.<sup>18</sup> Health insurers covering approximately 94% of those who have private insurance have decided to reimburse for Gardasil.<sup>19</sup>

### **Access through public insurance**

- 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>20, 21</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>22,23</sup> In November 2006, Merck announced that Gardasil has been added to the VFC contract.<sup>24</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, and Merck has agreed to provide Gardasil at a 20% discount.<sup>25,26</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>27</sup>

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

- School-based immunization requirements will promote rapid and widespread use.<sup>28</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>29</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>30</sup>
- More pediatricians support vaccination at older age groups (15+ years) than at younger age groups (12 years).<sup>31</sup>
- Parental acceptance is also high; reservations are generally overcome when parents are educated about HPV, cervical cancer and the vaccine.<sup>32</sup>
- A study by researchers at the University of Pennsylvania found women's attitudes towards HPV vaccines are affected by the way the vaccines are presented. For example, 63% of women surveyed said they were likely to be vaccinated against HPV when the vaccine was described as only protecting against cervical cancer, compared to 43% who indicated being likely to receive the vaccine when it was described as protecting against both cervical cancer and a sexually transmitted infection.<sup>33</sup>

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

- HPV is a sexually transmitted infection and 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).
- Mandatory vaccination has remained the most controversial issue. Opponents cite issues such as concerns about the cost, safety, parents' rights, and moral objections to a vaccine mandate for a sexually transmitted disease. Financing is another concern: if states make the vaccine mandatory, they must also address funding issues.
  - Some groups that support HPV vaccine development oppose making such vaccines mandatory. The Family Research Council, for example, says it “would oppose any measures to legally require vaccination or to coerce parents into authorizing it.”<sup>34</sup> Some in public health are concerned that if the vaccine does not become mandatory, it will create additional barriers to access.

### ***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 shows it’s not likely 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>35</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>36</sup>
- The public may not be unwilling to use tax dollars to pay for an STI prevention vaccine.
- There is no federal funding stream to support the purchase of vaccines for adults.
- New vaccines are costly because they are produced by technologically more sophisticated procedures.<sup>37</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>38</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>39</sup>
- Vaccine coverage standards established under state law may be so vague as to not constitute a meaningful standard from a legal perspective.<sup>40</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.<sup>41</sup>

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

- The public needs more education about HPV. One study by the National Institutes of Health found only 40% of women ages 18-75 had ever heard of HPV, and fewer than half of them were aware the virus is linked with cervical cancer. <sup>42</sup>
- 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, such as liquid-based Pap tests and/or HPV tests.

## What remains unknown?

- What is the potential impact for men, women who have had HPV, and sexually active women over age 26? Studies are currently underway to assess HPV vaccine efficacy in different populations, including males and women over the age of 26.
  - Will the vaccines offer protection against other HPV types? Research indicates, for example, that in addition to protecting against HPV 16 and HPV 18, Cervarix may also protect against incident infection with two other “high risk” types, HPV 31 and HPV 45.<sup>43</sup>
  - Will 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?
  - How long will vaccines protect against HPV? Will booster shots be needed?
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