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## Targeting Adolescents for an STD Vaccine: Parent Interest and Strategies to Encourage Vaccination

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On June 8<sup>th</sup>, 2006, the Food and Drug Administration (FDA) approved a vaccine against Human Papillomavirus (HPV).<sup>2</sup> HPV is the world's most common sexually transmitted disease and causes nearly 100 percent of cervical cancers in women.<sup>3</sup> The vaccine prevents HPV infection. Because there is no cure for HPV, the vaccine presents the first opportunity to reduce the thousands of deaths and millions of medical interventions HPV currently causes each year.

However, the vaccine's potential will only be fulfilled to the extent that females are vaccinated against HPV prior to exposure. Since most are first exposed shortly after becoming sexually active, the Centers for Disease Control and Prevention (CDC) is recommending routine vaccination of all 11- and 12-year-old girls and recommending catch-up vaccinations for older teens.<sup>4</sup>

Parent support of the HPV vaccine will be important to maximize vaccination rates, since research shows that "parents play an important role in guiding teens on the issue of immunization."<sup>5</sup> Not only are they pivotal in the decision to immunize, parents also play an important practical role, facili-

tating vaccination by providing access to a provider, insurance or other means of payment, and where necessary, legal consent.<sup>6</sup>

There is concern that parents will not encourage their young teens to be vaccinated against HPV because their teens might interpret vaccination as parental endorsement of early sexual activity. However, studies demonstrate that the majority of parents of young teens *are* interested in the vaccine and *will* encourage their children to be vaccinated. Of course, there is a not-insignificant percentage of parents who do not want to vaccinate their teens for HPV.

What distinguishes these two groups of parents are their different beliefs about the risks of HPV, the safety of vaccines, and the implications of vaccinating a young teen against an STD. In looking for ways to encourage parent acceptance, education that addresses erroneous beliefs in these areas appears to be an effective means to increase parent acceptance.

### What is HPV?

The Human Papillomavirus (HPV) infects more than 5.5 million people each year.<sup>7</sup> An estimated 70 percent to 80

percent of all sexually active people will become infected with HPV at some point in their lives.<sup>8</sup>

There are more than 100 different strains of HPV in existence. While most HPV infections will not lead to deadly outcomes, four strains of the virus can cause cell abnormalities that ultimately lead to cervical cancer.<sup>9</sup> HPV's prevalence has made cervical cancer the world's second leading cause of cancer deaths among women.<sup>10</sup> In addition to cervical cancer, HPV can cause penile cancer, genital warts, and recurrent respiratory papillomatosis (RRP) in babies born to infected women.<sup>11</sup>

The disease can be prevented. Abstinence is the best means of prevention. Condom use also may help, but the effectiveness of condoms is not conclusive. A recent study found consistent condom use can lower HPV transmission rates,<sup>12</sup> but many prior studies found condom use to be ineffective.<sup>13</sup>

Once infected, there is no cure for the virus, although regular medical care can limit its damaging effects. Regular Pap smears<sup>14</sup> in women often catch cervical lesions before they

1 Posting of Mary O. to "Immunized Against Innocence?" [http://blogs.modestlyyours.net/modestly\\_yours/2006/01/immunized\\_again.html](http://blogs.modestlyyours.net/modestly_yours/2006/01/immunized_again.html) (Jan. 15, 2006).

2 Gardiner Harris, *U.S. Approves Use of Vaccine for Cervical Cancer*, N.Y. Times (June 9, 2006), available at <http://www.nytimes.com/2006/06/09/health/09vaccine.html?ex=1154836800&en=874435cc541d7c15&ei=5070>

3 Zimet, Mays, et al., *Acceptability of Human Papillomavirus Immunization*, 9 J. Women's Health & Gender-Based Med. 1 (2000).

4 Centers for Disease Control, *ACIP Provisional Recommendations for the Use of Quadrivalent HPV Vaccine* (August 14, 2006), [http://www.cdc.gov/nip/recs/provisional\\_recs/hpv.pdf](http://www.cdc.gov/nip/recs/provisional_recs/hpv.pdf)

5 Society for Adolescent Medicine, *Adolescent Immunizations: A Position Paper of the Society for Adolescent Medicine*, 38 J.A.H. 3 (March 2006).

6 *Id.*

7 Koutsky, *Epidemiology of Genital Human Papillomavirus Infection*, 102 Am. J. Med. 5, Sup. 1 (1997); Slomovitz et al., *Are Women Ready for the HPV Vaccine?* Gynecologic Oncology (forthcoming 2006).

8 Harris, *supra*.

9 Koutsky, *supra*.

10 Harris, *supra*.

11 Kahn, *Vaccination as a Prevention Strategy for Human Papillomavirus-related Diseases*, 37 J. Adol. Health, 6, Supp. 1 (2005).

12 Winer, Hughes, Feng, et al. *Condom Use and the Risk of Genital Human Papillomavirus Infection in Young Women*, 354 New Eng. J. Med. 25 (June 2006).

13 See, e.g. *id.* (citing Winer, Lee, et al., *Genital Human Papillomavirus Infection: Rates and Risk Factors in a Cohort of Female University Students*, 157 Am. J. Epidemiology (2003); Ho, Bierman, et al., *Natural History of Cervicovaginal Papillomavirus Infection in Young Women*, 338 New Eng. J. Med. (1998) and others).

14 The Papanicolaou test, commonly referred to as a Pap smear, examines exfoliated cells from the cervix or vagina to detect abnormal cells, indicators of an HPV infection. Kroutsky, *supra*.

become cancerous or deadly.<sup>15</sup> Fortunately, most women in the United States have the ability to obtain regular Paps smears through public or private insurance.<sup>16</sup> For this reason, even though 2 million American women each year receive Pap smear results that suggest cancer or pre-cancerous lesions, only 3,700 women die of cervical cancer each year.<sup>17</sup>

Cervical cancer and cervical cancer deaths, however, disproportionately impact poor and minority women. For a multitude of reasons, poor and minority women often have less regular medical care.<sup>18</sup> As a result, cervical cancer is one of the top ten most common cancers in Hispanic, Black, and Asian/Pacific Islander women.<sup>19</sup>

HPV not only costs lives, it costs money. In 1998, the U.S. spent an estimated 3.4 billion dollars on HPV-related diseases.<sup>20</sup> For all of these reasons, a vaccine has been much anticipated.

## The Vaccine

Merck & Co., Inc. received FDA approval for the first HPV vaccine on June 8<sup>th</sup>, 2006. It is expected to be widely available this fall. GlaxoSmithKline is also developing an HPV vaccine and will seek FDA approval at the end of 2006.<sup>21</sup> Merck's vaccine, Gardasil, protects against four types of HPV:<sup>22</sup> types 16 and 18, which cause 70 percent of cervical cancers, and types 6 and 11, which cause 90 percent of genital warts cases.<sup>23</sup> An initial five-year study suggests that Gardasil is 100 percent effective against these four

HPV strains for at least five years and is likely to be effective even longer.<sup>24</sup> It is too soon to tell how long it will ultimately remain effective. Side effects to the vaccine appear to be few. The most common side effects have been soreness and redness at the injection site, and in fewer than 10 percent of patients, a mild fever.<sup>25</sup> The vaccine does not contain thimerosal, mercury, or infectious material – controversial substances found in some other vaccines.<sup>26</sup> Currently the vaccine is only approved for use in females, though it may be approved for use in males at a future date.<sup>27</sup>

The vaccine does not treat or cure HPV; it simply prevents infection. Therefore, it only works if individuals are inoculated before exposure to HPV. Most people are infected within just a few years of first sexual intercourse, with 30 percent infected within one year of first sexual intercourse.<sup>28</sup> For this reason, the CDC's Immunization Advisory Committee (ACIP) decided to recommend vaccinating against HPV prior to sexual onset. Since at least 62 percent of teens have had sexual intercourse by age 18,<sup>29</sup> ACIP decided to recommend routine vaccination of 11- to 12-year-old girls and gave general approval for females ages 9 to 26 to be vaccinated.<sup>30</sup>

## Will Parents Accept an HPV Vaccine for Young Teens?

The recommendation's focus on young girls has raised questions. Knowing the important role parents play in vaccination, many have been concerned that

parents will be unwilling to support vaccination of pre-adolescent and early adolescent girls against a disease that is exclusively transmitted through sexual contact.

However, research suggests otherwise. In multiple studies asking parents if they would vaccinate their adolescents against different STDs, results have shown acceptance rates of 55 percent to 90 percent. In one study, 55 percent of parents of 10- to 15-year-olds said they would be willing to vaccinate their children against HPV.<sup>31</sup> In another, approximately 67 percent of women with a child between 8 and 14 years of age stated they would consent to the vaccination.<sup>32</sup> And in a study of hypothetical HIV and herpes vaccines, up to 90 percent of parents endorsed vaccination.<sup>33</sup>

The consistency of results across these studies suggests that a majority of parents will encourage their daughters to be vaccinated against HPV. However, these results also suggest that up to 45 percent of parents initially may be against vaccination.

## Why Some Parents Are Concerned

Researchers have attempted to determine the characteristics that distinguish parents who are interested in vaccinating their teens from parents who are not. Notably, there is little socio-demographic difference between the two groups. There is no significant difference by race, education, or religious beliefs.<sup>34</sup> One study found an income difference; another study did not. Instead, the studies suggest that

15 An abnormal Pap smear suggests the presence of atypical cells, of which there are four gradations before the infection becomes cancerous. Depending on the diagnosis, an irregular Pap test will lead to more frequent check-ups or a colposcopy, which is the procedure used to remove abnormal cells before they become cancerous. *Id.*

16 *Id.*

17 The federal Title X Family Planning program provides reproductive health services, including Pap smears, to clients, regardless of ability to pay. Nearly two-thirds of Title X clients have incomes below 100 percent of the poverty level and 89 percent have incomes below 200 percent of the poverty level. In nearly 75 percent of U.S. counties, at least one provider of contraceptive services is funded by the Title X family planning program. DHHS, *Office of Family Planning*, <http://opa.osophos.dhhs.gov/titex/ofp.html>

18 Centers for Disease Control, *HPV Vaccine Questions & Answers*, <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine.htm>

19 CDC, *United States Cancer Statistics, Top Ten Cancer Sites* (2002), <http://apps.nccd.cdc.gov/uscs/Table.aspx?Group=3f&Year=2002&Display=n>; American Cancer Society, *California Cancer Facts & Figures* (2006), <http://www.ccrca.org/PDF/ACS2006.pdf>

20 Kahn, *supra*. (This figure includes the costs of Pap smears as well as managing pre-cancerous lesions, genital warts and cervical cancer).

21 *Id.*

22 *Id.*

23 *Id.*

24 Dempsey, Zimet, et al., *Factors That Are Associated With Parental Acceptance of Human Papillomavirus Vaccines: A Randomized Intervention Study of Written Information About HPV*, 117 *Pediatrics* 5 (2005).

25 CDC, *HPV Interim Vaccine Information Statement*, <http://www.cdc.gov/Nip/publications/VIS/vis-hpv.pdf#search=%22HPV%20vaccine%20information%20statement%22;STD%20facts%20HPV%20vaccine>, [www.cdc.gov/std/HPV/STDFact-HPV-vaccine.htm](http://www.cdc.gov/std/HPV/STDFact-HPV-vaccine.htm).

26 Thimerosal and mercury are preservatives. Although, so far, studies have found no causal link, many still believe vaccines containing these substances can cause autism, ADHD and other problems in children, and are reluctant to immunize their children with vaccines containing the substances. See U.S. F.D.A., *Thimerosal in Vaccines*, <http://www.fda.gov/cber/vaccine/thimfaq.htm>.

27 CDC, *HPV Interim Vaccine Information Statement*, *supra*.

28 Winer et al., *Genital Human Papillomavirus Infection Incidence and Risk Factors in a Cohort of Female University Students*, 157 *Am J. Epidemiol.* 218 (2003).

29 Slomovitz, Sun et al., *Are Women Ready for the HPV Vaccine?*, *Gynecologic Oncology* (forthcoming 2006).

30 Centers for Disease Control, *supra*, note 5.

31 Davis, Dickman, et al., *Human Papillomavirus Vaccine Acceptability Among Parents of 10-to-15 Year-Old Adolescents*, 8 *J Low. Genit. Tract. Dis.* 188 (2004).

32 Slomovitz, *supra*.

33 Zimet, Perkins, et al., *Predictors of STI vaccine acceptability among parents and their adolescent children*, 37 *J. Adol. Health* 6 (2005) (Because this study measured acceptance of potential HIV and herpes vaccine, the results may not be helpful in predicting parental acceptance of an HPV vaccine.)

34 *Id.* (Not associated with acceptance were race, parent age, child age, education or insurance status); Slomovitz, *supra* ("no differences in the patterns of [personal] acceptance when participants were grouped by religion, education, race, or income.").

what most differentiates these groups is their beliefs.

In the studies mentioned, four factors in particular were consistently implicated in decision-making about vaccination: parent perception of the health risks HPV poses; perceptions of the risk posed by vaccinations in general; concerns about the recommended age for vaccination; and concerns about HPV's mode of transmission.

### Parental Perception of the HPV Risk:

Studies show that parents are more likely to accept a vaccination for their child if they perceive their child to be at risk of infection. In one study, the more convinced parents were that their children might be vulnerable to HPV infection, the more likely they were to support vaccination. In fact, parents who believed their children vulnerable to HPV were more than twice as likely to support vaccination as parents who did not see their children as particularly at risk.<sup>36</sup> Similarly, parents who believed the emotional consequences<sup>37</sup> of infection would be particularly severe were almost twice as likely to support vaccination.<sup>38</sup> Other studies also have found that perceived risk of infection is a strong predictor of STD vaccine acceptance.<sup>39</sup>

### Perception of the Risk from Vaccination in General:

While some parents are leery of the HPV vaccine in particular, a certain percentage of parents are concerned about or opposed to vaccines in general. Roughly one-quarter of parents with children under age 6 believe that a child's immune system is "weak-

ened" by too many vaccines and that children receive more immunizations than is good for their health.<sup>40</sup> This anti-vaccine sentiment plays a role in parental opposition to the HPV vaccine. Among parents opposed to vaccinating their children against HPV, a subset indicate an aversion toward all vaccines, expressing the belief that vaccines are not "helpful, important, or effective."<sup>41</sup> Along similar lines, some parents have concerns about newly-introduced vaccines. Some parents fear unknown side effects and want to wait to vaccinate their children until vaccines become well established.<sup>42</sup>

### Recommended Age:

Some parents are put off by the recommendation that *young* girls be vaccinated for an STD. Parents are much more likely to support vaccination of an older adolescent than of a child between 8 and 12 years old.<sup>43</sup> Parental acceptance of vaccination seems to increase as proposed age of vaccination increases.<sup>44</sup>

However, the influence of recommended age on parent attitude is questionable. At least one study did not find a correlation between age and vaccine acceptance.<sup>45</sup> Where a correlation was found, age may actually be a substitute measure for perceived risk rather than an independent variable in and of itself. After all, only sexually active teens are at risk for HPV, and teens are more likely to engage in sex as they get older. Thus, parents may be more inclined to support vaccinating teens as they age due to the perception that they are more at risk than before.

### HPV's Mode of Transmission:

HPV's mode of transmission makes some parents less inclined to vaccinate. One study showed that approximately 6 percent of parents considered the sexual transmissibility of HPV a strong disincentive to vaccinate.<sup>46</sup> Four overlapping beliefs seem to come into play. Some parents fear that adolescents will view consent to the vaccine as tantamount to parental consent to engage in sexual activity.<sup>47</sup> Others have expressed an additional fear that vaccinating for HPV will encourage not only sex but unsafe sex. Parents who believed that vaccination would promote unsafe sex were about half as likely to support vaccination as parents who did not hold this view.<sup>48</sup> Third, some parents believe that vaccination is unnecessary because their children are not sexually active and therefore not at risk.<sup>49</sup> Finally, some parents believe vaccination against an STD is not appropriate when the disease can be avoided through abstinence. These parents believe promoting abstinence will provide as much or better protection against HPV and cervical cancer as the vaccine.<sup>50</sup>

### Strategies to Increase Parental Acceptance: Risk Education

Up to 70 percent of all parents currently are inclined to vaccinate their preadolescent or early adolescent children against HPV. One way to encourage even greater parent interest is risk education.

Parents are more willing to accept vaccination if they perceive their children to be at high risk for a disease and the corresponding vaccination to be safe. However, many parents are ill-informed about the real risks of HPV and

35 Compare Slomovitz, *id.* (no income difference) with Davis, *supra* (parents with lower annual incomes were more willing to accept vaccination than parents with higher annual incomes).

36 Zimet, *supra* at note 28.

37 Possible emotional consequences may be shame or social stigma if, for example, HPV manifests with genital warts.

38 Zimet, *supra* at note 28.

39 Slomovitz, *supra* (citing multiple studies).

40 Gellin, Maibach, & Marcuse, "Do Parents Understand Immunizations? A National Telephone Survey," 106 *Pediatrics* 1097(2000).

41 Davis, Dickman, et al., *Human Papillomavirus Vaccine Acceptability Among Parents of 10-to-15 Year-Old Adolescents*, 8 *J. Low. Genit. Tract Dis.* 3 (2004).

42 Poland & Jacobson, *Understanding Those Who Do Not Understand: A Brief Review of the Anti-vaccine Movement*, 19 *Vaccine* 2440 (2001). 43 Dempsey, *supra*.

44 Mays, Sturm, & Zimet, *Parental perspectives on Vaccinating Children* <?> Holcomb et al., *Knowledge and Behaviors Related to Human Papillomavirus Infection*, 17 *J. Am. Board Fam. Pract.* 1 (2004). *Against Sexu-*

*ally Transmitted Infections*, 58 *Soc. Sci. Med.* 1405 (2004).

45 Zimet, *supra* at note 28; Zimet, Mays, et al., *Parental Attitudes about Sexually Transmitted Infection Vaccination for Their Adolescent Children*, 159 *Arch. Pediatr.* 132 (2005).

46 Zimet, Mays, *supra*, at note 44.

47 Davis, *supra* ("Parents opposed to vaccination did perceive that their children would be more likely to initiate sexual intercourse at a younger age.")

48 Zimet, *supra* at note 28.

49 Slomovitz, *supra*; Zimet, *supra* at note 29.

50 "The scientific advance that the HPV vaccine represents should not distract us from the primary truth that abstinence until marriage and fidelity within marriage constitute the single best formula for sexual health." Peter Sprigg, "Pro-Family, Pro-Vaccine - But Keep It Voluntary," *Washington Post*, July 15, 2006, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/07/14/AR2006071401532.html> (Peter Sprigg is vice-president for policy at the Family Research Council.)

the vaccine. Despite the overwhelming prevalence of HPV, roughly a third of adults have never heard of it.<sup>51</sup> Among those who have, only 39 percent know that HPV could cause cervical cancer, and only 50 percent realize HPV is a sexually transmitted disease.<sup>52</sup> Many also do not know that it is incurable.<sup>53</sup>

Thus, one important tool to increase interest in the vaccination is education. In one study, parents were asked about their interest in the HPV vaccination and then provided a fact sheet. After reading about HPV's prevalence, seriousness, mode of transmission, and facts about the vaccine, acceptance rates jumped from 45 percent to 73 percent. (Forty-one percent of participants who originally were undecided or did not agree to vaccinate their teen ultimately decided to vaccinate.<sup>54</sup>)

While education is an effective intervention to encourage parental acceptance of a vaccine, only certain educational campaigns prove successful. In one study, when participants received an informational sheet on HPV by mail, the intervention did little to change parents' minds.<sup>55</sup> A researcher involved in the study believes the intervention was less effective because people were not accountable for reading the information received.<sup>56</sup>

Parent feedback shows that the most persuasive educational campaign uses health care providers to distribute information about the risks of HPV and vaccines. Parents have stated that the biggest influence on their vaccination decisions is provider recommendation,<sup>57</sup> and that providers are an important source of health information for them.<sup>58</sup> Thus, advocates creating education campaigns must take into account not only the message but the messenger.

## Education's Impact

Education campaigns target parents

whose concerns about the vaccine are based on erroneous beliefs about HPV, vaccines, and their risks. Not surprisingly, education has less impact on parents who oppose the vaccine for moral reasons. In the study cited above, even though acceptance rates jumped to 73 percent after an educational intervention, among those who remained in opposition, many believed that their child would engage in sexual activity, or engage in sex at an earlier age, if the child were vaccinated. This suggests that those whose concerns rest on moral beliefs may not be swayed by education on HPV's risks.<sup>59</sup>

Even so, after an appropriate educational campaign, anywhere from 73 to 90 percent of parents will be ready to consider the HPV vaccination for their child. These are encouraging numbers. Of course, parental interest does not guarantee a teen will be vaccinated. Many barriers, including cost and limited access to providers, may still prevent vaccination. In addition, parent interest does not guarantee a parent ultimately will consent for the child's vaccination, if that consent is necessary under state law. However, encouraging parental acceptance is an important first step towards maximizing HPV vaccination rates, and efforts to increase parental acceptance, such as risk education, should be promoted.

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## Minor Consent and HPV Vaccination

While parent participation in a health intervention is important, parent consent for that intervention is not always necessary. In every state, certain minors have the right to consent to the HPV vaccine on their own. Who and how many varies state by state. In some states, all minors have the right to consent to the HPV vaccination.<sup>1</sup> In other states, however, the right is currently limited to minors who meet one, or one of several, qualifying conditions. Depending on the state, the condition might be a minimum age standard;<sup>2</sup> a defined measure of maturity;<sup>3</sup> or a special status<sup>4</sup> or living situation.<sup>5</sup>

In many states, minors meeting just one of several qualifying conditions may consent to the HPV vaccination. In Alabama, for example, any minor 14 or older may consent to the vaccine.<sup>6</sup> In addition, minors who are pregnant, married, emancipated, or meet one of several other qualifying conditions may consent.<sup>7</sup>

The right to consent to HPV vaccination may derive from one law, or a patchwork of laws, depending on the state. Only by analyzing the spectrum of minor consent laws in each state will we have a complete picture of the current scope of the adolescent right to consent to the HPV vaccination.

1 E.g., N.C. Gen. Stat. § 90-21.5 (Minors of any age may consent for medical health services for prevention, diagnosis, and treatment of venereal disease.).

2 E.g. Ala. Code § 22-8-4 (Any minor who is 14 years old or older may consent for general medical care on his or her own behalf.). (This example does not define the complete scope of consent rights in Alabama. Minors not meeting this condition may be able to consent for the vaccination under a different statute.)

3 E.g. Ark. Code Ann. § 20-9-602(7) (Minors of any age may consent for medical care if they are "of sufficient intelligence to understand and appreciate the consequences of the proposed surgical or medical treatment or procedures."). (This example does not define the complete scope of consent rights in Arkansas. Minors not meeting this condition may be able to consent for the vaccination under a different statute.)

4 E.g. Ok. Stat. Ann. tit. 63 §§ 2601, 2602 (Emancipated minors may consent for health care.). (This example does not define the complete scope of consent rights in Oklahoma. Minors not meeting this condition may be able to consent for the vaccination under a different statute.)

5 E.g. Cal. Fam. Code § 6922 (Minors may consent for general care if they are 15 years old or older, living separate and apart from their parents, and managing their own financial affairs.). (This example does not define the complete scope of consent rights in California. Minors not meeting this condition may be able to consent for the vaccination under a different statute.)

6 Ala. Code § 22-8-4

7 See Ala. Code §§ 22-8-4, 22-8-5, 26-13-5.

51 Holcomb et al., *Knowledge and Behaviors Related to Human Papillomavirus Infection*, 17 J. Am. Board Fam. Pract. 1 (2004)

52 *Id.*

53 *Id.*

54 Davis, *supra*.

55 Dempsey, *supra*.

56 Personal phone conversation between Chiara Grabill and Dr. Gregory Zimet, June 9, 2006.

57 Dempsey, *supra*.

58 Holcomb, *supra*.

59 Davis, *supra*.

60 Zimet, Mays, et al., *Acceptability of Human Papillomavirus Immunization*, 9 J. Women's Health & Gender-Based Med. 1 (2000).