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POLICY FOCUS:

**PROMOTING HUMAN  
PAPILLOMA VIRUS  
VACCINE TO PREVENT  
GENITAL WARTS AND  
CANCERS**



THE FENWAY INSTITUTE

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## Promoting Human Papilloma Virus Vaccine to Prevent Genital Warts and Cancers

John Trinidad, MPH

### WHAT IS KNOWN TODAY

Human papilloma virus (HPV) is one of the most common sexually transmitted infections in the U.S. Every year 6 million people contract HPV, mostly through sexual contact. Currently, 20 million people in the US have detectable infection with HPV.<sup>1</sup> Most cases of genital warts, found in

risk for HPV and its related complications. Though rare among the general population, HPV-related anal cancer is 40–80 times more prevalent among HIV-infected MSM than among uninfected heterosexual men.<sup>6</sup>

## HPV vaccination could prevent thousands of cases of cervical, anal and other cancers each year in the U.S.

about 1% of the US population (3 million people), are caused by specific HPV types. Men who have sex with men (MSM) represent the majority of prevalent cases of genital warts.<sup>2</sup> HPV also causes several forms of cancer, including cervical cancer (11,000 cases per year), and anal cancer (estimated at 1600 cases per year in women and 900 cases per year in men).<sup>3,4</sup> HPV has also been implicated in some head and neck cancers.

HIV research has revealed that anal cancer is emerging as among the most important non-AIDS-defining malignancies. Despite the advent of antiretroviral therapy, the incidence of HPV-related malignancies, including anal cancer, is not declining.<sup>5</sup> MSM with HIV are at even greater

Prevention of HPV-related cancer includes primary and secondary methods. Primary prevention involves education regarding STI risk/behavioral modification and vaccination against HPV. Secondary prevention includes surveillance and treatment of HPV and HPV-related dysplasia prior to progression to cancer through routine vaginal and anal pap smears.<sup>7</sup> Vaccination against HPV has been shown to prevent infection with high-risk types of HPV (e.g., HPV-16, HPV-18 which cause 72% anal cancers and 70% of cervical cancers) and low-risk types (e.g., HPV-6, HPV-11 which cause the majority of genital warts).<sup>8,9</sup> Vaccination has been shown to prevent development of high-grade lesions among MSM.<sup>10</sup> A host of other cancers may also be prevented with HPV vaccination, including vulvar, penile, and some oropharyngeal cancers.

On October 25, 2011 the U.S. Advisory Committee on Immunization Practices (ACIP) expanded its recommendation for HPV vaccination from all girls and young women 11–26 to include boys

and young men aged 11–26, expanding the role of primary prevention in HPV related cancers.<sup>11</sup> While the recommendations are for vaccinations starting at age 11, they “can be started as young as age 9 years.” On February 27, 2012, the American Academy of Pediatrics updated its vaccination guidelines to reflect these recommendations.<sup>12</sup> Studies have shown that vaccination remains cost effective for MSM up to age 26.<sup>13, 14</sup> Many doctors offer HPV immunizations to men older than 26, especially if they believe that they have not been exposed to the virus.

As of 2010 the Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* reported that only 32% of eligible adolescent girls aged 13–17 in the U.S. completed the three-dose regimen of either quadrivalent or bivalent HPV vaccine. Idaho and Arkansas had the lowest rates of coverage for adolescent girls, below 20%. Six states had vaccination rates of above 40% for girls: Colorado,

Connecticut, Delaware, Massachusetts, Nebraska, and New Hampshire. New York City’s vaccination rate was also above 40%, but in the rest of New York State only 37.9% had had all three doses of the HPV vaccine. As of 2010 only 1.4% of adolescent boys had initiated the vaccination protocol, although at the time the data were collected from the National Immunization Survey—Teen, HPV vaccine for adolescent boys was not yet part of ACIP’s recommendations.<sup>15</sup> We hope

## Only 32% of adolescent girls aged 13–17 in the U.S. have completed the three-dose HPV vaccine.

that vaccination rates among boys and young men will increase as word of the ACIP recommendation gets out and pediatricians and other providers promote HPV vaccine for boys and young men.

### CURRENT POLICY

ACIP recommendation is a significant step toward widespread implementation of HPV vaccination to eligible recipients. Under the Affordable Care Act, all new private insurance plans are required to cover ACIP-recommended vaccinations without cost-sharing in the next plan year that occurs one year after the date of the recommendation.<sup>16</sup> This would mean that many insurers must fully cover HPV vaccine for boys and young men starting in December 2012, one year after the Centers for Disease Control and Prevention journal *Morbidity and Mortality Weekly Report* published the ACIP recommendation.<sup>17</sup> (Benefit year start dates vary from employer to employer.) However, some

insurance plans will be grandfathered under ACA and not required to cover ACIP-recommended vaccinations.<sup>18</sup> And the Vaccines for Children (VFC) program provides vaccines at no cost to Medicaid eligible recipients.

In Massachusetts, all of the major private insurance providers and MassHealth, the Commonwealth’s Medicaid program, cover HPV for boys and young men.<sup>19</sup> In August, 2011, Blue Cross/Blue Shield of Massachusetts, the largest insurance provider in the Commonwealth, announced it would cover HPV vaccination for all recommended patients in anticipation of the new guidelines expected later

that year from ACIP.<sup>20</sup>

Despite expansions in insurance coverage and the official recognition of HPV vaccine as a tool to decrease cancer, widespread HPV immunization represents a significant challenge. A vaccination mandate has been widely recognized as the most effective means of implementing vaccination protocols. School-based institutional mandates and implementation strategies were instrumental in eradicating polio from the U.S. and addressing

and 13-year-olds, 72% for 14- and 15-year-olds, and 66% for 16- and 17-year-olds respectively), with at least 81% of eligible young girls having received at least one of the doses. Notably, there is variance among states and across demographics. Australia has seen a drastic decline in the incidence of genital warts at sentinel STI clinics attributable to the advent of the HPV vaccine. Genital wart incidence has dropped 59% among women, and also 28% among men, indicating some herd immunity for males not vaccinated.<sup>23,24,25</sup>

## In Australia 73% of 12- and 13-year-old girls have completed the three-dose HPV vaccine.

outbreaks of measles in schools in the 1960s.<sup>21</sup> However, there remain major hurdles to using these methods in the U.S.

Immunization programs outside the U.S., however, have demonstrated increased vaccination rates and decreased clinical incidence of genital warts. For instance, the city of Ohtawara, Japan was able to reach 92.6% coverage of eligible 6th grade girls through the development of a free school-based vaccination program. This program has been emulated by four other Japanese municipalities.<sup>22</sup> In 2007, Australia funded a four-year, \$632 million Human Papillomavirus Vaccination Program. The program implemented school-based vaccination among eligible school-aged girls, general practice vaccination programs for young women under 26, and developed the National HPV Vaccination Program Register to monitor vaccination progress. As of 2009, completion of vaccination protocol for girls aged 12–18 ranged from 66%–73% (73% for 12-

Despite these data, opposition to mandated HPV vaccination makes a government mandate unlikely in the U.S.<sup>26,21,27</sup> Implementation of the HPV vaccine is in stark contrast to that of its most recent historical correlate, the hepatitis B vaccine. Like HPV, hepatitis B is largely spread through sexual

contact. Despite the sexual nature of hepatitis B transmission, state mandates now exist for children in every state except Alabama, Montana and South Dakota.<sup>28</sup> ACIP guidelines have been instrumental in institutionalizing neonatal and childhood vaccination protocols for hepatitis B since 1991.

In 2007, Governor Rick Perry of Texas issued Executive Order 65, mandating HPV vaccination of adolescent girls. However, amid controversy rooted in Governor Perry’s ties to Merck (the manufacturer of one form of HPV vaccine), the sexual nature of HPV acquisition, and the relative newness of the vaccine, the Texas House quickly overrode Governor Perry’s decision, passing HB 1098 to prohibit a mandated HPV vaccine.<sup>27,29</sup> Since then, forty-one states have proposed legislation to mandate vaccination<sup>30</sup>; only Washington, DC and Virginia have succeeded in passing legislation, but both have generous “opt-out” rules.<sup>27</sup>

As exemplified by Governor Perry's controversial mandate, negative opinions regarding large-scale implementation of HPV vaccination have been rooted in three core concerns: worries regarding ties to drug manufacturers; concerns—not borne out by the evidence—over the possibility of increased promiscuity after vaccination; and the concern about the safety of vaccination in general<sup>31-37</sup>. Republican Presidential candidate and Congresswoman Michele Bachmann (R-MN) made an even more extreme, unfounded claim in 2011, that HPV vaccine caused a woman's daughter

to "suffer...mental retardation as a result."<sup>38</sup>

Studies have shown that direct to consumer (DTC) advertising fails to provide enough information to allow consumers to make informed decisions regarding HPV vaccination.<sup>39</sup> In one study DTC advertising had little success increasing the number of those vaccinated.<sup>40</sup> And most shockingly, despite new guidelines, STI clinics have been slow to uptake the vaccine as part of regular practice.<sup>41</sup> At the end of 2010, only 7 of 42 STI clinics studied offered the vaccine at all.

### **CREATIVE STEPS NEEDED TO INCREASE HPV VACCINATION RATES AMONG BOTH MALES AND FEMALES**

The recent ACIP recommendations and AAP guidelines represent important milestones in the prevention of HPV and HPV-related cancers. Furthermore, they open the door to the possibility of addressing important health issues affecting women and gay and bisexual men. At this point in time, the HPV vaccine is underutilized.<sup>6</sup> Both initiation and completion of vaccination protocol are significant issues. As demonstrated in a 2010 study by Moore et al., even under "ideal conditions," where the vaccine is free and patients are recruited in a clinic setting, uptake of vaccine may be low among targeted populations. In this study, only 50.7% of patients offered free HPV vaccination received the first dose, and only 28% of patients completed the three-dose regimen.<sup>42</sup> The research and implementation literature document a multitude of barriers to vaccination. Negative attitudes and a poor

understanding of the vaccine's risks and benefits prevent parents and patients from making informed decisions regarding vaccination. As demonstrated

**Only 34% of U.S. physicians routinely recommend HPV vaccine for eligible patients.**

in a 2011 study, only 34% of prescribing physicians even routinely recommend HPV vaccination for eligible patients.<sup>43</sup> And as of 2011, the majority of STI clinics do not even carry HPV vaccines as part of protocol.<sup>41</sup> At the community level, there exist few, if any, government sponsored HPV vaccination implementation strategies. And at the federal and state level, there are major political hurdles to developing legislative mandates to vaccination.

## RECOMMENDATIONS

1. **Public health officials and political leaders should take creative steps to facilitate and promote vaccination uptake.** Although optimal coverage for vaccination recipients is from age 11–13, prior to sexual debut, studies have shown that HPV vaccination for males is both effective and cost effective up to age 26. Mandating or facilitating implementation of vaccines among young adults through social institutions serving young men may prove effective. The military, state and federally-funded universities and community colleges, and government-funded job training programs may be institutions where it makes sense to either encourage or mandate vaccination, similar to current requirements for tuberculosis screening; measles, mumps and rubella (MMR) vaccination; tetanus-diphtheria-pertussis (Tdap) vaccination; and meningitis vaccination requirements.
2. **Novel interventions should be implemented immediately to address the multiple barriers to vaccination.**
  - a. **HPV vaccination educational campaigns must be context specific.** In other words, male-focused educational campaigns must meet boys where they are, and include information that is relevant. That includes information regarding prevention of anal, oral and penile cancer as well as prevention of genital warts.<sup>44</sup> Campaigns to vaccinate young children should address parents directly to dispel unfounded fears related to increased promiscuity<sup>31</sup>, and to reiterate the safety and benefit of vaccination.
  - b. **Work must be done to increase the practice of recommending the HPV vaccine by providers to their patients.** The new American

Academy of Pediatrics guidelines represent a significant stride toward increasing provider recommendation behavior. But there remain large gaps that could possibly prevent recommendation by physicians to parents and eligible young adults. Incorporation of this guideline into family practice and infectious disease practices, and among STI clinics and clinicians, could greatly increase the rates of recommendation.

- c. **Structural barriers to obtaining vaccination must be removed.** Access to vaccination at STI clinics should increase, as these clinics disproportionately serve populations at risk for HPV. And there is the potential to offer vaccination at non-clinic sites (like pharmacies), similar to models for flu vaccine.
- d. **Cost barriers to obtaining vaccination must be addressed.** Though all U.S. children up to age 19 are covered for recommended vaccinations under the Vaccines For Children Program (VFC), and insurance companies must cover HPV vaccine starting in December 2012, there remains a population that may not be eligible for covered, reduced price, or free vaccination. Public education of insurers about the ACIP recommendation of HPV vaccine for boys and young men, and legislation to increase the coverage age for vaccines covered under the VFC Program to age 21, can increase access to the vaccine and improve public health outcomes. We also urge insurers to cover the vaccine for older women and men who may not have been exposed to HPV and who could benefit from the vaccine to avoid HPV-related genital warts and cancers.

3. **Research must be done to address gaps in knowledge in HPV vaccination.** These can include more detailed examinations of cost effectiveness, and optimal coverage in vulnerable populations (low socioeconomic status (SES), racial and ethnic minorities, homeless youth and sexual minorities). Research should also include identification of determinants of HPV vaccination (SES, location, intent), successful intervention models, and behaviors influenced by prior vaccination (number of partners, drug and alcohol use, etc).
4. **Research must be done to better develop and administer the HPV vaccine.** The current dosing regimen covers two to four strains of HPV and requires three injections to achieve optimal coverage. Research and development should pursue formulations and regimens that cover more strains of HPV and either require fewer injections, or are bundled with existing vaccinations.
5. **Further research should be conducted to understand the incremental benefits of vaccination of men and women above age 26.** Very few men in their late 20s and 30s have been exposed to all four strains of HPV prevented by the HPV vaccine. What would be the relative cost-effectiveness of providing HPV to this population, or a subgroup at high risk for HPV-related anal cancer, such as MSM or HIV-positive MSM?
6. **Research should examine the use of HPV vaccine in a therapeutic manner.** Might people be less likely to get diseases associated with HPV if they have already been exposed? Might HPV vaccine prevent an HPV-infected woman from getting cervical cancer in the future? Could the vaccine protect HPV-infected men and women from anal cancer?

Written by:

John Trinidad, MPH  
*Harvard School of Public Health  
and University of San Francisco  
School of Medicine*

Edited by:

Sean Cahill, PhD  
*Director of Health Policy Research*

Reviewed by:

Judith B. Bradford, PhD  
*Director of the Center for Population  
Research in LGBT Health  
Co-Chair of The Fenway Institute*

Harvey J. Makadon, MD  
*Director of the National LGBT  
Health Education Center*

Kenneth Mayer, MD  
*Medical Research Director,  
Co-Chair of The Fenway Institute*

Lori Panther, MD, MPH  
*Associate Medical Director  
for Clinical Research*

Rodney VanDerwarker, MPH  
*Administrative Director*

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