

## Mandatory Gardasil Vaccination in Adolescents

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## Introduction

The purpose of this paper is to discuss recent legislative changes about requiring mandatory vaccination of adolescents with Gardasil. In October 2006, Gardasil was approved by the Food and Drug Administration (FDA) to help prevent cervical, vaginal, and vulvar cancer caused by the Human Papilloma Virus (HPV). HPV is the virus responsible for genital warts through which are transmitted through sexual contact. The vaccine was originally intended for use in females, but is now recommended for use in males as well. Regardless of the gender of the individual, there is controversy about the need for the vaccine. The Gardasil vaccine is intended to be administered before an individual is exposed to HPV, hence young adolescents ages 11 and 12 are the targeted age group since the majority of them have yet to engage in sexual activity. Many parents, however, feel that once their child receives this vaccine that the child will then feel free to participate in sexual activities since they are “protected” from HPV. Also, there is a new issue surrounding the Gardasil vaccine’s recent addition to the Center for Disease Control’s (CDC) Childhood Immunization Schedule. Subsequently several states are pursuing legislation to require the vaccination prior to school attendance. This paper will look at the ethical issue of a state mandate requiring an adolescent to be vaccinated with Gardasil.

I choose to write about this topic because I have received the vaccine. When I was a senior in high school, the vaccine had just been approved and my parents were excited to help protect me in any way they could. However one day my mother mentioned to a coworker that her daughter was going to get “that new HPV vaccine.” The coworker not so enthusiastically replied, “Oh, my daughter won’t be needing *that*.” Regardless, I did receive the vaccine, yet controversy still exists today as to whether this vaccine is a go-ahead for adolescents to engage in sexual behaviors. Additionally, I am partial to this topic as I am a peer educator through the

Coterie Theater, teaching HIV/AIDS and sexual transmitted disease (STD) prevention to local teens in the Kansas City area. Often times I am asked by students about the vaccine, whether they should get it, and whether it is a cure. These types of questions clearly show the lack of education regarding this important new vaccine. It is imperative that the issues surrounding the Gardasil vaccine be addressed and brought to the attention of public so that adolescents can make clear, informed decisions when trying to protect themselves.

### **About HPV and the Vaccine**

According to the Centers for Disease Control and Prevention (CDC), “HPV infects approximately 20 million people in the United States with 6.2 million new cases each year,” and “cervical cancer is the second leading cancer killer of women worldwide.” In the United States, nearly “10,000 women are diagnosed with cervical cancer each year and 3,700 of these women die each year from this disease” (CDC, 2010, pg. 620). A Papanicolaou test (Pap smear) can be used to diagnose an HPV infection. It is recommended that sexually active women have an annual Pap smear exam to look for this virus and discuss other well woman issues. It is important to note that there is no cure for HPV, only treatment for related health problems.

As mentioned above, the Gardasil vaccine was approved by the FDA in October, 2006 to help “prevent four specific strains of HPV (6, 11, 16, and 18)” (McLemore, 2006, pg. 559). More importantly, “nearly 70 percent of cervical cancer cases and 90 percent of genital warts cases are linked to these four strains of HPV” (Hanson, 2010, pg. 1). Gardasil was created by the Merck Sharp & Dome pharmaceutical company as a prophylactic measure for the prevention of cervical cancer; it is not a cure for cervical cancer. The vaccine is a series of three intramuscular shots administered over six months and is targeted at “females age 11 and 12, but can be administered up to the age of 26” (Contraceptive Technology Update, 2007, pg. 32). It is a

recombinant vaccine that produces an immune response within the recipient while causing no risk of contracting the original disease, HPV. This immune response allows the recipient to produce antibodies against the four specific strains of HPV so that he or she will be able to defend against the virus if ever exposed. Additionally, as of October, 2009, the Gardasil vaccine was licensed “for use in males aged 9 through 26 years for prevention of genital warts” (CDC, 2010, pg. 620).

### **Issues**

Gardasil has been proven to be “more effective when administered prior to exposure to HPV,” which is before the initiation of sexual activity (Contraceptive Technology Update, 2008, pg. 127). Moreover, “in the U.S., sexual activity begins in ninth grade for 29.3% of girls, and 62.4% of twelfth grade girls report prior sexual activity” (Caron, Kispert, & McGrath, 2009, pg. 2). Consequently the targeted ages for both female and male recipients are ages 11 and 12. Currently, the CDC has updated the National Childhood Immunization schedule for children and adolescents to include “Gardasil, the first (HPV) vaccine...for females ages 11 to 12, and permissive use of the vaccine in females as early as age 9 and up to age 26,” (Contraceptive Technology Update, 2007, pg. 32). Given that this is the targeted age group, several states have begun requiring that young girls entering sixth grade in the public schools receive the Gardasil vaccination prior to attendance. Having a state mandate that all school girls be vaccinated against HPV has become an extremely controversial issue.

It is not unheard of for a state to require a child to receive a specific vaccination to attend school. Nearly every state mandates that school children receive most of the other vaccines in the Childhood Immunization schedule, such as those for tetanus, hepatitis B, chickenpox, and measles. The CDC creates these recommended immunization schedules so that the public may

be protect from serious, potential harm. However, it is important to take into account that never before has a vaccine been required for simply one gender of school children. School vaccination requirements are decided by state legislatures and regulatory bodies. 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;” however, “legislators in Texas passed H.B. 1098 to override the executive order” (Hanson, 2010, pg. 2). Following Texas’ actions, “19 states introduced and enacted legislation to require, fund or educate the public about the HPV Vaccine, including Colorado, Indiana, Iowa, Louisiana, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Texas, Utah, Virginia and Washington,” (Hanson, 2010, p. 2).

Reasons for controversy are vast, yet they center on the fact that some parents have problems giving a vaccine against an STD to adolescents. Other parents might “not want a vaccine against an STD at all, believing that their children could not be at risk, even though most reports show that half of high school students are having sex” (Iannelli, 2010, pg. 1). Still others think that Gardasil might encourage promiscuity among adolescents, since it could foster the belief that the vaccine “protects” against STDs. The reality is that Gardasil does not protect against other STDs, just HPV. Since HPV is spread through sexual contact, many parents are hesitant to talk to their adolescents about the issues surrounding this vaccine.

### **Review of Literature: Supporting**

Although the vaccine is fairly expensive, the Contraceptive Technology Update looked at the cost effectiveness of receiving the vaccine. The study took into account the cost of the vaccine, yearly Pap smear screenings, and the cost of treating cervical cancer and other illnesses targeted by the vaccine. Analysis findings indicated that “vaccination against HPV-16 and

HPV-18 would lead to lower cervical cancer rates and be economically attractive if high coverage can be achieved in the most important target group of 12-year-old girls” (Contraceptive Technology Update, 2008, p. 127). Meaning that, while the Gardasil vaccine may appear expensive to frugal consumers, it would prove beneficial to pay for one vaccine rather than spending large sums of money later in life for continuous, expensive treatments of cervical cancer. Additionally, because the Gardasil vaccine is included in the CDC’s Childhood Immunization schedule, it is available to young women 18 and younger who “are Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured and many insurance companies are setting policy for reimbursement for the vaccine,” (Contraceptive Technology Update, 2007, pg. 32).

Concerning the administration of Gardasil, findings from a recent study of Australian teens ages 12-18 indicate that “hypersensitivity reactions to the vaccine are uncommon and most girls in this age range can tolerate subsequent doses,” yet observation for 15 minutes after administration is recommended (Contraceptive Technology Update, 2009, pg. 14). As with many other vaccines, fainting and dizziness are common side effects after receiving Gardasil and some injection site tenderness was also noted, especially after the third and final dose. Since administration of the vaccine is well tolerated, it can foster positive interactions between providers and their young female clients. Not only does Gardasil help protect young women from contracting HPV, but it also “offers family planning programs an important way to serve young girls and initiate at a very young age the discussion of the use of contraception to prevent unintended pregnancy” (Contraceptive Technology Update, 2008, pg. 127). This important conversation leads to further discussions between young women and their care providers about

the necessity of protection to prevent pregnancy and other STDs, as well as how to avoid being a victim of physical or sexual abuse.

Today, the Gardasil vaccine is approved for use in males as well as females. In males HPV generally causes genital warts, but can also be linked to certain anal, penile, and oropharyngeal cancers. Warts specifically have an adverse effect on quality of life and cost an estimated “\$200 million per year in direct medical costs” (CDC, 2010, pg. 630). The vaccination of young men is especially important considering “HPV infection in men has been shown to contribute to HPV infection and subsequent cervical disease in women,” and there is a high rate of transmission of HPV in female partners of men with pre-existing penile warts (Contraceptive Technology Update, 2009, pg. 14). More importantly, “if large numbers of girls and women do not obtain the recommended vaccinations, then vaccination of men and boys could play a significant role in lowering infection rates among males and females,” (Contraceptive Technology Update, 2009, pg. 14). Through vaccinating young men, practitioners are not only decreasing the incidence of genital warts in this population, but they are also decreasing the chance that these individuals pass HPV to their partners later in life. By applying the concept of herd immunity, where 80% of a population is vaccinated against a certain disease and thus the entire population is then considered immune, health care providers can reduce the overall occurrence of HPV infections in both males and females.

In general, the Gardasil vaccine is largely approved. A recent study noted that not only did “70.2% accept vaccination for girls,” but that after introduction to the Gardasil vaccine, “HPV awareness increased”(Christian, Christian, & Hopenhayn, 2009, pg. 439). Even organizations such as Focus on the Family and the Christian Medical Association that don't believe the vaccine should be mandatory, strongly support the vaccine itself. This may be due to

the fact that whether or not an adolescent receives the vaccine, awareness about HPV and associated risky behaviors has increased overall. Adolescents are now more aware that the actions they choose to take today may affect them for the rest of their lives. Furthermore, the most apparent and probably most obvious reason for the acceptance of the vaccine is that “Gardasil is the first vaccine that may actually prevent a cancer” (Nelson, 2007, pg. 23). With the exception of the Hep B vaccine that is targeted to prevent liver cancer, there are very few vaccines that can make this astounding claim. There is no cure for cancer, so any vaccine that can help prevent such a devastating disease is truly amazing.

### **Review of Literature: Opposing**

A significant disadvantage of the Gardasil vaccine is related to the cost. According to the Contraceptive Technology Update in 2008, the vaccine series “costs about \$360,” not including the associated costs of office visits. While the vaccine is beginning to be accepted and covered by many health insurance companies, it is still an added expense. Considering that HPV is 100% preventable through abstinence from sexual activity, many parents may not see the importance of having their child receive a vaccine such as this. Therefore, the cost alone may deter some parents from having their children vaccinated with Gardasil.

Many experts are concerned that with the protection Gardasil provides, the female population may “become apathetic about continuing regular cervical screenings,” and stop scheduling yearly Pap smears all together (Calder, 2009, pg. 20). In order for the vaccine to be effective a strong national cervical screening program must be maintained and promoted by all practitioners. To elaborate this point, “if the community is led to believe they are protected against cervical cancer and do not maintain regular cervical screenings, there may actually be an increase in the incidence of cervical cancer” (Calder, 2009, pg. 20). This issue must be in the

forefront of any medical practitioner's mind when discussing or administering the Gardasil vaccine to female clients. The individual must impart the purpose of the vaccine; that it protects against only four strains of HPV; and stress the importance of continuing yearly Pap smear exams. Practitioners must discuss the fact that engaging in unprotected sex with multiple sex partners are risk factors for contracting HPV and even individuals that have been vaccinated should refrain from these activities. Additionally when discussing the annual Pap smear, the practitioner must remind female clients that the Pap smear looks for more than just cervical cancer and can help detect other STDs and abnormalities that may also require medical attention.

Finally, questions remain about Gardasil's overall effectiveness, the duration of its protection, and possible long-term adverse effects. A "total of 10,326 adverse events following immunization [with Gardasil] were reported," with syncope and fall related injuries being the worst (Contraceptive Technology Update, 2009, pg.14). While monitoring for 15 minutes after vaccine administration is recommended, this may not always be performed or documented. Data obtained from clinical trials shows that Gardasil is "100 percent effective against [HPV] types 16 and 18," yet it is unknown how effective the vaccine is against HPV strains 6 and 11, which the vaccine also targets (Calder, 2009, pg. 20). Currently, the vaccine is expected to provide protection against HPV "for at least 20 years," but the precise extent of its effectiveness is unknown (Contraceptive Technology Update, 2008, pg. 127). A booster may be administered later in life, yet this would be another cost to parents, while again placing their adolescent at risk for potential adverse effects of the Gardasil vaccination.

### **Conclusion**

When considering Gardasil as mandatory school vaccination, we must remember that Gardasil is merely a preventative factor to contracting HPV, not a cure for cervical or other HPV

related cancers. Abstinence is still the goal for teens and young adults and should be encouraged and taught in schools. Still, there is a high chance that even if an individual waits until marriage to engage in sexual activity, that his or her partner could have or have been exposed HPV, unless it is their first time engaging in sexual intercourse, too. While parents are disgruntled about the implications of this vaccine, the fact still remains that adolescents are engaging in sexual activities and therefore it is necessary to begin vaccination at such a young age. Not only would mandatory vaccination protect adolescents later in life, but it may also protect those who are victims of sexual abuse. It is unclear if the protection that Gardasil offers against HPV will be lifelong, but similar to other vaccines a booster dose could be provided later.

This topic is extremely important to us as nurses since both medical providers and school educators need to be aware of media reporting in order to alleviate fears that the public may experience about the Gardasil vaccine. Additionally it is our responsibility to inform adolescents as well as parents about the risk factors associated with contracting HPV; the importance of maintaining yearly Pap smears; and the usefulness of the Gardasil vaccine in preventing cervical cancer. I personally have gained insight to the legislative process surrounding mandatory school vaccinations and the importance of educating all parties, not just the individual that may be receiving the vaccine. It is evident that parents and practitioners must put aside their differences and recognize that Gardasil is one of the first vaccines that may actually prevent multiple forms of a cancer. Therefore it is our duty as medical professionals and parents to do what is best for adolescents and protect them in any and every way we can.

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