Mandating the HPV Vaccine

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Merck’s new vaccine, Gardasil, has been a controversial topic across the nation. Gardasil provides protection from four strains of the human papilloma virus (HPV), a sexually transmitted virus that can cause cervical cancer. What makes this vaccine controversial is that the virus that Gardasil provides protection from is acquired primarily through sexual contact, therefore talk of mandating this vaccine gives rise to the following ethical dilemmas: cost, limited data on safety and efficacy of the vaccine, incomplete coverage, possible decline of cervical cancer screening, false sense of security which may increase promiscuity or a decline in safe sex practices, and lastly parental responsibility vs. state responsibility. Despite these concerns, there are stronger arguments to recommend mandating the HPV vaccine across the states. After providing some background about HPV, the HPV vaccine, and vaccine mandating laws, I will address the ethical concerns involving mandating the HPV vaccine.

HUMAN PAILOMA VIRUS (HPV)

Genital HPV is a sexually transmitted disease (STD) that has been linked to cause cervical cancer in women. According to the Centers for Disease Control (CDC), 6.2 million people are infected every year with HPV and 15 percent (or 20 million) of the United States population is currently infected with HPV. Most people do not have any signs or symptoms of an infection, therefore, could unknowingly be passing it onto their partner(s). Half of those currently infected are between the ages of 15 and 24 years old. The CDC also estimates that by
the time women reach the age of 50 years old, 80 percent will have had at least one type of HPV infection in their life\textsuperscript{4}.

To date, 30 strands of HPV have been identified to cause a genital HPV infection, and one-third of those strands have been associated with cervical cancer. Virtually all cervical cancers are related to HPV and the strands 16 and 18 are known to cause 70 percent of cervical cancer cases\textsuperscript{1}. Luckily, 90 percent of women will clear an HPV infection within two years without complication. However, the other 10 percent can continue to have persistent infections that can progress to cervical cancer\textsuperscript{4}. The American Cancer Society reported that about 10,000 women were diagnosed with cervical cancer in 2006, and they estimated that over 11,000 women will be diagnosed with cervical cancer in 2007\textsuperscript{1}.

**HPV VACCINE**

On June 8, 2006, the Food and Drug Administration (FDA) approved the use of the first vaccine used for the prevention of HPV. Merck developed Gardasil, which is a 3-shot series quadrivalent vaccine used to protect against four common strains of HPV: 6, 11, 16, and 18. Strains 6 and 11 are responsible for over 90 percent of genital warts, and strains 16 and 18 are responsible for 70 percent of cervical cancers. Gardasil is indicated for females who are 11-26 years old and is recommended for females before they become sexually active\textsuperscript{6}.

Gardasil has been tested in many countries. Over 11,000 females around the world ranging from 9-26 years of age have received the vaccination to test the safety and efficacy of it. Thus far, the vaccine has been shown to be 100\% effective against strains 6, 11, 16, and 18 at
five years post receiving the vaccine. The most common side effects were injection site pain and swelling, fever, headache and nausea which all resolved on their own. The vaccine contains yeast product, so any allergy to yeast would be a contraindication. On the other hand, Gardasil does not contain thimerosal or mercury, which many parents have thought might be linked to autism.6

**VACCINE MANDATORY LAWS**

It is very common for states to pass laws mandating vaccinations for children as a prerequisite to enroll in public or private schools. Many states use the CDC’s recommended schedule of immunizations as a guide for the types of vaccinations a child should receive and when a child should receive it. These laws have played a crucial role in controlling vaccine preventable diseases in the United States. Through mandating vaccines, the United States population has significantly reduced and even eliminated some common diseases of our ancestors. For instance, diphtheria has caused over 10,000 deaths in United States resulting in its reputation of being the most dreaded of childhood diseases. Within 10 years after beginning to vaccinate children, the disease began to disappear. Today’s pediatricians rarely (if ever) see a case of it. Other examples of mandatory vaccine benefits are the status of smallpox and polio. In the 1950’s, polio paralyzed children by the thousands. As a result of mandatory vaccination against polio, there has not been a single case of wild type polio virus since 1979. One of the most common examples of the benefit of vaccinations is the eradication of smallpox. Smallpox killed millions of people every year around the world making it one of the most devastating diseases in the world at the time. Only twelve years after the World Health Organization
undertook an intensive vaccination campaign, smallpox was completely eradicated from the planet.\textsuperscript{18}

Another benefit of mandatory vaccination laws is that an increase in the number of people who are immune to a disease provides a benefit to individuals who are not immunized. Some children cannot get vaccines for certain medical or other reasons. In these cases, the immunity of the community around them decreases the chance that the un-immunized person will acquire the disease. On the other hand, if more people decide not to get immunized, then the risk for getting a disease increases.\textsuperscript{15}

Even if a vaccine is required by state law, many states offer exemptions for mandatory vaccinations. Exemptions range from medical conditions, religious beliefs, and philosophical or moral convictions. Even though these exceptions exist, they are not often exercised leading to a far majority of children to be vaccinated. Again, with a large number of vaccinated children, a small few who are not vaccinated will still benefit from the vaccine. After all, if a disease is not active in a community, it cannot be passed around.\textsuperscript{18}

**ETHICAL CONCERNS**

Presently, over 18 states in the United States are debating on whether or not to mandate the HPV vaccination\textsuperscript{14}. Some of the concerns with mandating the Gardasil vaccine are the cost of the vaccine, the limited data available, the incomplete coverage of the vaccine, the perceived risk of a decrease in cervical cancer screenings, possibility of promiscuity, and the state vs. parental responsibility of enforcing vaccinations.
Cost of the Vaccine:

Gardasil is a three shot series, and each shot is about $120. Even though this vaccination may be appealing to parents, the cost of it may deter many of them. However, the Vaccines for Children (VFC) federal program will provide vaccines to children and adolescents under the age of 19 for no charge. In addition, most insurance companies cover vaccines that have been mandated by the state. On the other hand, the cost of cervical cancer has been estimated to average about $3,800 million.

Limited Data on Safety and Effectiveness of the HPV Vaccine:

Although the HPV vaccine has been determined as safe and effective, the data to support this is limited and fairly new. Even though it is possible that the sample population used in research clinical trials may not experience side effects or adverse effects that people in the entire population may experience, there have not been any severe or serious side effects associated with the vaccine reported. To build more data on the safety of this vaccine, a post-licensure safety monitoring plan is in place to see how the general population reacts to this vaccine. In addition, the CDC and FDA sponsor a national reporting system that monitors reports of side effects that the public self-reports to the Vaccine Adverse Event Reporting System (VAERS).

In addition to the limited safety data, there is also limited data on the effectiveness of Gardasil. It has been established that the vaccine provides protection for at least five years.
However, the American College of Pediatricians points out that it can take about 20 years from the time of initial infection to death from cervical cancer. Therefore, it can take years before the actual efficacy of the vaccine is established. Because of this limited data, the American College of Pediatricians is not in favor of any law requiring this vaccine for school enrollment until further data is reported\textsuperscript{17}.

Based on the article from the American College of Pediatricians, one of their primary concerns is that girls will lose the effectiveness of the vaccination, since currently the longevity of the vaccine is unknown. However, Merck has plans to follow up with the females involved in the clinical trials, so before the rest of the general population will need a booster shot, information will be out indicating how long the vaccine is good for before a booster is indicated.

**Incomplete Coverage of the Vaccine:**

There is a concern that even if females are vaccinated with Gardasil, they will not be completely protected from developing cervical cancer. As stated earlier, Gardasil only provides protection against four strains of the HPV virus, and only two of those strains are linked to cervical cancer. And these two strains are not the only causes of cervical cancer, but they do cause 70 percent of cervical cancers. Another concern is that if women obtain the vaccine after they unknowingly become infected, they will not benefit from the vaccine.\textsuperscript{6}

If a woman is not vaccinated she has a higher chance of getting a HPV infection. Even if she has an infection, she could still be protected from the other strains that are in the vaccine. My concern on this issue would not be the incomplete coverage, but the cost of the vaccine if the
risk is still the same. In other words, if the vaccine provided someone no extra benefit, then the cost of the vaccine would not be worth it. So, the best strategy would be to provide the vaccine before a female becomes sexually active, as well as promote the annual screenings for cervical cancer.

**Cervical Cancer Screenings May Decrease:**

Currently, the main prevention of cervical cancer progression is routine screening with the Pap Test. The American Cancer Society recommends all females to receive an annual Pap Test after they become sexually active or once they turn 21, whichever comes first. The Pap Test has been shown to reduce the rate of cervical cancer by about 60 percent. However, the Pap Test is not perfect, there have been cases where it has given false negatives and it only works when it is done. The sensitivity of the Pap is only 70 percent. Therefore it misses about 30 percent of cervical cancers. Provider error represents another 10 percent of cancers that are missed even when a Pap Test is performed. It has also been shown that most of the women who are at risk for HPV infection fail to get a Pap Test, and at least half of the women who develop cervical cancer have either never had a Pap Test or do not receive a Pap Test regularly.¹

The CDC cervical cancer screening recommendations have not changed. In addition, the CDC has made it clear that the HPV vaccine is not replacing current screening methods for cervical cancer.⁶ The American Cancer Society also indicates that the HPV vaccine should not replace previous screening methods and that healthcare providers should ultimately explain this to patients.¹
Another way that this could be looked at is that a majority of women who do not receive annual cervical cancer screenings such as the Pap Test would benefit from the HPV vaccine. That way, even if they are not getting a complete prevention measure for cervical cancer, they are getting more prevention than they would have received anyway.

The HPV Vaccine May Promote Promiscuity:

One of the main arguments of opponents to mandating the HPV vaccine is that it will promote unsafe sex and multiple sex partners\textsuperscript{1-13}. The American Cancer Society points out that in order for adolescents to think casual sex is safer with the HPV vaccine, fear of HPV would have to be a motivation for safe sex practices and/or abstinence\textsuperscript{1}.

In a story for TIME magazine, author Nancy Gibbs writes, “When my 11-year old got her tetanus shot during her checkup last week, her pediatrician did not tell her that is was now safe to go dance barefoot on rusty nails.\textsuperscript{13}” Using the same concept, would a parent or pediatrician tell adolescent girls that after receiving the HPV vaccine to go out and have casual sex? Probably not. Also, when I surveyed about 100 high-school girls, their number one concern with sex was pregnancy followed by HIV. In addition, about 85 percent have never heard of HPV. Therefore, HPV was not strong cause for practicing safe sex and/or abstinence in this population.

In another survey I put together for a small sample of adults with children, I asked 122 parents what there views were about HPV, HIV, Hepatitis B. Parents were given the following information about HPV, HIV and Hepatitis B: \textsuperscript{1,2,4,5,7,8,9,10,14,16}
**HPV** is a sexually transmitted virus that may cause cervical cancer in women. Although most women’s immune system can eliminate the virus within two years, about 10 percent of those infected will not be able to clear the virus. This persistent infection can lead to the development of cervical cancer. The CDC has reported that over 6 million people are infected every year with HPV. Currently, about 20 million are infected with HPV. And it is estimated that 10 percent of them will be diagnosed with cervical cancer at some point in their life.

**HIV** is a sexually transmitted disease that can weaken the body’s immune system and is transmitted through sexually contact as well as bodily fluid exchange. In 2005, according to the CDC there were around 40,600 people diagnosed with HIV and over a million people were living with HIV/AIDS. Furthermore, the CDC reports that almost 80% of the people infected with HIV acquired the virus through sexual contact.

**Hepatitis B (HBV)** is a virus that attacks the liver. About 70 percent of people acquire the virus through sexual contact, although like HIV it can be transmitted through other bodily fluid exchange (i.e. blood transfusions). Similarly to HPV, most people will clear the virus, but those that do not can develop chronic liver disease. The CDC reports that in 1999, about 120,000 people were infected with HBV and about 420,000 were living with an HBV infection. This data is a little older than the other two STDs primarily because the Hepatitis B vaccination introduction has had a positive influence on the statistics of how many people are infected with HBV. The HBV vaccine has been available since 1981, and by
1999, 47 states have mandated the use of the HBV vaccine. This vaccine has come under some similar scrutiny that the HPV vaccine is currently receiving.

The following table was also given for easy reference:

<table>
<thead>
<tr>
<th>Virus</th>
<th>New Infections</th>
<th>Current Infections</th>
<th>% Transmitted Through Sexual Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV</td>
<td>6 million</td>
<td>20 million</td>
<td>100</td>
</tr>
<tr>
<td>HIV</td>
<td>40,600</td>
<td>Over 1 million</td>
<td>80</td>
</tr>
<tr>
<td>HBV*</td>
<td>120,000</td>
<td>420,000</td>
<td>70</td>
</tr>
</tbody>
</table>

* These results are from 1999, prior to mainstream of HBV vaccine.

Of the parents polled, 20 percent of parents were aware of HPV; however, 98 percent were unaware of how commonly people are infected or of the potentials dangers associated with HPV. Before given the above information, almost 90 percent of parents were more concerned about their children acquiring HIV. After given the above information, nearly 50 percent were still concerned about the children getting HIV, 35 percent were concerned about HPV and the rest were either concerned about HBV or undecided. Parents were also in favor of giving their children vaccines if they knew for sure the vaccine was 100 percent safe and effective. One of the most interesting results uncovered in this survey, was that over 80 percent of parents would be in favor of mandating a vaccine for HIV even though most of them felt it may encourage unsafe sex. This result seems very interesting because many people opposing the HPV vaccine are concerned that it may promote promiscuity. However, this did not seem to be an issue with a hypothetical HIV vaccine in the adult population I sampled. My thoughts are that the perceived threat was great enough to overcome the possibility of promiscuity. In addition, some comments that were made include:
“If my child is not raised to engage in premarital sex, then the state should not force me to give my child a vaccine he/she does not need.”

“I would rather know that my child is protected from some of these infection[s], then to wonder what they may or may not have. It’s a scary world out there!”

In conclusion, it seems that knowledge and perceived threat of the disease play a role in whether or not parents are supportive in mandating a vaccine or not. This is very similar to the results of the study done in California regarding the public opinion of HPV vaccine acceptance. From what I gathered, parents are either not aware of the potential complications of HPV or they do not think that their child would engage in risky behavior. Some additional information that I would have liked to gather is how well parents are aware of the amount of casual sex that occurs in junior high and high school kids. I would have also liked to address how parents think vaccines work and if they understand how vaccines not only affect the immunized individual, but also the people around them.

Parents vs. State Responsibility:

The second most popular concern with mandating the HPV vaccine is the issue of whether it should be the states’ responsibility or the parents’ responsibility to determine if a child is vaccinated. Historically, the state and local government have been responsible for the preservation of the public health, and in cases of communicable disease outbreaks, the state may enact mandatory vaccination laws.
According to the California Study of HPV vaccine acceptance, many parents did not perceive HPV as a risk, and were surprised to learn that 70 percent of 13 to 21 year olds are infected with HPV within 5 years of sexual activity onset. Furthermore, quite a few parents were unaware about the sexual activity of adolescents in their area. The results of a national survey of sexual activity of adolescents are as follows: 24% of females are sexually active by the age of 15, and 25% of those have had more that 4 partners; 40% of females are sexually active by the age of 16; 70% of females are sexually active by the age of 18.

Based on this information, parents are less likely to see HPV as a risk that their children will encounter at such a young age. I would hypothesize that if parents were more educated about HPV and cervical cancer and why it is important to vaccinate girls as young as 11 or 12 in order to prevent this sexually transmitted disease from potentially causing cervical cancer, then they would be more likely to accept a law mandating the HPV vaccine. Also, because the states are more likely to see the bigger picture of the problem and results of a vaccine, this area should fall under the state responsibility even though HPV is a STD. That is because, HPV is potentially life threatening and it can be passed onto many people without knowledge of it.

Typically, the vaccines that are mandatory are for diseases that are spread through air particles, which make them very easy to spread in a classroom. Two mandatory vaccines that do not prevent diseases that spread this way are the tetanus and hepatitis b vaccines. Tetanus is a toxin from bacteria that can be fatal, but is not contagious. In other words, you cannot get tetanus from someone else. Hepatitis B is another disease that is spread through sexual contact,
blood or other fluid exchange. One of the reasons the hepatitis B vaccination is mandatory, is because 30 percent of the time it is spread without sexual contact.¹⁶

**DISCUSSION**

As a healthcare provider, I am 100 percent in favor of receiving immunizations for vaccine preventable diseases. Personally, I would risk the minimal side effects of the vaccine instead of battling the disease. I am also in favor of letting patients decide what they choose to do to their bodies. The more information patients receive, the more educated choice they can make. With regard to the HPV vaccine, the choice to get or not to get the vaccine affects not only the individual, but also the community around the individual. Because of this, I feel that every female should receive the HPV vaccine unless of course there exists a medical reason or religious belief that would contraindicate the administration of the vaccine. Of course, the vaccine would be more effective if males received it as well. Unfortunately, there is little data on this because men can not get cervical cancer.

Sometimes I think that people forget that the risks of vaccinations are not as bad as the risks of getting the disease. Since the introduction of vaccine use, many of the diseases that our parents and grandparents dealt with were not an issue for our generation. When the disease that is prevented from the vaccine is perceived to be more dangerous than the possible side effects of a vaccine, then people tend not to focus on the side effects of the vaccine. On the other hand, when diseases are not common, that is when the side effects of the vaccines seem to get the most attention. For instance, presently, the measles, mumps and rubella vaccine has been getting some attention for the possible link to autism in children. I am willing to bet that if the measles,
mumps or rubella were still a cause of concern, that the possible effect of the vaccine would not be a big concern.

The varicella vaccine is another vaccine that is a concern of parents. Varicella, the virus that causes chicken pox, is not perceived to be a risk or that serious of a disease. After all, most people who get chicken pox recover without any complications. However, I had chicken pox, but I would give my children the varicella vaccine because I do remember how uncomfortable I was when I had the disease. Also, a bonus with receiving the vaccine is that those that are vaccinated do not have the risk of getting shingles when they are older. Shingles are a reactivation of the varicella vaccine, which can have some severe complications such as blindness.

In conclusion, although there have been concerns about mandating the HPV vaccine, history has taught us that this is the best way to eradicate or significantly decrease the prevalence of a disease. As a health care provider, I would fully recommend vaccines to every patient that does not have a contraindication to it. At the present time, if the HPV vaccine was made mandatory, there would be many people opposed to this vaccine. In time, as more data becomes available about the safety of the vaccine and as more people are made aware of the complications and commonality of HPV, the acceptance of HPV should increase. The best option would be to mandate the vaccine after more data has been published, and increase efforts to raise awareness about HPV.

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REFERENCES


