HPV Vaccine Controversy: Ethics, Economics, and Equality

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Introduction and Background

The debate over the Human Papillomavirus (HPV) vaccine represents a collision of two of the most controversial topics in healthcare in America, mandatory vaccination and teenage sexuality. Unsurprisingly, the argument is very politicized, in part due to state governments attempts to make the vaccine mandatory upon school admission for all girls. The arguments for and against the vaccine can largely be broken down into either ethical or economic issues, with the ethical issues split between concerns about the morality of a vaccine for a sexually transmitted infection and the question of parental rights in regards to mandatory vaccination. Further controversy has emerged over whether boys should receive the vaccine to protect them from the other diseases caused by HPV, and to decrease the sexual transmission of HPV to girls, who will later be at risk for cervical cancer. Despite support for the HPV vaccine by the American Academy of Pediatrics, the American Cancer Society, the Centers for Disease Control and Prevention, and other medical societies, there are still many controversial issues of HPV vaccination to be resolved.

Human Papillomavirus (HPV) and Cervical Cancer at a Glance

HPV in the US[1,3]	Cervical Cancer in the US[1,2]
• Over 100 types of HPV • Types 16 & 18 cause 70% of cervical cancer • Types 6 & 11 cause 90% of genital warts • 6 million HPV infections per year – 15% of the population* • ½ of HPV infections are in 15-25 year olds • Sexually transmitted – most common STI	• 9700 cases diagnosed per year • 3700 deaths per year • 500,000 precancerous cervical lesions identified per year • Median age of diagnosis is 47 years old • HPV is a "necessary precedent to cervical cancer"[4]

*This is likely an underestimate because HPV infections often clear quickly and without health consequences.[3]

Vaccines have been developed to prevent infection by certain strains of HPV. Cervarix protects against types 16 and 18, and Gardasil protects against 16 and 18, as well as types 6 and 11.[1,3] This paper will focus on Gardasil as it has been approved for longer and is the vaccine

most often referenced in the literature. Gardasil has been shown to be 100% efficacious in preventing persistent HPV infections from types 6, 11, 16, and 18.[1] This translates into the potential to prevent at least 70% of cervical cancer if the immunity conferred by the vaccine persists. There is not enough follow-up data yet to determine for how long protections lasts and if a booster vaccine is needed.[1]

The vaccine is considered very safe, however injection site adverse experiences, like redness, pain, and swelling, are very common.[1] Safety in pregnancy is still under review and the vaccine is not recommended in early pregnancy. The vaccine is currently recommended for girls ages 11-12, with catch-up vaccination in girls aged 13-26.[5] The recommended age is based on the statistics of sexual debut in the US, with one quarter of females reporting being sexually active by the age of 15.[1] Because the vaccine is most effective when given before any exposure, the recommended age of vaccination is set low to ensure that all girls are vaccinated before sexual debut.[1] The clinically indicated age of vaccine is one of the contested aspects of Gardasil, but it will not be explored in this paper.

The Controversy: *Mandatory HPV Vaccination – Ethics*

The ethics are multi-faceted with arguments falling on both sides of the line. One major concern about making the HPV vaccine mandatory is that it infringes on parent's autonomy in raising their children, especially in regards to values about sexual behavior.[4] There is concern among some parents that by giving a child a vaccine for a sexually transmitted infection at the age of 11 or 12, we are giving them "implicit permission to engage in risky sexual behaviors."[4] However, there has been no evidence to support this concern.[4] In fact it has been shown that adolescents are relatively unaware of HPV, and that fear of HPV or STIs in general has very little effect on their decision of whether or not to engage in sex.[4]

Further rebuttal of infringement on parental autonomy focuses on a cost-benefit ethical analysis. How much parental control is really lost due to mandatory vaccination? It seems a small price to pay for preventing a terrible disease that ends the life of women in their prime, and also causes significant distress in half a million women a year with precancerous lesions, who often must undergo multiple procedures.[2,1] The benefit of the HPV vaccine falls under the very basic ethic of using accepted medical technology to prevent serious diseases whenever possible, in order to minimize pain and suffering. Vaccines have long been accepted as an excellent way to prevent dangerous diseases from striking our citizens, and unlike advanced cervical cancer, some of these disease have effective treatments and yet the vaccine is still deemed necessary.[6] The value of a *vaccine that prevents cancer* should be relatively self-evident, and this vaccine is considered a major public health milestone.[4]

Further, there is a historical precedence in public health where a small infringement on personal autonomy is considered permissible when it will result in a large benefit for the population. Mandatory vaccination is one of those situations, in which our government and our citizens have accepted that parents should give up their right to refuse vaccination, except on religious grounds, because of the benefit of herd immunity that protects our nation's children. It is not often that our nation countenances interference in the parent-child relationship, but when not stepping in will lead to dire consequences, like cervical cancer, and the intervention is as relatively minor, it is reasonable and justified for public health to intercede for the child's benefit at the expense of the parent's preference.

Questions of power extend to the school, with many feeling that it is an overextension of a school's authority to mandate a vaccine for a disease that cannot be caught in the classroom, and is the result of "promiscuous but preventable behavior."[4] It is true that the HPV vaccine is

different from most other vaccinations that are required by schools, where it can be argued that the mandated vaccines are a safety issue based on contagiousness within the school setting. However, hepatitis B is "overwhelmingly a sexually transmitted infection," yet it has been part of the vaccines required by schools for over a decade.[7,1] This is because the best way to increase vaccination rates is to make a school mandate.[1] Time and again it has been shown that school-based mandates are very effective in increasing rates of vaccinations, as seen in Hepatitis B vaccination rates, which increased dramatically after it became mandatory for school.[2,1]

Further usefulness of school mandates are that they increase availability of a vaccine.[1] As stated by Ohri *et al.,* "school mandates motivate policy makers and implementers to improve vaccine access for underserved populations."[2] This is achieved through the federal Vaccine for Children Program, which provides free vaccines to all eligible children through the age of 18.[1] Hepatitis B again provides a good example, with its disparity "virtually eliminated…following recommendation for universal…vaccination."[1] Since cervical cancer has a significant heath disparity, with those of low socioeconomic status (SES) bearing 80% of the burden of the disease in the US, it is important to note that a school mandate has the potential to reduce this disparity.[1]

A very different ethical concern is that the vaccine only prevents 70% of cervical cancer, which means that surveillance via Pap smears must continue.[4] It is proposed that some women who are vaccinated may develop a false sense of security and forego the recommended screening.[4,8] Thus, vaccination may lead to a paradoxical rise in cervical cancer incidence, which is possible if less than 70% of the population is screened.[8] Harper *et al.* notes that "willful lack of screening participation is already occurring in our youngest women."[8] Further false security can occur if the protection of the vaccine is limited, especially if it lasts less than 15 years.[8] Women may not realize that they need a booster to retain immunity, and, coupled with less

screening, they could actually be at a increased risk of cervical cancer after the vaccine. This argument against the vaccine raises the need for education by health care professionals when giving the vaccine, and the need to continue to address cervical cancer risk during office visits. However, the need for a booster is not a sufficient reason to not give the primary vaccine.[7]

Mandatory HPV Vaccination – Economics

The economics of mandatory HPV vaccination center largely on the price and cost-effectiveness of the vaccine. The vaccine costs $360 for the three recommended doses.[2] This price is prohibitive for some families, and there is some concern that the price of the vaccine will increase the health disparity of cervical cancer by creating an even larger gap in preventative services based on SES.[1,2] This issue highlights the need for inclusion of the vaccine in the federal Vaccine for Children Program and mandated insurance coverage of the vaccine, although there may still be some families that cannot afford the vaccine or are uninsured and do not qualify for the federal vaccine program.[1,4,2,3] It may be necessary to include an exclusion clause for economic hardship in any legislation that mandates the vaccine, so that children who cannot receive the vaccine for monetary reasons are still permitted to attend school.

Opponents of the mandatory HPV vaccination also argue that because cervical cancer is not highly prevalent at 8.1 per 100,000 women and the majority HPV infections clear without health sequelae, that it is not cost effective to use this expensive vaccine in all women, especially when they will still have to continue cervical cancer screening.[9,4] This argument is put best by Vamos *et al.*, "a vaccine that offers incomplete protection against a virus, and in turn for a disease that is classified as "rare" in the [US] and that may, in fact, never develop at all as a pathological condition, constitutes inadequate medical justification for mandate."[4] However, there have been multiple cost-effectiveness analyses of the HPV vaccine and they have found

that vaccination of girls at age 12 is $3,000-$24,300 per quality-adjusted life year, which is considered very cost-effective for a vaccine. [2,1] Additionally, it becomes even more cost-effective when genital wart prevention is taken into account.[2,1] To put this in context, according to Vamos *et al.*, "some authorities estimate the economic burden of HPV infections and their sequelae to cost $5 billion per year in the United States alone."[4] In addition to the monetary cost, it is important when considering cost-effectiveness data to factor in quality of life and the improvement in women's lives when they do not have to fear what will be found on their Pap smears. Taking all of this into account, it is clear that the HPV vaccine is cost-effective in the prevention of cervical cancer in women.

HPV Vaccination for Boys – Equal Protection

The other significant controversy around the HPV vaccine is whether boys should also receive the vaccine. This debate is based on two different sets of reasoning, first, the need to protect males against other HPV-related disease. Second, vaccinating males would lead to increased protection of females against cervical cancer. Males are at risk of anal, penile, oral, and certain head and neck cancers caused by HPV, aside from the risk of genital warts.[1,10] Interestingly, males actually have a higher burden of oral HPV disease, at about three times the rate of women.[10] The reason this matters is that oral HPV infection (with type 16, which is most common) puts an individual at a 50-fold increased risk of oropharyngeal squamous cell carcinoma.[10] Of note, this type of cancer has increased in incidence by 225% in recent years.[10] Unfortunately, it has not yet been proven that the vaccine prevents oral HPV infection. Despite the likelihood that the vaccine prevents this oral cancer, it will need to be confirmed by research.[10] Based on the need for males to have protection from other HPV-related diseases, the

American Academy of Pediatrics now recommends vaccination of males aged 11-12, with catch-up vaccination for boys ages 13-21, and up to 26 years for men who have sex with men.[5]

The other issue is further protection from HPV for females via vaccination of males. Despite the common-sense rationale of this idea, male HPV vaccination has not been found to be cost effective in preventing female cervical cancer, especially if female vaccination rates are high.[11,1] This reasoning by itself is not considered sufficient for requiring boys to be vaccinated.[1]

Conclusion

After reviewing the multiple arguments for and against mandatory HPV vaccination, my final thoughts are that the HPV vaccine should be mandated for all children at the age of 12. The HPV is effective at preventing the multiple sequelae of HPV infection in both males and females, it is cost-effective, and it does not increase risky sexual behaviors. Despite its lack of contagiousness in the school setting, the best method for ensuring that children receive the HPV vaccine is by school mandate, which will increase the percentage receiving the vaccine and make the vaccine more accessible to those of low SES. Currently, no states have passed legislation mandating HPV vaccination for school admission, although 29 states are presently considering school-mandated HPV vaccination bills.[12] Further research is needed about the duration of protection by the vaccine, and education about continuing screening via Pap smears will need to be part of the vaccination process. While parents will be giving up a small amount of their autonomy, it is accepted that there are times when it is more important for public health to protect the child than to honor the parent's inclination. Further, the vaccine should be viewed as an opportunity for parents to discuss sexual morals and safe sexual behavior with their children before any the child has made the decision to become sexually active. The HPV vaccine is a significant public health milestone, and we, as a field, need to work at correcting misconceptions

about the vaccine and work with governments to pass HPV vaccine mandates for all boys and girls.

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