

HPV Vaccination Program for Sixth-Grade Girls in Washington, D.C.

A Cost-Benefit Analysis

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This cost-benefit analysis studies the most significant costs and benefits of the new requirement in Washington, D.C. that all parents of sixth-grade girls certify that their children are vaccinated against the Human Papillomavirus (HPV). The largest costs are the economic cost of purchasing the vaccine and the costs of administration to providers, which total just over \$2.1 million per year. Additional costs that cannot be easily monetized but are included conceptually include the potential for adverse events and opportunity costs of providers and parents. The largest potential for benefits from this policy relate to the two diseases prevented by the vaccine: genital warts and cervical cancer. By quantifying the cost of treatment for both diseases and estimating the economic value of lives lost, this analysis estimates the benefits to be nearly \$1.5 million yearly. Thus, the economic analysis finds this policy inefficient, since benefits greatly outweigh costs in all but one scenario of sensitivity analysis. The analysis also identifies the limitations of this study and of cost-benefit analysis generally, and cautions against the sole use of cost-benefit analysis, especially for health policy decisions.

Introduction

On May 4, 2007, the Washington, D.C. City Council enacted the *Human Papillomavirus Vaccination and Reporting Act of 2007* (Law 17-10), which went into effect in the fall of 2009. The legislation requires parents or legal

guardians of sixth-grade girls to certify whether or not their children have received the Human Papillomavirus (HPV) vaccine. Although the Washington law is commonly referred to as a mandate, it includes a generous opt-out provision for parents who object to it because of religious beliefs, medical inadvisability, or private decisions.

This cost-benefit analysis (CBA) studies the economic implications of the new law to determine whether the costs associated with the vaccination program outweigh the projected benefits. It begins with a brief summary of HPV epidemiology and the history of the HPV vaccine. It then outlines all relevant costs and benefits, quantify as many as possible, and compare the totals. This CBA concludes with policy recommendations based on my economic analysis.

Background

The Human Papillomavirus is the most common sexually-transmitted disease in the United States; about 20 million people are currently infected, and 6 million more contract it each year (CDC 2010). The virus spreads through sexual contact and poses the greatest risk to young men and women between the ages of 15 and 25 years, who account for 50 to 75 percent of all HPV infections (Krishnan 2008). There are more than 100 types of HPV, and although many infections are benign and resolve without treatment, four strains cause additional health complications: types 16 and 18 have been found to cause 70 percent of cervical cancer cases, and types six and 11 have been found to cause 90-100 percent of genital wart cases (Anderson 2005).

There is no cure for HPV and simple blood tests cannot detect infections. HPV infections are most commonly detected in women through Pap tests, which detect abnormal cell changes in the cervix that may be caused by HPV. Newly emerging DNA tests also detect the infection (Krishnan 2008). No screenings currently exist for men, even though men can spread HPV to their sexual partners and experience HPV-related diseases, such as genital warts and penile cancers.

In 2006, Merck & Co, Inc. introduced Gardasil, the first vaccine approved by the Food and Drug Administration (FDA) to prevent HPV

infection. It protects against the four strains of HPV that cause most cases of cervical cancer and genital warts. The FDA approved the vaccine for girls and women between the ages of nine and 26 years. The Advisory Committee on Immunization Practices (ACIP), a 15 member expert panel that provides advice and guidance on vaccination policy to the Centers for Disease Control and Prevention, recommends discretionary vaccination at ages nine and 10, routine administration at ages 11 or 12, and catch-up administration for ages 13 through 26. The vaccine is administered through a three-dose series and provides protection for at least nine years. The ACIP encourages women to continue to seek regular cervical cancer screenings regardless of their vaccination status (CDC 2009a).

Methods

This analysis of the Washington HPV vaccination program monetizes all of the relevant costs and benefits associated with the policy change using the absence of a vaccination program as the status quo. In other words, this paper compares the costs to the benefits associated with administering the vaccine to one year's cohort of sixth-grade girls. While the costs are limited to the immediate timeframe in which vaccination occurs, the benefits may accrue five to 25 years in the future - an issue that is addressed in the analysis and limitations sections. Costs include the economic cost of the vaccine; any administrative costs associated with the program and its implementation; the opportunity costs of time expended by the major stakeholders; and the costs of students' adverse reactions to the vaccine. These costs are borne by a variety of stakeholders, including students who experience pain and other negative health effects from vaccination; parents who incur increased obligations to take their children to the doctors; and the DC Department of Health, which must keep detailed vaccination records and respond to questions and concerns. The medical costs are paid for by the Vaccines for Children (VFC) program (a federally-funded program that provides vaccines to low-income children), private insurers, and individuals. Additionally, private providers and community health centers face opportunity costs and additional administrative burdens.

The primary benefits from implementing the HPV vaccination program for sixth-grade girls in Washington result from the reduced incidence and mortality due to cervical cancer and genital warts. These benefits are primarily avoided costs, which this analysis estimates as the savings associated with the economic cost of treating disease and the value of statistical lives (VSL) saved from cervical cancer deaths. The recipients of these benefits include individuals, who gain disease-free years, and third-party payers (Medicaid and private insurance), who avoid treatment costs.

The costs, benefits, and stakeholders associated with the Washington program are summarized in Table 1 and are described in greater depth in the following sections of this CBA.

Results/Analysis

Costs

The most significant cost associated with implementing the HPV vaccination program is the economic cost of purchasing the vaccine. This cost is measured using the price per dose that different types of purchasers pay for the vaccine. The Centers for Disease Control and Prevention (CDC) routinely publishes price lists for major vaccines in the United States. Government purchasers including Medicaid, VFC, and state health departments receive a discounted price that is negotiated by the CDC. The HPV vaccine costs government purchasers \$105.58 per dose and \$316.74 per three-dose series, while it costs private purchasers \$130.27 per dose and \$390.81 per three-dose series (CDC 2009b).

Other significant costs include those associated with administering the vaccine. The VFC allows providers to charge administrative fees which may not exceed the actual cost of administration. The Department of Health and Human Services specifies the maximum administrative charges in Washington as \$16.55 per vaccination (CDC 2004).¹ Non-VFC providers, however, do not publically provide data on their administrative costs. As explained below, the costs are estimated based on an approximate breakdown of children enrolled in the VFC program. This analysis assumes that

Table 1:
Costs, Benefits, and Stakeholders Summary

Costs	Paid By
Economic cost of vaccine	Vaccines for Children (VFC), Private insurers, Individuals
Administrative costs	DC Department of Health, Providers
Opportunity costs of time	Physicians, Parents
Adverse reactions	Students, Medicaid, Private Insurers
Benefits	Paid By
Reduced incidence of cervical cancer (economic cost of medical care)	Individuals, Medicaid, Private Insurers
Reduced mortality from cervical cancer	Individuals, Medicaid, Private Insurers
Reduced incidence of genital warts (economic cost of medical care)	Individuals, Medicaid, Private Insurers

Source: Author’s calculations.

VFC providers charge the maximum amount allowed, meaning that the total administrative costs for that population are close to \$50,000 per year. This figure most likely underestimates the true cost because it does not include the costs charged by non-VFC providers.

The next step in measuring costs is to determine the number of sixth-grade girls affected by the policy. During the 2005-2006 school year, approximately 6,000 girls between the ages of 11 and 12 years old were enrolled in public, private, charter, and parochial schools in Washington (DC Committee on Public Health 2007). More recent figures are not available, but this CBA assumes that the population of sixth-graders in Washington has not changed dramatically over the past four years. Of the 6,000 sixth-grade girls in Washington schools, approximately 3,200 (53 percent) were enrolled in public insurance programs such as Medicaid or Alliance, a subsidized health insurance program for low-income families who are not

eligible for Medicaid. These girls were therefore eligible to receive vaccines through the VFC program (DC Committee on Public Health 2007). For the purpose of this analysis, I assume that 50 percent of the girls affected by the policy are vaccinated through VFC and receive the lower CDC contract price for the vaccine.

An accurate estimate of the cost of the HPV vaccination program also includes the costs associated with adverse reactions to the vaccine. Evidence provided by the Vaccine Adverse Event Reporting System (VAERS) about the vaccination of over 26 million girls and women across the country since 2006 indicates that this cost is minimal.² As of January 1, 2010, more than 28 million doses of Gardasil were administered in the United States, and 15,829 adverse events (.06 percent of all cases) were reported. Upon further review, 92 percent of these adverse events were not serious, meaning that they did not include fainting, pain, swelling at injection site, headache, nausea, or fever. Only 8 percent (.0004 percent of all cases) of the adverse events were deemed serious, meaning that they involved hospitalization, permanent disability, life-threatening illness, or death (CDC 2010). It is important to note that although these events were associated with vaccine administration, a causal relationship between the vaccine and the adverse effects has not been established. Without a causal relationship, it is impossible to use VAERS data to accurately project future costs of adverse reactions associated with the vaccination program. Additionally, the data show that vaccine administration is infrequently associated with serious health complications (less than .001 percent of all cases). For these reasons, the costs of adverse reactions to the vaccine are not included in this analysis.

The final theoretical costs considered in this CBA are the opportunity costs faced by providers and parents. For providers, opportunity costs include the value of services they could have provided to patients if the Washington program had not required them to administer the HPV vaccine. Because the vaccine was recommended by ACIP for 11- and 12-year-old girls before the program took effect, health care providers most likely already devoted time to discussing the vaccine with their patients. While the program may produce a small increase in proportion of time spent administering vaccines versus other procedures, providers are unlikely to face

significant opportunity costs. Parents, on the other hand, face opportunity costs of the time required to take their children to the three appointments that are required for vaccination. Due to significant variation in the employment status of parents and location of vaccination sites, this cost varies tremendously across the population. Therefore, this analysis recognizes the cost for parents, but does not monetize it.

Benefits

The benefits for this CBA are considered using a societal approach. While many different stakeholders have the potential to benefit from decreased costs (including Medicaid, private insurance, and individuals) associated with the program, this analysis treats these stakeholders as a single entity. The expected benefits from the Washington vaccination policy result from the reduced incidence of cervical cancer and genital warts. Washington has one of the highest rates of cervical cancer in the country, at 13.5 cases per 100,000 residents.

Applying the incidence rate to the population of sixth-grade girls affected by the policy implies that .81 cases of cervical cancer will develop among the population over the course of the girls' lifetimes in the absence of an HPV vaccination program. In order to quantify the costs associated with cervical cancer treatment, this analysis uses calculations presented by Harrell Chesson et al. in a 2004 article in *Perspectives on Sexual and Reproductive Health*. Chesson et al. (2004) estimate that the lifetime cost of treatment per cervical cancer case falls between \$20,255 and \$36,912, depending on the stage of cancer. Based on his estimate of cost and frequency of each stage of cancer, this CBA estimates an average cost of \$22,121 per case.

It is important to note a few caveats to this estimate. First, the treatment costs are national averages and may not reflect higher prices in a metropolitan area like Washington. Second, they do not include non-medical costs of cervical cancer treatment, such as patient time. Finally, the incidence and mortality rates from cervical cancer vary dramatically across racial groups, with black females experiencing astronomically higher rates. The rates used in this analysis are ones that have been published for all females, which are closer to the very high rates for black females than the low rates for white

females. The high number of black school children in Washington justifies this assumption.

Methods for calculating the value of a statistical life vary greatly. Boardman and Greenberg's respected textbook on cost-benefit analysis suggests using a VSL of \$4 million (Boardman et al. 2007). Washington has a high mortality rate from cervical cancer that is exacerbated by socioeconomic factors that preclude early detection and effective treatment. The mortality rate from cervical cancer is 6.1 per 100,000 residents, which adjusts to .36 per 6,000 sixth-grade girls. Based on this estimate, the cost of mortality from cervical cancer in the absence of the vaccination program is approximately \$1.4 million. This issue will be revisited using more conservative and generous estimates of VSL in the sensitivity analysis of this CBA.

Genital warts are much more prevalent than cervical cancer, but the cost of treatment is significantly lower. Reliable estimates of the prevalence of genital warts are difficult to find, but a paper by Ralph Insigna uses data from private health insurance claims data to estimate prevalence in different age groups. Insigna (2003) estimates incidence rates that range from .43 to 6.20 cases per 1,000 female adolescents and young adults.

Adjusting Insigna's incidence rates for the population of sixth-grade girls in Washington, this CBA estimates an average incidence of 19.89 cases per 6,000 girls. The Chesson et al. (2004) paper used for cervical cancer costs also provides treatment cost estimates for genital warts. The authors assert that almost one quarter of all cases resolve without medical intervention, and the average treatment cost for the remaining 75 percent is \$446 (Chesson et al. 2004). Again, it is important to note that this cost represents only medical costs avoided by a mandatory vaccination policy. Given the intimate nature of genital warts, individuals could gain significant utility by avoiding infection, regardless of medical costs of treatment. However, these gains are difficult, if not impossible, to measure.

Given the costs and benefits detailed so far, the vaccination program produces negative net benefits, falling short of costs by nearly \$700,000. Table 2 outlines the costs and benefits that have already been described:

Table 2:
Summary of Costs and Benefits

Costs			
Price of Vaccine for CDC purchasers (3 doses)			\$316.74
Price of Vaccine for private purchasers (3 doses)			\$390.81
Number of Children Vaccinated			6,000
Eligible to Receive VFC			50%
Maximum Administrative Charge for VFC Providers			\$16.55
Total Costs			\$2,172,300.00
Benefits			
Expected Cases of Cervical Cancer			0.81
	DC Incidence Rate	13.5/100,000	
	Expected Incidence in Population	.81/6,000	
Percent Attributable to HPV-16/18			70%
Estimated Lifetime Treatment Costs			
	Localized Disease (57.5percent cases)	\$20,255	
	Pelvic Disease (34percent cases)	\$21,578	
	Distant Disease (8.5percent cases)	\$36,912	
	Weighted Average		\$22,121
Expected Cervical Cancer Deaths			
	DC Mortality Rate	6.1/100,000	
	Expected Mortality in Population	.36/6,000	0.36
Value of Statistical Life			\$4,000,000.00
Prevalence of Genital Warts			
	In US Population (Range)	.43-6.2/1,000	
	In Population (Range)	2.58-36.2/6,000	
	Expected in Population (Average)		19.89
Cost of Treatment		\$446	
	Cases Requiring No Treatment	25%	
	Total Cost of Treatment		\$334.50
Total Benefits			\$1,459,195.62
Net Benefits			(\$713,104.38)

Source: Author's calculations.

Sensitivity Analysis

The estimate with the most power to change this analysis is the VSL. Unfortunately, there is no consensus within economics literature about the appropriate value for VSL. Estimates range from as low as \$2.8 million to as high as \$7.87 million. In this analysis, Boardman and Greenberg's (2006) recommended middle estimate of \$4 million is used, as well as their sensitivity analysis of \$2 million to \$6 million. Lowering the VSL to \$2 million does not alter the direction of this CBA's findings, since it merely increases the magnitude of negative net benefits (see Appendix IV). When a VSL of \$6 million is used, however, the direction of these findings is reversed. Even with a high VSL, this analysis calculates a value of net benefits associated with implementing the policy of less than \$20,000, or less than 5 percent of the negative net benefits in the initial analysis.

A common concern in evaluating vaccination programs is the length of immunity. The FDA expects Gardasil to provide long-lasting protection and does not currently recommend a booster (CDC 2010). Thus this CBA assumes that the vaccination will last beyond the scope of this analysis and does not take the costs of boosters into account.

Finally, the estimates of disease incidence and prevalence rates are adjusted to see if they could affect the net benefits. I used the cervical cancer incidence and mortality rates for black females in Washington and the upper range of genital warts prevalence estimated by Insigna (2003). Even with these adjustments, however, the benefits still fell short of covering costs by over a quarter million dollars annually. Table 3 illustrates the results of the sensitivity analysis.

Table 3:

Partial Sensitivity Analysis Findings: Net Benefits

	Net Benefits
Original CBA Consideration	(\$713,104.38)
Low (\$2 million) VSL	(\$1,433,104.38)
High (\$6 million) VSL	\$6,895.62
High Disease Rates	(\$371,648.68)

Source: Author's calculations.

Limitations

The limitations in this analysis stem from omitting data that are relevant but inaccessible. It is unknown whether the generous opt-out provisions in the law will induce many families to choose not to have their children vaccinated, with obvious implications for the costs and benefits. Additionally, this analysis does not address the question of economic efficiency over time. Presumably as a greater share of the population is vaccinated, the incidence of HPV in the general public will begin to slow.

Finally, this analysis deals primarily with benefits that occur at an unknown future date. Economic approaches to policy analysis typically address this problem by discounting anticipated costs and benefits to present value figures. Methods for estimating future medical costs, however, face a high degree of uncertainty. The cost of medical care is rising almost exponentially, and some experts recommend adjusting projected costs to reflect a rate of medical inflation. At the same time, innovation in medical technology often leads to less-invasive and cheaper procedures. In light of this uncertainty, and the fact that the initial analysis led to a clear prevailing of costs over benefits, this CBA neither discounts its figures to represent their net present value nor adjusts its estimates to reflect anticipated changes in medical technology.

Recommendations

This CBA shows that it is economically inefficient for Washington, D.C. to require certification of vaccination for all sixth-grade girls. Benefits only outweigh costs when the value of a statistical life (a life that, we should note, has a one in 6,000 chance of developing cervical cancer to begin with) is greater than \$5 million. From an economic policy perspective, it is irresponsible to recommend a policy that is only efficient if the loss of less than one life is valued at an amount greater than the recommendations of half the economic literature.

However, while cost-benefit analysis can be an invaluable tool for policymakers to understand the implications of their choices, sound public policy should not rely solely on it due to serious limitations. Cost-benefit

analyses of health-related programs are especially difficult. They involve costs and benefits like pain, fear, and anxiety (and the absence of all of these) that are incredibly difficult to quantify.

Washington could attempt to reduce HPV (and thus cervical cancer and genital wart) infection rates through a number of potentially more cost-effective policies, including enhanced sexual education and improved access to cervical cancer screenings. Low-income and minority populations historically have low rates of accessing preventive care (including pap tests), and efforts to improve access would likely have public health (and potentially cost-saving) impacts well beyond the scope of HPV. Lawmakers could also revisit the issue of mandatory vaccination when and if the cost to purchase the vaccine becomes less, and consider alternate sources of funding (such as grants from private foundations) to demonstrate the impact of widespread vaccination on a population. Finally, the introduction of a new HPV vaccine, Cervarix, and the FDA's approval of Gardasil for young men, are new policy areas worthy of study.

After the FDA approved the use of Gardasil for young girls, state and local governments across the country pointed to high rates of HPV infection to introduce legislation mandating or encouraging vaccination for young girls in public schools. While the data show that HPV infection is widespread, as a result of successful widespread screening programs, the cervical cancer rate in the United States has fallen dramatically over the past 40 years. Therefore, a policy that proves economically inefficient in a city with abnormally high rates of cervical cancer may fare even worse in communities with lower rates. Efforts to encourage widespread HPV vaccination may be more cost-effective in developing countries where cervical cancer incidence and mortality is still extremely high, with over 550,000 new cases and 260,000 deaths reported worldwide in 2007 (Kaiser Family Foundation 2008).

This analysis alone, not unlike cost-benefit analysis as a discipline, is not sufficient for making informed policy decisions on a complex and important issue, and should be considered a springboard for more careful, methodical decision making.

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Notes

1. VFC: Federal Register. Content last reviewed February 18, 2010. <http://www.cdc.gov/vaccines/programs/vfc/fee-fedreg.htm#table>. Accessed March 16, 2010. For comparison, the mean allowable maximum is \$14.95. New York has the highest rate at \$17.85, and Arkansas has the lowest in the continental US at \$13.30.
2. VAERS is a national vaccine safety surveillance system run by the CDC and FDA to collect information about adverse reactions from vaccines licensed for use in the United States. "About the VAERS Program". *US Department of Health and Human Services*. <http://vaers.hhs.gov/about/index>

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