# Declining HPV Vaccination Rates in Delaware: Cause for Concern and Action

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From 2010 to 2013, Delaware's rates of HPV vaccination of females ranked among the highest in the nation.<sup>1</sup> Recently, the rate of completion has declined to one resembling the reported national rate.<sup>1</sup> This paper provides a brief background on HPV vaccination, a description of the efforts within Delaware which may have generated the promising earlier results, potential reasons for the decline in rates, and recommendations to increase vaccination rates in the future.

# Background

Rates of human papillomavirus (HPV) vaccination for adolescent females vary widely (>3 doses, 20.1% to 59.3%) across the United States (US) despite a Healthy People 2020 target of 80%.<sup>2</sup> Vaccination campaigns have fallen short of expectations for adolescents as four out of ten girls, and six out of ten boys have not started the HPV vaccine series.<sup>3</sup>

The American Academy of Pediatrics, American Academy of family Physicians, Centers for Disease Control and Prevention, and Advisory Committee on Immunization Practices (ACIP) all recommend routine HPV vaccination of females and males between 11 and 12 years old.<sup>4</sup>

These recommendations are aimed to foster vaccination before the initiation of sexual activity and potential exposure to HPV when the vaccine is most effective. Currently there are three approved HPV vaccines on the market in the US varying in protection, cost, and target population. Gardasil (Merck) is a quadrivalent vaccine that prevents infection by four strains of HPV (6, 11, 16, and 18) and was approved by the fDA in 2006 and is for use in both males and females ages 9-26. Cervarix® (GlaxoSmithKline) is a bivalent HPV vaccine approved by the fDA in 2009 and protects against HPV strains 16 and 18. Cervarix® can only be administered to females and has been approved for females only ages 10-25. In December 2014, Gardasil 9 a tetravalent HPV vaccine was licensed for use and approved by the fDA. This new vaccine protects against 9 strains of HPV: the four strains in the previous Gardasil vaccine, as well as 31, 33, 45, 52, and 58. It is projected most insurance plans will begin covering the new vaccine in 2017. Cervarix® and Gardasil are currently administered in 3 doses over 6 months, but there is ongoing research to determine whether 2 doses may be sufficient to provide adequate protection.<sup>5</sup> Eight years of follow-up data indicates the vaccines are still effective showing no evidence of reduced protection. Research is ongoing to determine if recipients will need a booster.<sup>1</sup>

Commonly cost has been identified as a barrier in preventative interventions. The majority of people in the target age group for the HPV vaccine have private insurance which is to cover vaccination without cost under the federal Affordable Care Act (ACA), This suggest other barriers are likely contributing in lowering rates vaccination.

# Method

Secondary analysis of a series of cross sectional surveys was employed using data from the National Immunization Survey (NIS –Teen). Data from the CDC's National Immunization Survey (NIS) from 2010 to 2014 was used to complete descriptive and graphical analysis of Delaware rates of HPV vaccination and national rates. The sample include teens ages 13 to 17. "The NIS is a list-assisted random- digit-dialing telephone survey followed by a mailed survey to children's immunization providers.<sup>1</sup>" Challenges exist with the data set when comparing across years of vaccination as in 2013, the CDC changed the number of measures reported adding >2. Prior to that time, the CDC reported a rate for >1 vaccination and >3, and completion.

# Results

Results for the rates of vaccination are presented in Table 1 displaying the change over time. Delaware went from among the highest completed vaccination rate of 84.4% compared to the national average of 70.7% in 2011. In 2014, 69.7% compared to national level of 69.3% indicating a significant drop in Delaware's rate.

Year	source	time 1	CI	time 2	CI	time 3	CI	Completed	CI
								series	
2014	National	60	1.9	50.3	1.9	39.7	1.9	69.3	2.4
2014	Delaware	67.6	9.3	51.4	9.9	42.3	9.8	69.7	11.8
2013	National	57.3	1.8	47.7	2	37.6	1.9	70.4	2.5
2013	Delaware	68.7	8.7	59.5	8.9	51.7	8.1	81.6	9.1
2012	National	53.8	1.9	43.4	1.9	33.4	1.7	66.7	2.6
2012	Delaware	67.2	9.8	64.5	9.9	50.4	10.8	76.6	10.8
2011	National	53	1.7			34.8	1.6	70.7	2.3
2011	Delaware	60.2	8.7			46.8	8.8	84.4	7.7
2010	National	48.7	1.8			32	1.7	69.6	3
2010	Delaware	63.9	8.55			40.4	9	68.6	12.1

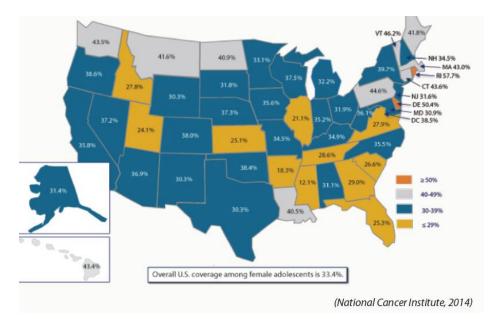
Table 1. NIS-Teen Vaccination Coverage Data, Coverage with Individual Vaccines by State 13-17 years

# Discussion

## Successful Strategies in Delaware

Prior to considering factors that may be responsible for the decline in vaccination rates for HPV and potential solutions, it is important to review the efforts that resulted in attaining previous high rates. For five years, the state of Delaware exceeded the national rate of HPV vaccination for girls (Table 1) and led the nation in reporting high numbers for vaccination. In the 2013 President's Cancer Panel's report on accelerating HPV Vaccine uptake, urgency for Action to Prevent Cancer, more than one-half of girls in only two states (Delaware and Rhode Island) had received the full HPV vaccine series in 2012 (Figure 1), while vaccine completion was less than 30 percent in 11 states.<sup>6</sup>

Figure 1. Percentage of 13- to 17-Year Old Girls Completing HPV Vaccination Series, U.S., 2012



Delaware's success in years 2010 to 2013 was the result of a multi-pronged approach that included a broad array of strategies to engage both public and professionals within the state. The lack of a comprehensive evaluation plan does not allow for the identification of the impact of individual initiatives but the high vaccination rates support the conclusion of success. The strategies are reviewed below.

The Delaware State Division of Public Health, Delaware Cancer Consortium, and a local marketing firm worked collaboratively in efforts to accelerate HPV vaccination uptake. Initiatives to publicize to health care providers, parents and appropriate aged children about getting vaccinated have been ongoing. Delaware's HPV campaign initially targeted women 18 to 26 years old, and in 2015 the campaign was expanded to include both males and females ages 11 to 12.

Campaigns were created with targeted approaches focused on parents, pediatricians and other primary care providers. These initial initiatives included: links sent to providers, Twitter, Facebook, Public Service Announcements (PSA), music station Pandora ads marketed to mothers, grocery cart inserts, and bus stop signs.

Delaware is somewhat unique in that it has a high percentage of schools with school-based health centers (SBHC) which likely contributed to the state's early success. These are contracted by the Division of Public Health and located in 29 public high schools within the state.<sup>7</sup> A multidisciplinary team of health professionals operates Delaware's SBHC and provide comprehensive health care services. The SBHC is designed to serve students who may lack access to other providers and address a broad range of health and health-related needs of students. Some of the services provided include: diagnosis and treatment of sexually transmitted infections; limited reproductive health services; HIV testing and counseling. All school-based health centers must receive written parental permission prior to providing medical, mental and nutritional health services to students.

One of the available services is immunizations for students covered by the VFC program. It has been suggested that SBHCs are an ideal setting for a recall or tracking system for immunizations because of the captive audience.<sup>8,9</sup> SBHCs allow for the administration of vaccines to children

without causing a major disruption to their school day or the need for their parent or guardian to potentially leave work three times to take them to complete the HPV series. Limited evidence in New Castle County SBHCs demonstrated SBHCs achieved a 78% completion rate of the HPV series. Part of the pilot involved administering the vaccines to commercially insured students and the results suggested the program was able to cover the cost of the vaccine. Current data does not allow us to show the amount of impact the SBHCs have had on the HPV vaccination rate overall in Delaware.

#### Potential factors resulting in the declining HPV immunization rates in Delaware

#### Parent Concerns

Parents concerns for not getting their child vaccinated have included: vaccine is not needed (19%), doctor did not recommend the vaccine (14%), concerns about the safety of the vaccine (13%), didn't know about the vaccine or the disease (13%), daughter is not sexually active and therefore does not need the vaccine (10%).<sup>3</sup> Most parents feel vaccines protect their children from potentially life threatening diseases. Recommendations to have adolescents vaccinated for HPV has been subject to public debate for its potential risks for increasing early sexual activity compared to the benefit of preventing future morbidity and mortality, which may contribute to variations in the rates of completion. Parental attitudes commonly noting their child is not sexually active have been a reason listed for not getting this population vaccinated.<sup>10</sup> A recent study using a large, longitudinal insurance database of females aged 12 to 18 examined whether HPV vaccination was associated with an increase in sexually transmitted infection (STI), a proxy for increased risky sexual behavior.<sup>11</sup> HPV vaccinated adolescent females and non-vaccinated females were compared for rates of STI. The study examined STI rates one year before vaccination and one year after in both groups and there was no increase in rates of STIs in the HPV vaccinated group.<sup>11</sup>

Safety concerns have also been raised through social media that have not been supported by large studies but remain as urban legends.<sup>12,13</sup>

Patient/parent factors include fatalistic belief about cancer.<sup>14</sup> Fatalistic views of survival have been reported in breast and other cancers in communities with higher prevalence rates. Lower HPV vaccination rates are associated with higher rates of HPV related morbidity.<sup>15</sup> As the period for display of HPV disorders is longer than the availability of the vaccine this suggests fatalism is impacting vaccine acceptance.

HPV concerns are part of continuing public fears of vaccinations in general. The Pew Foundation reports 13% of parents with children under the age of 18 do not believe that vaccinations for measles, mumps or rubella are safe for healthy children.<sup>16</sup> The Pew survey suggested the highest rates of those who feel vaccines are unsafe are between 18 to 29 years of age (15%) and non-white (17%). Others have reported higher rates of non-vaccination in the children of young white college educated parents.<sup>17</sup>

While these reports reflect national trends in vaccinations, there are local sources adding to vaccination fears. A local health teacher at a high school in Delaware reports that she teaches the required curriculum but publicly stated: "Both shots (the flu shot and Gardasil) are incredibly toxic, incredibly unnecessary, and are doing incredible damage to the health of our children"; "flu shots make you more likely to get sick. Gardasil makes you more likely to get HPV.<sup>18</sup>"

Reports of the failure of vaccines to provide full protection are both part of urban legends and scientific reports that parents and teens consider in seeking vaccinations.

#### **Provider concerns**

Provider reasons indicating a reluctance to discuss the vaccine include: parents express mixed or negative opinions about the vaccine, more likely to strongly recommend the vaccine to older adolescents than to those ages 11 and 12, and financial barriers related to the vaccine's cost and reimbursement issues.<sup>19</sup> Additional concerns are reported related to the framing of the counseling discussion.

Some providers are uncomfortable having a sexually related discussion with eleven year old patients in the presence of their parents.<sup>20</sup> Others have made the HPV counseling approach more age specific focusing their discussion on cancer risk reduction with younger patients and their parents while using HPV vaccination as an entry point for discussion of sexual activity with older adolescents.<sup>21</sup> While pediatricians and other primary care providers have been encouraged to discuss the risks and benefits of HPV, a percentage of physicians do not endorse the vaccine or discuss its use in those considered high risk.<sup>22</sup> The resistance among physicians is surprising given the safety and demonstrated effectiveness of the HPV vaccine in reducing the risk of a number of cancers and other pathologies.

There are system issues that impact the initiation of and completion of the vaccination series. Missed clinical opportunities are a primary reason why the US has not achieved high rates of HPV vaccinations. According to the CDC, between the years 2007 and 2012, if all of the missed opportunities during health care visits were removed, 93% of girls aged 13–17 would have received at least their first dose of the vaccine by 2012.<sup>3</sup> Primary care providers report there are limited opportunities during the care of adolescents that are typically seen for episodic care to initiate HPV discussions.<sup>21</sup> Further, 50% of the providers reported they did not schedule second and third follow-up visits to complete the series in those who had initiated it. The providers reported a lack of systems to track the need for follow-up visits or the lack of resources to call the patients.

#### Potential paths forward to improve HPV vaccination rates

The reduction in the rates of vaccination suggest the need for a change or reapplication of strategies which contributed to DE's early success. These include school, primary care partnerships, optimizing the use of electronic medical records systems, targeting at risk and/ or high yield groups and strategies to address patient/family concerns.

#### Vaccine School Mandates

Individual state laws establish vaccination requirements (and exemptions) for public and private school children, and are primarily decided by state legislatures. Some states have granted regulatory bodies (i.e. Health Department, Board of Health) the power to determine vaccine requirements.

There is continued debate surrounding whether or not to require girls and boys to be vaccinated against HPV and whether this should be a mandatory school vaccine. Individuals may support availability of the vaccine but do not necessarily support a school mandate. Concerns cited include cost of the vaccine, safety, and parents' rights to refuse; in addition, moral objections

related to a vaccine mandate for a sexually transmitted disease. According to the CDC's Public Health Law Program, several reasons for vaccine exemption exist including medical, religious and philosophical exemptions or a combination of those.<sup>3</sup>

Many states have introduced legislation to mandate HPV as a required school vaccine; however, some bills included language for providing information only on the vaccine while others pushed for mandatory requirement. There are few jurisdictions that require HPV vaccines for school attendance.<sup>3</sup>

## Other School-Based Opportunities and Partnerships with Primary Care

Another potential opportunity would be an expansion of the vaccination program in the SBHCs to cover commercially insured students as well as those students covered by the VFC program. Enhanced communication with primary care providers and use of the state vaccine registry would facilitate both initiation and completion of the HPV series. Enhancements to the state's immunization registry, DelVax, may further facilitate the success of this complex vaccine series in that electronic/web-based entry allows for more up to date records and current programming allows for a reminder/recall system that individual sites can access.

## Electronic Health Records

Electronic health records (EHR) seem like a potential solution for more effective reminders to address the system level barriers but this requires further development. In a study comparing prompted and unprompted cohorts, those receiving an EHR prompt were more likely to get an HPV vaccine (34.9% compared to 21.5%) and complete the vaccine series.<sup>23</sup> Patients were more likely to start the vaccine and more likely to complete if their health care provider (HCP) received a prompt alerting them to patients who were due for a shot during any appointment.<sup>23</sup> Informing patients and HCP during an appointment increased uptake and completion of the series. A systematic review of reminder systems, however, found mixed success in raising vaccination rates which suggests this may be an emerging strategy.<sup>24</sup>

## A Targeted Approach

All states face challenges in determining their expenditures in meeting the health needs of the public. As the demographic for the vaccine expanded, the public health marketing strategies changed as well. Current initiatives include: broadcast (terrestrial radio, Pandora); stands at fitness centers, posters/cards at 72 physician offices state wide (Obstetrics and Gynecology, Pediatrics and Primary Care); banners/signage at malls and shopping outlets (ads in highly populated areas: food courts, location maps); print (ads in Delaware Today, Delaware Medical Journal); digital media (Google text, Bing, MaxPoint). In addition, all high school school-based health centers in the state received banner ads and HPV marketing materials. These mass media tactics will run through July 2016.

An additional strategy to increasing vaccination rate overall is targeting geographic pockets of low vaccination rates. This method has demonstrated effectiveness on both the targeted area and impact on it neighbors which may be more effective than broad efforts in some states.<sup>25</sup> The enhancement in Delaware's tracking system will support more effective feedback to providers while also assisting in directing public health messaging to specific sub populations within the state.

## Addressing Personal Factors in Increasing Vaccination

While these technological advancements are important strategies in enhancing vaccinations rates, they are not likely to change the attitudes of those parents, teens and health teachers who believe the urban legends surrounding HPV vaccination, nor providers who may not see HPV as a priority. Each of these are likely to require face to face conversations with a trusted provider/mentor who is equipped with detailed knowledge about the benefits of vaccination. Additionally, providers will need ongoing knowledge of current common misperceptions and research of emerging risks associated with vaccinations as well as test strategies to assist parents, teens and teachers to make evidence based benefit and risk assessment of their need for vaccination. In January 2016, an e-mail blast from the Immunization Coalition of Delaware was sent to health care providers with CDC tips and suggestions on how to increase rates and improve awareness of HPV and encouraging the providers to be champions of HPV vaccinations in their community.

## Conclusion

In order to once again become a leader in HPV vaccination nationally, we need to improve parents', caregivers', and adolescents' understanding of HPV vaccines as a protective measure against cancer and decrease the stigma associated with vaccination. Cancer prevention messages should further incorporate the importance of early vaccination. We also have the opportunity to build upon Delaware's strong start to HPV vaccination by better utilizing available technology to coordinate and track care, incorporate vaccination strategies into acute care visits and better utilize our existing SBHC infrastructure. While going as far as to legislatively mandate HPV vaccination may not be necessary, a coordinated approach at the local and state level with attention to high priority areas should allow us to achieve Healthy People 2020 goals and become a national leader. Given the safety and efficacy data, physicians should recommend the vaccination with at the same confidence as all other vaccines in the American Council on immunization practices regimen and not create undue hesitancy by relating this vaccine to sexual activity.<sup>26</sup>

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