

**REPORT TO THE TWENTY-FIFTH LEGISLATURE
STATE OF HAWAI‘I
2009**

**PURSUANT TO H.C.R. 51
REQUESTING THE DEPARTMENT OF HEALTH TO ASSESS THE
ADVANTAGES AND DISADVANTAGES OF REQUIRING CERVICAL
CANCER VACCINATIONS FOR GIRLS BEFORE THEY ENTER THE
SEVENTH GRADE**

Prepared by

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October 2008

Executive Summary HCR 51

On July 24, 2008, The State of Hawai‘i Department of Health Immunization Branch convened the School Immunization and Examination Attendance Requirements Working Group, comprising members representing numerous immunization-related stakeholder organizations, to assist the Department in assessing the advantages and disadvantages of requiring cervical cancer vaccinations for girls before they enter the 7th grade.

Working Group members were provided with a presentation describing the epidemiology of human papillomavirus (HPV) infection and the vaccine developed to prevent HPV infection caused by HPV types 6, 11, 16 and 18.¹ Following this presentation, group members discussed the perceived advantages and disadvantages of a HPV vaccine requirement for girls at 7th grade school entry.

The Working Group concluded that although the vaccine has many benefits, they would not recommend requiring the HPV vaccine for girls prior to 7th grade entry at this time. A number of significant disadvantages, including inconsistent health insurance coverage, the high cost of the vaccine, inequality of access to the vaccination, and the substantial administrative burden that would be placed on school personnel, would need to be addressed prior to the consideration of a HPV mandate.

¹ Types 6 and 11 cause 90% of genital warts, and 16 and 18 lead to 70% of all cervical cancers.

I. Introduction

This report is written to satisfy a request in House Concurrent Resolution No. 51 ("H.C.R. No. 51") for the Hawai'i Department of Health to report its findings and recommendations after assessing the advantages and disadvantages of requiring cervical cancer vaccinations for girls before they enter the 7th grade.

To fulfill this legislative request, the Department of Health utilized an existing working group comprising 15 community and department stakeholder organizations. This group was convened by the Immunization Branch in 2007 to assess Hawai'i school immunization and examination requirements and determine, based on review of current national recommendations, peer-reviewed and evidence-based findings, and community factors, whether revisions to those requirements should be recommended. Stakeholder input has been invaluable in helping the Department understand the complex issues that may arise as a result of changing these requirements.

On July 24, 2008, the issue of a human papillomavirus (HPV) vaccine 7th grade school entry requirement for girls was brought before this body for analysis and discussion. Present at this meeting were representatives from immunization-related stakeholder organizations including the American Academy of Pediatrics – Hawai'i Chapter, Kaiser Permanente, Kamehameha Schools, Punahou School, and the Department of Health Family Health Services Division, Disease Investigation Branch, Public Health Nursing Branch, and Immunization Branch. Although unable to attend, the Hawai'i Academy of Family Physicians and the Department of Education Student Support Services Branch were provided with the opportunity to comment on minutes from the meeting and this report.

Members attending this meeting were provided with a presentation describing the epidemiology of HPV as well as the vaccine developed to prevent HPV infection caused by HPV types 6, 11, 16, and 18 (see Appendix A). The presentation was followed by discussion concerning the benefits and disadvantages of requiring HPV vaccinations for girls prior to 7th grade entrance. The following is a summary of this discussion.

II. Advantages of Requiring HPV Vaccines for Girls at 7th Grade Entry:

A. Reduction of the cervical cancer burden

Epidemiological studies have clearly demonstrated the association between persistent HPV infection and cervical and other cancers (Walboomers et al., 1999). Nationally, it is estimated that 20 million persons are currently infected with HPV, with 6.2 million new infections occurring each year (Weinstock et al., 2004). Of those infected, approximately 10% of women will develop persistent HPV infection and are at the greatest risk of developing high-grade cervical cancer precursor lesions (cervical intra-epithelial neoplasia or CIN 2,3) and cancer (Centers for Disease Control and Prevention, 2006). Data from the National Cancer Institute (2008)

indicate that the Hawai'i cervical cancer incidence rate is 6.3 cases per 100,000 annually with a mortality rate of 2.2 deaths per 100,000 (National incidence: 7.9 cases and 2.4 deaths per 100,000, respectively). Implementation of a mandatory HPV vaccination requirement for girls prior to 7th grade entry may contribute to the reduction of HPV infections and cervical cancer in Hawai'i.

B. Increased awareness and utilization of a highly effective vaccination

Mandating HPV vaccine prior to 7th grade entry would require approximately 7,000 girls per year to receive the vaccination series (State of Hawai'i Department of Education, 2008; Hawai'i Council of Private Schools, 2008). School vaccination mandates ensure that persons from all ethnic and socioeconomic groups receive required vaccines.

Clinical trials among women ages 16 to 26 years have demonstrated that the quadrivalent HPV vaccine is almost 100% effective in preventing infection and disease associated with HPV types included in the vaccine. Studies have also shown that the vaccine is safe and immunogenic² for girls as young as 9 years of age (Centers for Disease Control and Prevention, 2006).

C. The pre-adolescent visit is a standard of pediatric care, presenting a convenient opportunity for providers to administer the first dose of the HPV vaccination series

The Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) recommend that pre-teens receive several vaccines at their 11 or 12 year old check-up. Recommended vaccines include tetanus-diphtheria-acellular pertussis (Tdap), meningococcal conjugate (MCV4), and human papillomavirus (HPV) vaccine (for girls). However, unlike the single-dosed Tdap and MCV4 vaccines, HPV requires a total of 3 doses to complete its series. Working Group members expressed concern regarding the difficulty in ensuring series completion for the HPV vaccine.

III. Disadvantages of Requiring HPV Vaccines for Girls at 7th Grade Entry:

A. HPV-Specific Issues

1. New vaccine

As the vaccine has been licensed only since June 2006 and official vaccine recommendations were not published by CDC until March 2007, working group members expressed concerns that the HPV vaccine may not yet be fully incorporated into routine medical practice. An "implementation period" of

² Capable of inducing the body's ability to resist infection by a specific disease agent.

several years is often necessary for providers to routinely stock and offer new vaccines and for the public to become aware of the vaccine's benefits.

2. Parental perceptions regarding HPV vaccine

Despite the Food and Drug Administration (FDA) licensing HPV vaccine as safe and effective, recent media reports have raised doubts about the vaccine's safety and the safety of vaccination in general. CDC has countered this misinformation by reiterating the rigorous safety standards required for vaccine approval and the ongoing vaccine safety monitoring process. Media reports, unfortunately, frequently influence parental opinions regarding vaccination. In addition, the simple fact that HPV is a sexually transmitted disease may introduce unique barriers to compliance with a HPV vaccination mandate not previously encountered with other required vaccines.

3. Unique communicability of HPV

Although the benefits of school-entry immunization requirements are many, requiring a vaccine for school entry has origins in protecting others from contracting highly infectious agents, such as measles and pertussis (whooping cough), in which cases infection occurs via ordinary casual contact, especially in settings such as schools where students are closely congregated. Because HPV is primarily transmitted by sexual contact, school children are not placed at significant risk of contracting HPV through routine interaction in the school environment.

4. Vaccine is currently gender-specific

Studies are currently underway to determine the effectiveness of the vaccine in preventing HPV infection in males, and when additional information is available, it is possible that the licensing indications and vaccine recommendations may be broadened to include both sexes. It may be premature at this time, if the HPV vaccine recommendations are expanded to include males in the near future, to require HPV vaccination for girls prior to 7th grade entry. School personnel have also expressed concerns regarding the administrative burden of monitoring compliance with a vaccine requirement that would apply to only a subset of the incoming 7th grade population.

B. Insurance Coverage, Cost, and Supply

1. Reimbursement for HPV vaccine purchase and administration

Hawai'i insurers are mandated to cover recommended vaccines for children less than age 5 years. For HPV vaccine, which is recommended for girls ages 11-12 years, insurance coverage, reimbursement, and co-payment costs can vary widely. This is additionally complicated by the fact that HPV vaccine is very expensive.

The private sector cost for the vaccine is \$125.29, resulting in a total cost of \$375.87 for the complete 3-dose HPV series.

2. Inconsistent availability of vaccine in provider offices

Because of the high cost of HPV vaccine and the variability in reimbursement, immunization providers have reported a considerable financial burden if they choose to maintain a supply of the vaccine for administration to their privately insured patients. The Department of Health Vaccines for Children Program, conversely, supplies the vaccine free of charge to participating providers for administration to girls ages 9 through 18 years, who have Quest/Medicaid insurance, are uninsured, are underinsured (have medical insurance that does not cover HPV vaccine), or are American Indian/Alaska Natives. This potential inequality of access to the vaccine presents a considerable barrier to successful implementation of a HPV vaccination mandate.

3. Vaccine administration cost

In addition to the high cost of the vaccine itself, parents seeking the vaccine for their children may be confronted with additional expenses related to vaccine administration, such as a vaccine administration fee or office visit fee, which may not be covered by their health insurance plan.

C. Administrative Burden

1. Burden on school personnel

If the majority of children are not vaccinated **prior** to a vaccination mandate, the primary responsibility to assure vaccination falls on school personnel, rather than public and private healthcare providers. To reduce the compliance burden on schools, it is important to ensure that there is significant acceptance and use of a vaccine in the recommended populations before adding it to the vaccinations required for school entry. Such is not yet the case with the HPV vaccine. Recently published data from the National Immunization Survey – Teen, indicate that only 25.1 percent (22.3-28.1 [95% CI]) of surveyed females ages 13 through 17 years reported receiving at least one dose of HPV vaccine in 2007 (Centers for Disease Control and Prevention, 2008). In a time of increasing budget restrictions, this additional administrative burden placed on schools would be especially difficult to justify.

2. Series vaccine follow-up burden

Because the HPV vaccine series consists of 3 doses typically administered over a period of 6 months (dose 2 administered a minimum of one month after the first dose and dose 3 administered at least 12 weeks after the 2nd dose and at least 24 weeks after the first dose), school personnel would need to dedicate additional

time and training to screen immunization records to ensure vaccine minimum intervals are met, as well as time and effort involved in the multiple follow-ups required to ensure that students receive their missing doses.

IV. Recommendations:

At this time, the Department of Health School Immunization and Examination Attendance Requirements Working Group does not recommend requiring cervical cancer vaccinations for girls before entrance to 7th grade.

A phased approach to the implementation of new vaccines is critical to ensure that the necessary elements are in place to support a school entry requirement, including adequate:

- Health insurance coverage
 - Provider organizations stressed the necessity of ensuring that all health plans, mutual benefit societies and self-insured plans cover HPV vaccine under their health plan benefits to achieve uniform vaccination of adolescent females
- Vaccine supply
- Acceptance and use of the vaccination

Consideration of a HPV school entry vaccination mandate should occur only after these basic areas have been satisfactorily addressed.

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Human Papillomavirus: Epidemiology and Prevention

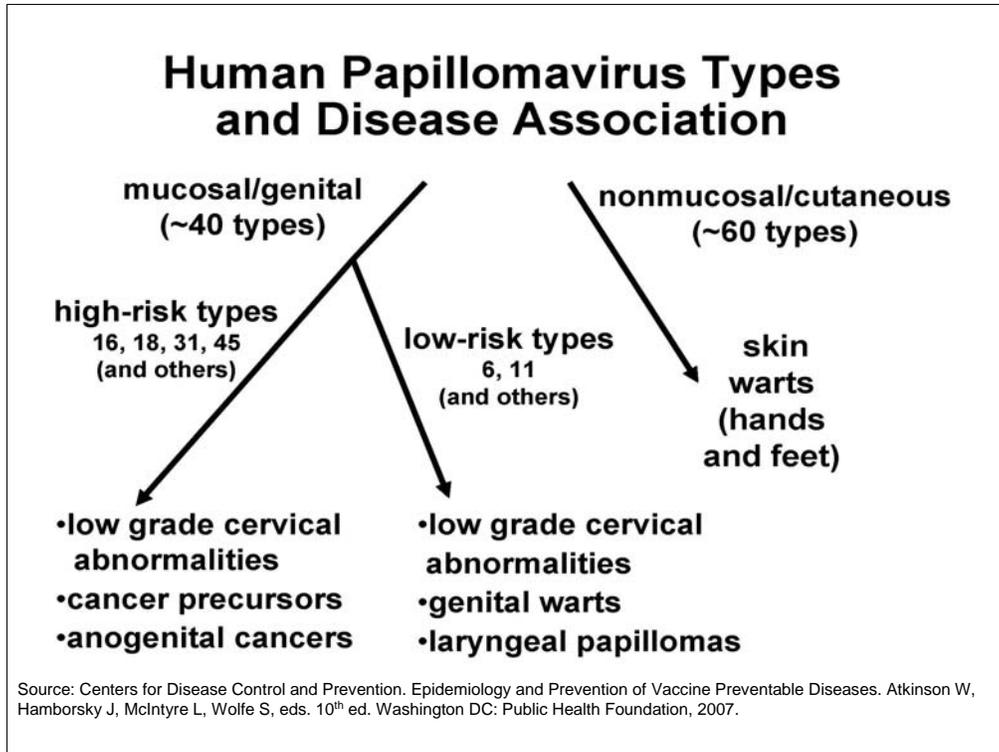
School Immunization and Examination
Attendance Requirements Working Group
July 24, 2008

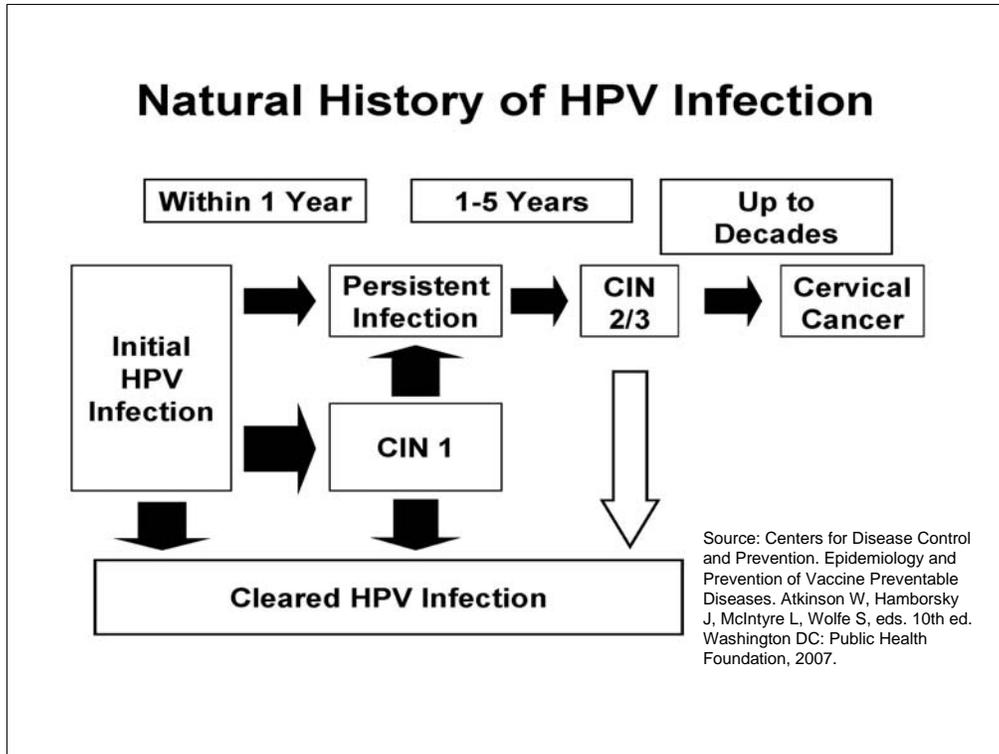


Human Papillomavirus (HPV)

More than 100 types identified

- 16 types classified as “**High-risk**”
 - Can cause precancerous cervical cell abnormalities
 - Detected in 99% of cervical cancers
 - 70% of cervical cancers worldwide are caused by types 16 & 18
- 24 types classified as “**Low-risk**”
 - Can cause
 - benign or low-grade cervical cell abnormalities
 - Genital warts
 - Laryngeal papillomas
 - Includes types 6 & 11







HPV Epidemiology

- Reservoir - Human
- Transmission - Direct contact, usually sexual
- Temporal pattern - None, no known seasonal variation
- Communicability - presumed to be high because of the large number of new infections estimated to occur each year.



HPV Disease Burden in the US

- The most common sexually transmitted infection in the US
 - Estimated 20 million currently infected
 - 6.2 million new infections per year
- Common among adolescents and young adults
- More than 80% of sexually active women will have been infected by age 50
- Infection also common in men



Cervical Cancer Disease Burden in the US

- HPV is the major cause of cervical cancer in women
- 2006 data:
 - 9,700 new cervical cancer cases
 - 3,700 cervical cancer deaths



2 Population-Based Studies on HPV Prevalence

- 18-25 years (N = 3262): 26.9% prevalence of any type
 - types 6 or 11 = 2.2%
 - Types 16 or 18 = 7.8%
- 14-59 years (N = 1921): 26.8% prevalence of any type
 - Highest prevalence among females 20-24 years old
 - 1.3% for type 6; 0.1% for type 11; 1.5% for type 16; 0.8% for type 18

Reference: MMWR March 12, 2007 / 56(Early Release);1-24



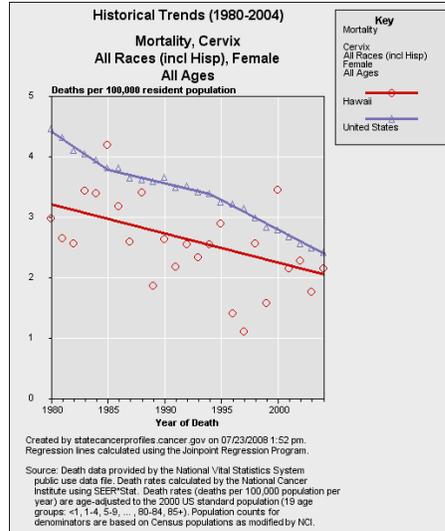
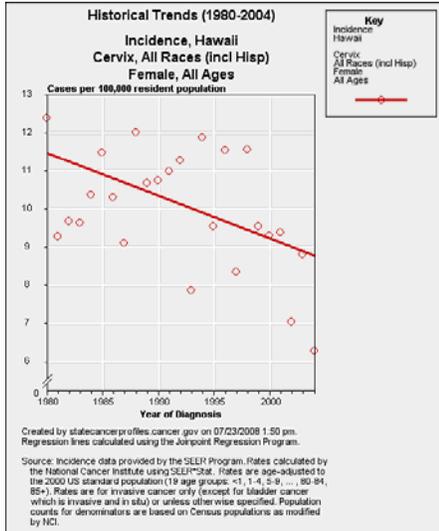
Cervical Cancer Incidence and Mortality

- Cervical cancer incidence among all ages
 - US (2004): 7.9 cases per 100,000
 - Hawaii (2004): 6.3 cases per 100,000
- Cervical cancer mortality among all ages
 - US (2004): 2.4 deaths per 100,000
 - Hawaii (2004): 2.2 deaths per 100,000
- Healthy People 2010 objective:
 - Reduce the mortality rate from cervical cancer to 2.0 deaths per 100,000 females

Reference: <http://statecancerprofiles.cancer.gov> (National Cancer Institute; State Cancer Profiles)



HPV Incidence and Mortality Trends, 1980-2004





HPV Vaccine

- First vaccine developed to prevent cervical cancer and genital warts due to HPV
- Protects against four types of HPV:
 - HPV types 16 & 18: cause ~70% of cervical cancers
 - HPV types 6 & 11: cause 90% of genital warts



HPV Vaccine

- Licensed - June 2006
- Trade name - Gardasil®
- Girls and women, ages 9 through 26 years
- Three-dose series (0, 2, 6 months)



HPV Vaccine

- Efficacy
 - ~100% vaccine efficacy in preventing cervical precancers, genital warts
 - >99% developed antibodies post vaccination
- Duration of Immunity
 - At least 5 years



ACIP Recommendations for use of HPV Vaccine

- Routine vaccination of females aged 11-12 years
- Catch-up vaccination of females aged 13-26 years



Groups for which vaccine is not licensed

- Females aged <9 years and >26 years
- Males



Contraindications and Precautions

- Persons with a history of immediate hypersensitivity to yeast or to any vaccine component
- Pregnant women
- Moderate or severe acute illness



Vaccine Safety

- Tested in over 11,000 females (aged 9-26 years)
- Studies found vaccine was safe and caused no serious side effects
- Most common side effect: pain at injection site



Vaccine Safety

- Since 2006, more than 12 million doses distributed
- Number of serious adverse events reported to VAERS: <7%
- CDC, working with the FDA, continues to monitor the safety of the vaccine



HPV Vaccine Pricing

- Public-sector costs:
 - \$100.59 per dose
 - \$301.77 per 3 dose series
- Private-sector costs:
 - \$125.29 per dose
 - \$375.87 per 3 dose series
- Insurance coverage varies



Working Group Discussion

- Advantages of requiring HPV vaccination for girls at 7th grade entry
- Disadvantages of requiring HPV vaccination for girls at 7th grade entry