State of Alaska Epidemiology **Bulletin**

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Quadrivalent Human Papillomavirus Vaccine Now Available through the Alaska Immunization Program

Background

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Most infections with HPV are asymptomatic and self-limited. However, a small proportion of infections become persistent and can lead to cervical cancer in women or other anogenital cancers and genital warts in both men and women. The burden of HPV in the United States is substantial (Box).

Box. Burden of HPV Infection in the United States[1]

- HPV is the most common sexually transmitted infection, with:
  ~20 million people currently infected and
  ~6.2 million new infections annually.
- 74% of new infections are in persons aged 15–24 years.
- Almost all cervical cancers are caused by HPV. In 2007 an estimated 11,100 new cases of cervical cancer will be diagnosed and approximately 3,700 women will die from cervical cancer.
- 4 billion dollars are spent annually on the prevention and treatment of HPV-related conditions.

Approximately 40 HPV types infect the genital area and are categorized by their association with cervical cancer. Low-risk types can cause benign cervical cell changes, genital warts, and laryngeal papillomas. More than 90% of anogenital warts are associated with types 6 and 11. High-risk HPV types act as carcinogens in the development of cervical and other anogenital cancers; types 16 and 18 are associated with 70% of these cancers.[1]

HPV Vaccine

In June 2006, the quadrivalent HPV vaccine Gardasil® (Merck and Co., Inc.) was licensed for use in females aged 9–26 years. The vaccine contains the L1 major capsid proteins of HPV types 6, 11, 16, and 18 and is manufactured using recombinant DNA technology. Gardasil does not contain live virus, thimerosal, or antibiotics.

Efficacy

Vaccine efficacy has been shown to be 100% for prevention of HPV types 16 and 18 related cervical intraepithelial neoplasia (CIN).[1] Efficacy is 99% for prevention of external genital lesions caused by all HPV vaccine types.[2] Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, females who may have already been exposed to HPV also should be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types will receive full benefit from vaccination. The vaccine will provide less benefit to females if they have already been infected with one or more of the four HPV vaccine types.[3] The use of HPV vaccine does not eliminate the need for Pap test screening, since 30% of cervical cancers are caused by HPV types not included in the vaccine.[3]

Adverse Reactions

Mildly to moderately severe local reactions are the most common adverse reactions reported and include pain (84%), swelling (25%), and erythema (25%).[2] Ten percent of vaccine recipients reported fever within 15 days of vaccination, compared to 9% of placebo recipients.[2] No serious adverse reactions have been reported.

Recommendations for Immunization

Quadrivalent HPV vaccine is licensed for all females aged 9–26 years. The routine recommended age for administration is 11–12 years, but catch-up immunization is recommended for unvaccinated females aged 13–26 years. HPV vaccine is not approved for use in boys and men, although efficacy studies among males are underway.

State-supplied Vaccine Available for Women Aged 9–18 Years

Due to an increase in federal funding, the Alaska Immunization Program is now able to provide HPV vaccine for *all* females aged 9–18 years. This represents a change from a previous *Bulletin* announcement.[4] Furthermore, individual patient screening to determine eligibility for the federal Vaccines for Children (VFC) Program will not be required.

Vaccine Availability for Women Aged 19–26 Years

Women aged 19–26 years who wish to be vaccinated may obtain HPV immunization from private providers. The vaccine is covered through many private insurance plans, though coverage will vary between policies. Medicaid covers the majority of the cost for eligible women aged 19–20 years. Also, women aged 19–26 years who meet income eligibility requirements may qualify for the Adult Vaccine Patient Assistance Program established by Merck. and Co., Inc., the manufacturer of HPV vaccine.[5]

Recommended Schedule

HPV vaccine is administered intramuscularly in a 3-dose schedule. The second and third doses should be given 2 and 6 months after the first dose. The minimum interval between the first and second doses is 4 weeks, and between the second and third doses is 12 weeks. The vaccine can be administered at the same visit as other age-appropriate vaccines, including Tdap and meningococcal conjugate vaccines.

Contraindications and Precautions

The only contraindication to administration of HPV vaccine is a severe allergic reaction (i.e., acute respiratory distress or collapse) to a vaccine component. Precautions to vaccination include moderate or severe acute illness, although a minor acute illness is not a reason to defer vaccination.

The vaccine currently is not recommended during pregnancy; however, if vaccine is administered during pregnancy, no intervention is needed. Patients and health care providers should report exposure to HPV vaccine during pregnancy by calling the manufacturer's vaccine in pregnancy registry at (800) 986-8999.

Vaccine Storage

Gardasil should be stored at 35°–46°F (2°–8°C) and protected from light. The vaccine should be removed from refrigeration immediately before administration. HPV vaccine must not be exposed to freezing temperatures. Frozen vaccine should not be used and should be returned to the Alaska Immunization Program.

References

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