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Clinical Decision Points:
Profiles in Patient Care for Nurse Practitioners and Physician Assistants
Based on a Series of National CME/CE Symposia

Q&A: HPV Prevention

What Your Colleagues Around the Country Want to Know...

Q: Are there any contraindications for the quadrivalent human papillomavirus (HPV) vaccine?

A: The quadrivalent HPV vaccine is contraindicated in patients with a known hypersensitivity to any component of the vaccine, including yeast, or in those who had hypersensitivity reactions with a previous dose of the vaccine. Vaccination may be delayed in patients with a febrile illness, but low-grade fever or mild upper respiratory tract infections are not considered contraindications to the administration of the vaccine. Because the HPV vaccine is an intramuscular injection, patients with bleeding disorders or those who are taking anticoagulants may be at risk for hematoma after injection.

Q: Is HPV vaccination approved for use in males?

A: No. The US Food and Drug Administration (FDA) has not approved use of the HPV vaccine for boys or men. However, the quadrivalent HPV vaccine is being evaluated in a randomized, double-blind, placebo-controlled study involving 4065 men aged 16 to 26 years. Preliminary data show the quadrivalent HPV vaccine was 90% effective in preventing external genital lesions (genital warts or penile/perineal/perianal intraepithelial neoplasia) associated with any vaccine-related HPV type in the per-protocol population at 7 months. Results should help determine whether including males in vaccination programs will decrease the morbidity and mortality associated with HPV-related diseases in men.

Q: Has HPV vaccination been proven efficacious in women aged >26 years?

A: Although HPV vaccination currently is approved by the FDA only for 9- to 26-year-old females, women >26 years of age remain at risk for HPV infection and its related diseases. Studies have demonstrated that the quadrivalent HPV vaccine is highly efficacious in adult women, as very few have been exposed to all vaccine HPV types. The FUTURE III study, which included 3817 women aged 24 to 45 years, found the quadrivalent HPV vaccine was 91% effective in reducing the



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combined incidence of HPV 6-, 11-, 16-, and 18-associated persistent infection (as defined by the detection of the same HPV type ≥ 2 times during the approximate median follow-up period of 6 to 12 months), CIN, or external genital lesions in this patient population.

Q: What is the best response to individuals who are resistant to HPV vaccination because of safety concerns or parental objections?

A: Large-scale studies have shown the quadrivalent HPV vaccine to be safe. In the FUTURE trials and other clinical studies, which have included nearly 18 million doses of the quadrivalent HPV vaccine in the United States and more than 30 million doses worldwide, adverse events among recipients of the vaccine predominately involved pain, swelling, erythema, and fever. With the exception of fever, all were injection-site reactions that occurred within 5 days postvaccination. Few subjects (0.1%) discontinued due to adverse events.

Studies have shown that the most effective age for girls to be vaccinated is between 9 and 11 years of age, when exposure to HPV is at its lowest. However, some parents express concern that vaccination against HPV infection would promote earlier onset of sexual activity in their children, or believe that their children are at low risk for acquiring HPV infection and do not need to be vaccinated. Endorsement of the HPV vaccine by healthcare professionals is likely to increase vaccine acceptance. Indeed, a brief educational intervention about HPV and HPV vaccination has demonstrated success in increasing parental acceptance of the vaccine.

Q: Is HPV vaccination appropriate for immunocompromised patients?

A: Yes. Females who are immunocompromised, either from disease or medication, may receive the quadrivalent HPV vaccine; however, the immune response to vaccination and vaccine efficacy may be less than in immunocompetent females.