Vaccination against Human Papillomavirus

Amanda F. Dempsey, MD, PhD, MPH

Genital human papillomavirus (HPV) infection is one of the most common sexually transmitted infections worldwide and can result in a variety of clinical sequelae, including cervical dysplasia, cervical cancer, other anogenital cancers, genital warts, and recurrent laryngeal papillomatosis. Most episodes of HPV resolve spontaneously without clinical manifestations, yet because of the high prevalence of this infection in the population, a heavy clinical, financial, and public health burden from the follow-up and management of HPV-associated diseases is still incurred.

Two HPV vaccines that appear to provide excellent protection from infection and disease associated with a subset of the most clinically important HPV types have recently been developed. One of these, a quadrivalent vaccine (Gardasil®, Merck & Co), was licensed in June 2006 by the US Food and Drug Administration for use in girls and women 9 to 26 years of age, and has also been approved in several other countries. A bivalent vaccine (Cervarix™, GlaxoSmithKline) is expected to be licensed in the near future. These vaccines hold remarkable promise for dramatically reducing the incidence of HPV-related diseases in the United States, and may have an even greater impact in countries where other cervical cancer prevention programs, such as routine Papanicolau (Pap) smear–based screening, are not widely available.

Successful administration of HPV vaccines to the target population requires thoughtful evaluation of the expected economic, clinical, and health system infrastructure impacts of widespread HPV immunization. The clinical benefits afforded to patients, and the potential economic benefits to managed care health plans and other payers, are tempered by current limitations in the health system infrastructure to systematically deliver these vaccines to young women and by barriers to vaccine acceptance at the patient, provider, and societal levels. This supplement to *The American Journal of Managed Care* provides information on the epidemiology of HPV and HPV-associated illnesses as a rationale for immunization, explores the anticipated impacts of vaccination on health outcomes, and describes potential barriers to HPV vaccine introduction. With the recent licensure of the first HPV vaccine, these topics have emerged at the forefront of discussion among the various stakeholders with an interest in HPV and cervical cancer prevention, including managed care and public health officials, medical providers, parents, and patients.

The first article by Trottier and Franco describes in detail the epidemiology and natural history of HPV infection and cervical cancer, risk factors for HPV acquisition, the role of different cancer and HPV screening modalities, and strategies for preventing HPV and cancer, including HPV vaccination. In the second article by Hymel, the development and clinical efficacy of HPV vaccines are described, the expected financial and health impacts of vaccination are explored, and specific issues currently under debate related to the implementation of HPV vaccine programs are highlighted. In the final article, Dempsey and Davis discuss the evidence supporting a range of potential barriers to HPV vaccination, including parental

Address correspondence to: Amanda F. Dempsey, MD, PhD, University of Michigan, 300 NIB, Ann Arbor, MI 48109-0456. E-mail:adempsey@med.umid.edu.

and provider acceptance of HPV vaccines, public perceptions about cervical cancer and vaccination, vaccine economics and financing, and practice infrastructure.

These articles provide a framework for ongoing discussion about the optimal mechanism to incorporate HPV immunization programs into existing clinical services and provide insights into the educational and health system needs for successful administration of these vaccines. With well-planned vaccine implementation strategies that incorporate these issues, the full health benefits of HPV vaccines are more likely to be realized.