

High Efficacy Anticipated for Two HPV Vaccines

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JACKSONVILLE, FLA. — Both vaccines to prevent human papillomavirus infection will be highly effective, Dr. Diane M. Harper predicted at a conference on STD prevention sponsored by the Centers for Disease Control and Prevention.

Approximately 600 women participated in efficacy studies for a quadrivalent vaccine (Gardasil, Merck), and another 1,100 par-

ticipated in efficacy studies for a bivalent vaccine (Cervarix, GlaxoSmithKline). All women were screened at baseline to ensure seronegativity for high-risk strains 16 and 18 of the human papillomavirus (HPV) as well as for strains 6 and 11, which are also included in the quadrivalent product.

"The response was 100% for the bivalent and 89% for the quadrivalent for persistent, vaccine-specific HPV types for those who got the vaccine on time," Dr. Harper said. The recommended regimen for both vac-

cines is a 0.5-cc injection at 0, 2, and 6 months. In the studies, 94% of participants received all three doses, although not all according to protocol. The off-schedule efficacy was 95% and 89%, respectively, but these differences were not statistically different. "It indicated these will work in a real-world setting," she added.

Goals of vaccination include reduction of HPV transmission and anogenital lesions, "but most importantly we want to reduce incidence of cervical cancer," said

Dr. Harper, director of the Gynecologic Cancer Prevention Research Group at the Norris Cotton Cancer Center, Lebanon, N.H. She added that prevention of other anogenital cancers may be a serendipitous benefit of the vaccines. The quadrivalent vaccine has been licensed, and the bivalent vaccine may be cleared for marketing by the end of this year.

Both vaccines target high-risk HPV type 16, the type primarily implicated in cervical cancer. Type 16, taken together with types 18 (also in both vaccines), 31, and 45, accounts for 81% of cervical cancers, Dr. Harper said. The bivalent vaccine, "although it was designed for 16 and 18, is just as efficacious for HPV 45 and half effective for HPV 31, so that is exciting," said Dr. Harper, who is also a professor of community and family medicine and obstetrics and gynecology at Dartmouth Medical School, Hanover, N.H. Dr. Har-

THINK **COPD** FIRST:

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Factors to consider

Chronic obstructive pulmonary disease (COPD) is a prevalent and important health concern.¹ Patients can benefit if physicians diagnose and treat this progressive disease, but COPD is usually not identified in patients until it has advanced to moderate severity levels.²

► Smoking: The most common cause of COPD¹

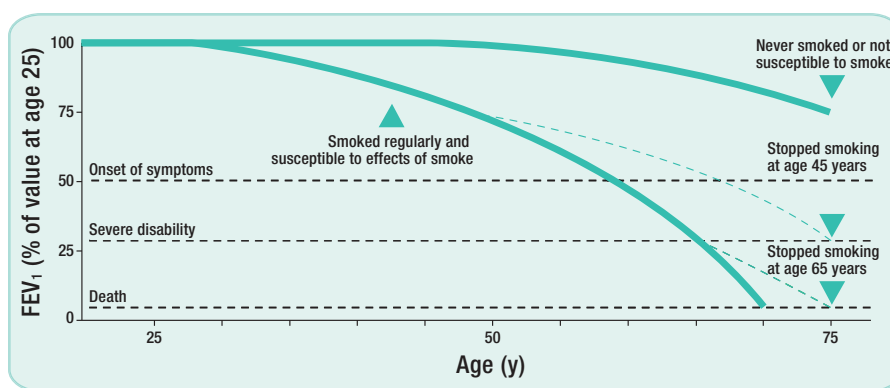
When you see a patient with breathing problems who is also a smoker, think COPD first. That's because smoking causes approximately 80% to 90% of COPD cases.³

► Identifying COPD

Due to the prominent role smoking plays in the development of COPD, physicians should consider COPD in patients 45 years of age or older⁴ with a history of smoking and respiratory symptoms.¹ These include chronic cough,¹ sputum production,¹ dyspnea,^{1,2} and wheezing.² Patients with COPD may also report that they are unable to perform daily activities.² Sometimes, COPD is misdiagnosed as asthma—but COPD is actually more common than asthma in patients 45 years of age or older.⁴ When diagnosing COPD, it's important to keep in mind that it can present as chronic bronchitis or emphysema^{5,6}; in fact, most COPD patients have both.^{5,6} Diagnosis should be confirmed with spirometry.^{1,2}

► Proper COPD diagnosis leads to appropriate intervention

Patients diagnosed with COPD should be advised to stop smoking. Since airway narrowing is a component of chronic bronchitis and emphysema, effective bronchodilation is required for both.^{2,7} Evidence-based guidelines state that bronchodilators are central to the treatment of COPD.^{1,2}



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By "thinking COPD first," physicians can intervene earlier and treat patients with COPD appropriately.



'This is the only disease other than infant influenza where you see higher titers from the vaccine than from the disease.'

DR. HARPER

er was also a consultant for Merck and GlaxoSmithKline and a researcher for the efficacy trials of each vaccine.

"These vaccines are preventive, they are not therapeutic—that is important to know," Dr. Harper said. "These prevent possible infection by HPV. These are not vaccines that prevent cancer." Because it is important that prevention lasts a long time, the need for a booster shot is anticipated with the bivalent vaccine 7-10 years later, Dr. Harper said. "We don't know if the quadrivalent vaccine will require a booster."

Researchers found high antibody titers at 7 months in the study participants who received all doses by 6 months. "This is the only disease other than infant influenza where you see higher titers from the vaccine than from the disease itself," Dr. Harper said.

Participants in the quadrivalent vaccine efficacy trials who reported prior exposure to HPV had antibody titers twice those of participants who were exposure naive. Dr. Harper said, "It's important to know that the vaccine works well in people previously exposed to HPV. It is good because women at all ages are at risk."

Adverse effects at local injection sites, including pain, erythema, and edema, were similar for both vaccines versus placebo. Other side effects such as headaches, gastrointestinal problems, and fatigue occurred at similar, "acceptable" rates in placebo and vaccine recipients, Dr. Harper said.

Other safety concerns with vaccines include new-onset autoimmune disease and musculoskeletal problems. "We can say no in both cases," Dr. Harper said. "So there is no concern about new-onset diseases, at least up to 4.5 years. We will continue to follow that."

References: 1. Celli BR, MacNee W, and ATS/ERS Task Force committee members. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. *Eur Respir J.* 2004;23:932-946. 2. Global Initiative for Chronic Obstructive Lung Disease. *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: Updated 2005.* Bethesda, Md/Geneva, Switzerland: National Heart, Lung, and Blood Institute/World Health Organization; 2005. Available at: <http://www.goldcopd.org>. Accessed March 9, 2006. 3. Bernstein AB, Hing E, Moss AJ, et al. *Health Care in America: Trends in Utilization.* Hyattsville, Md: U.S. Department of Health and Human Services; 2004. DHHS publication no. 2004-1031. Available at: <http://www.cdc.gov/nchs/data/misc/healthcare.pdf>. Accessed March 9, 2006. 4. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Summary health statistics for U.S. adults: national health interview survey, 2003 (updated 2005). Data from the National Health Interview Survey. DHHS publication no. (PHS) 2005-1553. 5. Soriano JB, Davis KJ, Coleman B, et al. The proportional Venn diagram of obstructive lung disease: two approximations from the United States and the United Kingdom. *Chest.* 2003;124:474-481. 6. Celli BR, Snider GL, Hefner J, and the committee for the American Thoracic Society. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med.* 1995;152:S77-S120. 7. Casaburi R, Conoscenti CS. Lung function improvements with once-daily tiotropium in chronic obstructive pulmonary disease. *Am J Med.* 2004;117:33S-40S. 8. Fletcher C, Peto R. The natural history of chronic airflow obstruction. *Br Med J.* 1977;1:1645-1648.



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