ACIP Updates Adult Immunization Schedule

BY DIANA MAHONEY

Revised recommendations for human papillomavirus vaccination—including a permissive recommendation for young men—and for measles, mumps, rubella immunization are part of the newly issued 2010 immunization schedule from the Advisory Committee on Immunization Practices at the Centers for Disease Control and Prevention.

The new schedule also includes updated indications and schedule information for hepatitis A and B vaccination, as well as clarifications about meningococcal and *Haemophilus influenzae* type B vaccination.

Clinicians must overcome patients' perception of vaccines as necessary only for children and travelers, and 'make immunizations integral to each encounter ... in primary and specialty care settings.'

The 2010 Recommended Adult Immunization Schedule, which earned ACIP approval in October 2009, reflects current recommendations for the licensed vaccines, according to the schedule's accompanying report (Ann. Intern. Med. 2010;152:36-9). The schedule is approved by the American College of Physicians, as well as the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists.

The revised schedule includes these changes:

► For human papillomavirus (HPV), a bivalent vaccine (HPV2) has been licensed for use in females. Therefore, either the bivalent or quadrivalent (HPV4) vaccination can be used for women between 19 and 26 years. In addition, HPV4 may be given to males aged 9-25 years "to reduce their likelihood of acquiring genital warts," according to the revised schedule.

► For influenza vaccination, the term "seasonal" has been added to distinguish between seasonal and pandemic influenza vaccines.

► For measles, mumps, rubella (MMR) vaccination, most adults born after 1957 do not require repeat vaccination if they have documentation of having received at least one dose of the vaccine. Women without documentation of rubella vaccination should receive a dose of the MMR vaccine. Health care workers, college students, international travelers, and individuals who have been exposed to measles or mumps in an outbreak setting should receive two doses of MMR. When a second MMR dose is indicated, it should be administered 4 weeks after the first dose.

Health care facilities should "consider" MMR vaccination for unvaccinated health care workers born before 1957 who do not have evidence of immunity or disease, and should "recommend" vaccination of this group during an outbreak.

► For hepatitis A, vaccination is recommended for unvaccinated individuals who anticipate close personal contact with an international adoptee from a country with intermediate or high endemicity to hepatitis A. The first dose should be given at least 2 weeks before the arrival of the adoptee.

► For the three-dose hepatitis B vaccine, the second dose should be administered 1 month after the first dose, and the third dose should be administered at least 2 months after the second. If using the combined hepatitis A and B vaccine, three doses should be administered at 0, 1, and 6 months. Alternatively, a four-dose schedule, administered on days 0, 7, 21, and 30, followed by a 12-month booster, may be used.

► For meningococcal vaccination, the conjugate vaccine (MCV4) is preferred for adults aged 55 years or younger, while the polysaccharide vaccine (MPSV4) is recommended for adults older than 55 years. Revaccination with MCV4 after 5 years is recommended for individuals who continue to be at risk for infection, such as adults with anatomic or functional asplenia. However, it is not recommended for individuals whose only risk factor is continued on-campus residence.

► For *Haemophilus influenzae* type B (Hib) vaccination, there is no recommendation for individuals older than age 5 years. One dose of the vaccine is not contraindicated in certain high-risk patients who have not received the vaccine previously, including those patients with sickle cell disease, leukemia, HIV infection, or splenectomy.

Although vaccines are among the most effective strategies for preventing individual illness and protecting public health, "deaths from vaccine-preventable illnesses still occur in the United States," noted Dr. Robert H. Hopkins Jr. and Dr. Keyur S. Vyas of the University of Arkansas, Little Rock, in an accompanying editorial.

Clinicians must overcome patients' perception of vaccines as necessary only for children and travelers, Dr. Hopkins and Dr. Vyas added. "Our challenge is to change this perception and to make immunizations integral to each encounter for physicians who care for adults in primary and specialty care settings."

In addition, the importance of immunization "should be imparted directly to our patients, as well as to students and residents early in their training, as an essential component of the comprehensive care of adults in ambulatory and inpatient settings," they said (Ann. Intern. Med. 2010;152:59-60). ■

The complete 2010 Adult Immunization Schedule will be available in English and Spanish at www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm.

Disclosures: *Members of ACIP disclosed relationships with MedImmune, Sanofi Pasteur, Novartis, and Wyeth. According to the report, members with conflicts are not permitted to vote if the conflict involves the vaccine or agent being considered. Dr. Hopkins and Dr. Vyas reported no potential conflicts of interest.*

FDA Finds No Cancer Link for Ezetimibe or Simvastatin

BY ELIZABETH MECHCATIE

A review of data from three studies indicates that simvastatin, ezetimibe, or the combination of the two are not likely to be increase the risk of cancer or death from cancer, but that the association cannot be "definitively ruled out," the Food and Drug Administration announced.

Based on available data, 'FDA believes it is unlikely that Vytorin or Zetia increase the risk of cancer or cancer-related death, but ... an association cannot be definitively ruled out.'

The FDA announcement is a follow-up to an announcement made by the agency in August 2008 about a safety review of these products, based on the preliminary results of the Simvasatatin and Ezetimibe in Aortic Stenosis (SEAS) trial of 1,873 patents with aortic stenosis, which found a higher rate of cancer (11.1%) among those on Vytorin 10/40 (10 mg of ezetimibe and 40 mg of simvastatin), compared with those on placebo (7.5%). The number of cancer-related deaths was also higher among those on Vytorin in this study. Vytorin is a combination of simvastatin (Zocor) and ezetimibe (Zetia).

The FDA has finished a review of data from SEAS, which is completed, and interim data from two large ongoing studies with lower doses of Vytorin, the SHARP (Study of Heart and Renal Protection) and IMPROVE-IT (Improved Reduction of Outcomes: Vytorin Efficacy International Trial).

"Based on the currently available information, FDA believes it is unlikely that Vytorin or Zetia increase the risk of cancer or cancer-related death, but at this time an association cannot be definitively ruled out," the statement said. "FDA is not advising healthcare professionals or consumers to stop using these medications, but to continue to evaluate the clinical benefits and potential risks of Vytorin or Zetia compared to other FDA-approved cholesterol lowering medications."

The SHARP study compares Vytorin (10/20 mg) to placebo, to determine whether reducing cholesterol with the combination product can prevent heart disease and strokes in patients with kidney disease.

IMPROVE-IT is comparing the clinical benefit (the reduction in the risk of the composite end point of cardiovascular death, major coronary events, and stroke) of Vytorin (10/40 mg) to 40 mg of simvastatin, in high-risk subjects with stabilized high-risk acute coronary syndrome.

An interim analysis of a total of 20,617 patients from these two studies found no increased risk of cancer associated with Vytorin. There were 97 cancer-related deaths, however, compared with 72 deaths among those in the control groups, but the difference was not statistically significant.

The cancer risk associated with Vytorin will be evaluated further when these studies are completed in 2010 (SHARP) and 2012 (IMPROVE-IT), according to the FDA.

Other factors that the agency considered in its review included animal studies that did not find an association between ezetimibe and an increased incidence of cancer.

In addition, there was not a consistent increase in the risk of cancer over time in the SEAS study, which would be expected if the drug caused cancer or promoted the growth of preexisting cancers, and the increase in cancer and cancer deaths in the study was due to combining a variety of cancer types, according to the statement. ■

The notice can be found at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm194964.htm. Adverse events can be reported at www.fda.gov/medwatch or 800-332-1088.

VERBATIM

'They wanted to evaluate a model of a car, but instead of using a 2010 model, they used a 2006 model.'

Dr. Rick Kennison, on the Institute of Medicine's review of continuing medical education, p. 44