FDA Strengthens Syncope Warning for Gardasil

BY MICHELE G. SULLIVAN

Patients who receive the Gardasil vaccine should sit or lie down in the office for at least 15 minutes after vaccination to prevent possible injury from falling during syncope, while being observed for paleness, sweating, dizziness, or other signs of a possible vasovagal reaction, the Food and Drug Administration recommended.

Because of continued reports of syncope and related traumatic injury, the FDA has requested that Merck and Co. Inc., manufacturer of the vaccine, add this information to the warnings and precautions section of the label.

"The addition of syncope to the [label] emphasizes that health care providers and consumers should be alert that fainting may occur following vaccination with Gardasil, sometimes resulting in falling and injuries," the FDA said in a public information statement. "These are preventable by having Gardasil recipients remain seated or lying down for 15 minutes following vaccination and closely watching them for the following warning signs and symptoms: paleness, sweating, dizziness, ringing in ears or vision changes, which generally occur before fainting."

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Up to 40% of adolescent syncope associated with Gardasil is also accompanied by tonic-clonic seizure-like activity, the FDA said. "If an individual faints and especially if seizure-like activity occurs, the individual should be placed in a position, such as lying down, to help restore blood flow to the brain."

Syncope has been listed on the Gardasil label as a possible adverse event since October 2007, the statement said. However, the FDA's Vaccine Adverse Event Reporting System (VAERS) continues to receive reports of traumatic injuries related to fainting and falling after vaccination. In light of this, the agency decided to strengthen the label warning.

Fainting doesn't appear to be unique to Gardasil, the statement added. "Syncope has been reported after administration of other adolescent and adult vaccines. … It can also occur with certain medications, after blood donation, or in response to pain."

The fact sheet did not give details of the injuries associated with all these events. However, 70 episodes of syncope in U.S. patients were reported in the May 2, 2008, issue of the Morbidity and Mortality Weekly Report (2008; 57:457-60). These events occurred from January 2005 to July 2007. The reports noted that about 5% of the spells were considered serious; 38 occurred on the same day as vaccination and 37 required hospitalization.

As of May 1, 2009, there were 13,758 VAERS reports of adverse events following more than 24 million Gardasil vaccinations in the United States. Of these reports, 93% were considered nonserious and 7% serious. Nonserious adverse events include fainting, pain and swelling at the injection site, headache, nausea, and fever.

However, the vaccine is still considered a safe and effective one, the FDA said in the public information statement. "Based on all of the information we have today, the Centers for Disease Control and Prevention continues to recommend Gardasil vaccination for the prevention of four types of human papillomavirus. As with all approved vaccines, CDC and FDA will continue to closely monitor the safety of Gardasil. Any problems detected with this vaccine will be reported to health officials, health care providers, and the public, and needed action will be taken to ensure the public's health and safety." ■

Information regarding adverse events that are associated with Gardasil is available on the FDA's VAERS Web site (www.cdc.gov/vaccinesafety/vaers/gardasil.htm).