

Department of Health and Human Services-Centers for Disease Control and Prevention
June 11, 2009

Dear Partners:

On Tuesday, The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) revised the label for Gardasil, a vaccine to protect against cervical, vulvar and vaginal cancers caused by Human Papillomavirus (HPV) types 16 and 18 and genital warts caused by HPV types 6 and 11. The revised label includes new information in the Warnings and Precautions section noting that individuals who faint sometimes have tonic-clonic (jerking) movements and seizure-like activity.

Information on syncope has been in Gardasil's labeling for both healthcare providers and patients since 2007. However, FDA and CDC continue to receive reports of traumatic injuries in individuals who have fainted and fallen after receiving Gardasil. The addition of this information to the Warnings and Precautions section is intended to remind healthcare providers that Gardasil recipients should be observed closely for 15 minutes after vaccination. Vaccine recipients should be encouraged to remain seated or lying down for this length of time and be alert for signs and symptoms that can occur before fainting, such as paleness, sweating, nausea, dizziness and ringing in ears or vision changes.

Syncope has been reported after administration of other adolescent and adult vaccines, so it is not unique to Gardasil or even vaccines. Syncope can also occur with certain medications, after blood donation or in response to pain. Jerking movements, loss of bladder control, and other signs that resemble seizures may occur, but these do NOT mean that the person is having a seizure. Syncope and its associated signs and symptoms usually last only a short time (seconds to minutes) and resolve when the patient is placed in a position, such as lying down, to restore adequate blood flow to the brain.

Information about this change may be found on the [FDA's web site](#). Additional information regarding syncope following vaccination may be found in the May 2, 2008, issue of the Morbidity and Mortality Weekly Report at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm>

The revised package insert, patient information, and background on the labeling revision can be found on the [FDA's web site](#).

We encourage you to share this important information with your staff or members. If you or your members have any questions, please contact CBER at 800-835-4709 or ocod@fda.hhs.gov.

Thank you,

NCIRD Health Communication Science Office

Janice Pimer, LPN
Member Services Manager
Missouri Primary Care Association
3325 Emerald Lane
Jefferson City, MO 65109
P: (573) 636-4222
F: (573) 636-4585

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