MedicalXpress

H1N1 vaccine associated with small but significant risk of Guillain-Barre syndrome

July 10 2012

Guillain-Barre syndrome (GBS) is usually characterized by rapidly developing motor weakness and areflexia (the absence of reflexes). "The disease is thought to be autoimmune and triggered by a stimulus of external origin. In 1976-1977, an unusually high rate of GBS was identified in the United States following the administration of inactivated 'swine' influenza A(H1N1) vaccines. In 2003, the Institute of Medicine (IOM) concluded that the evidence favored acceptance of a causal relationship between the 1976 swine influenza vaccines and GBS in adults. Studies of seasonal influenza vaccines administered in subsequent years have found small or no increased risk," according to background information in the article. "In a more recent assessment of epidemiologic studies on seasonal influenza vaccines, experimental studies in animals, and case reports in humans, the IOM Committee to Review Adverse Effects of Vaccines concluded that the evidence was inadequate to accept or reject a causal relationship."

Philippe De Wals, M.D., Ph.D., of Laval University, Quebec City, Canada and colleagues conducted a study to assess the risk of GBS following pandemic influenza vaccine administration. In fall 2009 in Quebec an immunization campaign was launched against the 2009 influenza A(H1N1) pandemic strain. By the end of the year, 4.4 million residents had been vaccinated. The study included follow-up over the 6-month period of October 2009 through March 2010 for suspected and confirmed GBS cases reported by physicians, mostly neurologists, during active surveillance or identified in the provincial hospital summary discharge database. Immunization status was verified.

Over the 6-month period, 83 confirmed GBS cases were identified. Twenty-five confirmed cases had been vaccinated against 2009 influenza A(H1N1) 8 or fewer weeks before disease onset, with most (19/25) vaccinated 4 or fewer weeks before onset. Analysis of data indicated a small but significant risk of GBS following influenza A(H1N1) vaccination. The number of cases attributable to vaccination was approximately 2 per 1 million doses. The excess risk was observed only in persons 50 years of age or older.

"In Quebec, the individual risk of hospitalization following a documented influenza A(H1N1) infection was 1 per 2,500 and the risk of death was 1/73,000. The H1N1 vaccine was very effective in preventing infections and complications. It is likely that the benefits of immunization outweigh the risks," the authors write.

In an accompanying editorial, Mark C. Steinhoff, M.D., of the Cincinnati Children's Hospital Medical Center, and Noni E. MacDonald, M.D., M.Sc., F.R.C.P.C., of Dalhousie University, Halifax, Nova Scotia, Canada, write that "taken together, these studies partially assuage concerns about safety of adjuvanted pandemic influenza vaccines during pregnancy."

"However, more studies are needed examining other types of vaccine adjuvants. In addition, observational studies of vaccines are limited by biases, including selection bias, as well as confounding by indication. Thus, future studies with improved statistical designs including prospective follow-up studies using virological end points with adjustments for selection, seasonality, and other biases are needed to confirm these data."

More information: *JAMA*. 2012;308[2]:175-181.
JAMA. 2012;308[2]:184-185.