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MMWR EARLY RELEASE REPORTS ON H1N1 INFLUENZA VACCINE SAFETY

On December 4, CDC published an MMWR Early Release titled, "Safety of Influenza A (H1N1) 2009 Monovalent Vaccines--United States, October 1-November 24, 2009." The first paragraph is reprinted below.

The Food and Drug Administration (FDA) licensed the first 2009 influenza A (H1N1) monovalent vaccines ("H1N1 vaccines") on September 15, 2009. The H1N1 vaccines are available as a live, attenuated monovalent vaccine (LAMV) for intranasal administration and as monovalent, inactivated, split-virus or subunit vaccines for injection (MIV). The licensure and manufacturing processes for the monovalent H1N1 vaccines were the same as those used for seasonal trivalent inactivated (TIV) or trivalent live, attenuated influenza vaccine (LAIV); none of these vaccines contains an adjuvant. Vaccine safety monitoring is an important component of all vaccination programs. To assess the safety profile of H1N1 vaccines in the United States, CDC reviewed vaccine safety results for the H1N1 vaccines from 3,783 reports received through the U.S. Vaccine Adverse Event Reporting System (VAERS) and electronic data from 438,376 persons vaccinated in managed-care organizations in the Vaccine Safety Datalink (VSD), a large, population-based database with administrative and diagnostic data, in the first 2 months of reporting (as of November 24). VAERS data indicated 82 adverse event reports per 1 million H1N1 vaccine doses distributed, compared with 47 reports per 1 million seasonal influenza vaccine doses distributed. However, no substantial differences between H1N1 and seasonal influenza vaccines were noted in the proportion or types of serious adverse events reported. No increase in any adverse events under surveillance has been seen in VSD data. Many agencies are using multiple systems to monitor H1N1 vaccine safety. Healthcare providers and the public are encouraged to report adverse health events that occur after vaccination. . . .

To access the complete Early Release in web-text (HTML)

format, go to: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e1204a1.htm?s_cid=mm58e1204a1_e