Xiao-Feng Liang, et al: Safety of Influenza A (H1N1) Vaccine in Postmarketing Surveillance in China N Engl J Med 2011; 364:638-647 February 17, 2011

BACKGROUND

On September 21, 2009, China began administering vaccines, obtained from 10 different manufacturers, against 2009 pandemic influenza A (H1N1) virus infection in priority populations. We aimed to assess the safety of this vaccination program.

METHODS

We designed a plan for passive surveillance for adverse events after immunization with the influenza A (H1N1) vaccine. Physicians or vaccination providers were required to report the numbers of vaccinees and all adverse events to their local Center for Disease Control and Prevention (CDC), which then reported the data to the Chinese CDC through the online National Immunization Information System's National Adverse Event Following Immunization Surveillance System. Data were collected through March 21, 2010, and were verified and analyzed by the Chinese CDC.

RESULTS

A total of 89.6 million doses of vaccine were administered from September 21, 2009, through March 21, 2010, and 8067 vaccinees reported having an adverse event, for a rate of 90.0 per 1 million doses. The age-specific rates of adverse events ranged from 31.4 per 1 million doses among persons 60 years of age or older to 130.6 per 1 million doses among persons 9 years of age or younger, and the manufacturerspecific rates ranged from 4.6 to 185.4 per 1 million doses. A total of 6552 of the 8067 adverse events (81.2%; rate, 73.1 per 1 million doses) were verified as vaccine reactions; 1083 of the 8067 (13.4%; rate, 12.1 per 1 million doses) were rare and more serious (vs. common, minor events), most of which (1050) were allergic reactions. Eleven cases of the Guillain–Barré syndrome were reported, for a rate of 0.1 per 1 million doses, which is lower than the background rate in China.

CONCLUSIONS

No pattern of adverse events that would be of concern was observed after the administration of influenza A (H1N1) vaccine, nor was there evidence of an increased risk of the Guillain–Barré syndrome.