Excess Risk of GBS Low With H1N1 Vaccine

BY MICHELE G. SULLIVAN

FROM THE MMWR

The excess risk of developing Guillain-Barré syndrome associated with receipt of the pandemic influenza A(H1N1) vaccine is less than 1 case per 1 million vaccinations—a rate comparable to that seen for some trivalent seasonal influenza vaccines.

Preliminary results released in the Morbidity and Mortality Weekly Report found 326 confirmed new cases of the neurological disorder from Oct. 1, 2009 through May 10, 2010 (MMWR 2010;59:1-5).

Of these patients, 27 reported having had the pandemic flu vaccine within 42 days of the onset of GBS—the time period considered plausible for any biologic link between the two. Most of these patients reported an antecedent illness typically related to GBS onset (gastrointestinal illness or respiratory infection).

"Notably, this high proportion of antecedent illnesses associated with GBS suggests that a number of the GBS illnesses observed after vaccination might be attributable to other antecedent illnesses," wrote C. Prothro of the California Emerging Infections Program, Oakland, and co-authors. "Historically, 40%-70% of GBS patients report experiencing antecedent infectious illness."

If the preliminary analysis is confirmed—which the CDC expects to happen by this fall—then the attributable rate of GBS would be 0.71 per 100,000 person-years, corresponding to an excess GBS rate of 0.8 cases per 1 million vaccinations, the report said.

Although the report deemed the risk of vaccination-related GBS to be low with pandemic flu vaccine, it did recommend caution for patients with GBS who might consider vaccination.

"Persons with a history of GBS should discuss potential risks and benefits with their health-care providers before receiving any influenza vaccine," K.R. Copeland of the National Opinion Research Center, Chicago, and co-authors wrote in an accompanying editorial note. "However, risk assessment should take into account that influenza and influenza-like illnesses are associated with significant morbidity and mortality, including a hospitalization rate of 222 per 1 million population and a death rate of 9.7 per 1 million population for H1N1-associated illnesses, as well as possible increased risk for GBS."

Of the 326 confirmed GBS cases, 27 had documentation proving pandemic flu vaccination within the 42-day window; vaccination status could not be determined in 25, and 274 were not vaccinated.

Sixteen of the 27 (59%) who received the vaccine experienced antecedent symptoms before their GBS diagnosis. The program found no clustering of GBS between vaccination and illness onset.

Among the 27 with GBS who were vaccinated, 4 (15%) required ventilator support, and 1 was hospitalized for 30 days. Among the 274 GBS patients who were not vaccinated, 37 (14%) required ventilator support, and 34 (12%) were hospitalized for 30 days after illness onset. Eight GBS patients died (2%); none of them had received the pandemic flu vaccine.

The CDC study used data gathered by its Emerging Infections Program. The program has collaborated with state health centers and academic medical centers in 10 states to rapidly identify new GBS cases following pandemic flu vaccination.

The surveillance areas included Connecticut, Maryland, Minnesota, New Mexico, Tennessee, and New York state (excluding Manhattan), and selected metropolitan counties in California, Colorado, Georgia, and Oregon. GBS incidence was calculated and compared for the vaccinated and unvaccinated populations. ■

VITALS

Major Finding: For every 1 million people who receive the pandemic influenza vaccine, about 1 additional person will develop Guillain-Barré syndrome.

Data Source: A nationwide federal Guillain Barré Syndrome surveillance system.

Disclosures: None noted.