Guillain-Barré Risk From Menactra Under Review

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ATLANTA — Data available thus far suggest that the overall risk for Guillain-Barré syndrome following receipt of the meningococcal conjugate vaccine is not significantly increased, Dr. Robert L. Davis reported at the winter meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

From July 2005 through January 2007, a total of 19 cases of Guillain-Barré syndrome (GBS) occurring within 6 weeks of vaccination with the meningococcal conjugate vaccine (MCV4/Menactra) were reported to the passive Vaccine Adverse Events Reporting System (VAERS). The onset interval was 2-33 days following immunization.

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Seventeen of the 19 were aged 11-19 years old.

Information from the eight managed care organizations participating in the Vaccine Safety Datalink (VSD) indicates that approximately 94% of MCV recipients are 11-19 years old, said Dr. Davis, director of the CDC's Immunization Safety Office.

In the VSD Rapid Cycle Project from April 2006 through January 2007, there were no cases of GBS reported among vaccine recipients aged 11-19 years old within 6 weeks of vaccination. A total of 0-1 case was expected. However, "not finding any GBS after MCV4 vaccination in 11- to 19-year-olds does not offer substantial reassurance regarding MCV4 safety," Dr. Davis said.

The overall observed reporting rate for GBS after MCV4 vaccination in VAERS, 1.78 per million person-months, was not higher than expected.

With use of two data sources, the VSD and the Healthcare Utilization Project (HCUP), the expected rates of GBS are 1.13 and 1.11 per million person-months, respectively. If these data accurately represent the true magnitude of increased risk after MCV4 vaccination, then there would be an excess of just 0.89 cases per million doses of MCV4 administered, Dr. Davis said.

However, there was a difference in rate ratio when vaccine recipients were divided by age, 11- to 14-year-olds vs. 15- to 19-year-olds: For the younger set, the observed vs. expected is 1.0/4.2, for a rate ratio of 0.25 when controlled for season. In contrast, among the 15- to 19-year-olds, the observed/expected ratio is 16/6.5, for a rate ratio of 2.48, again controlling for season.

Seasonality plays a role by age, because the older group is more likely to receive MCV4 prior to school entry whereas the 11- to 14-year-olds are receiving it year-round, Dr. Davis pointed out.

The data are subject to major limitations. On one hand, the passive nature of VAERS means that underreporting is likely, which would raise the risk estimates. On the other, there were no surges in GBS cases reported to VAERS after any of the three notices published in the CDC's Morbidity and Mortality Weekly Report, which would be expected if underreporting were marked, he noted.

"Although there appears to be a small increased risk for GBS after MCV4 vaccination in the 15- to 19-year-old age category, the inherent limitations of VAERS require that these findings be viewed with caution. Substantial uncertainty exists regarding the risk estimate, using the HCUP or the VSD background incidence rate," he said.

However, he added, "the timing of neurologic symptoms within 1-5 weeks of vaccination among reported cases is of concern."

A larger study led by Harvard Pilgrim is expected to yield additional data regarding the risk for GBS following MCV4 in approximately 2 years.

Ongoing evaluation of GBS after MCV4 vaccination is also being performed within VSD, Dr. Davis said.

All cases of Guillain-Barré syndrome in a patient following receipt of Menactra should be reported to VAERS, online at http://vaers.hhs.gov or by calling toll-free at 800-822-7967. ■