MCV4 as Effective as Polysaccharide Vaccine

BY MIRIAM E. TUCKER

ATLANTA — The effectiveness of the meningococcal conjugate vaccine within 3 years of vaccination is estimated to be between 80% and 90%, an analysis by the Centers for Disease Control and Prevention found.

The quadrivalent meningococcal conjugate vaccine (MCV4, Menactra) was licensed based on safety and immunogenicity data showing that it was noninferior to the meningococcal polysaccharide vaccine, which is 85% effective against serogroup C. In prelicensure clinical trials, the seroresponse of MCV4 was 92% for serogroup C and 82% for serogroup Y. The current study provides the first estimate of clinical vaccine effectiveness of MCV4, which is recommended for routine immunization of 11- to 18-year-olds. The results suggest that it is about as effective as the meningococcal polysaccharide vaccine, Jessica MacNeil said at a meeting of the CDC's Advisory Committee on Immunization Practices.

The data came from 20 participating sites of CDC's Active Bacterial Core Surveillance (ABCs) and MeningNet sites between January 2005 (when MCV4 was licensed) and December 2008.

Among vaccinated individuals, 14 confirmed cases of meningococcal disease—8 (57%) serogroup C and 6 (43%) serogroup Y—were identified at 6 of the 20 sites. All had received MCV4, but there was no common lot among them. The median time from vaccination to disease onset was 395 days (range, 43-1,021), said Ms. MacNeil of the CDC's division of bacterial diseases, National Center for Immunization and Respiratory Diseases.

Half of the 14 cases were among college students, and 2 were in military recruits. The median age at vaccination was 18 years (range, 13-20), and the median age at the time of disease was 20 years (range, 15-22).

Nearly half of the cases occurred within the first year following vaccination, with the other cases occurring at either 1-2 years or more than 2 years post vaccination. Because MCV4 coverage was low in 2005 and 2006, only individuals who were vaccinated early have had time to be observed 2 or 3 years after vaccination. This distribution is expected to change with time, Ms. MacNeil noted.

All but one of the infected patients was hospitalized, with a mean hospitalization duration of 3 days (range, 0-46). Meningitis was reported in six of the patients (43%) and bacteremia in eight (57%). Nine had underlying medical conditions. There were three deaths, for a 21% case fatality rate.

A simulation approach using varying estimates of vaccine effectiveness was used to determine whether the 14 cases represent an expected number among vaccinated individuals. The analysis used an incidence of serogroup C and Y disease among 13- to 18-year-olds of 0.38/100,000. This incidence rate is similar to the observed rates in the unvaccinated individuals that were calculated using data from the 20 participating case-control study sites, she said.

If MCV4 were 90% effective, there would be an expected median of 7 cases, with a 2.9% probability of observing 14 or more cases of meningococcal disease in vaccinated persons. If vaccine efficacy were just 80%, there would be an expected median of 15 cases, with a 66.1% probability of seeing 14 or more cases. Thus, "based on our best estimates of MCV4 coverage, vaccine effectiveness appears to be greater than 80% but is unlikely to be 90% effective," Ms. MacNeil said.

With coverage held constant at 50% for all persons 18 years of age or older during 2005-2008, if MCV4 were 90% effective, there is a 5% chance of seeing 14 cases in vaccinated persons; if MCV4 were 85% effective, there is a 47% chance of seeing 14 cases. "Even with high estimates of coverage in our sensitivity analysis, MCV4 appears to be between 80% to 90% effective," she added.

The ACIP meningococcal working group expects more data to be available in 1-3 years to further evaluate vaccine effectiveness, Ms. MacNeil said. The CDC is in the process of expanding its MCV4 effectiveness case-control study to additional sites. ■