Menactra Appears to Be Reaching Target Teens

BY PATRICE WENDLING
Chicago Bureau

KANSAS CITY, MO. — The strategy of immunizing all children at the 11- to 12-year preadolescent visit and those entering high school with the new meningococcal conjugate vaccine appears to be working, according to preliminary Centers for Disease Control and Prevention data.

Uptake of Menactra vaccine was higher in these target age groups compared with nontargeted 13- and 16-year-olds in a study of 619,371 adolescents, Dr. Pascale Wortley and associates reported at the National Immunization Conference sponsored by the Centers for Disease Control and Prevention.

Menactra (made by Sanofi Pasteur) was licensed in January 2005 for use in persons aged 11-55 years, and is recommended for all children at the 11- to 12-year preadolescent visit, those entering high school, college students living in dormitories, U.S. military recruits, and others who choose to be vaccinated.

The study also indicated that heavy demand during the summer months did cause a vaccine shortage.

"Even though the total number of teens vaccinated did not exceed the amount of vaccine available, because it was all concentrated over the space of a few months, it did create a shortage situation," said Dr. Wortley of the CDC's Immunization Services Division in Atlanta.

The investigators analyzed data from 619,371 adolescents aged 11-16 years vaccinated with Menactra (MCV4) in 2005 at five of eight managed care organizations participating in the Vaccine Safety Datalink.

The five managed care organizations experienced a rapid increase in immunizations among the three age groups (11-12 years, 14-15 years, and 13- and 16-year-olds) between May and August, followed by a rapid decline to a relatively steady rate by Sept. 30. Overall, 73% of vaccinations were given between June and August, said Dr. Wortley, who presented the results on behalf of lead author Dr. Suchita Lorick, also of the CDC in Atlanta.

At the end of 2005, the cumulative coverage was 12% for ages 11-12 years, 11% for ages 14-15 years, and 8% for ages 13 and 16 years.

Compared with the group of 13- and 16-year-olds, the risk ratios for receiving Menactra for those aged 11-12 years and 14-15 years were 1.49 and 1.29, respectively.

Coverage among 11- to 12-year-olds reached nearly 35% at one of the HMO sites with an explicit policy targeting this age group, compared with less than 15% at two other larger HMO sites that reported experiencing some degree of vaccine shortage in 2005, she said.

Because of the strong summer usage, the investigators decided to compare Menactra uptake patterns with uptake for the old polysaccharide meningococcal formulation (Menomune, also made by Sanofi Pasteur) and the tetanus and diphtheria (Td) vaccine. They used data from the 2003-2004 Vaccine Safety Datalink and 2004 data from the MarketScan databases, representing 40 self-insured employers and more than 1 million 11- to 16-year-olds.

All three vaccines experienced increased usage during the summer, which comes as no surprise given the number of school physical examinations conducted at this time of year, Dr. Wortley said.

The September decline observed in Menactra usage likely was not related to the Food and Drug Administration's and CDC's notice in October 2005 that Guillain-Barré Syndrome could be associated with Menactra, she added.

"Clearly, vaccination had already decreased dramatically before that notice appeared," Dr. Wortley said. "It looks like the uptick was related to the ACIP [Advisory Committee on Immunization Practices] recommendation, and potentially, the trend down was not related to the [Guillain-Barré Syndrome] notice."

The CDC's Advisory Committee on Immunization Practices published its recommendations for Menactra in May 2005 after debating the age group or groups for which the vaccine should be recommended. Older adolescents (17-18 years) have the highest rates of meningococcal disease (1.7 per 100,000). But younger teens, who have somewhat lower rates of infection, are more likely to visit their physicians through the already established preadolescent health care visit and high school–entry physical examination. ■

Zostavax Elicits Antibody Response in Younger Group

BY MIRIAM E. TUCKER
Senior Writer

BALTIMORE — The herpes zoster vaccine is as immunogenic in adults aged 50-59 as it is in those aged 60 and older, Santosh C. Sutradhar, Ph.D., reported at a conference on vaccine research sponsored by the National Foundation for Infectious Diseases.

Zostavax, manufactured by Merck & Co., was licensed by the U.S. Food and Drug Administration in May 2006 for the prevention of herpes zoster in adults aged 60 and older only. Merck had sought an indication for those aged 50-59 years, but an earlier FDA advisory panel had recommended against it because data on safety and efficacy in that age group were lacking, as were overall data on duration of immunity for the vaccine.

In October 2006, the Advisory Committee on Immunization Practices recommended universal use of Zostavax among adults aged 60 and older.

Nonetheless, epidemiologic data suggest that the annual risk of developing herpes zoster actually begins to increase markedly around age 50 years and rises sharply afterward. Thus, "it is important to assess the immunogenicity and safety of Zostavax in this age group," said Dr. Sutradhar, senior biometrician at Merck & Co., West Point, Pa.

In combined data from two protocols that had been presented separately to the FDA, the vaccine was administered to 389 subjects aged 50-59 and to 733 aged 60 and older. Of those, 377 and 731, respectively, completed the 28-day follow-up. Antibody response, assessed by geometric mean fold rise of varicella zoster virus antibody from prevaccination to 4 weeks post vaccination, was increased substantially in both groups, by 2.6 in the younger group, compared with 2.3 in the older subjects.

Both of those levels exceeded the predefined threshold for "acceptable" antibody response, and the response for the younger group met the "noninferiority" criteria, compared with that of the older group, he said.

Adverse events within 28 days following vaccination were more common in the 50- to 59-year-olds, with 60% reporting one or more total adverse events, compared with 44% of the 60-plus group. Vaccine-related adverse events were reported by 52% and 35%, respectively. Injection-site reactions were the most common of these, reported by 50% of the younger subjects and 34% of the older ones. Systemic vaccine-related adverse events were far less common, reported by 6% and 3%, respectively, and no subject in either age group reported any serious vaccine-related adverse events.

Merck is working with the FDA to develop a protocol that will provide vaccine efficacy data as well as additional safety data specifically for the 50- to 59-year-old age group, as had been done previously with those aged 60 and older in the Shingles Prevention Study (SPS). Those findings, from more than 38,000 adults older than 60, showed that the vaccine reduced the burden of illness related to herpes zoster pain, the incidence of postherpetic neuralgia, and the incidence of herpes zoster (N. Engl. J. Med. 2005;352:2271-84).

Merck hopes to launch the new protocol sometime this year, according to a company spokeswoman. ■

Sports Team Athletes, Staff Urged to Take a Shot at Flu Immunization

BY KATE JOHNSON
Montreal Bureau

QUEBEC CITY — Promoting flu shots among sports team members is worth the effort, but it may be more difficult to convince the team's support staff, coaches, and trainers to follow suit, according to Dr. Robert McCormack, chief medical officer for the Canadian Olympic Team.

Dr. McCormack, who is also an orthopedic surgeon at the University of British Columbia, Vancouver, spoke at the joint annual meeting of the Canadian Academy of Sport Medicine and the Association Québécoise des Médecins du Sport about his successful efforts to promote flu vaccination among members of the Canadian 2006 Winter Olympic team.

"To my knowledge, there was not one case of influenza," he said, noting that during the 1988 Winter Olympics in Calgary, influenza devastated teams from all over the world.

But whether it's an Olympic team or not, immunization is one of the final stepping stones to a team's and athlete's success, especially if one considers the years of training that precede these events, Dr. McCormack said.

After the campaign before the 2006 Winter Olympics, Dr. McCormack and his colleagues immunized 76% of the Canadian team's athletes. But, those rates dipped to 66% for the support staff and 40% for coaches, resulting in an immunization rate of only 65% for the team overall.

Reasons given for not getting immunized centered on a lack of confidence in the benefits and concerns about the risks, said Dr. McCormack, who emphasized that the way in which the suggestion of immunization is presented is important.

"It really boils down to framing. You can report the percentage of people who will still get the flu and who will have side effects, or you can focus on the percentage of people who will be disease free and with no side effects," he said. And it may be even more difficult to promote immunization in individualized sports: The Canadian short-track skating, hockey, and curling teams, for example, had immunizations rates of 100%, whereas in decentralized, individual sports, such as snowboarding and figure skating, the rates were only 30%. ■

COURTESY DR. ROBERT MCCORMACK

The Canadian Women's Hockey team won gold at the 2006 Winter Olympics. All the players were immunized.