Vaccine Effect Might Depend on Needle Length

BY HEIDI SPLETE
Senior Writer

WASHINGTON — Vaccine site has little impact on the vaccine's effect, but using a 25-mm needle instead of a 16-mm needle may be more effective in administering flu vaccine to older patients, based on results of a study conducted at the Mayo Clinic in Rochester, Minn.

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices currently recommends influenza vaccination for all adults older than 50 years, but studies have shown that vaccine efficacy may be reduced in older adults, said Dr. Prikish Tosh, an infectious disease fellow at the Mayo Clinic.

"We wondered whether vaccine site had any effect," said Dr. Tosh, who presented the study results at the joint annual meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy and the Infectious Diseases Society of America.

He and his colleagues also examined whether a longer needle would increase penetration into the muscle and affect immunogenicity and reactogenicity in older patients. Flu vaccine manufacturers recommend 25-mm needles, but some single-dose vials are currently packaged with 16-mm needles, Dr. Tosh said.

Dr. Tosh and colleagues randomized 133 adults aged 50-88 years to receive the trivalent inactivated influenza vaccine in either the deltoid muscle or the deltoid fat pad. The groups were similar in terms of age, gender, weight, and other demographic characteristics. Patients who were immunocompromised or had previously received the vaccine were excluded.

Antibody titers for each of the three strains of influenza in the vaccine were measured at baseline and at 4-6 weeks after vaccination.

The researchers found no significant differences in antibody response rates between the two groups. "The results … were surprising," Dr. Tosh said. "At baseline, the antibody levels in the two groups were the same. However, after vaccination, we were expecting to see a substantial difference between the two groups. But we didn't see any difference for any of the three vaccine components."

The researchers found no significant differences in immunogenicity between those who seroconverted and those who did not.

"Injecting in the fat pad did increase reactogenicity," Dr. Tosh noted. The patients who received deltoid fat pad injections reported significantly more redness and swelling, compared with those who had intramuscular injections (34% and 5%, respectively).

In a subset analysis, 66 patients underwent ultrasound before vaccination to assess fat pad thickness and to determine whether the intramuscular injections succeeded. "Based on the ultrasound, a 25-mm needle would have worked for 97% of the subjects," Dr. Tosh noted. A 25-mm needle would have penetrated the muscle in all of the men and all but 3% of the women, but a 16-mm needle would have failed to penetrate the muscle in 26% of men and 51% of women, he said.

Dr. Tosh stated that he had no financial conflicts to report. ■

ACIP Opts Against Revising Needle Length Guidelines

BY SHARON WORCESTER
Southeast Bureau

ATLANTA — Despite new data suggesting that current Centers for Disease Control and Prevention recommendations regarding needle length for intramuscular vaccine injections might be flawed, the CDC's Advisory Committee on Immunization Practices favors maintaining the current recommendations.

The new data published this year by Dr. William Lippert and associates suggest that the currently recommended needle lengths increase risk of overpenetration and striking of bone and periosteum (Pediatrics 2008;122:e556-63). In some cases, the CDC recommendations are nearly twice what the study authors recommended, based on their review of 250 diagnostic MRI and CT scans. For example, in boys weighing 140 kg or less and in girls weighing 115 kg or less, the authors recommended a 5/8-inch needle length, while the current CDC recommendations call for a 1-inch needle length in these groups, according to Dr. Andrew Kroger of the CDC and ACIP's General Recommendations Working Group, which proposed the revision at ACIP's fall meeting.

Most working group members favored changing the general recommendations to "partially adopt" the new data by adding footnotes that incorporate the new data, Dr. Kroger said.

A proposed footnote states that "some experts recommend a needle shorter than 1 inch (25 mm) for children/adolescents 3 years through 18 years who weigh less than 140 kg (males) or less than 115 kg (females)."

However, several ACIP members argued against any change, saying that in years of practice they have not seen the types of complications noted in the study and arguing that the proposed change complicates matters for health care providers.

"Overall, I think that any change is unworkable," said Dr. Michael S. Marcy of the UCLA Center for Vaccine Research in Torrance, Calif.

The Lippert study is "interesting, but perhaps irrelevant," Dr. Marcy said, noting that a recommendation for shorter needle length for some children might outweigh any benefits—especially given the fact that an increasing number of pediatric patients are overweight or obese, which could lead to increased risk of subcutaneous vs. intramuscular injection with use of shorter needles.

The committee asked the working group to maintain the current recommendations in the updated general recommendations report the group is currently drafting. The first half of the revised report was presented at the meeting.

The last report, adopted in 2006, includes a grid calling for the use of a 5/8-inch needle in newborns injected at the anterolateral thigh, a 1-inch needle in those aged 1-12 months injected at the anterolateral thigh, a 1- to 1¼-inch needle in those aged 1-2 years injected at the anterolateral thigh or a 5/8- to 1-inch needle in those injected at the deltoid muscle of the arm, and a 5/8- to 1-inch needle in those aged 3-18 years injected at the deltoid muscle of the arm or a 1- to 1¼-inch needle in those injected at the anterolateral thigh.

Although the grid does not emphasize injection technique, the text of the recommendation in the report does address technique, Dr. Kroger noted.

The second half of the revised draft of the General Recommendations report, which addresses immunization issues relevant to all vaccines and which addresses topics ad hoc that cannot be attributed to a single vaccine, will be presented to ACIP in February 2009. The revised report is scheduled for publication in December 2009. ■

PCV7 Cut Disease in All Ages, But Non-PCV7 Serotypes Emerge

BY HEIDI SPLETE
Senior Writer

WASHINGTON — The 7-valent pneumococcal conjugate vaccine (PCV7) has prevented about 210,000 cases of invasive pneumococcal disease and 14,000 disease-related deaths in the United States since its introduction 7 years ago, according to data from the Centers for Disease Control and Prevention in Atlanta.

"This far into our program, the effects have been very sustainable," said Dr. Cynthia Whitney of the Centers for Disease Control and Prevention, adding that overall disease rates dropped after vaccination and have remained stable since 2002.

Dr. Whitney presented data based on a surveillance population of 18.5 million people at the jointly held annual Interscience Conference on Antimicrobial Agents and Chemotherapy and the annual meeting of the Infectious Diseases Society of America.

From 1998 to 2007, she and her colleagues identified cases of laboratory-confirmed invasive pneumococcal disease (IPD) through eight U.S. sites that continuously participated in Active Bacterial Core surveillance, a nationwide program to track vaccination rates and collect isolates.

Children younger than age 5 years were the target age group for disease reduction with PCV7. The disease rates in this age group dropped from 100 cases per 100,000 at a baseline measurement in 1998 to about 25 cases per 100,000 in 2007. For disease caused by PCV7 serotypes (4, 6B, 9V, 14, 18C, 19F, 23F), the rate was less than a single case per 100,000 in 2007, she added.

The PCV7 rates have continued to drop, but the overall rates have flattened in the last few years. An increase in disease caused by non-PCV7 serotypes has contributed to the plateau effect, Dr. Whitney explained. In particular, the incidence of disease caused by serotype 19A has increased consistently since 2002.

Although vaccine-type disease decreased and 19A disease increased, these changes occurred mostly between 2002 and 2006, and the rates in 2006 and 2007 were similar. "It may be that now, 8 years into the vaccine program, we are finally reaching a steady state for some of these changes," Dr. Whitney observed.

The benefits of PCV7 extend to all ages, she emphasized. "Very few people older than 5 years have received the vaccine, so the herd effect has been important."

Data from 2007 show some disease in all age groups. But only 7% of 2007 cases were caused by PCV7 serotypes. By contrast, 20% were caused by 19A, and 58% were caused by serotypes that are included in the PCV13 vaccine (1, 3, 5, 6A, 7F, 19A). The PCV13 vaccine data are under review, and the vaccine may be licensed in the United States next year.

"Recommending the 7-valent vaccine to a small part of the population, kids younger than 2 years, has led to substantial community protection," said Dr. Whitney.

Ideally, the upcoming PCV13 vaccine will have an even greater impact on pneumococcal disease, she said.

Dr. Whitney said she had no conflicts of interest to disclose. ■