

ACIP: Give Meningococcal Booster Dose at 16

BY MIRIAM E. TUCKER

FROM A MEETING OF THE CDC'S ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ATLANTA – A booster dose of meningococcal conjugate vaccine should be given to adolescents at 16 years of age if they received a first dose at age 11-12 years, and a booster should be given 5 years after the first dose – up to age 21 years – to those who first received the vaccine at age 13-15 years.

That was the vote of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention on Oct. 27th, but it was not unanimous. The panel was split 6 to 5, with 3 abstentions. Following that vote, ACIP also voted to include the booster dose under the federal Vaccines for Children program. The CDC usually adopts the ACIP's recommendations but is not obligated to do so.

In 2007, ACIP recommended that the quadrivalent meningococcal conjugate vaccine (MCV4), sold under the brand names Menactra and Menveo, be given to 11- to 12-year-olds at the established preteen visit, and to 13- to 18-year-olds who had not been previously vaccinated.

At that time, it was assumed that this would protect teenagers through the peak age in disease seen in 16- to 21-year-olds, said Dr. Amanda Cohn of the CDC's National Center for Immunization and Respiratory Diseases (NCIRD).

However, recent data have suggested that immunity from the vaccine wanes within 5 years after vaccination, thereby possibly failing to protect those at highest risk,

particularly college students living in dorms. "We're missing protecting the group that the recommendation was intended to protect," Dr. Cohn commented.

A cost-effectiveness analysis presented at the ACIP meeting by Dr. Ismael Ortega-Sanchez, also with the NCIRD, showed that giving just one dose of MCV4 to all 11-year-olds was the least cost-effective of several options the ACIP considered, at \$281,000 per quality adjusted life year (QALY).

Giving one dose just to 15-year-olds would cost \$121,000/QALY, while giving doses to all 11-year-olds and 16-year-olds – the option chosen – comes to \$157,000/QALY.

For comparison, vaccinating all healthy 12- to 17-year-olds against influenza – already recommended by CDC – costs \$128,000/QALY, Dr. Ortega-Sanchez said.

Despite the emerging evidence that the current practice of giving MCV4 vaccine to 11- to 12-year-olds is not the ideal option, many panel members and audience members expressed concern about removing the recommendation to give the vaccine at that age since it is part of the now-established preadolescent vaccination visit "platform" that also includes human papillomavirus and diphtheria-tetanus-pertussis vaccinations. Moreover, it does protect those aged 11- to 13-year-olds against meningococcal disease.

While the evidence is now clear that the level of protective antibody against *Neisseria meningitidis* drops to

suboptimal levels 5 years after receipt of MCV4, the level of disease does not appear to have been affected yet.

Indeed, "We are currently at historic low rates of meningococcal disease," Dr. Cohn said, adding that the ACIP working group's aim was to make a change in order to prevent those rates from rising again.

However, the sizable minority of the panel who opposed the addition of the booster dose for 16-year-olds cited cost and lack of cost-effectiveness. Among them was ACIP member Dr. Lance Chilton. "I'm worried that we don't have data that would support cost-effectiveness of a 2-dose regimen. It's certainly better than the current 11- to 12-year only vaccination, but to me the cost-effectiveness data don't justify [the vote]," he said in an interview.

Dr. Chilton of the University of New Mexico, Albuquerque, said he would have preferred simply giving MCV4 at mid-adolescence. "I'm in favor of the preadolescent platform, but I don't think that changing the MCV4 to age 15-16 [years] would appreciably diminish that platform. Adding another platform is probably a good idea."

As CDC employees, Dr. Cohn and Dr. Ortega-Sanchez have no financial conflicts. Dr. Chilton stated at the beginning of the meeting that he also had no conflicts of interest.

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Tdap for Seniors Protects Infants

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for a rate of 16 cases per 100,000 population. Ten deaths have been reported among infants aged 2 months or younger.

The California state health department has recommended Tdap for all individuals aged 10 years and older who have not yet received it – particularly women of childbearing age (including those who are pregnant), others who have contact with young infants, and individuals older than 64 years of age – and also as a replacement for the old tetanus-diphtheria (Td) vaccine for wound management, even though the vaccine is not licensed for those aged 7-9 years or 64 years and older.

The state also said that Tdap should be given without regard to the interval since the previous Td dose, said Dr. Harriman, who is also a registered nurse.

Dr. Jennifer Liang of the CDC's National Center for Immunization and Respiratory Diseases (NCIRD) presented similar draft document language for the ACIP to vote on.

In 2005, the ACIP adolescent recommendation (for those aged 11-12 years) had said that an interval of at least 5 years between Td and Tdap was "encouraged" to reduce the risk for local and systemic reactions, particularly the limb swelling that – although usually benign – can be frightening for parents.

The new language, unanimously approved by ACIP (with one abstention), says that adolescents aged 11-18 years who have completed the recommended

five-dose childhood diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP)/diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) vaccination series and adults age 19-64 years should receive a single dose of Tdap in place of one Td dose. Adolescents should receive Tdap at a preventive care visit at 11-12 years of age, Dr. Liang said.

In addition, adolescents or adults who have not received a dose of Tdap – or for whom the status is unknown – should be immunized as soon as feasible, regardless of the interval since the last tetanus- or diphtheria-containing vaccine.

The second vote, to recommend Tdap for adults aged 65 years and older, was taken following presentations by Dr. Wayne Weston of GlaxoSmithKline and Dr. Michael Decker of Sanofi Pasteur, demonstrating immunogenicity and safety of Boostrix and Adacel, respectively, in adults aged 64 and older. GSK has filed an application with the Food and Drug Administration for an indication in that age group; Sanofi Pasteur is working on its application.

The recommendation says that adults aged 65 years and older who have or who anticipate having close contact with an infant aged younger than 12

months (such as a grandparent, child care provider, or health care provider) should receive a single dose of Tdap to protect against pertussis and to reduce the likelihood of transmission of pertussis to infants aged younger than 12 months (who are not yet fully immunized).

In addition, for adults aged 65 and older, a single dose of Tdap vaccine may be given in place of a Td vaccine in those who have not previously received Tdap.

Finally, the committee voted another off-label use of Tdap in children aged 7-10 years with incomplete or unknown pertussis vaccine history.

For those children, a single dose of Tdap is recommended to protect against pertussis. If further doses of tetanus- and diphtheria-containing vaccines are needed, then children aged 7-10 years should be vaccinated according to catch-up guidance.

Further guidance is forthcoming regarding revaccination.

Children aged 7-10 years who have never been vaccinated against tetanus, diphtheria, or pertussis or who have unknown vaccine status should receive a series of three vaccinations containing

tetanus and diphtheria toxoids. The preferred schedule is a single dose of Tdap, followed by a dose of Td more than 4 weeks after Tdap and another dose of Td 6-12 months later. If not given as the first dose, Tdap can be substituted for any of the other Td doses in the series.

Although the California pertussis outbreak has raised the urgency of these recommendations, the ACIP has actually been working on increasing pertussis immunization for at least 2 years, working group chair Dr. Mark H. Sawyer said in an interview.

"The main idea of all of this is to free up people's ability to receive vaccine in special circumstances, such as an outbreak. ... But this was already on our agenda. Pertussis has been a recognized problem for some time now. The California outbreak just illuminated its importance. But it's not unique to California. Other states are having significant problems with pertussis," said Dr. Sawyer, professor of pediatrics at the University of California, San Diego.

As a CDC employee, Dr. Liang has no financial conflicts. Dr. Harriman and Dr. Sawyer also stated that they had no financial conflicts.

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