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'Both pediatricians and family physicians may take a wait-and-see attitude,' said Dr. Jonathan Temte, the AAFP liaison to ACIP.

RotaTeq's Adoption By FPs Uncertain

BY MIRIAM E. TUCKER
Senior Writer

ATLANTA — Rotavirus immunization may be back.

At a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the committee voted to recommend that all infants receive Merck & Co.'s newly licensed oral rotavirus vaccine (RotaTeq) at 2, 4, and 6 months of age, and to provide coverage for it under the Vaccines for Children program.

The American Academy of Pediatrics' Committee on Infectious Diseases is likely to follow suit when it votes later this year, AAP coliaison Dr. Keith Powell said in an interview.

"I don't think this is an area where [AAP] will fall out with ACIP. It's an exciting new vaccine," said Dr. Powell, professor and chair of pediatrics at Northeastern Ohio University, Roots-town.

But American Academy of Family Physicians liaison, Dr. Jonathan Temte, noted that although he expects that AAFP will also support the ACIP recommendation, his "biggest concern is in terms of cost issues." And, he added, "Rotavirus vaccine carries with it the perception of intussusception. ... I think that both pediatricians and family physi-

cians may take a wait-and-see attitude."

RotaTeq, a pentavalent bovine-human-derived rotavirus vaccine, is the first to be licensed since Wyeth's rhesus-derived RotaShield was pulled from the market in 1999 when it was found to be associated with an increased risk for intussusception. At this writing, GlaxoSmith-Kline's two-dose, human-derived Rotarix is still awaiting U.S. market approval.

At the ACIP meeting, Dr. Penny M. Heaton of Merck summarized the efficacy and safety data
See RotaTeq page 8

INSIDE



Electromagnetic Minefields

Tell cardiac device wearers what to avoid—at all costs.

PAGE 14

Prevention Piles Up

Abdominal aortic aneurysm screening in high-risk patients is now a Medicare benefit.

PAGE 5



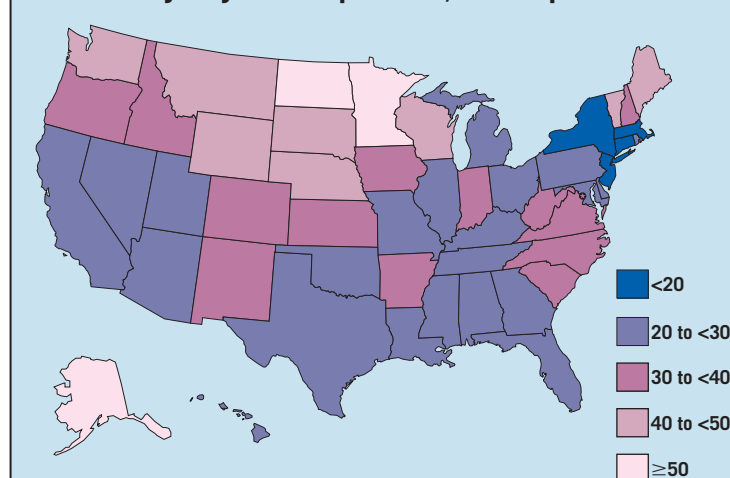
It's All Bad

Identifying the trigger of allergic contact dermatitis involves heavy-duty detection work.

PAGE 42

VITAL SIGNS

Family Physicians per 100,000 Population



Sources: 2004 data, American Medical Association, U.S. Census Bureau

RICHARD FRANK/ELSEVIER GLOBAL MEDICAL NEWS

ACIP: Immunize 2- to 5-Year-Olds Against the Flu

Outpatient, ED visits spurred the decision.

BY MIRIAM E. TUCKER
Senior Writer

ATLANTA — All children aged 2-5 years should be immunized annually against influenza, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended unanimously at its winter meeting.

The new recommendation, which is expected to be approved and published by the CDC prior to the next flu season, expands the age group to be targeted for routine influenza immunization beyond the current 6-23 months to include all children aged 6-59 months, as well as their household contacts. The committee

also voted to add coverage of influenza vaccine for 24- to 59-month-olds in the Vaccines for Children program.

The American Academy of Pediatrics' Committee on Infectious Disease is expected to endorse the recommendation later this year, Dr. Carol J. Baker, the AAP coliaison to ACIP, said in an interview.

Among the data leading to the ACIP vote were those presented by Dr. Katherine A. Poehling, of Vanderbilt University, Nashville, showing that during two recent influenza seasons, rates of outpatient and emergency room visits for children aged 2-5 years were nearly identical to those for children aged 6-23 months. Indeed,

See Flu page 26

Risks of Hormone Therapy Dwarfed Benefits in WHI

BY MITCHEL L. ZOLER
Philadelphia Bureau

BETHESDA, MD. — In retrospect, perhaps the most startling thing about the hormone therapy study of the Women's Health Initiative was how wrong most experts had been beforehand about the benefits of estrogen in postmenopausal women.

Before the study, some had questioned the ethics of running a hormone-therapy trial with a placebo arm. But now, almost 4 years after the early halt to the estrogen-plus-progestin arm of the Women's Health Initiative

(WHI), the final-outcomes balance sheet shows many risks and few benefits. The second, estrogen-only arm of WHI ran a little longer and compiled better results, with the risks of treatment roughly equaling its benefits. But the bottom line for both forms of hormone therapy is that they are now recommended only for select clinical situations.

Results from both the estrogen-plus-progestin and the estrogen-only arms showed no benefit from hormone therapy in women aged 50-79 for heart disease, the primary end point for
See Hormone Therapy page 50

Reimbursement Will Be a Barrier

RotaTeq from page 1

from their prelicensure trials. A total of 71,799 infants received either RotaTeq or placebo, with the first dose given at 6-12 weeks of age and the next two given at 4- to 10-week intervals. The vaccine prevented 95.8% of hospitalizations, 93.7% of emergency department visits, and 86% of office visits for rotavirus acute gastroenteritis.

In a smaller study of 1,358 infants who received RotaTeq or placebo concomitantly with other routine vaccines given to infants at 2, 4, and 6 months of age, there was no reduction in geometric mean antibody titers to diphtheria-tetanus vaccine, inactivated poliovirus vaccine, *Haemophilus influenzae* type b vaccine, or pneumococcal conjugate vaccine. There was evidence of a reduced response to one of the pertussis antigens (pertactin), but that problem was not seen upon additional testing, Dr. Heaton said.

In a safety analysis, intussusception occurred within 42 days of receiving a dose in 6 of 6,143 vaccine recipients and 5 of 5,579 placebo recipients, an insignificant difference. Between 42 days and 1 year, there were 7 more intussusceptions in the vaccine group and 10 in the placebo group, again insignificant. No intussusceptions occurred in the vaccine group after the study was completed, compared with four in the placebo group.

Vaccine recipients did experience slightly higher rates of diarrhea (10.4% vs. 9.1%) and vomiting (6.7% vs. 5.4%). Rates of fever and irritability did not differ between vaccine and placebo recipients, she reported.

Despite the reassuring safety results, Dr. Temte's prediction that some physicians may wait a bit before embracing the new vaccine was supported by the preliminary results of a survey of 286 pediatricians who responded out of a total 431 recruited from a random sample of AAP members. Dr. Allison Kempe, of the Colorado Health Outcomes Program at the University of Colorado, Denver, presented the findings to the committee.

The survey was sent by mail and e-mail during January and February 2006. (RotaTeq was licensed on Feb. 3.) Among the respondents, 65% reported that more than half their patients had private insurance; 78% of respondents participated in the Vaccines for Children program. Of the respondents, 100% were aware of the previous problems with RotaShield, even though 38% had never administered it, Dr. Kempe noted.

Although 82% "strongly agreed" that rotavirus infection is the most frequent cause of severe diarrheal disease in children younger than 2 years of age in the United States, just over half (51%) of the respondents strongly agreed that "there is a need for a safe and effective rotavirus vaccine" in the United States. When

asked what they would do if ACIP and AAP recommended the vaccine for routine use, 50% said they would "strongly recommend" it to their patients, whereas 34% said they would "recommend but not strongly."

Although 51% said they would begin administering the vaccine within 6 months of a recommendation, 28% said they'd wait 6 months to a year, whereas the rest either would wait longer or weren't sure what they would do. Reasons given for delaying longer than 6 months included "wait for insurers to cover" (90%), "wait to see if side effects present" (81%), "wait to see if vaccine supplies adequate" (65%), "wait to see if other providers using vaccine" (36%), and "wait to see if parents accepting of vaccine" (20%).

Issues deemed to be a barrier to giving rotavirus vaccine included "failure of some insurance companies to cover vaccination" (51%), "lack of adequate reimbursement for vaccination" (42%), and "parents' reluctance because of withdrawal of previous rotavirus vaccine" (27%), she reported.

Indeed, although no sign of increased rates of intussusception was seen in Merck's prelicensure trials, both the company and the

CDC will conduct extensive ongoing postmarketing surveillance to look for intussusception and other infrequent adverse events.

Penina Haber, of the CDC's Immunization Safety Office, described two of the surveillance methods by which RotaTeq's safety will be monitored once it's out on the market. One—the Vaccine Adverse Event Reporting System—is a national passive surveillance system that accepts adverse event reports from health care providers and the public. Reports to VAERS will be reviewed specifically for intussusception and other serious events associated with the rotavirus vaccine, and extensive follow-up of each will be conducted, she said.

The other surveillance system—the Vaccine Safety Datalink—is a collaboration between the CDC and eight U.S. HMOs comprising an annual birth cohort of more than 90,000 infants, also will be monitored by both the CDC and the Food and Drug Administration (FDA) for possible increased intussusception or other adverse events using a "rapid cycle analysis" method, which allows for "real time" assessment, she said.

Christopher Mast, Ph.D., of Merck, outlined the company's plans for postlicensure safety studies, which will include the original 71,799 subjects from the prelicensure studies, as well as an additional 44,000 vaccinated children who will be followed for 30 days after each dose and at alternate intervals for a secondary analysis. Merck's postlicensure efforts will complement the CDC/FDA efforts, he said. ■

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New Dietary Guides Focus on Cardiovascular Health in Kids

BY KATE JOHNSON
Montreal Bureau

New dietary recommendations from the American Heart Association and the American Academy of Pediatrics mark the organizations' first substantial revision of pediatric nutritional guidelines in 24 years, according to Dr. Samuel S. Gidding, chair of the group that drafted the report (Pediatrics 2006;117:544-59).

"This document is an evolution based on new research and new challenges," said Dr. Gidding, a pediatric cardiologist at Alfred I. duPont Hospital for Children in Wilmington, Del., and professor of pediatrics at Jefferson Medical College. "There are a number of things in this document that are unique and did not appear in our 1982 document or subsequent modifications."

The new guidelines, which focus on optimal nutrition for cardiovascular health, were revised in response to both the obesity epidemic and to a wealth of new research on pediatric nutrition that have emerged since 1982, Dr. Gidding said in an interview.

Significant changes in the current document include the focus on optimal nutrition even before birth.

"Every cardiovascular document before this has begun at age 2 years, but in this one we go all the way back to the maternal-fetal unit since there's emerging research that the prenatal environment has an influence on the development of risk factors." He said this emphasis is particularly appropriate given the new document's increased focus on primordial prevention—the avoidance of the development of cardiovascular risk factors.

New also is the document's focus on the discrepancy between what children are currently eating and acceptable pediatric nutrition. In one-third of children, by age 2 years, the most commonly consumed vegetable is french fries, and fruit is completely absent from the diet, the guidelines noted.

The recommendations come with tables and tips for physicians and parents aimed at reversing such trends, including the suggestion that "new healthy foods might need to be introduced repeatedly, as many as 10 times, to establish taste preferences."

The topic of eating behaviors also is new in the document, which touches on the concept of influencing children's healthy versus unhealthy food choices. Parents are encouraged to lead by example and not to use foods as punishments or rewards. "Two natural parental impulses, pressuring children to eat and restricting access to specific foods, are not recommended because they often lead to overeating, dislikes, and paradoxical interest in forbidden items."

And another departure from the older guidelines is that recommendations for caloric intake are based on a sedentary rather than active lifestyle, with the caveat that more active children will require additional calories.

"The message portrayed ... is clear: To be sedentary, have a nutritionally adequate diet, and to avoid excessive caloric intake in contemporary society is difficult," the authors wrote. Exercise is recommended to help balance the energy intake/expenditure equation.

"A key philosophic underpinning of the document is the concept of discretionary calories," Dr. Gidding explained. "These are calories that you need as fuel, independent of your nutritional needs. If you are sedentary, that's very few. A typical teenager who has an excess consumption of nutrient-poor foods and is sedentary ends up compromising himself on both ends—both with inadequate nutrition and excess caloric intake."

The stronger focus on food quality—both its caloric and nutritional content—is a response to society's current concept of "kid food," which tends to be high in fat and sugar and low in fiber and nutrients. "This revision strongly conveys the message that food and beverages that fulfill nutritional requirements are appropriate for growing and developing infants, children, and adolescents. Calorie-dense foods and beverages with minimal nutritional content must return to their role as occasional discretionary items in an otherwise balanced diet," the authors wrote.

Another new aspect of the revised guidelines is the public health component, in recognition of the fact that food consumption and preparation have moved largely out of the home. According to the document, "Sources of nourishment include schools, child care and after-school youth programs, restaurants, vending machines, convenience stores, work sites, and foods prepared by industry designed for minimal preparation time in the household."

The document is intended to provide tools for physicians to use in clinical practice and to guide public health initiatives, Dr. Gidding said. "Physicians remain the most authoritative source of health information in the community. Therefore, it's our responsibility to provide this information. We can't always make people listen, but we have to keep trying to provide the message so that it gets across."

Because being overweight has become "normal" in the current environment, health efforts may at times seem futile, Dr. Gidding said. However, long-term results are possible.

"People who think the current situation is unredeemable should remember that tobacco use rates are currently half what they were in 1960 and cholesterol levels have fallen significantly in adults, with an accompanying dramatic decline in heart disease. In the 1950s when you went on an airplane, you got cigarettes with your dinner. We've got to change what people think are normal behaviors today and make healthy eating seem normal," Dr. Gidding said. ■

The recommendations can be viewed online at www.pediatrics.org/cgi/content/full/117/2/544.