

# Most Should Get Birth Dose Against Hepatitis B

*ACIP recommendation says waiting to vaccinate infants weighing more than 2 kg should be 'rare.'*

BY MIRIAM E. TUCKER  
Senior Writer

ATLANTA — The birth dose of hepatitis B vaccine is now the standard of care, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention voted at its meeting.

Although giving newborns their first dose of hepatitis B vaccine prior to discharge has already been deemed the "preferred" practice by the CDC, the American Academy of Family Physicians, and the American Academy of Pediatrics, the groups have allowed providers the alternative of administering during the first 2 months of age if the mother is hepatitis B surface antigen (HBsAg) negative.

Now ACIP has updated its recommendation—pending approval by the CDC—to say that withholding of the birth dose in a medically stable infant weighing 2,000 g or more at birth should be "rare" and must be documented in the infant's medical chart, along with the laboratory report confirming the mother's antigen-negative status. Both AAFP and AAP will consider endorsing the new policy, their ACIP liaisons told FAMILY PRACTICE NEWS.

"Core to the ACIP recommendations is having standing orders, which the [AAP's Committee on Infectious Diseases] supports as long as there is some physician discretion," said Margaret Rennels, M.D., AAP's co-liaison to ACIP.

Eric E. Mast, M.D., chief of the prevention branch in the CDC's Division of Viral Hepatitis, said that implementation of the infant immunization series beginning in 1991 has resulted in a 93% reduction in hepatitis B incidence in persons younger than 20 years. "We've been very successful in preventing infections in children and adolescents, but there are still gaps in the perinatal hepatitis B-prevention program," he said.

In particular, only about 50% of expected infants born to HBsAg-positive mothers are identified for case management, which has been shown to increase successful completion of postexposure immunization. In addition, there have been numerous documented incidences of failure to test women with unknown HBsAg status at the time of delivery and failure to administer appropriate immunoprophylaxis to infants.

Giving the first dose of hepatitis B vac-

cine soon after birth to all infants weighing 2,000 g or more should minimize the risk for infection because of errors in maternal HBsAg testing or reporting or from exposure to persons with chronic HBV infection in the household and can increase the likelihood of completing the vaccine series, he explained.

Still, some panel members expressed discomfort with the idea of removing a degree of provider autonomy, while others wanted to remove the "opt out" clause altogether. In the end, the committee opted for the compromise language to require documentation for "rare" deferrals.

"This sets a high bar of things to consider. The chart record is critical. ... It emphasizes that the birth dose is the standard of care," said panel member Guthrie S. Birkhead, M.D., director of the Center for Community Health, New York State Department of Health, Albany.

Fellow ACIP member Janet R. Gilsdorf, director of pediatric infectious diseases at the University of Michigan, Ann Arbor, agreed. "What I want is for every child in America to get that birth dose."

Also included in the recommendation is a call for delivery hospitals to implement standing orders for review of maternal HBsAg test results for all pregnant women at the time of delivery and for women to be tested if the result was not document-

ed. Immunoprophylaxis should be administered to all infants born to women who are HbsAg positive and to those with unknown status, and both the maternal test results and the infant hepatitis B vaccination status should be documented in the infant's medical record.

Standing orders should also address the management of infants weighing less than 2,000 g at birth, including ensuring initiation of postexposure immunization of infants born to HBsAg-positive mothers and to mothers who were not screened, and documenting the maternal HBsAg test results on the infant's medical record.

In other votes pertaining to hepatitis B vaccination, ACIP said providers should review immunization records for all children aged 11-12 years and those born in hepatitis B-endemic countries, including all of Asia, the Pacific Islands, and Africa. Hepatitis B vaccine should be offered to all such individuals not previously vaccinated.

Foreign-born HBsAg-positive persons are expected to be an increasing source of transmission—in 2001-2002, 42% of verified hepatitis B cases among children born after 1991 were born outside the United States (MMWR 2004;53:1015-8). The number of people coming into the United States with HBV infection is 10 times greater than the number currently becoming infected here, Dr. Mast noted. ■

## Educate Parents to Back Watchful Waiting for Ear Infections

BY CHRISTINE KILGORE  
Contributing Writer

Watchful waiting for nonsevere acute otitis media can be as acceptable to parents as immediate antibiotic treatment—if parents are properly educated about the options, new study findings and survey results indicate.

Parents' satisfaction with their children's care was no different among parents whose children were randomized to receive either immediate antibiotic treatment or watchful waiting in an outcomes study of the two approaches. The parents all were educated at the study site—a pediatric clinic in Galveston, Texas—about the risks and benefits of treatment.

In a separate study, only a minority of parents who were randomly surveyed by mail about a hypothetical visit for an ear infection—without being given much information—said they would feel comfortable with a watchful waiting approach. Most said they would feel neutral or dissatisfied with such an approach.

The studies show that "when it's properly explained, parents are equally satisfied with watchful waiting and antibiotic treatment [for nonsevere acute otitis media]," said Allan S. Lieberthal, M.D., who led development of the American Academy of Pediatrics' guidelines on the diagnosis and management of acute otitis media.

"Now we need tools for educating parents within the confines of a busy pediatric office," he said in an interview.

Investigators in the randomized study used a handheld flip chart for a 5- to 10-

minute review with parents of the definition and causes of ear infections, characteristics of nonsevere and severe acute otitis media (AOM), antibiotic resistance and costs, rate of symptom response to antibiotics, and possible adverse outcomes associated with immediate treatment versus observation.

Parent satisfaction was no different between a group of 111 children randomized to a watchful waiting group and 112 randomized to receive immediate antibiotics, either at day 12 or day 30 after the children were seen, reported David P. McCormick, M.D., of the University of Texas, Galveston, and his colleagues (Pediatrics 2005;115:1455-65).

In the survey, 5,129 parents in 16 Massachusetts communities were asked to rate their level of satisfaction "if your child's doctor diagnosed an ear infection and recommended waiting 1 or 2 days before starting antibiotics (to see if the symptoms get better on their own)."

Of 2,054 parents who returned the survey, 34% said they would be somewhat or extremely satisfied. Another 26% indicated they would be neutral, and the remaining 40% said they would be somewhat or extremely dissatisfied, reported Jonathan A. Finkelstein, M.D., of Harvard Medical School, Boston, and his associates (Pediatrics 2005;115:1466-73).

Both studies were conducted before the

AAP guidelines were published last year.

In addition to offering new insight into issues of parent acceptance, findings from the randomized study affirm what the guidelines say: that some children with nonsevere AOM may be observed with watchful waiting as long as they maintain nonsevere status and are kept comfortable with appropriate symptom management, Dr. Lieberthal said.

Of the children randomized to the watchful waiting group, 66% completed the study without antibiotics.

Immediate antibiotic treatment was associated with 16% fewer treatment failures—a difference that the investigators said was larger than they "expected from [their] review of the literature"—and improved symptom control.

Antibiotic treatment also was associated, however, with increased antibiotic-related adverse events. And although immediate treatment resulted in eradication of *Streptococcus pneumoniae* carriage in the majority of children, the *S. pneumoniae* strains cultured from children in the antibiotic group at day 12 were more likely to be multidrug-resistant than were strains from the watchful waiting group, the investigators reported.

"Watchful waiting seems to be an alternative that is acceptable to parents, reduces the number and cost of antibiotic

prescriptions, and reduces the percent of multidrug-resistant bacteria colonizing the nasopharynx of children after an episode of AOM," Dr. McCormick and his associates said.

Regardless of the intervention, children who had received antibiotics within the previous 30 days were more than twice as likely to fail treatment as those who had not recently received antibiotics.

In addition to parent education, key factors for implementation of a watchful waiting strategy include access to follow-up care, management of AOM symptoms, and a method to classify AOM severity, the investigators said.

They assessed AOM severity based on four factors: parental perception of severity, otoscopic examination, body temperature, and tympanogram scores.

However, "in retrospect," they reported, they "could have obtained the same results"—identifying 87% of the nonsevere cases identified with the four-factor scoring system—by using a two-factor scoring system that omitted body temperature and tympanogram.

"Most children with AOM are afebrile at the time of diagnosis as a result of antipyretic medication," they said. "Practicing clinicians rarely use the tympanogram to make a diagnosis of AOM."

Dr. Lieberthal, cochair of the AAP's subcommittee on management of AOM and professor of pediatrics at the University of Southern California, Los Angeles, said the issue of how to accurately and uniformly assess AOM severity is still unresolved. "We still need a validated scoring system." ■

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