# Hepatitis B Vaccine Booster May Be Needed

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BALTIMORE — Immunity to hepatitis B might wane 15 years after vaccination among those who received the vaccine series beginning at birth, Dr. Stephanie R. Bialek said at a conference on vaccine research. The conference was sponsored by the National Foundation for Infectious Diseases.

Data from long-term follow-up studies have established that people who received the three-dose hepatitis B vaccine series beginning after 6 months of age have long-term protection against chronic hepatitis B infection and do not need booster shots.

In that population, breakthrough infections occur in only 0%-7% of individuals more than 20 years after vaccination, and most of those are asymptomatic. Chronic hepatitis B infection is extremely rare, occurring in fewer than 1%, said Dr. Bialek, a medical officer in the division of viral hepatitis at the Centers for Disease Control and Prevention.

However, it is not known whether the same is true for those who begin the vaccine series at birth, a practice that was first recommended in the United States in 1992. Thus far, 10-year data in that population suggest that breakthrough infections are rare, occurring in 0%-6%, and there have been no reports of chronic infections among vaccine responders.

On the other hand, protective concentrations of antibody to hepatitis B surface antigen (anti-HBs), defined as levels greater than 10 mIU/mL, are present in fewer than 20% at 10 years, compared with more than 50% at 7-22 years among those vaccinated beginning after 6 months of age, Dr. Bialek noted.

Now, new data from a study conducted in Micronesia suggest that protection in those vaccinated as newborns may begin to subside at around 15 years. The Federated States of Micronesia, a U.S.-affiliated jurisdiction in the western Pacific where hepatitis B virus infection had historically been endemic, implemented hepatitis B vaccination beginning at birth in 1989.

Micronesian adolescents who had received three doses of recombinant hepatitis B vaccine (at birth, at the age of 2 months, and at age 6 months) and who had tested negative for antibody to hepatitis B core antigen (anti-HBc) 2 years after the primary vaccination were followed for 15 years after the primary vaccination. Recombivax had been given in doses of 5 mcg at birth, followed by doses of 2.5 mcg at 2 and 6 months. Today, 5 mcg is recommended for all three doses, she noted.

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In 2006, investigators were able to track down 105 of the 238 children who had received three doses of hepatitis B vaccine, were anti-HBc negative, and had been tested for anti-HBs at 35 months. By then, they had a median age of 15.8 years, with a median of 15.1 years since completion of the vaccine series. A total of eight (7.6%) were anti-HBc positive, but none was HBsAg positive.

Booster doses of vaccine were given to the 96 who were anti-HBc negative in 2006. Of these, only 7 (7%) had anti-HBs concentrations greater than 10 mIU/mL at the time they were given the booster, and only about half (45, or 47%) had anamnestic anti-HBs responses at 14 days after the booster (defined as an increase in anti-HBs concentration greater than 10 mIU/mL). Absence of an anamnestic response might indicate waning immunity, Dr. Bialek said.

Limitations of this study include the fact that maternal HBsAg status was not known, postvaccination testing had not been performed (some of the participants may have been nonresponders), and the vaccine dose used for the second and third doses was half of the currently recommended dose.

And importantly, "Just because they didn't boost doesn't mean they're not protected," Dr. Bialek said in an interview following her presentation. At least two ongoing studies are investigating this issue further, she added. ■