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Adverse events associated with hepatitis B vaccine in U.S. children less than six years of age, 1993 and 1994

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Abstract

Purpose: This study evaluated infrequent adverse reactions to hepatitis B vaccine by investigating the association of this vaccine with adverse health outcomes for U.S. children less than six years of age. The evaluation of the association between hepatitis B vaccine and chronic arthritis provides needed data, relevant to the Institute of Medicine's Report that there are inadequate data available to assess the causal relationship of hepatitis B vaccine to arthritis risk.

Methods: The 1993 (n = 5505 children) and 1994 (n = 6515 children) National Health Interview Survey (NHIS) datasets were analyzed to provide post-marketing surveillance data from probability samples of the U.S. population. Incident cases of adverse events were determined from the temporal association between the hepatitis B vaccination and the adverse events. Logistic regression modeling was used to adjust for potential confounding.

Results: Controlling for age, race, and gender simultaneously in the 1994 NHIS, hepatitis B vaccine was found to be associated with prevalent arthritis [odds ratio (OR) = 5.91, 95% confidence interval (CI) = 1.05-33.14], incident acute ear infections (OR = 1.60, 95% CI = 1.00-2.58), and incident pharyngitis/nasopharyngitis (OR = 1.41, 95% CI = 0.95-2.09).

Conclusions: Evidence from this study suggests that hepatitis B vaccine is positively associated with adverse health outcomes in the general population of US children.

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