

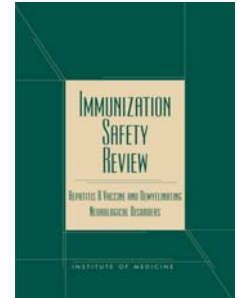
In Summary...

from the INSTITUTE OF MEDICINE

Shaping the Future for Health

Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders

At the request of the Centers for Disease Control and Prevention and the National Institutes of Health, the Institute of Medicine (IOM), an arm of the National Academies, evaluated whether or not the hepatitis B vaccine can cause neurological disorders. In *Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders*, the IOM committee carefully examines this hypothesized link and addresses other vaccine-safety issues.



Immunization advisory bodies recommend that all infants, adolescents, and high-risk adults receive the hepatitis B vaccine for protection from serious liver disease, including cirrhosis and hepatocellular carcinoma. These recommendations have been viewed skeptically by some because of concerns about the safety of the vaccine and because of a perception that hepatitis B infection is not a serious risk to the general population. The Immunization Safety Review Committee reviewed the evidence regarding the hypothesis that the hepatitis B vaccine causes demyelinating neurological disorders, such as multiple sclerosis and Guillain-Barré syndrome.

There is a theoretical basis for the hypothesis that vaccines, including the hepatitis B vaccine, could cause demyelinating disorders. A review of the scant and indirect evidence that relevant biological mechanisms could operate in humans in response to the hepatitis B vaccine to produce disease provides weak support for this theory. However, the committee found that the epidemiological evidence (i.e. from studies of vaccine-exposed populations and their control groups or of patients with these diseases and their control groups) favors rejection of a causal relationship between the hepatitis B vaccine in adults and multiple sclerosis. The evidence was inadequate to accept or reject a causal relationship between the hepatitis B vaccine and all other demyelinating conditions.

Demyelinating disorders are often quite devastating, as are the sequelae of chronic hepatitis B infection. The committee found evidence that some parents and health care workers are skeptical about the vaccine due more to a perception that the vaccine is unnecessary, rather than due to a large concern about the safety of the vaccine. The committee is aware, however, that there are some people who very much object to the vaccine on the basis of the perception that not all infants and children are at risk for hepatitis B infection and on the basis of concerns about the safety. Because of the lack of epidemiological data on conditions other than MS in adults, the committee recommends further attention in the form of research and communication. However, the committee does not recommend that national and federal vaccine advisory bodies review the hepatitis B vaccine on the basis of concerns about demyelinating disorders.

Where can I get more information on this issue?

You should discuss with your doctor any concerns or questions you have regarding your child's vaccinations. You can learn more about the Immunization Safety Review Committee and read the full report titled *Immunization Safety Review: Hepatitis B and Demyelinating Neurological Disorders* at www.iom.edu/imsafety. From this website, you may also download copies of this abstract. To contact the project staff, please email (imsafety@nas.edu) or phone us (202/334-1342).

Any adverse effects experienced by your child after a vaccination should be reported to your doctor. Additional reporting information can be found through:

Vaccine Adverse Event Reporting System

1-800-922-7967

www.vaers.org/vaers.htm

National Vaccine Injury Compensation Program

1-800-338-2382

www.hrsa.gov/osp/vicp/qanda.htm

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Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders is available for sale from the National Academy Press, 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP's on-line bookstore at www.nap.edu.

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