

Hepatitis B Vaccine Safety: Table of Evidence

Citation	Purpose	Method	Outcomes
Eriksen, E. M., Perlman, J. A., Miller, A., Marcy, S. M., Lee, H., Vadheim, C., ... & Black, S. (2004). Lack of association between hepatitis B birth immunization and neonatal death: a population-based study from the Vaccine Safety Datalink Project. <i>The Pediatric Infectious Disease Journal</i> , 23(7), 656-662.	To evaluate the potential association between neonatal death and newborn immunization with hepatitis B vaccine. More than 350,000 live births from 1993 to 1998.	Ascertained all deaths under 29 days of age. The proportions of deaths among vaccinated and unvaccinated newborns and reviewed causes and circumstances of their deaths were compared	No significant difference was found in the proportion of HBV-vaccinated (31%) and unvaccinated (35%) neonates dying of unexpected causes.
Lewis, E., Shinefield, H. R., Woodruff, B. A., Black, S. B., Destefano, F., Chen, R. T., & Ensor, R. (2001). Safety of neonatal hepatitis B vaccine administration. <i>The Pediatric Infectious Disease Journal</i> , 20(11), 1049-1054.	To determine whether hepatitis B vaccination of newborns increases the incidence of fever and/or suspected sepsis.	3,302 infants were vaccinated within 21 days of birth with hepatitis B vaccine; 2,353 were not. Data were collected from clinical information systems, and lab data for blood and CSF cultures were obtained.	There were no significant differences between vaccinated and unvaccinated newborns in the proportion of infants who received care for fever, allergic reactions, seizures or other neurologic events in the first 21 days of life. No increase in medical procedures were attributed to receipt of hepatitis B vaccine
Woo, E. J., Miller, N. B., Ball, R., & VAERS Working Group. (2006). Adverse events after hepatitis AB combination vaccine. <i>Vaccine</i> , 24(14), 2685-2691.	From May 2001 to September 2003, the Vaccine Adverse Event Reporting System (VAERS) received 305 reports of adverse events after HEPAB.	Evaluated medical records to seek correlation or causation between vaccines and adverse events.	Detailed medical review did not suggest a clear pattern of evidence supporting a causal relationship with the vaccine, except for injection site reactions and some allergic reactions
DeStefano F, Verstraeten T, Jackson LA, et al. Vaccinations and Risk of Central Nervous System Demyelinating Diseases in Adults. <i>Arch Neurol</i> . 2003;60(4):504-509.	To evaluate the association between vaccination and onset of multiple sclerosis or optic neuritis.	440 case subjects and 950 control subjects matched in HMO, sex, and date of birth.	Vaccination against hepatitis B, influenza, tetanus, measles, or rubella is not associated with an increased risk of multiple sclerosis or optic neuritis.

This educational handout was created by the Vaccine Task Force of the EMES Initiative.

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pg. 1

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doi:10.1001/archneur.60.4.504			
Niu MT, Salive ME, Ellenberg SS. Neonatal deaths after hepatitis B vaccine: the vaccine adverse event reporting system, 1991-1998. <i>Arch Pediatr Adolesc Med.</i> 1999 Dec;153(12):1279-82	To evaluate reports of neonatal deaths (aged 0-28 days) after hepatitis B immunization reported to VAERS.	All US neonates whose deaths after Hep B vaccination given alone were reported to VAERS from 1991- 1998.	Data suggest that Hep B immunization is not causing a clear increase in neonatal deaths.
Mikaeloff Y, Caridade G, Rossier M, Suissa S, Tardieu M. Hepatitis B vaccination and the risk of childhood-onset multiple sclerosis. <i>Arch Pediatr Adolesc Med.</i> 2007 Dec;161(12):1176-82.	To investigate whether vaccination against hep B increases the risk of multiple sclerosis in childhood.	143 case patients with MS were matched to 1,122 controls	Vaccination against Hep B does not seem to increase the risk of a first episode of MS in childhood.
Sestili C, Grazina I, La Torre G. HBV vaccine and risk of developing multiple sclerosis: a systematic review and meta-analysis. <i>Human Vaccines & Immunotherapeutics.</i> 2018 Sep 27 DOI: 10.1080/21645515.2018.1528835	To perform a systematic review of the relationship between Hep B vaccination and multiple sclerosis.	Research was conducted on Pubmed, ISI Web of Science, and Scopus. Meta-analysis and metaregression were performed. 7 articles were selected.	Results showed that Hep B vaccination is not associated with an increased risk of developing MS.
Yu O, Bohlke K, Hanson CA, Delaney K, et al. Hepatitis B vaccine and risk of autoimmune thyroid disease: a Vaccine Safety Datalink study. <i>Pharmacoepidemiol Drug Saf.</i> 2007 Jul;16(7):736-45	To test the hypothesis that hep B vaccine increases the risk of autoimmune thyroid disease	Vaccine Safety Datalink study with 355 Graves' disease cases, 418 Hashimoto's thyroiditis cases, and 1102 controls, from administrative data recorded by three health maintenance organizations (HMOs) and verified cases by medical record review.	No increased risk of Graves' disease or Hashimoto's thyroiditis, following receipt of hepatitis B vaccine was observed

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