Ambulatory Care

Hepatitis B Vaccination Safety

Mark R Geier and David A Geier

BACKGROUND: Recent studies have suggested that adult hepatitis B vaccination may be associated with adverse reactions.

OBJECTIVE: To further examine the relative risk, percentage association, and statistical significance of arthritic, immunologic, and gastrointestinal adverse reactions reported after adult hepatitis B vaccination compared with control vaccines.

DESIGN: The Vaccine Adverse Events Reporting System (VAERS) database was analyzed for the incidence of adverse reactions after adult hepatitis B immunization compared with the incidence of adverse reactions reported to VAERS about vaccine control groups.

SETTING: The medical and scientific communities have generally accepted that hepatitis B vaccine, a highly purified, genetically engineered single-antigen vaccine, is a safe vaccine.

METHODS: The VAERS database was analyzed from 1997 to 2000 for adverse reactions associated with adult hepatitis B vaccination and from 1991 to 2000 for adverse reactions reported about vaccine control groups.

RESULTS: The results showed a statistically significant increase in the incidence of adverse reactions reported after adult hepatitis B vaccination when compared with the incidence of adverse reactions reported to VAERS about control vaccines.

CONCLUSIONS: Patients and physicians need to be fully informed of the potential adverse reactions associated with hepatitis B vaccination so that together they can make an informed consent decision about the risk versus the benefit. Patients who may have had an associated adverse reaction to hepatitis B vaccine should be made aware that they may be eligible for compensation from the no-fault Vaccine Compensation Act, administered by the US Court of Claims.

KEY WORDS: adverse reaction, hepatitis B vaccine, VAERS.

Ann Pharmacother 2002;36:370-4.

Previous studies have reported that there may be an association between hepatitis B vaccination and adverse reactions.[1-6] Arthritic, immunologic, and gastrointestinal adverse reactions after hepatitis B vaccination were examined. The general consensus of these studies was that the adult female population, within fairly close temporal association of hepatitis B vaccination, was at increased risk for developing associated adverse reactions. The scientific literature does contain other reports of hepatitis B vaccine being associated with arthritic, immunologic, and gastrointestinal adverse reactions.[7-12] These studies primarily focus on a case report or a series of case reports of adverse reactions attributed to hepatitis B vaccination. Currently, studies by Schoenfeld and Aron-Maor[13] and Grotto et al.[14] have attempted to review hepatitis B vaccination and associated adverse events. These 2 studies indicated that hepatitis B vaccine is associated with a number of different types of adverse reactions, but both studies, because of their relatively small size, were unable to make any causal links between hepatitis B vaccination and adverse reactions. The purpose of the present study is to further examine the relative risk, percentage association, and statistical significance of arthritic, immunologic, and gastrointestinal adverse reactions after adult hepatitis B vaccination compared with vaccine control groups in the US.

Author information provided at the end of the text.

Methods

To further examine the association between adult hepatitis B vaccination and arthritic, immunologic, and gastrointestinal adverse reactions, we made a retrospective examination of the information reported to the

Vaccine Adverse Events Reporting System (VAERS) database from 1997 to 2000 using Microsoft Access. VAERS is a passive epidemiologic database that has been maintained by the Centers for Disease Control and Prevention (CDC) in Atlanta, GA, since 1990. All vaccine-associated adverse reactions are to be reported to this database, as mandated by US law. A study by the CDC has helped to validate the VAERS database.[15] Our recent studies have shown an association between hepatitis B vaccination and arthritic, immunologic, and gastroenterologic symptoms based on our analysis of the VAERS database.[1-6] We have also reported on the incidence of adverse reactions in the state of Texas, arthritic symptoms after rubella vaccination, and joint-related adverse reaction after anthrax vaccination in light of biological warfare scenarios based on analysis of the VAERS database.[16-18]

The arthritic, immunologic, and gastrointestinal adverse reactions reported to the VAERS database examined in this study were as follows: arthritis, arthrosis, arthralgia, myelitis, vasculitis, Guillain–Barré syndrome, thrombocytopenia, liver function test abnormalities, erythema, and hepatitis. We also examined the number of reaction reports, emergency department (ED) visits, life-threatening reactions, hospitalizations, disabilities, and deaths reported to the VAERS database after vaccination. These categories for adverse reactions were based on descriptions of adverse reactions by those reporting them and by defined reporting fields contained on the VAERS database.

The incidence rates calculated in this study were based on the estimates of the CDC for the number of doses administered during the period examined. The CDC estimates indicated that 16 204 207 adult hepatitis B vaccinations were administered during this study period. Additionally, as controls, tetanus toxoid vaccine and tetanus–diphtheria (Td) vaccine–associated adverse reactions reported to VAERS from 1991 to 2000 in adults were analyzed, so as to maximize the background reporting rates of adverse reactions reported to the VAERS database. The CDC estimates indicated that 22 774 922 tetanus toxoid vaccinations and 129 293 354 Td vaccinations were administered to adults from 1991 to 2000. The incidence rates of adult-associated adverse reactions in the tetanus toxoid vaccine and Td vaccine recipients provided a background rate to compare against the incidence rates of associated adverse reactions in adult hepatitis B vaccine recipients. The use of χ^2 statistical analysis determined whether the elevated incidence rates of associated adverse reactions in adult hepatitis B vaccine recipients were statistically significant compared with our vaccine control groups. We accepted a p value of 0.05 as statistically significant. The use of vaccine control groups to determine whether there is a statistically associated relationship between a vaccine and specific type of reactions has been validated by several of our recent publications.[4-6,16-18]

Results

Table 1 summarizes the incidence rate per 10 million vaccinations of reaction reports, ED visits, life-threatening reactions, hospitalizations, disabilities, and deaths reported to the VAERS database after tetanus toxoid, Td, and adult hepatitis B vaccination among those residing in the US. Table 2 summarizes the adverse reactions reported to the VAERS database after adult hepatitis B vaccination among those residing in the US. Table 3 compares the reactivity of tetanus toxoid vaccine and adult hepatitis B vaccine administration among those residing in the US. Table 4 compares the relative reactivity of Td vaccine and adult hepatitis B vaccine administration among those residing in the US.

Our analysis, in Table 1, shows a statistically significant increase in the incidence of total reaction reports, ED visits, hospitalizations, and disabilities ($p = 0.01$) and life-threatening reactions ($p = 0.05$) reported after adult hepatitis B vaccination compared with our tetanus vaccine control group. Our analysis also showed a statistically significant increase in the incidence of total reaction reports, ED visits, life-threatening reactions, hospitalizations, and disabilities ($p = 0.01$) reported after adult hepatitis B vaccination compared with our Td vaccine control group. In comparing the incidence of adverse reactions after adult hepatitis B vaccination with our tetanus vaccine control group, in Table 3, we found a statistically significant increase in the incidence of arthralgia, arthrosis, myelitis, vasculitis, hepatitis, erythema and liver function test abnormalities ($p = 0.01$), and arthritis and thrombocytopenia ($p = 0.05$). We also found a statistically significant increase in the incidence of arthralgia, arthrosis, arthritis, thrombocytopenia, hepatitis, erythema and liver function test abnormalities ($p = 0.01$), and myelitis and vasculitis ($p = 0.05$), when comparing the incidence of adverse reactions after adult hepatitis B vaccination compared with our Td vaccine control group in Table 4. We found that an increased risk of death and Guillain–Barré syndrome also occurred after adult hepatitis B vaccination compared with our tetanus toxoid and Td vaccine control groups; however, this did not achieve statistical significance. The relative risk of adverse reactions after adult hepatitis B vaccination remained ≥2 (a ≥67% association with adult hepatitis B vaccination) compared with our vaccine control groups for every adverse reaction we examined in this study.

Discussion

The prediction, both from the vaccine design and early clinical trials on hepatitis B vaccines, that this type of vaccine would be well tolerated and result in few adverse re-

Table 1. Adverse Reactions Reported After Vaccination[a]

	Incidence per 10 Million Vaccines					
Type of Vaccine	Reaction Reports	ED Visits	Life-Threatening Reactions	Hospitalizations	Disabilities	Deaths
Tetanus	343	149	7.9	15	11	1.3
Td vaccine	565	239	4.9	21	3.2	0.7
Hepatitis B (adult)	1159	498	25	59	38	2.5

ED = emergency department; Td = tetanus–diphtheria.
[a]Hepatitis B vaccine has statistically significantly more total reactions, ED visits, hospitalizations, and disabilities ($p = 0.01$) than our tetanus toxoid and Td vaccine controls. Hepatitis B vaccine has statistically significantly more life-threatening reactions than our tetanus toxoid vaccine control group ($p = 0.05$) and more life-threatening reactions than our Td vaccine control group ($p = 0.01$).

actions is not borne out by our analysis of the VAERS database. Rather, our analysis indicated that hepatitis B vaccine was associated with large numbers of potentially serious adverse reactions. Our analysis showed that the 35-year-old female population was at increased risk for developing an associated adverse reaction between 3 and 11 days after hepatitis B vaccination. The data further showed that autoimmunity may be involved in associated adverse reactions after hepatitis B vaccination because the majority of patients having adverse reactions after hepatitis B vaccine were female (approximate female:male ratio = 3:1). The basis for autoimmunity in the development of adverse reactions after vaccination has been described in a recent publication by Shoenfeld and Aron-Maor.[13] The rate of developing an adverse reaction, based on our numbers in adults, was approximately 211/10 million doses of hepatitis B vaccine. However, because adverse reactions after hepatitis B vaccine were unexpected, adverse reactions reported to the VAERS database were undoubtedly underreported.

In examining the adverse reactions after hepatitis B vaccination, it is important to understand both how the current vaccine available in the US is manufactured and what the effect of hepatitis B infection is on the general population. The currently used genetically engineered vaccines, developed and licensed during the 1980s, are most commonly produced by inserting the gene for the hepatitis B surface antigen (HbsAg) into the yeast *Saccharomyces cerevisiae*.[19,20] After the yeast grows, vaccine is produced by lysing the yeast to free HbsAg particles, which are separated from yeast components by biochemical and biophysical processes. Vaccine particles are 20–21 nm in size. In the US, there are 2 available recombinant vaccines produced in yeast (SmithKline Beecham, Energix-B; Merck, Recombivax).[19-21] Both current manufacturers of hepatitis B vaccine in the US state that their hepatitis B vaccines are "generally well tolerated." However, both companies, in their package inserts, go on to warn that as with any vaccine, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions. The medical and scientific communities have generally accepted the claim of the vaccine manufacturers that hepatitis B vaccine, a highly purified, genetically engineered single-antigen vaccine, is a safe vaccine. According to the CDC, the existing studies have failed to confirm that hepatitis B vaccine causes any chronic diseases. Specifically, hepatitis B vaccine has not been shown to cause chronic fatigue syndrome nor does it cause autoimmune diseases such as rheumatoid arthritis or multiple sclerosis. The CDC further maintains that adverse event surveillance in the US has failed to link hepatitis B vaccination to any serious adverse events.[22,23]

Table 2. Adult Hepatitis B Vaccination Adverse Reactions

Type of Reaction	No. of Female Reports	No. of Male Reports	Mean Age (y)	Mean Onset (d)	Incidence per 10 Million Vaccinations
Arthralgia	148	46	37.3 ± 12.0	3.3 ± 5.2	122
Arthrosis	30	9	36.4 ± 10.5	4.8 ± 5.8	24
Arthritis	16	7	33.9 ± 11.8	8.4 ± 7.3	14
Myelitis	8	1	29.1 ± 9.9	3.3 ± 4.9	5.6
Vasculitis	5	1	38.3 ± 16.1	11.3 ± 9.3	4.3
Guillain–Barré syndrome	2	4	29.8 ± 12.5	9.7 ± 10.0	4.3
Thrombocytopenia	7	6	27.3 ± 11.6	9.5 ± 7.9	8.0
Hepatitis	6	3	36.4 ± 18.1	11.8 ± 7.2	5.6
Liver function test abnormalities	14	10	40.9 ± 17.3	8.8 ± 10.3	14.8
Erythema	11	3	31.1 ± 14.5	11.9 ± 18.8	8.6

Table 3. A Comparison of Adverse Reactions Between Tetanus Toxoid and Adult Hepatitis B Vaccine

Adverse Reaction	Tetanus Toxoid Vaccinations[a]	Adult Hepatitis B Vaccinations[a]	Adult Hepatits B Vaccination vs. Tetanus Toxoid		
			Relative Risk	Percentage Association (%)	χ^2 Association (p value)
Arthralgia	18	122	6.6	87	0.01
Arthrosis	2.6	24	9.2	90	0.01
Arthritis	3.5	14	4.0	80	0.05
Myelitis	0	5.6		100	0.01
Vasculitis	0.44	4.3	9.8	91	0.01
Guillain–Barré syndrome	2.2	4.3	2.0	67	NS
Thrombocytopenia	1.8	8.0	4.4	81	0.05
Hepatitis	0.44	5.6	13	93	0.01
Liver function test abnormalities	0.88	15	17	94	0.01
Erythema	0.44	8.6	19.5	95	0.01

NS = not significant.
[a]Incidence per 10 million vaccinations.

The possible mechanisms by which hepatitis B vaccine, a single-purified antigen, could cause adverse reactions in close temporal association with vaccination, mostly in adult women, is intriguing. One possible mechanism is that the HbsAg might mimic an inflammatory response signal in a sensitive patient. Alternately, the HbsAg might attach to cells, signaling them to undergo apoptosis. Our data suggest the need to further investigate these possible mechanisms.

It should be remembered that hepatitis B vaccines were developed to combat the deadly effects of natural hepatitis B infection. Hepatitis B is one of the most important infectious causes of acute and chronic liver disease in the US and worldwide. Each year, approximately 300 000 persons in the US acquire new hepatitis B virus (HBV) infection; 25 000 are reported with acute hepatitis.[24,25] Between 18 000 and 30 000 persons become HBV carriers, adding to a pool of 750 000–1 million HBV carriers, who are at risk of chronic liver disease, including chronic active hepatitis, cirrhosis, and primary hepatocellular carcinoma (PHC). Between 4000 and 5000 persons die from HBV infection annually, including 300 due to fulminant hepatitis, 3000 to 4000 due to cirrhosis, and 600 to 1000 due to PHC. The CDC has estimated the direct costs of HBV infection to exceed $500 million annually in the US.[26] We believe, on the basis of these data, that the reaction rate observed after adult hepatitis B vaccination in this study seems to be far outweighed by the benefits of the continued use of the vaccine.

Summary

Our results in this study confirmed and extended our previous findings that suggested that there is indeed an increased risk for adverse reactions after adult hepatitis B vaccination. Patients and physicians need to be fully informed of the potential adverse reactions associated with hepatitis B vaccination, so that, together, they can make an informed consent decision about the risk versus the benefit. Hepatitis B vaccination should be included in the differential diagnosis of patients who develop arthritic, immunologic, and gastrointestinal symptoms after hepatitis B vaccination. Clinicians in the US should make a concerted effort to report adverse reactions after adult hepatitis B vaccination to VAERS, so that more accurate incidence rates for adverse reactions after adult hepatitis B vaccination may be determined. The VAERS program can be contacted at 1-800-822-7967, 24 hours a day. Those patients who have had an associated arthritic, immunologic, or gastrointestinal reaction within 3 weeks of hepatitis B vaccination in the US should be aware that they may be eligible to seek compensation under the no-fault Vaccine Compensation Act, administered by the US Court of Claims. The Vaccine Compensation Act program can be reached by calling 1-800-338-2382.

Mark R Geier MD PhD, President, The Genetic Centers of America, Silver Spring, MD
David A Geier, President, MedCon, Inc., Silver Spring
Reprints: Mark R Geier MD PhD, The Genetic Centers of America, 14 Redgate Ct., Silver Spring, MD 20905-5726, FAX 301/989-1543, E-mail mgeier@erols.com

References

1. Geier MR, Geier DA. Hepatitis B vaccine and gastroenterologic adverse reactions (letter). Hepatogastroenterology 2001;48(37).
2. Geier MR, Geier DA. Arthritic reactions and hepatitis B vaccination: an analysis of the Vaccine Adverse Events Reporting System (VAERS) from 1990 through 1997 (letter). Clin Exp Rheumatol 2000;18:789-90.
3. Geier MR, Geier DA. Immunological reactions and hepatitis B vaccine (letter). Ann Intern Med 2001;134:1155.
4. Geier DA, Geier MR. Hepatitis B vaccination and adult associated gastrointestinal reactions: a follow-up analysis. Hepatogastroenterology (in press).

Table 4. A Comparison of Adverse Recations Between Td and Adult Hepatitis B Vaccination

Adverse Reaction	Td Vaccinations[a]	Adult Hepatitis B Vaccinations[a]	Adult Hepatitis Vaccination vs. Td		
			Relative Risk	Percentage Association (%)	χ^2 Association (p value)
Arthralgia	27	122	4.5	82	0.01
Arthrosis	3.9	24	6.2	86	0.01
Arthritis	2.4	14	5.8	85	0.01
Myelitis	0.85	5.6	6.6	87	0.05
Vasculitis	0.39	4.3	11	92	0.05
Guillain–Barré syndrome	2.2	4.3	2.0	67	NS
Thrombocytopenia	0.70	8.0	11	92	0.01
Hepatitis	0.46	5.6	12	92	0.01
Liver function test abnormalities	0.62	14.8	24	96	0.01
Erythema	1.2	8.6	7.2	88	0.01

NS = not significant; Td = tetanus–diphtheria.
[a]Incidence per 10 million vaccinations.

5. Geier DA, Geier MR. Hepatitis B vaccination and arthritic adverse reactions: a follow-up analysis of the Vaccine Adverse Events Reporting System (VAERS) database from July 1990 through August 1999 (letter). Clin Exp Rheumatol (in press).
6. Geier MR, Geier DA. Immunological reactions and hepatitis B vaccine (letter). Ann Intern Med (in press).
7. Vautier G, Carty JE. Acute sero-positive rheumatoid arthritis occurring after hepatitis vaccination (letter). Br J Rheumatol 1994;33:991.
8. Gross K, Combe C, Kruger K, Schattenkirchner M. Arthritis after hepatitis B vaccination. Report of three cases. Scand J Rheumatol 1995;24:50-2.
9. Maillefert JF, Sibilia J, Toussirot E, Vignon E, Eschard JP, Lorcerie B, et al. Rheumatic disorders developed after hepatitis B vaccination. Rheumatology (Oxf) 1999;38:978-83.
10. Lilic D, Ghosh SK. Liver dysfunction and DNA antibodies after hepatitis B vaccination (letter). Lancet 1994;344:1292-3.
11. Herroelen L, Keyser JD, Ebinger G. Central-nervous-system demyelination after immunisation with recombinant hepatitis B vaccine (letter). Lancet 1991;338:1174-5.
12. Le Hello C, Cohen P, Bousser MG, Letellier P, Guillevin L. Suspected hepatitis B vaccination related vasculitis. J Rheumatol 1999;26:191-4.
13. Shoenfeld Y, Aron-Maor A. Vaccination and autoimmunity: 'vaccinosis' a dangerous liaison? J Autoimmun 2000;14:1-10.
14. Grotto I, Mandel Y, Ephros M, Ashkenazi I, Shemer J. Major adverse reactions to yeast-derived hepatitis B vaccines — a review. Vaccine 1998; 16:329-34.
15. Singleton JA, Lloyd JC, Mootrey GT, Salive ME, Chen RT. An overview of the Vaccine Adverse Events Reporting System (VAERS) as a surveillance system. Vaccine 1999;17:2908-17.
16. Geier DA, Geier MR. An analysis of the reactivity of vaccines administered in the state of Texas from 1991 through 1999: based upon the Vaccine Adverse Events Reporting System (VAERS) database. Texas Med (in press).
17. Geier DA, Geier MR. Rubella vaccine and arthritic adverse reactions: an analysis of the Vaccine Adverse Events Reporting System (VAERS) database from 1991 through 1998. Clin Exp Rheumatol 2001;19:724-6.
18. Geier DA, Geier MR. Anthrax vaccination and joint related adverse reactions in light of biological warfare scenarios. Clin Exp Rheumatol (in press).
19. Emini EA, Ellis RW, Miller WJ, McAleer WJ, Scolnick EM, Gerety RJ. Production and immunological analysis of recombinant hepatitis B vaccine. J Infect 1986;13(suppl A):3-9.
20. Stephene J. Development and production aspects of a recombinant yeast-derived hepatitis B vaccine. Vaccine 1990;8(suppl):S69-73.
21. Tron F, Degos F, Brechot C, Courouce AM, Goudeau A, Marie FN, et al. Randomized dose range study of a recombinant hepatitis B vaccine produced in mammalian cells and containing the S and PreS2 sequences. J Infect Dis 1989;160:199-204.
22. Andre FE. Clinical experience with a recombinant DNA hepatitis B vaccine. Southeast Asian J Trop Med Public Health 1988;19:501-10.
23. Greenberg DP. Pediatric experience with recombinant hepatitis B vaccines and relevant safety and immunogenicity studies. Pediatr Infect Dis J 1993;12:438-45.
24. Advisory Committee for Immunization Practices (ACIP). Recommendations for protection against viral hepatitis. MMWR Morb Mortal Wkly Rep 1990;38(S).
25. Centers for Disease Control and Prevention. Hepatitis surveillance report no. 52. Atlanta: US Department of Health and Human Services, Public Health Service, 1990.
26. Hadler SC, Margolis HS. Hepatitis B immunization: vaccine types, efficacy, and indications for immunization. Curr Clin Top Infect Dis 1992; 12:282-308.

EXTRACTO

TRASFONDO: Estudios recientes sugieren que la vacunación para hepatitis B en adultos podría estar asociada con reacciones adversas.

OBJETIVO: El propósito de este estudio es investigar más a fondo el riesgo relativo, el porciento de asociación y el significado estadístico de las reacciones adversas inmunológicas, gastrointestinales y de artritis reportadas luego de la vacunación para hepatitis B en adultos comparados a un grupo control.

DISEÑO: Se analizó la base de datos del Sistema de Reportes de Eventos Adversos a Vacunas (VAERS, por sus siglas en inglés) para la incidencia de reacciones adversas luego de inmunización contra hepatitis B en adultos comparado a la incidencia de reacciones adversas reportadas a VAERS luego de vacunas a grupos control.

ESCENARIO: Las comunidades médicas y científicas han aceptado en términos generales que la vacuna de hepatitis B, altamente purificada, creada genéticamente y de un sólo antígeno, es una vacuna segura.

MÉTODOS: La base de datos de VAERS fue analizada para reacciones adversas a vacunación contra hepatitis B en adultos desde 1997 a 2000, y para reacciones adversas a vacunas en grupo control desde 1991 a 2000.

RESULTADOS: Los resultados demostraron un aumento estadísticamente significativo en la incidencia de reacciones adversas reportadas luego de vacunación contra hepatitis B en adultos comparada a la incidencia de reacciones adversas reportadas a VAERS luego de vacunación en grupo control.

CONCLUSIONES: Los pacientes y los médicos necesitan estar bien informados sobre las reacciones adversas potenciales asociadas a vacunación contra hepatitis B, para que juntos puedan tomar una decisión informada sobre los riesgos versus los beneficios. Los pacientes que puedan haber sufrido una reacción adversa a la vacuna de hepatitis B deben ser informados que pueden ser elegibles para compensación de acuerdo a la Ley de Compensación de Vacunas, administrada por la Corte de Querellas de los Estados Unidos.

Giselle Rivera-Miranda

RÉSUMÉ

RAPPEL: Des études récentes suggèrent que la vaccination de l'adulte contre l'hépatite B peut être associée à des effets indésirables.

OBJECTIF: Le sujet de cette étude était d'examiner de plus près le risque relatif, le pourcentage d'associations et la significativité statistique des effets indésirables rhumatologiques, immunologiques et gastrointestinaux rapportés après vaccination de sujets adultes contre l'hépatite B par comparaison à des vaccinations témoins.

SCHEMA D'ETUDE: La base de données du système de notification des effets indésirables des vaccins (VAERS) a été analysée par rapport à l'incidence des effets indésirables consécutifs à l'immunisation de sujets adultes contre l'hépatite B, par comparaison à celle des effets indésirables signalés à VAERS après la vaccination de groupes témoins.

CONCEPT: Les communautés médicales et scientifiques ont en général considéré que le vaccin contre l'hépatite B, vaccin hautement purifié, produit par génie génétique et composé d'un seul antigène est un vaccin sûr.

METHODES: La base de données VAERS a été analysée de 1997 à 2000 pour les effets indésirables associés à la vaccination de l'adulte contre l'hépatite B, et de 1991 à 2000 pour les effets indésirables rapportés suite à la vaccination de groupes témoins.

RESULTATS: Les résultats ont montré une augmentation statistiquement significative de l'incidence des effets indésirables rapportés à la suite de vaccinations d'adultes contre l'hépatite B par comparaison à celle rapportée à VAERS à la suite de vaccinations témoins.

CONCLUSIONS: Les patients et les médecins doivent être pleinement informés des effets indésirables potentiels associés à la vaccination contre l'hépatite B, de façon à ce qu'ensemble ils puissent convenir de manière éclairée de la décision du rapport bénéfice/risque. Les patients qui pourraient avoir souffert d'un effet indésirable associé au vaccin de l'hépatite B devraient être informés qu'ils peuvent prétendre à un dédommagement en vertu de la loi sur la compensation de l'alea vaccinal, auprès de la cour des plaintes des Etats-Unis.

Michel Le Duff