HEPATITIS B VACCINE

Is It Safer Than Hepatitis B?

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1. WHAT IS THE HEPATITIS B VACCINE?

The hepatitis B vaccine was introduced in 1981 for use in high-risk populations, and then in 1991 it was used for mass vaccination of infants. It has significantly reduced the incidence of reported cases of acute hepatitis B infections; however, about 50% of vaccinated children lose their immunity by age 5,[1] and the vaccine has not made a measurable impact on the prevalence of chronic hepatitis B infection.[2,3]

2. WHAT ARE SIDE EFFECTS OF THE HEPATITIS B VACCINE?

Common side effects of the hepatitis B vaccine include fever, diarrhea, and fatigue/weakness.[4] A more serious potential side effect is seizure, which may occur in about 1 in 1,300 children vaccinated with the hepatitis B vaccine.[5-8] Although severe adverse events have been observed following hepatitis B vaccination, including neurological disorders (e.g., encephalitis, transverse myelitis, optic neuritis, multiple sclerosis, and Guillain-Barré syndrome) and autoimmune diseases (e.g., systemic lupus erythematosus, rheumatoid arthritis, and type 1 diabetes), the Institute of Medicine (IOM) states that "the evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine" and those conditions.[9] For children, the hepatitis B vaccine contains 250 mcg of aluminum. This amount is 75 times greater than the maximum safe level of aluminum in the bloodstream per day for a 7.3-pound (3.3-kilogram) infant, derived from the Agency for Toxic Substances and Disease Registry (ATSDR), a division of the U.S. Department of Health and Human Services (HHS) (Fig. 1).[10] Additionally, the manufacturer's package insert states that the hepatitis B vaccine has not been evaluated for its "carcinogenic or mutagenic potential," or its potential to impair fertility.[4,11]

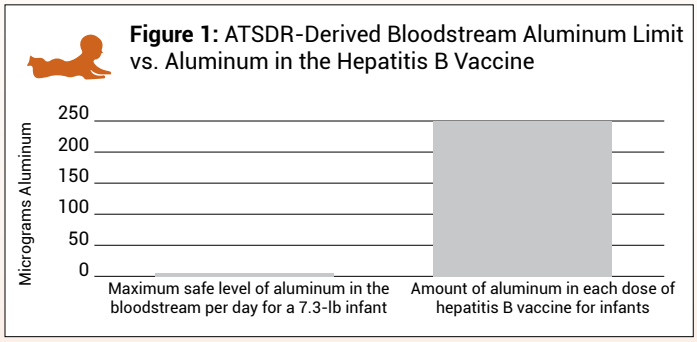

Figure 1: ATSDR-Derived Bloodstream Aluminum Limit vs. Aluminum in the Hepatitis B Vaccine

3. HOW ARE RISKS OF VACCINE SIDE EFFECTS MEASURED?

Methods to measure vaccine risks include surveillance systems, clinical trials, and epidemiological studies.

4. HOW ACCURATE IS SURVEILLANCE OF SIDE EFFECTS FROM THE HEPATITIS B VACCINE?

The government tracks reported cases of vaccine side effects through the Vaccine Adverse Event Reporting System (VAERS). Approximately 114 cases of permanent injury and death from the hepatitis B vaccine are reported to VAERS annually.[12] However, VAERS is a passive reporting system — authorities do not actively search for cases and do not actively remind doctors and the public to report cases. These limitations can lead to significant underreporting.[13] The Centers for Disease Control and Prevention (CDC) states, "VAERS receives reports for only a small fraction of actual adverse events."[14] Indeed, as few as 1% of serious side effects from medical products are reported to passive surveillance systems.[15] In addition, VAERS reports are not proof that a side effect occurred, as the system is not designed to thoroughly investigate all cases.[16] As a result, VAERS does not provide an accurate count of hepatitis B vaccine side effects.

5. HOW ACCURATE ARE CLINICAL TRIALS OF THE HEPATITIS B VACCINE?

The CDC states, "Prelicensure trials are relatively small — usually limited to a few thousand subjects — and usually last no longer than a few years. Prelicensure trials usually do not have the ability to detect rare adverse events or adverse events with delayed onset."[13] Clinical trials of the hepatitis B vaccine in particular usually involved only a few

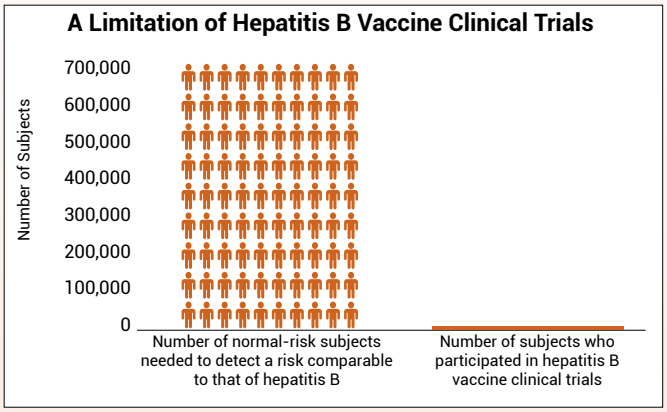

Figure 2: There are not enough subjects in clinical trials to prove that the hepatitis B vaccine poses less risk than hepatitis B for children at normal risk of exposure.

hundred subjects per study.[17] In the pre-vaccine era, annually fatal hepatitis B occurred in less than 1 in 7,000,000 children under age 10 at normal risk of exposure (i.e., were not born to an infected mother, did not live with an infected individual, and did not live in a community with a large number of infected individuals).[18] Therefore, about 1 in 700,000 such children contracted fatal hepatitis B in a 10-year span. A few hundred subjects in clinical trials are not enough to prove that the hepatitis B vaccine causes less permanent injury or death than hepatitis B in children at normal risk of exposure (Fig. 2).

6. HOW ACCURATE ARE EPIDEMIOLOGICAL STUDIES OF THE HEPATITIS B VACCINE?

Epidemiological studies are hindered by the effects of chance. For example, the IOM cited a 1999 study involving about 135,000 subjects that looked for an association between the hepatitis B vaccine and certain adverse events.[19,20] Although the study found no association between the hepatitis B vaccine and the adverse events, it did not rule out the possibility that the hepatitis B vaccine increases the risk of an adverse event that leads to permanent injury by up to 110%. Consequently, the study did not rule out the possibility that such adverse events might occur up to 180 times more often than death from hepatitis B in children at normal risk of exposure: 1 in 3,900 compared to 1 in 700,000 (Fig. 3 and Table 1). The range of possibilities found in the study makes the result inconclusive; even large epidemiological studies are not accurate enough to prove that hepatitis B vaccine causes less permanent injury or death than hepatitis B in children at normal risk of exposure.

7. IS THE HEPATITIS B VACCINE SAFER THAN HEPATITIS B?

It has not been proven that the hepatitis B vaccine is safer than hepatitis B for children at normal risk of exposure. The vaccine package insert raises questions about safety testing for cancer, genetic mutations, and impaired fertility. Although VAERS tracks some adverse events, it is too inaccurate to measure against the risk of hepatitis B. Clinical trials including a few hundred subjects do not have the ability to detect less common, serious adverse reactions, and epidemiological studies are limited by the effects of chance. Safety studies of the hepatitis B vaccine are lacking in statistical power. A review of hepatitis B vaccine safety studies conducted by the IOM found that the evidence was inadequate to rule out the possibility that hepatitis B vaccination leads to more than two dozen neurological and autoimmune disorders.[9] Because contracting a case of hepatitis B with permanent sequelae (aftereffects) is so rare in children at normal risk of exposure, the level of accuracy of the research studies available is insufficient to rule out the possibility that the hepatitis B vaccine causes greater permanent injury or death than hepatitis B in normal-risk children.

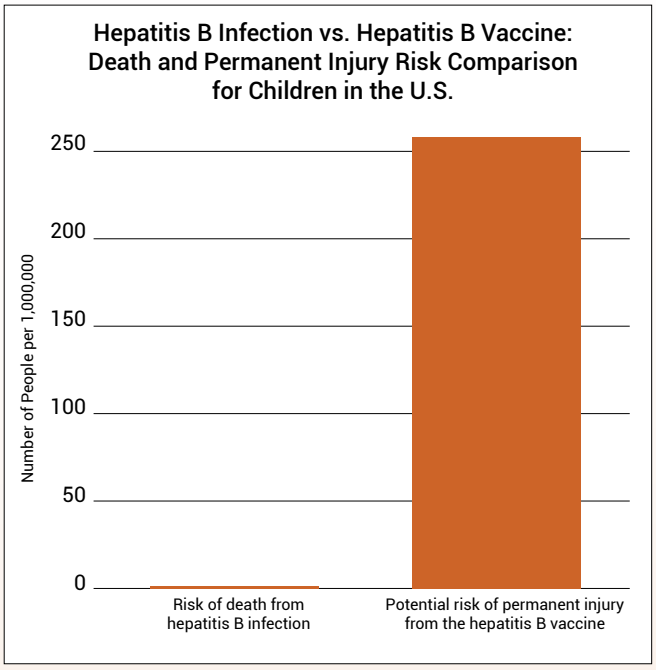

Figure 3: A 1999 study cited by IOM did not rule out the possibility that the hepatitis B vaccine can cause an adverse event leading to permanent injury 180 times more often than hepatitis B can be fatal for U.S. children at normal risk of exposure.

Table 1: Statistical Analysis of an Epidemiological Study with 135,000 Children

RR = Relative risk
(risk in group vaccinated with hepatitis B vaccine) ÷
(risk in group not vaccinated with hepatitis B vaccine)

CI = Confidence interval
(possible range of RR due to effects of chance)

RR reported in study
= 0.9 (95% CI, 0.4 to 2.1)

Potential RR = 2.1
(potential 110% greater risk than unvaccinated group risk)

Unvaccinated group risk recorded in study
= 25 in 107,469

110% of 25 in 107,469
= 1 in 3,900 additional risk in group vaccinated with the hepatitis B vaccine

All references and the Hepatitis B Disease Information Statement (DIS) are available at physiciansforinformedconsent.org/hepatitis-b-vaccine.

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