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# **Hepatitis B Vaccine Linked** to Onset of Diabetes















June 13, 2000 (San Antonio) -- Faced with an ever-growing list of required and recommended vaccinations for children -- as well as occasional reports of safety problems linked to vaccines -- many parents understandably feel confused. No doubt adding to that confusion are reports that the vaccine against hepatitis B, a bloodborne illness that can cause liver cancer, may actually lead to the development of type 1 diabetes in children.

Type 1 diabetes is the form where the body doesn?t make the insulin it needs. An Italian study presented here at the annual meeting of the American Diabetes Association suggests that children who get the hepatitis B vaccine are at greater risk for developing type 1 disease than those who have never been vaccinated. On the basis of their research, Paolo Pozzilli, MD, and colleagues say doctors should exercise caution in giving the vaccine to children who have close relatives with type 1 diabetes

But because type 1 diabetes is relatively rare in the overall population, thorough studies involving several hundred thousand participants are needed to prove a solid link, says Marion Rewers, MD, who was not involved in the study. So the jury is still out, he says.

"The possibility of a link between hepatitis B vaccine [and type 1 diabetes ] is an interesting research area and has been recognized as such by a number of investigators across the world," he tells WebMD. He says that at two recent meetings, researchers "were in unanimous agreement that there was no association. We need a monitoring system, so that if an association is found in the future, it can be promptly identified." Rewers, a pediatric endocrinologist, is a

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Colorado in Denver and chair of the ADA council on epidemiology and statistics.

The CDC recommends that the hepatitis B vaccine be a part of routine vaccination schedules for U.S. infants.

The hepatitis B vaccine is now required in Italy, says Pozzilli, a professor of pediatrics at the University of Rome. Further, there is a low, relatively stable rate of type 1 diabetes there. These conditions allowed the researchers to compare the rate of diabetes in vaccinated children with that in unvaccinated groups.

Investigators compared 150,000 children who had been vaccinated at age 3 months to an equal number of unvaccinated children. To assess the risk of developing type 1 diabetes in children who got the vaccine later, after vaccination became mandatory in Italy, 400,000 children who were vaccinated at age 12 were compared with children who had not been vaccinated.

In the group as a whole, the rates of type 1 diabetes were 46 per 100,000 for children who had been vaccinated and 34 per 100,000 for children who had not. For those vaccinated at age 12, the rates were 17.8 per 100,000 for vaccinated children and 6.9 per 100,000 for unvaccinated children.

Although these may seem like large groups to study, they are not big enough for scientists to see clear patterns for type 1 diabetes, Rewers says. For a study like this to have value, the database should involve as many as 250,000 people in both the vaccinated and unvaccinated groups, he says.

"Caution is necessary when the potential of vaccine-related risks is studied," Rewers tells WebMD. "Without sound supportive data, [parents] can become unduly alarmed and stop immunizing their children." When immunization rates drop, diseases that can cause serious illness -- and death -- return, he tells WebMD.

The National Institutes of Health and the CDC are jointly establishing a system known as "sentinel monitoring areas," Rewers tells WebMD. The agencies will track the rate of type 1 diabetes in these areas -consisting of selected counties in the U.S. -- and will determine whether the rate is related to things like immunizations,

recommended infant feeding schedules, and outbreaks of infection





## **Hepatitis B Vaccine Link...**

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Rewers has not been involved with the development of any vaccine and has no ties to any company that manufactures vaccines.

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