Diabetes and Vaccines

1. Is there evidence to show that vaccines cause diabetes?

No, there have been no verified findings to show that vaccines cause diabetes or increase the risk of developing diabetes in humans.

The only evidence suggesting a possible increase in risk has come from Dr. John B. Classen (Classen 1996; Classen and Classen 1997). Other researchers who have studied the issue have not found an increased risk of diabetes associated with vaccination (Parent 1997, Dahlquist 1995, Blom 1991, Heijbel 1997, Hyoty 1993). These other studies, however, all examined the relationship of vaccination and development of diabetes without regard to when the vaccines were administered. Still, the results of these other studies are relevant to the question of a possible increase in risk of diabetes and they do not support such an association with vaccination.

2. What is the evidence that there might be a connection between diabetes and the timing of vaccination?

Dr. Bart Classen has suggested that certain vaccines if given at birth may decrease the occurrence of diabetes, whereas if initial vaccination is performed after 2 months of age the occurrence of diabetes increases. He bases his theory on results from experiments in laboratory animals, as well as comparisons of the rates of diabetes between countries with different immunization schedules (Classen and Classen 1997). Many of the animal experiments involved anthrax vaccine, which is rarely used in infants and children. The comparisons between countries included vaccines which are infrequently used in the U.S. (BCG) or are no longer used (smallpox).

Dr. Classen also has performed an analysis of data from a large study conducted in Finland of Haemophilus influenzae type B (Hib) vaccine. Over 100,000 children were randomly assigned to receive either 4 doses of vaccine starting at 3 months of age or a single dose at 24 months. Over about a 10 year follow up period, 205 children in the multiple dose group developed diabetes compared with 185 in the single dose group. These results are inconclusive because the exact number of children in each group is not known and the noted differences may not be statistically significant (that is, they could be due to "chance").

3. How convincing are Dr. Classen's findings?

Dr. Classen's results are not consistent with current scientific thinking and have not been verified by other researchers. Trying to apply findings from laboratory animals to humans is fraught with uncertainty. Findings that are noted in animals cannot be directly applied to people because of the large biological differences. Comparison of diabetes rates between countries with different vaccination policies also provides weak evidence because many factors, including different
vaccination schedules, may differ by country. Many factors, including genetic predisposition and a number of possible environmental exposures unrelated to vaccines, may influence the development of diabetes in different countries.

4. What would be the implications of the findings if they were true?

The suggestion that immunization at birth could protect against developing diabetes would be a very positive development and would require re-evaluation of the benefits and risks of administering certain vaccines at birth if possible.

The possibility that certain vaccines that are administered at 2 months of age or later may increase risk would be of more immediate concern. The degree of concern, however, would depend on the magnitude of the increase in risk. At present, the possibility of any increase in risk is only theoretical and no firm data are available on potential magnitude. From the Finnish Hib trial analysis, Dr. Classen suggests that Hib vaccine may increase IDDM risk by as much as 10 percent (Classen and Classen 1997). In the U.S., a person's risk of developing type 1 diabetes by age 20 is about 36 in 10,000. Applying a 10 percent increase, results in a theoretical increase in risk of 4 in 10,000.

5. What do these findings indicate for current immunization policies and practices?

In 1995, the National Institutes of Health (NIH) convened a group of knowledgeable scientists and public health authorities to meet with Dr. Classen and review the evidence regarding a possible association between vaccines and diabetes. It was the consensus of the meeting participants that there was no clear evidence that would support a change in immunization policies and practices. The additional evidence since that time is not sufficient to change this conclusion.

6. What is being done to monitor the safety of vaccines?

To assure the safety of vaccines, The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and other Federal agencies routinely monitor and conduct research to examine any new evidence that would suggest possible problems with the safety of vaccines. Current activities to further explore a possible association between vaccines and diabetes include: 1) NIH is sponsoring an extensive review of the world's literature and on-going research on this subject; 2) NIH is planning an international conference on infections (including immunization) and diabetes; and 3) CDC is conducting a large epidemiologic study of vaccinations and risk of Type 1 diabetes, with a focus on timing of vaccinations.

For more information about vaccines and vaccinations, contact CDC's National Immunization Information Hotline: 1-800-232-2522, English, or 1-800-232-0233, Spanish; or visit CDC's Internet page http://www.cdc.gov/nip
References

Blom L, Nystrom L, Dahlquist G. The Swedish childhood diabetes study: Vaccinations and infections as risk determinants for diabetes in childhood.


Heijbel H, Chen RT, Dahlquist G. Cumulative incidence of childhood-onset IDDM is unaffected by pertussis immunization. Diabetes Care 1997;20:173-175.
