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Public should be told that vaccines may have long term adverse effects

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EDITOR—Jefferson's editorial about vaccination and its adverse effects mentions our research.[1] We found that immunisation starting at birth was associated with a decreased risk of insulin dependent diabetes, while immunisation starting after age 2 months was associated with an increased risk of diabetes in both rodents and humans.[2] We initiated a collaboration with Dr Jaakko Tuomilehto to study the effect of *Haemophilus influenzae* type b vaccine on the incidence of diabetes. Roughly 116 000 Finnish children were randomised to receive either four doses of the vaccine, starting at 3 months of age, or one dose at 24 months of age.[3] We calculated the incidence of insulin dependent diabetes in both groups until age 10 and in a group that did not receive the vaccine—a cohort that included all 128 500 children born in Finland in the 24 months before the study of the vaccine began.

A conference was held in Bethesda, Maryland, in May 1998 to discuss our data. At the conference we stated that the data on the vaccine support our published findings that immunisation starting after the age of 2 months is associated with an increased risk of diabetes. Our analysis is further supported by a similar rise in diabetes after immunisation with *H influenzae* type b vaccine in the United States[4] and United Kingdom.[5] Furthermore, the increased risk of diabetes in the vaccinated group exceeds the expected decreased risk of complications of *H influenzae* meningitis.

Research into immunisation has been based on the theory that the benefits of immunisation far outweigh the risks from delayed adverse events and so long term safety studies do not need to be performed. When looking at diabetes—only one potential chronic adverse event—we found that the rise in the prevalence of diabetes may more than offset the expected decline in long term complications of *H influenzae* meningitis. Thus diabetes induced by vaccine should not be considered a rare potential adverse event. The incidence of many other chronic immunological diseases, including asthma, allergies, and immune mediated cancers, has risen rapidly and may also be linked to immunisation.

We believe that the public should be fully informed that vaccines, though effective in preventing infections, may have long term adverse effects. An educated public will probably increasingly demand proper safety studies before widespread immunisation. We believe that the outcome of this decision will be the development of safer vaccine technology.

References

1. Jefferson T. Vaccination and its adverse effects: real or perceived. *BMJ.* 1998;317:159–160. . (18 July.) [PMC free article] [PubMed] [Google Scholar]

2. Classen DC, Classen JB. The timing of pediatric immunization and the risk of insulin-dependent diabetes mellitus. *Infect Dis Clin Pract.* 1997;6:449–454. [Google Scholar]

3. Eskola J, Kayhty H, Takala AK, Peltola H, Ronnberg PR, Kela E, et al. A randomized, prospective field trial of a conjugated vaccine in the protection of infants and young children against invasive Haemophilus influenzae type b disease. *N Engl J Med.* 1990;323:1381–1387. [PubMed] [Google Scholar]

4. Dokheel TM. An epidemic of childhood diabetes in the United States. *Diabetes Care.* 1993;16:1606–1611. [PubMed] [Google Scholar]

5. Gardner S, Bingley PJ, Sawtell PA, Weeks S, Gale EA. Rising incidence of insulin dependent diabetes in children under 5 years in Oxford region: time trend analysis. *BMJ.* 1997;315:713–716. [PMC free article] [PubMed] [Google Scholar]