



Safety of Vaccines Used for Routine Immunization in the United States



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Evidence-Based
Practice

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Diphtheria Toxoid, Tetanus Toxoid, and Acellular Pertussis-Containing Vaccines

The IOM studied diphtheria toxoid, tetanus toxoid, and acellular pertussis-containing vaccines alone and in combination, in both children and adults. The IOM committee did not find evidence that “favors acceptance” of causal relationships for any conditions. They found the evidence “favors rejection” of a causal relationship between type 1 diabetes and vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens.²⁰⁷⁻²¹¹ The IOM committee found the evidence is “inadequate to accept or reject” causal relationships between diphtheria toxoid-, tetanus toxoid- or acellular pertussis-containing vaccine and the following: infantile spasms; seizures; cerebellar ataxia; autism; ADEM; transverse myelitis; MS relapse in children; serum sickness; immune thrombocytopenic purpura; and SIDS.

We found no additional studies in children published after the IOM search date; our review of their findings leads to a rating of moderate strength of evidence for each of the associations they investigated.

Meningococcal Vaccine

The IOM found the evidence “convincingly supports” a causal relationship with anaphylaxis in children who may be allergic to ingredients. The committee found the evidence “inadequate to accept or reject” causal relationships between meningococcal vaccine and the following: encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, and chronic headache. The IOM conclusion does not differentiate between meningococcal conjugate or meningococcal polysaccharide vaccine.

We found two studies of quadrivalent meningococcal conjugate vaccine in children (Table 28)^{212,213} published after the IOM report. A trial in Saudi Arabia found no statistical association with Grade 2 or 3 fever, malaise, myalgia or headache in the short term. A trial in the United States and South America²¹³ found vaccination was not associated with severe change in eating habits, severe irritability, severe persistent crying, severe sleepiness or urticaria in the year following vaccination. Per the findings of the IOM, strength of evidence is moderate that meningococcal vaccine may cause anaphylaxis in children who are allergic to ingredients. Strength of evidence is insufficient to determine an association between meningococcal vaccine and the serious adverse events encephalitis, encephalopathy, ADEM, transverse myelitis, MS, Guillain-Barré syndrome, CIDP, and chronic headache. Strength of evidence is insufficient to determine association with less serious events such as headache, irritability, and urticaria.