The National Vaccine Injury Compensation Program (VICP)

MMR Vaccine and Diabetes Mellitus

Advisory Commission on Childhood Vaccines
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Public petition to add MMR-Diabetes Mellitus (DM) to the Vaccine Injury Table (VIT)

42 U.S.C. § 300aa-14(c)(2)

"Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following –

(A) Receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding."

Current scientific literature

- 2012 IOM Report concluded “The evidence favors rejection of a causal relationship between MMR vaccine and Type 1 Diabetes”
  - IOM committee had a high degree of confidence in the epidemiologic evidence: null association.
  - The IOM committee assessed the mechanistic evidence regarding an association between MMR vaccine and type 1 diabetes as lacking.

Current scientific literature

- The Cochrane Collaboration: Vaccines for measles mumps and rubella in children (Review) (2012)
  - Goal: Assess the effectiveness and adverse effects associated with the MMR vaccine in children up to 15 years of age
  - Reviewed and assessed studies in the Cochrane Central Register of Controlled Trials
  - Conclusion (specific to DM): MMR vaccine was unlikely to be associated with Type 1 DM

Current scientific literature

- Duderstadt et al (2012)
  - Hypothesis: To evaluate whether vaccination increases the risk of type 1 DM in active component US military personnel
  - Retrospective cohort study among active US military personnel
  - Identified first time diagnosis of Type 1 diabetes between 1/2002 – 12/2008 and estimated risk ratios between individual vaccine exposures and Type 1 diabetes
  - Result: No increased risk of diagnosed Type 1 diabetes and any of the study vaccines, including MMR vaccine
- No studies regarding MMR vaccine and Type 2 DM

Relevant literature

- IOM (Institute of Medicine). 2012. Adverse effects of vaccines: Evidence and causality. Washington, DC: The National Academies Press.
  - Altobelli, E., R. Petrocelli, A. Verrotti, and M. Valenti. 2003. Infections and risk of type I diabetes in childhood: A population-based case-control study. *European Journal of Epidemiology* 18(5):425 - 430.
  - Blom, L., L. Nystrom, and G. Dahlquist. 1991. The swedish childhood diabetes study. Vaccinations and infections as risk determinants for diabetes in childhood. *Diab tologia* 34(3):176-181.
  - DeStefano, F., J. Mullooly, C. Okoro, R. Chen, S. Marcy, J. Ward, C. Vadheim, S. Black, H. Shinefield, R. Davis, and K. Bohlke. 2001. Childhood vaccinations, vaccination timing, and risk of type 1 diabetes mellitus. *Pediatrics* 108(6):E112.
  - Hviid, A., M. Stellfeld, J. Wohlfahrt, and M. Melbye. 2004. Childhood vaccination and type 1 diabetes. *New England Journal of Medicine* 350(14):1398-1404.
  - Patterson, C. C. 2000. Infections and vaccinations as risk factors for childhood type I (insulin-dependent) diabetes mellitus: A multicentre case-control investigation. *Diab tologia* 43(1):47-53.

Relevant literature

- Demicheli, V., A. Rivetti, et al. (2012). "Vaccines for measles, mumps and rubella in children." Cochrane Database Syst Rev **2**: CD004407
  - Hviid, A., M. Stellfeld, J. Wohlfahrt, and M. Melbye. 2004. Childhood vaccination and type 1 diabetes. *New England Journal of Medicine* 350(14):1398-1404.
- Duderstadt, S., C. Rose Jr., T. Real, J. Sabatier, B. Stewart, G. Ma, U. Yerubandi, A. Eick, J. Tokars, M. McNeil. 2012. Vaccination and risk of type 1 diabetes mellitus in active component U.S. Military, 2002–2008. *Vaccine* 30:813-819.

ACCV recommendation

1. Add MMR-Diabetes Mellitus to Vaccine Injury Table

2. Do not add MMR-Diabetes Mellitus to Vaccine Injury Table and publish a notice in the Federal Register with reasons why