

A Case-Control Study Evaluating the Relationship Between Thimerosal-Containing *Haemophilus influenzae* Type b Vaccine Administration and the Risk for a Pervasive Developmental Disorder Diagnosis in the United States

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Abstract Thimerosal is an organic mercury (Hg)-containing compound (49.55 % Hg by weight) historically added to many multi-dose vials of vaccine as a preservative. A hypothesis testing case-control study evaluated automated medical records in the Vaccine Safety Datalink (VSD) for organic Hg exposure from Thimerosal in *Haemophilus influenzae* type b (Hib)-containing vaccines administered at specific times within the first 15 months of life among subjects diagnosed with pervasive developmental disorder (PDD) ($n=534$) in comparison to controls. The generally accepted biologically non-plausible linkage between Thimerosal exposure and subsequent diagnosis of febrile seizure ($n=5886$) was examined as a control outcome. Cases diagnosed with PDD received significantly more organic Hg within the first 6 months of life (odds ratio (OR)=1.97, $p<0.001$) and first 15 months of life (OR=3.94, $p<0.0001$) than controls, whereas cases diagnosed with febrile seizure were no more likely than controls to have received increased organic Hg. On a per microgram of organic Hg basis, cases diagnosed with a PDD in comparison to controls were at significantly greater odds (OR=1.0197, $p<0.0001$) of receiving increasing organic Hg exposure within the first 15 months of life, whereas cases diagnosed febrile seizure were no more likely than controls (OR=0.999, $p>0.20$) to have received increasing organic Hg exposure within the first 15 months of life. Routine childhood

vaccination is an important public health tool to reduce the morbidity and mortality associated with infectious diseases, but the present study provides new epidemiological evidence of a significant relationship between increasing organic Hg exposure from Thimerosal-containing vaccines and the subsequent risk of PDD diagnosis in males and females.

Keywords Autism · Ethylmercury · Merthiolate · Thimerosal · Thiomersal · Vaccine

Introduction

Thimerosal is an organic mercury (Hg)-containing compound (49.55 % Hg by weight) historically added to many multi-dose vials of vaccine as a preservative since the 1930s [1]. Thimerosal is initially metabolized into ethyl-Hg compounds and thiosalicylate and rapidly binds onto thiol groups found on many proteins in human blood [2]. It is then actively transported across the blood brain barrier, including by the L-type neutral amino acid carrier transport (LAT) system, into human neuronal cells [3, 4], where it significantly accumulates and persists for many months following exposure and alters numbers of neurons in the dentate gyrus of the hippocampus and thalamus [5, 6].

In 2008, an ecological birth cohort assessment of Thimerosal exposure in infants and neurodevelopment disorders within the computerized medical records of the Vaccine Safety Datalink (VSD) database was undertaken [7]. A total of 278,624 subjects were examined in birth cohorts from 1990–1996 that had received their first oral polio vaccination by 3 months of age in the VSD. The birth cohort prevalence rate of the medically diagnosed pervasive developmental disorders (PDDs) of autism and autism spectrum disorder (ASD) was

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