

Article

## A Dose-Response Relationship between Organic Mercury Exposure from Thimerosal-Containing Vaccines and Neurodevelopmental Disorders

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*Received: 12 July 2014; in revised form: 7 August 2014 / Accepted: 26 August 2014 /*

*Published: 5 September 2014*

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**Abstract:** A hypothesis testing case-control study evaluated concerns about the toxic effects of organic-mercury (Hg) exposure from thimerosal-containing (49.55% Hg by weight) vaccines on the risk of neurodevelopmental disorders (NDs). Automated medical records were examined to identify cases and controls enrolled from their date-of-birth (1991–2000) in the Vaccine Safety Datalink (VSD) project. ND cases were diagnosed with pervasive developmental disorder (PDD), specific developmental delay, tic disorder or hyperkinetic syndrome of childhood. In addition, putative non-thimerosal-related outcomes of febrile seizure, failure to thrive and cerebral degenerations were examined. The cumulative total dose of Hg exposure from thimerosal-containing hepatitis B vaccine (T-HBV) administered within the first six months of life was calculated. On a per microgram of organic-Hg basis, PDD (odds ratio (OR) = 1.054), specific developmental delay (OR = 1.035), tic disorder (OR = 1.034) and hyperkinetic syndrome of childhood (OR = 1.05) cases were significantly more likely than controls to receive increased organic-Hg exposure. By

contrast, none of the non-thimerosal related outcomes were significantly more likely than the controls to have received increased organic-Hg exposure. Routine childhood vaccination may be an important public health tool to reduce infectious disease-associated morbidity/mortality, but the present study significantly associates organic-Hg exposure from T-HBV with an increased risk of an ND diagnosis.

**Keywords:** attention deficit; autism; ethylmercury; merthiolate; thiomersal

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## 1. Introduction

Thimerosal is an organic-mercury (Hg) compound (49.55% Hg by weight) added to vaccines as a preservative, typically at concentrations from 0.005% to 0.01% (12.5 µg organic-Hg or 25 µg organic-Hg per 0.5-mL vaccine dose) [1]. Thimerosal rapidly dissociates into ethyl-Hg chloride, ethyl-Hg hydroxide and sodium thiosalicylate in saline solutions [2], and the resulting ethyl-Hg species have high affinities for being bound to free thiols in living systems [3]. U.S. Infants receiving the recommended routine childhood vaccination schedule in the 1990s may have been exposed to bolus doses of Hg nominally ranging from 12.5 µg organic Hg to 62.5 µg organic-Hg that collectively added up to nominally 200 µg organic-Hg from thimerosal-containing vaccines (TCVs) during the first six months of life (>50% of all Hg exposure when considering environmental sources of Hg) [4].

A hypothesis testing case-control study was undertaken to evaluate the potential dose-response relationship between organic-Hg exposure from thimerosal-containing hepatitis B vaccines (T-HBVs) administered within the first six months of life and the subsequent risk of being diagnosed with specific neurodevelopmental disorders (NDs) within the Vaccine Safety Datalink (VSD) database.

## 2. Experimental Section

### 2.1. Institutional Review Board Approval

The study protocol employed was approved by the Centers for Disease Control and Prevention (CDC), the Institutional Review Board (IRB) of Kaiser Permanente North-West (KPNW) and the IRB of Kaiser Permanente Northern California (KPNC). The data were analyzed at the secure Research Data Center of the National Center for Health Statistics in Hyattsville, MD. The views expressed in this study do not necessarily reflect those of the CDC nor Kaiser Permanente.

The VSD project was created in 1991 by the National Immunization Program (NIP) of the CDC [5–7]. The project links medical event information, specific vaccine history and selected demographic information from the computerized databases of several Health Maintenance Organizations (HMOs). The cohort examined was comprised of individuals with non-missing date of birth and non-missing gender, who were HMO-enrolled from birth.