

Early Downward Trends in Neurodevelopmental Disorders Following Removal of Thimerosal-Containing Vaccines

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ABSTRACT

Contemporaneously with the epidemic rise in neurodevelopmental disorders (NDs), first observed in the United States during the 1990s, the childhood immunization schedule was expanded by the U.S. Centers for Disease Control and Prevention (CDC) to include several additional thimerosal-containing vaccines (TCVs). On July 7, 1999, a joint recommendation was made by the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (PHS) to remove thimerosal from vaccines. A two-phase study was undertaken to evaluate trends in diagnosis of new NDs entered into the Vaccine Adverse Event Reporting System (VAERS) and the California Department of Developmental Services (CDDS) databases on a reporting quarter basis, from 1994 through 2005. Significant increasing trends in newly diagnosed NDs were observed in both databases 1994 through mid-2002. Significant decreasing trends in newly diagnosed NDs were observed in both databases from mid-2002 through 2005. The results indicate that the trends in newly diagnosed NDs correspond directly to the expansion and subsequent contraction of the cumulative mercury dose to which children were exposed from TCVs through the U.S. immunization schedule.

Background

In 2004, the Department of Health and Human Services and the American Academy of Pediatrics (AAP) issued an Autism A.L.A.R.M., stating that 1 in 166 children currently have an autistic disorder, and 1 in 6 children have a developmental and/or behavioral disorder. Autism, once rare, is now more prevalent than childhood cancer, diabetes, and Down syndrome.¹ Epidemic trends in neurodevelopmental disorders (NDs) were first observed in the United States during the 1990s,¹⁻⁸ and cannot be explained by immigration, changed diagnostic criteria, or improved identification.^{1,6-8}

Autism is an ND characterized by impairments in social relatedness and communication, repetitive behaviors, and stereotypic abnormal movements.¹ While genetic factors are important in the pathogenesis of autistic disorders, a role for environmental factors has received considerable attention.

Exposure to mercury has previously been shown to cause immune, sensory, neurological, motor, and behavioral dysfunctions similar to traits defining or associated with autistic disorders, and with similarities in neuroanatomy, neurotransmitters, and biochemistry.^{9,11} Furthermore, recent research that codes children's communicative, social, affective, repetitive behaviors, and toy play from videotapes of the toddlers' first and second birthday parties demonstrates that the regression associated with autistic disorders clearly manifests between the ages of 12 and 24 months,¹³ concurrent with the exposure to thimerosal-containing childhood vaccines (TCVs).

Thimerosal is an ethylmercury-containing compound (49.6% mercury by weight) that was historically added to many vaccines at the preservative level (0.005% to 0.01%). The U.S. Centers for Disease Control and Prevention (CDC), from the late 1980s through the 1990s, expanded the number of doses of TCVs to be administered to U.S. infants. To five doses of diphtheria-tetanus-whole-cell-pertussis (DTP) vaccine were added three doses of hepatitis B (Hep b) vaccine and four of *Haemophilus influenzae* type b (Hib) vaccine. Additionally, the CDC began recommending three doses of influenza vaccine for certain infant populations. An infant who received all of these vaccines on schedule could have received as much as 200 micrograms (μg) of mercury during the first 6 months of life.¹⁴

In response to theoretical concerns about the cumulative doses of mercury from TCVs, the AAP and the U.S. Public Health Service (PHS) issued a joint statement on July 7, 1999, calling for the removal of thimerosal from all vaccines.¹⁴ It has been estimated that the last thimerosal-containing Hep b, diphtheria-tetanus-acellular-pertussis (DTaP) and Hib vaccines were manufactured in 2000-2001 and expired at the end of 2002 (or early 2003).¹⁴ Table 1 summarizes significant historical dates in the use of pediatric TCVs in the United States.

Considering all significant environmental exposures to mercury, such as through breast milk, TCVs represent almost 50% of the total mercury dose some infants received.¹⁵ The 187.5 μg of mercury through TCVs plus the average of 164 μg from breast milk during the first 6 months exceeded the methylmercury safety guidelines established by the U.S. Environmental Protection Agency (EPA), Health Canada, the World Health Organization (WHO), the Agency for Toxic Substances Disease Registry (ATSDR), and the U.S. Food and Drug Administration (FDA).¹⁵ With no additional exposure from any source, these doses also exceeded the methylmercury guidelines for the first year of life set by all of these agencies except the FDA.¹⁵

Despite its removal from many childhood vaccines, thimerosal is still routinely added to some formulations of influenza vaccine administered to U.S. infants, as well as to several other vaccines (e.g. tetanus-diphtheria and monovalent tetanus) administered to older children and adults. In 2004, the Institute of Medicine (IOM) of the U.S. National Academy of Sciences (NAS) retreated from the stated 1999 goal of the AAP and the PHS to remove thimerosal from U.S. vaccines as soon as possible.¹⁶ Furthermore, many nations still add thimerosal to many of their pediatric vaccines, and WHO and several vaccine manufacturers still advocate the continued use of thimerosal in pediatric vaccines. As a result, assessing the safety of TCVs is a matter of significant importance.

Examinations of the Vaccine Adverse Event Reporting System (VAERS), the U.S. Department of Education, and the Vaccine Safety Datalink (VSD) databases showed significant links between exposure to TCVs and NDs.¹⁷⁻²³ Specifically, data from VAERS showed that additional doses of mercury from thimerosal-containing DTaP in comparison to thimerosal-free DTaP (administered in the late 1990s), and additional doses of thimerosal-containing DTP and Hib in comparison to *diphtheria-*