



# The Science

Children's  
Health Defense



# Generation 1: CDC's Unpublished Verstraeten Study on Hep B Showed Dramatic Increased Risk of Autism (7.6X), Sleep Disorders (5X), Speech Disorders (2.1X) and Neurodevelopmental Disorders (1.8X)

Verstraeten, Thomas M., MD, NIP, Division of Epidemiology and Surveillance, Vaccine Safety and Development Branch, Mailstop E-61, 770-639-8327.

EIS Class Year of Entry: 1999

No previous EIS Conference presentations

Mackel Award consideration: No

Number of abstracts submitted: 2, priority this abstract: 1

Strong preference for poster presentation: No

Thomas M. Verstraeten, R. Davies, D. Gu, F DeStefano

**Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.**

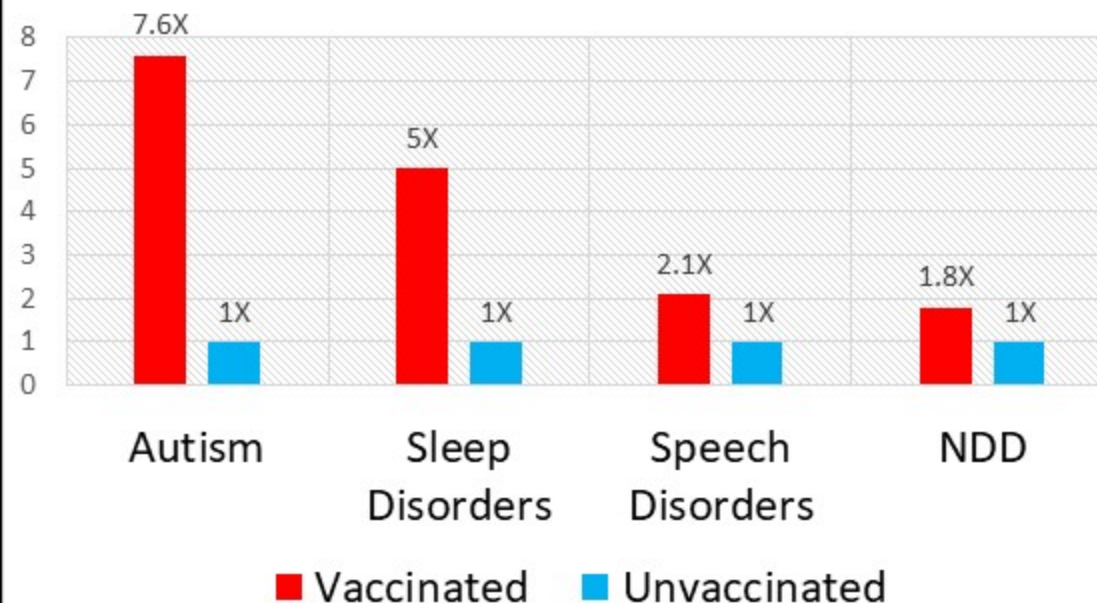
**Background:** Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. We assessed the risk for neurologic and renal impairment associated with past exposure to thimerosal-containing vaccine using automated data from the Vaccine Safety Datalink (VSD). VSD is a large linked database from four health maintenance organizations in Washington, Oregon and California, containing immunization, medical visit and demographic data on over 400,000 infants born between '91 and '97.

**Methods:** We categorized the cumulative ethylmercury exposure from thimerosal containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six. We applied proportional hazard models adjusting for HMO, year of birth, and gender, excluding premature babies.

**Results:** We identified 286 children with degenerative and 3702 with developmental neurologic disorders, and 310 with renal disorders. The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8-31.5), nonorganic sleep disorders (RR 5.0, 95% CI = 1.6-15.9), and speech disorders (RR 2.1, 95% CI = 1.1-4.0). For the neurologic degenerative

or renal impairment. Further confirmatory studies are needed.

## Vaccinated vs. Unvaccinated Risk



CDC UNPUBLISHED DATA OBTAINED BY FOIA

**“The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI=1.8-31.5), nonorganic sleep disorder (RR 5.0, 95% CI=1.6-15.9), and speech disorders (RR 2.1, 95% CI=1.1-4.0).”**

# DTP and Tetanus Vaccinations Increase the Odds of Allergies (1.63X) in Children

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*J Manipulative Physiol Ther.* 2000 Feb;23(2):81-90

**Effects of diphtheria-tetanus-pertussis or tetanus vaccination on allergies and allergy-related respiratory symptoms among children and adolescents in the United States.**

Hanitz JE<sup>1</sup>, Moenstern H

Author information

**Abstract**

**BACKGROUND:** Findings from animal and human studies confirm that diphtheria and tetanus toxoids and pertussis (DTP) and tetanus vaccinations induce allergic responses; associations between childhood vaccinations and subsequent allergies have been reported recently.

**OBJECTIVE:** The association of DTP or tetanus vaccination with allergies and allergy-related respiratory symptoms among children and adolescents in the United States was assessed.

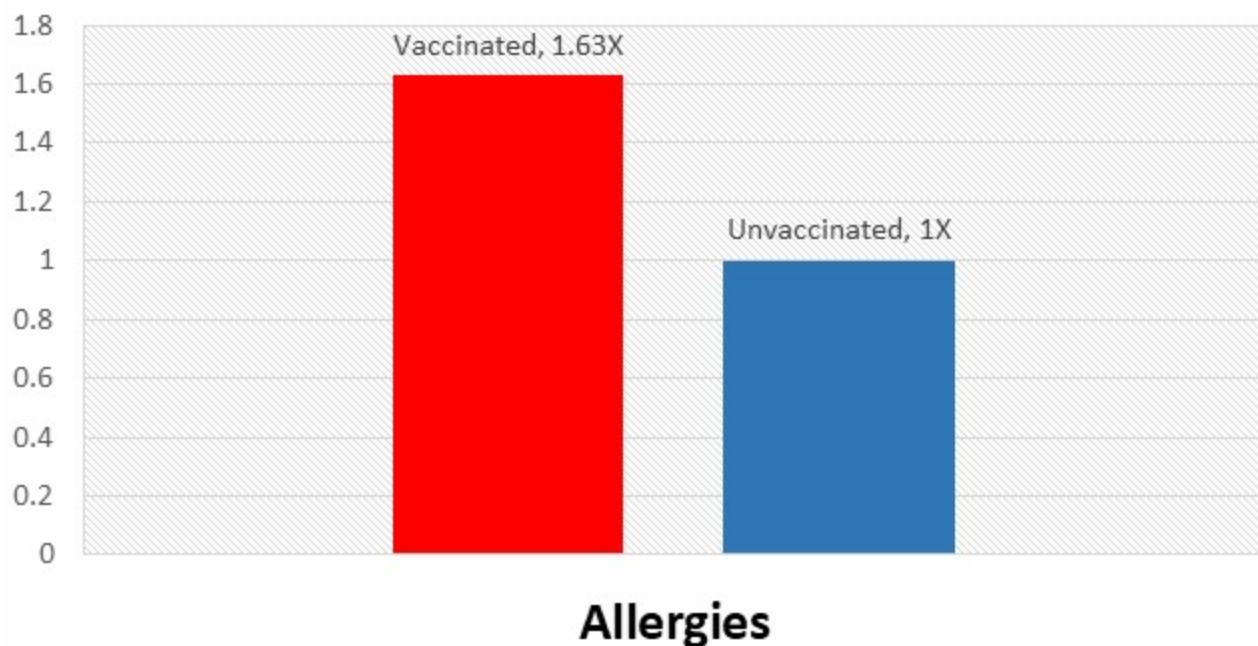
**METHODS:** Data were used from the Third National Health and Nutrition Examination Survey on infants aged 2 months through adolescents aged 16 years. DTP or tetanus vaccination, lifetime allergy history, and allergy symptoms in the past 12 months were based on parental or guardian recall. Logistic regression modeling was performed to estimate the effects of DTP or tetanus vaccination on each allergy.

**RESULTS:** The odds of having a history of asthma was twice as great among vaccinated subjects than among unvaccinated subjects (adjusted odds ratio, 2.00; 95% confidence interval, 0.59 to 6.74). The odds of having had any allergy-related respiratory symptom in the past 12 months was 63% greater among vaccinated subjects than unvaccinated subjects (adjusted odds ratio, 1.63; 95% confidence interval, 1.05 to 2.54). The associations between vaccination and subsequent allergies and symptoms were greatest among children aged 5 through 10 years.

**CONCLUSIONS:** DTP or tetanus vaccination appears to increase the risk of allergies and related respiratory symptoms in children and adolescents. Although it is unlikely that these results are entirely because of any sources of bias, the small number of unvaccinated subjects and the study design limit our ability to make firm causal inferences about the true magnitude of effect.

Published Feb 2000

## Relative Odds Between Vaccinated and Unvaccinated Children



**"The odds of having had any allergy-related respiratory symptom in the past 12 months was 63% greater among vaccinated subjects than unvaccinated subjects. Conclusions: DTP or tetanus vaccination appears to increase the risk of allergies and related respiratory symptoms in children and adolescents."**



# Hepatitis B Vaccines Increase the Odds for Special Education by 8.63X

Original Articles

## Hepatitis B triple series vaccine and developmental disability in US children aged 1–9 years

Carolyn Gallagher & Melody Goodman

Pages 997–1008 | Accepted 14 Nov 2007, Published online: 13 Nov 2008

Download citation | <https://doi.org/10.1080/02772240701806501>

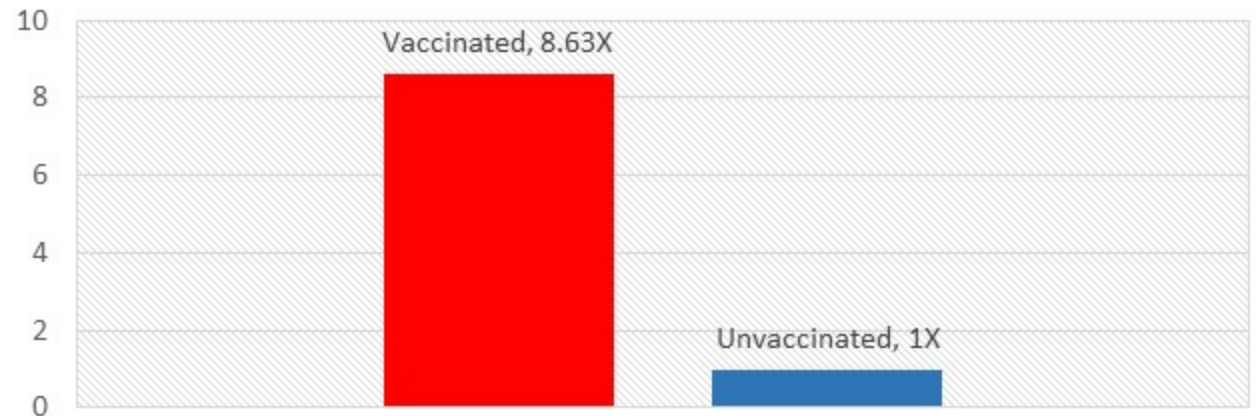
[Full Article](#) [Figures & data](#) [References](#) [Citations](#) [Metrics](#) [Reprints & Permissions](#) [Get access](#)

### Abstract

This study investigated the association between vaccination with the Hepatitis B triple series vaccine prior to 2000 and developmental disability in children aged 1–9 years ( $n = 1824$ ), proxied by parental report that their child receives early intervention or special education services (EIS). National Health and Nutrition Examination Survey 1999–2000 data were analyzed and adjusted for survey design by Taylor Linearization using SAS version 9.1 software, with SAS callable SUDAAN version 9.0.1. The odds of receiving EIS were approximately nine times as great for vaccinated boys ( $n = 46$ ) as for unvaccinated boys ( $n = 7$ ), after adjustment for confounders. This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys.

Published Oct 2008

## Boys Receiving Special Education in Vaccinated vs. Unvaccinated Sample



## Proportion Receiving Special Education Services

**“The odds of receiving EIS were approximately nine times as great for vaccinated boys ( $n=46$ ) as for unvaccinated boys ( $n=7$ ) after adjustment for confounders.”**

# Hepatitis B Vaccines in Male Newborns Increased the Odds of Autism 3X

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*J Toxicol Environ Health A*. 2010;73(24):1665-77. doi: 10.1080/15287394.2010.519317.

**Hepatitis B vaccination of male neonates and autism diagnosis, NHIS 1997-2002.**

Gallagher CM<sup>1</sup>, Goodman MS.

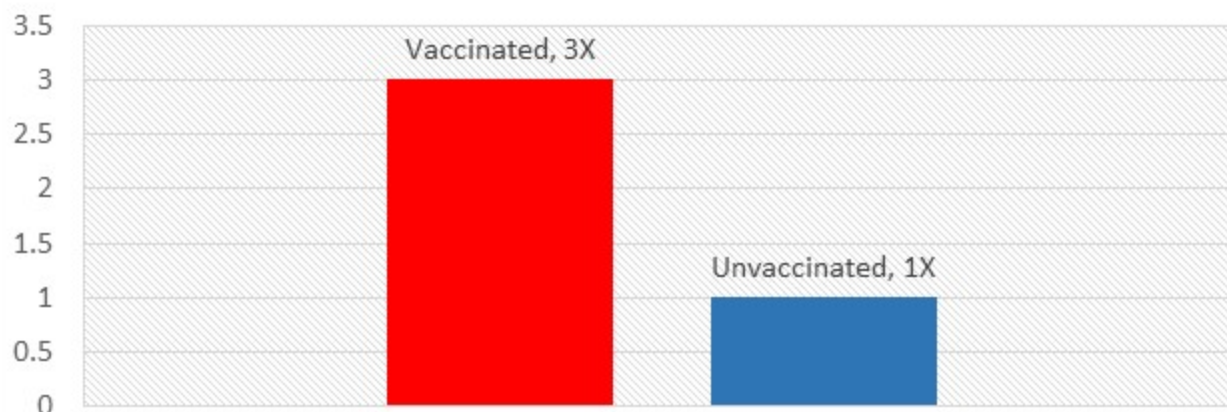
[Author information](#)

**Abstract**

Universal hepatitis B vaccination was recommended for U.S. newborns in 1991; however, safety findings are mixed. The association between hepatitis B vaccination of male neonates and parental report of autism diagnosis was determined. This cross-sectional study used weighted probability samples obtained from National Health Interview Survey 1997-2002 data sets. Vaccination status was determined from the vaccination record. Logistic regression was used to estimate the odds for autism diagnosis associated with neonatal hepatitis B vaccination among boys age 3-17 years, born before 1999, adjusted for race, maternal education, and two-parent household. Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life. Non-Hispanic white boys were 64% less likely to have autism diagnosis relative to nonwhite boys. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk.

Published Nov 2010

## Relative Odds Autism Diagnoses in Male Newborns Vaccinated with Hep B vs. Unvaccinated



Autism in Males

**“Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life. Non-Hispanic white boys were 64% less likely to have autism diagnosis relative to nonwhite boys. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk.”**

# Flu Shot Increases Rate of Non-Flu Infection 4.4X

## BRIEF REPORT

### Increased Risk of Noninfluenza Respiratory Virus Infections Associated With Receipt of Inactivated Influenza Vaccine

Benjamin J. Cowling,<sup>1</sup> Vicky J. Fang,<sup>1</sup> Hiroshi Nishiumi,<sup>1,2</sup> Kwok-Hung Chan,<sup>3</sup> Sophia Ng,<sup>1</sup> Dennis K. M. Ip,<sup>1</sup> Susan S. Chiu,<sup>4</sup> Gabriel M. Leung,<sup>1</sup> and J. S. Malik Peiris<sup>1,5</sup>

<sup>1</sup>School of Public Health, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong SAR, China; <sup>2</sup>PRESTO, Japan Science and Technology Agency, Saitama; <sup>3</sup>Department of Microbiology, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Queen Mary Hospital; <sup>4</sup>Department of Pediatrics and Adolescent Medicine, The University of Hong Kong, Queen Mary Hospital; and <sup>5</sup>Centre for Influenza Research, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong SAR, China

We randomized 115 children to trivalent inactivated influenza vaccine (TIV) or placebo. Over the following 9 months, TIV recipients had an increased risk of virologically-confirmed non-influenza infections (relative risk: 4.40; 95% confidence interval: 1.31-14.8). Being protected against influenza, TIV recipients may lack temporary non-specific immunity that protected against other respiratory viruses.

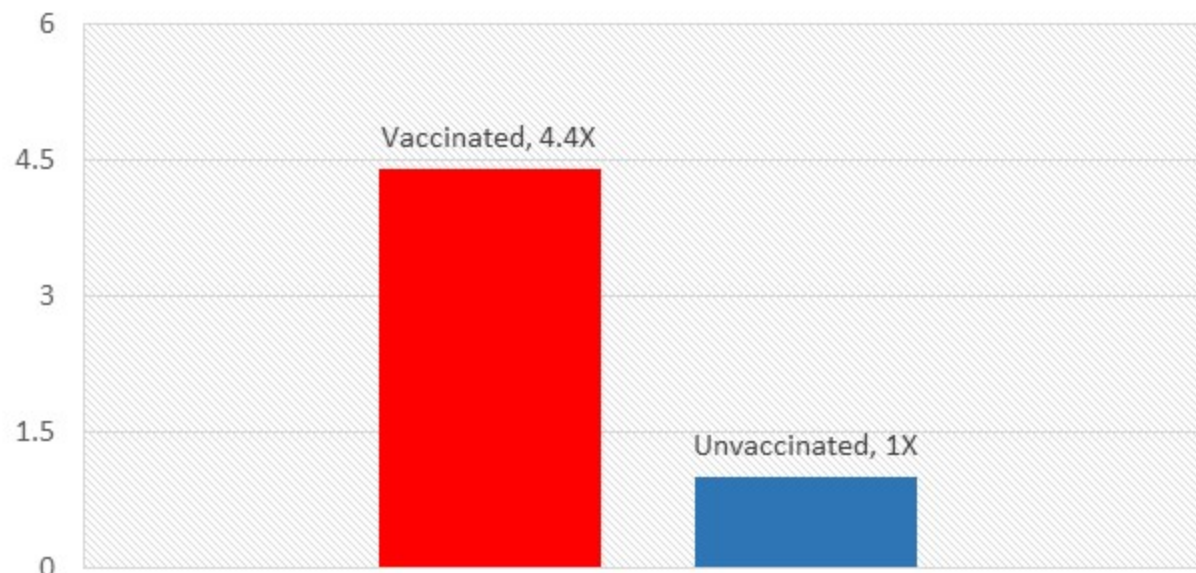
## METHODS

### Recruitment and Follow-up of Participants

In a double-blind randomized controlled trial, we randomly allocated children aged 6–15 years to receive 2008–2009 seasonal trivalent influenza inactivated vaccine (TIV; 0.5 mL Vaxigrip; Sanofi Pasteur) or placebo [16]. Serum specimens were obtained from participants before vaccination from November through December 2008, a month after vaccination, in midstudy around April 2009, and at the end of the study from August through October 2009. Participants were followed up for illnesses through symptom diaries and telephone calls, and illness reports in any household member triggered home visits during which nasal and throat swab specimens (NTSs) were collected from all household members. We defined the follow-up period for each participant from 14 days after receipt of TIV or placebo to collection of midstudy serum samples as the winter season and from collection of midstudy samples through final serum sample obtainment as the summer season.

Proxy written informed consent was obtained for all participants from their parents or legal guardians, with additional written assent from those ≥8 years of age. The study protocol was approved by the Institutional Review Board of Hong Kong University.

## Vaccinated vs. Unvaccinated Risk of Non-Flu Infections



## Relative Risk of Non-Flu Infections

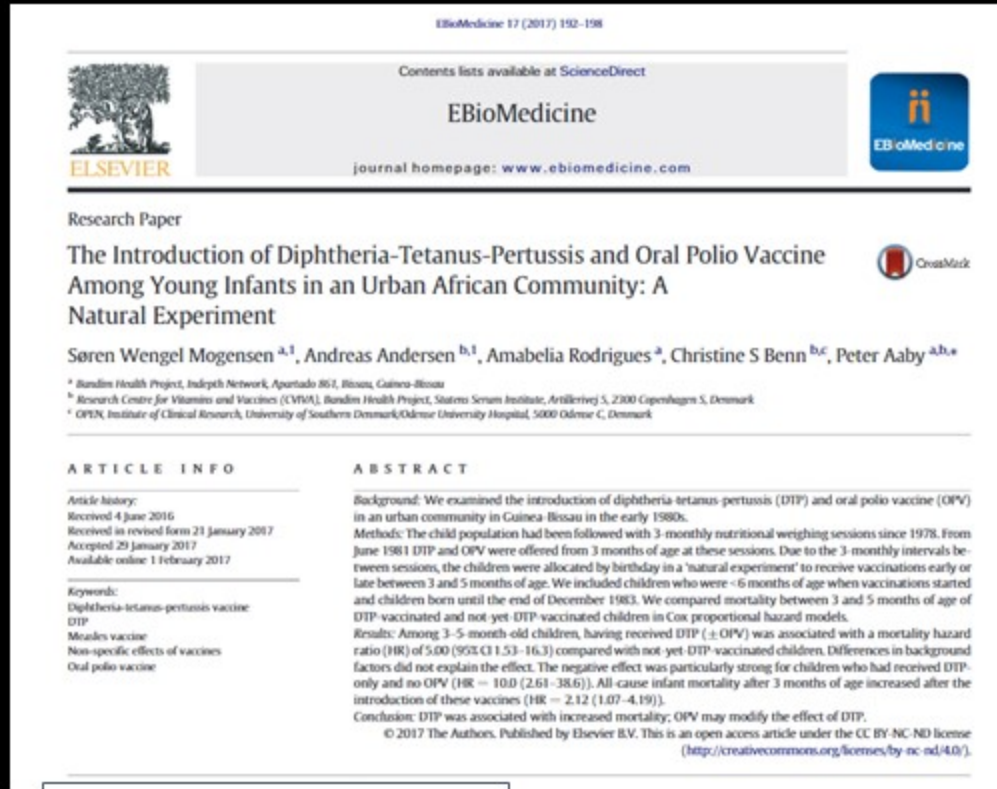
Published Mar 2012

“There was no statistically significant difference in the risk of confirmed seasonal influenza infection between recipients of TIV or placebo.”

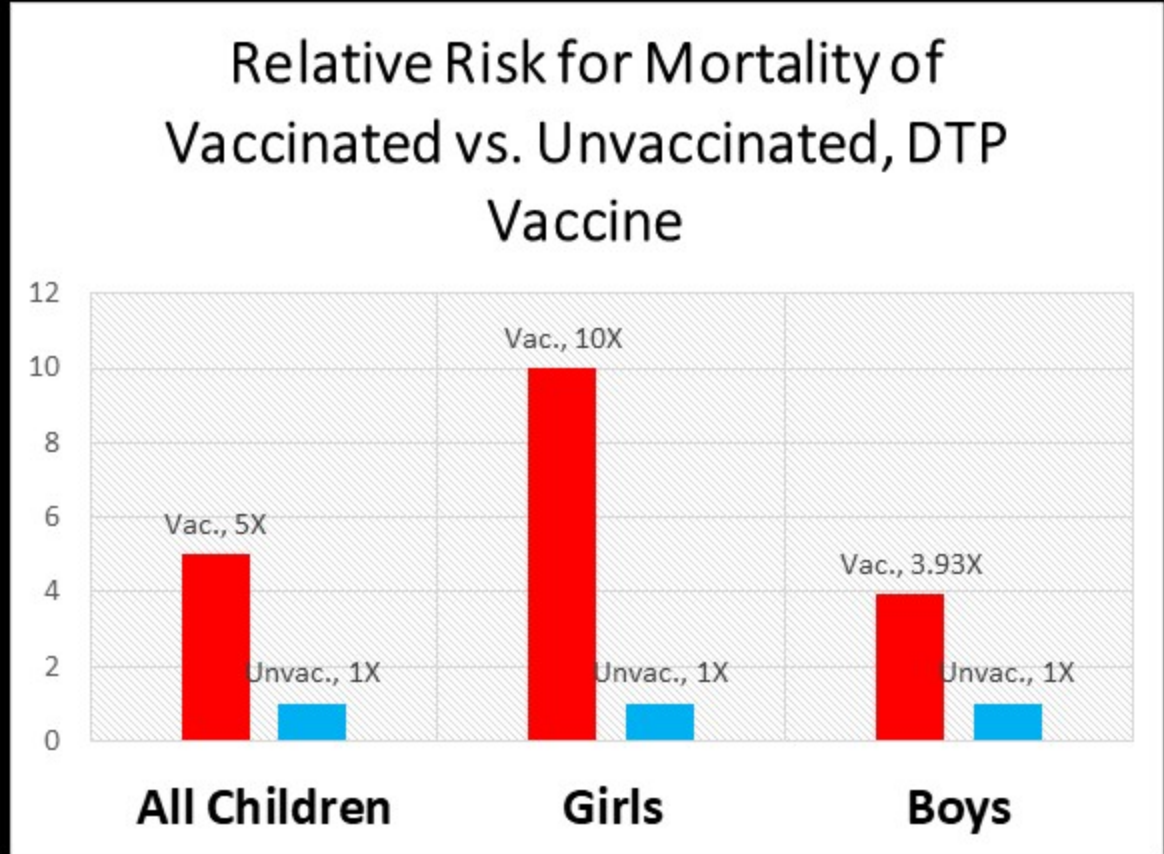
“TIV recipients had higher risk of confirmed non-influenza respiratory virus infection.”



# DTP Increases Mortality in Girls 10X



Published Jan 2017



**“DTP vaccinations were associated with increased infant mortality even though there was no vaccine-induced herd immunity. When unvaccinated controls were normal children who had not yet been eligible for vaccination, mortality was 5 times higher for DTP-vaccinated children.”**

**“All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus, or pertussis.”**

**Table 3**

Mortality rate and hazard rate (HR) for children from 3 months of age until first examination without vaccination or 6 months of age. Natural experiment.

Age group 3–5 months	Mortality rate (deaths/person-years)	HR (95% CI) of DTP vs unvaccinated
All		
Unvaccinated (N = 651)	4.5 (5/111.4)	
DTP ( $\pm$ OPV) (N = 462)	17.4 (11/63.1)	5.00 (1.53–16.3)
DTP only (N = 101)	35.2 (5/14.2)	10.0 (2.61–38.6)

**10X**

# Vaccination of Preemies Increased Odds of Neurodevelopmental Disorders 6.6X

Journal of Translational Science



Research Article

ISSN: 2059-268X

## Preterm birth, vaccination and neurodevelopmental disorders: a cross-sectional study of 6- to 12-year-old vaccinated and unvaccinated children

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<sup>a</sup>Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, 350 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, USA

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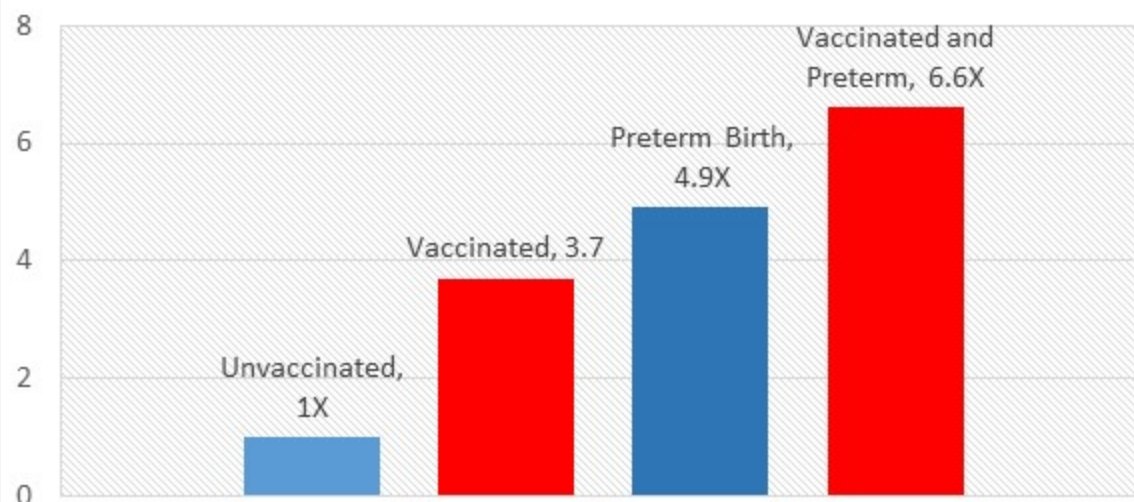
<sup>a</sup>President, National Home Education Research (NHERI), P.O. Box 13939, Salem, OR 97309, USA

### Abstract

From about 8% to 27% of extremely preterm infants develop symptoms of autism spectrum disorder, but the causes are not well understood. Preterm infants receive the same doses of the recommended vaccines and on the same schedule as term infants. The possible role of vaccination in neurodevelopmental disorders (NDD) among premature infants is unknown, in part because pre-licensure clinical trials of pediatric vaccines have excluded ex-preterm infants. This paper explores the association between preterm birth, vaccination and NDD, based on a secondary analysis of data from an anonymous survey of mothers, comparing the birth history and health outcomes of vaccinated and unvaccinated homeschooled children 6 to 12 years of age. A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated, 7.5% had an NDD (defined as a learning disability, Attention Deficit Hyperactivity Disorder and/or Autism Spectrum Disorder), and 7.7% were born preterm. No association was found between preterm birth and NDD in the absence of vaccination, but vaccination was significantly associated with NDD in children born at term (OR 2.7, 95% CI: 1.2, 6.0). However, vaccination coupled with preterm birth was associated with increasing odds of NDD, ranging from 5.4 (95% CI: 2.5, 11.9) compared to vaccinated but non-preterm children, to 14.5 (95% CI: 5.4, 38.7) compared to children who were neither preterm nor vaccinated. The results of this pilot study suggest clues to the epidemiology and causation of NDD but question the safety of current vaccination practices for preterm infants. Further research is needed to validate and investigate these associations in order to optimize the impact of vaccines on children's health.

Published April 2017

## Relative Risk of Neurodevelopmental Disorders, Pre-term Birth and Vaccinated vs. Unvaccinated



## Risk of Neurodevelopmental Disorders

**“Vaccination (i.e., receipt of one of more of the recommended vaccines) was significantly associated with NDD, while preterm birth without vaccination was not. Preterm birth coupled with vaccination, however, was associated with a synergistic increase in the odds of NDD, suggesting the possibility that vaccination could precipitate adverse neurodevelopmental outcomes in preterm infants. These results provide clues to the epidemiology and causation of NDD but question the safety of current vaccination programs for preterm infants.”**





# Vaccination Increases Risk of Allergic Rhinitis (30X), Allergy (3.1X), ADHD (4.2X), Autism (4.2X), Eczema (2.9X), Learning Disability (5.2X) and Neurodevelopmental Disorders (3.7X)

Journal of Translational Science



Research Article

ISSN: 2059-268X

## Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

Anthony R Mawson<sup>1\*</sup>, Brian D Ray<sup>2</sup>, Azad R Bhuiyan<sup>3</sup> and Binu Jacob<sup>4</sup>

<sup>1</sup>Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

<sup>2</sup>President, National Home Education Research Institute, PO Box 13939, Salem, OR 97309, USA

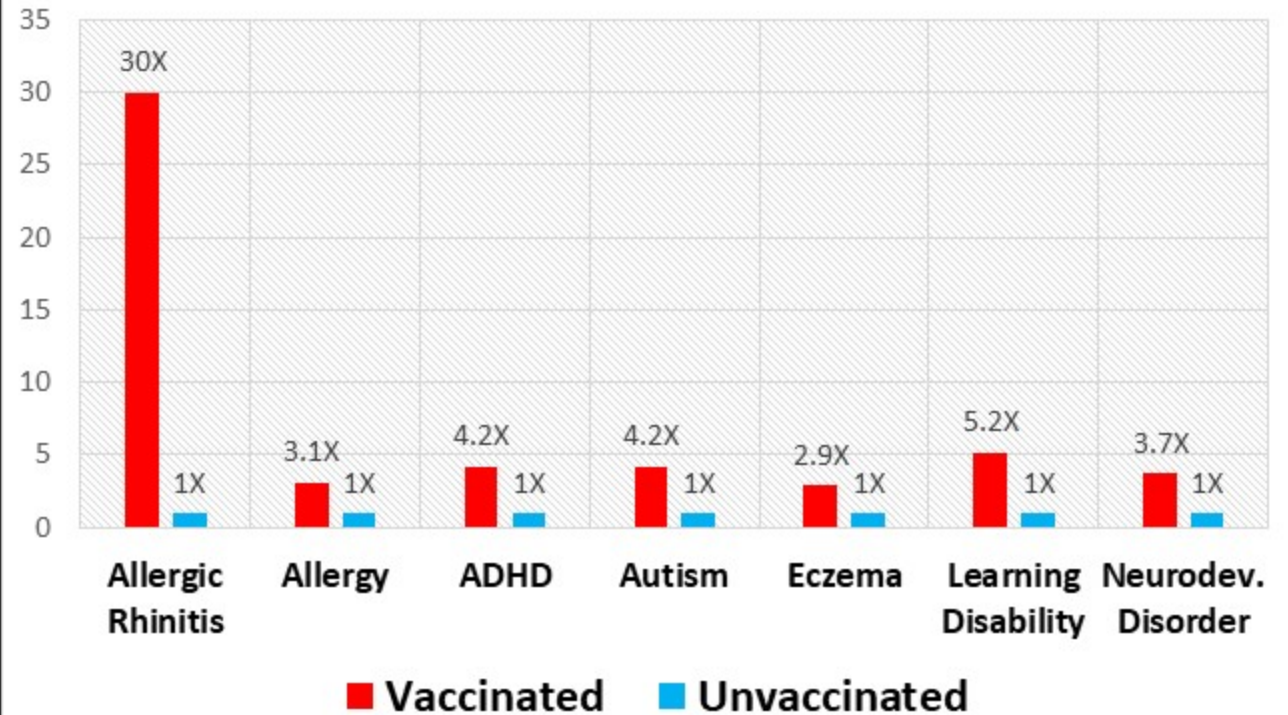
<sup>3</sup>Associate Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

<sup>4</sup>Former graduate student, Department of Epidemiology and Biostatistics School of Public Health, Jackson State University, Jackson, MS 39213, USA

### Abstract

Vaccinations have prevented millions of infectious illnesses, hospitalizations and deaths among U.S. children, yet the long-term health outcomes of the vaccination schedule remain uncertain. Studies have been recommended by the U.S. Institute of Medicine to address this question. This study aimed 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, and 2) to determine whether an association found between vaccination and neurodevelopmental disorders (NDD), if any, remained significant after adjustment for other measured factors. A cross-sectional study of mothers of children educated at home was carried out in collaboration with homeschool organizations in four U.S. states: Florida, Louisiana, Mississippi and Oregon. Mothers were asked to complete an anonymous online questionnaire on their 6- to 12-year-old biological children with respect to pregnancy-related factors, birth history, vaccinations, physician-diagnosed illnesses, medications used, and health services. NDD, a derived diagnostic measure, was defined as having one or more of the following three closely-related diagnoses: a learning disability, Attention Deficient Hyperactivity Disorder, and Autism Spectrum Disorder. A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated. The vaccinated were less likely than the unvaccinated to have been diagnosed with chickenpox and pertussis, but more likely to have been diagnosed with pneumonia, otitis media, allergies and NDD. After adjustment, vaccination, male gender, and preterm birth remained significantly associated with NDD. However, in a final adjusted model with interaction, vaccination but not preterm birth remained associated with NDD, while the interaction of preterm birth and vaccination was associated with a 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5). In conclusion, vaccinated homeschool children were found to have a higher rate of allergies and NDD than unvaccinated homeschool children. While vaccination remained significantly associated with NDD after controlling for other factors, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD. Further research involving larger, these unexpected findings in order to optimize the impact of vaccines on

## Odds of Chronic Diseases for Vaccinated vs. Unvaccinated Children



Published April 2017

"In this pilot study of vaccinated and unvaccinated homeschool children, reduced odds of chickenpox and whooping cough were found among the vaccinated, as expected, but unexpectedly increased odds were found for many other physician-diagnosed conditions."



# Vaccination Increases Type I Diabetes 3X

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*J Pediatr Endocrinol Metab*, 2003 Apr-May;16(4):495-508.

**Clustering of cases of type 1 diabetes mellitus occurring 2-4 years after vaccination is consistent with clustering after infections and progression to type 1 diabetes mellitus in autoantibody positive individuals.**

Classen JB<sup>1</sup>, Classen DC.

Author information

**Abstract**

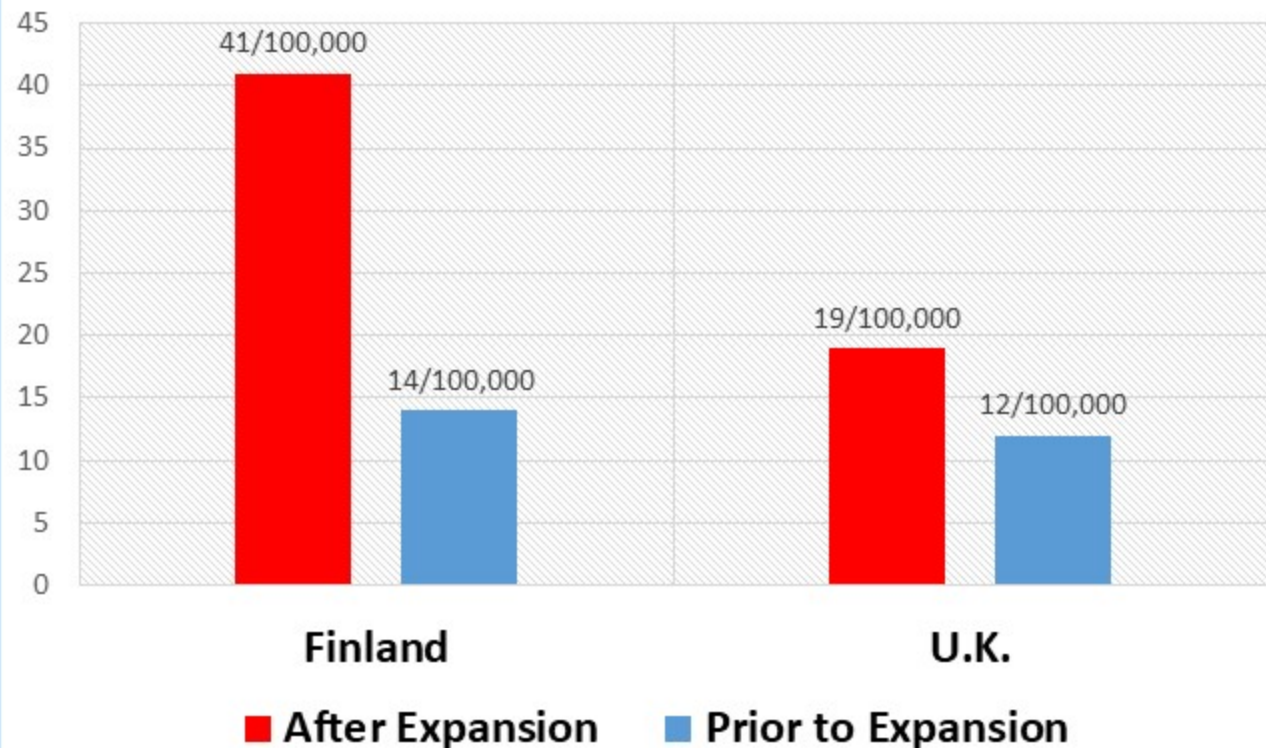
**OBJECTIVE:** We previously analyzed data from a hemophilus vaccine trial and identified clusters of extra cases of type 1 diabetes mellitus (T1DM) caused by the vaccine that occurred between 36 and 48 months after immunization. Published reports indicate clustering of cases of T1DM occurring approximately 2-4 years after mumps infection. Others have reported a 2-4 year delay between the onset of autoantibodies and the development of T1DM. We attempted to determine whether similar clustering of cases of T1DM occurred after immunization with vaccines other than hemophilus.

**METHODS:** We searched MEDLINE and reviewed references from published papers to find databases on the incidence of T1DM and then searched MEDLINE to determine whether changes in immunization occurred in these regions during the times the incidence of DM was being recorded.

**RESULTS:** Distinct rises in the incidence of T1DM occurred 2-4 years following the introduction of the MMR and pertussis vaccines. A drop in the incidence of T1DM was detected between 3-4 years following discontinuation of pertussis and BCG vaccines.

**CONCLUSION:** The identification of clusters of cases of T1DM occurring in consistent temporal time periods allowed a link between the hemophilus vaccine and T1DM to be established. The current findings indicate there are also clusters of cases of T1DM occurring 2-4 years post-immunization with the pertussis, MMR, and BCG vaccine. The data are consistent with the occurrence of clusters following mumps infection and the progression to T1DM in patients with antipancreatic autoantibodies.

## Type I Diabetes Incidence per 100,000 Prior to and After Expansion of Vaccination Schedules



**“The identification of clusters of cases of Type I diabetes occurring in consistent temporal patterns allowed a link between the hemophilus vaccine and Type I diabetes... there are also clusters of cases of Type I diabetes occurring 2-4 years post-immunization with the pertussis, MMR and BCG vaccines.”**



# Polio Vaccination Increases Type I Diabetes 2.5X

*The Open Pediatric Medicine Journal*, 2008, 2, 7-10

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## Risk of Vaccine Induced Diabetes in Children with a Family History of Type 1 Diabetes

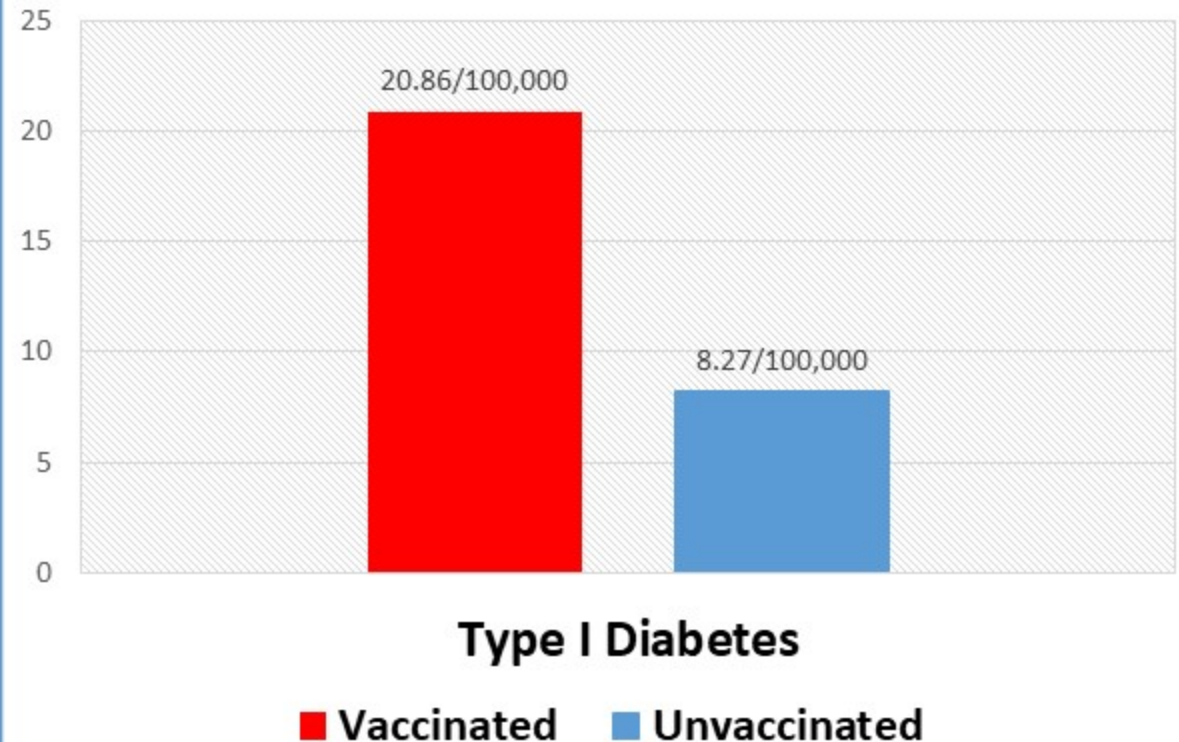
John Barthelow Classen\*

*Classen Immunotherapies Inc., 6517 Montrose Avenue, Baltimore, MD 21212, USA*

**Abstract:** Cohort data from Denmark in all children born from January 1, 1990 to December 31, 2000 was analyzed to assess the association between immunization and type 1 diabetes in all Danish children and in a subgroup where children had a sibling with type 1 diabetes. Pediatric vaccines were associated with a statistically significant increased risk of type 1 diabetes in 12 of 21 endpoints in the general population. The rate ratios in children who received at least one dose of a specific vaccine were also elevated in the subgroup and were statistically the same as in the general population. Three doses of the hemophilus vaccine were associated with a rate ratio of 1.23 ( $1.02 < RR < 1.48$ ) and an absolute risk in the general population of three cases/100,000 per year compared to 1.58 ( $0.60 < RR < 4.15$ ) and an absolute risk of 2885 cases/100,000 per year in the subgroup with a sibling with type 1 diabetes. The hemophilus immunization is associated with a cumulative attributable risk of 2.3/100 (2.3%) in the subgroup.

**Keywords:** Type 1 diabetes mellitus, vaccines, hemophilus, pertussis, polio.

## Type I Diabetes Incidence per 100,000 Children Vaccinated or Unvaccinated with All 3 Recommended Polio Vaccines



**“Pediatric vaccines were associated with a statistically significant increased risk of type 1 diabetes in 12 of 21 endpoints in the general population.”**



# Raw CDC Data Shows Vaccination on Time with MMR Increased Odds of Autism 3.64X

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*Pediatrics*, 2004 Feb;113(2):259-66.

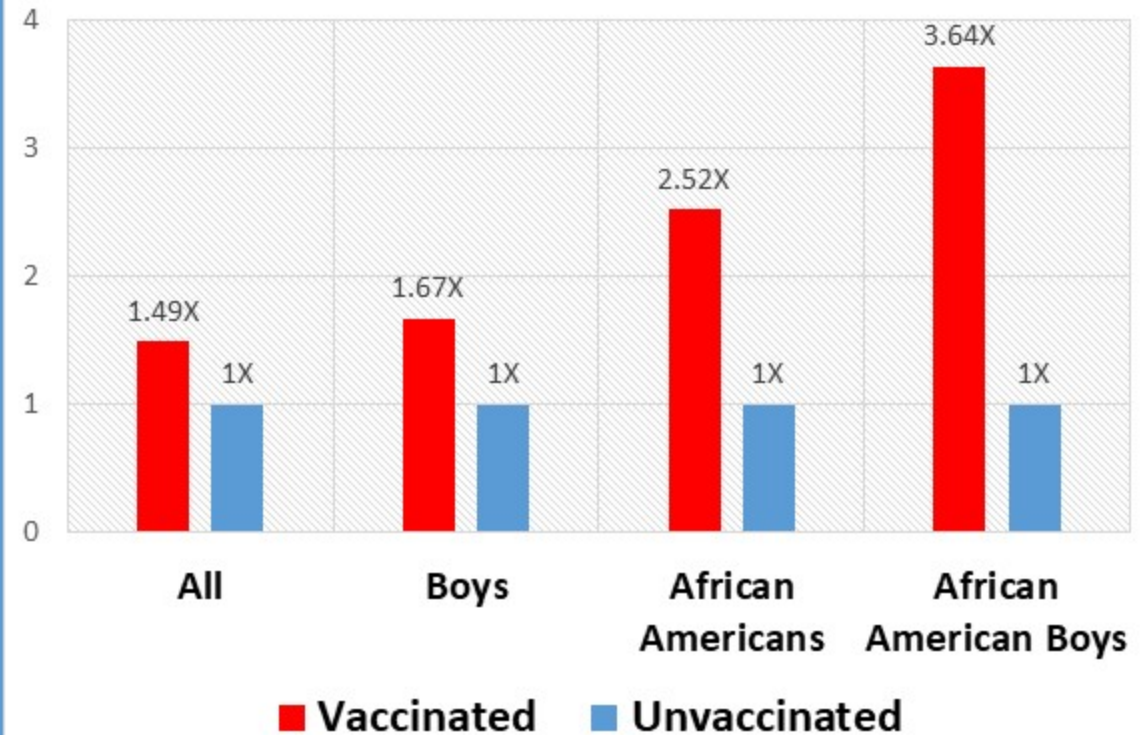
**Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan atlanta.**

DeStefano F<sup>1</sup>, Bhasin TK, Thomson WW, Yeargin-Allsopp M, Boyle C.

Author information

**Abstract**  
**OBJECTIVE:** To compare ages at first measles-mumps-rubella (MMR) vaccination between children with autism and children who did not have autism in the total population and in selected subgroups, including children with regression in development.  
**METHODS:** A case-control study was conducted in metropolitan Atlanta. Case children (N = 624) were identified from multiple sources and matched to control children (N = 1824) on age, gender, and school. Vaccination data were abstracted from immunization forms required for school entry. Records of children who were born in Georgia were linked to Georgia birth certificates for information on maternal and birth factors. Conditional logistic regression was used to estimate odds ratios (ORs).  
**RESULTS:** The overall distribution of ages at MMR vaccination among children with autism was similar to that of matched control children; most case (70.5%) and control children (67.5%) were vaccinated between 12 and 17 months of age. Similar proportions of case and control children had been vaccinated before 18 or before 24 months. No significant associations for either of these age cutoffs were found for specific case subgroups, including those with evidence of developmental regression. More case (93.4%) than control children (90.6%) were vaccinated before 36 months (OR: 1.49; 95% confidence interval: 1.04-2.14 in the total sample; OR: 1.23; 95% confidence interval: 0.64-2.36 in the birth certificate sample). This association was strongest in the 3- to 5-year age group.  
**CONCLUSIONS:** Similar proportions of case and control children were vaccinated by the recommended age or shortly after (ie, before 18 months) and before the age by which atypical development is usually recognized in children with autism (ie, 24 months). Vaccination before 36 months was more common among case children than control children, especially among children 3 to 5 years of age, likely reflecting immunization requirements for enrollment in early intervention programs.

## Odds of Autism for MMR Vaccine Before and After 36 Months of Age



CDC UNPUBLISHED DATA OBTAINED BY FOIA

# Thimerosal-Containing Hepatitis B Series Increases Odds of Autism 3.39X

*Transl Neurodegener.* 2013 Dec 19;2(1):25. doi: 10.1186/2047-9158-2-25.

**A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States.**

Geier DA, Hooker RS, Kern JK, King PG, Sykes LK, Geier MR<sup>1</sup>.

Author information

## Abstract

**BACKGROUND:** Autism spectrum disorder (ASD) is defined by standardized criteria of qualitative impairments in social interaction, qualitative impairments in communication, and restricted and stereotyped patterns of behavior, interests, and activities. A significant number of children diagnosed with ASD suffer a loss of previously-acquired skills, which is suggestive of neurodegeneration or a type of progressive encephalopathy with an etiological pathogenic basis occurring after birth. To date, the etiology of ASD remains under debate, however, many studies suggest toxicity, especially from mercury (Hg), in individuals diagnosed with an ASD. The present study evaluated concerns about the toxic effects of organic-Hg exposure from Thimerosal (49.55% Hg by weight) in childhood vaccines by conducting a two-phased (hypothesis generating/hypothesis testing) study with documented exposure to varying levels of Thimerosal from vaccinations.

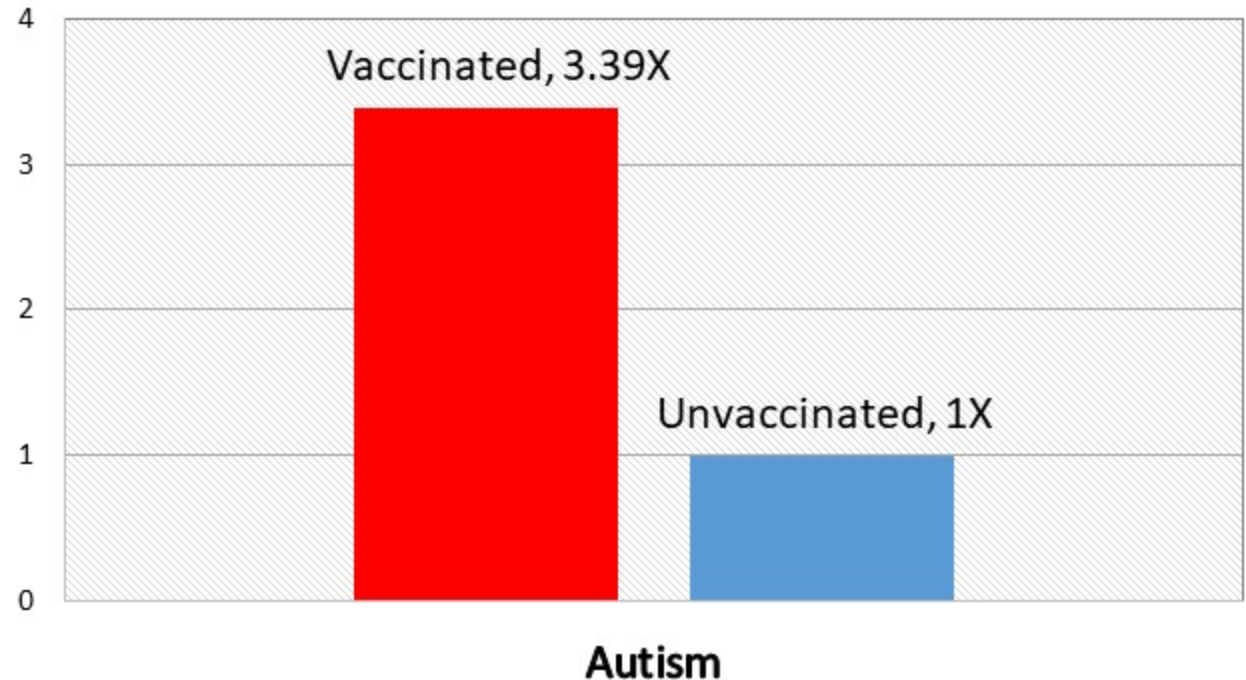
**METHODS:** A hypothesis generating cohort study was undertaken to evaluate the relationship between exposure to organic-Hg from a Thimerosal-containing Diphtheria-Tetanus-acellular-Pertussis (DTaP) vaccine in comparison to a Thimerosal-free DTaP vaccine administered, from 1998 through 2000, for the risk of ASD as reported in the Vaccine Adverse Event Reporting System (VAERS) database (phase I). A hypothesis testing case-control study was undertaken to evaluate the relationship between organic-Hg exposure from Thimerosal-containing hepatitis B vaccines administered at specific intervals in the first six months of life among cases diagnosed with an ASD and controls born between 1991 through 1999 in the Vaccine Safety Datalink (VSD) database (phase II).

**RESULTS:** In phase I, it was observed that there was a significantly increased risk ratio for the incidence of ASD reported following the Thimerosal-containing DTaP vaccine in comparison to the Thimerosal-free DTaP vaccine. In phase II, it was observed that cases diagnosed with an ASD were significantly more likely than controls to receive increased organic-Hg from Thimerosal-containing hepatitis B vaccine administered within the first, second, and sixth month of life.

**CONCLUSIONS:** 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 supporting an association between increasing organic-Hg exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an ASD diagnosis.

PMD: 24354891 PMCID: PMC3876266 DOI: 10.1186/2047-9158-2-25

## Odds of Receiving an Autism Diagnosis from Receiving Thimerosal-Containing Hepatitis B Vaccines



**“It was observed that cases diagnosed with an ASD were significantly more likely than controls to receive increased organic-Hg from Thimerosal-containing hepatitis B vaccine administered within the first, second, and sixth month of life.”**



# Human Papilloma Virus Vaccine Increases the Odds of Asthma 8.01X

SAGE Open Med. 2019 Jan 8;7:2050312118822650. doi: 10.1177/2050312118822650. eCollection 2019.

**A cross-sectional study of the relationship between reported human papillomavirus vaccine exposure and the incidence of reported asthma in the United States.**

Geier DA<sup>1,2</sup>, Kern JK<sup>1,2</sup>, Geier MR<sup>1,2</sup>.

Author information

## Abstract

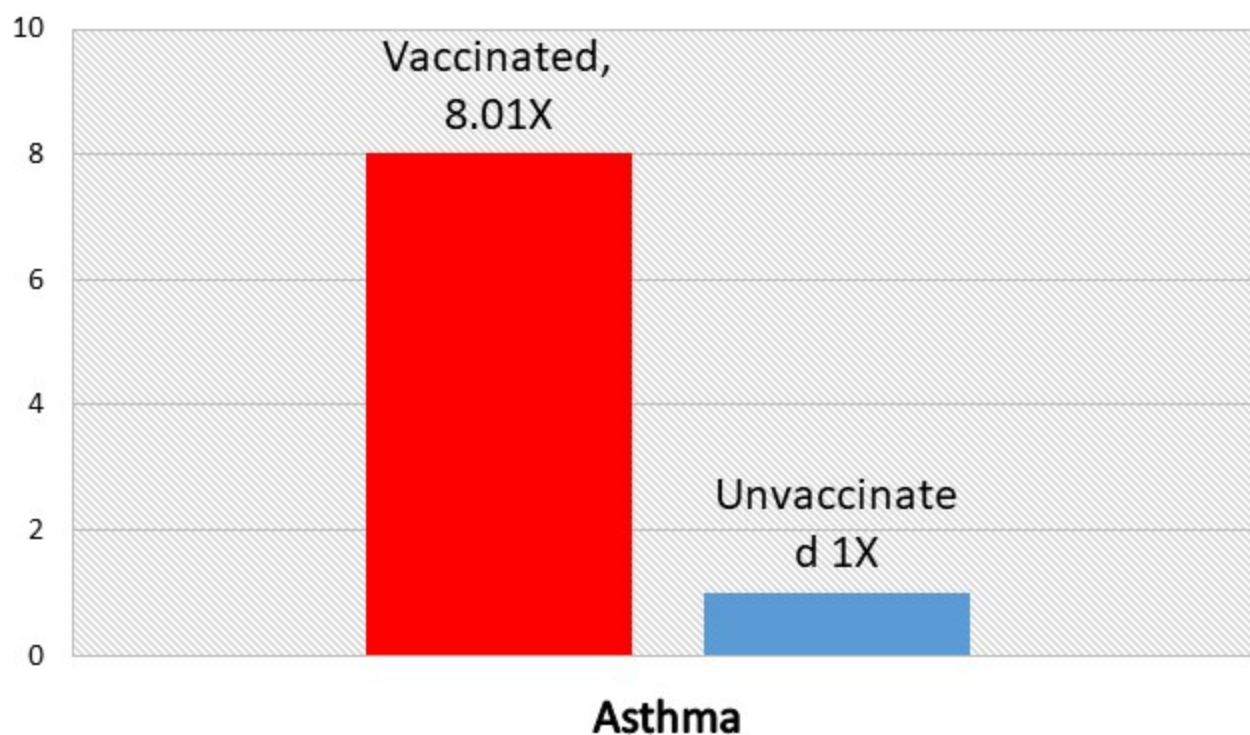
**OBJECTIVES:** Asthma is a chronic disorder that affects persons of all ages impacting the quality of their lives. This cross-sectional hypothesis-testing study evaluated the relationship between human papillomavirus vaccine and the risk of an incident asthma diagnosis in a defined temporal period post-vaccination.

**METHODS:** The 2015-2016 National Health and Nutrition Examination Survey data were examined for a group of 60,934,237 weighted persons between 9 and 26 years old in Statistical Analysis Software.

**RESULTS:** Reported incident asthma significantly clustered in the year of reported human papillomavirus vaccination. When the data were separated by gender, the effects observed remained significant for males but not females.

**CONCLUSION:** The results suggest that human papillomavirus vaccination resulted in an excess of 261,475 asthma cases with an estimated direct excess lifetime cost of such persons being US\$42 billion. However, it is unclear what part of the vaccine and/or vaccine medium may have increased an individual's susceptibility to an asthma episode, whether the asthma diagnosis represented one asthma episode or if it is chronic, and how much therapeutic support was needed (if any) and for how long, which would impact cost. Despite the negative findings in this study, routine vaccination is an important public health tool, and the results observed need to be viewed in this context.

## Odds of Asthma Diagnosis After HPV Vaccine



**“The results suggest that human papillomavirus vaccination resulted in an excess of 261,475 asthma cases with an estimated direct excess lifetime cost of such persons being US\$42 billion.”**



# Thimerosal-Containing Hepatitis B Series Increases Odds of Premature Puberty 2.1X

Toxics, 2018 Nov 15;6(4). pii: E67. doi: 10.3390/toxics6040067.

## Premature Puberty and Thimerosal-Containing Hepatitis B Vaccination: A Case-Control Study in the Vaccine Safety Datalink.

Geier DA<sup>1,2</sup>, Kern JA<sup>3,4,5</sup>, Geier MR<sup>6,7</sup>.

© Author information

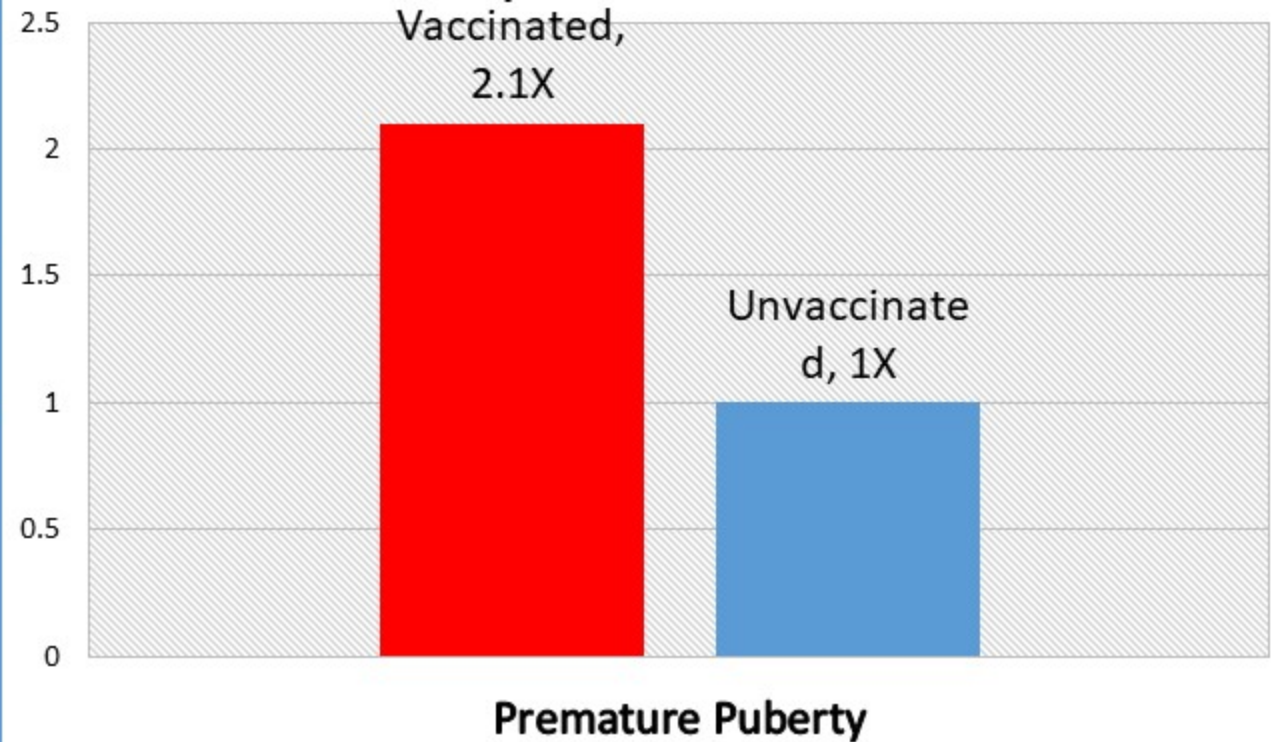
### Abstract

Studies suggest a relationship between exposure to endocrine disruptors, such as mercury (Hg), and premature puberty. Hg exposure from Thimerosal-containing hepatitis B vaccine, administered at specific intervals within the first six months of life, and the child's long-term risk of being diagnosed with premature puberty (ICD-9 code: 259.1), was retrospectively examined, using a hypothesis-testing, longitudinal case-control design on prospectively collected data, in the Vaccine Safety Datalink (VSD). Cases diagnosed with premature puberty were significantly more likely to have received increased exposure to Hg from hepatitis B vaccines preserved with Thimerosal given in the first month after birth (odds ratio (OR) = 1.803), first two months after birth (OR = 1.768), and first six months after birth (OR = 2.0955), compared to control subjects. When the data were separated by gender, the effects remained among females but not males. Female cases, as compared to female controls, were significantly more likely in a dose-dependent manner to have received a greater exposure to Hg from hepatitis B vaccines preserved with Thimerosal, given in the first six months after birth (OR = 1.0281 per  $\mu\text{g}$  Hg). The results of this study show a dose-dependent association between increasing organic Hg exposure from Thimerosal-containing hepatitis B vaccines administered within the first six months of life and the long-term risk of the child being diagnosed with premature puberty.

**KEYWORDS:** ethylmercury; mercury; methylate; premature puberty; thiomersal

PMID: 30445743 PMCID: PMC6316152 DOI: 10.3390/toxics6040067

## Odds of Receiving an Premature Puberty Diagnosis from Receiving Thimerosal-Containing Hepatitis B Vaccines



“The results of this study show a dose-dependent association between increasing organic Hg exposure from Thimerosal-containing hepatitis B vaccines administered within the first six months of life and the long-term risk of the child being diagnosed with premature puberty.”

# MMR Vaccine Increases Risk of Crohn's Disease 3.01X and Ulcerative Colitis 2.53X

Lancet, 1995 Apr 29;345(8957):1071-4.

## Is measles vaccination a risk factor for inflammatory bowel disease?

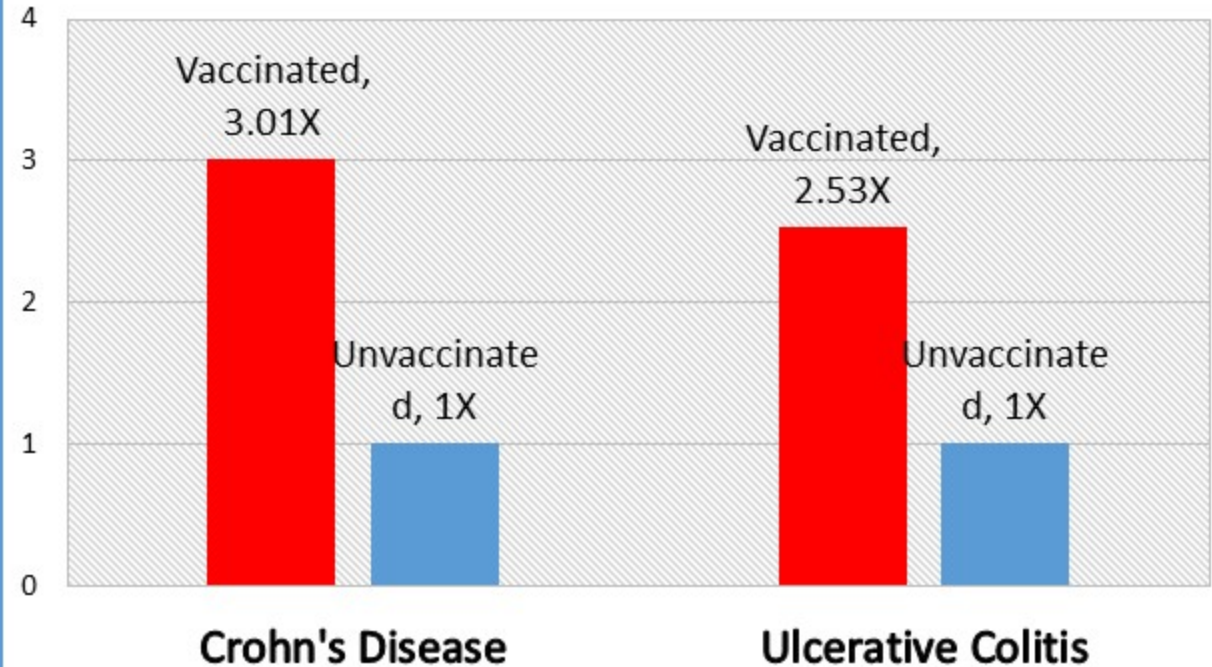
Thompson NP<sup>1</sup>, Montgomery SM, Pounder RE, Wakefield AJ.

⊕ Author information

### Abstract

Measles virus may persist in intestinal tissue, particularly that affected by Crohn's disease, and early exposure to measles may be a risk factor for the development of Crohn's disease. Crohn's disease and ulcerative colitis occur in the same families and may share a common aetiology. In view of the rising incidence of inflammatory bowel disease (Crohn's disease and ulcerative colitis), we examined the impact of measles vaccination upon these conditions. Prevalences of Crohn's disease, ulcerative colitis, coeliac disease, and peptic ulceration were determined in 3545 people who had received live measles vaccine in 1964 as part of a measles vaccine trial. A longitudinal birth cohort of 11,407 subjects was one unvaccinated comparison cohort, and 2541 partners of those vaccinated was another. Compared with the birth cohort, the relative risk of developing Crohn's disease in the vaccinated group was 3.01 (95% CI 1.45-6.23) and of developing ulcerative colitis was 2.53 (1.15-5.58). There was no significant difference between these two groups in coeliac disease prevalence. Increased prevalence of inflammatory bowel disease, but not coeliac disease or peptic ulceration, was found in the vaccinated cohort compared with their partners. These findings suggest that measles virus may play a part in the development not only of Crohn's disease but also of ulcerative colitis.

## Risk of Crohn's Disease and Ulcerative Colitis After MMR Vaccine



**“These findings suggest that measles virus may play a part in the development not only of Crohn's disease but also of ulcerative colitis.”**





# Thimerosal Containing Hepatitis B Vaccines – When Compared to Children Vaccinated Without Thimerosal - Increased Odds of ADHD 1.98X

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National Institutes of Health

Format: Abstract  
Advanced

J Trace Elem Med Biol. 2018 Mar;46:1-9. doi: 10.1016/j.jtemb.2017.11.001. Epub 2017 Nov 8.

**A cross-sectional study of the relationship between infant Thimerosal-containing hepatitis B vaccine exposure and attention-deficit/hyperactivity disorder.**

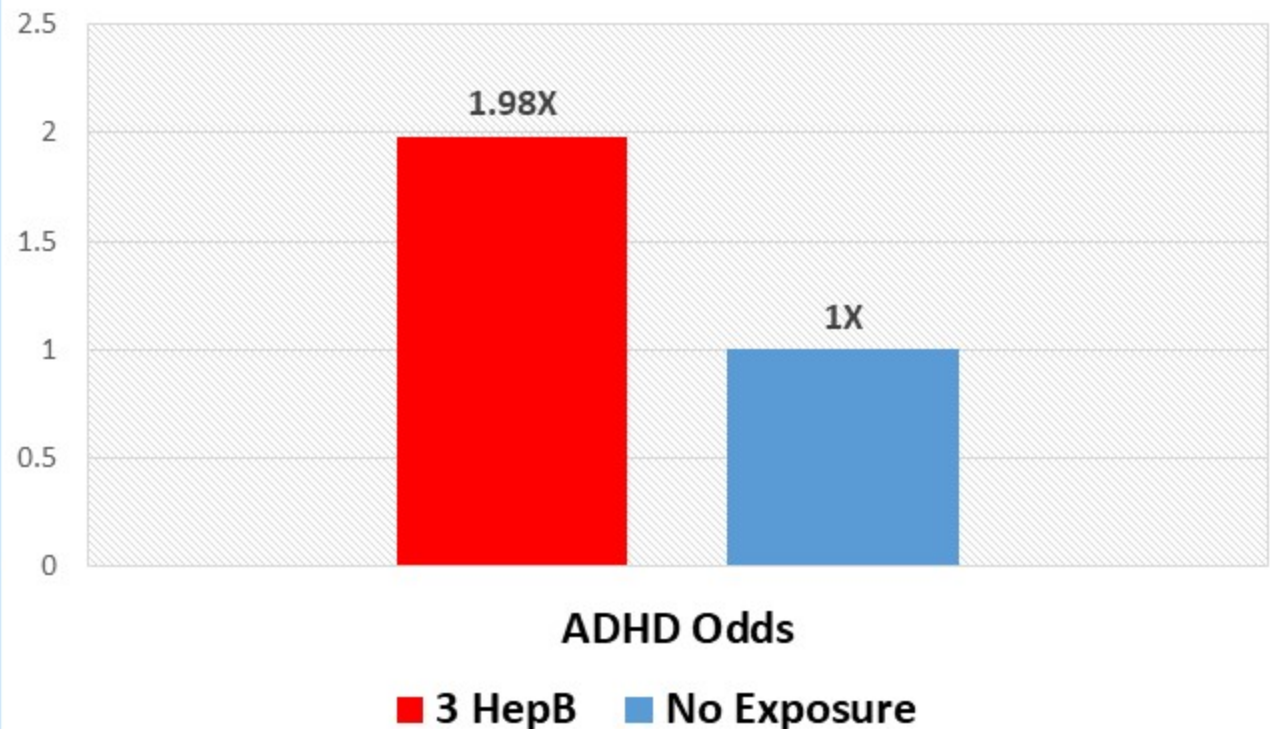
Geier DA<sup>1</sup>, Kern JK<sup>2</sup>, Homme KG<sup>3</sup>, Geier MR<sup>4</sup>.

Author information

**Abstract**  
Attention-deficit/hyperactivity disorder (ADHD) is characterized by a marked pattern of inattention and/or hyperactivity-impulsivity that is inconsistent with developmental level and interferes with normal functioning in at least two settings. This study evaluated the hypothesis that infant Thimerosal-containing hepatitis B vaccine (T-HepB) exposure would increase the risk of an ADHD diagnosis. This cross-sectional study examined 4393 persons between 13 and 19 years of age from the combined 1999-2004 National Health and Nutritional Examination Survey (NHANES) by analyzing demographic, immunization, socioeconomic, and health-related variables using the SAS system. Three doses of T-HepB exposure in comparison to no exposure significantly increased the risk of an ADHD diagnosis using logistic regression (adjusted odds ratio=1.980), linear regression (adjusted beta-coefficient=0.04747), Spearman's rank (Rho=0.04807), and 2x2 contingency table (rate ratio=1.8353) statistical modeling even when considering other covariates such as gender, race, and socioeconomic status. Current health status outcomes selected on an a priori basis to not be biologically plausibly linked to T-HepB exposure showed no relationship with T-HepB. The observed study results are biologically plausible and supported by numerous previous epidemiological studies, but because the NHANES data is collected on a cross-sectional basis, it is not possible to ascribe a direct cause-effect relationship between exposure to T-HepB and an ADHD diagnosis. During the decade from 1991 to 2001 that infants were routinely exposed to T-HepB in the United States (US), an estimated 1.3-2.5 million children were diagnosed with ADHD with excess lifetime costs estimated at US \$350-\$660 billion as a consequence of T-HepB. Although Thimerosal use in the HepB in the US has been discontinued, Thimerosal remains in the HepB in developing countries. Routine vaccination is an important public health tool to prevent infectious diseases, but every effort should be made to eliminate Thimerosal exposure.

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## Odds of ADHD Diagnosis After Exposure to Thimerosal Containing Triple HepB Series



**“During the decade from 1991 to 2001 that infants were routinely exposed to T-HepB (thimerosal containing HepB) in the United States (US), an estimated 1.3-2.5 million children were diagnosed with ADHD with excess lifetime costs estimated at US \$350-\$660 billion as a consequence of T-HepB.”**



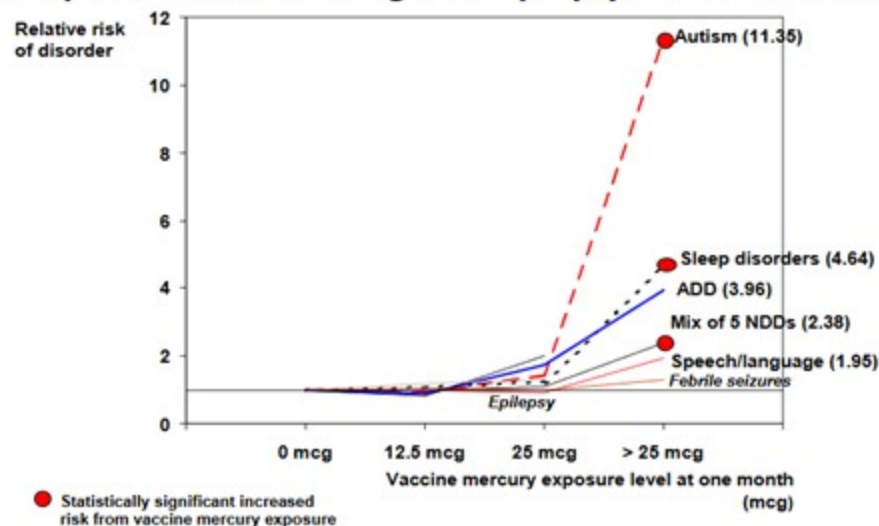
# Highest Levels of Thimerosal Exposure Increase Autism Risk 11.35X

## GENERATION ZERO

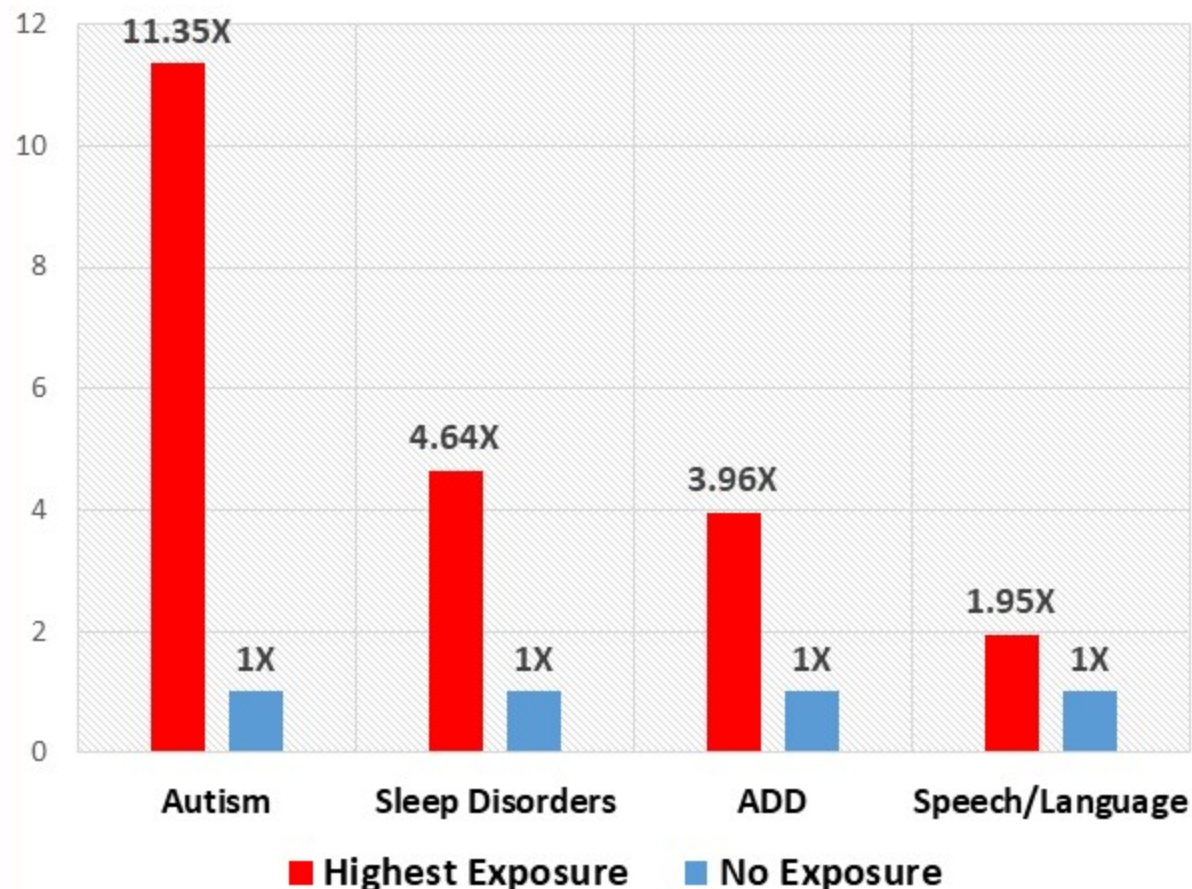
*Thomas Verstraeten's First Analyses of the Link Between Vaccine Mercury Exposure and the Risk of Diagnosis of Selected Neuro-Developmental Disorders Based on Data from the Vaccine Safety Datalink: November-December 1999*

Safe Minds  
September 2004

## ONE MONTH EXPOSURE: SUMMARY ANALYSIS OF FIVE NDDs Comparison to Control Diagnoses Epilepsy and Febrile Seizures



## Highest Level of Exposure Versus No Exposure



CDC UNPUBLISHED DATA OBTAINED BY FOIA

# Two H1N1-Containing Influenza Vaccines Prior to and During Pregnancy Increases Miscarriage Odds by 7.7X

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US National Library of Medicine  
National Institutes of Health

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Vaccine. 2017 Sep 25;35(40):5314-5322. doi: 10.1016/j.vaccine.2017.06.069.

**Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010-11 and 2011-12.**

Donahue JG<sup>1</sup>, Kleke BA<sup>2</sup>, King JP<sup>3</sup>, DeStefano F<sup>4</sup>, Mascola JM<sup>5</sup>, Irving SA<sup>6</sup>, Cheetham TC<sup>7</sup>, Glanz JM<sup>8</sup>, Jackson LA<sup>9</sup>, Klein NP<sup>10</sup>, Nalewaj AL<sup>11</sup>, Weintraub E<sup>12</sup>, Balongia EA<sup>13</sup>.

Ⓜ Author information

**Abstract**

**INTRODUCTION:** Inactivated influenza vaccine is recommended in any stage of pregnancy, but evidence of safety in early pregnancy is limited, including for vaccines containing A/H1N1pdm2009 (pH1N1) antigen. We sought to determine if receipt of vaccine containing pH1N1 was associated with spontaneous abortion (SAB).

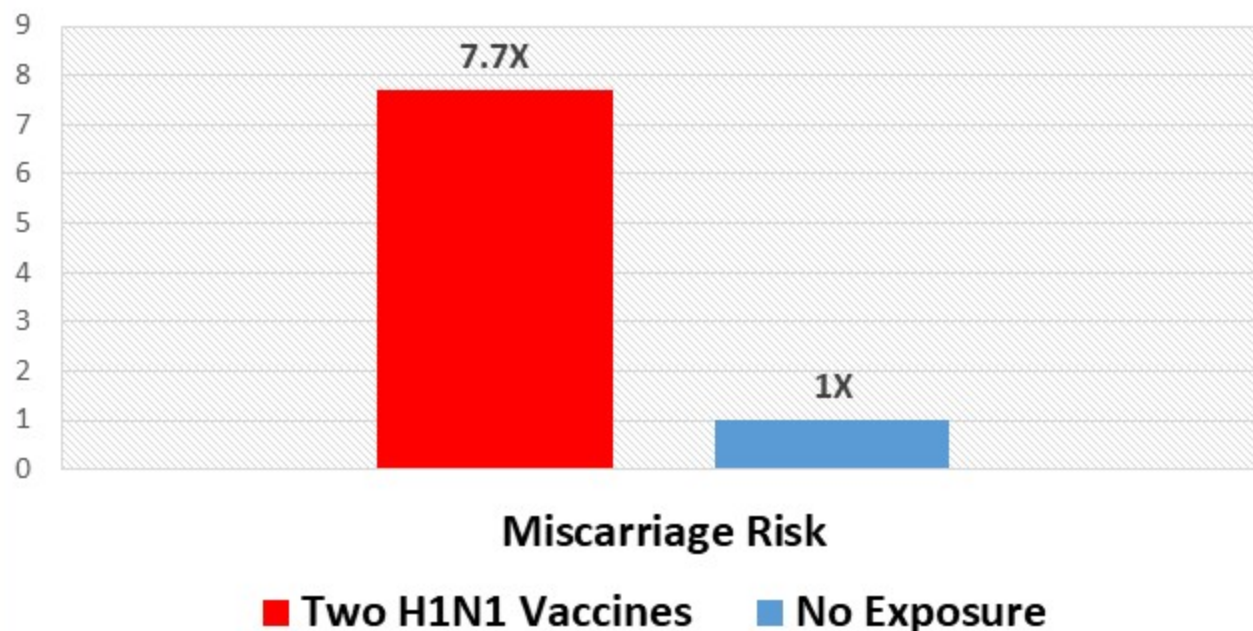
**METHODS:** We conducted a case-control study over two influenza seasons (2010-11, 2011-12) in the Vaccine Safety Datalink. Cases had SAB and controls had live births or stillbirths and were matched on site, date of last menstrual period, and age. Of 919 potential cases identified using diagnosis codes, 485 were eligible and confirmed by medical record review. Exposure was defined as vaccination with inactivated influenza vaccine before the SAB date; the primary exposure window was the 1-28days before the SAB.

**RESULTS:** The overall adjusted odds ratio (aOR) was 2.0 (95% CI, 1.1-3.6) for vaccine receipt in the 28-day exposure window; there was no association in other exposure windows. In season-specific analyses, the aOR in the 1-28days was 3.7 (95% CI 1.4-9.4) in 2010-11 and 1.4 (95% CI 0.6-3.3) in 2011-12. The association was modified by influenza vaccination in the prior season (post hoc analysis). Among women who received pH1N1-containing vaccine in the previous influenza season, the aOR in the 1-28days was 7.7 (95% CI 2.2-27.3); the aOR was 1.3 (95% CI 0.7-2.7) among women not vaccinated in the previous season. This effect modification was observed in each season.

**CONCLUSION:** SAB was associated with influenza vaccination in the preceding 28days. The association was significant only among women vaccinated in the previous influenza season with pH1N1-containing vaccine. This study does not and cannot establish a causal relationship between repeated influenza vaccination and SAB, but further research is warranted.

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## Odds of Miscarriage Within 28 Days of H1N1-Containing Influenza Vaccine in Women Receiving the Same Vaccine in the Previous Year



**“SAB (spontaneous abortion) was associated with influenza vaccination in the preceding 28 days. The association was significant only among women vaccinated in the previous influenza season with pH1N1-containing vaccine.”**



# H1N1 Influenza Vaccine Increases Risks of Bell's Palsy (1.34X), Paraesthesia (1.25X) and Inflammatory Bowel Disease (1.25X) in High Risk Patients

PubMed  
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National Institutes of Health

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H1N1 Bardage 2011  
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BMJ. 2011 Oct 12;343:d5956. doi: 10.1136/bmj.d5956.

**Neurological and autoimmune disorders after vaccination against pandemic influenza A (H1N1) with a monovalent adjuvanted vaccine: population based cohort study in Stockholm, Sweden.**

Bardage G<sup>1</sup>, Persson J, Orqvist A, Bereman U, Ludvigsson JF, Granath F.

Author information

**Abstract**

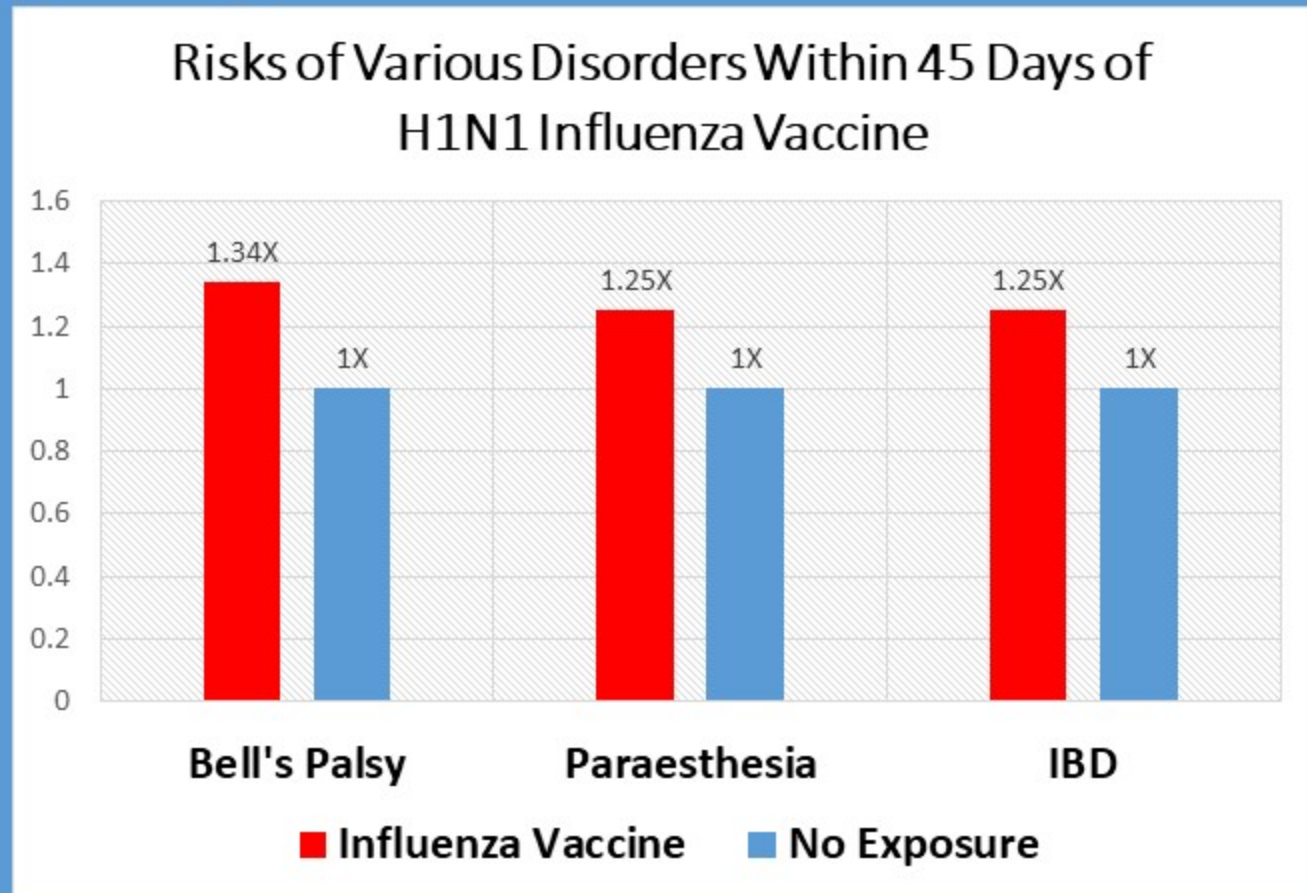
**OBJECTIVE:** To examine the risk of neurological and autoimmune disorders of special interest in people vaccinated against pandemic influenza A (H1N1) with Pandemrix (GlaxoSmithKline, Middlesex, UK) compared with unvaccinated people over 8-10 months.

**DESIGN:** Retrospective cohort study linking individualised data on pandemic vaccinations to an inpatient and specialist database on healthcare utilisation in Stockholm county for follow-up during and after the pandemic period.

**SETTING:** Stockholm county, Sweden. Population All people registered in Stockholm county on 1 October 2009 and who had lived in this region since 1 January 1998; 1,024,019 were vaccinated against H1N1 and 921,005 remained unvaccinated.

**MAIN OUTCOME MEASURES:** Neurological and autoimmune diagnoses according to the European Medicines Agency strategy for monitoring of adverse events of special interest defined using ICD-10 codes for Guillain-Barré syndrome, Bell's palsy, multiple sclerosis, polyneuropathy, anaesthesia or hypoaesthesia, paraesthesia, narcolepsy (added), and autoimmune conditions such as rheumatoid arthritis, inflammatory bowel disease, and type 1 diabetes; and short term mortality according to vaccination status.

**RESULTS:** Excess risks among vaccinated compared with unvaccinated people were of low magnitude for Bell's palsy (hazard ratio 1.25, 95% confidence interval 1.06 to 1.48) and paraesthesia (1.11, 1.00 to 1.23) after adjustment for age, sex, socioeconomic status, and healthcare utilisation. Risks for Guillain-Barré syndrome, multiple sclerosis, type 1 diabetes, and rheumatoid arthritis remained unchanged. The risks of paraesthesia and inflammatory bowel disease among those vaccinated in the early phase (within 45 days from 1 October 2009) of the vaccination campaign were significantly increased; the risk being increased within the first six weeks after vaccination. Those vaccinated in the early phase were at a slightly reduced risk of death than those who were unvaccinated (0.94, 0.91 to 0.98), whereas those vaccinated in the late phase had an overall reduced mortality (0.68, 0.64 to 0.71). These associations



**“Relative risks were significantly increased for Bell's palsy, paraesthesia, and inflammatory bowel disease after vaccination, predominantly in the early phase of the vaccination campaign.**



# HPV Vaccination Increases Odds of Memory Impairment (1.23X) and Involuntary Movement (1.53X)

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National Institutes of Health

PubMed yaju tsubaki papilloma  
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Jan J Nurs Sci. 2019 Jan 28; doi: 10.1111/jns.12252. [Epub ahead of print]

**Safety concerns with human papilloma virus immunization in Japan: Analysis and evaluation of Nagoya City's surveillance data for adverse events.**

Yaju Y<sup>1</sup>, Tsubaki H<sup>2</sup>.

Author information

**Abstract**

**AIM:** To assess the safety of human papilloma virus (HPV) vaccines by using data from the "Nagoya City Cervical Cancer Immunization Program Survey".

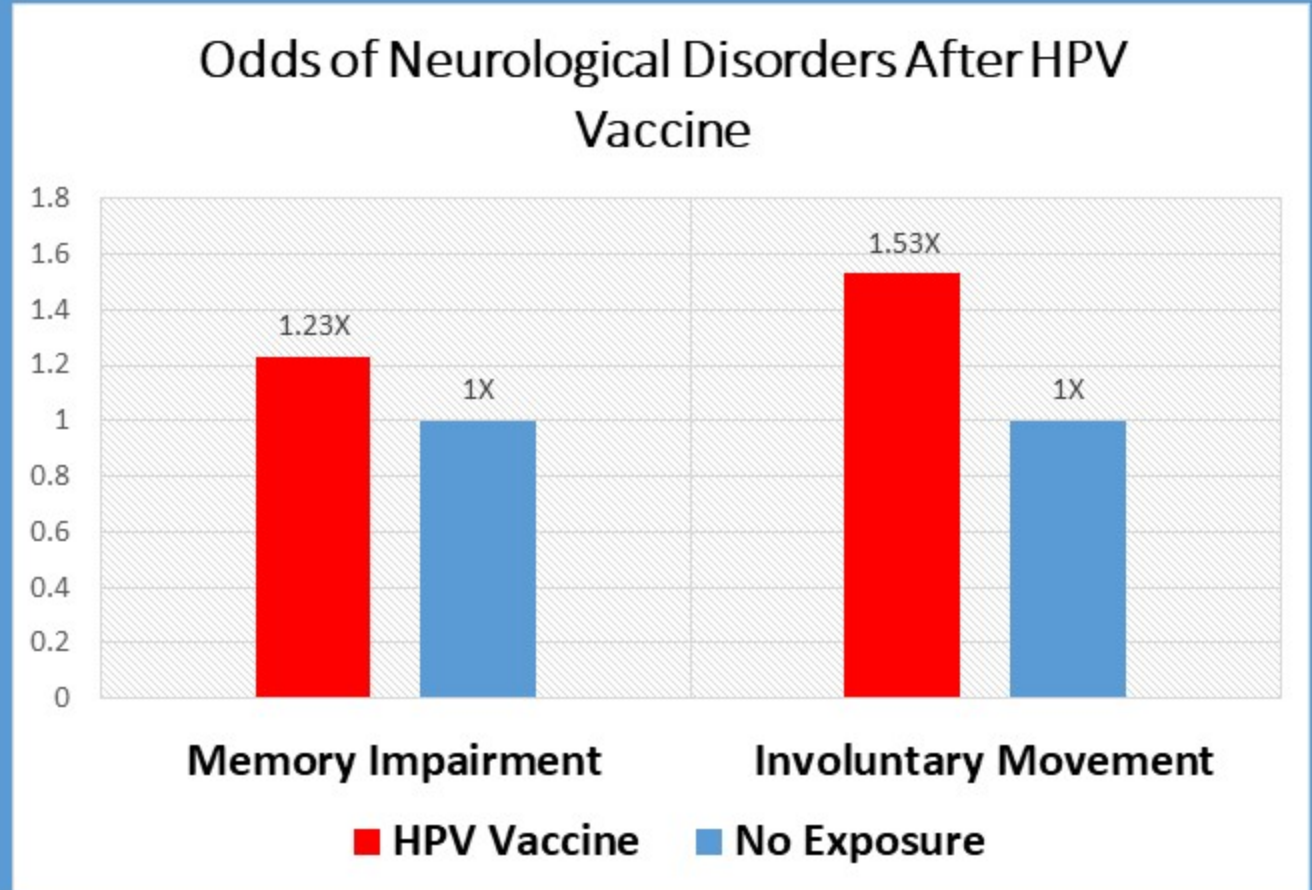
**METHODS:** Unadjusted odds ratios (OR) were calculated between HPV-vaccinated cases and un-vaccinated controls. Age-stratified analyses were performed to evaluate the interaction between age and events. Adjusted ORs were also estimated with multiple logistic regression models.

**RESULTS:** In the 15-16-year-old group, the unadjusted ORs were significantly higher for symptoms of memory impairment, dyscalculia, and involuntary movement. The age-adjusted multivariate analyses demonstrated that the vaccinated cases were less likely than the unvaccinated controls to have experienced symptoms in almost all symptoms, except for two symptoms such as involuntary movement and weakness. However, study period-adjusted multivariate analyses demonstrated that the vaccinated cases were significantly more likely than un-vaccinated controls to have experienced symptoms of memory impairment and involuntary movement.

**CONCLUSIONS:** Based on our analysis using data from the Nagoya City surveillance survey, a possible association between HPV vaccination and distinct symptoms such as cognitive impairment or movement disorders exists. A consistent causal relationship between HPV vaccination and these symptoms remains uncertain. However, given the seriousness of symptoms, we believe that a more comprehensive and large-scale study is essential to confirm the safety of HPV vaccination.

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**KEYWORDS:** adverse events; human papilloma virus; surveillance; vaccine



**“Based on our analysis using data from the Nagoya City surveillance survey, a possible association between HPV vaccination and distinct symptoms such as cognitive impairment or movement disorders exists.”**

# Thimerosal Containing Triple HepB Series in the First Six Months of Life Increases Odds of Emotional Disturbances by 2.37X

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National Institutes of Health

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Brain. 2017;31(2):272-278. doi: 10.1093/brain/aww052. Epub 2017 Jan 19.

**Thimerosal exposure and disturbance of emotions specific to childhood and adolescence: A case-control study in the Vaccine Safety Datalink (VSD) database.**

Geier DA<sup>1,2</sup>, Kern JS<sup>1,3</sup>, Homme KG<sup>4</sup>, Geier MR<sup>1,2</sup>.

Author information

**Abstract**

**BACKGROUND:** This study evaluated Thimerosal-containing childhood vaccines and the risk of a diagnosis called disturbance of emotions specific to childhood and adolescence (ED). Thimerosal is an organic-mercury (Hg)-containing compound used in some vaccines.

**METHODS:** A hypothesis-testing prospective, longitudinal case-control study evaluated Hg exposure from Thimerosal in hepatitis B vaccines administered at specific times within the first 6 months of life and its association with medically diagnosed ED (313.xx) (n = 517) in children born between 1991-2000 in comparison to controls (n = 27 491) in the Vaccine Safety Datalink (VSD) database.

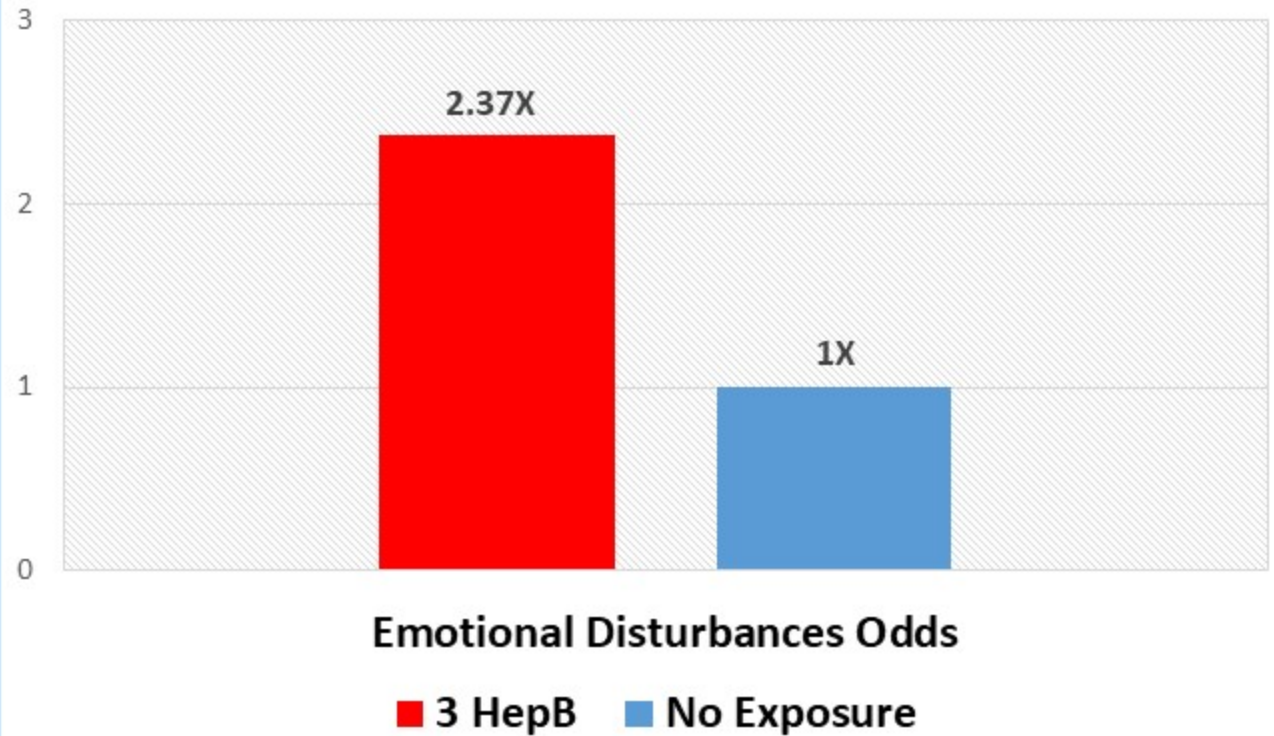
**RESULTS:** Cases diagnosed with ED were significantly more likely than controls to have received increased Hg exposure within the first month of life (odds ratio (OR) = 1.3384), the first 2 months of life (OR = 1.3367) and the first 6 months of life (OR = 2.37). When the data were separated by gender, similar significant adverse effects were observed for males, but not females. On a per microgram Hg basis, cases diagnosed with ED were significantly more likely than controls to have received increased exposure within the first 6 months of life (OR = 1.025 per microgram Hg).

**CONCLUSIONS:** The results show a significant relationship between Hg exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an ED diagnosis.

**KEYWORDS:** Emotional disturbances; anxiety; ethylmercury; mercury; merthiolate; shyness; social impairment; thiomersal

PMID: 28102704 DOI: 10.1093/brain/aww052.2016.1250950

## Odds of Emotional Disturbances After Exposure to Thimerosal Containing Triple HepB Series



**“The results show a significant relationship between mercury exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an emotional disturbances diagnosis.”**



# HPV Vaccine Increases the Risk of Celiac Disease by 1.56X

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US National Library of Medicine  
National Institutes of Health

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J Intern Med. 2018 Feb;263(2):154-165. doi: 10.1111/jim.12694. Epub 2017 Oct 18.

**Human papillomavirus vaccination of adult women and risk of autoimmune and neurological diseases.**

Hvid A<sup>1</sup>, Svanström H<sup>1</sup>, Scheller NM<sup>1</sup>, Grönlund O<sup>2</sup>, Pasternak B<sup>1,3</sup>, Arnheim-Dahlström L<sup>2</sup>.

⊕ Author information

**Abstract**

**BACKGROUND:** Since 2006, human papillomavirus (HPV) vaccines have been introduced in many countries worldwide. Whilst safety studies have been reassuring, focus has been on the primary target group, the young adolescent girls. However, it is also important to evaluate safety in adult women where background disease rates and safety issues could differ significantly.

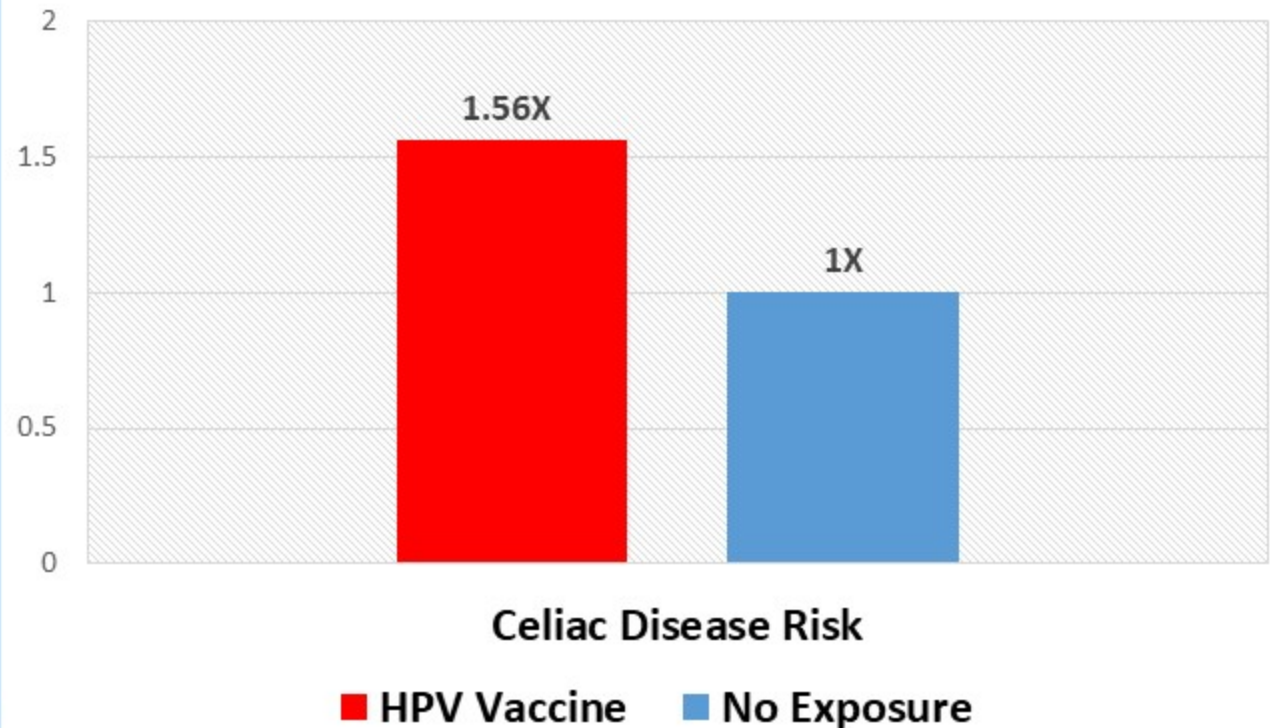
**OBJECTIVE:** We took advantage of the unique Danish and Swedish nationwide healthcare registers to conduct a cohort study comparing incidence rate ratios (RRs) of 45 preselected serious chronic diseases in quadrivalent HPV (qHPV)-vaccinated and qHPV-unvaccinated adult women 18-44 years of age.

**METHODS:** We used Poisson regression to estimate RRs according to qHPV vaccination status with two-sided 95% confidence intervals (95% CIs).

**RESULTS:** The study cohort comprised 3 126 790 women (1 195 865 [38%] Danish and 1 930 925 [62%] Swedish) followed for 16 386 459 person-years. Vaccine uptake of at least one dose of qHPV vaccine was 8% in the cohort: 18% amongst Danish women and 2% amongst Swedish. We identified seven adverse events with statistically significant increased risks following vaccination: Hashimoto's thyroiditis, coeliac disease, localized lupus erythematosus, pemphigus vulgaris, Addison's disease, Raynaud's disease and other encephalitis, myelitis or encephalomyelitis. After taking multiple testing into account and conducting self-controlled case series analyses, coeliac disease (RR 1.56 [95% confidence interval 1.29-1.89]) was the only remaining association.

**CONCLUSION:** Unmasking of conditions at vaccination visits is a plausible explanation for the increased risk associated with qHPV in this study because coeliac disease is underdiagnosed in Scandinavian populations. In conclusion, our study of serious adverse event rates in qHPV-vaccinated and qHPV-unvaccinated adult women 18-44 years of age did not raise any safety issues of concern.

## Risk of Celiac Disease Diagnosis After HPV Vaccination



**“Relative Risks for celiac disease were increased for both the period any time after vaccination (RR 1.56, 1.29–1.89), the first 179 days (1.54, 1.16–2.03) and the more than 180 days after vaccination period (1.58, 1.22–2.05).”**

# The H1N1 and Seasonal Influenza Vaccines Both Given During Pregnancy Increase Fetal Loss by 11.4X Compared to the Seasonal Influenza Vaccine Only

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goldman gs influenza  
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Hum Exp Toxicol. 2013 May;32(5):464-75. doi: 10.1177/0960327112455067. Epub 2012 Sep 27.

**Comparison of VAERS fetal-loss reports during three consecutive influenza seasons: was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season?**

Goldman GS<sup>1</sup>.

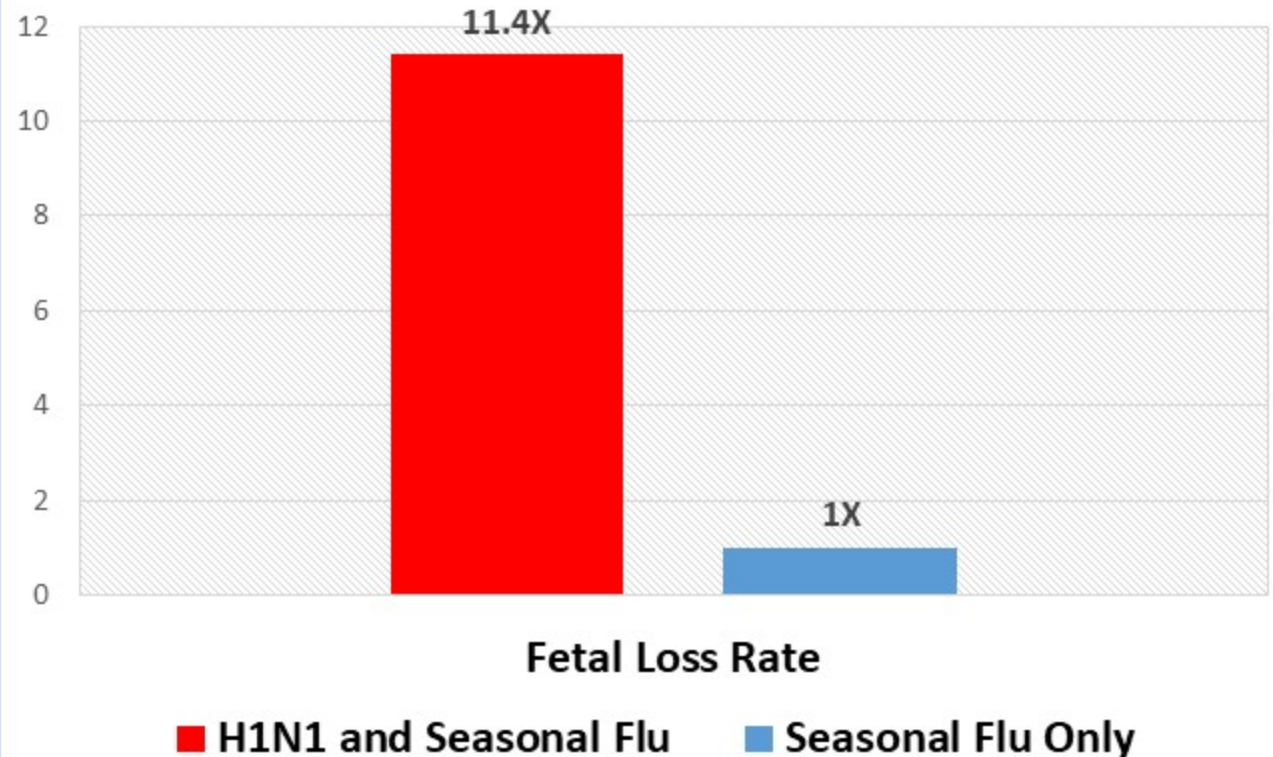
Author information

**Abstract**  
The aim of this study was to compare the number of inactivated-influenza vaccine-related spontaneous abortion and stillbirth (SB) reports in the Vaccine Adverse Event Reporting System (VAERS) database during three consecutive flu seasons beginning 2008/2009 and assess the relative fetal death reports associated with the two-vaccine 2009/2010 season. The VAERS database was searched for reports of fetal demise following administration of the influenza vaccine/vaccines to pregnant women. Utilization of an independent surveillance survey and VAERS, two-source capture-recapture analysis estimated the reporting completeness in the 2009/2010 flu season. Capture-recapture demonstrated that the VAERS database captured about 13.2% of the total 1321 (95% confidence interval (CI): 815-2795) estimated reports, yielding an ascertainment-corrected rate of 590 fetal-loss reports per million pregnant women vaccinated (or 1 per 1695). The unadjusted fetal-loss report rates for the three consecutive influenza seasons beginning 2008/2009 were 6.8 (95% CI: 0.1-13.1), 77.8 (95% CI: 66.3-89.4), and 12.6 (95% CI: 7.2-18.0) cases per million pregnant women vaccinated, respectively. The observed reporting bias was too low to explain the magnitude increase in fetal-demise reporting rates in the VAERS database relative to the reported annual trends. Thus, a synergistic fetal toxicity likely resulted from the administration of both the pandemic (A-H1N1) and seasonal influenza vaccines during the 2009/2010 season.

**KEYWORDS:** Human toxicology; Thimerosal; immunization; influenza vaccine; spontaneous abortion; stillbirth

PMID: 23023030 PMCID: PMC3688271 DOI: 10.1177/0960327112455067  
[Indexed for MEDLINE] Free PMC Article

Rate of Fetal Loss in Women Receiving Both the H1N1 and Seasonal Flu Vaccines



“Because of the order of magnitude increase in fetal-loss report rates, from 6.8 fetal-loss reports per million pregnant women vaccinated in the single-dose 2008/2009 season to 77.8 in the two-dose 2009/2010 season, further long-term studies are needed to assess adverse outcomes in the surviving children.”



# H1N1 Influenza Vaccine (Pandemrix) Increases Rate of Narcolepsy in Swedish Children by 25X

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Neurology, 2013 Apr 2;80(14):1315-21. doi: 10.1212/WNL.0b013e31828ab26f. Epub 2013 Mar 13.

**Increased childhood incidence of narcolepsy in western Sweden after H1N1 influenza vaccination.**

Scatás A<sup>1</sup>, Darin N, Hallböök T.

Author information

**Abstract**

**OBJECTIVES:** To assess the incidence of narcolepsy between January 2000 and December 2010 in children in western Sweden and its relationship to the Pandemrix vaccination, and to compare the clinical and laboratory features of these children.

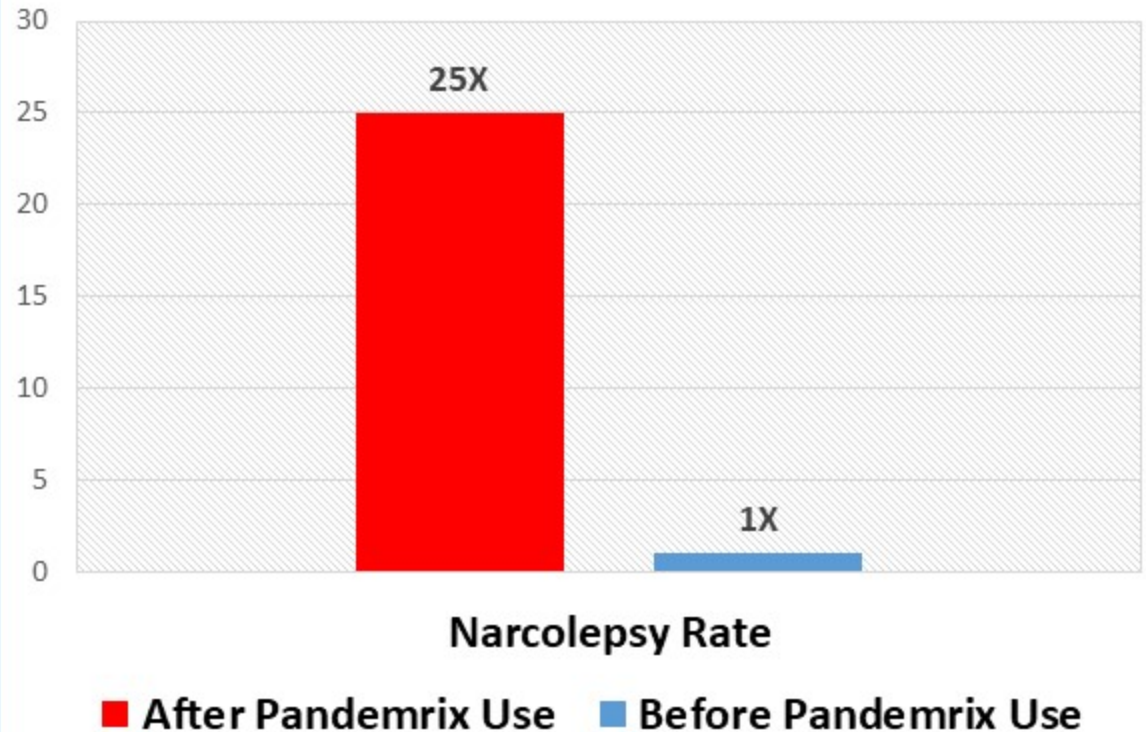
**METHODS:** The children were identified from all local and regional pediatric hospitals, child rehabilitation centers, outpatient pediatric clinics, and regional departments of neurophysiology. Data collection was performed with the aid of a standardized data collection form, from medical records and telephone interviews with patients and parents. The laboratory and investigational data were carefully scrutinized.

**RESULTS:** We identified 37 children with narcolepsy. Nine of them had onset of symptoms before the H1N1 vaccination and 28 had onset of symptoms in relationship to the vaccination. The median age at onset was 10 years. All patients in the postvaccination group were positive for human leukocyte antigen (HLA)-DQB1\*0602. Nineteen patients in the postvaccination group, compared with one in the prevaccination group, had a clinical onset that could be dated within 12 weeks.

**CONCLUSION:** Pandemrix vaccination is a precipitating factor for narcolepsy, especially in combination with HLA-DQB1\*0602. The incidence of narcolepsy was 25 times higher after the vaccination compared with the time period before. The children in the postvaccination group had a lower age at onset and a more sudden onset than that generally seen.

**Comment in**  
Association between H1N1 vaccination and narcolepsy-cataplexy: flu to sleep. [Neurology. 2013]

Rate of Narcolepsy in Sweden Before and After the Use of the H1N1 Vaccine



**“The incidence of narcolepsy was 25 times higher after the vaccination compared with the time period before. The children in the postvaccination group had a lower age at onset and a more sudden onset than that generally seen.”**

# Risk of Chorioamnionitis in Pregnant Women Vaccinated with Tdap Versus Pregnant Women Not Vaccinated with Tdap

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JAMA. 2014 Nov 12;312(18):1897-904. doi: 10.1001/jama.2014.14825.

**Evaluation of the association of maternal pertussis vaccination with obstetric events and birth outcomes.**

Kharbanda EO<sup>1</sup>, Vazquez-Benitez G<sup>1</sup>, Lipkind HS<sup>2</sup>, Klein NP<sup>3</sup>, Cheetham TC<sup>4</sup>, Naleway A<sup>5</sup>, Omer SB<sup>6</sup>, Hambidge SJ<sup>7</sup>, Lee GM<sup>8</sup>, Jackson ML<sup>9</sup>, McCarthy NJ<sup>10</sup>, DeStefano F<sup>10</sup>, Nordin JD<sup>1</sup>.

@ Author information

**Abstract**

**IMPORTANCE:** In 2010, due to a pertussis outbreak and neonatal deaths, the California Department of Health recommended that the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) be administered during pregnancy. Tdap is now recommended by the Advisory Committee on Immunization Practices for all pregnant women, preferably between 27 and 36 weeks' gestation. Limited data exist on Tdap safety during pregnancy.

**OBJECTIVE:** To evaluate whether maternal Tdap vaccination during pregnancy is associated with increased risks of adverse obstetric events or adverse birth outcomes.

**DESIGN AND SETTING:** Retrospective, observational cohort study using administrative health care databases from 2 California Vaccine Safety Datalink sites.

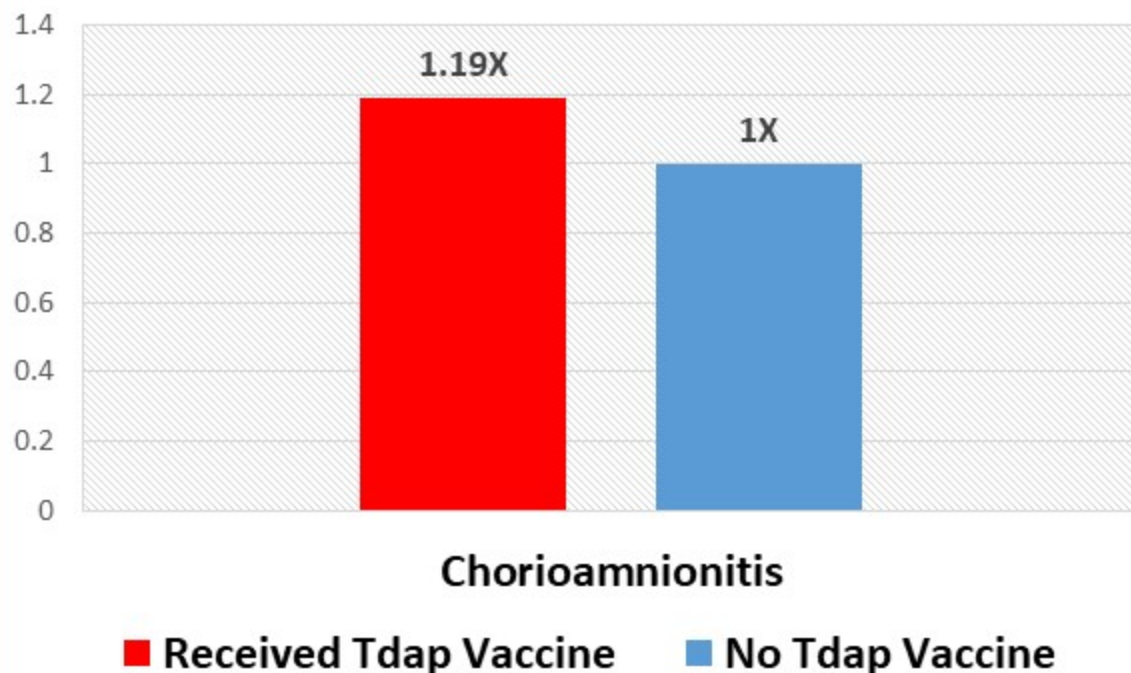
**PARTICIPANTS AND EXPOSURES:** Of 123,494 women with singleton pregnancies ending in a live birth between January 1, 2010, and November 15, 2012, 26,229 (21%) received Tdap during pregnancy and 97,265 did not.

**MAIN OUTCOMES AND MEASURES:** Risks of small-for-gestational-age (SGA) births (<10th percentile), chorioamnionitis, preterm birth (<37 weeks' gestation), and hypertensive disorders of pregnancy were evaluated. Relative risk (RR) estimates were adjusted for site, receipt of another vaccine during pregnancy, and propensity to receive Tdap during pregnancy. Cox regression was used for preterm delivery, and Poisson regression for other outcomes.

**RESULTS:** Vaccination was not associated with increased risks of adverse birth outcomes: crude estimates for preterm delivery were 6.3% of vaccinated and 7.8% of unvaccinated women (adjusted RR, 1.03; 95% CI, 0.97-1.09); 8.4% of vaccinated and 8.3% of unvaccinated had an SGA birth (adjusted RR, 1.00; 95% CI, 0.96-1.06). Receipt of Tdap before 20 weeks was not associated with hypertensive disorder of pregnancy (adjusted RR, 1.09; 95% CI, 0.99-1.20); chorioamnionitis was diagnosed in 6.1% of vaccinated and 5.5% of unvaccinated women (adjusted RR, 1.19; 95% CI, 1.13-1.26).

**CONCLUSIONS AND RELEVANCE:** In this cohort of women with singleton pregnancies that ended in live birth, receipt of Tdap during pregnancy was not associated with increased risk of hypertensive disorders of pregnancy or preterm or SGA birth, although a small but statistically significant increased risk of chorioamnionitis diagnosis was observed.

## Rate of Chorioamnionitis in Pregnant Women Vaccinated With Tdap Versus Unvaccinated Pregnant Women



**“Among women who received Tdap at anytime during pregnancy, 6.1% were diagnosed with chorioamnionitis compared with 5.5% of unexposed women. After adjusting for site, receipt of 1 or more other vaccines in pregnancy and the propensity score, the adjusted relative risk (RR) was 1.19 (95% CI, 1.13–1.26).”**



# First Dose of Rotavirus Vaccine (Rotarix) Increases Intussusception Odds by 5.8X

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N Engl J Med. 2011 Jun 16;364(24):2283-92. doi: 10.1056/NEJMoa1012952.

## Intussusception risk and health benefits of rotavirus vaccination in Mexico and Brazil.

Patel MM<sup>1</sup>, López-Collada VR, Bulhões MM, De Oliveira LH, Bautista Márquez A, Flannery B, Esparza-Aguilar M, Montenegro Renginer EJ, Luna-Cruz ME, Sato HK, Hernández-Hernández Ldel C, Toledo-Cortina G, Cerón-Rodríguez M, Osnaya-Romero N, Martínez-Alcazar M, Aguinaga-Villasenor RG, Plassencia-Hernández A, Fajano-González F, Hernández-Peredo Rezk G, Gutiérrez-Ramírez SF, Dorame-Castillo R, Tinajero-Pizano R, Mercado-Villagas B, Barbosa MB, Maluf EM, Ferreira LB, de Carvalho FM, dos Santos AB, Cesar ED, de Oliveira ME, Silva CL, de Los Angeles Cortes M, Ruiz Matus C, Tate J, Gangiullo P, Parashar UD.

Ⓜ Author information

### Abstract

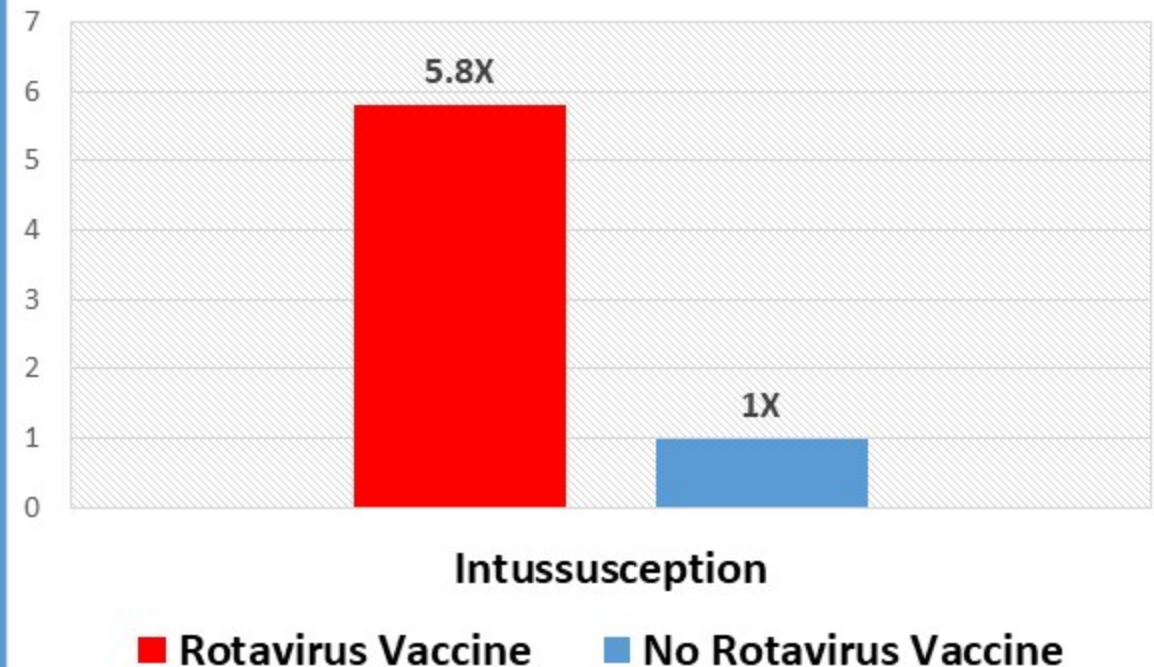
**BACKGROUND:** Because postlicensure surveillance determined that a previous rotavirus vaccine, RotaShield, caused intussusception in 1 of every 10,000 recipients, we assessed the association of the new monovalent rotavirus vaccine (RV1) with intussusception after routine immunization of infants in Mexico and Brazil.

**METHODS:** We used case-series and case-control methods to assess the association between RV1 and intussusception. Infants with intussusception were identified through active surveillance at 69 hospitals (16 in Mexico and 53 in Brazil), and age-matched infants from the same neighborhood were enrolled as controls. Vaccination dates were verified by a review of vaccination cards or clinic records.

**RESULTS:** We enrolled 615 case patients (285 in Mexico and 330 in Brazil) and 2050 controls. An increased risk of intussusception 1 to 7 days after the first dose of RV1 was identified among infants in Mexico with the use of both the case-series method (incidence ratio, 5.3; 95% confidence interval [CI], 3.0 to 9.3) and the case-control method (odds ratio, 5.8; 95% CI, 2.6 to 13.0). No significant risk was found after the first dose among infants in Brazil, but an increased risk, albeit smaller than that seen after the first dose in Mexico—an increase by a factor of 1.9 to 2.6—was seen 1 to 7 days after the second dose. A combined annual excess of 96 cases of intussusception in Mexico (approximately 1 per 51,000 infants) and in Brazil (approximately 1 per 68,000 infants) and of 5 deaths due to intussusception was attributable to RV1. However, RV1 prevented approximately 80,000 hospitalizations and 1300 deaths from diarrhea each year in these two countries.

**CONCLUSIONS:** RV1 was associated with a short-term risk of intussusception in approximately 1 of every 51,000 to 68,000 vaccinated infants. The absolute number of deaths and hospitalizations averted because of vaccination far exceeded the number of intussusception cases that may have been associated with vaccination. (Funded in part by the GAVI Alliance and the U.S. Department of Health and Human Services.).

## Odds of Intussusception Before and After the First Rotavirus Vaccine (Case-Control Method)



**“An increased risk of intussusception 1 to 7 days after the first dose of RV1 was identified among infants in Mexico with the use of both the case-series method (incidence ratio, 5.3; 95% confidence interval [CI], 3.0 to 9.3) and the case-control method (odds ratio, 5.8; 95% CI, 2.6 to 13.0).”**

# Measles Vaccination Versus Measles Infection Increases the Odds of Atopy (Allergy) by 2.8X

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Lancet, 1996 Jun 29;347(9018):1792-6.

## Measles and atopy in Guinea-Bissau.

Shaheen SQ<sup>1</sup>, Aaby P, Hall AJ, Barker DJ, Heyes CB, Shiell AW, Goudiaby A.

Author information

**Abstract**

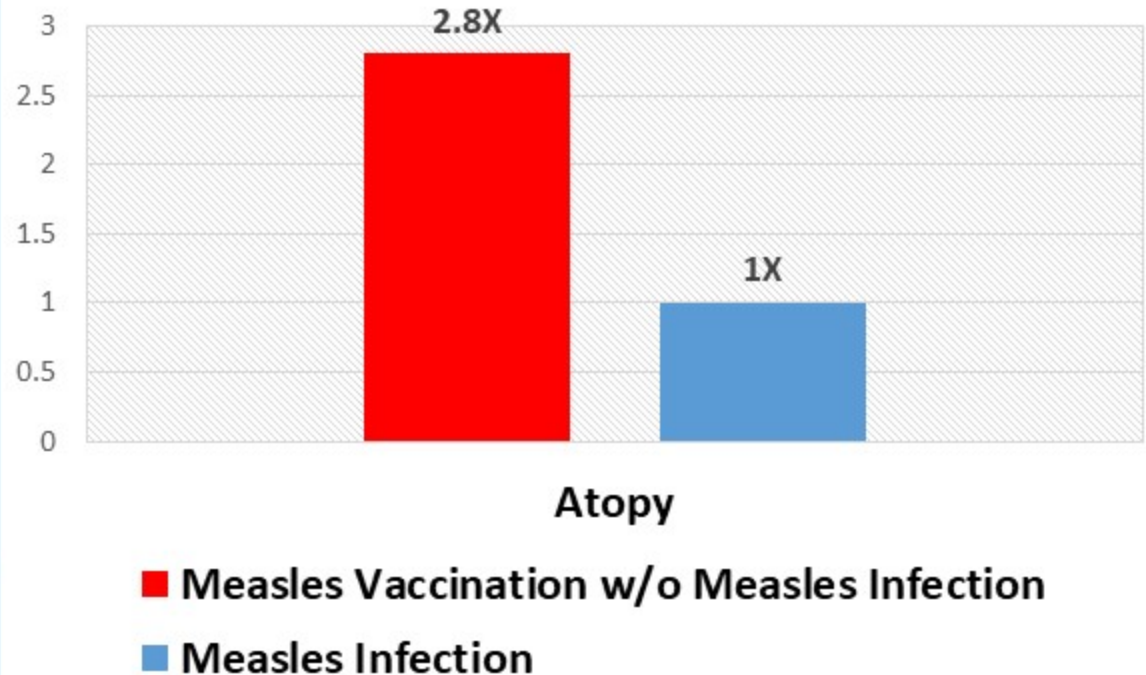
**BACKGROUND:** Epidemiological studies have led to speculation that infections in early childhood may prevent allergic sensitisation but evidence to support this hypothesis is lacking. We investigated whether measles infection protects against the development of atopy in children of Guinea-Bissau, West Africa.

**METHODS:** We conducted a historical cohort study in Bandim, a semi-rural district of Bissau, the capital of Guinea-Bissau. 395 young adults, first surveyed in 1978-80 aged 0-6 years, were followed up in 1994. Our analyses were restricted to 262 individuals still living in Bandim for whom a measles history, documented in childhood, was judged to be reliable. We defined atopy as skin-prick test positivity ( $\geq$  or = 3 mm weal) to one or more of seven allergens.

**FINDINGS:** 17 (12.8 percent) of 133 participants who had had measles infection were atopic compared with 33 (25.6 percent) of 129 of those who had been vaccinated and not had measles (odds ratio, adjusted for potential confounding variables 0.36 [95 percent CI 0.17-0.78],  $p=0.01$ ). Participants who had been breastfed for more than a year were less likely to have a positive skin test to housedust mite. After adjustment for breastfeeding and other variables, measles infection was associated with a large reduction in the risk of skin-prick test positivity to housedust mite (odds ratio for *Dermatophagoides pteronyssinus* 0.20 [0.05-0.81],  $p=0.02$ ; *D farinae* 0.20 [0.06-0.71],  $p=0.01$ ).

**INTERPRETATION:** Measles infection may prevent the development of atopy in African children.

## Odds of Atopy in Vaccinated Children Versus Children Previously Infected with Measles



“17 (12.8%) of 133 participants who had had measles infection were atopic compared with 33 (25.6%) of 129 of those who had been vaccinated and not had measles”



# Higher Exposure to Thimerosal from Infant Vaccines Increases the Odds of Motor Tics (2.19X) and Phonic Tics (2.44X) in Boys

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thompson price 2007 thimerosal

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N Engl J Med. 2007 Sep 27;357(13):1281-92.

**Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years.**

Thompson WW<sup>1</sup>, Price C, Goodson B, Shay DK, Benson P, Hinrichsen VL, Lewis E, Eriksen E, Ray P, Marcy SM, Dunn J, Jackson LA, Liew TA, Black S, Stewart G, Weintraub ES, Davis RL, DeStefano F; Vaccine Safety Datalink Team.

Ⓜ Author information

**Abstract**

**BACKGROUND:** It has been hypothesized that early exposure to thimerosal, a mercury-containing preservative used in vaccines and immune globulin preparations, is associated with neuropsychological deficits in children.

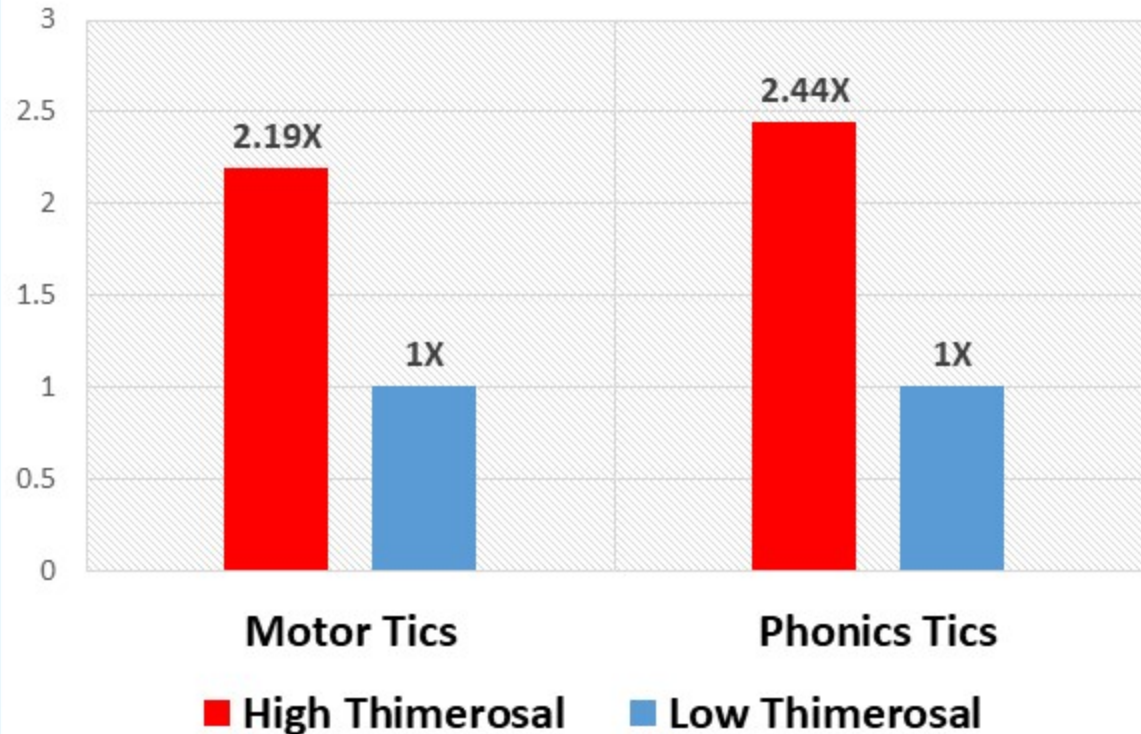
**METHODS:** We enrolled 1047 children between the ages of 7 and 10 years and administered standardized tests assessing 42 neuropsychological outcomes. (We did not assess autism-spectrum disorders.) Exposure to mercury from thimerosal was determined from computerized immunization records, medical records, personal immunization records, and parent interviews. Information on potential confounding factors was obtained from the interviews and medical charts. We assessed the association between current neuropsychological performance and exposure to mercury during the prenatal period, the neonatal period (birth to 28 days), and the first 7 months of life.

**RESULTS:** Among the 42 neuropsychological outcomes, we detected only a few significant associations with exposure to mercury from thimerosal. The detected associations were small and almost equally divided between positive and negative effects. Higher prenatal mercury exposure was associated with better performance on one measure of language and poorer performance on one measure of attention and executive functioning. Increasing levels of mercury exposure from birth to 7 months were associated with better performance on one measure of fine motor coordination and on one measure of attention and executive functioning. Increasing mercury exposure from birth to 28 days was associated with poorer performance on one measure of speech articulation and better performance on one measure of fine motor coordination.

**CONCLUSIONS:** Our study does not support a causal association between early exposure to mercury from thimerosal-containing vaccines and immune globulins and deficits in neuropsychological functioning at the age of 7 to 10 years.

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## Odds of Tics in Boys Exposed to High Versus Low Levels of Thimerosal in Infant Vaccines



“Among boys, higher exposure to mercury from birth to 7 months was associated with ... a higher likelihood of motor and phonic tics, as reported by the children’s evaluators.”

# Delaying the First Three DPT Vaccine Doses Reduces Asthma Risk by 61%

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McDonald Huq 2008 pertussis asthma

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J Allergy Clin Immunol. 2008 Mar;121(3):626-31. doi: 10.1016/j.jaci.2007.11.034. Epub 2008 Jan 18.

**Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma.**

McDonald KL<sup>1</sup>, Huq SJ, Lix LM, Bedker AB, Kozynski AL.

Author information

**Abstract**

**BACKGROUND:** Early childhood immunizations have been viewed as promoters of asthma development by stimulating a T(H)2-type immune response or decreasing microbial pressure, which shifts the balance between T(H)1 and T(H)2 immunity.

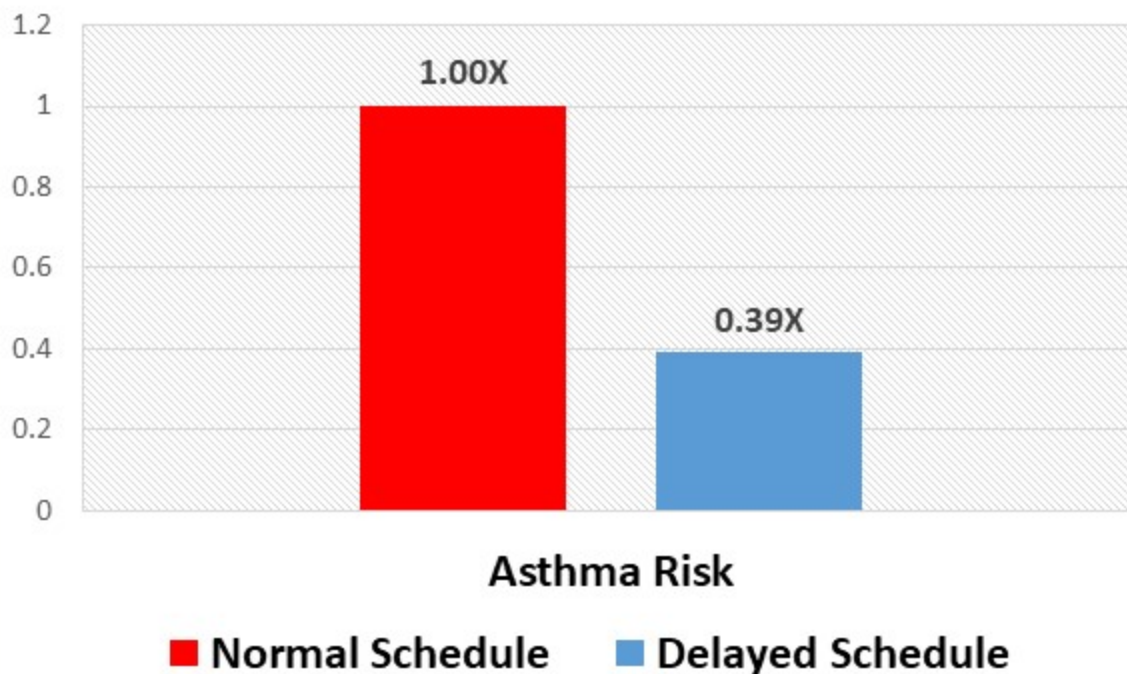
**OBJECTIVE:** Differing time schedules for childhood immunizations may explain the discrepant findings of an association with asthma reported in observational studies. This research was undertaken to determine whether timing of diphtheria, pertussis, tetanus (DPT) immunization has an effect on the development of childhood asthma by age 7 years.

**METHODS:** This was a retrospective longitudinal study of a cohort of children born in Manitoba in 1995. The complete immunization and health care records of cohort children from birth until age 7 years were available for analysis. The adjusted odds ratio for asthma at age 7 years according to timing of DPT immunization was computed from multivariable logistic regression.

**RESULTS:** Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months. The likelihood of asthma in children with delays in all 3 doses was 0.39 (95% CI, 0.18-0.86).

**CONCLUSION:** We found a negative association between delay in administration of the first dose of whole-cell DPT immunization in childhood and the development of asthma; the association was greater with delays in all of the first 3 doses. The mechanism for this phenomenon requires further research.

## Risk of Asthma Following the Recommended Schedule of DPT Versus a Delayed Schedule



**“Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months. The likelihood of asthma in children with delays in all 3 doses was 0.39 (95% CI, 0.18-0.86).”**



# Exposure to Higher Levels of Thimerosal in Infant Vaccines Before 13 Months of Age Increases the Rate of Premature Puberty by 6.45X

Indian J Med Res 131, April 2010, pp 500-507

## Thimerosal exposure & increasing trends of premature puberty in the vaccine safety datalink

David A. Geier<sup>\*,\*\*</sup>, Heather A. Young<sup>\*</sup> & Mark R. Geier<sup>\*</sup>

<sup>\*</sup>The Institute of Chronic Illnesses, Inc., Silver Spring, MD, <sup>\*\*</sup>CoMeD, Inc., Silver Spring, MD, <sup>\*</sup>The George Washington University School of Public Health & Health Services, Department of Epidemiology & Biostatistics, Washington, DC & <sup>\*</sup>ASD Centers, LLC, USA

Received December 12, 2008

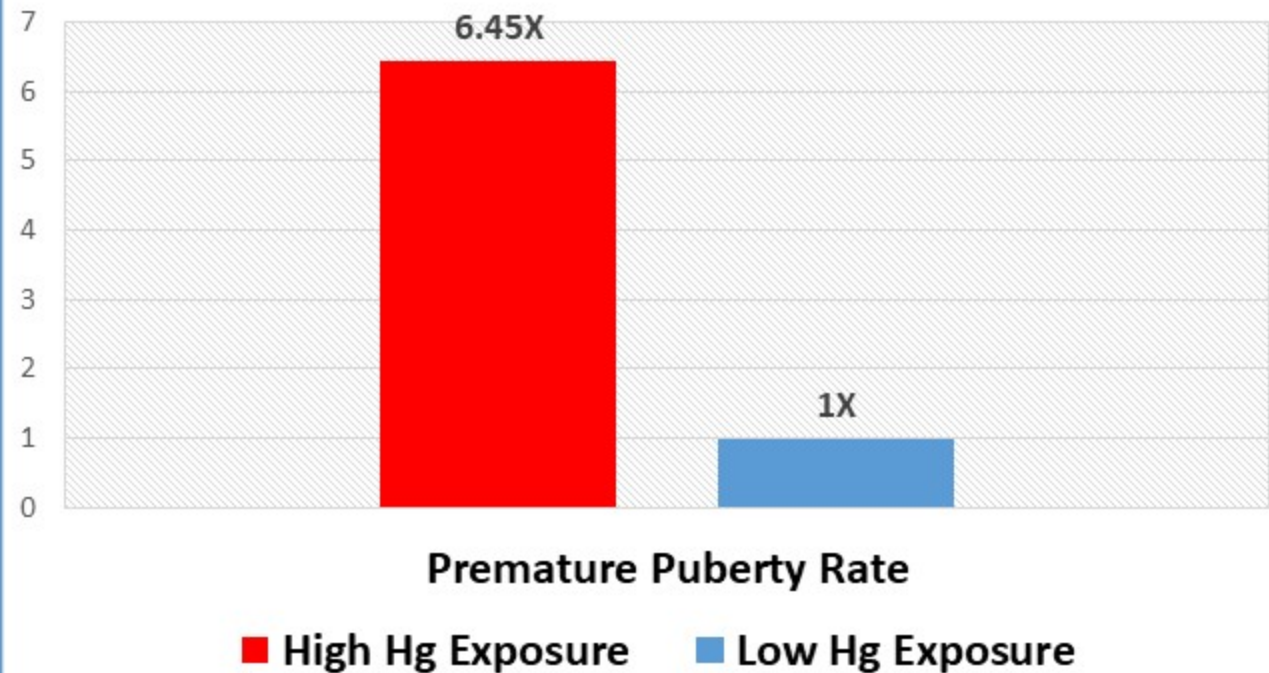
**Background & objectives:** The US Agency for Toxic Substances and Disease Registry (ATSDR) reports that mercury (Hg) is a known endocrine disruptor and it adversely affects the steroid synthesis pathway in animals and humans, and may interact to enhance the risk for a child developing premature puberty. An association between premature puberty and exposure to Hg from thimerosal-containing vaccines (TCVs) was evaluated in computerized medical records within the Vaccine Safety Datalink (VSD).

**Methods:** A total of 278,624 subjects were identified in birth cohorts from 1990-1996. The birth cohort prevalence rates of medically diagnosed International Classification of Disease, 9<sup>th</sup> revision (ICD-9) premature puberty and control outcomes were calculated. Exposures to Hg from TCVs were calculated by birth cohort for specific exposure windows from birth-7 months and birth-13 months of age. Poisson regression analysis was used to model the association between the prevalence of outcomes and Hg doses from TCVs.

**Results:** Significantly increased ( $P<0.0001$ ) rate ratios were observed for premature puberty for a 100 µg difference in Hg exposure from TCVs in the birth-7 months (rate ratio=5.58) and birth-13 months (rate ratio=6.45) of age exposure windows. By contrast, none of the control outcomes had significantly increased rate ratios with Hg exposure from TCVs.

**Interpretation & conclusions:** Routine childhood vaccination should be continued to help reduce the morbidity and mortality associated with infectious diseases, but efforts should be undertaken to remove Hg from vaccines. Additional studies should be done to evaluate the relationship between Hg exposure and premature puberty.

## Rate of Premature Puberty Diagnosis After Exposure to 100 Additional Micrograms Mercury in Thimerosal Containing Vaccines (TCVs)



**“Significantly increased ( $P<0.0001$ ) rate ratios were observed for premature puberty for a 100 µg difference in Hg exposure from TCVs in the birth-7 months (rate ratio=5.58) and birth-13 months (rate ratio=6.45) of age exposure windows. By contrast, none of the control outcomes had significantly increased rate ratios with Hg exposure from TCVs.”**