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Generation 1: CDC's Unpublished Verstraeten Study on Hep B Showed Dramatic Increased Risk of Autism (7.6X), Sleep Disorders (5X), Speech Disorders (2.1X) and Neurodevelopmental Disorders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

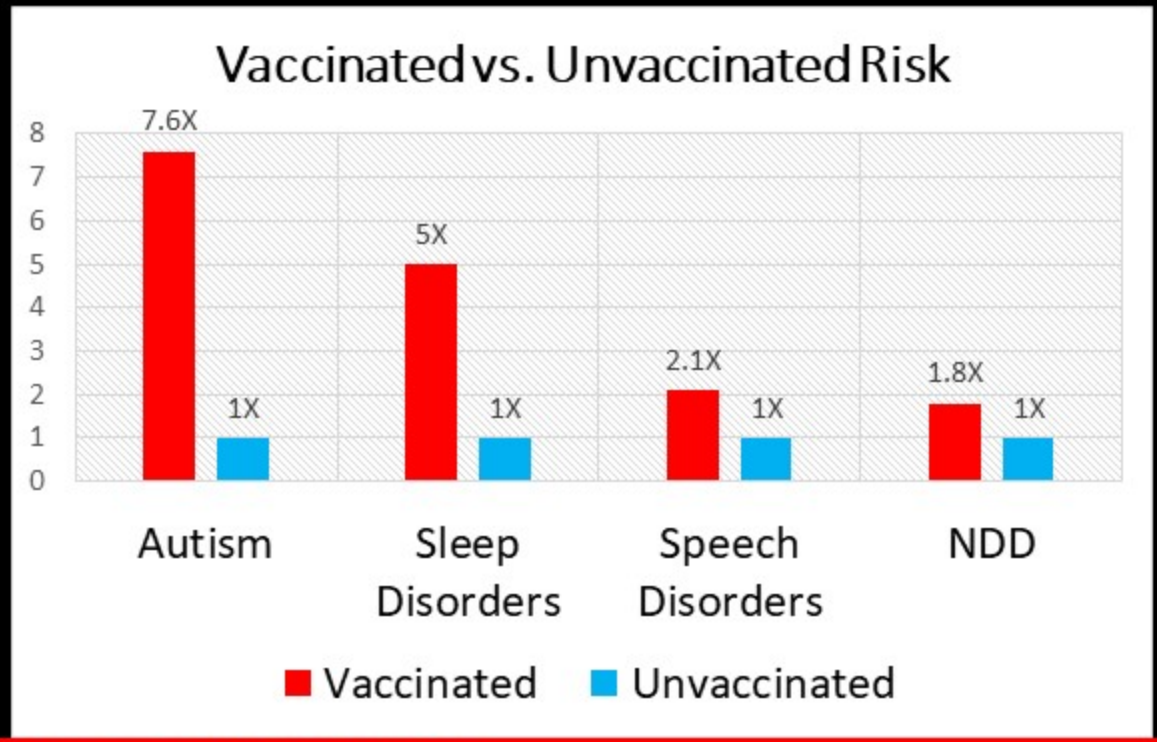
Increased risk of developmental neurologic impairment after high exposure to thimerosal-containing vaccine in first month of life.

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.

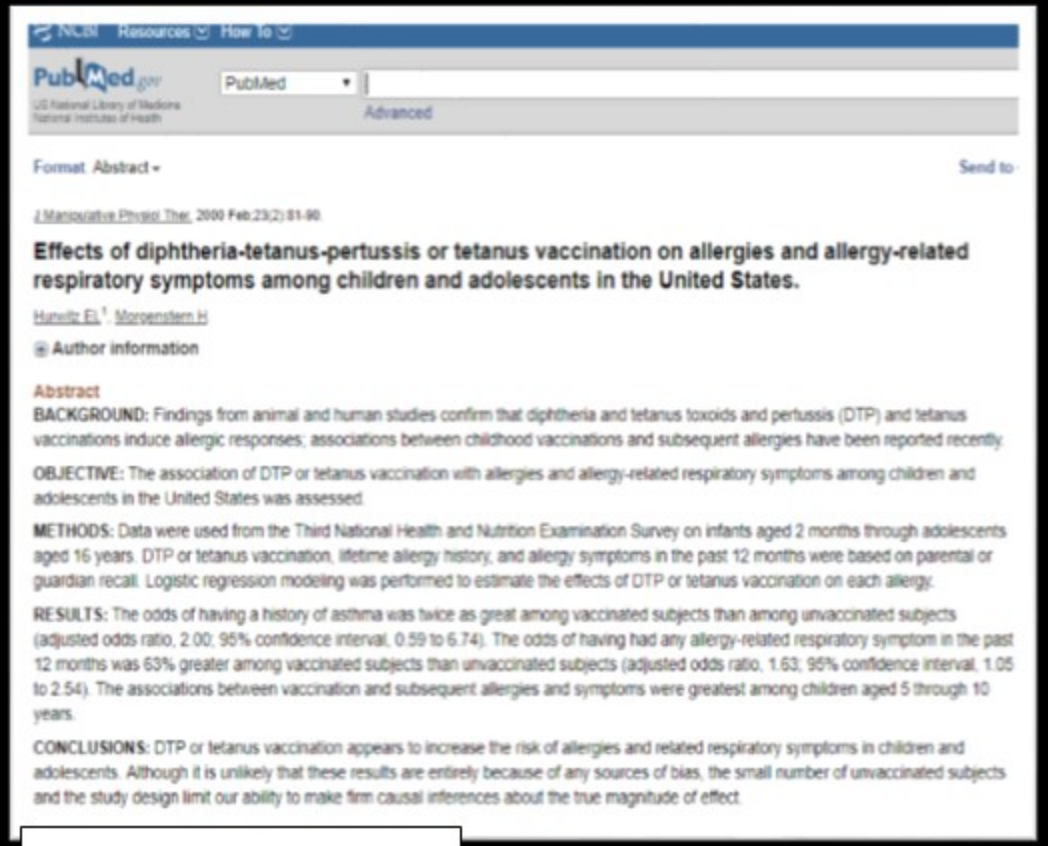


CDC UNPUBLISHED DATA OBTAINED BY FOIA

"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)."

Children's Health Defense

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.

Hurwitz EL[1], Morgenstern 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.

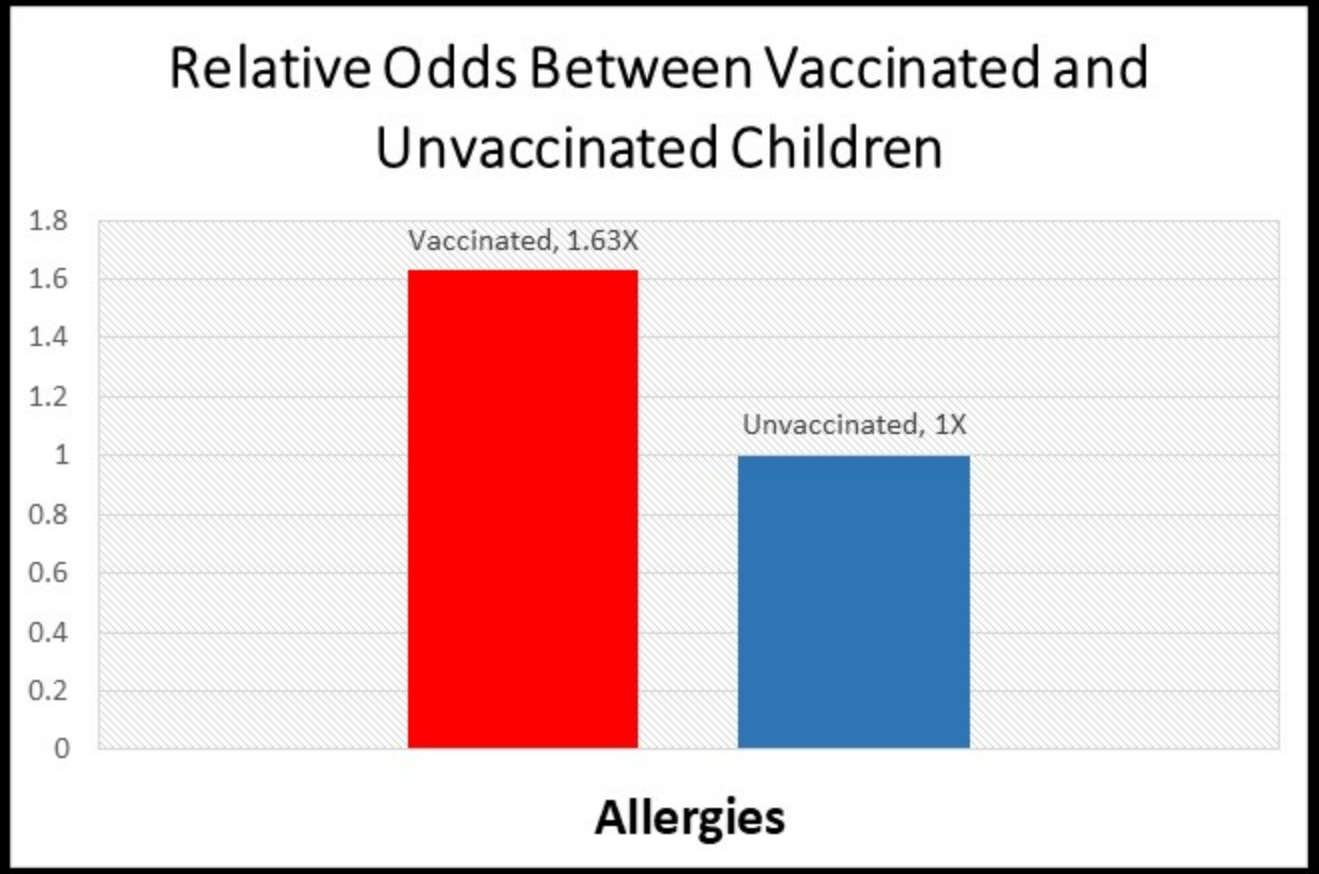
OBJECTIVE: The association of DTP or tetanus vaccination with allergies and allergy-related respiratory symptoms among children and adolescents in the United States was assessed.

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



"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."

Children's Health Defense

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

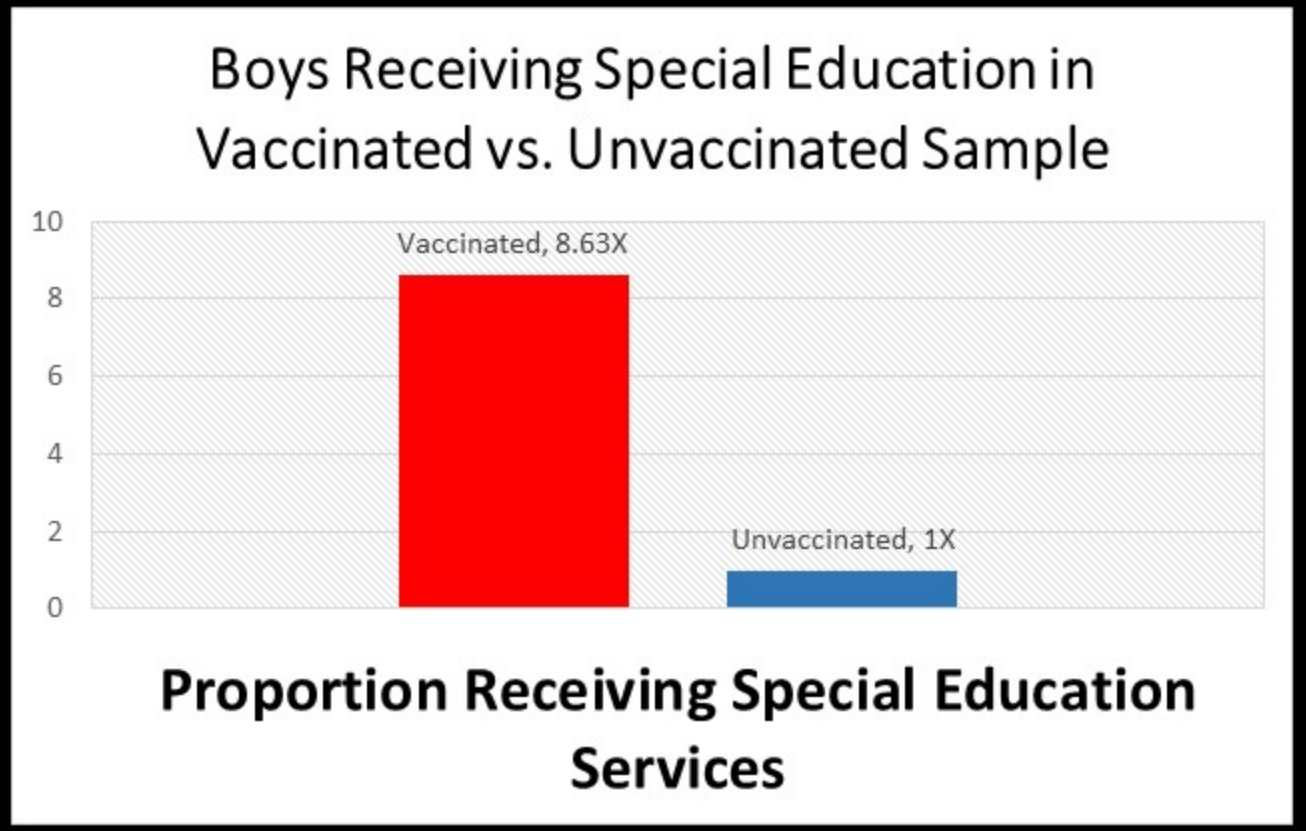
Download citation https://doi.org/10.1080/02772240701806501

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



"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."

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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.

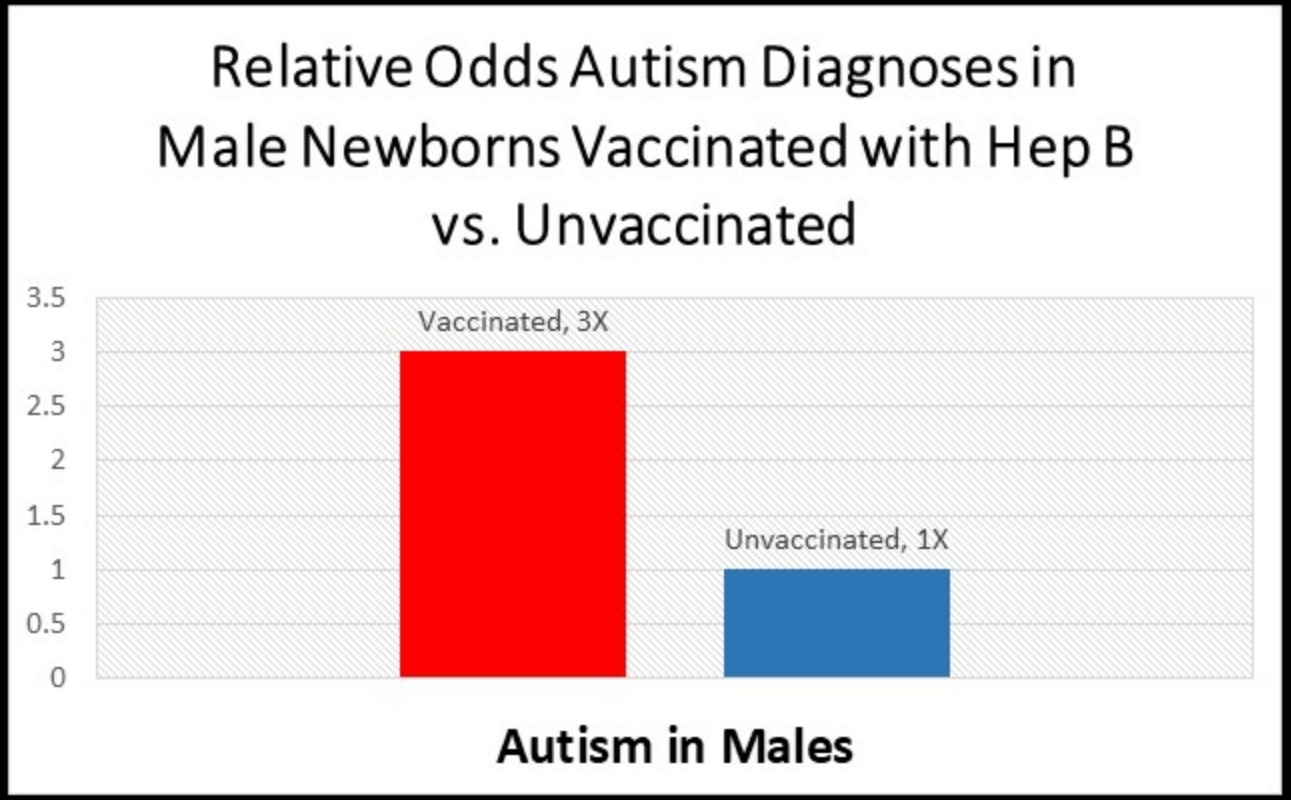
Gallagher CM[1], Goodman MS.

⊕ 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



"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."

Children's Health Defense

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,[1] Vicky J. Fang,[1] Hiroshi Nishiura,[1,2] Kwok-Hung Chan,[3] Sophia Ng,[1] Dennis K. M. Ip,[1] Susan S. Chiu,[4] Gabriel M. Leung,[1] and J. S. Malik Peiris[1,5]

[1]School of Public Health, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong SAR, China; [2]PRESTO, Japan Science and Technology Agency, Saitama; [3]Department of Microbiology, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Queen Mary Hospital, [4]Department of Pediatrics and Adolescent Medicine, The University of Hong Kong, Queen Mary Hospital, and [5]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.

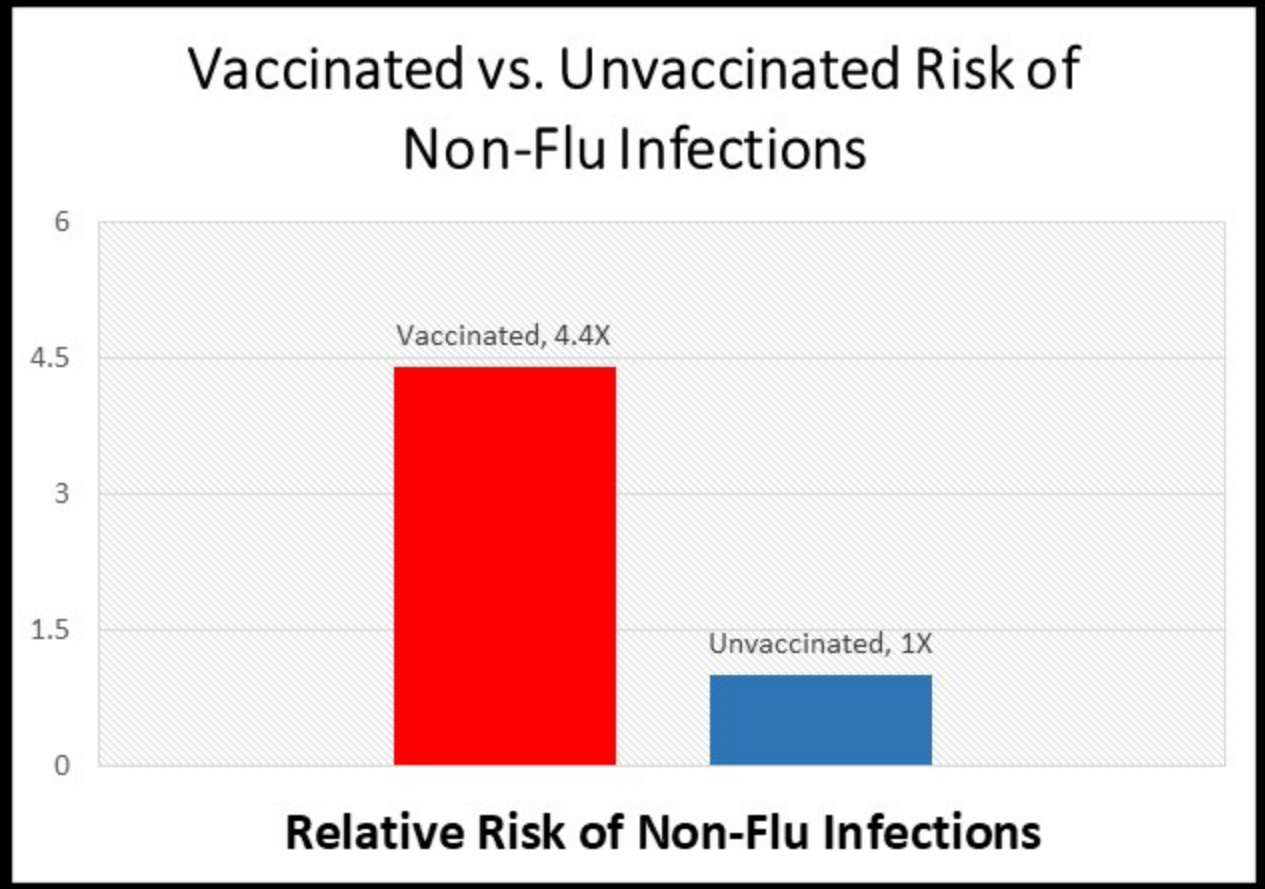
METHODS

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.

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."

Children's Health Defense

DTP Increases Mortality in Girls 10X

EBioMedicine 17 (2017) 192–198

Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com

Research Paper

The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment

Søren Wengel Mogensen [a,1], Andreas Andersen [b,1], Amabelia Rodrigues [a], Christine S Benn [b,c], Peter Aaby [a,b,*]

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[b] Research Centre for Vitamins and Vaccines (CVIVA), Bandim Health Project, Statens Serum Institute, Artillerivej 5, 2300 Copenhagen S, Denmark
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ARTICLE INFO

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Keywords:
Diphtheria-tetanus-pertussis vaccine
DTP
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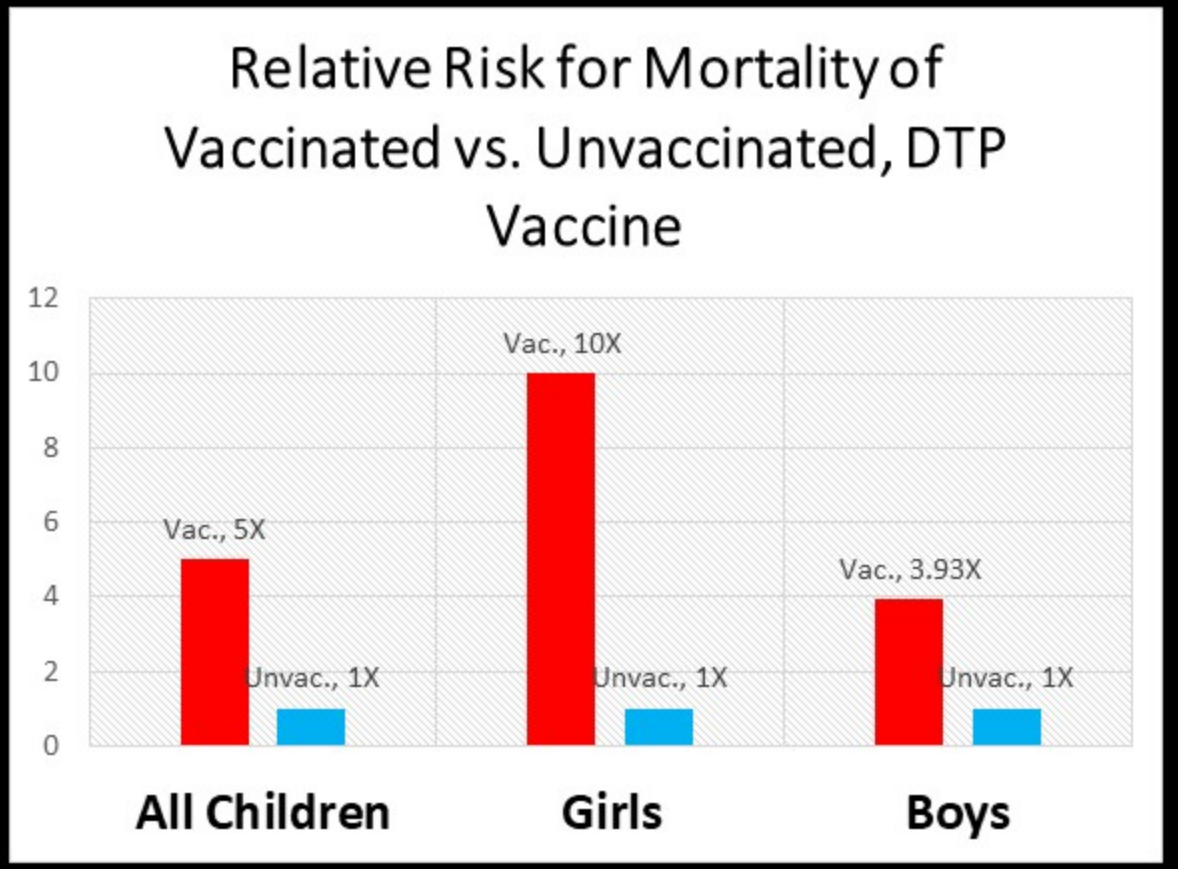
Non-specific effects of vaccines
Oral polio vaccine

ABSTRACT

Background: We examined the introduction of diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau in the early 1980s.
Methods: The child population had been followed with 3-monthly nutritional weighing sessions since 1978. From June 1981 DTP and OPV were offered from 3 months of age at these sessions. Due to the 3-monthly intervals between sessions, the children were allocated by birthday in a 'natural experiment' to receive vaccinations early or late between 3 and 5 months of age. We included children who were <6 months of age when vaccinations started and children born until the end of December 1983. We compared mortality between 3 and 5 months of age of DTP-vaccinated and not-yet-DTP-vaccinated children in Cox proportional hazard models.
Results: Among 3–5-month-old children, having received DTP (±OPV) was associated with a mortality hazard ratio (HR) of 5.00 (95% CI 1.53–16.3) compared with not-yet-DTP-vaccinated children. Differences in background factors did not explain the effect. The negative effect was particularly strong for children who had received DTP-only and no OPV (HR = 10.0 (2.61–38.6)). All-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19)).
Conclusion: DTP was associated with increased mortality; OPV may modify the effect of DTP.

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) DTP vs unvaccinated
All Unvaccinated (N = 651)	4.5 (5/111.4)	DTP (±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

Children's Health Defense

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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[1]Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, 350 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, USA

[2]Associate Professor, School of Public Health, Jackson State University, Jackson, MS 39213, USA

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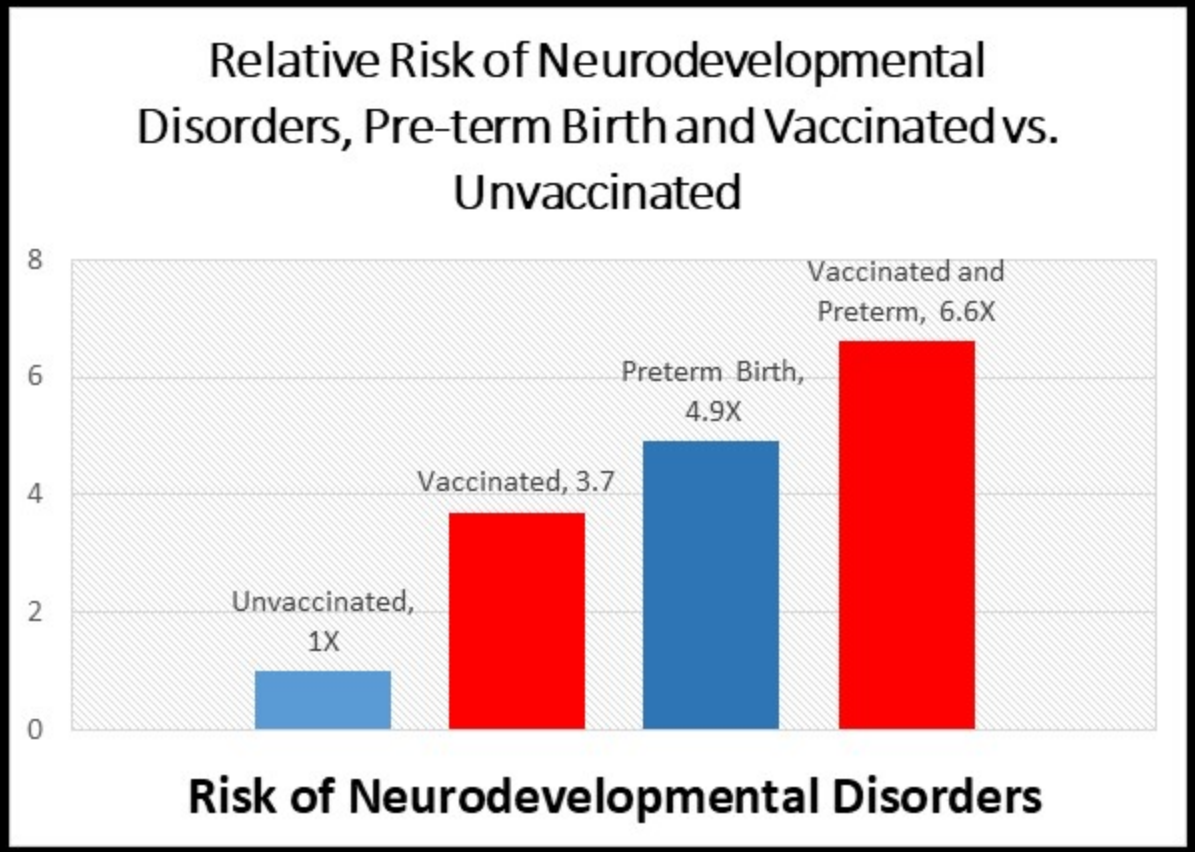
Abstract

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 homeschool 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



"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."

Children's Health Defense

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

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[1]Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[2]President, National Home Education Research Institute, PO Box 13939, Salem, OR 97309, USA

[3]Associate Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

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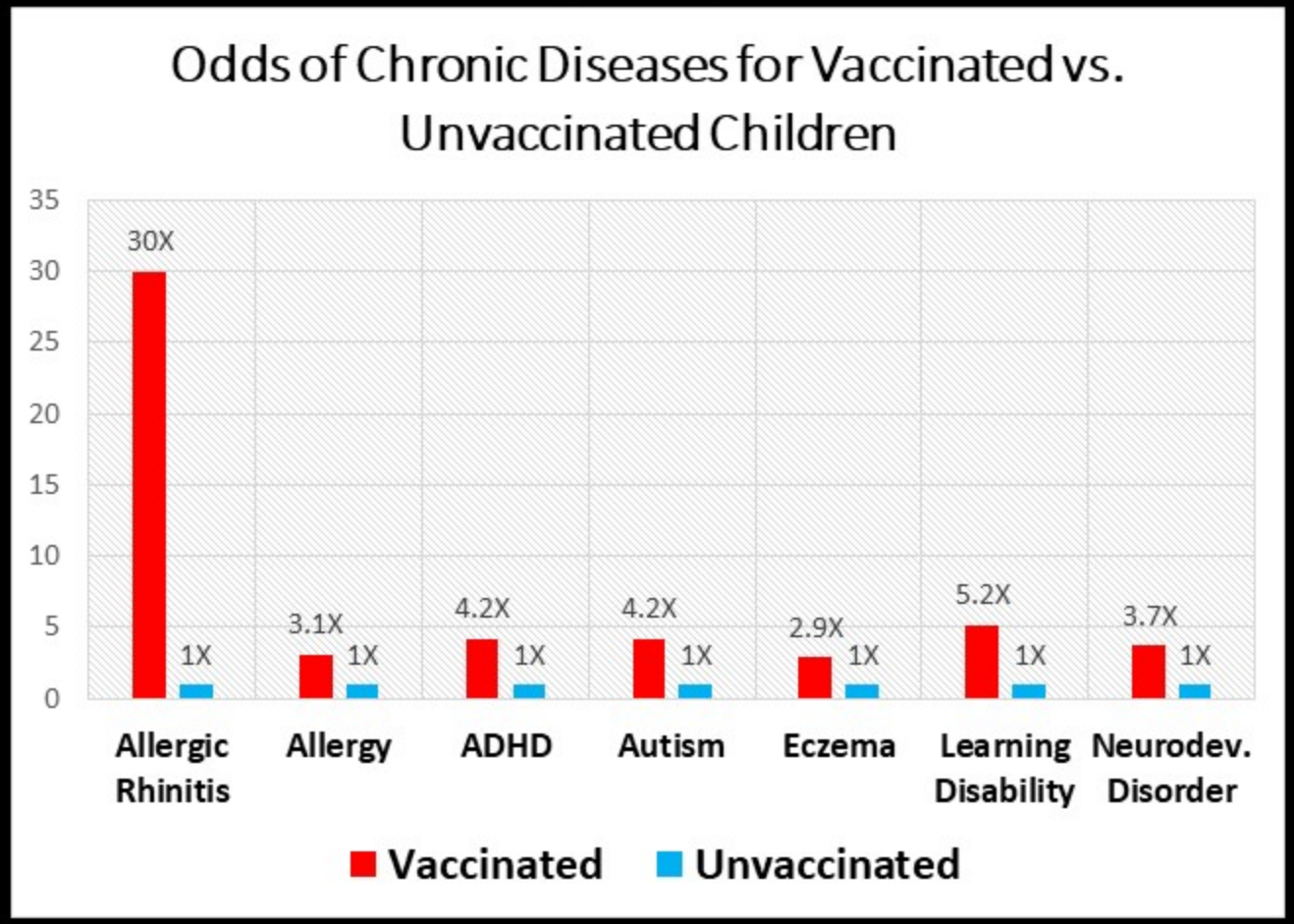
Abstract

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, [illegible]ese unexpected findings in order to optimize the impact of vaccines on



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."

Children's Health Defense

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[1], Classen DC

Author information

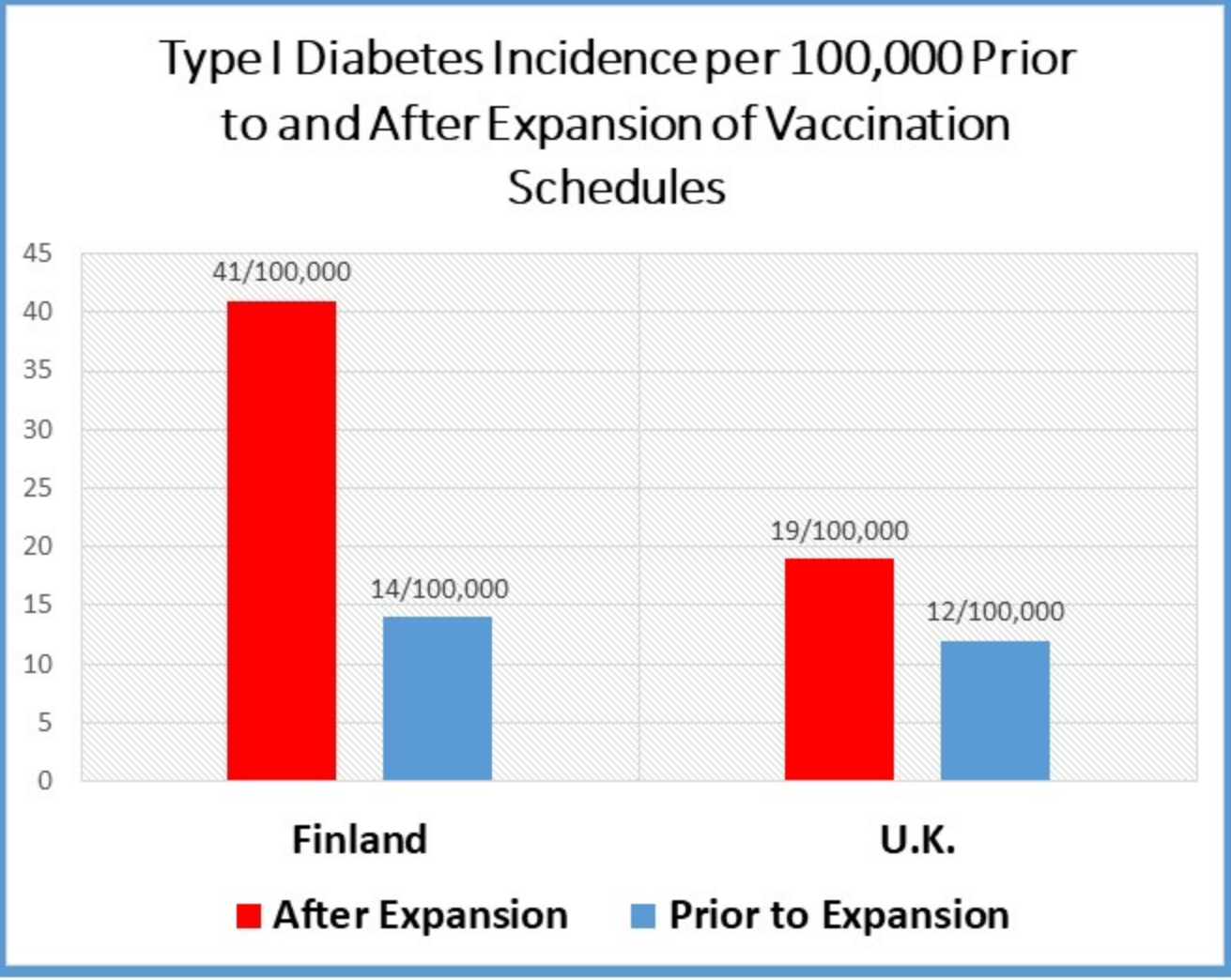
Abstract

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 the 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.



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"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 7

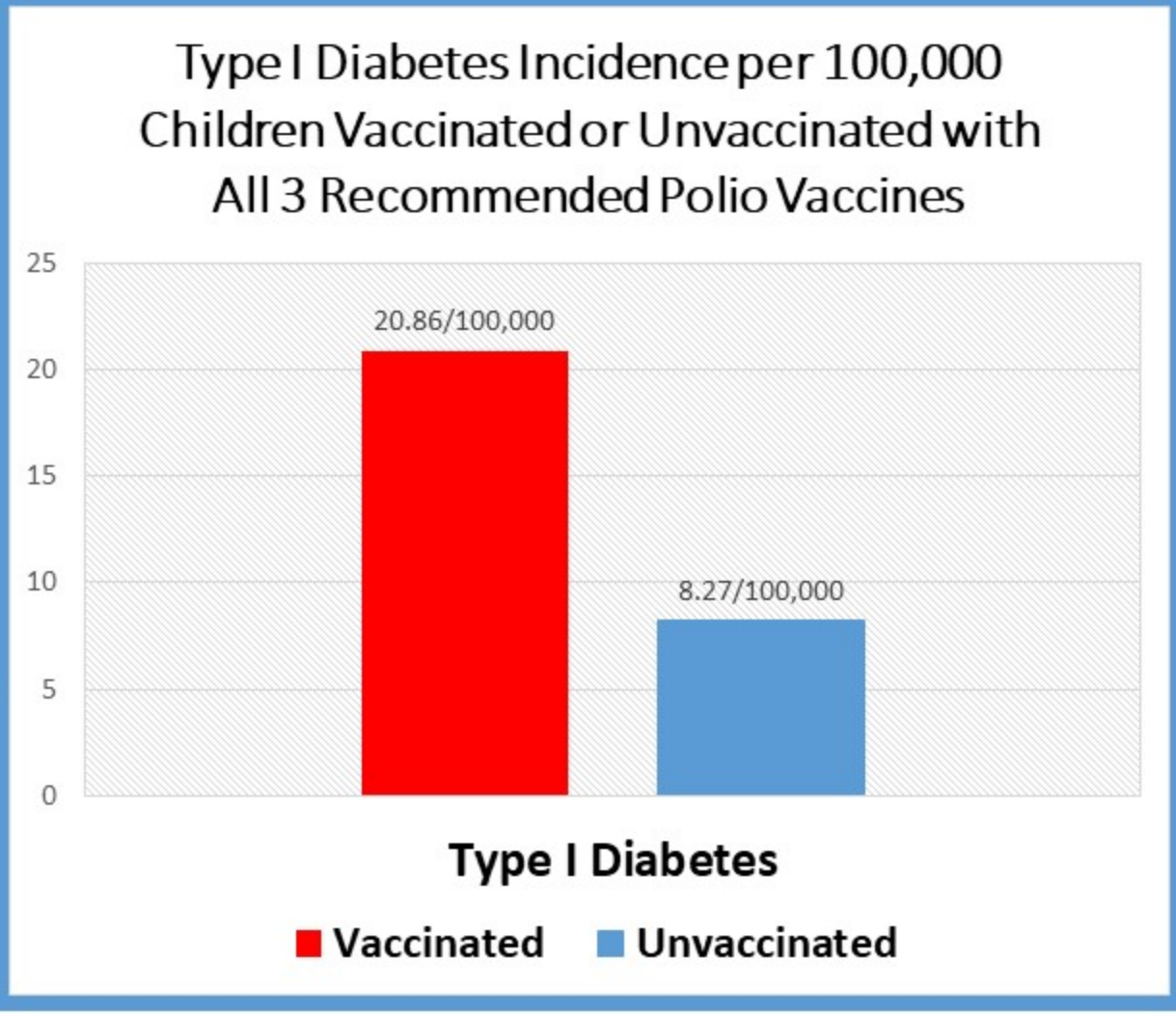
Risk of Vaccine Induced Diabetes in Children with a Family History of Type 1 Diabetes

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.



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

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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[1], Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C.

⊕ Author information

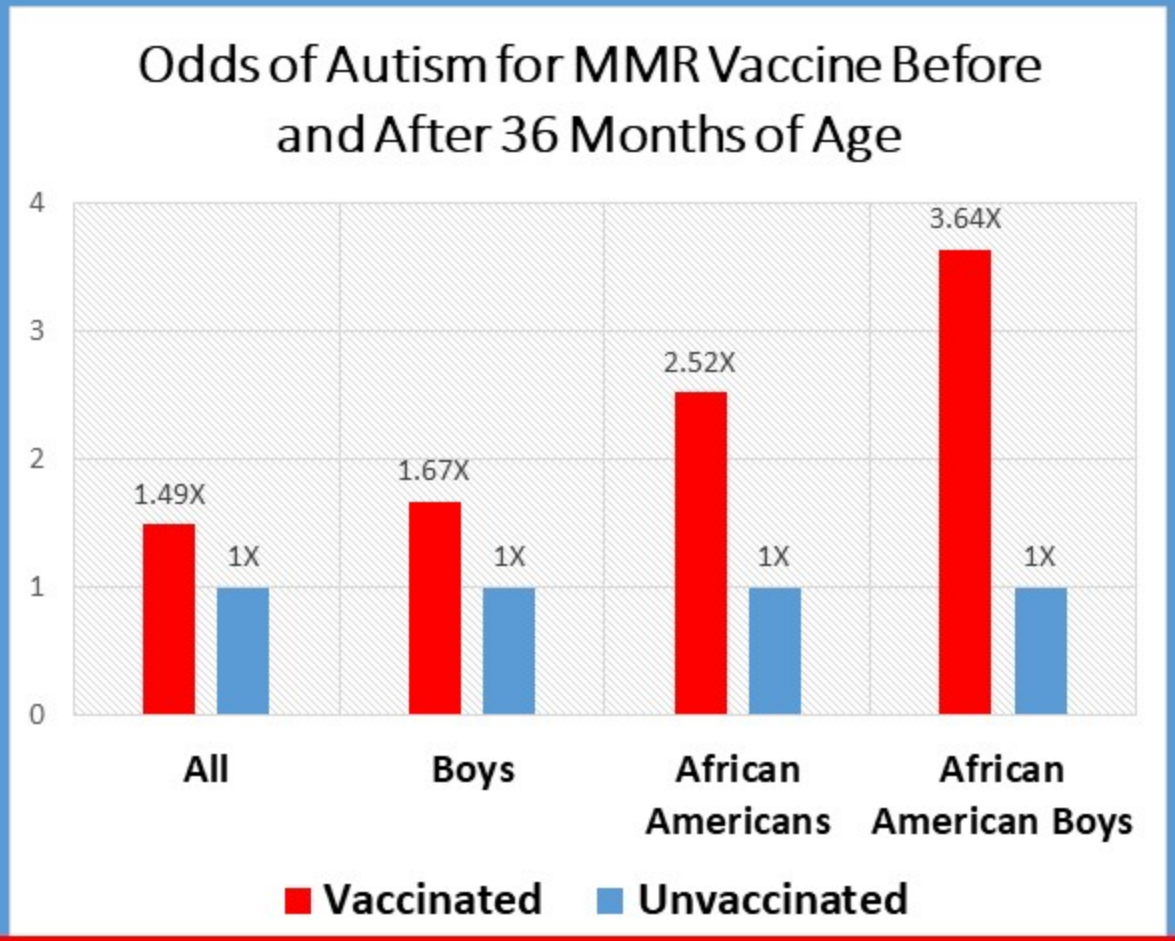
Abstract

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.



CDC UNPUBLISHED DATA OBTAINED BY FOIA

Children's Health Defense

Press Release, August 2014: "I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal Pediatrics. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism." – Dr. William Thompson, *CDC senior vaccine safety scientist*

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 BS, Kern JK, King PG, Sykes LK, Geier MR[1].

⊕ Author information

Abstract

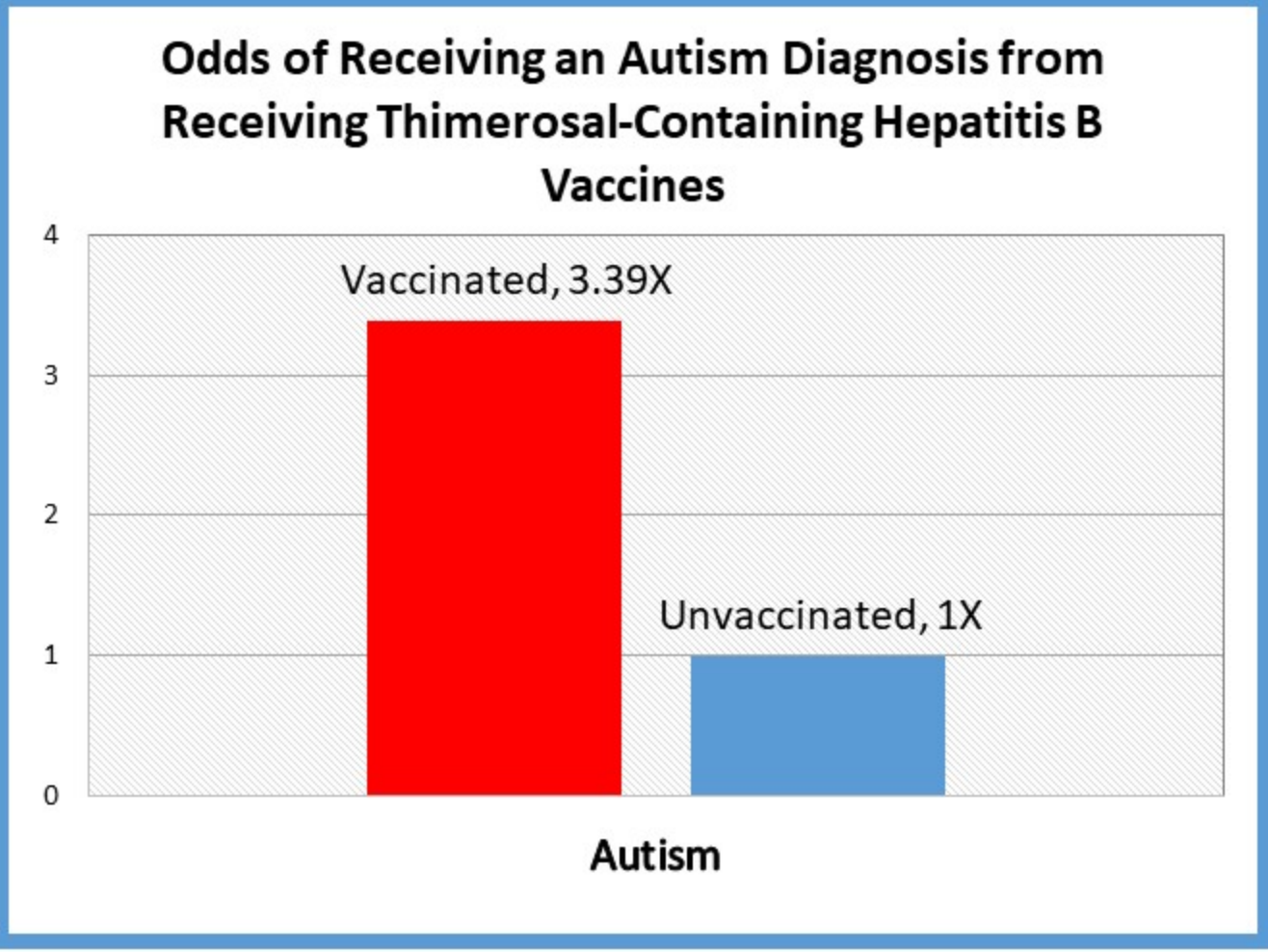
BACKGROUND: Autism spectrum disorder (ASD) is defined by standardized criteria of qualitative impairments in social interaction, qualitative impairments in communication, and restricted and stereotyped patterns of behavior, interests, and activities. A significant number of children diagnosed with ASD 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.

PMID: 24354891 PMCID: PMC3878266 DOI: 10.1186/2047-9158-2-25



"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."

Children's Health Defense

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[1,2], Kern JK[1,2], Geier MR[1,2].

Author information

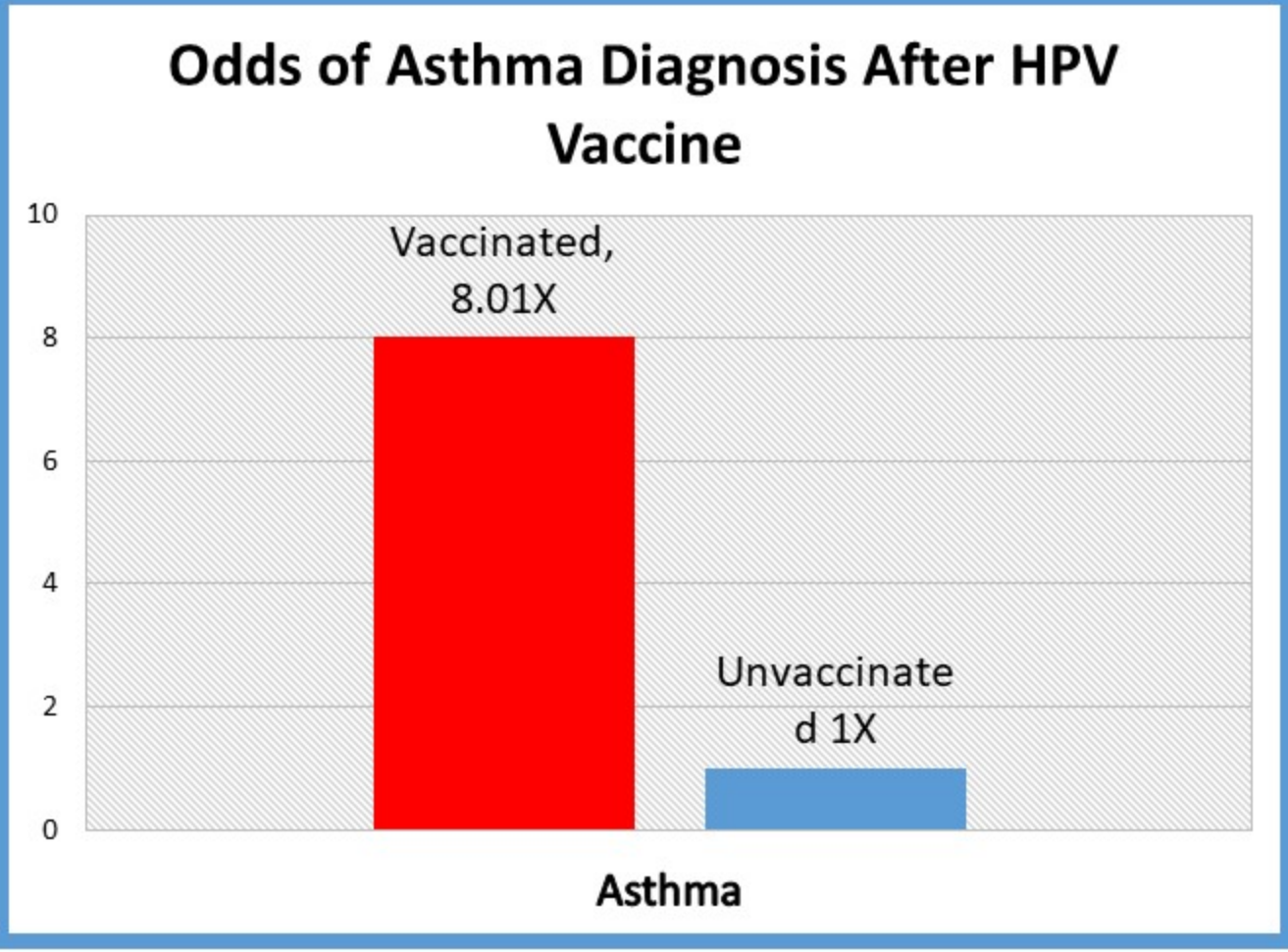
Abstract

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.



"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."

Children's Health Defense

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[1,2], Kern JK[3,4,5], Geier MR[6,7].

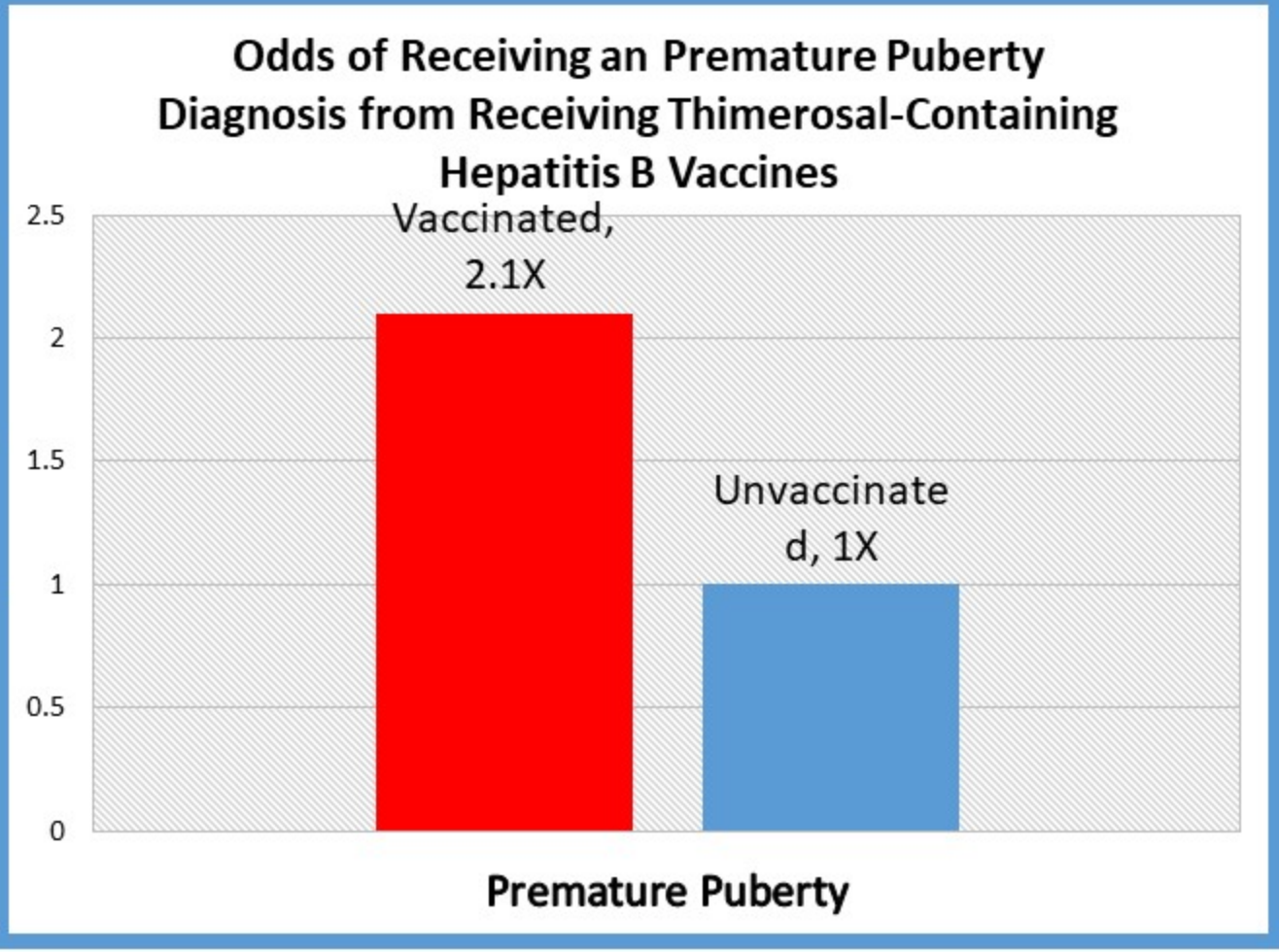
Author information

Abstract

Studies suggest a relationship between exposure to endocrine disrupters, 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 µg 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; merthiolate; premature puberty; thiomersal

PMID: 30445743 PMCID: PMC6316152 DOI: 10.3390/toxics6040067



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"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.

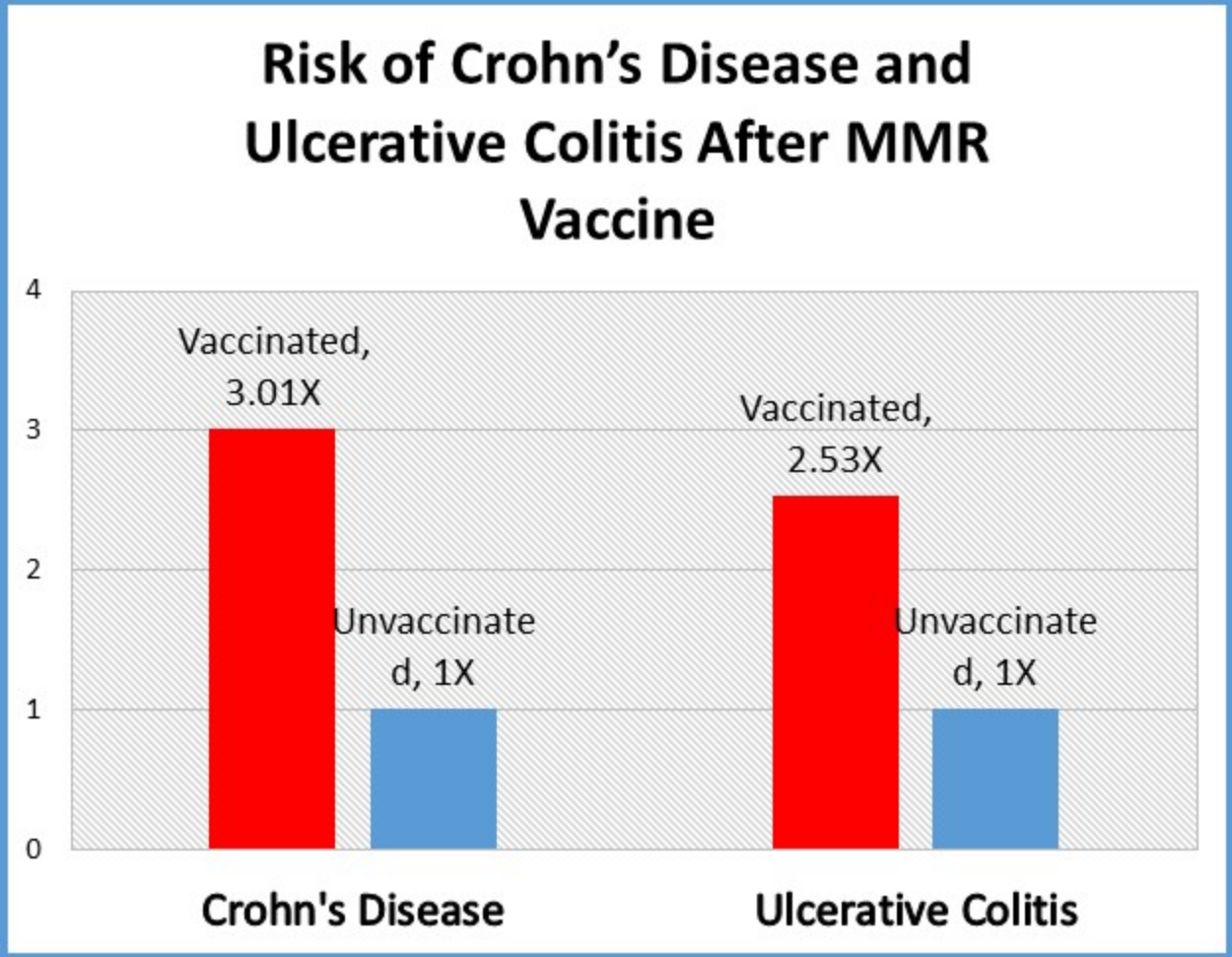
Is measles vaccination a risk factor for inflammatory bowel disease?

Thompson NP[1], 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.



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

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

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

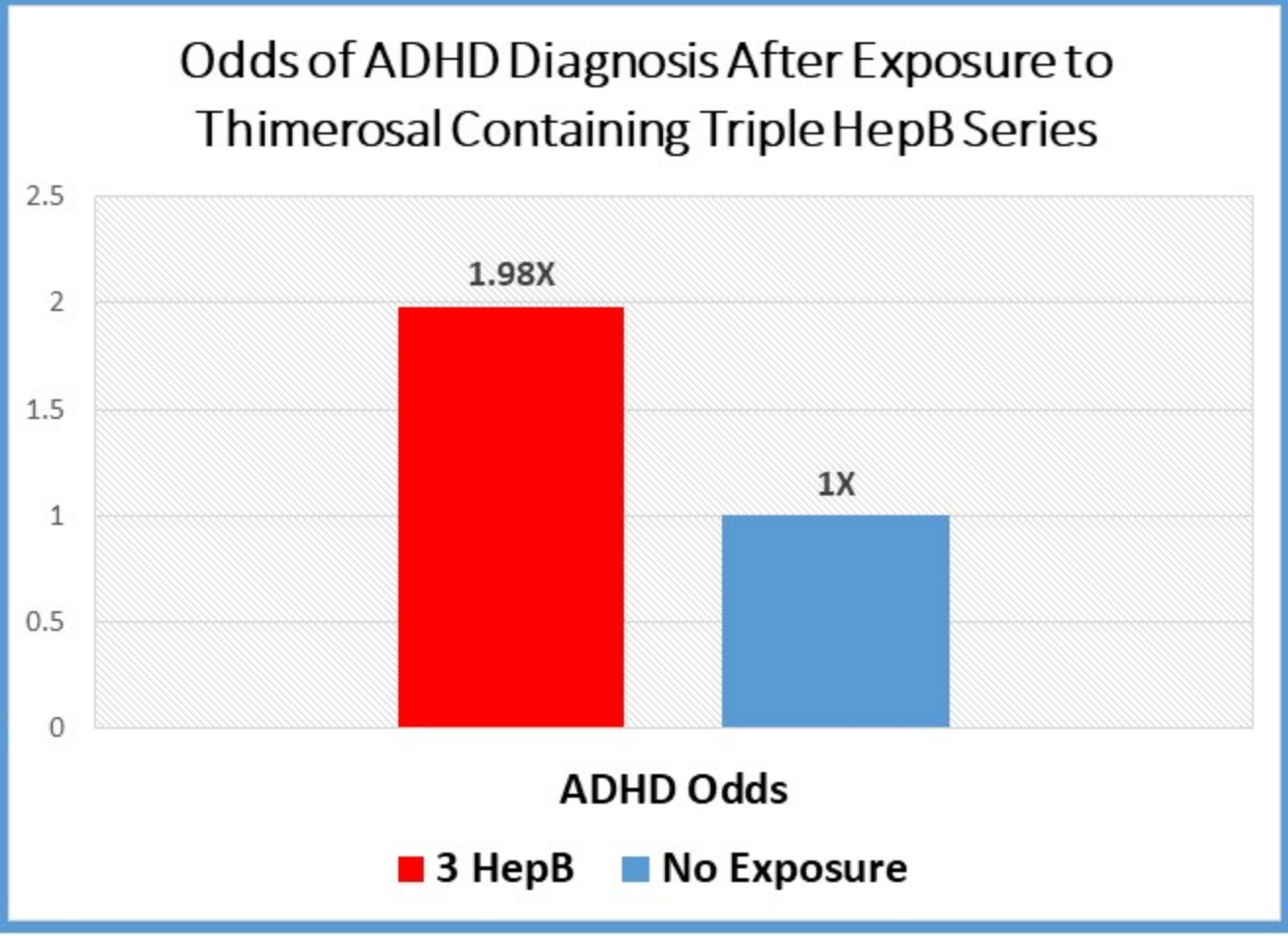
A cross-sectional study of the relationship between infant Thimerosal-containing hepatitis B vaccine exposure and attention-deficit/hyperactivity disorder.

Geier DA[1], Kern JK[2], Homme KG[3], Geier MR[4].

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 2×2 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.



Children's Health Defense

"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."

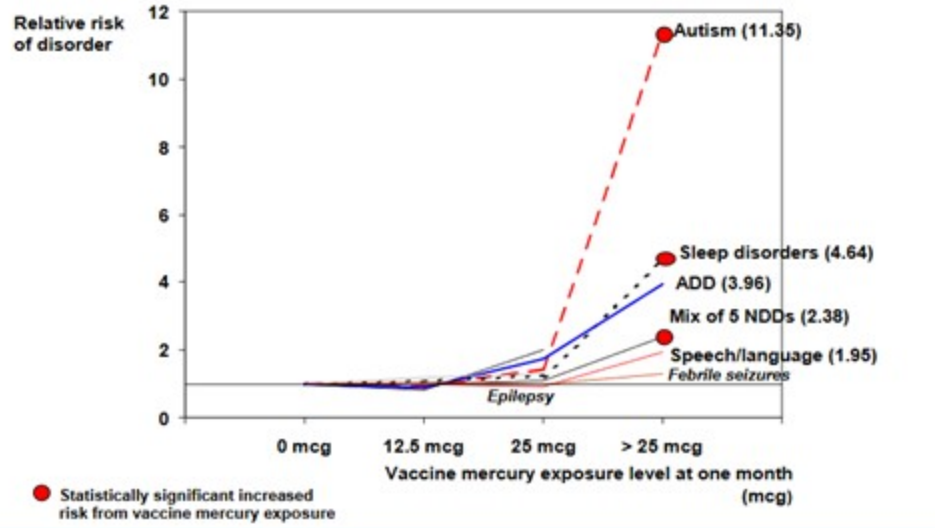
Highest Levels of Thimerosal Exposure Increase Autism Risk 11.35X

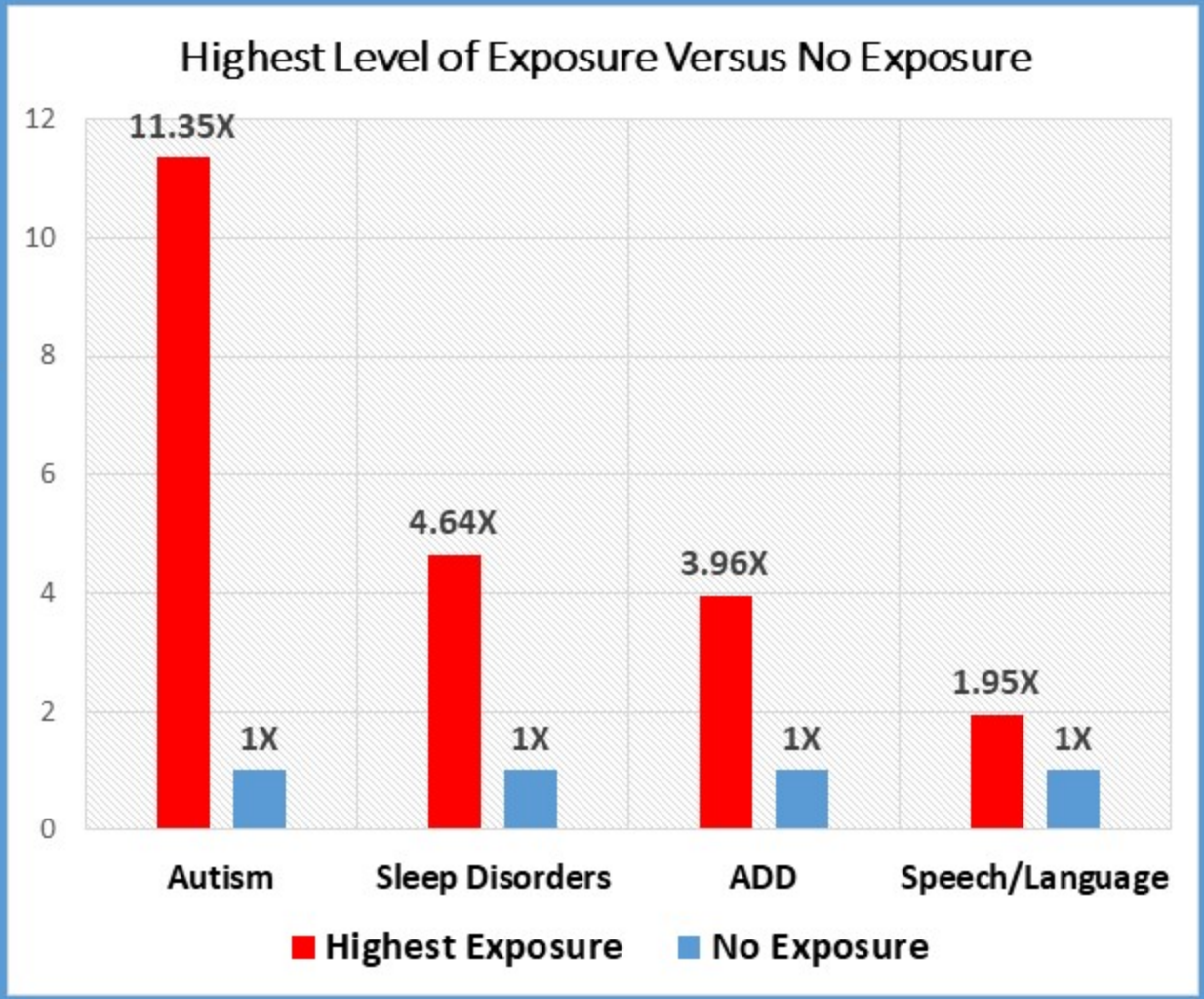
GENERATION ZERO

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





CDC UNPUBLISHED DATA OBTAINED BY FOIA

Children's Health Defense

"Autism risks were the highest of all the diagnostic codes, with a relative risk at one month of 11.35 between the high and zero exposure groups."

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

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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[1], Kieke BA[2], King JP[3], DeStefano F[4], Mascola MA[5], Irving SA[6], Cheetham TC[7], Glanz JM[8], Jackson LA[9], Klein NP[10], Naleway AL[11], Weintraub E[12], Belongia EA[13].

Author information

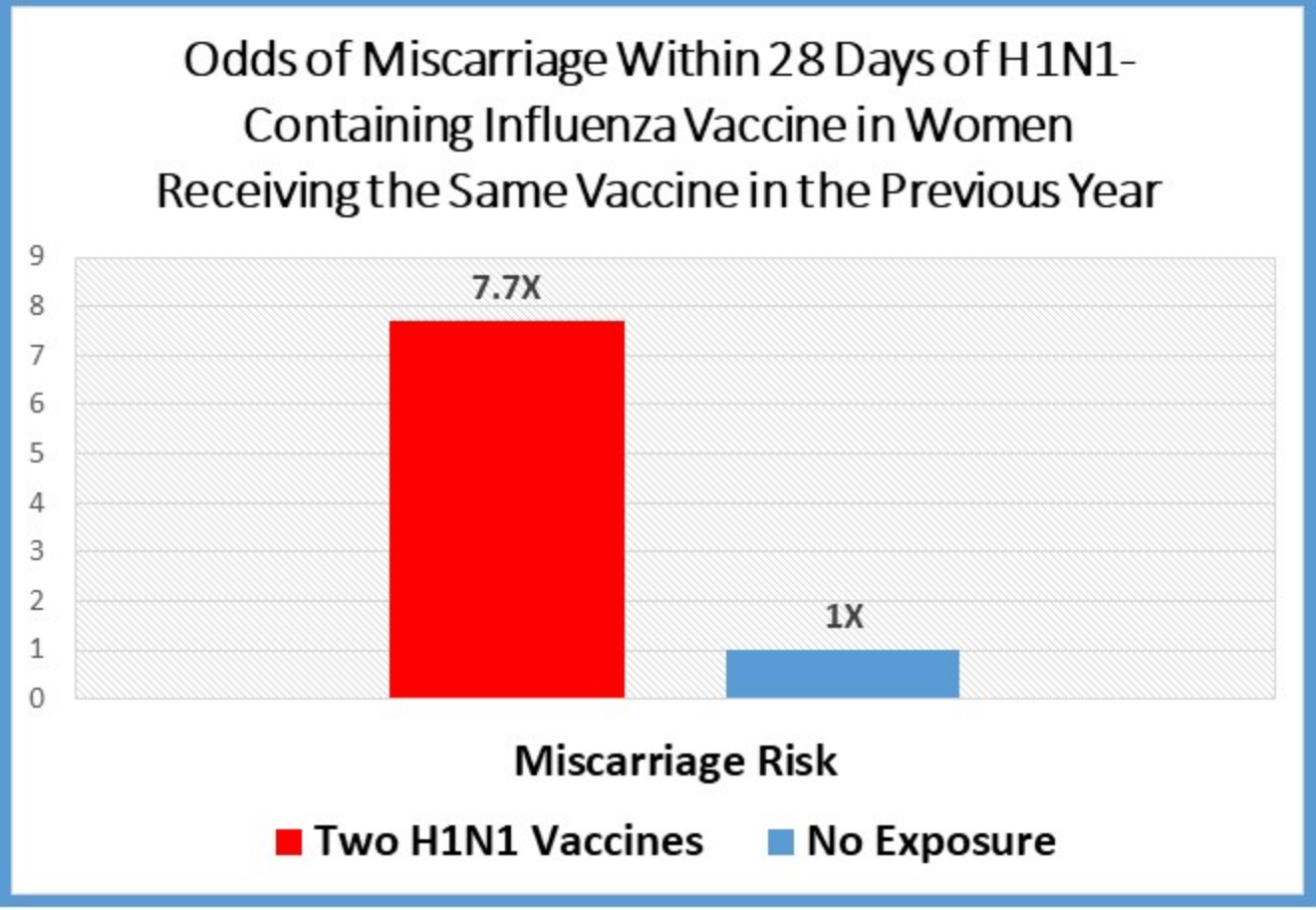
Abstract

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.



Children's Health Defense

"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

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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 C[1], Persson I, Ortqvist A, Bergman U, Ludvigsson JF, Granath F.

Author information

Abstract

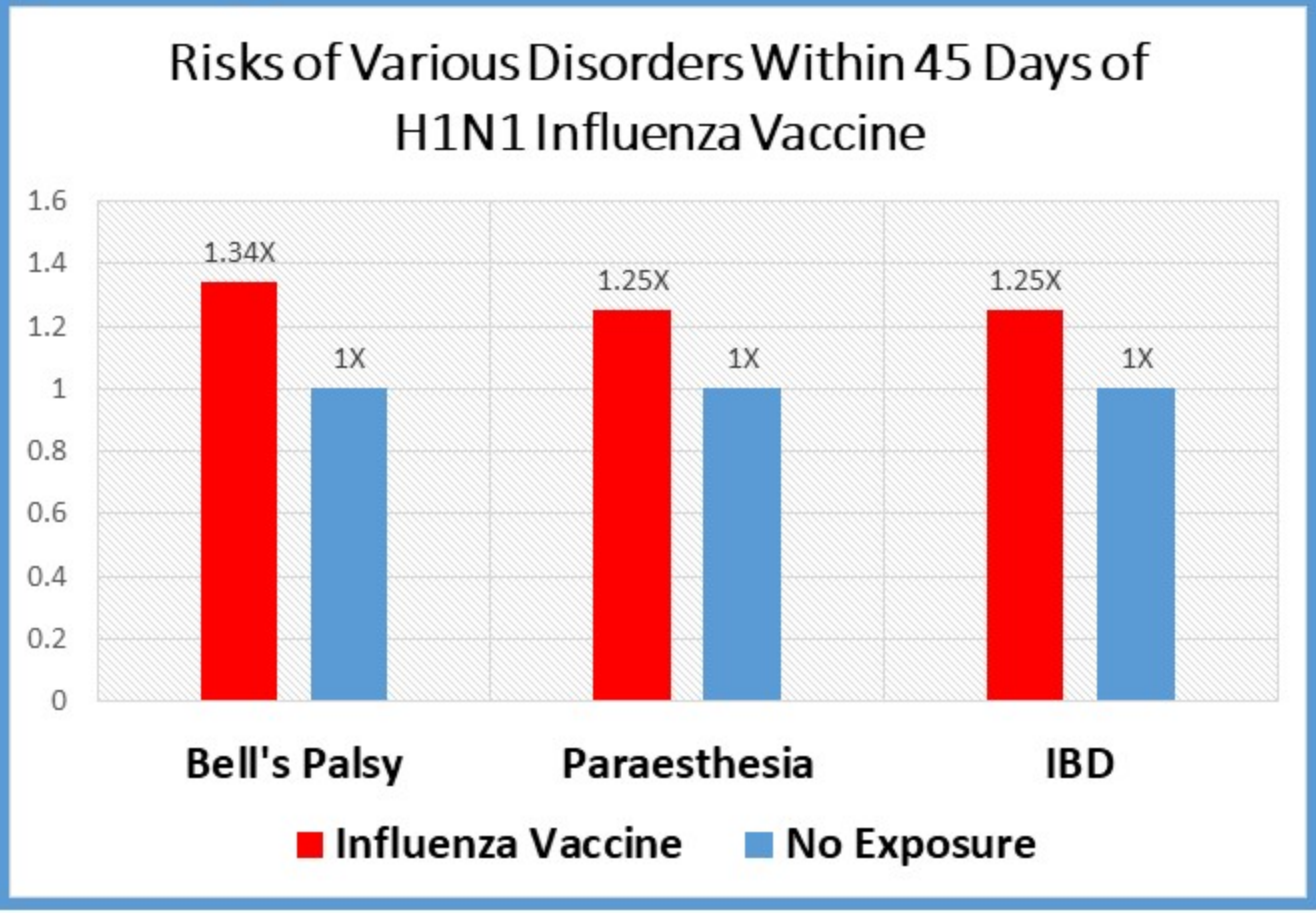
OBJECTIVE: To examine the risk of neurological and autoimmune disorders of special interest in people vaccinated against pandemic influenza A (H1N1) with Pandemrix (GlaxoSmithKline, Middlesex, UK) compared with unvaccinated people over 8-10 months.

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.

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

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Jpn J Nurs Sci. 2019 Jan 28. doi: 10.1111/jjns.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[1], Tsubaki H[2].

Author information

Abstract

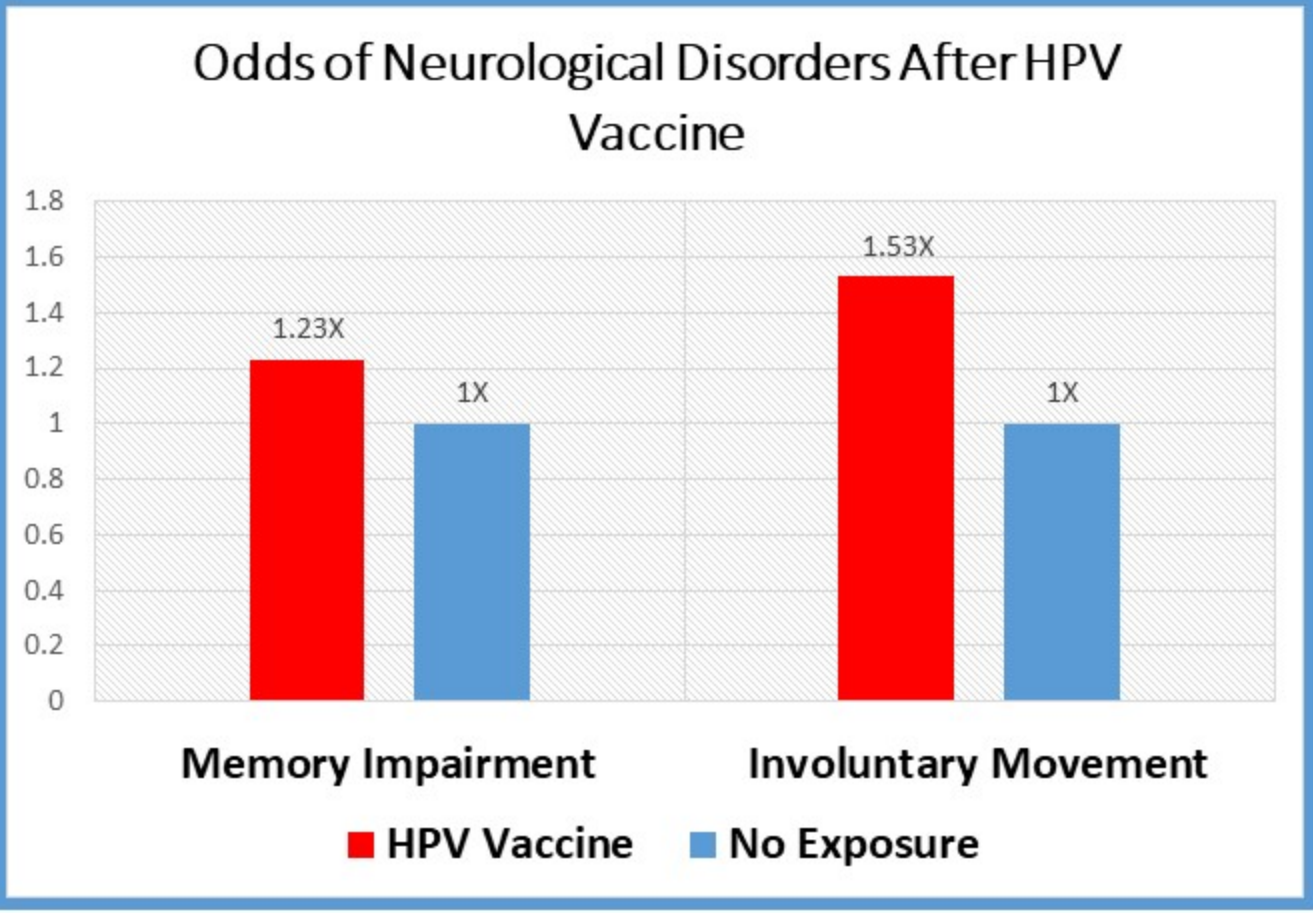
AIM: To assess the safety of human papilloma virus (HPV) vaccines by using data from the "Nagoya City Cervical Cancer Immunization Program Survey".

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.

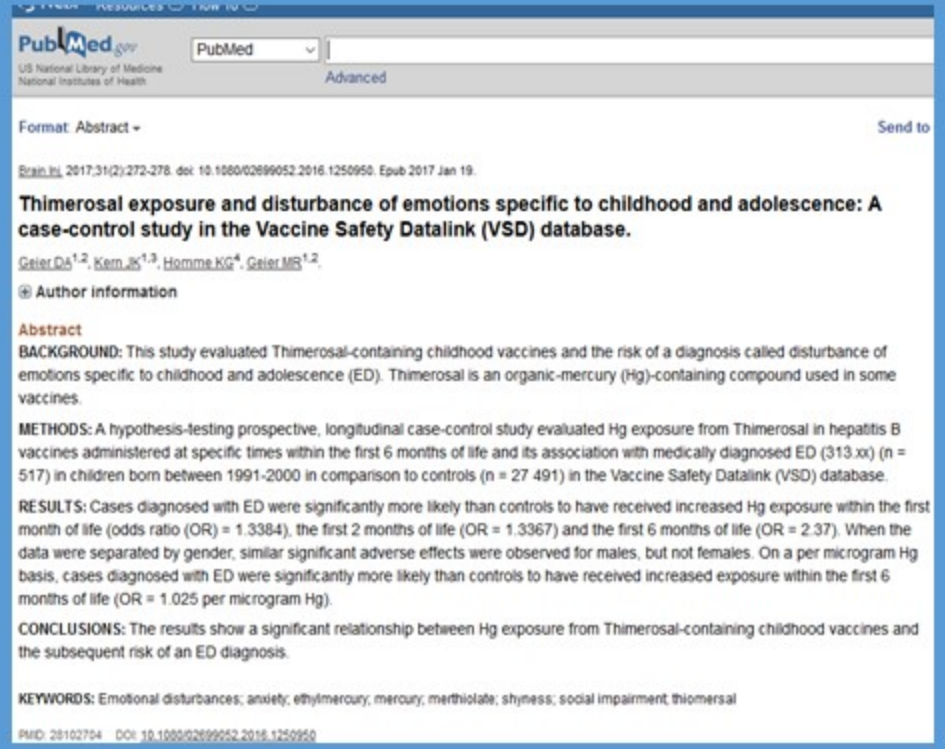
KEYWORDS: adverse events; human papilloma virus; surveillance; vaccine



Children's Health Defense

"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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Brain Inj. 2017;31(2):272-278. doi: 10.1080/02699052.2016.1250950. 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[1,2], Kern JK[1,3], Homme KG[4], Geier MR[1,2].

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.

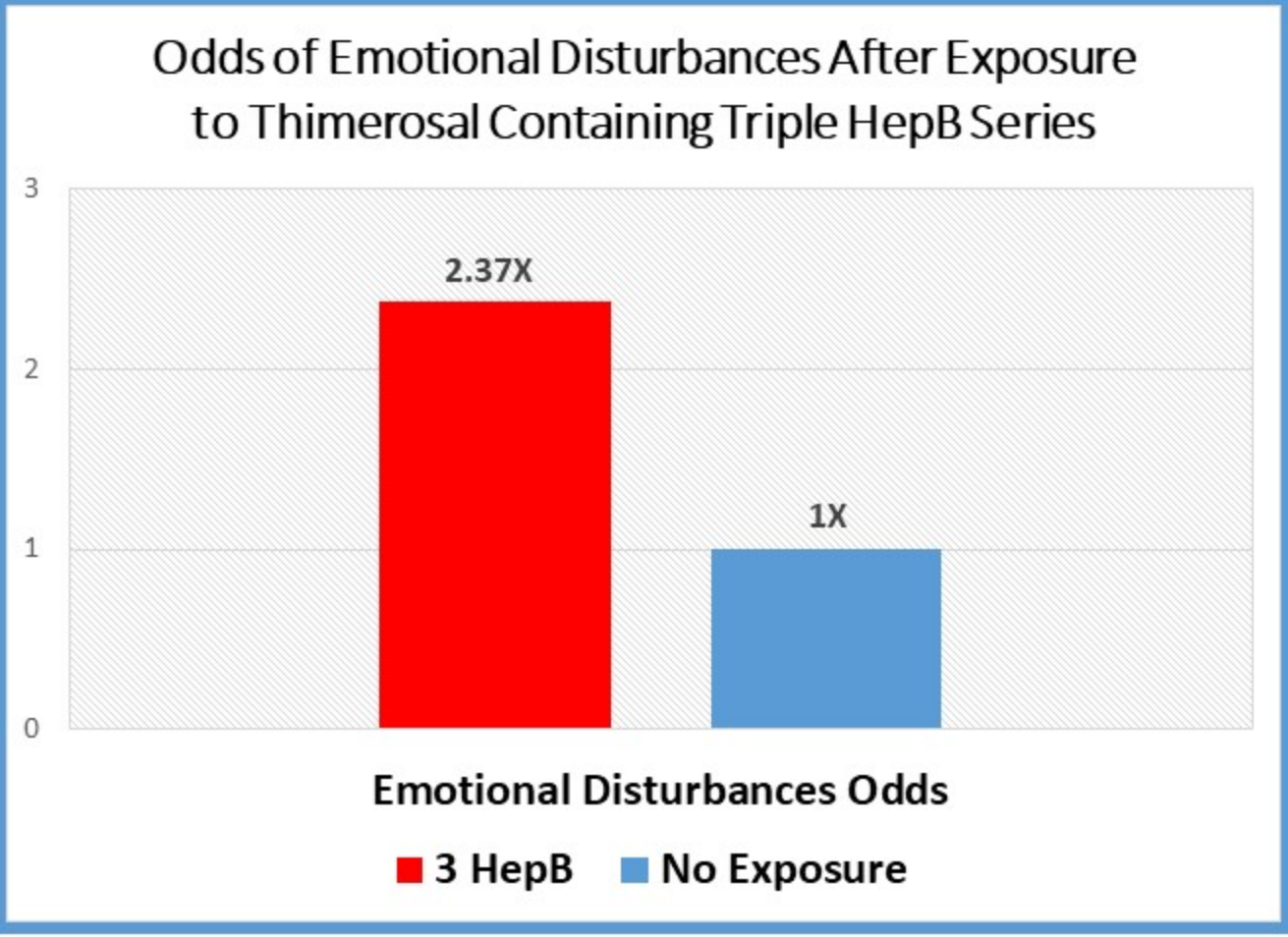
METHODS: A hypothesis-testing prospective, longitudinal case-control study evaluated Hg exposure from Thimerosal in hepatitis B vaccines administered at specific times within the first 6 months of life and its association with medically diagnosed ED (313.xx) (n = 517) in children born between 1991-2000 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: 10.1080/02699052.2016.1250950



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

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HPV Vaccine Increases the Risk of Celiac Disease by 1.56X

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J Intern Med. 2018 Feb;283(2):154-165. doi: 10.1111/joim.12694. Epub 2017 Oct 18.

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

Hviid A[1], Svanström H[1], Scheller NM[1], Grönlund O[2], Pasternak B[1,3], Arnheim-Dahlström L[2].

Author information

Abstract

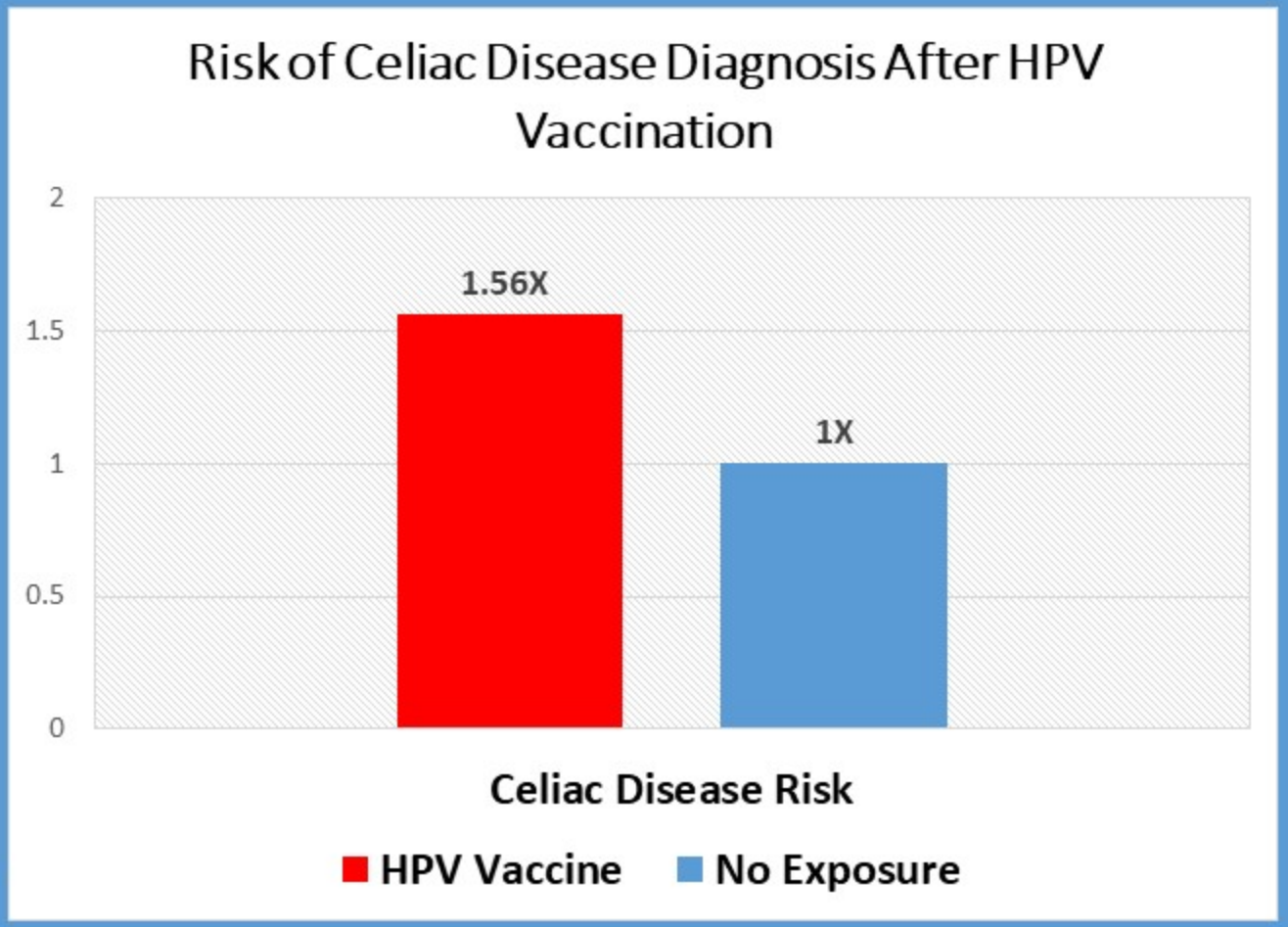
BACKGROUND: Since 2006, human papillomavirus (HPV) vaccines have been introduced in many countries worldwide. Whilst safety studies have been reassuring, focus has been on the primary target group, the young adolescent girls. However, it is also important to evaluate safety in adult women where background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



Children's Health Defense

"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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PubMed | 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[1].

Author information

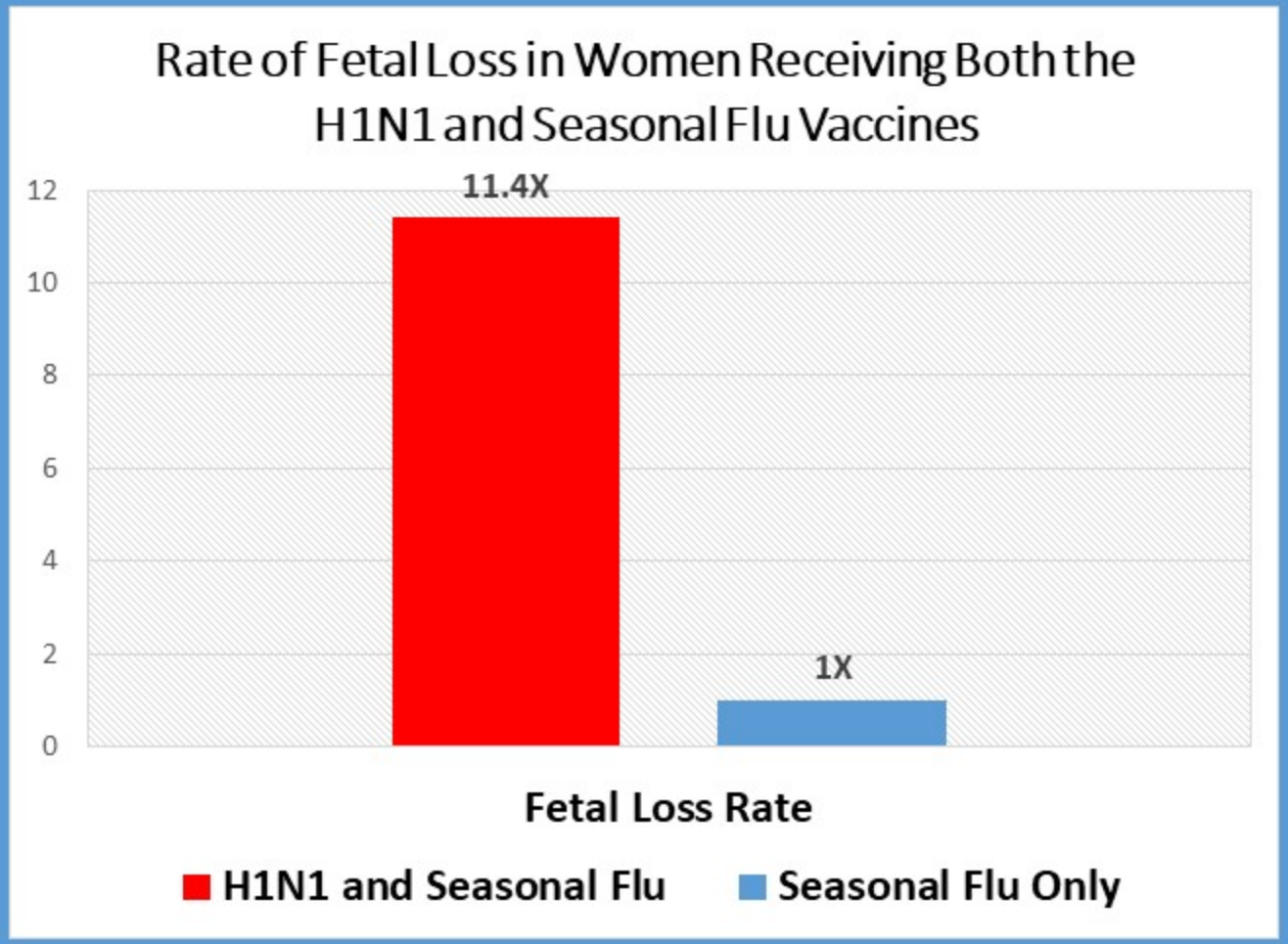
Abstract

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: PMC3888271 DOI: 10.1177/0960327112455067

[Indexed for MEDLINE] Free PMC Article



Children's Health Defense

"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."

Swine Flu 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.

Szakács A[1], 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.

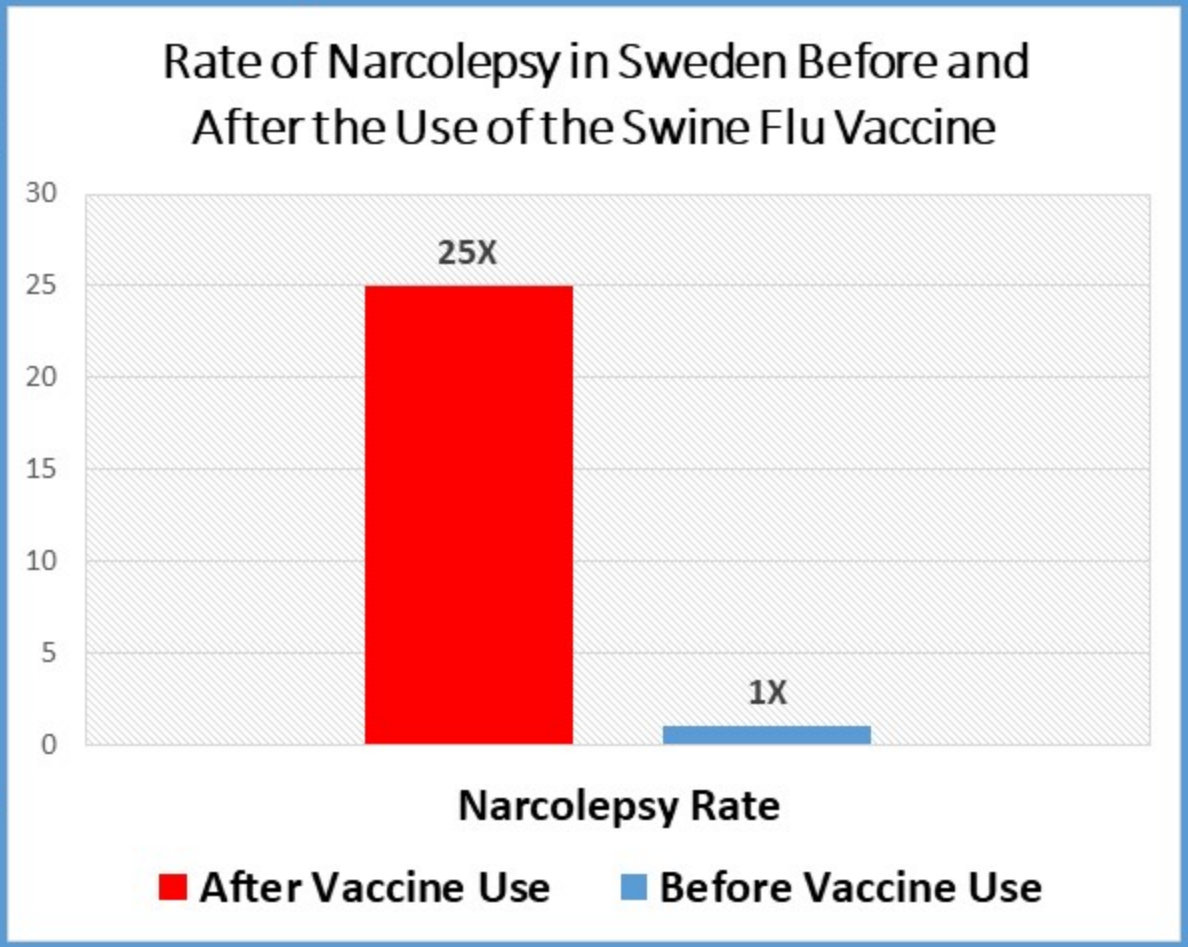
METHODS: The children were identified from all local and regional pediatric hospitals, child rehabilitation centers, outpatient pediatric clinics, and regional departments of neurophysiology. Data collection was performed with the aid of a standardized data collection form, from medical records and telephone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



"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."

Children's Health Defense

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.2014.14828.

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

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

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.

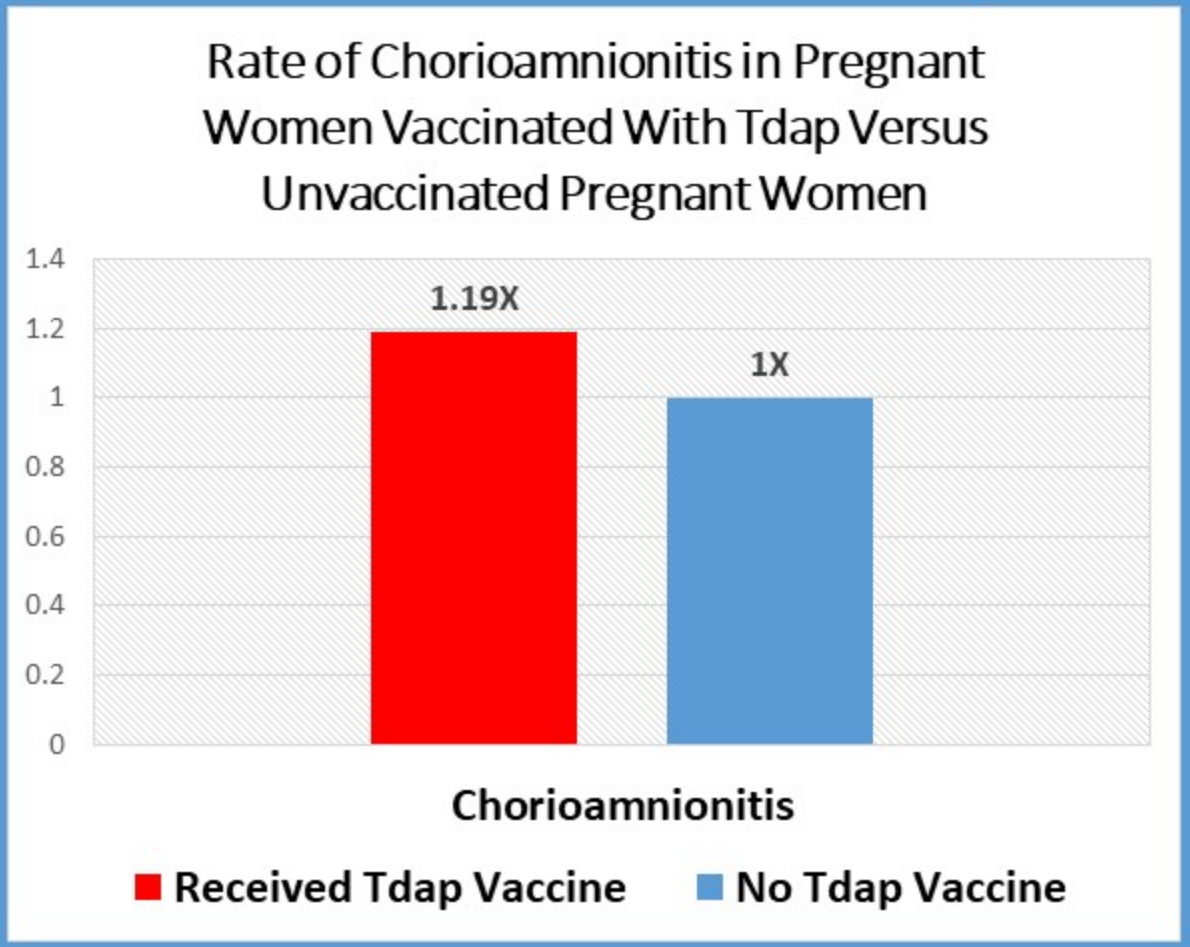
DESIGN AND SETTING: Retrospective, observational cohort study using administrative health care databases from 2 California Vaccine Safety Datalink sites.

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.



"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)."

Children's Health Defense

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[1], López-Collada VR, Bulhões MM, De Oliveira LH, Bautista Márquez A, Flannery B, Esparza-Aguilar M, Montenegro Renoiner EI, Luna-Cruz ME, Sato HK, Hernández-Hernández Ldel C, Toledo-Cortina G, Cerón-Rodríguez M, Osnaya-Romero N, Martínez-Alcazar M, Aquinaga-Villasenor RG, Plascencia-Hernández A, Fojaco-González F, Hernández-Peredo Rezk G, Gutierrez-Ramírez SF, Dorame-Castillo R, Tinajero-Pizano R, Mercado-Villegas B, Barbosa MR, Maluf EM, Ferreira LB, de Carvalho FM, dos Santos AR, Cesar ED, de Oliveira ME, Silva CL, de Los Angeles Cortes M, Ruiz Matus C, Tate J, Gargiullo P, Parashar UD.

Author information

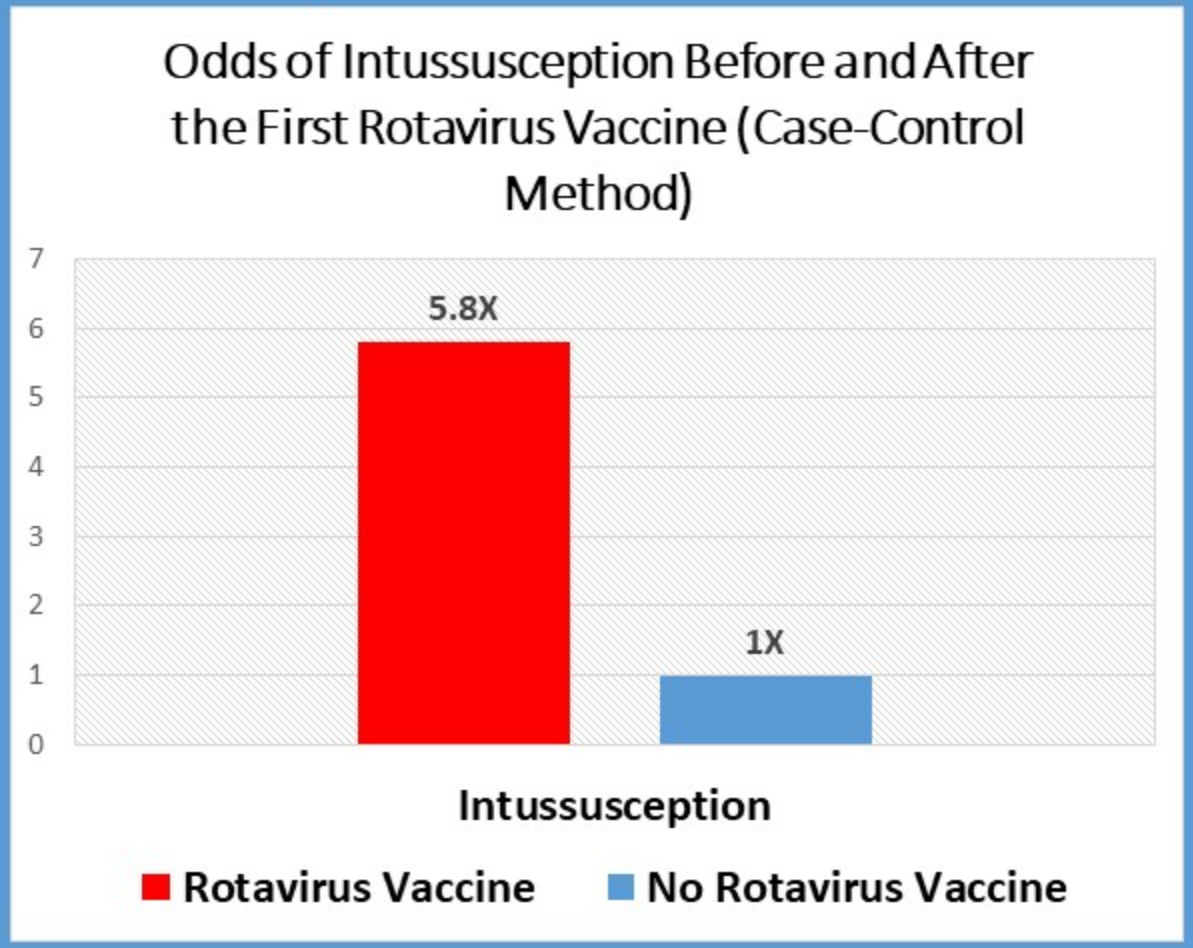
Abstract

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.).



"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)."

Children's Health Defense

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

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PubMed | Shaheen Lancet Aaby Measles Atopy 1996

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

Measles and atopy in Guinea-Bissau.

Shaheen SO[1], Aaby P, Hall AJ, Barker DJ, Heyes CB, Shiell AW, Goudiaby A.

Author information

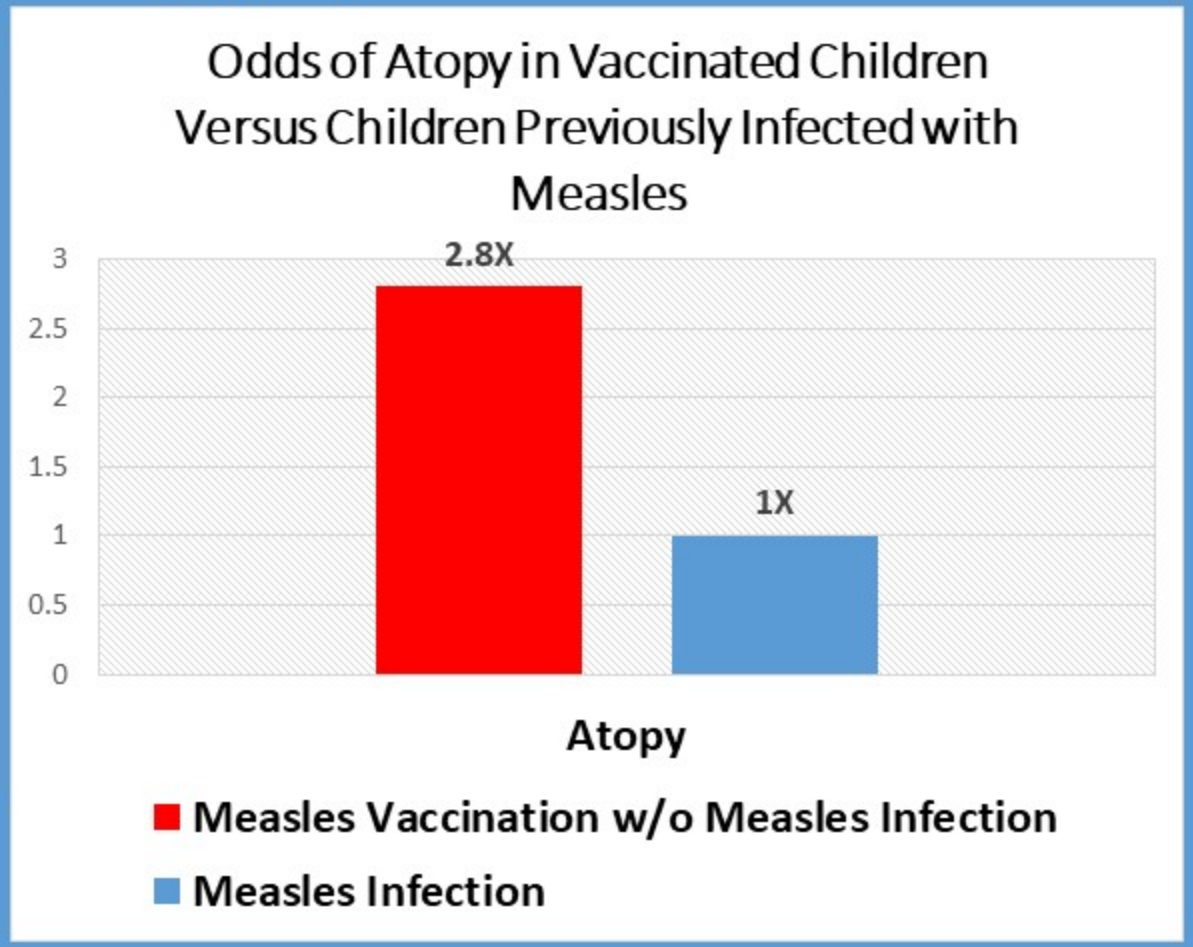
Abstract

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 (> 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=O.O1). 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.



"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"

Children's Health Defense

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

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

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

Author information

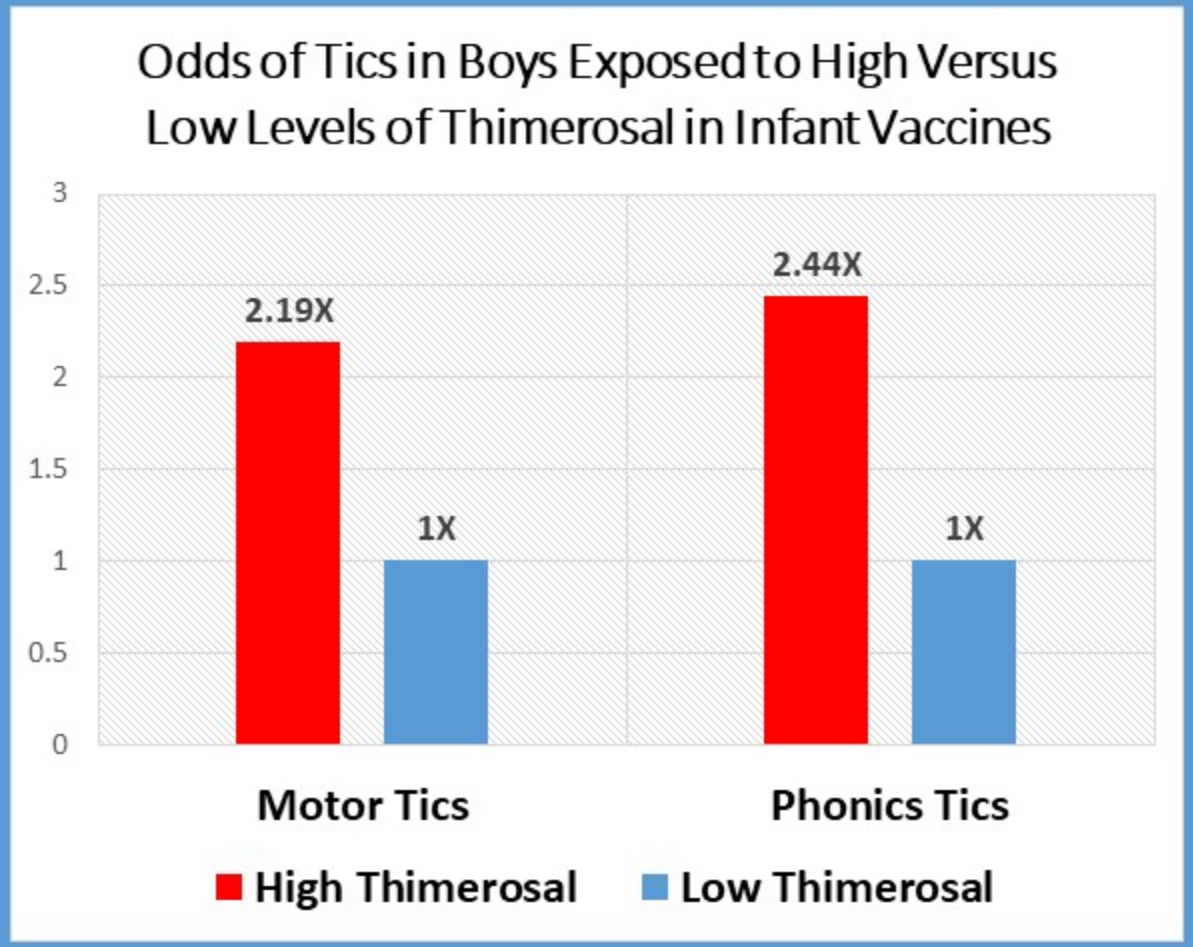
Abstract

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.



"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."

Children's Health Defense

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

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PubMed | 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[1], Huq SI, Lix LM, Becker AB, Kozyrskyj AL.

Author information

Abstract

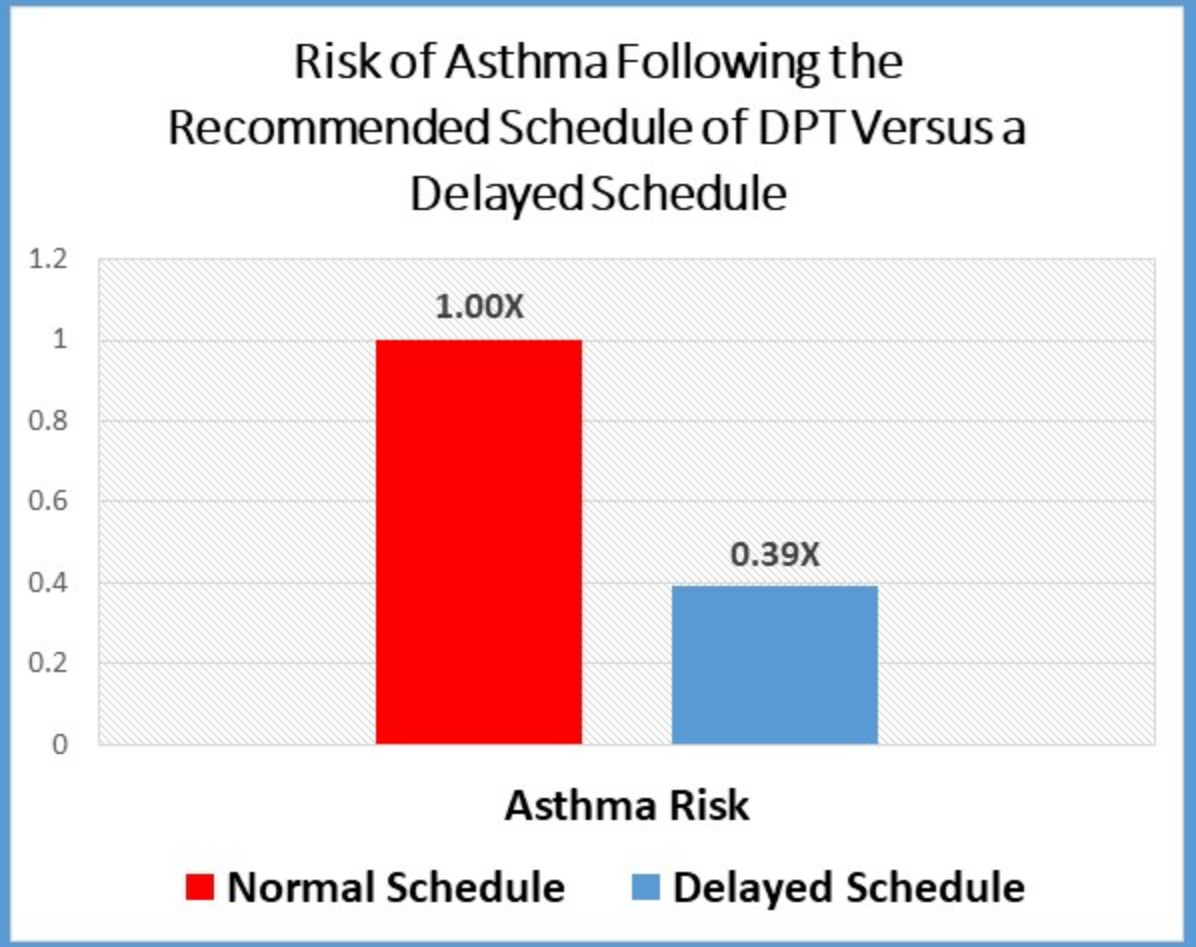
BACKGROUND: Early childhood immunizations have been viewed as promoters of asthma development by stimulating a T(H)2-type immune response or decreasing microbial pressure, which shifts the balance between T(H)1 and T(H)2 immunity.

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.



"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)."

Children's Health Defense

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*,**, Heather A. Young* & Mark R. Geier#

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

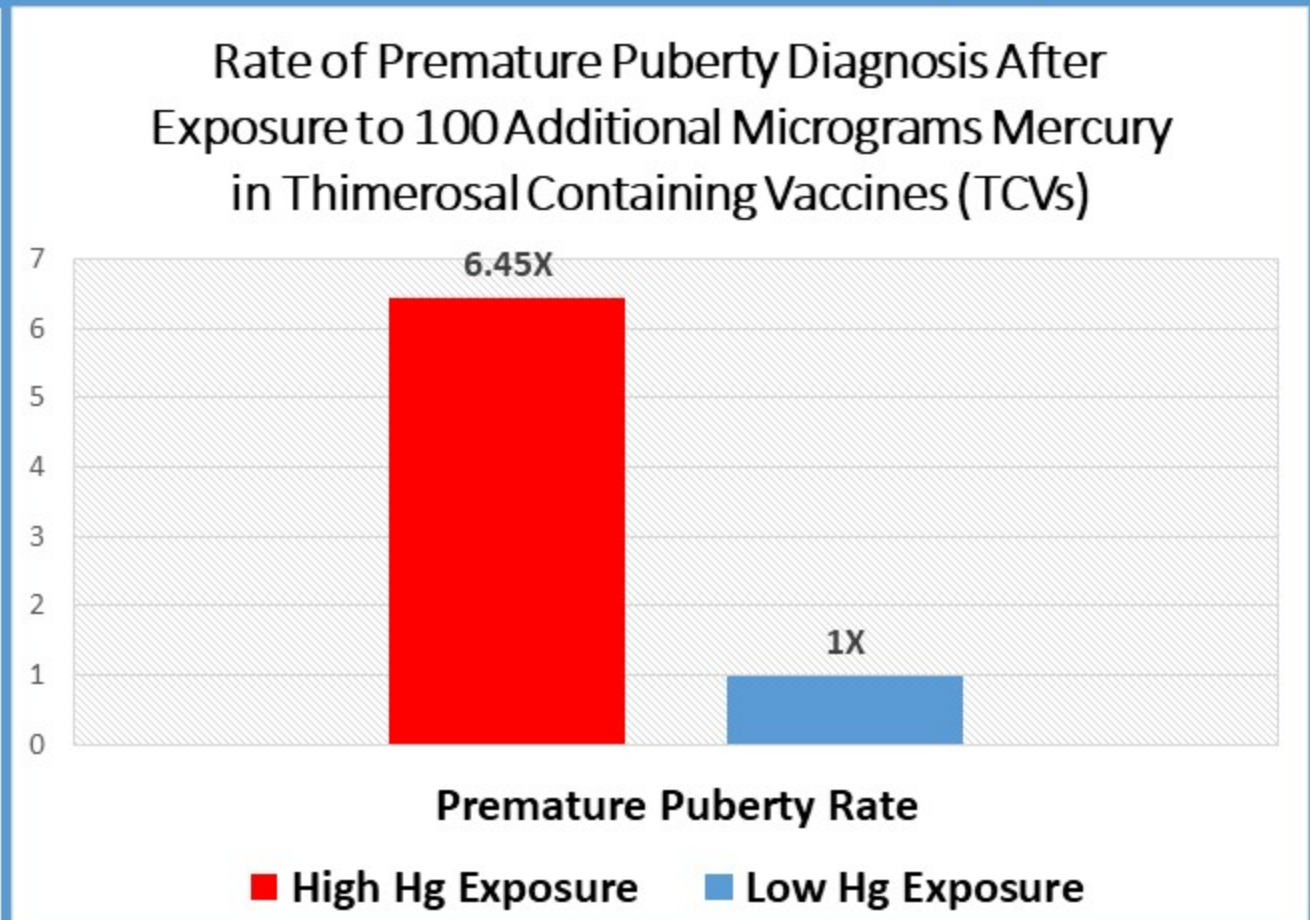
Received December 12, 2008

***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, 9th 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.



"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."

Children's Health Defense

Addition of the Hepatitis B Vaccine in 1988 Increased the Rate of Type 1 Diabetes 1.62X in Children in New Zealand

Infectious Diseases In Clinical Practice

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Classen David C.; Classen, John Barthelow

Infectious Diseases in Clinical Practice: September-October 1997 - Volume 6 - Issue 7 - ppg 449-454
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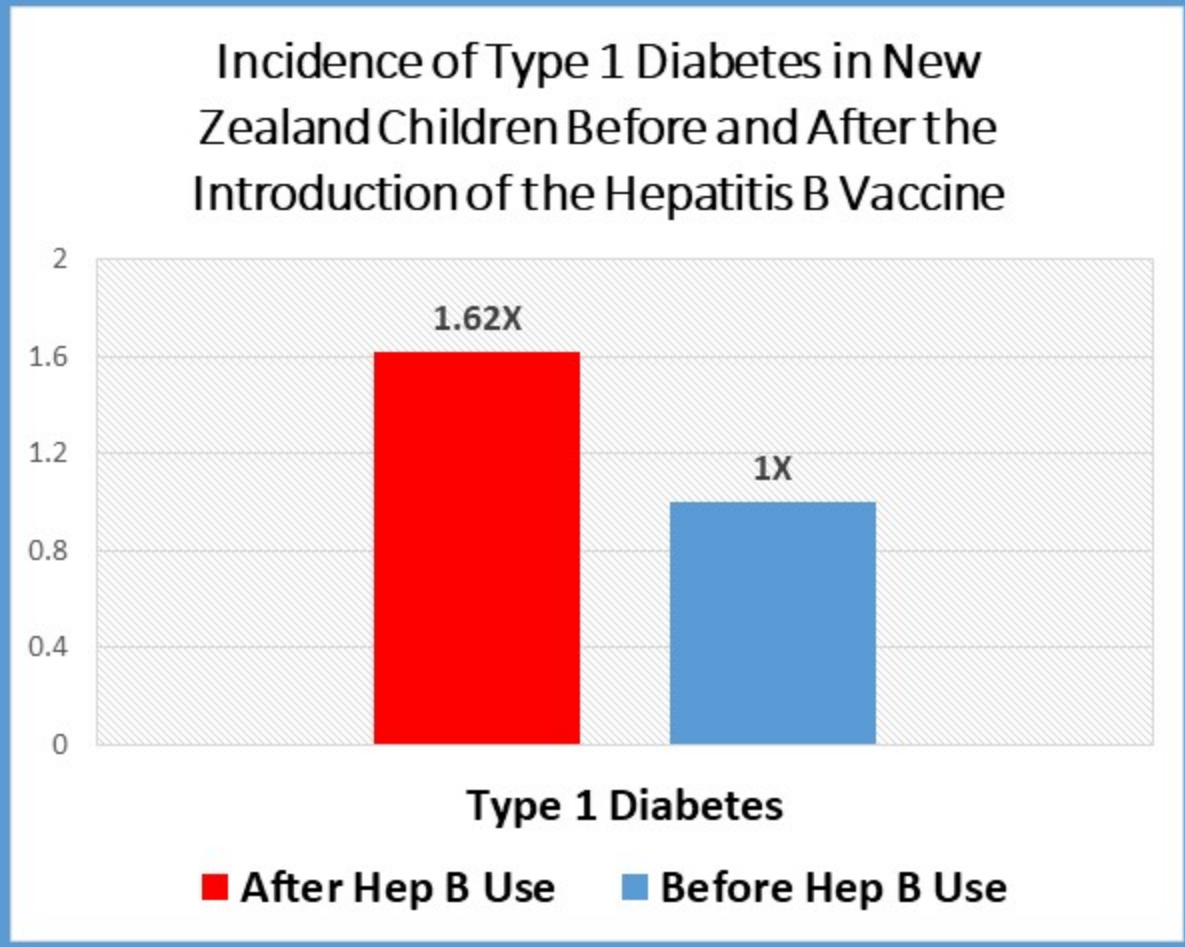
HYPOTHESIS

THE TIMING OF PEDIATRIC IMMUNIZATION AND THE RISK OF INSULIN-DEPENDENT DIABETES MELLITUS

by David C. Classen and John Barthelow Classen



"The incidence of type I diabetes in persons 0-19 years old living in Christchurch rose from 11.2 cases per 100,000 children annually in the years before the immunization program, 1982-1987, to 18.1 cases per 100,000 children annually (*P* = .0008) in the years following the immunization, 1989-1991."

Children's Health Defense

DTP Vaccination Increases Mortality by 2.45X in Girls Previously Receiving the BCG (Tuberculosis) Vaccine

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Trans R Soc Trop Med Hyg. 2016 Dec;110(10):570-581. Epub 2016 Nov 17.

Is diphtheria-tetanus-pertussis (DTP) associated with increased female mortality? A meta-analysis testing the hypotheses of sex-differential non-specific effects of DTP vaccine.

Aaby P[1,2], Rayn H[2,3], Fisker AB[4,2,3], Rodrigues A[4], Benn CS[4,2,3].

Author information

1 Bandim Health Project, Indepth Network, Apartado 861, Bissau, Guinea-Bissau p.aaby@bandim.org.
2 Research Centre for Vitamins and Vaccines (CVIVA), Bandim Health Project, Statens Serum Institut, Artillerivej 5, 2300 Copenhagen S, Denmark.
3 OPEN, Institute of Clinical Research, University of Southern Denmark/Odense University Hospital.
4 Bandim Health Project, Indepth Network, Apartado 861, Bissau, Guinea-Bissau.

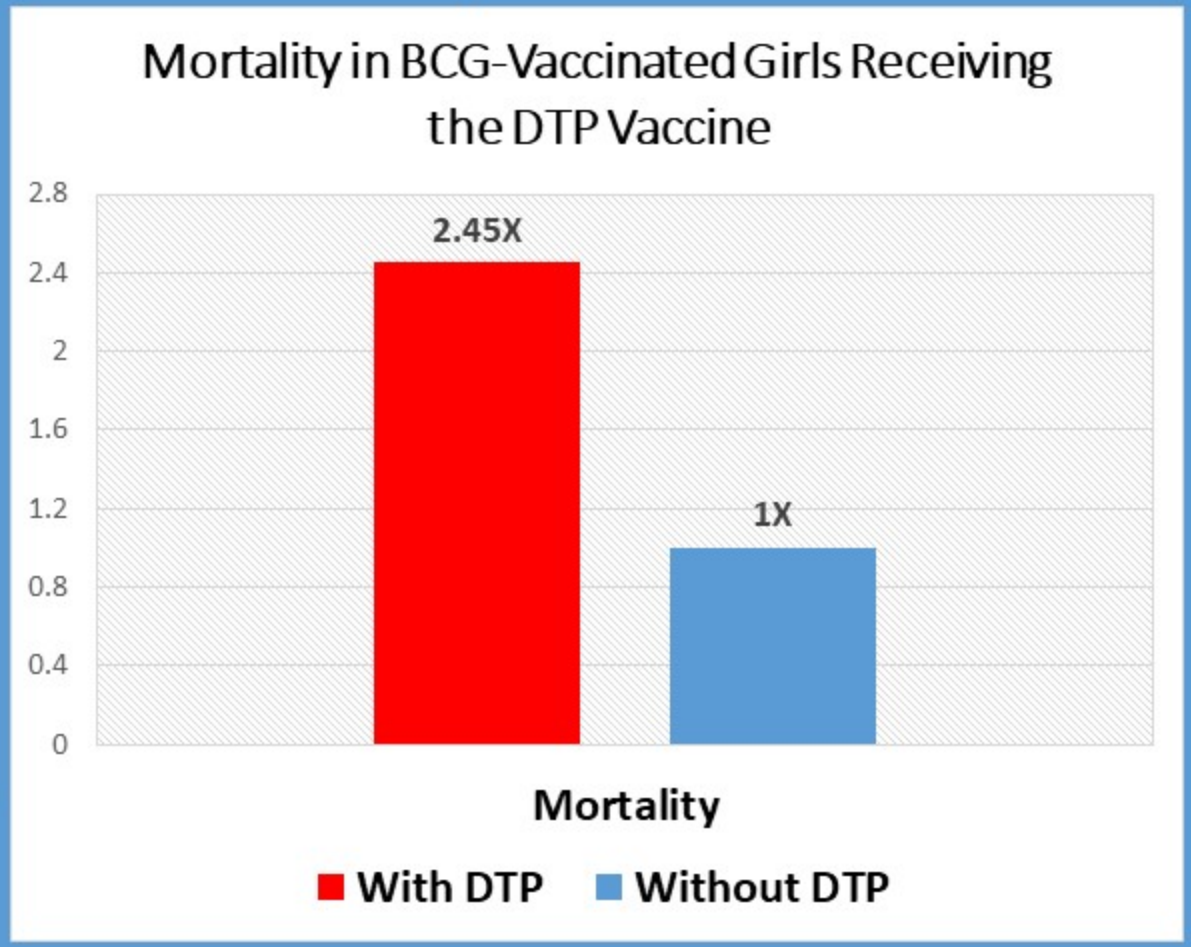
Abstract

BACKGROUND: Ten years ago, we formulated two hypotheses about whole-cell diphtheria-tetanus-pertussis (DTP) vaccination: first, when given after BCG, DTP increases mortality in girls and, second, following DTP there is an increase in the female/male mortality rate ratio (MRR). A recent review by WHO found no convincing evidence that DTP increases mortality in females.

METHODS: We used previous DTP reviews as well as the recent WHO review for assessing the hypotheses. As pre-specified we excluded studies with survival or frailty bias; if children had received BCG and DTP simultaneously; and if the children had received neonatal vitamin A.

RESULTS: In seven studies of BCG-vaccinated children, DTP vaccination was associated with a 2.54 (95% CI 1.68-3.86) increase in mortality in girls (with no increase in boys [ratio 0.96, 0.55-1.68]). In 10 studies of BCG-vaccinated children, the female-to-male mortality ratio was 2.45 (1.48-4.06) times higher after DTP than before DTP. In 15 studies of children who had received DTP after previous BCG vaccination, mortality was 1.53 (1.21-1.93) times higher in girls than boys. The findings were similar in studies conducted before and after formulation of the hypotheses.

CONCLUSIONS: The two hypotheses were confirmed in the studies that fulfilled pre-specified criteria.



"In seven studies of BCG-vaccinated children, DTP vaccination was associated with a 2.54 (95% CI 1.68–3.86) increase in mortality in girls (with no increase in boys [ratio 0.96, 0.55–1.68]). The ways in which the female and the male immune systems may respond differently to vaccinations in infants are only beginning to be studied."

Children's Health Defense

Higher Number of Vaccine Doses Prior to One Year of Age Increases Infant Mortality by 1.83X

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Hum Exp Toxicol. 2011 Sep;30(9):1420-8. doi: 10.1177/0960327111407644. Epub 2011 May 4.

Infant mortality rates regressed against number of vaccine doses routinely given: is there a biochemical or synergistic toxicity?

Miller NZ[1], Goldman GS.

Author information

1 Think Twice Global Vaccine Institute, USA. neilzmiller@gmail.com [corrected]

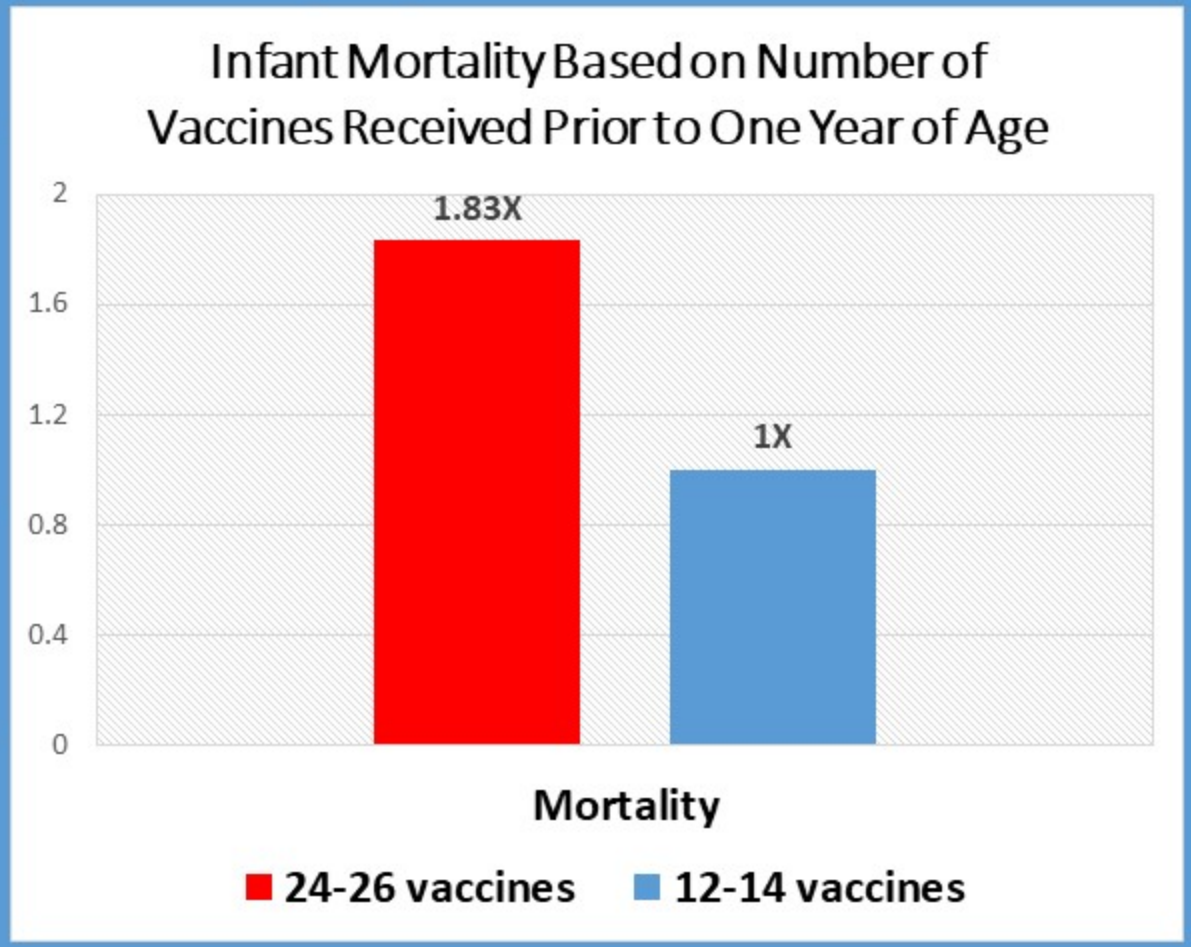
Erratum in
Hum Exp Toxicol. 2011 Sep;30(9):1429.

Abstract

The infant mortality rate (IMR) is one of the most important indicators of the socio-economic well-being and public health conditions of a country. The US childhood immunization schedule specifies 26 vaccine doses for infants aged less than 1 year--the most in the world--yet 33 nations have lower IMRs. Using linear regression, the immunization schedules of these 34 nations were examined and a correlation coefficient of $r = 0.70$ ($p < 0.0001$) was found between IMRs and the number of vaccine doses routinely given to infants. Nations were also grouped into five different vaccine dose ranges: 12-14, 15-17, 18-20, 21-23, and 24-26. The mean IMRs of all nations within each group were then calculated. Linear regression analysis of unweighted mean IMRs showed a high statistically significant correlation between increasing number of vaccine doses and increasing infant mortality rates, with $r = 0.992$ ($p = 0.0009$). Using the Tukey-Kramer test, statistically significant differences in mean IMRs were found between nations giving 12-14 vaccine doses and those giving 21-23, and 24-26 doses. A closer inspection of correlations between vaccine doses, biochemical or synergistic toxicity, and IMRs is essential.

PMID: 21543527 PMCID: PMC3170075 DOI: 10.1177/0960327111407644

[Indexed for MEDLINE] Free PMC Article



"Using the Tukey-Kramer test, statistically significant differences in mean IMRs (infant mortality rates) were found between nations giving 12–14 vaccine doses and those giving 21–23, and 24–26 doses."

Children's Health Defense

One Dose of the DTP Vaccine Increases Infant Mortality by 1.84X

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BMJ. 2000 Dec 9;321(7274):1435-8.

Routine vaccinations and child survival: follow up study in Guinea-Bissau, West Africa.

Kristensen I[1], Aaby P, Jensen H.

Author information

1 Bandim Health Project, Apartado 861, Bissau, Guinea-Bissau.

Abstract

OBJECTIVE: To examine the association between routine childhood vaccinations and survival among infants in Guinea-Bissau.

DESIGN: Follow up study.

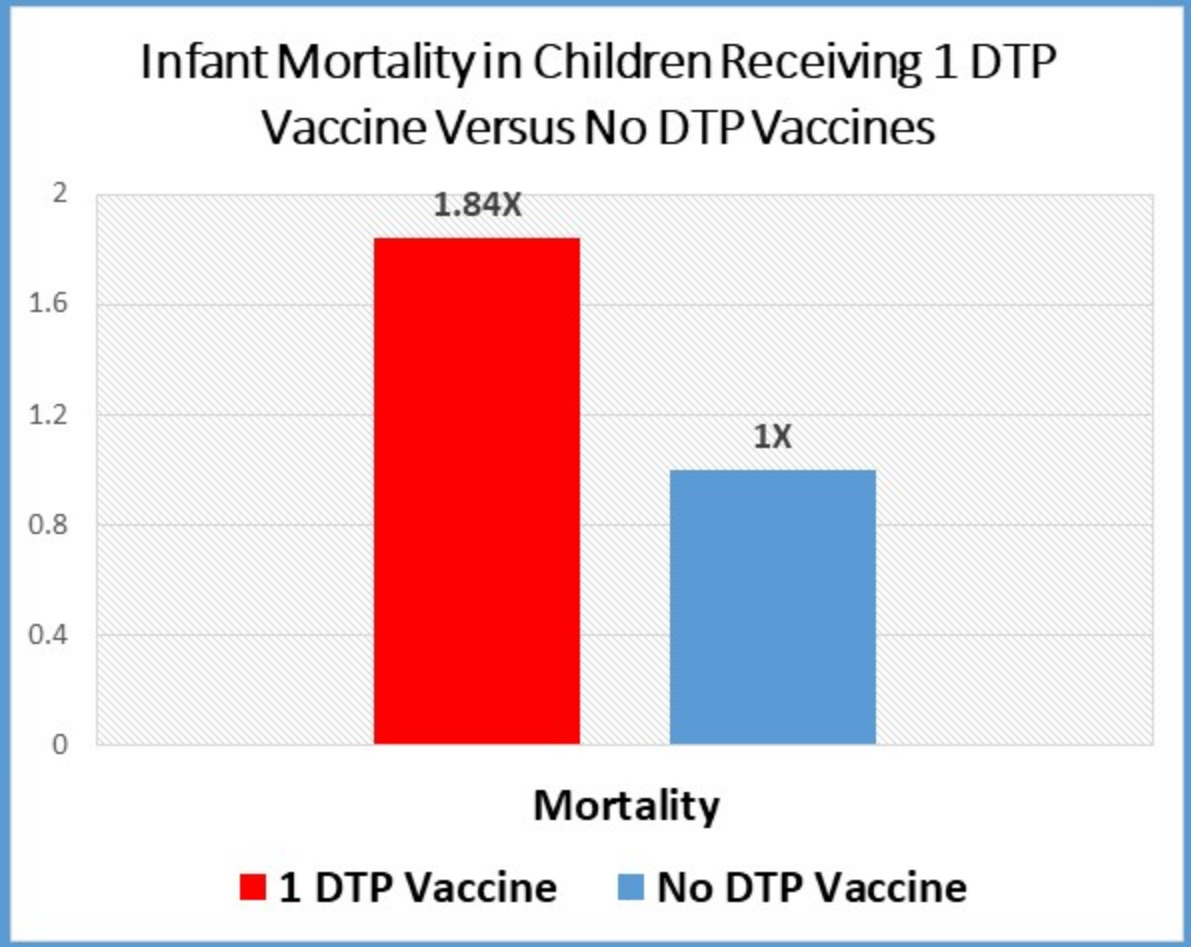
PARTICIPANTS: 15 351 women and their children born during 1990 and 1996.

SETTING: Rural Guinea-Bissau.

MAIN OUTCOME MEASURES: Infant mortality over six months (between age 0-6 months and 7-13 months for BCG, diphtheria, tetanus, and pertussis, and polio vaccines and between 7-13 months and 14-20 months for measles vaccine).

RESULTS: Mortality was lower in the group vaccinated with any vaccine compared with those not vaccinated, the mortality ratio being 0.74 (95% confidence interval 0.53 to 1.03). After cluster, age, and other vaccines were adjusted for, BCG was associated with significantly lower mortality (0.55 (0.36 to 0.85)). However, recipients of one dose of diphtheria, tetanus, and pertussis or polio vaccines had higher mortality than children who had received none of these vaccines (1.84 (1.10 to 3.10) for diphtheria, tetanus, and pertussis). Recipients of measles vaccine had a mortality ratio of 0.48 (0.27 to 0.87). When deaths from measles were excluded from the analysis the mortality ratio was 0.51 (0.28 to 0.95). Estimates were unchanged by controls for background factors.

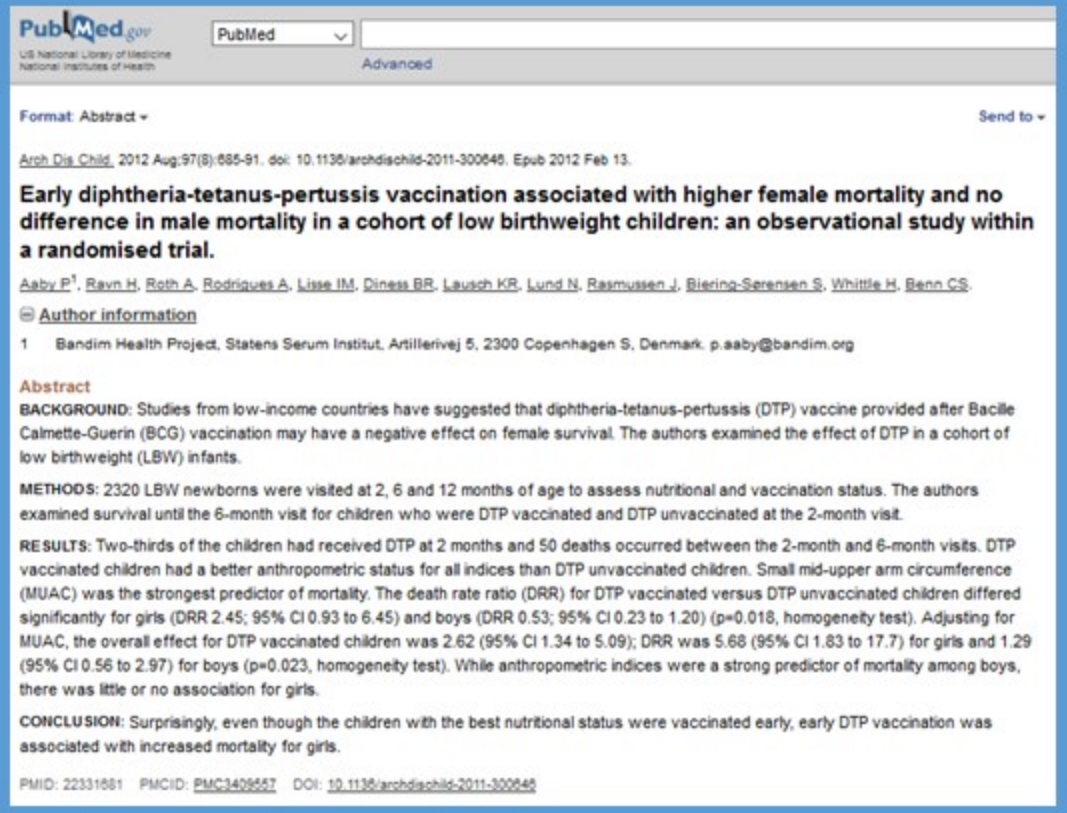
CONCLUSIONS: These trends are unlikely to be explained exclusively by selection biases since different vaccines were associated with opposite tendencies. Measles and BCG vaccines may have beneficial effects in addition to protection against measles and tuberculosis.



"One dose of diphtheria, tetanus, and pertussis vaccine was associated with a mortality ratio of 1.84 (1.10 to 3.10) and two to three doses with a ratio of 1.38 (0.73 to 2.61) compared with children who had received no dose of these vaccines."

Children's Health Defense

Early DTP Vaccination in Girls Increased Infant Mortality by 5.68X



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Arch Dis Child. 2012 Aug;97(8):685-91. doi: 10.1136/archdischild-2011-300646. Epub 2012 Feb 13.

Early diphtheria-tetanus-pertussis vaccination associated with higher female mortality and no difference in male mortality in a cohort of low birthweight children: an observational study within a randomised trial.

Aaby P[1], Ravn H, Roth A, Rodrigues A, Lisse IM, Diness BR, Lausch KR, Lund N, Rasmussen J, Biering-Sørensen S, Whittle H, Benn CS.

Author information

1 Bandim Health Project, Statens Serum Institut, Artillerivej 5, 2300 Copenhagen S, Denmark. p.aaby@bandim.org

Abstract

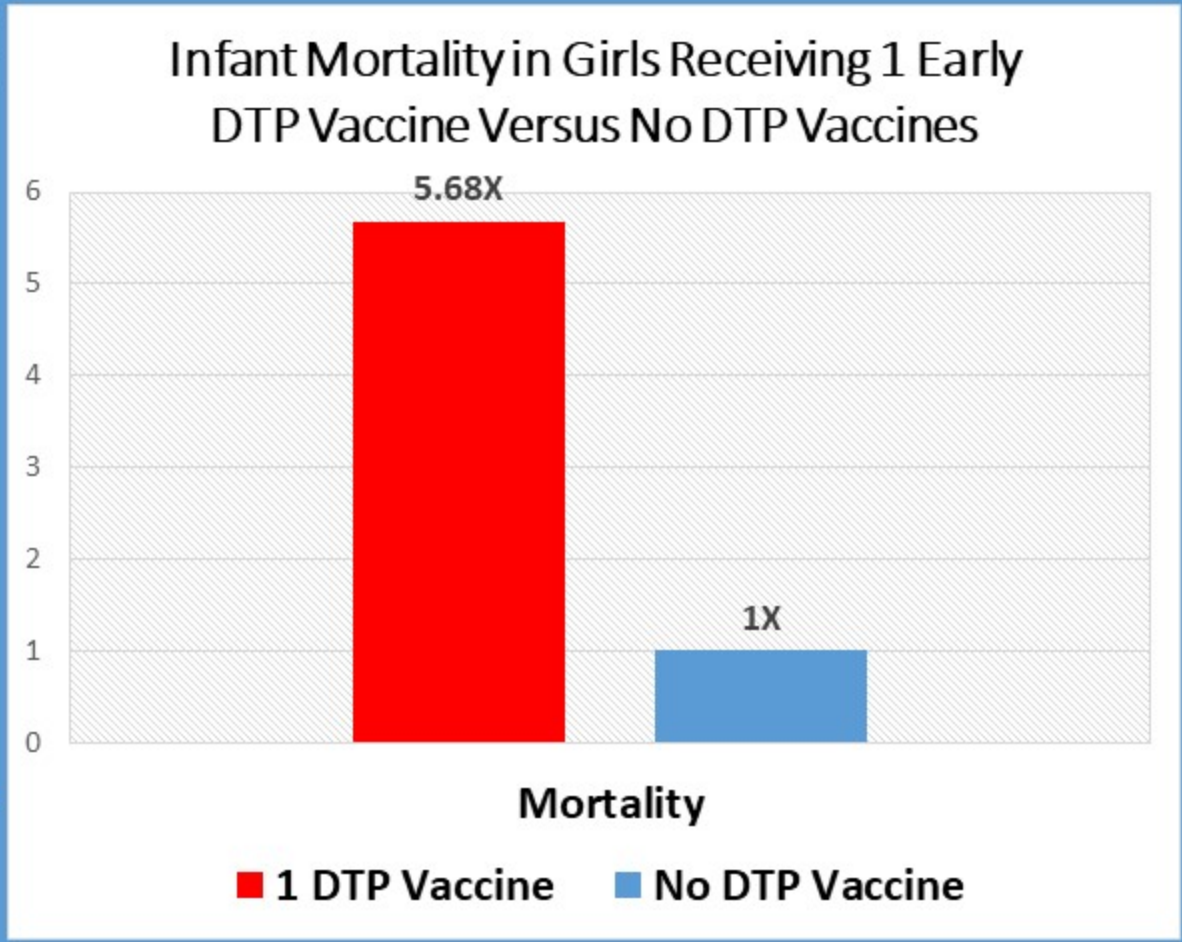
BACKGROUND: Studies from low-income countries have suggested that diphtheria-tetanus-pertussis (DTP) vaccine provided after Bacille Calmette-Guerin (BCG) vaccination may have a negative effect on female survival. The authors examined the effect of DTP in a cohort of low birthweight (LBW) infants.

METHODS: 2320 LBW newborns were visited at 2, 6 and 12 months of age to assess nutritional and vaccination status. The authors examined survival until the 6-month visit for children who were DTP vaccinated and DTP unvaccinated at the 2-month visit.

RESULTS: Two-thirds of the children had received DTP at 2 months and 50 deaths occurred between the 2-month and 6-month visits. DTP vaccinated children had a better anthropometric status for all indices than DTP unvaccinated children. Small mid-upper arm circumference (MUAC) was the strongest predictor of mortality. The death rate ratio (DRR) for DTP vaccinated versus DTP unvaccinated children differed significantly for girls (DRR 2.45; 95% CI 0.93 to 6.45) and boys (DRR 0.53; 95% CI 0.23 to 1.20) (p=0.018, homogeneity test). Adjusting for MUAC, the overall effect for DTP vaccinated children was 2.62 (95% CI 1.34 to 5.09); DRR was 5.68 (95% CI 1.83 to 17.7) for girls and 1.29 (95% CI 0.56 to 2.97) for boys (p=0.023, homogeneity test). While anthropometric indices were a strong predictor of mortality among boys, there was little or no association for girls.

CONCLUSION: Surprisingly, even though the children with the best nutritional status were vaccinated early, early DTP vaccination was associated with increased mortality for girls.

PMID: 22331681 PMCID: PMC3409557 DOI: 10.1136/archdischild-2011-300646



"Surprisingly, even though the children with the best nutritional status were vaccinated early, early DTP vaccination was associated with increased mortality."

Children's Health Defense

Receipt of Both the BCG and DTP Vaccines Increased Infant Mortality in Girls by 2.4X

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Trop Med Int Health. 2005 Oct;10(10):947-55.

Evaluation of non-specific effects of infant immunizations on early infant mortality in a southern Indian population.

Moulton LH[1], Rahmathullah L, Halsey NA, Thulasiraj RD, Katz J, Tielsch JM.

Author information

1 Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD 21205, USA. lmoulton@jhsph.edu

Abstract

OBJECTIVE: The aim of this study was to assess the relationship between receipt of routine childhood immunizations and infant mortality before 6 months of age.

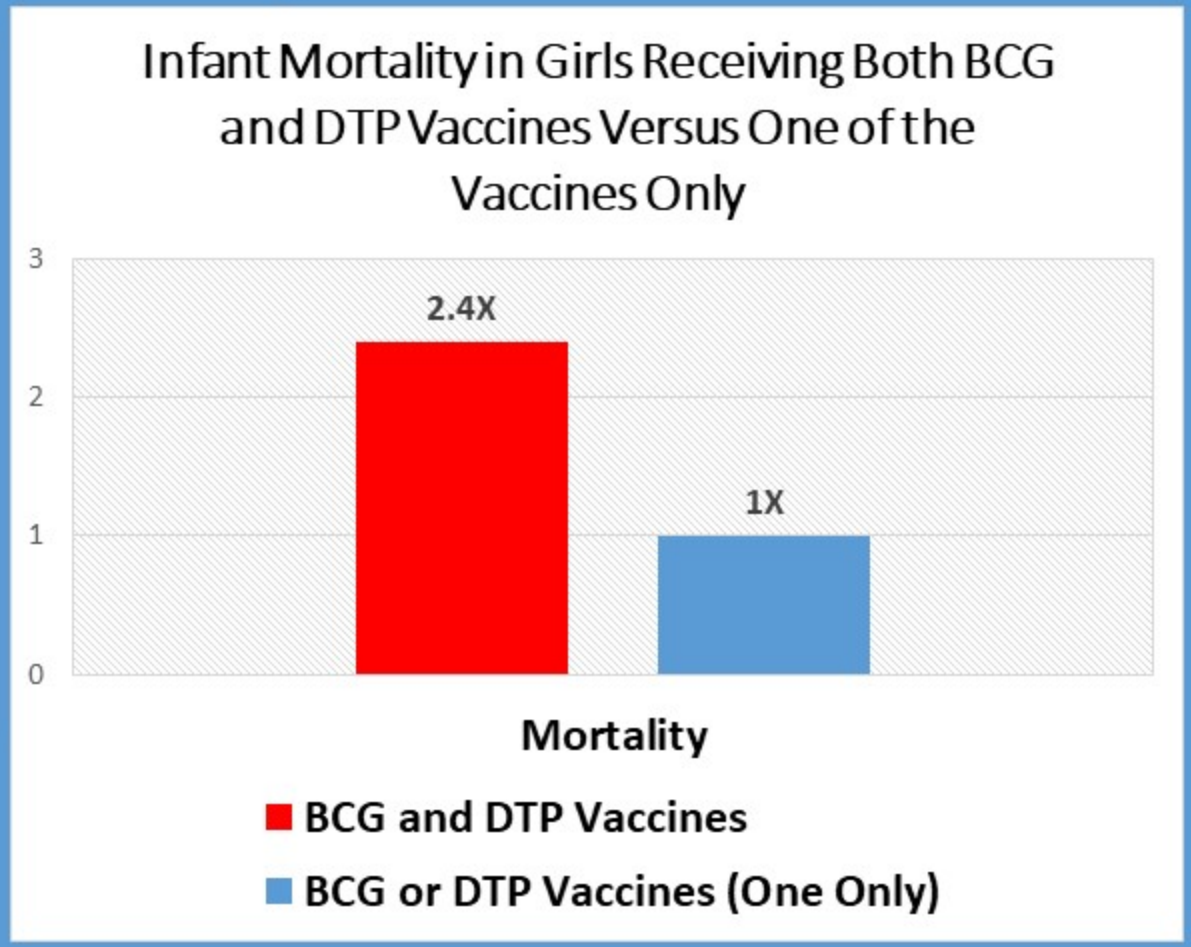
METHODS: This was an observational study of 10,274 infants, in a randomized trial of vitamin A supplementation, who received the study dose and survived to at least 1 week of age. The primary outcome was mortality before 6 months of age, analysed in Cox regression models as a function of vaccine receipt and gender.

RESULTS: Receipt of Bacille Calmette Guerin (BCG) or diphtheria, tetanus, polio (DTP) vaccine was associated with significant reductions of one-half to two-thirds of mortality hazards; among girls, those who received both BCG and DTP experienced higher mortality than those who received only one of the two vaccines (hazards ratio 2.4; 95% confidence interval 1.2-5.0).

CONCLUSION: The reduced mortality rate associated with receipt of BCG or DTP may be due to both biological and selection factors; the analyses regarding the combined effect of these vaccines and gender need to be replicated in other settings.

PMID: 16185228 DOI: 10.1111/j.1365-3156.2005.01434.x

[Indexed for MEDLINE] Free full text



"Among girls, those who received both BCG and DTP experienced higher mortality than those who received only one of the two vaccines (hazards ratio 2.4; 95% confidence interval 1.2–5.0)."

Children's Health Defense

Receipt of the Second and Third Dose of the DTP Vaccine Increases Infant Mortality by 4.36X

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Int J Epidemiol. 2004 Apr;33(2):374-80.

The introduction of diphtheria-tetanus-pertussis vaccine and child mortality in rural Guinea-Bissau: an observational study.

Aaby P[1], Jensen H, Gomes J, Fernandes M, Lisse IM.

Author information

1 Bandim Health Project, Apartado 861, Bissau, Guinea-Bissau. psb@mail.gtelecom.gw

Abstract

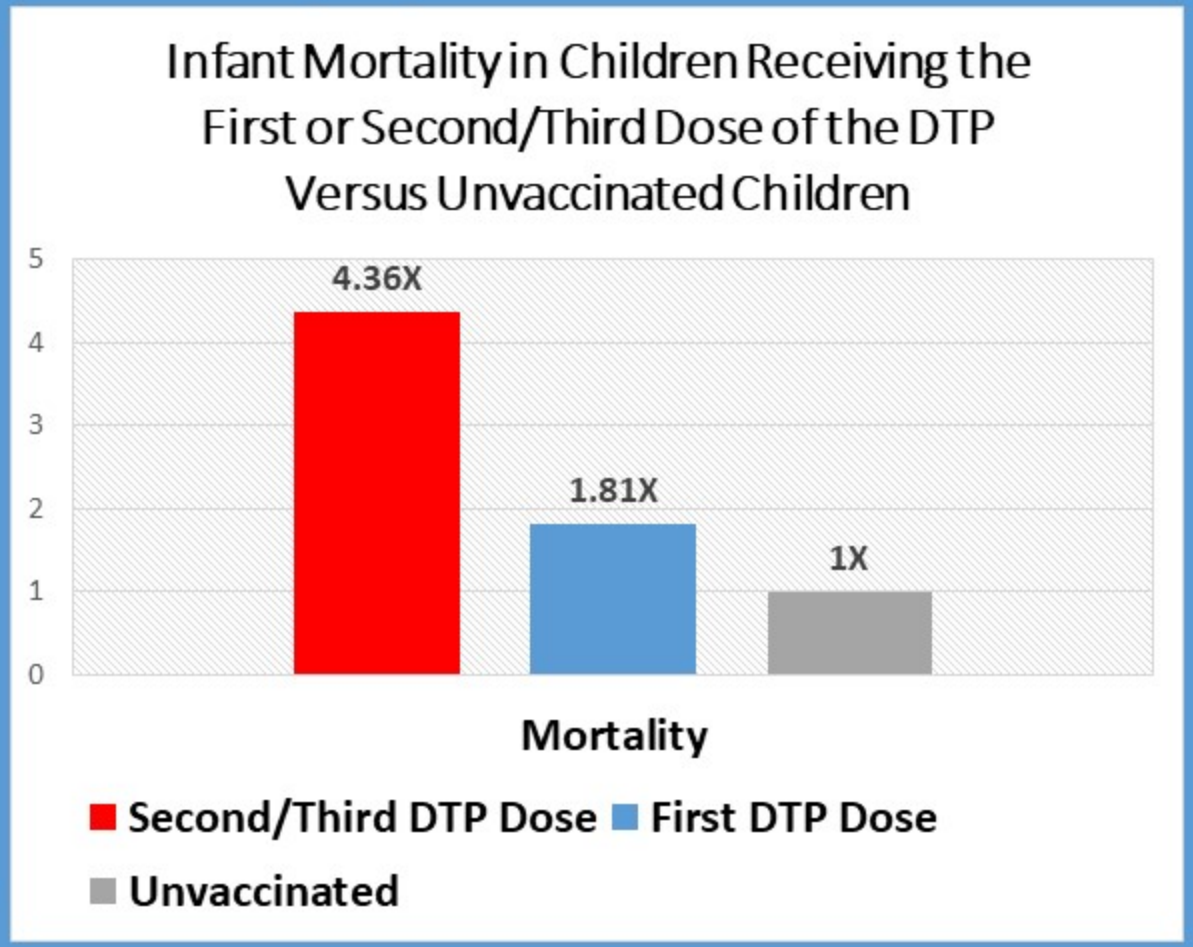
BACKGROUND: and objective Previous studies from areas with high mortality in West Africa have not found diphtheria-tetanus-pertussis (DTP) vaccine to be associated with the expected reduction in mortality, a few studies suggesting increased mortality. We therefore examined mortality when DTP was first introduced in rural areas of Guinea-Bissau in 1984-1987. Setting Twenty villages in four regions have been followed with bi-annual examinations since 1979.

SUBJECTS: In all, 1657 children aged 2-8 months. Design Children were weighed when attending the bi-annual examinations and they were vaccinated whenever vaccines were available. DTP was introduced in the beginning of 1984, oral polio vaccine later that year. We examined mortality for children aged 2-8 months who had received DTP and compared them with children who had not been vaccinated because they were absent, vaccines were not available, or they were sick.

MAIN OUTCOME MEASURE: Mortality over the next 6 months from the day of examination for vaccinated and unvaccinated children.

RESULTS: Prior to the introduction of vaccines, children who were absent at a village examination had the same mortality as children who were present. During 1984-1987, children receiving DTP at 2-8 months of age had higher mortality over the next 6 months, the mortality rate ratio (MR) being 1.92 (95% CI: 1.04, 3.52) compared with DTP-unvaccinated children, adjusting for age, sex, season, period, BCG, and region. The MR was 1.81 (95% CI: 0.95, 3.45) for the first dose of DTP and 4.36 (95% CI: 1.28, 14.9) for the second and third dose. BCG was associated with slightly lower mortality (MR = 0.63, 95% CI: 0.30, 1.33), the MR for DTP and BCG being significantly inversed. Following subsequent visits and further vaccinations with DTP and measles vaccine, there was no difference in vaccination coverage and subsequent mortality between the DTP-vaccinated group and the initially DTP-unvaccinated group (MR = 1.06, 95% CI: 0.78, 1.44).

CONCLUSIONS: In low-income countries with high mortality, DTP as the last vaccine received may be associated with slightly increased mortality. Since the pattern was inversed for BCG, the effect is unlikely to be due to higher-risk children having received vaccination. The role of DTP in high mortality areas needs to be clarified.



"The MR (mortality rate) was 1.81 (95% CI: 0.95, 3.45) for the first dose of DTP and 4.36 (95% CI: 1.28, 14.9) for the second and third dose."

Children's Health Defense

Vaccination increases the risk of asthma (11.4X) and hay fever (10X) in children with no family history of those disorders

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J Allergy Clin Immunol. 2005 Apr;115(4):737-44.

The relationship between vaccine refusal and self-report of atopic disease in children.

Enriquez R[1], Addington W, Davis F, Freels S, Park CL, Hershow RC, Persky V.

Author information

1 Division of Allergy, Pulmonary and Critical Care Medicine, School of Medicine, T-1218 Medical Center North, 1161 21st Avenue South, Nashville, TN 37232-2650, USA. Rachel.Enriquez@vanderbilt.edu

Abstract

BACKGROUND: In the last 3 decades, there has been an unexplained increase in the prevalence of asthma and hay fever.

OBJECTIVE: We sought to determine whether there is an association between childhood vaccination and atopic diseases, and we assessed the self-reported prevalence of atopic diseases in a population that included a large number of families not vaccinating their children.

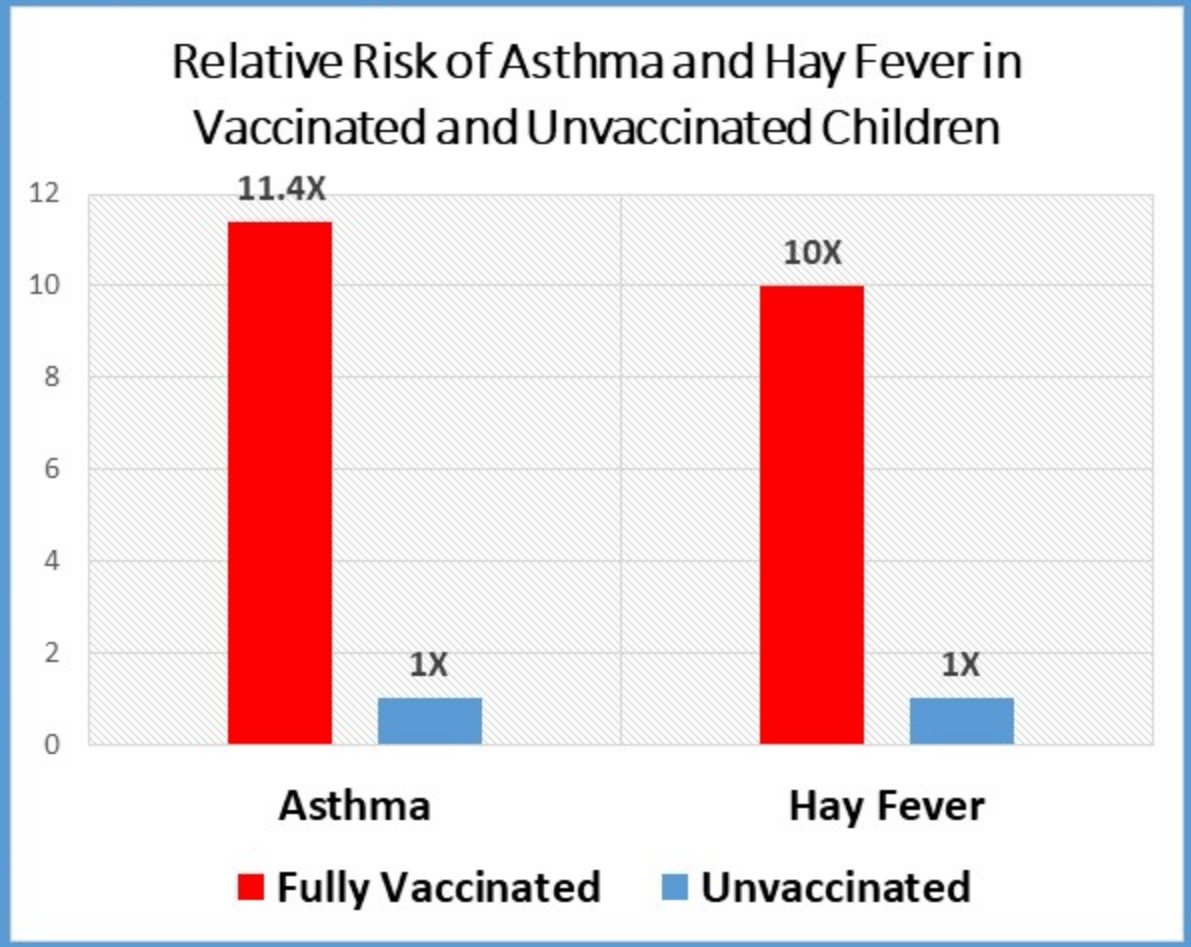
METHODS: Surveys were mailed to 2964 member households of the National Vaccine Information Center, which represents people concerned about vaccine safety, to ascertain vaccination and atopic disease status.

RESULTS: The data included 515 never vaccinated, 423 partially vaccinated, and 239 completely vaccinated children. In multiple regression analyses there were significant (P < .0005) and dose-dependent negative relationships between vaccination refusal and self-reported asthma or hay fever only in children with no family history of the condition and, for asthma, in children with no exposure to antibiotics during infancy. Vaccination refusal was also significantly (P < .005) and negatively associated with self-reported eczema and current wheeze. A sensitivity analysis indicated that substantial biases would be required to overturn the observed associations.

CONCLUSION: Parents who refuse vaccinations reported less asthma and allergies in their unvaccinated children. Although this relationship was independent of measured confounders, it could be due to differences in other unmeasured lifestyle factors or systematic bias. Further research is needed to verify these results and investigate which exposures are driving the associations between vaccination refusal and allergic disease. The known benefits of vaccination currently outweigh the unproved risk of allergic disease.

PMID: 15805992 DOI: 10.1016/j.jaci.2004.12.1128

[Indexed for MEDLINE]



"In multiple regression analyses there were significant (P<.0005) and dose dependent negative relationships between vaccination refusal and self-reported asthma or hay fever only in children with no family history of the condition and, for asthma, in children with no exposure to antibiotics during infancy."

Children's Health Defense

Vaccination with DTP simultaneously with measles vaccine or DTP after measles vaccine increased risk of death (2.59X)

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Trans R Soc Trop Med Hyg. 2015 Jan;109(1):77-84. doi: 10.1093/trstmh/tru186.

Sex-differential and non-specific effects of routine vaccinations in a rural area with low vaccination coverage: an observational study from Senegal.

Aaby P[1], Nielsen J[2], Benn CS[2], Trape JF[3].

Author information

1 Institut de Recherche pour le Développement (IRD), Laboratoire de Paludologie, Epidémiologie et Zoologie afrotropicales, BP 1386, Dakar, Senegal Bandim Health Project, Indepth Network, Apartado 861, Bissau, Guinea-Bissau p.aaby@bandim.org.

2 Research Center for Vitamins and Vaccines (CVIVA), Statens Serum Institut, Copenhagen, Denmark.

3 Institut de Recherche pour le Développement (IRD), Laboratoire de Paludologie, Epidémiologie et Zoologie afrotropicales, BP 1386, Dakar, Senegal.

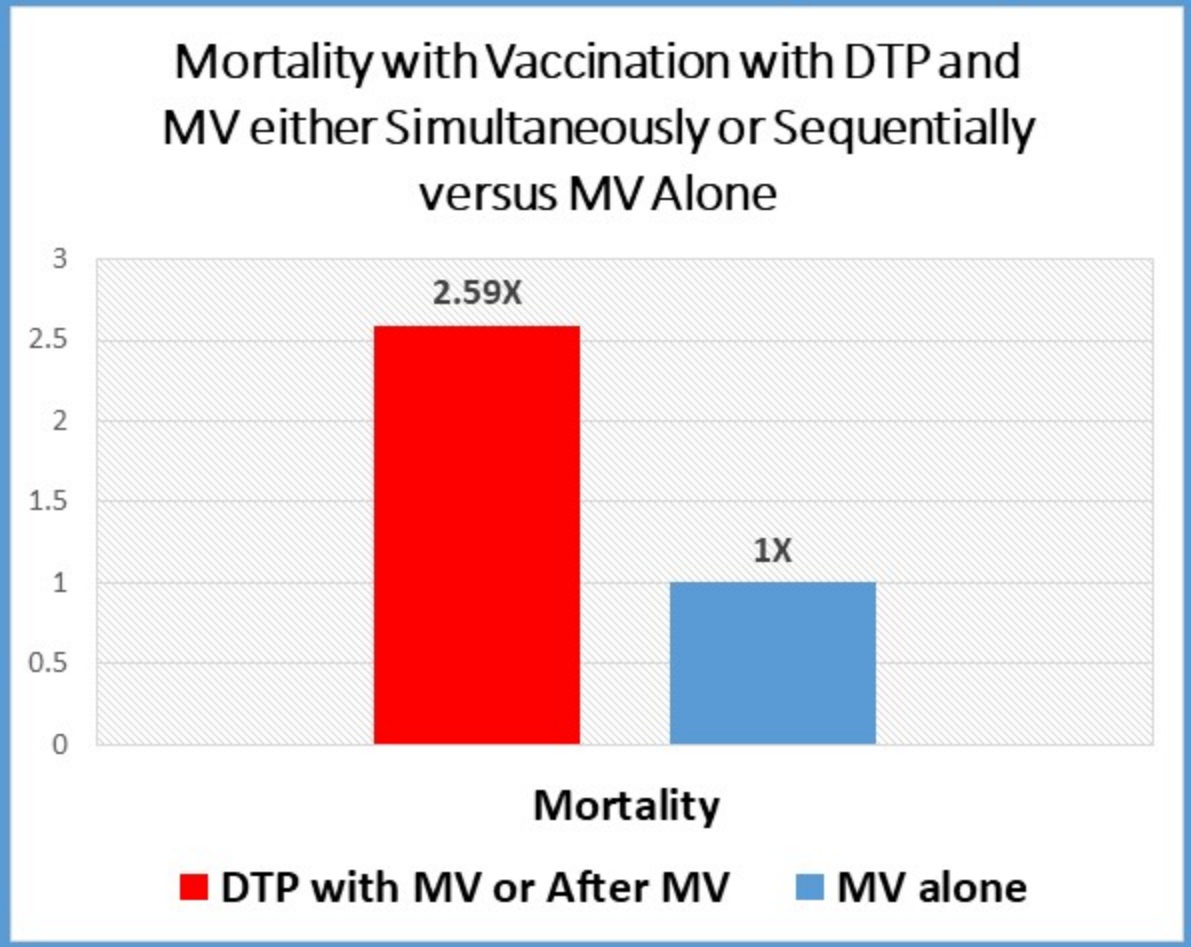
Abstract

BACKGROUND: We examined the potential sex-differential and non-specific effects of bacille Calmette-Guérin (BCG), diphtheria-tetanus-pertussis (DTP) and measles vaccine (MV) in a rural area of Senegal.

METHODS: The 4133 children born in the area between 1996 and 1999 were included in the study. Vaccinations were provided at three health centres. Vaccine information was collected through 3-monthly home visits. The survival analysis compared the effects of BCG and DTP according to the following sequence of vaccinations: BCG-first, BCG+DTP1-first, or DTP1-first. We compared DTP and MV between 9 and 24 months of age, as 9 months is the minimum age for MV.

RESULTS: At 12 months the vaccination coverage was 44%, 46% and 9%, respectively, for BCG, DTP1 and MV. Most children received BCG+DTP1-first and this combination was associated with a significantly lower mortality rate ratio (MRR) of 0.69 (0.53-0.89) compared with unvaccinated children. There was no benefit for children receiving BCG-first or DTP1-first. The female-male MRR was 0.79 (0.64-0.96) among unvaccinated children, but was significantly inversed with 1.45 (1.00-2.10) for children receiving DTP vaccination (test of homogeneity, p=0.006). Children who had received DTP simultaneously with MV or DTP after MV had significantly higher mortality (MRR=2.59 [1.32-5.07]) compared with children having MV-only as their most recent vaccination. After 9 months, the female-male MRR was 0.61 (0.31-1.19) for measles-vaccinated children but remained 1.54 (1.03-2.31) for DTP-vaccinated children who had not received MV (p=0.01).

CONCLUSIONS: The sequence of routine vaccinations is important for the overall impact on child survival and these vaccines are associated with sex-differential effects.



"Children who had received DTP simultaneously with MV or DTP after MV had significantly higher mortality (MRR=2.59 [1.32–5.07]) compared with children having MV-only as their most recent vaccination."

Children's Health Defense

Hepatitis B Vaccination Increases the Odds (3.1X) of a Multiple Sclerosis Diagnosis

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Neurology. 2004 Sep 14;63(5):838-42.

Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study.

Hernán MA[1], Jick SS, Olek MJ, Jick H.

Author information

1 Department of Epidemiology, Harvard School of Public Health, 677 Huntington Avenue, Boston, MA 02115, USA. miguel_hernan@post.harvard.edu

Abstract

BACKGROUND: A potential link between the recombinant hepatitis B vaccine and an increased risk of multiple sclerosis (MS) has been evaluated in several studies, but some of them have substantial methodologic limitations.

METHODS: The authors conducted a nested case-control study within the General Practice Research Database (GPRD) in the United Kingdom. The authors identified patients who had a first MS diagnosis recorded in the GPRD between January 1993 and December 2000. Cases were patients with a diagnosis of MS confirmed through examination of medical records, and with at least 3 years of continuous recording in the GPRD before their date of first symptoms (index date). Up to 10 controls per case were randomly selected, matched on age, sex, practice, and date of joining the practice. Information on receipt of immunizations was obtained from the computer records.

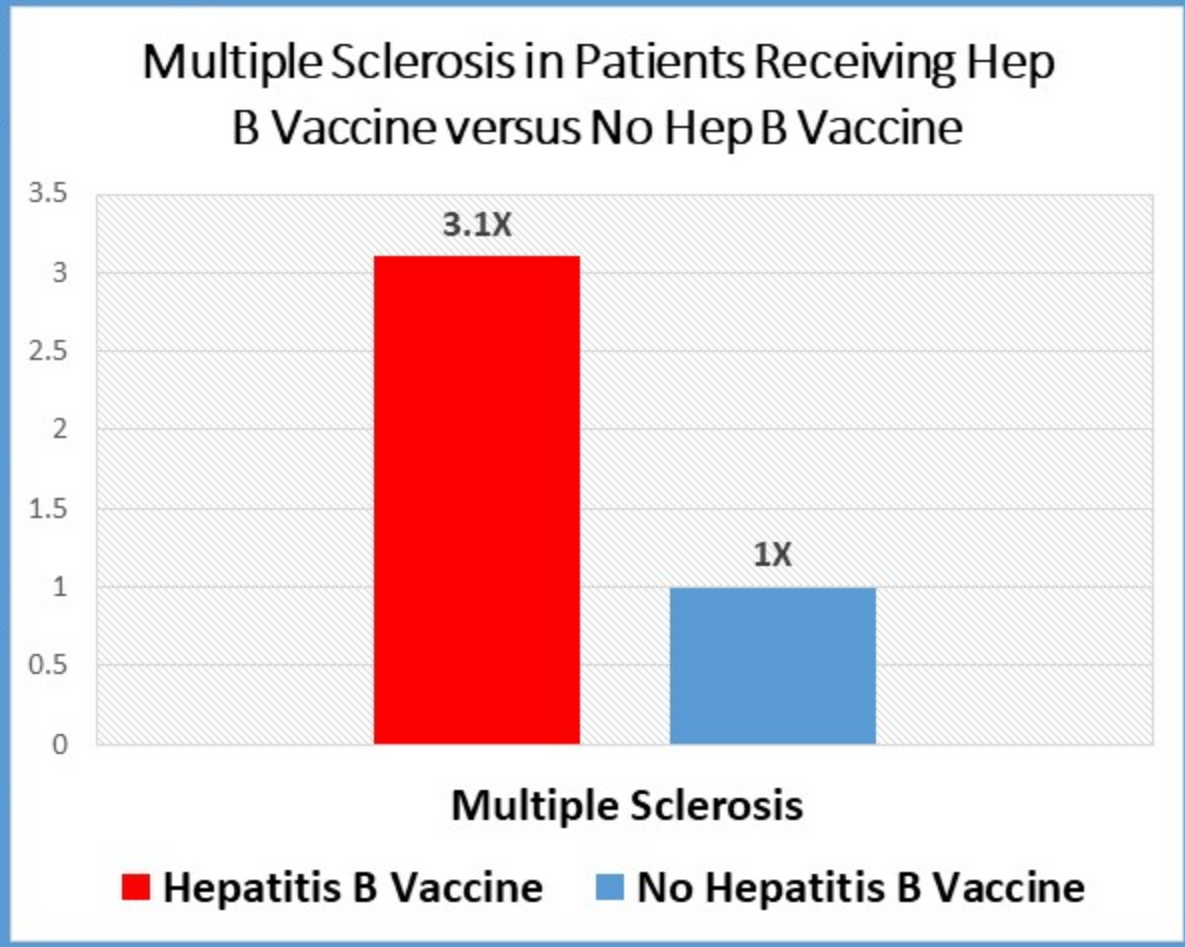
RESULTS: The analyses include 163 cases of MS and 1,604 controls. The OR of MS for vaccination within 3 years before the index date compared to no vaccination was 3.1 (95% CI 1.5, 6.3). No increased risk of MS was associated with tetanus and influenza vaccinations.

CONCLUSIONS: These findings are consistent with the hypothesis that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of MS, and challenge the idea that the relation between hepatitis B vaccination and risk of MS is well understood.

Comment in

Does the hepatitis B vaccine cause multiple sclerosis? [Neurology. 2004]
Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. [Neurology. 2005]
Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. [Neurology. 2005]

PMID: 15365133 DOI: 10.1212/01.wnl.0000138433.61870.82



"The OR of MS for vaccination within 3 years before the index date compared to no vaccination was 3.1 (95% CI 1.5, 6.3). No increased risk of MS was associated with tetanus and influenza vaccinations."

Children's Health Defense

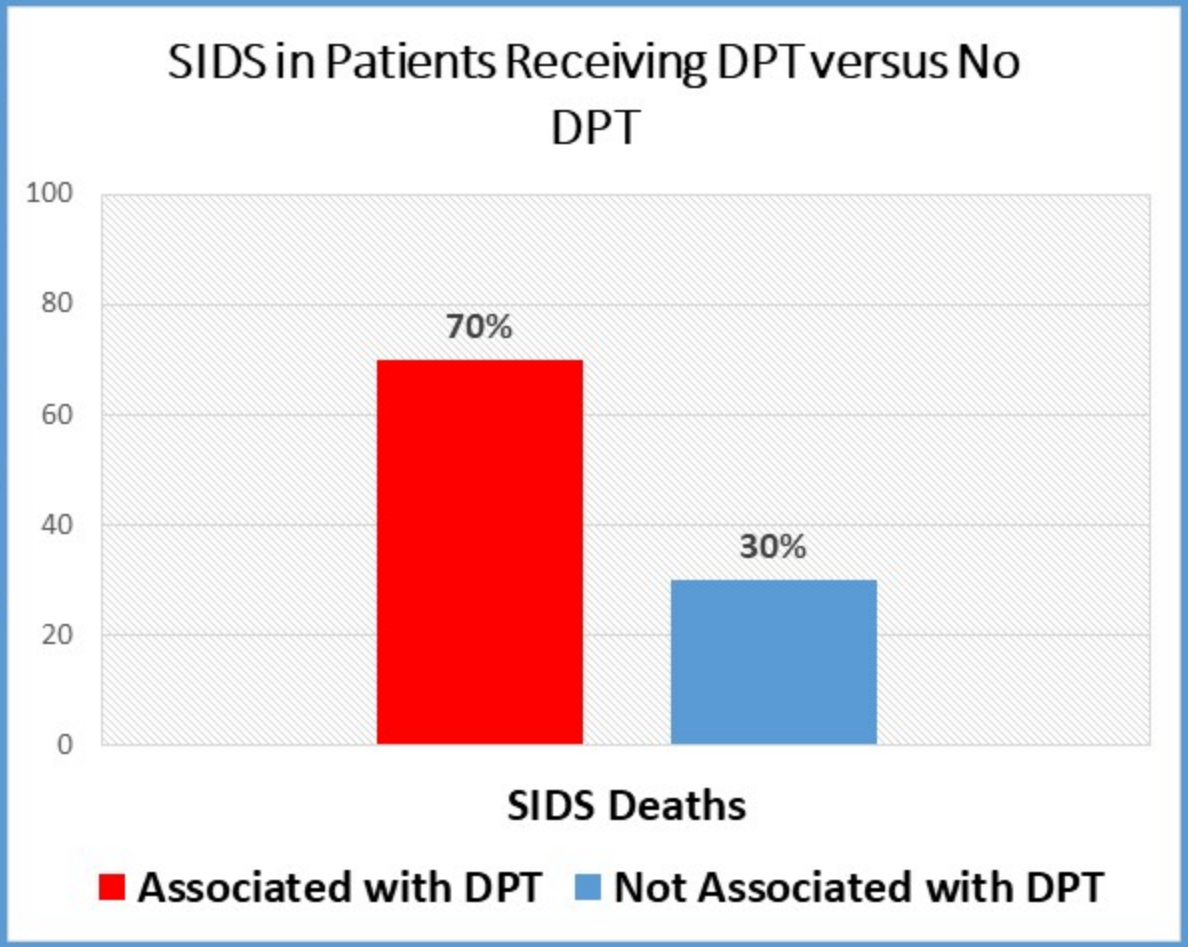
70% of SIDS Deaths Occur Within Three Weeks of DPT Vaccination

Diphtheria-Pertussis-Tetanus (DPT) Immunization: A Potential Cause of the Sudden Infant Death Syndrome (SIDS) 10:00 AM 3

WILLIAM C. TORCH, Reno, NV

A recent report of eight DPT-associated cot deaths in Tennessee, and knowledge of four sudden deaths within 3½ to 19 hours of inoculation in Nevada (in three infants and one 3-year-old child) stimulated a study on the relationship of SIDS to DPT immunization in over 200 randomly reported SIDS cases. Preliminary data on the first 70 cases studied shows that ⅔ had been immunized prior to death. DPT #1, 2, and 3 were administered on the average at age 2, 4, and 6 months, respectively. In the DPT SIDS group, 6.5% died within 12 hours of inoculation; 13% within 24 hours, 26% within 3 days, and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively. Significant SIDS clustering occurred within the first 2 to 3 weeks of DPT #1, 2, 3, or 4. The age range of the DPT group was 59 days to 3 years (mean age, 3 months); for the non-DPT group, 17 to 172 days (mean age, 2 months). SIDS frequencies peaked at age 2 months in the non-DPT group, and had a biphasic peak occurrence at 2 and 4 months in the DPT group. DPT #1 and 2 were associated with more SIDS than #3 or 4 (ratio 30:11:4:1). Males and females were equally affected. Cot death occurred maximally in the fall/winter season in the non-DPT group, but was nonseasonal in the DPT group. Death occurred most often in sleep in healthy allergy-free infants following brief periods of irritability, crying, lethargy, upper respiratory tract symptoms, and sleep disturbance. Autopsy findings in both groups were typical of SIDS, (e.g. petechiae of lung, pleura, pericardium, and thymus; vascular congestion; pulmonary edema; pneumonitis; and brain edema). In conclusion, these data show that DPT vaccination may be a generally unrecognized major cause of sudden infant and early childhood death, and that the risks of immunization may outweigh its potential benefits. A need for reevaluation and possible modification of current vaccination procedures is indicated by this study.

April 1982 NEUROLOGY (NY) 32(2) A169



"In the DPT SIDS group, 6.5% died within 12 hours of inoculation; 13% within 24 hours, 26% within 3 days, and 37%, 61%, and 70% within 1, 2, and 3 weeks, respectively."

Children's Health Defense

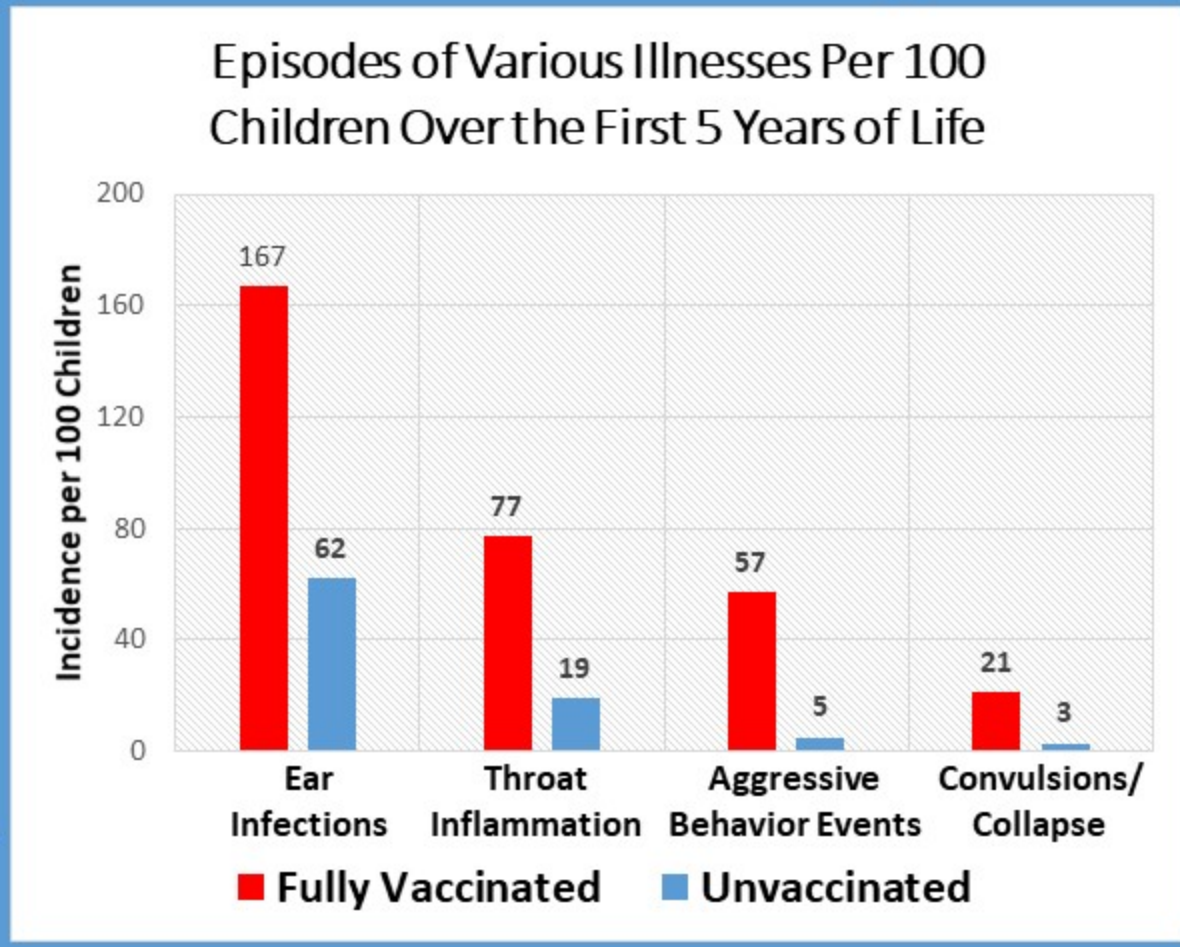
Netherlands Fully Vaccinated Versus Unvaccinated Study, 2004

The NVKP (Nederlandse Vereniging Kritisch Prikken) [in English: Dutch Association for Conscientious Vaccination] is an independent association made up of therapists, doctors and parents, amongst others. The NVKP's aim is freedom of choice for parents when it comes to vaccinating their children, based on honest, comprehensive and independent information. We view the current 'one size fits all' vaccination policy with great concern. The NVKP is therefore urging the adoption of more thorough independent research by representatives from different disciplines.

NVKP
PO Box 1106
4700 BC Roosendaal
The Netherlands

Information number: ***0900 - 2020171***
Email: info@nvkp.nl
Website: www.nvkp.nl

The survey:
The NVKP survey was conducted in the Netherlands in the latter half of 2004 with the parents of 635 children, and involved both members and non-members of the NVKP. The survey was geographically distributed over the entire country, and the postal codes of the respondents are known. We asked the parents to fill in a questionnaire with questions about the health of their child or children. All parents were subsequently approached for supplementary information and were asked to answer control questions. The personal details of all the participating parents and children are known. Questionnaires that were not filled out properly or questionnaires from parents who did not react to our request for supplementary information and/or control questions were not included in the results.
Questionnaires from the parents of children that were not vaccinated in the normal way – that is, not entirely in accordance with Dutch Vaccination Programme (RVP) – and questionnaires from the parents of children that were not entirely unvaccinated were also excluded from this survey.



"The NVKP survey was conducted in the Netherlands in the latter half of 2004 with the parents of 635 children, and involved both members and non-members of the NVKP."

Children's Health Defense

Netherlands Fully Vaccinated Versus Unvaccinated Study, 2004

The NVKP (Nederlandse Vereniging Kritisch Prikken) [in English: Dutch Association for Conscientious Vaccination] is an independent association made up of therapists, doctors and parents, amongst others. The NVKP's aim is freedom of choice for parents when it comes to vaccinating their children, based on honest, comprehensive and independent information. We view the current 'one size fits all' vaccination policy with great concern. The NVKP is therefore urging the adoption of more thorough independent research by representatives from different disciplines.

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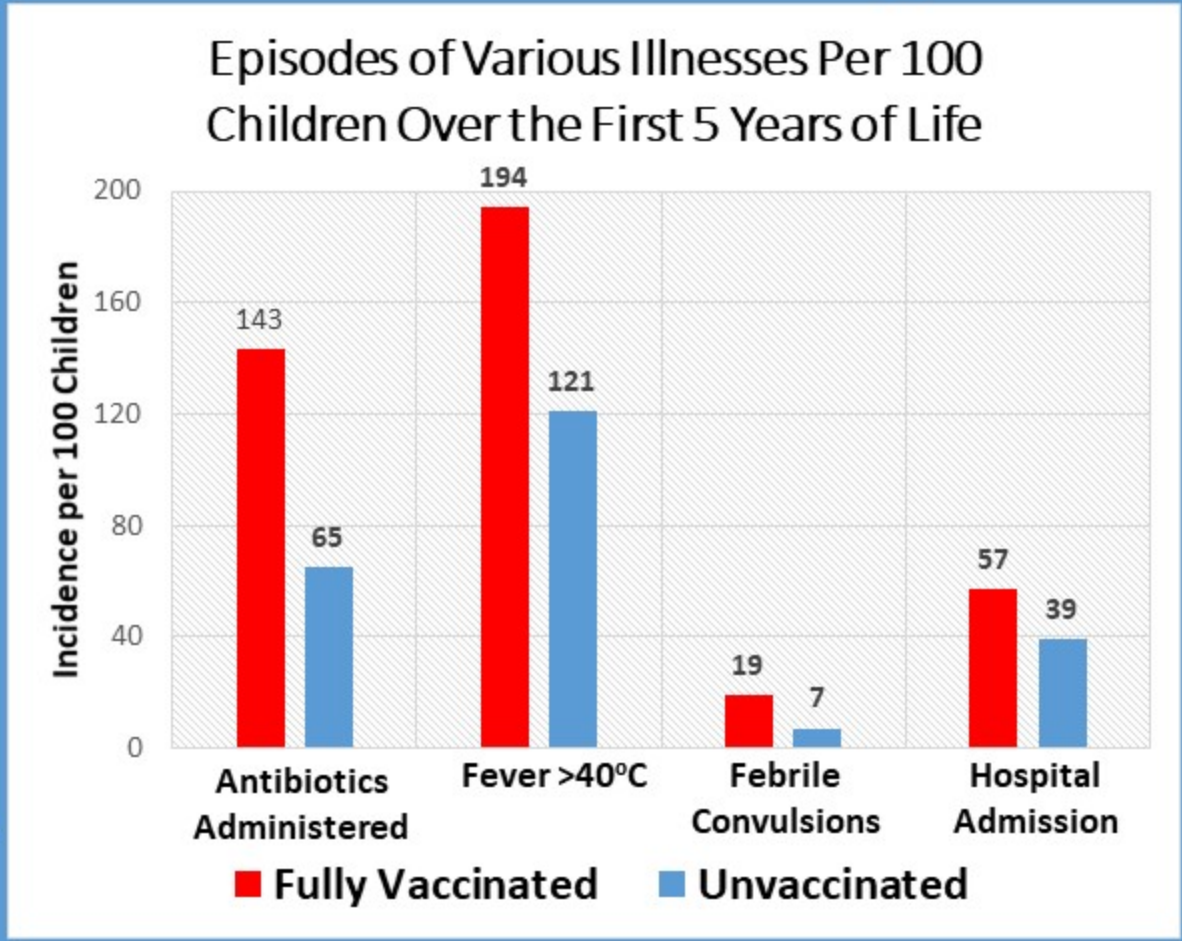

"The NVKP survey was conducted in the Netherlands in the latter half of 2004 with the parents of 635 children, and involved both members and non-members of the NVKP."

Children's Health Defense

Netherlands Fully Vaccinated Versus Unvaccinated Study, 2004

The NVKP (Nederlandse Vereniging Kritisch Prikken) [in English: Dutch Association for Conscientious Vaccination] is an independent association made up of therapists, doctors and parents, amongst others. The NVKP's aim is freedom of choice for parents when it comes to vaccinating their children, based on honest, comprehensive and independent information. We view the current 'one size fits all' vaccination policy with great concern. The NVKP is therefore urging the adoption of more thorough independent research by representatives from different disciplines.

NVKP
PO Box 1106
4700 BC Roosendaal
The Netherlands

Information number: ***0900 - 2020171***
Email: info@nvkp.nl
Website: www.nvkp.nl

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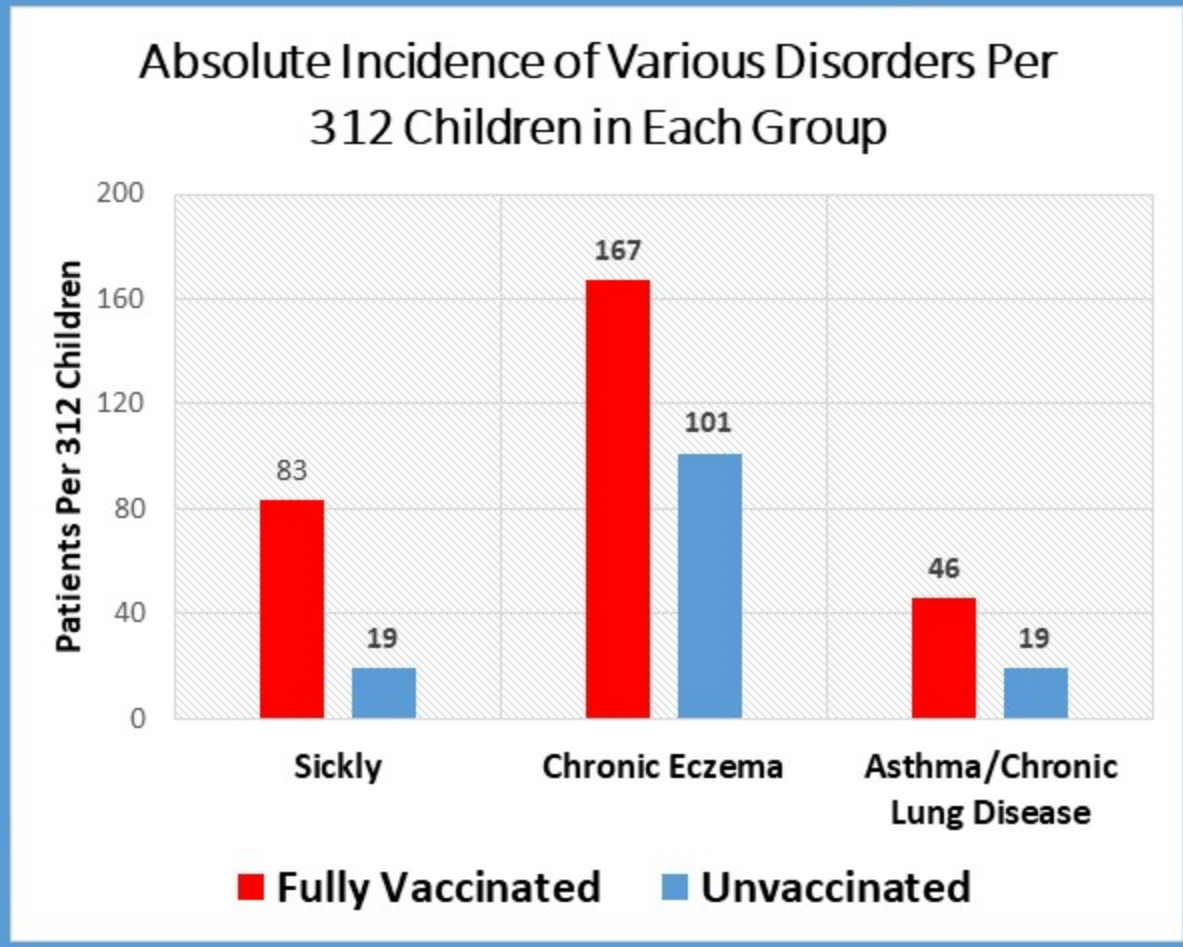

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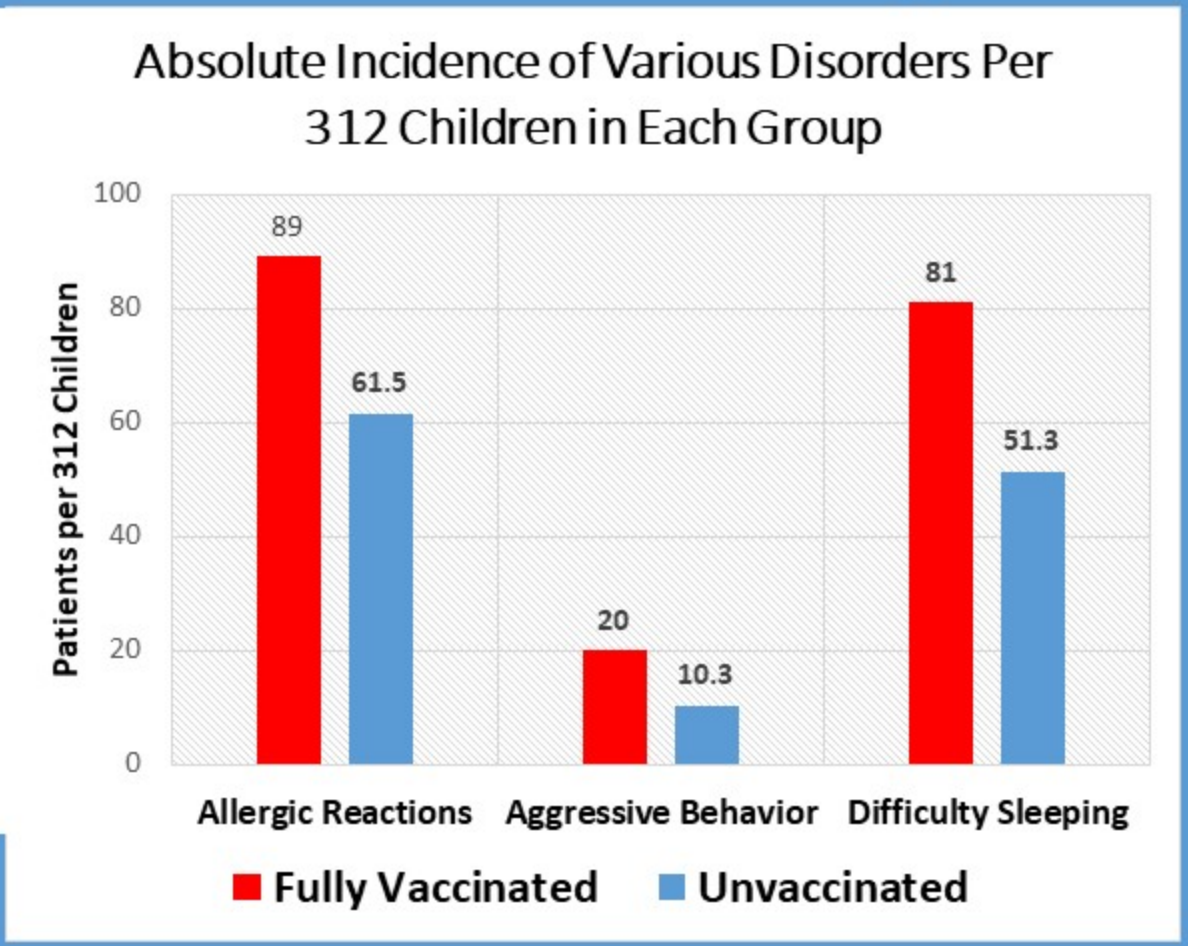

"The NVKP survey was conducted in the Netherlands in the latter half of 2004 with the parents of 635 children, and involved both members and non-members of the NVKP."

Children's Health Defense

January 2020 Pentagon Study Shows Influenza Vaccination Increases Risk of Coronavirus by 36%

ABSTRACT

Purpose: Receiving influenza vaccination may increase the risk of other respiratory viruses, a phenomenon known as virus interference. Test-negative study designs are often utilized to calculate influenza vaccine effectiveness. The virus interference phenomenon goes against the basic assumption of the test-negative vaccine effectiveness study that vaccination does not change the risk of infection with other respiratory illness, thus potentially biasing vaccine effectiveness results in the positive direction. This study aimed to investigate virus interference by comparing respiratory virus status among Department of Defense personnel based on their influenza vaccination status. Furthermore, individual respiratory viruses and their association with influenza vaccination were examined.

Results: We compared vaccination status of 2880 people with non-influenza respiratory viruses to 3240 people with pan-negative results. Comparing vaccinated to non-vaccinated patients, the adjusted odds ratio for non-flu viruses was 0.97 (95% confidence interval (CI): 0.86, 1.09; p = 0.60). Additionally, the vaccination status of 3349 cases of influenza were compared to three different control groups: all controls (N = 6120), non-influenza positive controls (N = 2880), and pan-negative controls (N = 3240). The adjusted ORs for the comparisons among the three control groups did not vary much (range: 0.46–0.51).

Conclusions: Receipt of influenza vaccination was not associated with virus interference among our population. Examining virus interference by specific respiratory viruses showed mixed results. Vaccine derived virus interference was significantly associated with coronavirus and human metapneumovirus; however, significant protection with vaccination was associated not only with most influenza viruses, but also parainfluenza, RSV, and non-influenza virus coinfections.

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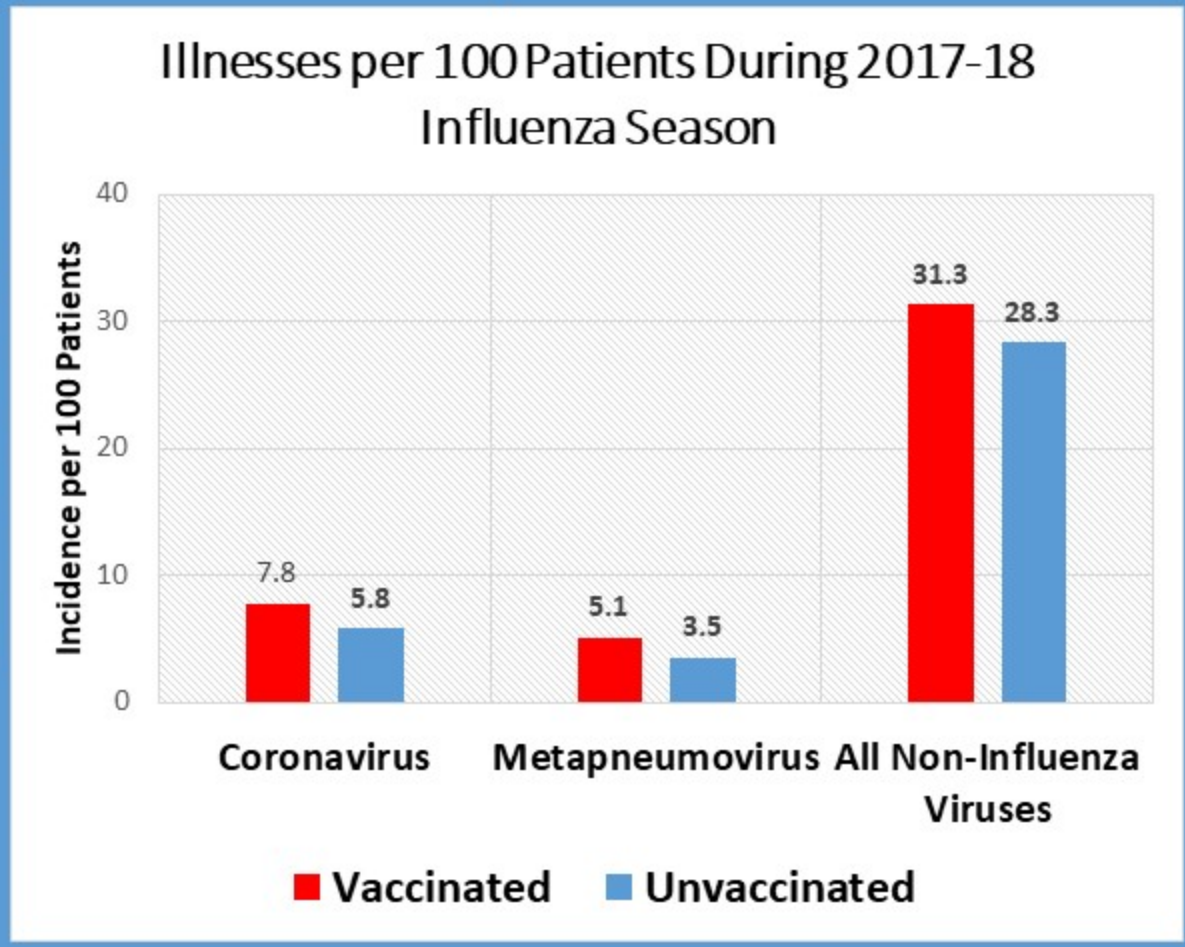


Wolff 2020 Vaccine https://doi.org/10.1016/j.vaccine.2019.10.005

"Vaccine derived virus interference was significantly associated with coronavirus and human metapneumovirus."

Children's Health Defense

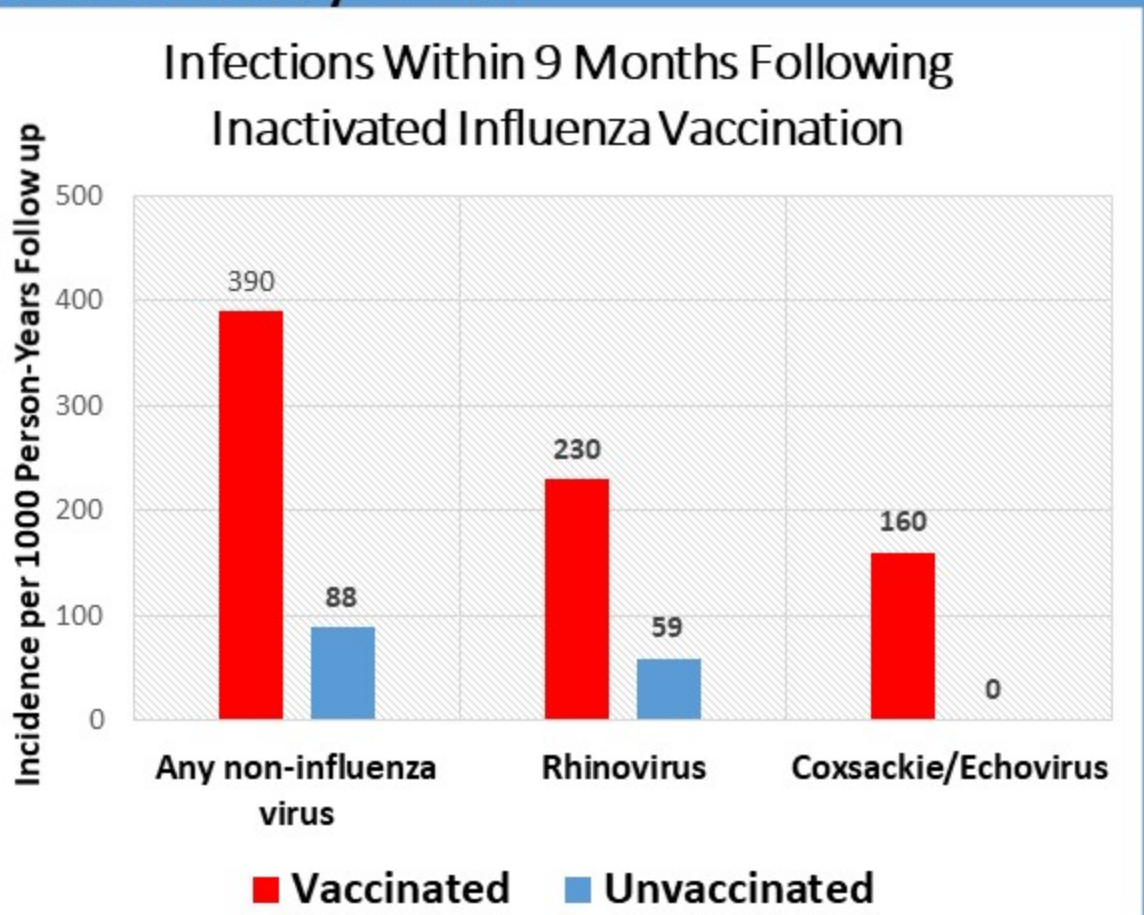
Influenza Vaccination Increases the Risk of Non-Influenza Viral Respiratory Infections by 4.4X

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

Benjamin J. Cowling,[1] Vicky J. Fang,[1] Hiroshi Nishiura,[1,2] Kwok-Hung Chan,[3] Sophia Ng,[1] Dennis K. M. Ip,[1] Susan S. Chiu,[4] Gabriel M. Leung,[1] and J. S. Malik Peiris[1,5]

[1]School of Public Health, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong SAR, China; [2]PRESTO, Japan Science and Technology Agency, Saitama; [3]Department of Microbiology, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Queen Mary Hospital, [4]Department of Pediatrics and Adolescent Medicine, The University of Hong Kong, Queen Mary Hospital, and [5]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.



Cowling et al. 2012 Clinical Infectious Diseases DOI: 10.1093/cid/cis307

"Over the following 9 months, TIV recipients had an increased risk of virologically confirmed non-influenza infections (relative risk: 4.40; 95% confidence)." "In TIV recipients there were 4 detections with both rhinovirus and coxsackie/echovirus, and 1 detection with both coxsackie/echovirus and coronavirus NL63."

Children's Health Defense

Influenza Vaccination Increases Risk of Acute Viral Respiratory Infections by 4.8X

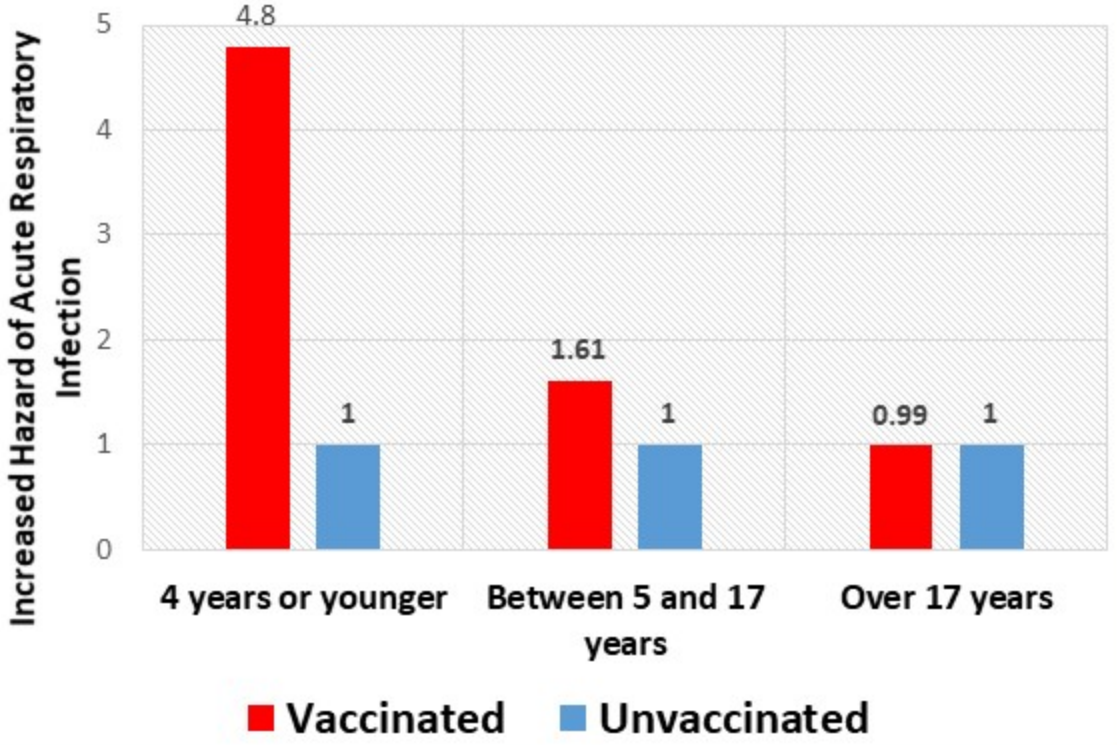
ABSTRACT

Background: A barrier to influenza vaccination is the misperception that the inactivated vaccine can cause influenza. Previous studies have investigated the risk of acute respiratory illness (ARI) after influenza vaccination with conflicting results. We assessed whether there is an increased rate of laboratory-confirmed ARI in post-influenza vaccination periods.

Methods: We conducted a cohort sub-analysis of children and adults in the MoSAIC community surveillance study from 2013 to 2016. Influenza vaccination was confirmed through city or hospital registries. Cases of ARI were ascertained by twice-weekly text messages to household to identify members with ARI symptoms. Nasal swabs were obtained from ill participants and analyzed for respiratory pathogens using multiplex PCR. The primary outcome measure was the hazard ratio of laboratory-confirmed ARI in individuals post-vaccination compared to other time periods during three influenza seasons.

Results: Of the 999 participants, 68.8% were children, 30.2% were adults. Each study season, approximately half received influenza vaccine and one third experienced ≥1 ARI. The hazard of influenza in individuals during the 14-day post-vaccination period was similar to unvaccinated individuals during the same period (HR 0.96, 95% CI [0.60, 1.52]). The hazard of non-influenza respiratory pathogens was higher during the same period (HR 1.65, 95% CI [1.14, 2.38]); when stratified by age the hazard remained higher for children (HR 1·71, 95% CI [1.16, 2.53]) but not for adults (HR 0.88, 95% CI [0.21, 3.69]).

Conclusion: Among children there was an increase in the hazard of ARI caused by non-influenza respiratory pathogens post-influenza vaccination compared to unvaccinated children during the same period. Potential mechanisms for this association warrant further investigation. Future research could investigate whether medical decision-making surrounding influenza vaccination may be improved by acknowledging patient experiences, counseling regarding different types of ARI, and correcting the misperception that all ARI occurring after vaccination are caused by influenza.



Rikin et al. 2018 Vaccine https://doi.org/10.1016/j.vaccine.2018.02.105

"Among children there was an increase in the hazard of ARI caused by non-influenza respiratory pathogens post-influenza vaccination compared to unvaccinated children during the same period."

Children's Health Defense

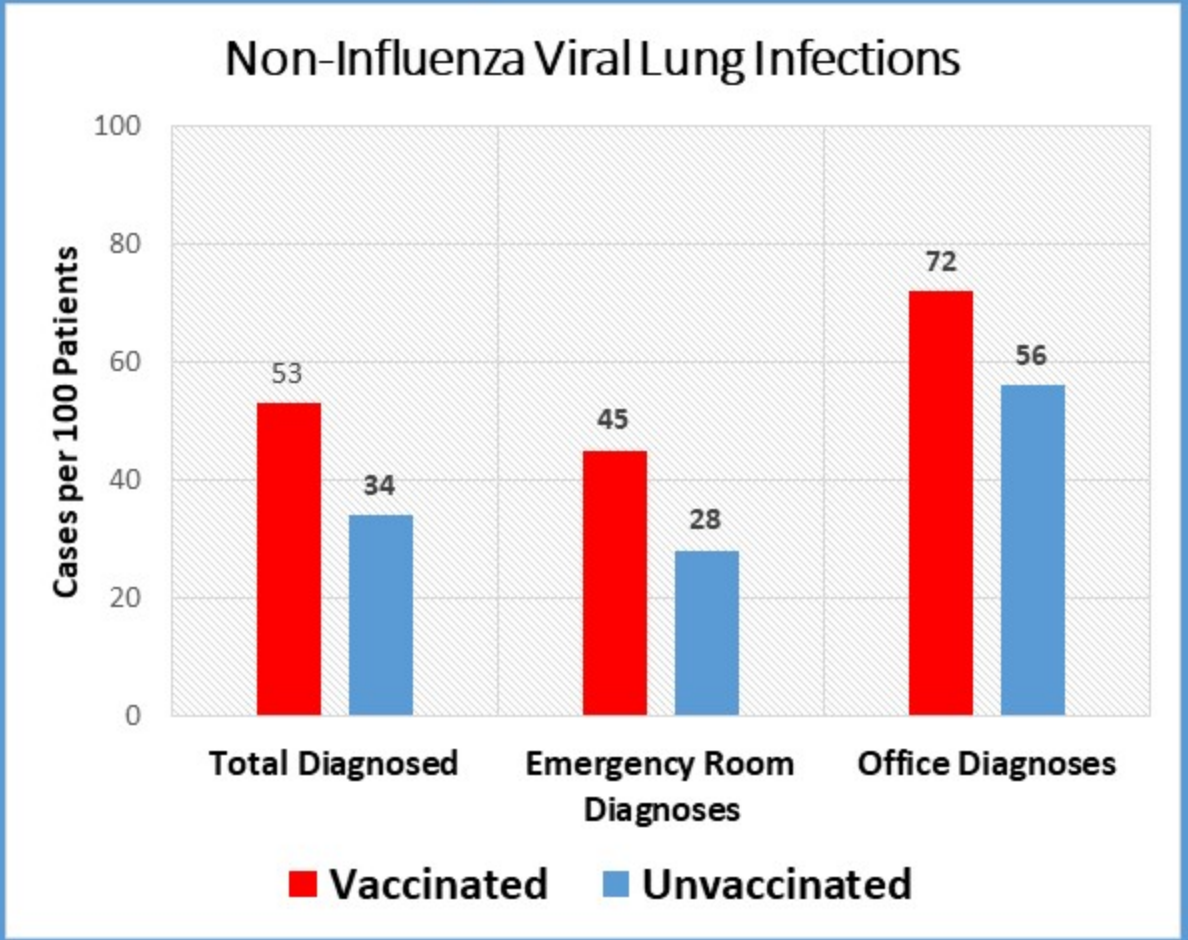
Influenza Vaccination Increases the Risk of Non-Influenza Viral Lung Infections in Children by 55%

Background: The Western Australian Influenza Vaccine Effectiveness study commenced in 2008 to evaluate a new program to provide free influenza vaccine to all children aged 6 to 59 months. We aimed to assess the protective effect of inactivated influenza vaccination in these children.

Methods: We conducted a prospective case–control study in general practices and a hospital emergency department, testing all eligible patients for influenza and a range of other common respiratory viruses. Influenza vaccine effectiveness (VE) against laboratory-confirmed influenza was estimated with cases defined as children with an influenza-like illness who tested positive and controls as those with an influenza-like illness who tested negative for influenza virus. We calculated VE using the adjusted odds ratio from multivariate logistic regression. As a surrogate marker for adequate specimen collection, we explored the difference in VE point estimates defining controls as children in whom another respiratory virus was detected.

Results: A total of 75 children were enrolled from general practices and 214 through the emergency department, with 12 (27%) and 36 (17%), respectively, having laboratory-confirmed influenza. Using all the influenza-negative controls, the adjusted VE was 58% (95% confidence interval, 9–81). When controls were limited to those with another virus present, the adjusted VE was 68% (95% confidence interval, 26–86).

Conclusions: VE estimates were higher when controls included only those children with another respiratory virus detected. Testing for other common respiratory viruses enables the control group to be restricted to those for whom an adequate sample is likely.



"Within the control group, there was a higher percentage of full vaccination among children who tested positive for another respiratory virus compared with those who tested negative."

Children's Health Defense

Kelly et al. 2011 Pediatric Infectious Disease Journal DOI: 10.1097/INF.0b013e318201811c

Influenza Vaccination Increases the Rate of Non-Influenza "Influenza-Like Infections" in Children by 1.6X

Epidemiology of respiratory viral infections in children enrolled in a study of influenza vaccine effectiveness

Alexa Dierig,[a,b] Leon G. Heron,[a,c,d] Stephen B. Lambert,[e,f] Jiehui Kevin Yin,[a,c] Julie Leask,[a,c,d] Maria Yui Kwan Chow,[a,c] Theo P. Sloots,[e] Michael D. Nissen,[e] Iman Ridda,[c] Robert Booy[a,c,d]

[a]National Centre for Immunisation Research and Surveillance, The Children's Hospital at Westmead, Westmead, NSW, Australia. [b]University Children's Hospital both Basel, Basel, Switzerland. [c]Sydney Medical School, The University of Sydney, Sydney, NSW, Australia. [d]Marie Bashir Institute, sydney, NSW, Australia. [e]Queensland Paediatric Infectious Disease Laboratory, Queensland Children's Medical Research Institute, Queensland Children's Health Service, Brisbane, Qld, Australia. [f]Clinical and Statewide Services, Pathology Queensland Central, Herston, Qld, Australia.

Correspondence: Alexa Dierig, University Children's Hospital both Basel, Spitalstr. 33, 4031 Basel, Switzerland. E-mail: alexadierig@web.de

Accepted 24 November 2013. Published Online 31 January 2014.

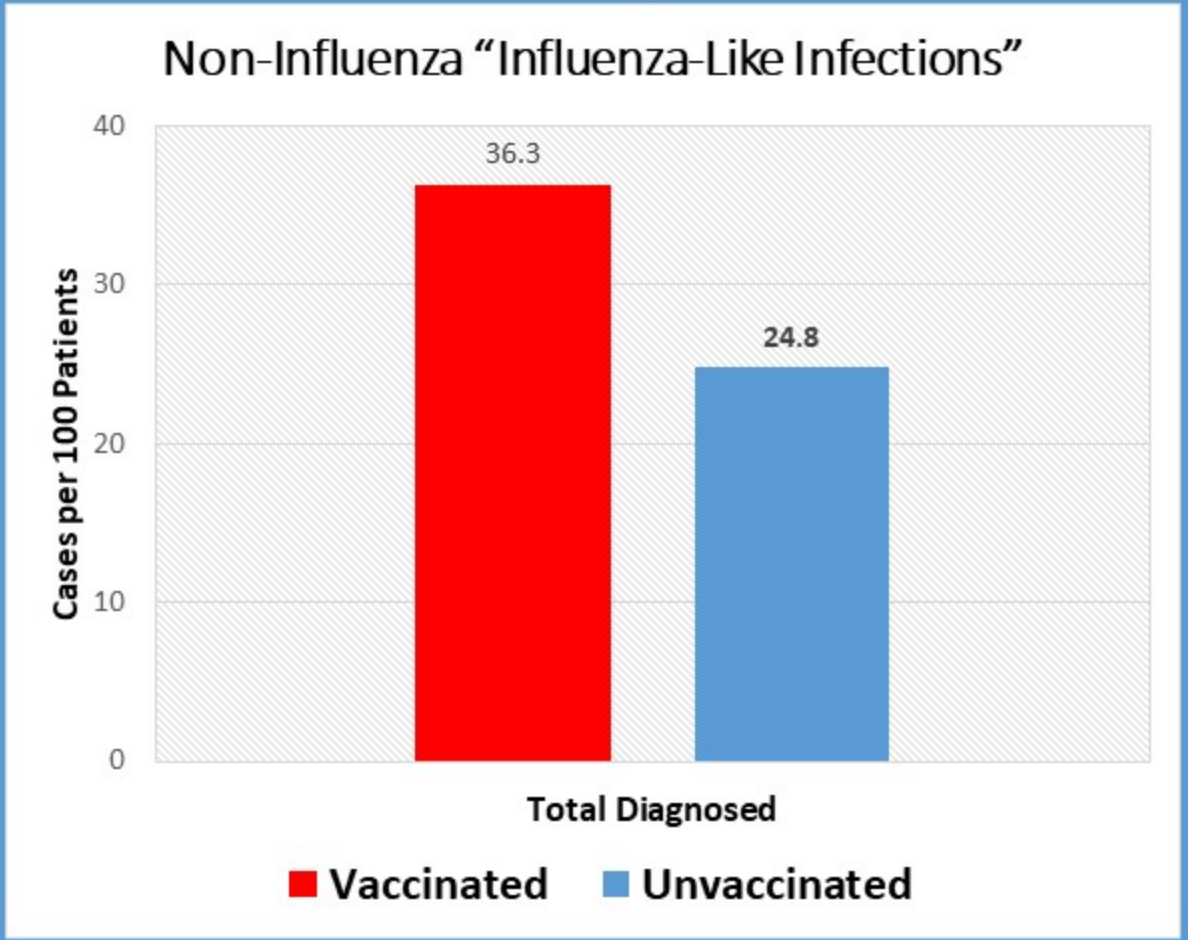
Background Influenza-like illness (ILI) confers a high annual morbidity in young children. We report the epidemiology of ILIs in children who participated in an influenza vaccine effectiveness study during the 2010 Southern Hemisphere influenza season in Sydney, Australia.

Methods Children aged 0·5–3 years were prospectively recruited from child care centres (CCCs). We classified them as fully vaccinated, partially vaccinated and unvaccinated according to their receipt of unadjuvanted vaccines containing influenza A (H1N1)pdm09. For 13 weeks commencing 30 July 2010, parents reported when their children developed an ILI (fever ≥37·8°C/feverishness plus ≥1 respiratory symptom) and collected nose and/or throat swabs for multiplex respiratory virus polymerase chain reaction (PCR) testing. Health impacts were assessed by telephone interview at enrolment and two weeks after each ILI.

Results There were 124 ILIs reported in 105 of 381 enrolled children. Swabs were taken in 117 ILIs: 175 viruses were identified from 103 swabs. Adeno- and rhinoviruses were most frequently identified; 44% of swabs yielded multiple viruses. No virus was associated with more severe symptoms, although rhinovirus-related ILIs lasted longer. Nose swabs had a higher virus detection rate than throat swabs.Influenza-vaccinated children were 1·6 times (P = 0·001) more likely than unvaccinated children to have a non-influenza ILI.

Conclusion Adeno- and rhinoviruses were the most common viruses causing ILI. Swabs taken by parents are an effective method for sample collection. Influenza-like illness was more common in children vaccinated against influenza in this observational study, but prior health-seeking behaviour may have contributed to this difference.

Keywords Children, influenza, respiratory viral infections.



"Influenza-vaccinated children were 1.6 times (P = 0.001) more likely than unvaccinated children to have a non-influenza ILI."

Dierig et al. 2014 Influenza and Other Respiratory Viruses DOI:10.1111/irv.12229

Children's Health Defense

Vaccinated Children Have a 5.9X Greater Risk of Pneumonia and a 3.8X Greater Risk of Ear Infections

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

Anthony R Mawson[1]*, Brian D Ray[2], Azad R Bhuiyan[3] and Binu Jacob[4]

[1]Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[2]President, National Home Education Research Institute, PO Box 13939, Salem, OR 97309, USA

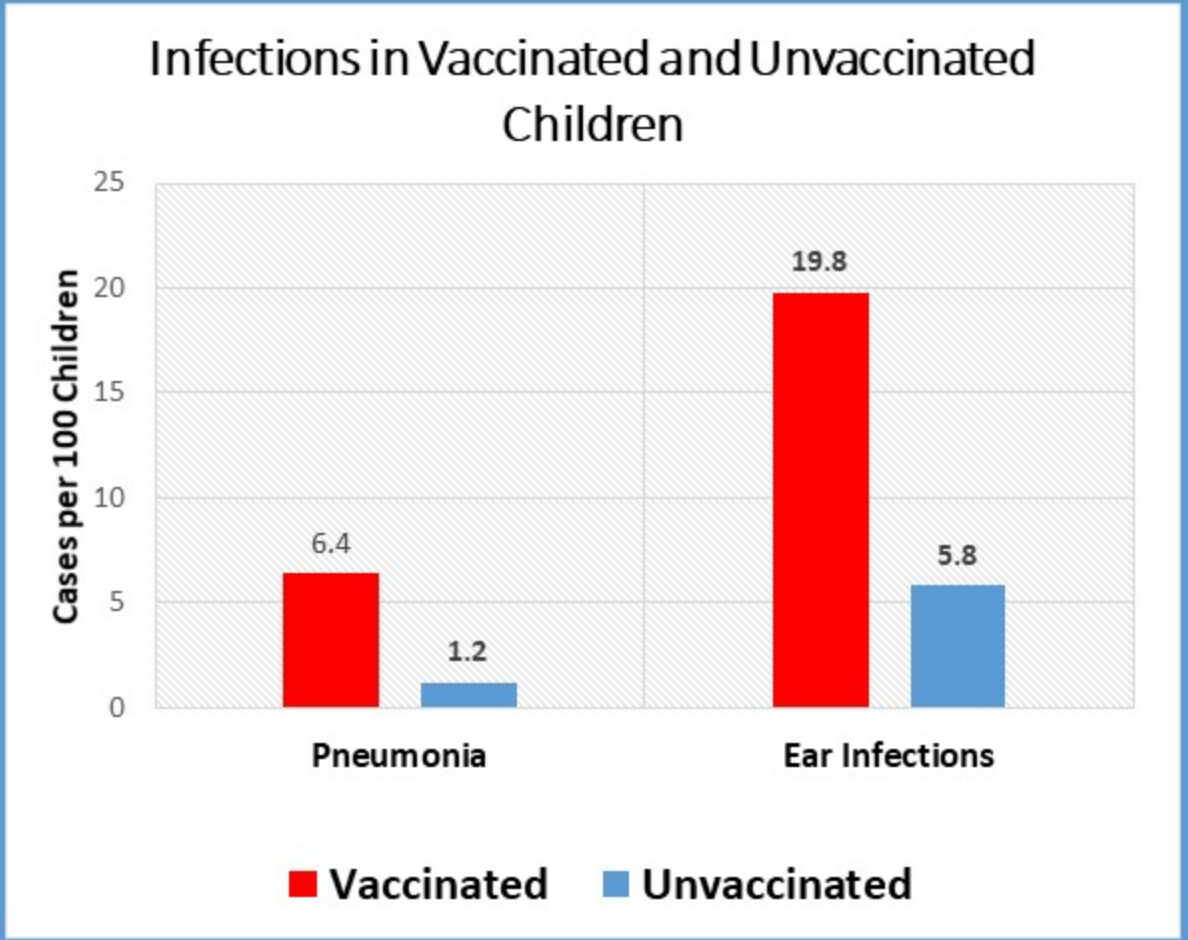
[3]Associate Professor, Department of Epidemiology and Biostatistics, School of Public Health, Jackson State University, Jackson, MS 39213, USA

[4]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, independent samples and stronger research designs is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health.

Mawson et al. 2017 Journal of Translational Science doi: 10.15761/JTS.1000186



"However, the vaccinated were significantly more likely than the unvaccinated to have been diagnosed with otitis media (19.8% vs. 5.8%, p <0.001; OR 3.8, 95% CI: 2.1, 6.6) and pneumonia (6.4% vs. 1.2%, p = 0.001; OR 5.9, 95% CI: 1.8, 19.7)."

Children's Health Defense

Pandemrix Flu Shot Increases Odds of Narcolepsy by 14.4X in Children and Adolescents

BMJ. 2013 Feb 26;346:f794. doi: 10.1136/bmj.f794.

Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis.

Miller E[1], Andrews N, Stellitano L, Stowe J, Winstone AM, Shneerson J, Verity C.

Author information

Abstract

OBJECTIVE: To evaluate the risk of narcolepsy in children and adolescents in England targeted for vaccination with ASO3 adjuvanted pandemic A/H1N1 2009 vaccine (Pandemrix) from October 2009.

DESIGN: Retrospective analysis. Clinical information and results of sleep tests were extracted from hospital notes between August 2011 and February 2012 and reviewed by an expert panel to confirm the diagnosis. Vaccination and clinical histories were obtained from general practitioners.

SETTING: Sleep centres and paediatric neurology centres in England.

PARTICIPANTS: Children and young people aged 4-18 with onset of narcolepsy from January 2008.

MAIN OUTCOME MEASURES: The odds of vaccination in those with narcolepsy compared with the age matched English population after adjustment for clinical conditions that were indications for vaccination. The incidence of narcolepsy within six months of vaccination compared with the incidence outside this period measured with the self controlled cases series method.

RESULTS: Case notes for 245 children and young people were reviewed; 75 had narcolepsy (56 with cataplexy) and onset after 1 January 2008. Eleven had been vaccinated before onset; seven within six months. In those with a diagnosis by July 2011 the odds ratio was 14.4 (95% confidence interval 4.3 to 48.5) for vaccination at any time before onset and 16.2 (3.1 to 84.5) for vaccination within six months before onset. The relative incidence from the self controlled cases series analysis in those with a diagnosis by July 2011 with onset from October 2008 to December 2010 was 9.9 (2.1 to 47.9). The attributable risk was estimated as between 1 in 57,500 and 1 in 52,000 doses.

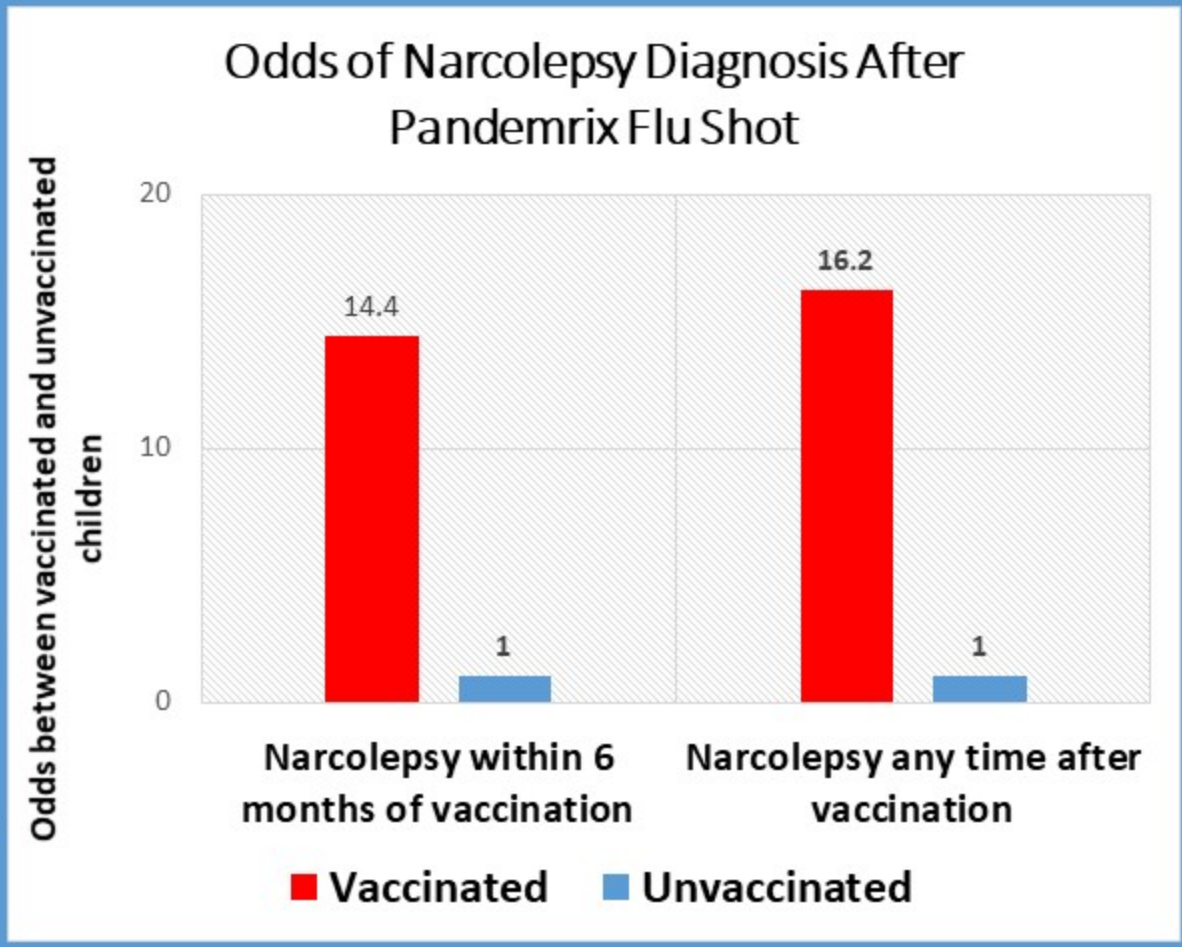
CONCLUSION: The increased risk of narcolepsy after vaccination with ASO3 adjuvanted pandemic A/H1N1 2009 vaccine indicates a causal association, consistent with findings from Finland. Because of variable delay in diagnosis, however, the risk might be overestimated by more rapid referral of vaccinated children.

Comment in

Is the adjuvant solely to blame? [BMJ. 2013]

Is the risk of narcolepsy also increased with non-adjuvanted flu vaccines? [BMJ. 2013]

PMID: 23444425 DOI: 10.1136/bmj.f794



Miller et al. 2013 British Medical Journal doi: 10.1136/bmj.f794

"The increased risk of narcolepsy after vaccination with ASO3 adjuvanted pandemic A/H1N1 2009 vaccine indicates a causal association, consistent with findings from Finland. "

Children's Health Defense

Influenza Vaccination Increases Inflammatory Response by 39% in Pregnant Women

Vaccine. 2011 Nov 8;29(46):8982-7. doi: 10.1016/j.vaccine.2011.09.039. Epub 2011 Sep 22.

Inflammatory responses to trivalent influenza virus vaccine among pregnant women.

Christian LM[1], Iams JD, Porter K, Glaser R.

⊕ Author information

Abstract

OBJECTIVE: In the U.S., seasonal trivalent influenza virus vaccine (TIV) is currently universally recommended for all pregnant women. However, data on the maternal inflammatory response to vaccination is lacking and would better delineate the safety and clinical utility of immunization. In addition, for research purposes, vaccination has been used as a mild immune trigger to examine in vivo inflammatory responses in nonpregnant adults. The utility of such a model in pregnancy is unknown. Given the clinical and empirical justifications, the current study examined the magnitude, time course, and variance in inflammatory responses following seasonal influenza virus vaccination among pregnant women.

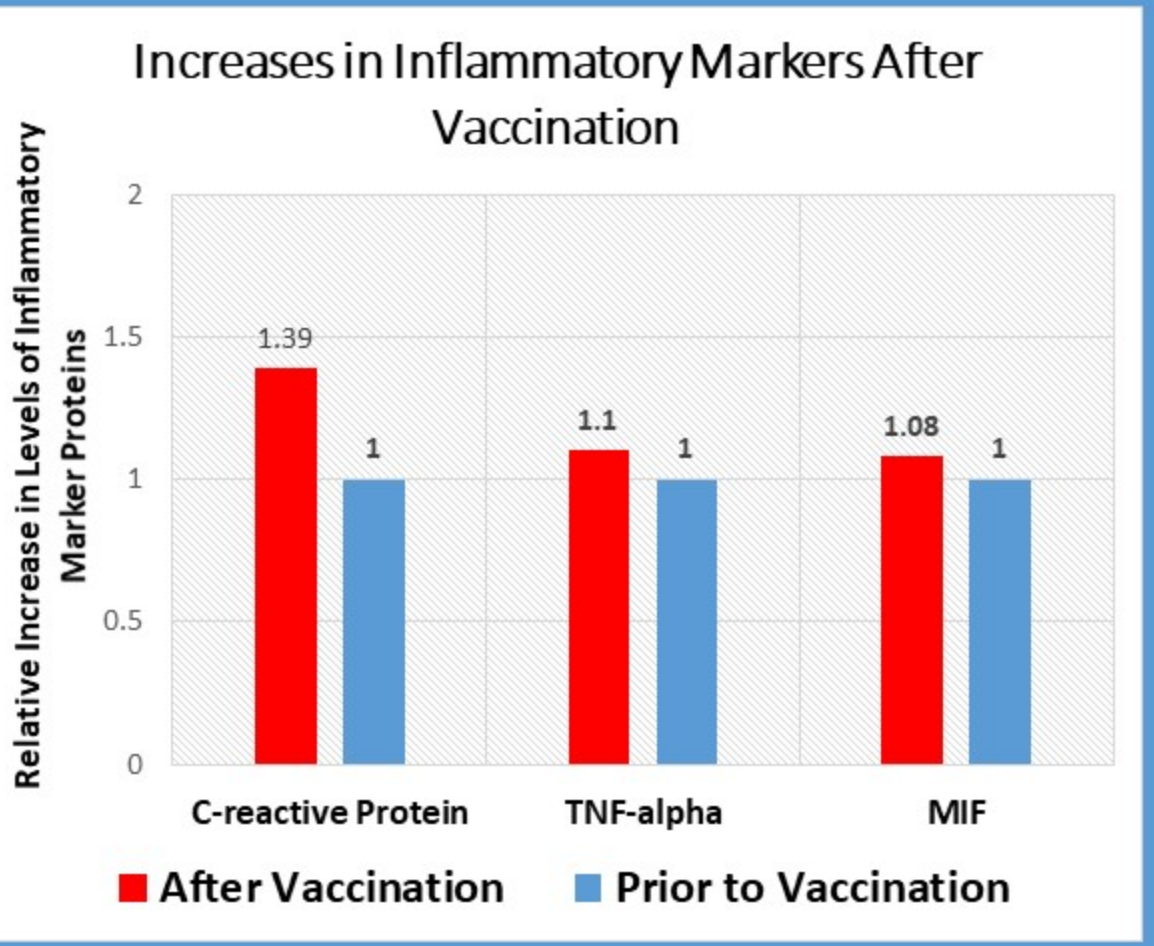
METHODS: Women were assessed prior to and at one day (n=15), two days (n=10), or approximately one week (n=21) following TIV. Serum interleukin (IL)-6, tumor necrosis factor (TNF)-α, C-reactive protein (CRP), and macrophage migration inhibitory factor (MIF) were determined by high sensitivity immunoassay.

RESULTS: Significant increases in CRP were seen at one and two days post-vaccination (ps<05). A similar effect was seen for TNF-α, for which an increase at two days post-vaccination approached statistical significance (p=.06). There was considerable variability in magnitude of response; coefficients of variation for change at two days post-vaccination ranged from 122% to 728%, with the greatest variability in IL-6 responses at this timepoint.

CONCLUSIONS: Trivalent influenza virus vaccination elicits a measurable inflammatory response among pregnant women. There is sufficient variability in response for testing associations with clinical outcomes. As adverse perinatal health outcomes including preeclampsia and preterm birth have an inflammatory component, a tendency toward greater inflammatory responding to immune triggers may predict risk of adverse outcomes, providing insight into biological mechanisms underlying risk. The inflammatory response elicited by vaccination is substantially milder and more transient than seen in infectious illness, arguing for the clinical value of vaccination. However, further research is needed to confirm that the mild inflammatory response elicited by vaccination is benign in pregnancy.

PMID: 21945263 PMCID: PMC3204610 DOI: 10.1016/j.vaccine.2011.09.039

Christian et al. Vaccine 2011
doi:10.1016/j.vaccine.2011.09.039



"In sum, this study demonstrates that trivalent influenza virus vaccine (TIV) elicits a measurable inflammatory response during pregnancy, and that considerable variability is seen between women in the magnitude of this response."

Children's Health Defense

Influenza Vaccination Increases Inflammatory Response by 173% and Induces Platelet Activation and Cardiac Imbalance

J Intern Med. 2011 Jan;269(1):118-25. doi: 10.1111/j.1365-2796.2010.02285.x. Epub 2010 Oct 22.

Inflammation-related effects of adjuvant influenza A vaccination on platelet activation and cardiac autonomic function.

Lanza GA[1], Barone L, Scalone G, Pitocco D, Squeglia GA, Mollo R, Nerla R, Zaccardi F, Ghirlanda G, Crea F.

Author information

Abstract

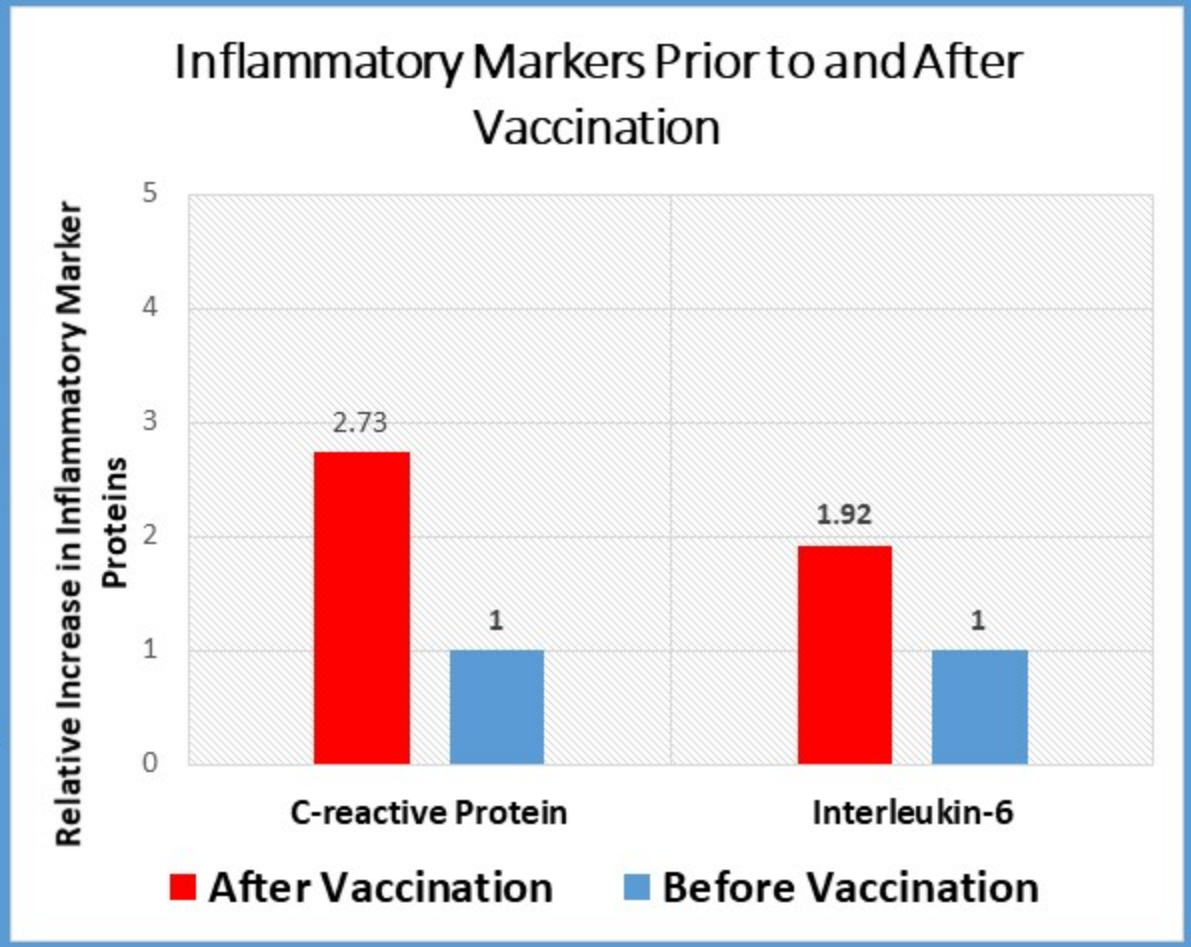
BACKGROUND: Inflammation, platelet reactivity and cardiac autonomic dysfunction increase the risk of cardiovascular events, but the relationships between these prognostic markers are poorly defined. In this study, we investigated the effect of an inflammatory stimulus (influenza A vaccine) on platelet activation and cardiac autonomic function.

METHODS: We measured serum C-reactive protein (CRP) and interleukin-6 levels, monocyte-platelet aggregates (MPAs) and monocyte/platelet receptor expression before and after adjuvant influenza A vaccination in 28 patients with type II diabetes (mean age 62.1 ± 8 years, 18 men). Twenty-four-hour Holter electrocardiogram was recorded 24 h before and after vaccination; heart rate variability (HRV) was assessed as a measure of cardiac autonomic function.

RESULTS: Inflammatory cytokines, MPA formation and monocyte/platelet receptor expression increased after vaccination. CRP was 2.6 ± 2.8 and 7.1 ± 5.7 mg L^{-1} 48 h before and after vaccination, respectively ($P < 0.0001$). HRV parameters decreased after vaccination compared to baseline, with very low-frequency amplitude showing the most significant change (34.6 ± 11.8 and 31.0 ± 10.2 ms 48 h before and after vaccination, respectively; $P = 0.002$). A significant correlation was found between percentage changes in CRP levels and in most HRV variables, with the most significant correlations between changes in CRP levels and changes in standard deviation of all normal RR intervals ($r = 0.43$; $P = 0.02$).

CONCLUSIONS: Together with an inflammatory reaction, influenza A vaccine induced platelet activation and sympathovagal imbalance towards adrenergic predominance. Significant correlations were found between CRP levels and HRV parameters, suggesting a pathophysiological link between inflammation and cardiac autonomic regulation. The vaccine-related platelet activation and cardiac autonomic dysfunction may transiently increase the risk of cardiovascular events.

PMID: 20964738 DOI: 10.1111/j.1365-2796.2010.02285.x



Lanza et al. 2011 J Intern Med
doi: 10.1111/j.1365-2796.2010.02285.x

"Together with an inflammatory reaction, influenza A vaccine induced platelet activation and sympathovagal imbalance towards adrenergic predominance… The vaccine-related platelet activation and cardiac autonomic dysfunction may transiently increase the risk of cardiovascular events."

Children's Health Defense

Influenza Vaccination Increases Susceptibility to and Damage Caused by Non-Target Flu Strains

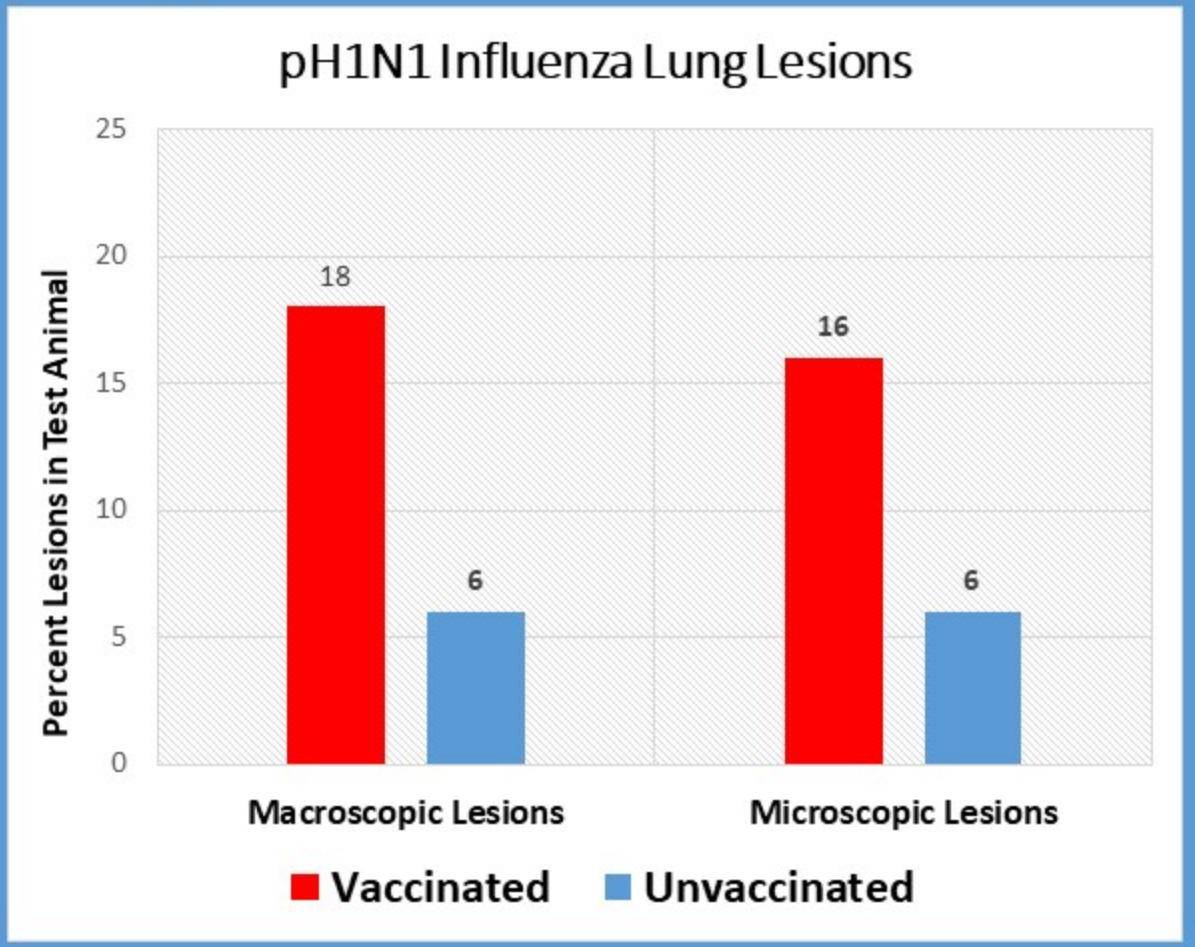
INFLUENZA

Vaccine-Induced Anti-HA2 Antibodies Promote Virus Fusion and Enhance Influenza Virus Respiratory Disease

Surender Khurana,[1] Crystal L. Loving,[2] Jody Manischewitz,[1] Lisa R. King,[1] Phillip C. Gauger,[3] Jamie Henningson,[4] Amy L. Vincent,[2]* Hana Golding[1]*

Vaccine-induced disease enhancement has been described in connection with several viral vaccines in animal models and in humans. We investigated a swine model to evaluate mismatched influenza vaccine-associated enhanced respiratory disease (VAERD) after pH1N1 infection. Vaccinating pigs with whole inactivated H1N2 (human-like) virus vaccine (WIV-H1N2) resulted in enhanced pneumonia and disease after pH1N1 infection. WIV-H1N2 immune sera contained high titers of cross-reactive anti-pH1N1 hemagglutinin (HA) antibodies that bound exclusively to the HA2 domain but not to the HA1 globular head. No hemagglutination inhibition titers against pH1N1 (challenge virus) were measured. Epitope mapping using phage display library identified the immunodominant epitope recognized by WIV-H1N2 immune sera as amino acids 32 to 77 of pH1N1-HA2 domain, close to the fusion peptide. These cross-reactive anti-HA2 antibodies enhanced pH1N1 infection of Madin-Darby canine kidney cells by promoting virus membrane fusion activity. The enhanced fusion activity correlated with lung pathology in pigs. This study suggests a role for fusion-enhancing anti-HA2 antibodies in VAERD, in the absence of receptor-blocking virus-neutralizing antibodies. These findings should be considered during the evaluation of universal influenza vaccines designed to elicit HA2 stem-targeting antibodies.

Khurana et al. 2013 Sci Translational Med
DOI: 10.1126/scitranslmed.3006366



"Vaccinating pigs with whole inactivated H1N2 (human-like) virus vaccine (WIV-H1N2) resulted in enhanced pneumonia and disease after pH1N1 infection."

Children's Health Defense

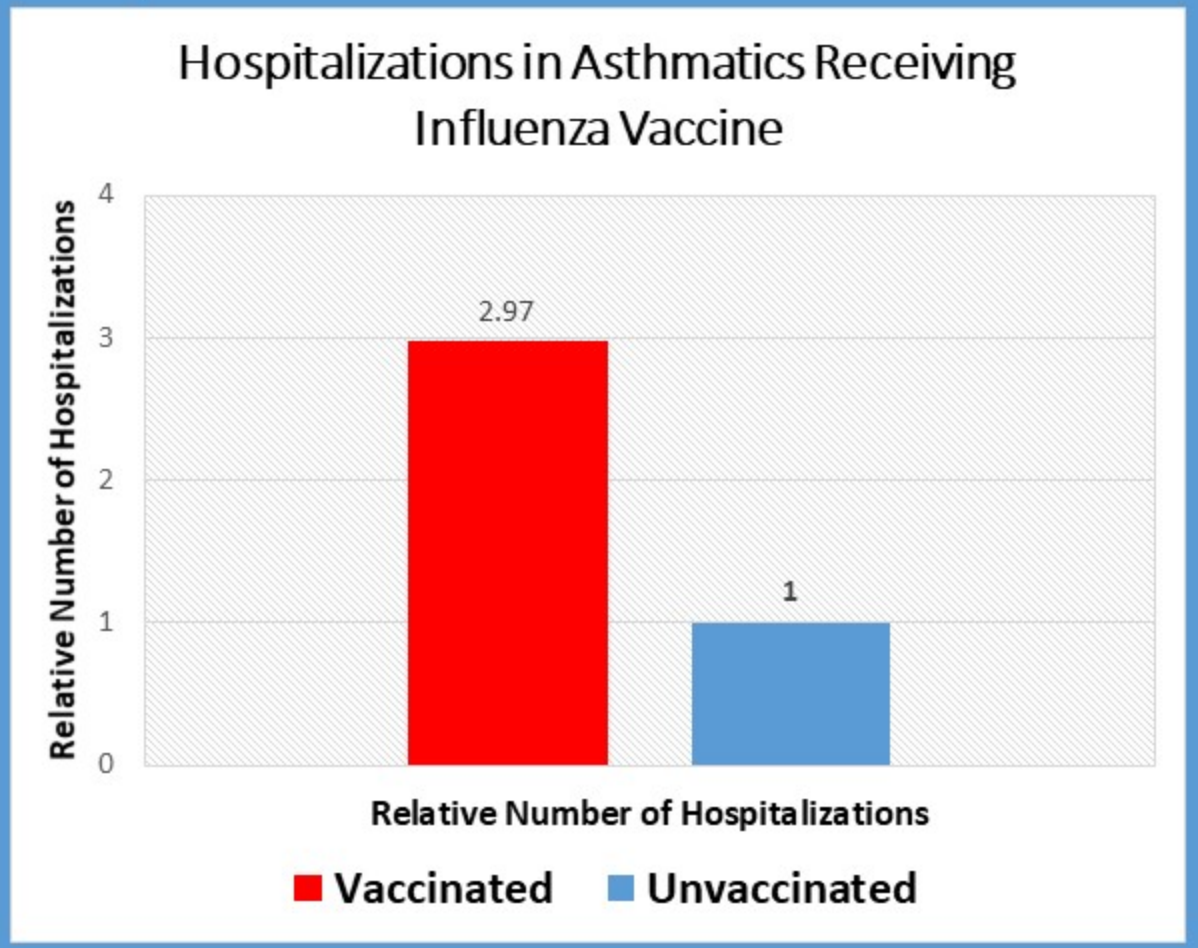
Influenza Vaccination Increases Hospitalizations in Asthmatic Patients by 2.97X

Flu Vaccination in Asthmatics: Does It Work?.

A. Y. Joshi, MD[1], V. N. Iyer, MD,MPH[1], M. F. Hartz, MD[1], G. W. Volcheck, MD,Ph.D[1], A. M. Patel, MD[1] and J. T. Li, MD,Ph.D[1].
Email: joshi.avni@mayo.edu

[1]Mayo Clinic College of Medicine, Rochester, MN.

INTRODUCTION: Influenza is known to be associated with asthma exacerbation but the effectiveness of the trivalent inactivated flu vaccine (TIV) in asthmatics is unknown.
METHODS: We conducted a ***cohort study*** of all pediatric subjects(6 months to 18 years age) who were evaluated at Mayo Clinic, Rochester, MN, USA who had laboratory confirmed influenza during each flu season from 1999–2006 to evaluate the efficacy of TIV. A case control analysis was performed with the cases and the controls being the subjects with asthma who did and did not required hospitalization with the influenza illness respectively.
RESULTS:
There were 236 subjects with laboratory confirmed influenza from 1996–2006.
In assessing the effectiveness of the TIV for preventing hospitalization with influenza in all subjects, there was an overall trend towards higher rates of hospitalization in subjects who got the TIV as compared to the ones who did not get the TIV(OR:2.97, CI: 1.3,6.7).Using Cochran–Mantel–Haenszel (CMH) test for Asthma status stratification, there was a significant association between hospitalization in asthmatic subjects and TIV (P=0.006).
In the asthmatic subset:
There was no association between ER visit and receiving the TIV ,severity of asthma and the risk of hospitalization or the hospital length of stay and receiving the TIV.
In assessing access to medical care, there was no association between hospitalizations and health care insurance plans (Odds ratio:0.3, P= 0.13)
CONCLUSION:
1) TIV did not provide any protection against hospitalization in pediatric subjects' esp. children with asthma. On the contrary, we found a 3– fold increased risk of hospitalization in subjects who did get the TIV vaccine.This may be a reflection not only of the vaccine effectiveness but also the population of children who are more likely to get the vaccine.
2) More studies are needed to assess not only the immunogenicity but also efficacy of different influenza vaccines in asthmatic subjects.



Joshi et al. 2009 American Thoracic Society Conference Abstract

"In assessing the effectiveness of the TIV for preventing hospitalization with influenza in all subjects, there was an overall trend towards higher rates of hospitalization in subjects who got the TIV as compared to the ones who did not get the TIV(OR:2.97,CI: 1.3,6.7). "

Children's Health Defense

Multiple Vaccinations Given Simultaneously Increases Odds of Cardiac Events in Premature Infants by 3.62X

Primary Immunization of Premature Infants with Gestational Age <35 Weeks: Cardiorespiratory Complications and C-Reactive Protein Responses Associated with Administration of Single and Multiple Separate Vaccines Simultaneously

Massroor Pourcyrous, MD, Sheldon B. Korones, MD, Kristopher L. Arheart, PhD, and Henrietta S. Bada, MD

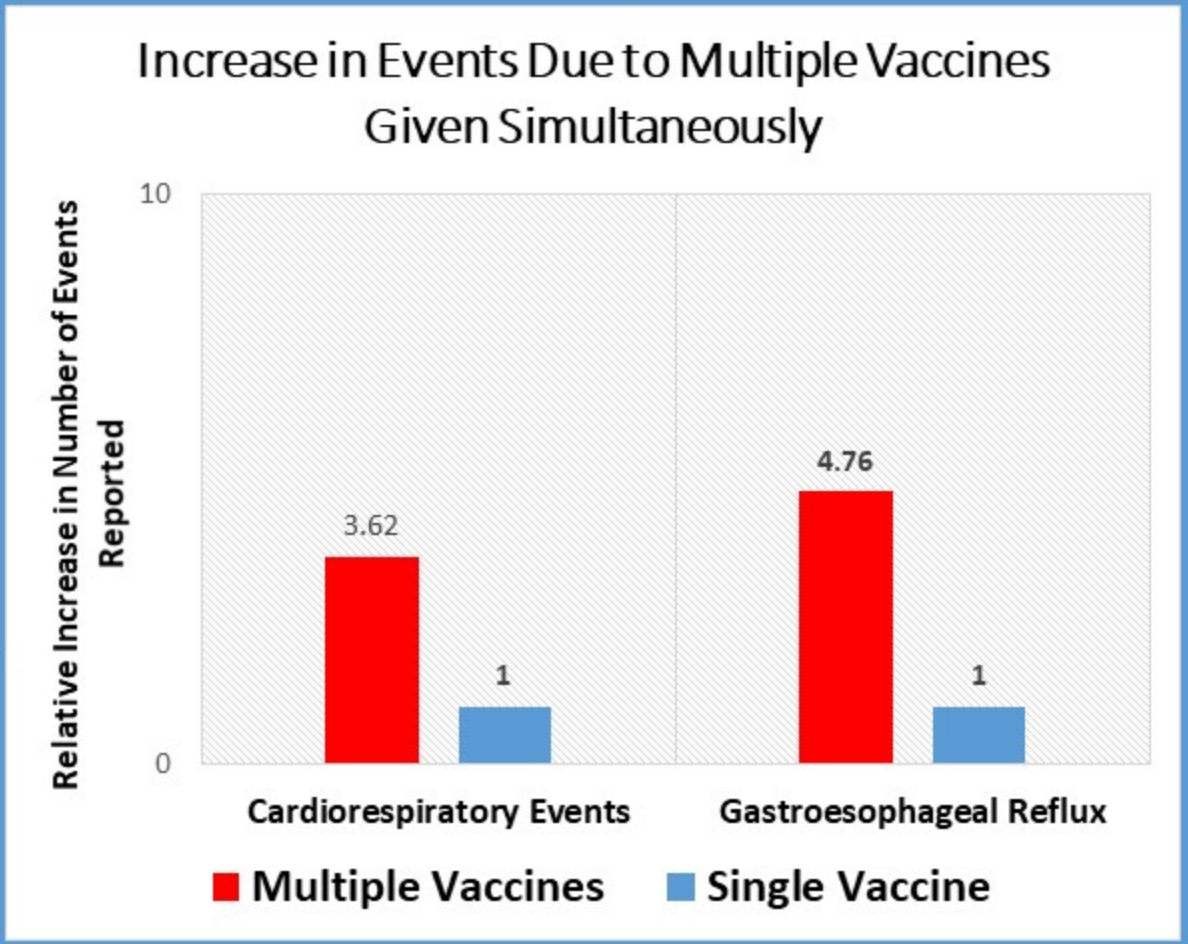
Objective To determine the incidence of cardiorespiratory events and abnormal C-reactive protein (CRP) level associated with administration of a single vaccine or multiple separate vaccines simultaneously.

Study design Prospective observational study on 239 preterm infants at ≥2 months of age in the neonatal intensive care unit (NICU). Each infant received either a single vaccine or multiple vaccines on one day. CRP levels and cardiorespiratory manifestations were monitored for 3 days following immunization.

Results Abnormal elevation of CRP level occurred in 85% of infants administered multiple vaccines and up to 70% of those given a single vaccine. Overall, 16% of infants had vaccine-associated cardiorespiratory events within 48 hours postimmunization. In logistic regression analysis, abnormal CRP values were associated with multiple vaccines (OR, 15.77; 95% CI 5.10-48.77) and severe intraventricular hemorrhage (IVH) (OR, 2.28; 95% CI 1.02-5.13). Cardiorespiratory events were associated marginally with receipt of multiple injections (OR, 3.62; 95% CI 0.99-13.25) and significantly with gastroesophageal reflux (GER) (OR, 4.76; 95% CI 1.22-18.52).

Conclusion CRP level is expected to be elevated in the 48 hours following immunization. In a minority of infants immunized, cardiorespiratory events were associated with presumed need for intervention. Underlying medical conditions and possibly multiple injections are associated with cardiorespiratory events. Precautionary monitoring following immunizations is warranted. *(J Pediatr 2007;151:167-72)*

Pourcyrous et al. 2007 J Pediatr
DOI 10.1016/j.jpeds.2007.02.059



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Children's Health Defense

Vaccination During the First Year of Life Increases the Odds of Developmental Delays by 2.18X

Original Article

SAGE Open Medicine

Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders

SAGE Open Medicine
Volume 8: 1–11
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SAGE

Brian S Hooker[1] and Neil Z Miller[2]

Abstract

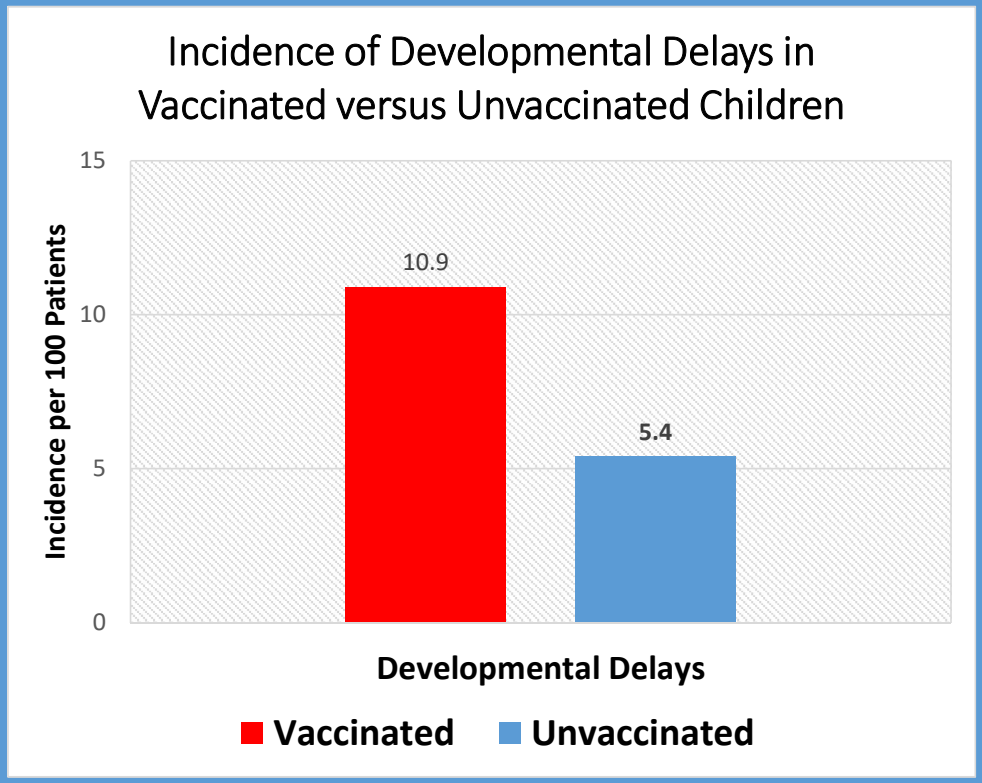
Objective: The aim of this study was to compare the health of vaccinated versus unvaccinated pediatric populations.

Methods: Using data from three medical practices in the United States with children born between November 2005 and June 2015, vaccinated children were compared to unvaccinated children during the first year of life for later incidence of developmental delays, asthma, ear infections and gastrointestinal disorders. All diagnoses utilized International Classification of Diseases–9 and International Classification of Diseases–10 codes through medical chart review. Subjects were a minimum of 3 years of age, stratified based on medical practice, year of birth and gender and compared using a logistic regression model.

Results: Vaccination before 1 year of age was associated with increased odds of developmental delays (OR = 2.18, 95% CI 1.47–3.24), asthma (OR = 4.49, 95% CI 2.04–9.88) and ear infections (OR = 2.13, 95% CI 1.63–2.78). In a quartile analysis, subjects were grouped by number of vaccine doses received in the first year of life. Higher odds ratios were observed in Quartiles 3 and 4 (where more vaccine doses were received) for all four health conditions considered, as compared to Quartile 1. In a temporal analysis, developmental delays showed a linear increase as the age cut-offs increased from 6 to 12 to 18 to 24 months of age (ORs = 1.95, 2.18, 2.92 and 3.51, respectively). Slightly higher ORs were also observed for all four health conditions when time permitted for a diagnosis was extended from ⩾ 3 years of age to ⩾ 5 years of age.

Conclusion: In this study, which only allowed for the calculation of unadjusted observational associations, higher ORs were observed within the vaccinated versus unvaccinated group for developmental delays, asthma and ear infections. Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination.

Hooker and Miller, SAGE Open Medicine 2020
https://doi.org/10.1177/2050312120925344



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Children's Health Defense

Vaccination During the First Year of Life Increases the Odds of Asthma by 4.49X

Original Article

SAGE Open Medicine

Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders

SAGE Open Medicine
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Hooker and Miller, SAGE Open Medicine 2020
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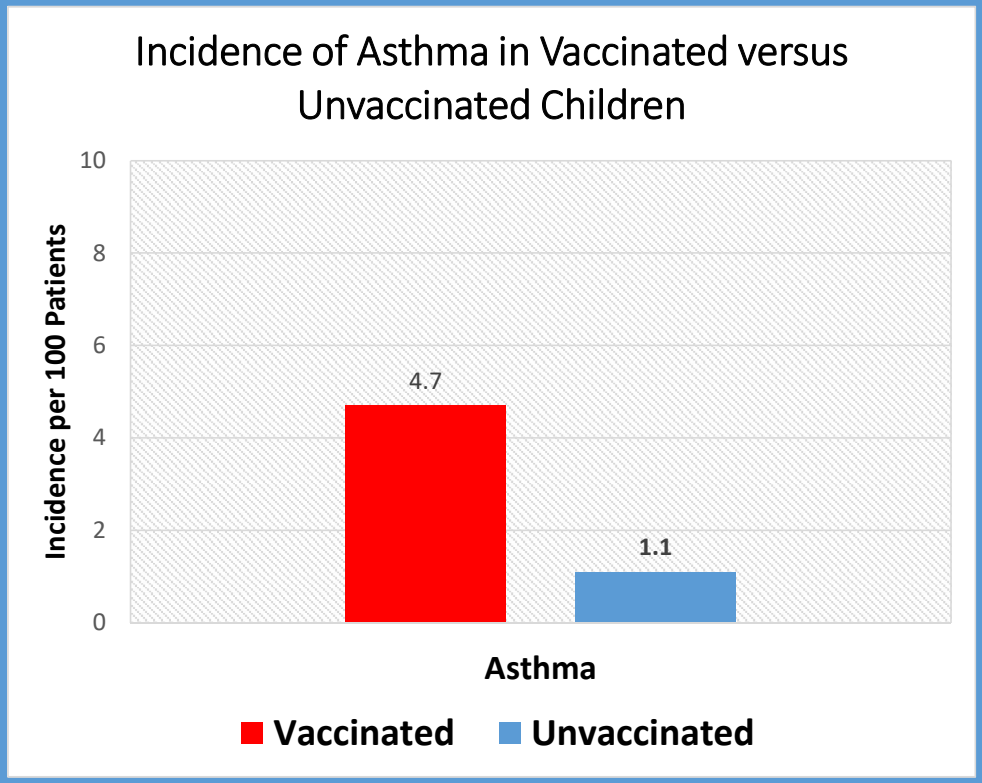

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Children's Health Defense

Vaccination During the First Year of Life Increases the Odds of Ear Infections by 2.13X

Original Article

SAGE Open Medicine

Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders

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Hooker and Miller, SAGE Open Medicine 2020
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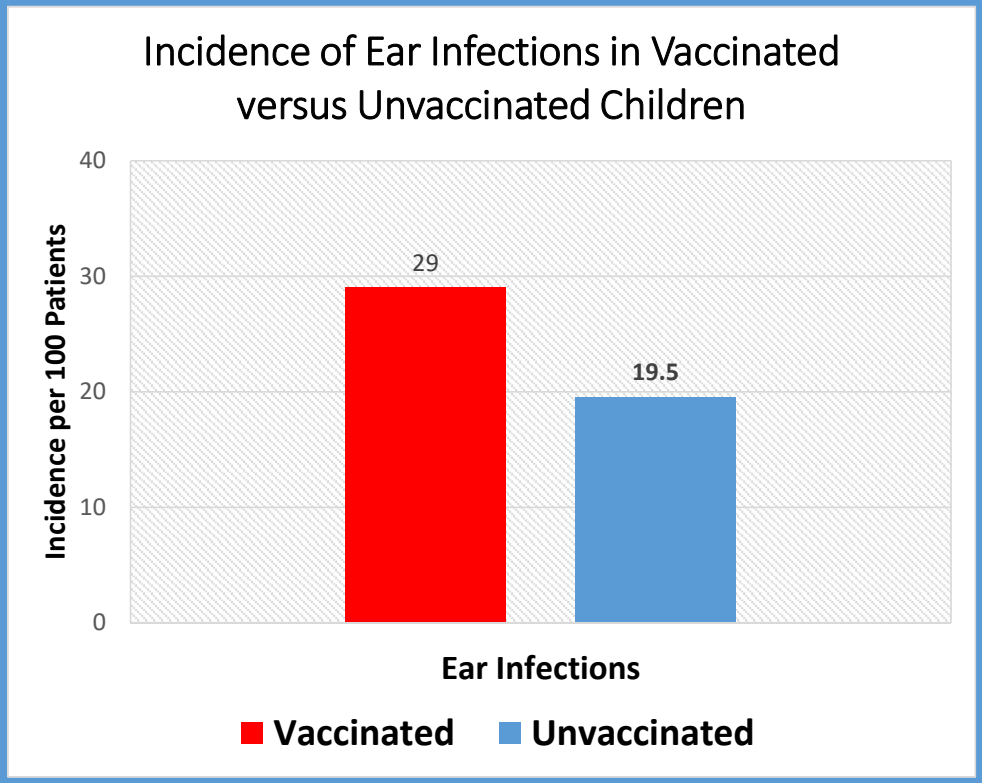

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Children's Health Defense

Vaccination During the First Year of Life Increases the Odds of Gastrointestinal Disorder by 2.48X

Original Article

SAGE Open Medicine

Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders

SAGE Open Medicine
Volume 8: 1–11

DOI: 10.1177/2050312120925344
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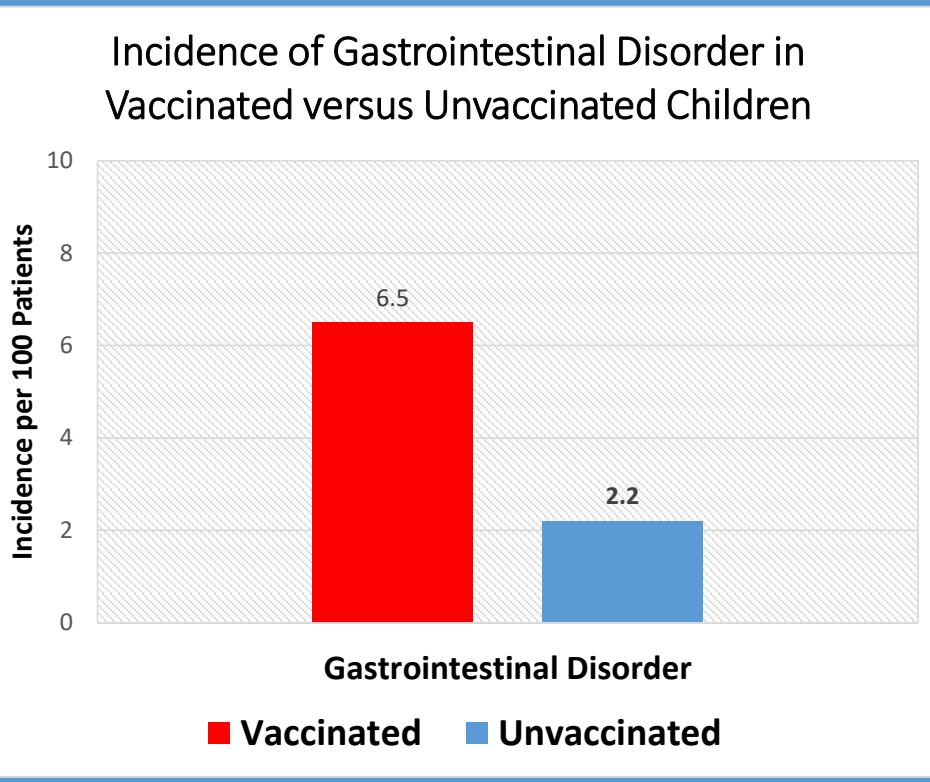


Hooker and Miller, SAGE Open Medicine 2020
https://doi.org/10.1177/2050312120925344

"Statistical significance was seen for gastrointestinal disorders when… additional time was permitted for a diagnosis."

Children's Health Defense

Vaccination With the Hepatitis B Vaccine Series Increases the Odds of Liver Problems in Children 294%

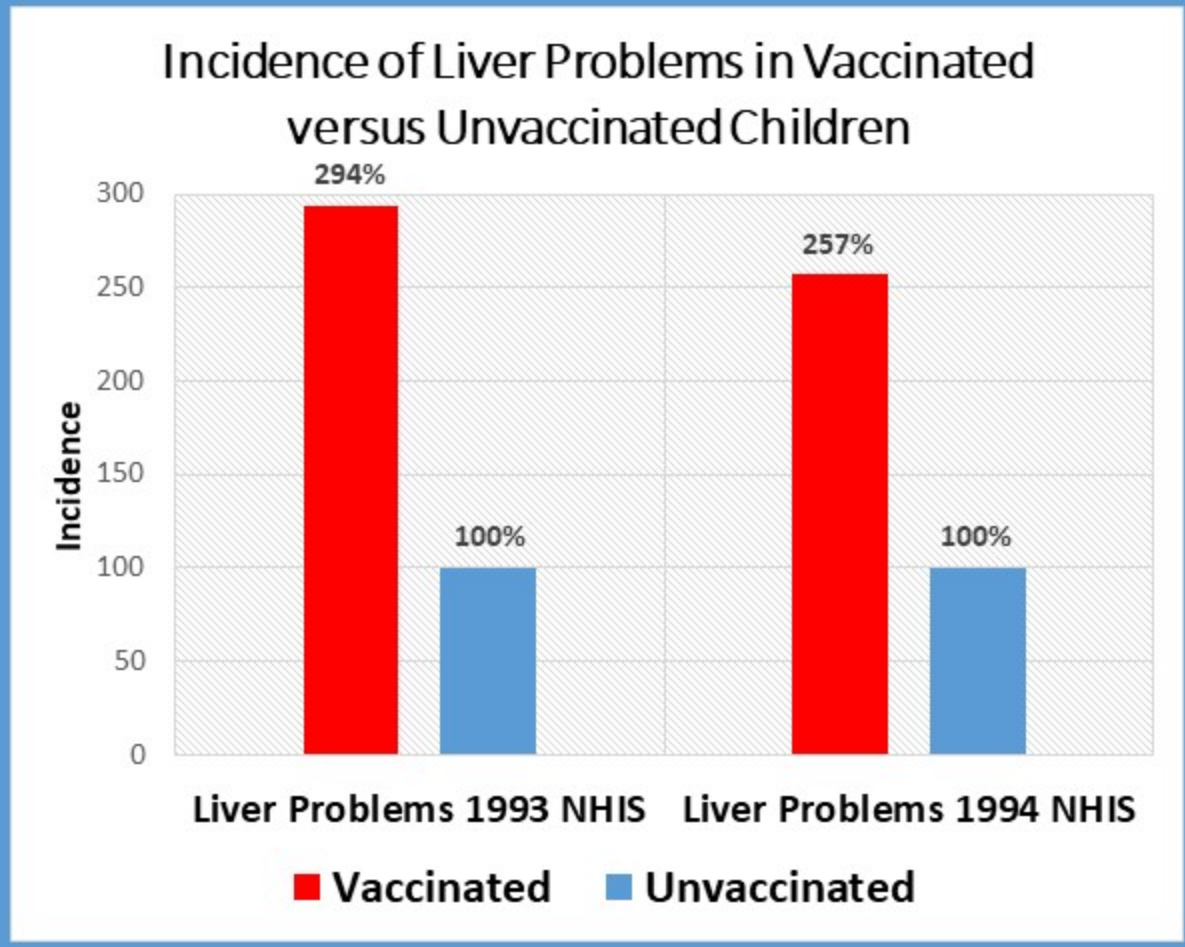
Hepatitis B Vaccine and Liver Problems in U.S. Children Less Than 6 Years Old, 1993 and 1994

Monica A. Fisher and Stephen A. Eklund

Data to assess the benefits and risks of hepatitis B vaccine for the general population of U.S. children are sparse. This study addressed the problem of external validity found in previous studies of high risk populations by evaluating the benefit of hepatitis B vaccination for the general population of American children. We calculated the risk of liver problems among hepatitis B vaccinated and non-hepatitis B vaccinated children using logistic regression. Hepatitis B vaccinated children had an unadjusted odds ratio of 2.94 and age-adjusted odds ratio of 2.35 for liver problems compared with non-hepatitis B vaccinated children in the 1993 National Health Interview Survey. Hepatitis B vaccinated children had an unadjusted odds ratio of 2.57 and age-adjusted odds ratio of 1.53 for liver problems compared with non-hepatitis B vaccinated children in the 1994 National Health Interview Survey dataset. (Epidemiology 1999;10:337–339)

Keywords: adverse effects, child, hepatitis B, hepatitis B vaccine, infant, risk, risk assessment.

Fisher and Eklund, Epidemiology 1999
https://insights.ovid.com/pubmed?pmid=10230847



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Children's Health Defense

Polio Vaccine Increases the Risk of Crohn's Disease by 228% and Ulcerative Colitis by 348%

Fasiha Kanwal, Section Editor

Vaccination and Risk for Developing Inflammatory Bowel Disease: A Meta-Analysis of Case–Control and Cohort Studies

Guillaume Pineton de Chambrun,[*,‡,§,‖] Luc Dauchet,[§,¶] Corinne Gower-Rousseau,[*,‡,§] Antoine Cortot,[*,‡,§] Jean-Frédéric Colombel,[#] and Laurent Peyrin-Biroulet[§,**]

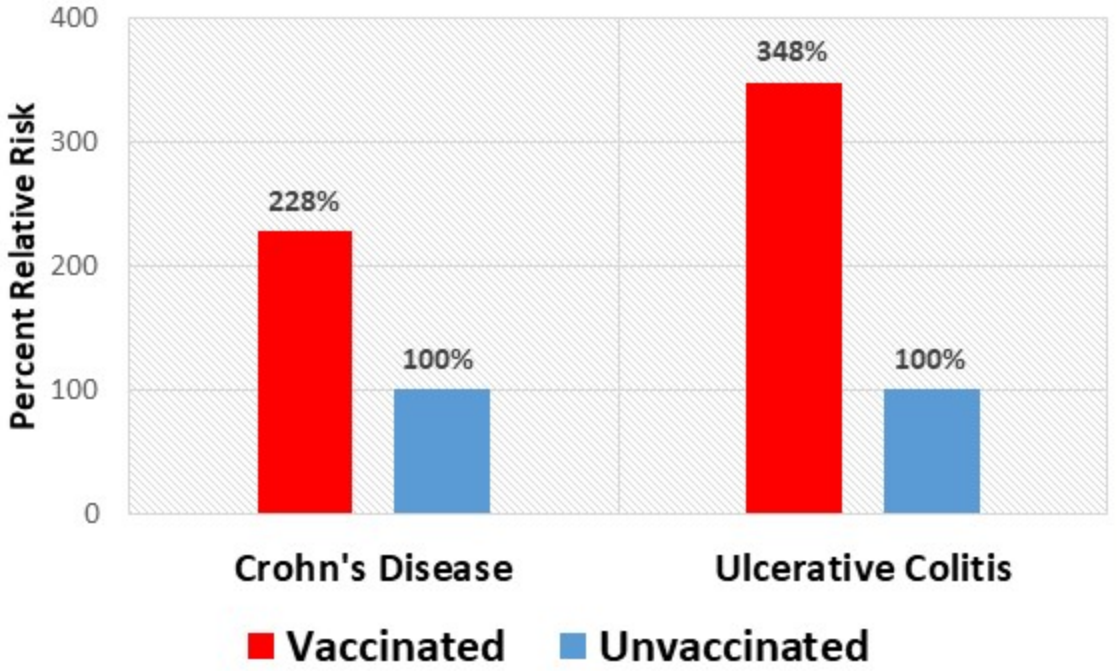
This article has an accompanying continuing medical education activity on page e130. Learning Objective–Upon completion of this activity, successful learners will be able to discuss the implication of vaccination and environmental factors in the development of inflammatory bowel disease.

BACKGROUND & AIMS: Environmental factors may play a key role in the pathogenesis of inflammatory bowel disease (IBD). Whether vaccination is associated causally with IBD is controversial. We performed a meta-analysis of case–control and cohort studies on the association between vaccination and the risk for IBD.

METHODS: Studies and abstracts investigating the relationship between vaccination and subsequent risk for developing IBD were reviewed. Childhood or adult immunizations with any vaccine type, at any dose, and with any vaccine schedule were used as inclusion criteria.

RESULTS: Eleven studies were included in the systematic review and meta-analysis: 8 case–control studies and 3 cohort studies. Studied vaccines were bacille Calmette–Guérin), vaccines against diphtheria, tetanus, smallpox, poliomyelitis, pertussis, H1N1, measles, rubella, mumps, and the combined measles, mumps, and rubella vaccine. Only a few details about vaccine type or route of administration were found in studies. Overall, there was no association between childhood immunization and risk for developing IBD: bacille Calmette–Guérin, relative risk (RR) of 1.04 (95% confidence interval [CI], 0.78–1.38), diphtheria, RR of 1.24 (95% CI, 0.80–1.94), tetanus, RR of 1.27 (95% CI, 0.77–2.08), smallpox, RR of 1.08 (95% CI, 0.70–1.67), poliomyelitis, RR of 1.79 (95% CI, 0.88–3.66), an measles containing vaccines, RR of 1.33 (95% CI, 0.31–5.80) in cohort studies, and RR of 0.85 (95% CI, 0.60–1.20) in case–control studies. Subgroup analysis for Crohn's disease (CD) and ulcerative colitis (UC) found an association between the poliomyelitis vaccine and risk for developing CD (RR, 2.28; 95% CI, 1.12–4.63) or UC (RR, 3.48; 95% CI, 1.2–9.71). The RR of developing IBD after H1N1 vaccination was 1.13 (95% CI, 0.97–1.32).

CONCLUSIONS: Results of this meta-analysis show no evidence supporting an association between childhood immunization or H1N1 vaccination in adults and risk of developing IBD. The association between the poliomyelitis vaccine and the risk for CD or UC should be analyzed with caution because of study heterogeneity.



Pineton de Chambrun et al., Clin Gastroenterol Hepatol 2015
http://dx.doi.org/10.1016/j.cgh.2015.04.179

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Children's Health Defense

Vaccination in non-Persian Gulf War Veterans Increases Odds of Neurological and Pain Symptoms

American Journal of Epidemiology
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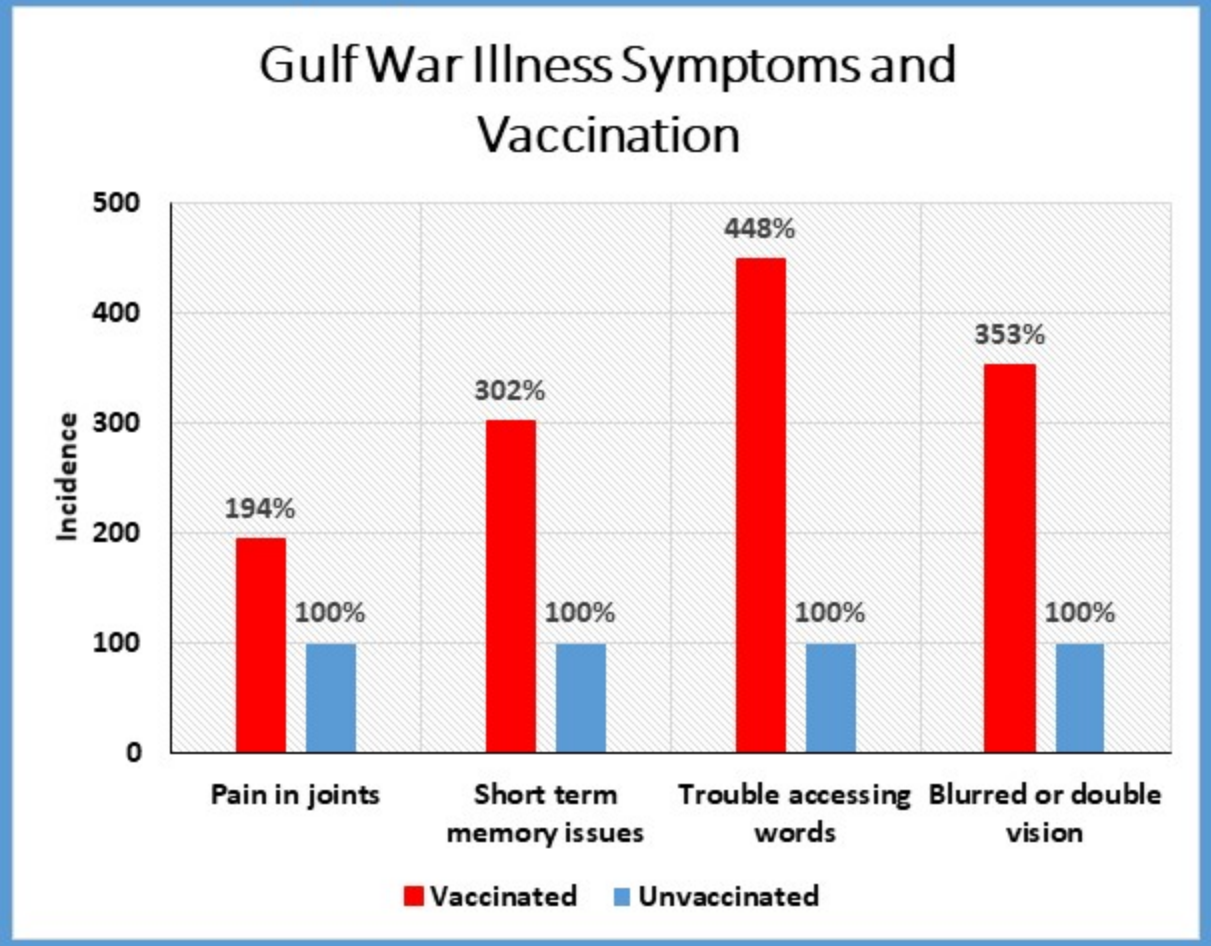
Vol. 152, No.
Printed in U.S.

Prevalence and Patterns of Gulf War Illness in Kansas Veterans: Association of Symptoms with Characteristics of Person, Place, and Time of Military Service

Lea Steele

Gulf War veterans have reported health problems that they attribute to their military service, but little is understood about the nature or extent of these conditions. To determine whether Kansas Gulf War veterans are affected by excess health problems, a population-based survey of 1,548 veterans who served in the Persian Gulf War (PGW) and 482 veterans who served elsewhere (non-PGW) was conducted in 1998. Gulf War illness, defined as having chronic symptoms in three of six domains, occurred in 34% of PGW veterans, 12% of non-PGW veterans who reported receiving vaccines during the war, and 4% of non-PGW veterans who did not receive vaccines. The prevalence of Gulf War illness was lowest among PGW veterans who served on board ship (21%) and highest among those who were in Iraq and/or Kuwait (42%). Among PGW veterans who served away from battlefield areas, Gulf War illness was least prevalent among those who departed the region prior to the war (9%) and most prevalent among those who departed in June or July of 1991 (41%). Observed patterns suggest that excess morbidity among Gulf War veterans is associated with characteristics of their wartime service, and that vaccines used during the war may be a contributing factor. *Am J Epidemiol* 2000;152:992–1002.

fatigue syndrome, chronic; Persian Gulf syndrome; risk factors; symptoms and general pathology; veterans



Steele, Am J Epidemiol 2000
https://pubmed.ncbi.nlm.nih.gov/11092441/

"Gulf War Illness, defined as having chronic symptoms in three of six domains, occurred in 34% of PGW veterans, 12% of non-PGW veterans who reported receiving vaccines during the war and 4% of non-PGW veterans who did not receive vaccines."

Children's Health Defense

Vaccination Increases Odds of Gulf War Illness 260%

Articles

Health of UK servicemen who served in Persian Gulf War

Catherine Unwin, Nick Blatchley, William Coker, Susan Ferry, Matthew Hotopf, Lisa Hull, Khalida Ismail, Ian Palmer, Anthony David, Simon Wessely

Summary

Background Various symptoms in military personnel in the Persian Gulf War 1990–91 have caused international speculation and concern. We investigated UK servicemen.

Methods We did a cross-sectional postal survey on a random sample of Gulf War veterans (Gulf War cohort, n=4248) and, stratified for age and rank, servicemen deployed to the Bosnia conflict (Bosnia cohort, n=4250) and those serving during the Gulf War but not deployed there (Era cohort, n=4246). We asked about deployment, exposures, symptoms, and illnesses. We analysed men only. Our outcome measures were physical health, functional capacity (SF-36), the general health questionnaire, the Centers for Disease Control and Prevention (CDC) multisymptom criteria for Gulf War illness, and post-traumatic stress reactions.

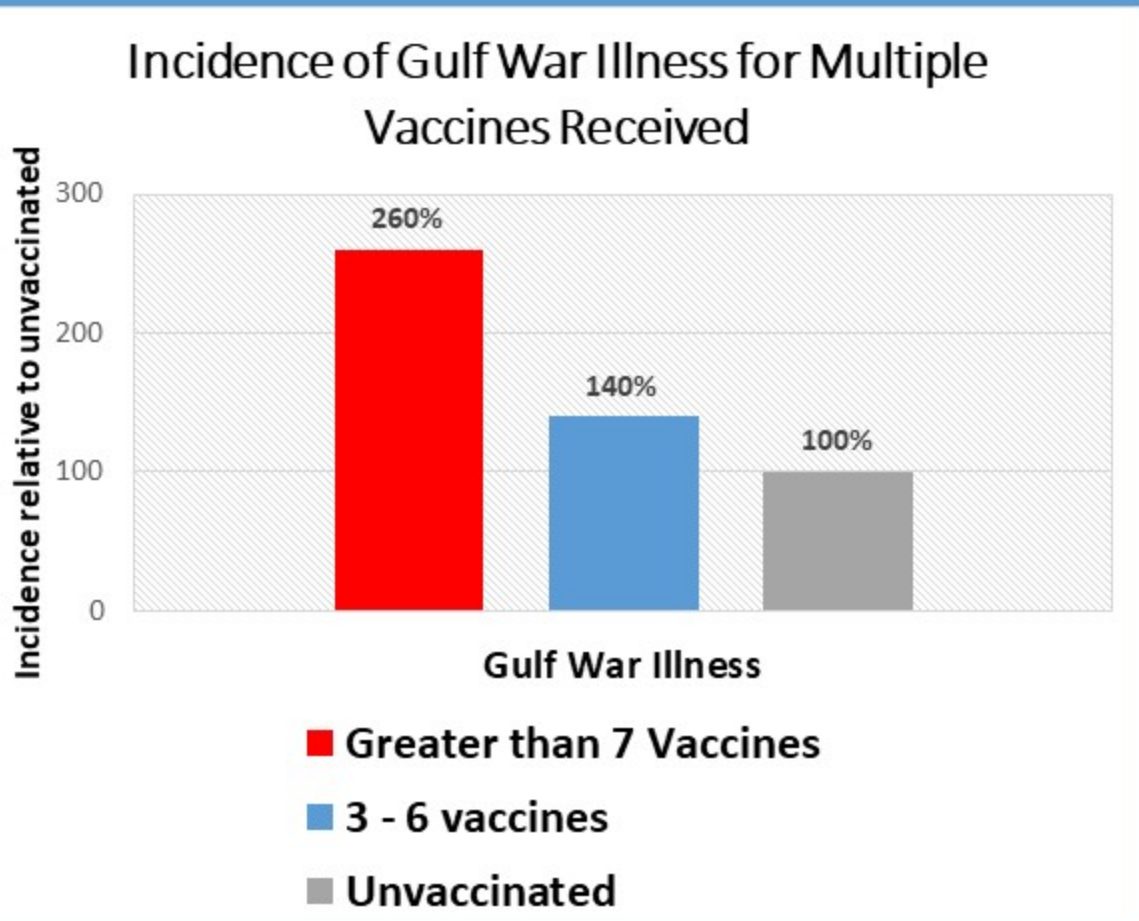
Findings There were 8195 (65·1%) valid responses. The Gulf War cohort reported symptoms and disorders significantly more frequently than those in the Bosnia and Era cohorts, which were similar. Perception of physical health and ability were significantly worse in the Gulf War cohort than in the other cohorts, even after adjustment for confounders. Gulf War veterans were more likely than the Bosnia cohort to have substantial fatigue (odds ratio 2·2 [95% CI 1·9–2·6]), were found in all cohorts, however, they may not be unique and causally implicated in Gulf-War-related illness. A specific mechanism may link vaccination against biological warfare agents and later ill health, but the risks of illness must be considered against the necessity of protection of servicemen.

Lancet 1999; **353:** 169–78

Introduction

From late 1990, the UK deployed 53 462 military personnel to the Persian Gulf War. In the months after the end of the war, anecdotal reports emerged in the USA of various disorders affecting Gulf War veterans. In the UK, similar observations surfaced in 1993, after a television broadcast in June. Some UK Gulf War veterans have experienced health problems since their return. Such anecdotal reports cannot, however, establish whether these complaints have any particular pattern, nor whether they are related to Gulf War service.

Previous studies of the health of Gulf War veterans have had limitations. Comparisons with non-military populations may be misleading, since military recruitment involves medical screening. Clinical assessment programmes for non-randomly selected veterans with symptoms cannot provide epidemiological information or



Unwin et al., The Lancet 1999
https://pubmed.ncbi.nlm.nih.gov/9923871/

"Vaccination against biological warfare and multiple routine vaccinations were associated with CDC multisymptom syndrome in the Gulf War cohort."

Children's Health Defense

Multiple Vaccination During Deployment Increases Odds of Gulf War Illness 500% and Fatigue 340%

Role of vaccinations as risk factors for ill health in veterans of the Gulf war: cross sectional study

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Abstract

Objectives To explore the relation between ill health after the Gulf war and vaccines received before or during the conflict. To test the hypothesis that such ill health is limited to military personnel who received multiple vaccines during deployment and that pesticide use modifies any effect.

Design Cross sectional study of Gulf war veterans followed for six to eight years after deployment.

Setting UK armed forces.

Participants Military personnel who served in the Gulf and who still had their vaccine records.

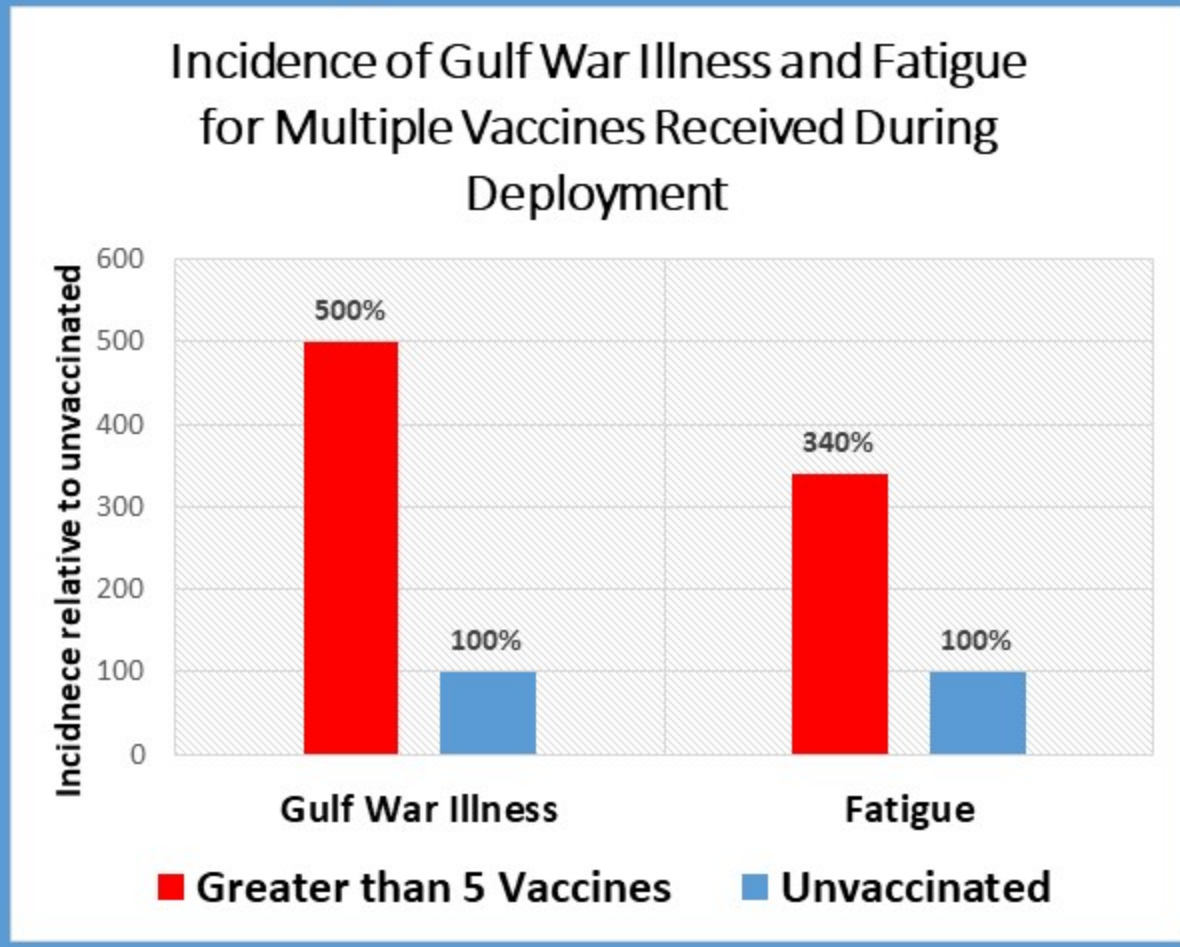
Main outcome measures Multisymptom illness as classified by the Centers for Disease Control and Prevention; fatigue; psychological distress; post-traumatic stress reaction; health perception; and physical functioning.

Results The response rate for the original survey was 70.4% (n = 3284). Of these, 28% (923) had vaccine records. Receipt of multiple vaccines before deployment was associated with only one of the six health outcomes (post-traumatic stress reaction). By contrast five of the six outcomes (all but post-traumatic stress reaction) were associated with multiple vaccines received during deployment. The strongest association was for the multisymptom illness

increase the likelihood that they suffered long term health consequences. The first was that for UK (but not US) service personnel pertussis was used as an adjuvant to stimulate the immune response to anthrax vaccine. The second was that multiple vaccines were given simultaneously. This reflected the need to keep the personnel up to date with routine vaccines; to protect them from infectious diseases such as cholera and typhoid, which were potential health hazards during deployment; and to protect them from the threat of biological warfare agents—namely, plague and anthrax. The third aspect was that many of the vaccines were given after the personnel were deployed. Rook and Zumla suggested that deployment was a stress which would in itself lead to increased circulating corticosteroids, and this too would influence cytokine profiles.[1] Finally, they speculated that there might have been an interaction between the vaccine regimen and pesticides—especially organophosphate pesticides—used in the Gulf to cause a Th2 promoting effect.

We have previously reported on a large (n = 3284) cohort study of male Gulf war veterans who were compared with non-deployed service personnel and veterans of peacekeeping duties in Bosnia.[2] We found increased rates of ill health for all health outcomes in those who served in the Gulf. Among many other

Hotopf et al., BMJ 2000
https://pubmed.ncbi.nlm.nih.gov/10818024/



"Among veterans of the Gulf war there is a specific relation between multiple vaccinations given during deployment and later ill health."

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