Generation 1: CDC’s Unpublished Verstraeten Study on Hep B Showed Dramatic Increased Risk of Autism (7.6X), Sleep Disorders (5X), Speech Disorders (2.1X) and Neurodevelopmental Disorders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, 770-636-8327.
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 vaccines 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 pertussis and tetanus diphtheria vaccines. Data was collected from the Vaccine Safety Datalink (VSD) of children reaching 18 months of age, with thimerosal exposure in the first month of life. The relative risk for developing a neurologic development disorder was 1.8 (95% confidence interval [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group.

Methods: The cumulative ethylmercury exposure from thimerosal-containing vaccines after one month of life was assessed. The prevalence of neurologic disorders was lower in the thimerosal exposure group than 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).

CDC UNPUBLISHED DATA OBTAINED BY FOIA

“The relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] = 1.1-2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 ug) to the unexposed group. Within this group we also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI=1.8-31.5), nonorganic sleep disorder (RR 5.0, 95% CI=1.6-15.9), and speech disorders (RR 2.1, 95% CI=1.1-4.0).”
DTP and Tetanus Vaccinations Increase the Odds of Allergies (1.63X) in Children

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

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 SUSSAN version 5.0.1. 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.

Proportion Receiving Special Education Services

“The odds of receiving EIS were approximately nine times as great for vaccinated boys (n=46) as for unvaccinated boys (n=7) after adjustment for confounders.”
Hepatitis B Vaccines in Male Newborns Increased the Odds of Autism 3X

Published Nov 2010

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

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

"TIV recipients had higher risk of confirmed non-influenza respiratory virus infection."
DTP Increases Mortality in Girls 10X

Relative Risk for Mortality of Vaccinated vs. Unvaccinated, DTP Vaccine

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“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.”
Vaccination of Preemies Increased Odds of Neurodevelopmental Disorders 6.6X

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

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 preterm infants is obscure, in part because pre-term clinical trials of vaccines have excluded or preterm infants. This paper explores the association between preterm birth, vaccination and NDD, based on a secondary analysis of data from an anonymous registry of children born between 1999 and 2009. The study included 3,990 children, of which 284 (7.1%) were vaccinated. The prevalence of NDD was significantly higher in vaccinated children (OR 2.5, 95% CI 1.3-4.8). The results of this study suggest that vaccination coupled with preterm birth may increase the risk of NDD. Further research is needed to understand the potential role of vaccination in the development of NDD.

“Vaccination (i.e., receipt of one of more of the recommended vaccines) was significantly associated with NDD, while preterm birth without vaccination was not. Preterm birth coupled with vaccination, however, was associated with a synergistic increase in the odds of NDD, suggesting the possibility that vaccination could precipitate adverse neurodevelopmental outcomes in preterm infants. These results provide clues to the epidemiology and causation of NDD but question the safety of current vaccination programs for preterm infants.”
Vaccination Increases Risk of Allergic Rhinitis (30X), Allergy (3.1X), ADHD (4.2X), Autism (4.2X), Eczema (2.9X), Learning Disability (5.2X) and Neurodevelopmental Disorders (3.7X)

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

Anthony R. Massaro, Brian D. Ray, Azar R. Bhatia and Ben Jacob

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 encouraged by the U.S. Institute of Medicine to address this question. To study this, an anonymous online questionnaire was sent to 12- to 16-year-old children to compare vaccinated and unvaccinated children on a range of health outcomes, and to determine whether an association found between vaccination and neurodevelopmental disorders (NDD) is significant for better outcomes. A cross-sectional study of children aged 6 to 12 years old was conducted in collaboration with a large school in the U.S. state of Florida, with additional schools in Louisiana, Mississippi, and Oregon. Mothers were asked to complete an anonymous online questionnaire twice a year from 2010 to 2015, excluding children with reported NDD. Children were categorized as vaccinated or unvaccinated, based on their vaccination status. Vaccinated children were less likely than unvaccinated children to have been diagnosed with asthma, allergies, ADHD, autism, eczema, and NDD. After adjusting for age, gender, and parents' birth control method, vaccination was significantly associated with NDD, but not with birth weight or gestational period. Vaccinated children were more likely to have been diagnosed with autism, ADHD, and eczema. However, a final adjusted model with interaction terms did not show a significant association between vaccination and NDD. The interaction term between maternal birth control method and vaccination status was not significant. Further research is needed to clarify these findings and to investigate the impact of vaccination on the health of vaccinated and unvaccinated children.

In this pilot study of vaccinated and unvaccinated homeschool children, reduced odds of chickenpox and whooping cough were found among the vaccinated, as expected, but unexpectedly increased odds were found for many other physician-diagnosed conditions.
Vaccination Increases Type I Diabetes 3X

**Abstract**

**OBJECTIVE:** We previously analyzed data from a hemophilus vaccine trial and identified clusters of cases of type 1 diabetes mellitus (T1DM) leading by the vaccine that occurred between 30 and 40 months after immunization. Published reports indicate clustering of cases of T1DM occurring approximately 2-4 years after mumps infection. Citizens 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 T1DM was being increased.

**RESULTS:** Distinct peaks 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 2-4 years following discontinuation of pertussis and BCG vaccines.

**CONCLUSION:** The identification of clusters of cases of T1DM 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.

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

<table>
<thead>
<tr>
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<th>After Expansion</th>
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<td>41/100,000</td>
<td>14/100,000</td>
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<tr>
<td>U.K.</td>
<td>19/100,000</td>
<td>12/100,000</td>
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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.”
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 (1.00<RR<1.48) and an absolute risk in the general population of three cases/100,000 per year compared to 1.58 (1.06<RR<2.15) 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 2.21/100 (2.2%) in the subgroup.

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

Type 1 Diabetes Incidence per 100,000 Children Vaccinated or Unvaccinated with All 3 Recommended Polio Vaccines

"Pediatric vaccines were associated with a statistically significant increased risk of type 1 diabetes in 12 of 21 endpoints in the general population."
Raw CDC Data Shows Vaccination on Time with MMR Increased Odds of Autism 3.64X

**Format: Abstract**
Pediatrics, 2014 Feb;133(2):359-66

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., Braun B.K., Thompson W.W., Yarmysh M., Alter M., Boyle J.

**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 controls (N = 1824) on age, gender, and school. Vaccination data were abstracted from immunization forms requested 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 cases (70.5%) and controls (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 cases (93.6%) than control children (90.8%) were vaccinated before 36 months (OR = 1.49; 95% confidence interval: 1.61-2.97 in the total sample; OR = 1.73; 95% confidence interval: 1.64-2.56 in the birth certificate sample). This association was strongest in the 3- to 6-year age group.

**Conclusion:** Similar proportions of case and control children were vaccinated by the recommended age. Children who received the MMR vaccine before age 18 months were at increased risk for autism. Young children who received the MMR vaccine before age 15 months were at increased risk for autism.

**CDC Unpublished Data Obtained by FOIA**

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.
**Abstract**

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 (4.35%, Hg by weight) in childhood vaccines by conducting a two-phase 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, and 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 1). 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 1996 in the Vaccine Safety Datalink (VSD) database (phase 2).

**RESULTS:** In phase 1, 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 2, 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 increased organic-Hg exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an ASD diagnosis.

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“**It was observed that cases diagnosed with an ASD were significantly more likely than controls to receive increased organic-Hg from Thimerosal-containing hepatitis B vaccine administered within the first, second, and sixth month of life.”**
Human Papilloma Virus Vaccine Increases the Odds of Asthma 8.01X

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

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 53,024,237 weighted persons between 9 and 25 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 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.”
Thimerosal-Containing Hepatitis B Series Increases Odds of Premature Puberty 2.1X

Abstract
Studies suggest a relationship between exposure to endocrine disruptors, such as mercury (Hg), and premature puberty. Hg exposure from Thimerosal-containing hepatitis B vaccine, administered at specific intervals within the first six months of life, and the child’s long-term risk of being diagnosed with premature puberty (ICD-9 code: 259.1), was retrospectively examined using a hypothesis-testing longitudinal case-control design on prospectively collected data in the Vaccine Safety Datalink (VSD). Cases diagnosed with premature puberty were significantly more likely to have received increased exposure to Hg from hepatitis B vaccines preserved with Thimerosal given in the first month after birth (odds ratio (OR) = 1.600), first two months after birth (OR = 1.768), and first six months after birth (OR = 2.000), 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 = 1.6281 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.

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

<table>
<thead>
<tr>
<th>Vaccinated, 2.1X</th>
<th>Unvaccinated, 1X</th>
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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

Is measles vaccination a risk factor for inflammatory bowel disease?

Thompson HP, Montgomery TH, Feurer RC, Wene JC

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 etiology. 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 11,437 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 (1.16-5.68). 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.”
Thimerosal Containing Hepatitis B Vaccines – When Compared to Children Vaccinated Without Thimerosal - Increased Odds of ADHD 1.98X

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

Abstract
Attention-deficit/hyperactivity disorder (ADHD) is characterized by a marked pattern of inattention and 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 2,393 persons between 13 and 19 years of age from the combined 1996-2003 National Health and Nutrition 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 = 1.98). A linear regression (adjusted beta-coefficient = 0.047) of the data from the study suggests that the increase in ADHD risk is not linear but rather quadratic. Current health status outcomes were selected as a priori based on previous studies showing associations with ADHD.

“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

“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

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

“SAB (spontaneous abortion) was associated with influenza vaccination in the preceding 28 days. The association was significant only among women vaccinated in the previous influenza season with pH1N1-containing vaccine.”
H1N1 Influenza Vaccine Increases Risks of Bell’s Palsy (1.34X), Paraesthesia (1.25X) and Inflammatory Bowel Disease (1.25X) in High Risk Patients

“Relative risks were significantly increased for Bell’s palsy, paraesthesia, and inflammatory bowel disease after vaccination, predominantly in the early phase of the vaccination campaign.”
HPV Vaccination Increases Odds of Memory Impairment (1.23X) and Involuntary Movement (1.53X)

“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

“The results show a significant relationship between mercury exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an emotional disturbances diagnosis.”
HPV Vaccine Increases the Risk of Celiac Disease by 1.56X

“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

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?

Abstract

The aim of this study was to compare the number of macerated 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 analyses estimated the reporting completeness in the 2009/2010 flu season. Capture-recapture demonstrated that the VAERS database captured about 13.2% of the total TGD1 (95% confidence interval (CI): 8.1-27.9%) estimated reports, yielding an ascertainment-corrected rate of 290 fetal-loss reports per million pregnant women vaccinated (or 1 per 1665). The unadjusted fetal-loss report rates for the three consecutive influenza seasons beginning 2008/2009 were 6.8 (95% CI: 0.1-13.7), 77.6 (95% CI: 66.3-89.4), and 12.6 (95% CI: 7.2-18.6) 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.

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

Fetal Loss Rate

- H1N1 and Seasonal Flu
- Seasonal Flu Only

“Because of the order of magnitude increase in fetal-loss report rates, from 6.8 fetal-loss reports per million pregnant women vaccinated in the single-dose 2008/2009 season to 77.8 in the two-dose 2009/2010 season, further long-term studies are needed to assess adverse outcomes in the surviving children.”
H1N1 Influenza Vaccine (Pandemrix) Increases Rate of Narcolepsy in Swedish Children by 25X

“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.”
"Among women who received Tdap at anytime during pregnancy, 6.1% were diagnosed with chorioamnionitis compared with 5.5% of unexposed women. After adjusting for site, receipt of 1 or more other vaccines in pregnancy and the propensity score, the adjusted relative risk (RR) was 1.19 (95% CI, 1.13–1.26)."
First Dose of Rotavirus Vaccine (Rotarix) Increases Intussusception Odds by 5.8X

An increased risk of intussusception 1 to 7 days after the first dose of RV1 was identified among infants in Mexico with the use of both the case-series method (incidence ratio, 5.3; 95% confidence interval [CI], 3.0 to 9.3) and the case-control method (odds ratio, 5.8; 95% CI, 2.6 to 13.0).
Measles Vaccination Versus Measles Infection Increases the Odds of Atopy (Allergy) by 2.8X

“17 (12.8%) of 133 participants who had had measles infection were atopic compared with 33 (25.6%) of 129 of those who had been vaccinated and not had measles”
Higher Exposure to Thimerosal from Infant Vaccines Increases the Odds of Motor Tics (2.19X) and Phonic Tics (2.44X) in Boys

"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.”
“Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months. The likelihood of asthma in children with delays in all 3 doses was 0.39 (95% CI, 0.18-0.86).”
Exposure to Higher Levels of Thimerosal in Infant Vaccines Before 13 Months of Age Increases the Rate of Premature Puberty by 6.45X

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 Illness, Inc., Silver Spring, MD; *ChefeVo, Inc., Silver Spring, MD; *The George Washington University School of Public Health & Health Services, Department of Epidemiology & Biostatistics, Washington, DC; *ASID Centers, LLC, USA

Received December 12, 2008

Background & objectives: The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) reports that mercury (Hg) is a known endocrine disruptor and it adversely affects the sexual development pathway in animals and humans, and may interact to enhance the risk for a child developing premature puberty. An association between perinatal 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 7,460+1,000 subjects were identified in birth cohorts from 1999-2006. The birth cohort prevalence rates of medically diagnosed International Classification of Diseases, 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.

Implication & 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.

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