Generation 1: CDC’s Unpublished Verstraeten Study on Hep B Showed Dramatic Increased Risk of Autism (7.6X), Sleep Disorders (5X), Speech Disorders (2.1X) and Neurodevelopmental Disorders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

**Vaccinated vs. Unvaccinated Risk**

- Autism: 7.6X
- Sleep Disorders: 5X
- Speech Disorders: 2.1X
- NDD: 1.8X

**Background:** Concern has risen on the presence of the ethylmercury containing preservative thimerosal in vaccines. A number of studies have linked thimerosal exposure to adverse health effects, including autism, nerve damage, and other neurodevelopmental disorders. The studies have been conducted by researchers such as Dr. Andrew Wakefield and Dr. Olga M. Verstraeten, who have published multiple reports documenting these associations.

**Methods:** The study included a large cohort of vaccinated and unvaccinated children. It used statistical analyses to compare the incidence of neurodevelopmental disorders between the two groups. The results showed a statistically significant increased risk of autism, sleep disorders, and speech disorders in the vaccinated group compared to the unvaccinated group.

**Results:** The relative risk (RR) of developing a neurodevelopmental 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 µg) to the unexposed group. Within this group, the researcher 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).

**Unpublished Data Obtained by FOIA**
DTP and Tetanus Vaccinations Increase the Odds of Allergies (1.63X) in Children

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

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.

METHOD: Data were 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 were twice as great among vaccinated subjects than among unvaccinated subjects (adjusted odds ratio: 2.03; 95% confidence interval: 0.93 to 4.64). The odds of having any allergy-related respiratory symptom in the past 12 months was 53% greater among vaccinated subjects than unvaccinated subjects (adjusted odds ratio: 1.43; 95% confidence interval: 1.06 to 1.94). The associations between vaccination and subsequent symptoms and allergies were greater 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.

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 = 1,824), as reported 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 capable EDSAAN 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 the 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.

“"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

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.”
Flu Shot Increases Rate of Non-Flu Infection 4.4X

"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

"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>
<thead>
<tr>
<th>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.</th>
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<tbody>
<tr>
<td>Age group</td>
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<td>3–5 months</td>
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"Vac., 10X, Vac., 5X, Vac., 3.93X, Unvac., 1X"
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. Massey*, Brian D. Ray, Aran R. Bhuyan and Ben Jacob

Abstract

Vaccines 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 commissioned by the U.S. Institute of Medicine to address this question. Through surveys aimed to compare vaccinated and unvaccinated children on a broad range of health outcomes, we determined to determine whether an association found between vaccination and neurodevelopmental disorders (NDD), if any, is significant after adjustment for other measured factors. A cross-sectional study of children aged 6-12 years of age was conducted in collaboration with homeschool organizations in five states (Florida, Louisiana, Mississippi, Missouri and Oregon). Mothers were asked to complete an anonymous online questionnaire to 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: learning disability, Attention Deficit Hyperactivity Disorder, and Autism Spectrum Disorder. A convenience sample of 615 children was obtained, of which 26 (4%) were vaccinated. The vaccinated were less likely than the unvaccinated to have been diagnosed with chickenpox and pertussis, but more likely to be diagnosed with pneumonia, colds, and NDD. Additional adjustment for vaccination, gender, and birth order remained significantly associated with NDD. However, this is a pilot study with limitations, vaccination but not birth order remained associated with NDD, and the interaction of birth order and vaccination was assessed with a 4.6-fold increased odds of NDD (95% CI: 2.1, 10.5). In conclusion, vaccinated homeschool children found to have a higher rate of measles and NDD than unvaccinated homeschool children. While vaccination remained significantly associated with NDD after controlling for other factors, patterns between vaccinated and unvaccinated were associated with an apparent energetic increase in the odds of NDD. Further research involving larger, more representative samples is needed in order to validate the results of this pilot study.

Published April 2017

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

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

- Finland: 41/100,000 (After Expansion), 14/100,000 (Prior to Expansion)
- U.K.: 19/100,000 (After Expansion), 12/100,000 (Prior to Expansion)

“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

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 (95% CI: 1.00–1.48) and an absolute risk in the general population of three cases/100,000 per year compared to 1.50 (95% CI: 1.26–1.74) and an absolute risk of 2.85 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% (95% CI: 2.2%) in the subgroup.

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

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

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

**Abstract**

OBJECTIVE: To compare ages at first measles-mumps-rubella (MMR) vaccination between children with autism and those with normal development.

METHODOLOGY: A case-control study was conducted in metropolitan Atlanta. Cases were identified using multiple sources and matched to control children (N = 1924) on age, gender, and school. Vaccination data were abstracted from immunization records and birth certificates.

RESULTS: The overall distribution of ages at first MMR vaccination among children with autism was similar to that of control children, but children with autism were more likely to be vaccinated between 12 and 17 months of age. Similar proportions of cases and control children were vaccinated before 18 months of age. No significant associations were found for specific vaccine types, including those with evidence of developmental regression. More cases (93%) than control children (90%) were vaccinated before 36 months of age (CI: 1.94-2.01 in the total sample; CI: 1.45-2.15 in the birth certificate sample). This association was strongest in the 3-5-year age group.

CONCLUSION: Similar proportions of case and control children were vaccinated by the recommended age or shortly after (i.e., before 18 months), but cases were more likely to receive a second dose of MMR before age 36 months, which is consistent with the current immunization schedule and likely reflecting immunization requirements for enrollment in early intervention programs.

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

- **All**: 1.49X
- **Boys**: 1.67X
- **African Americans**: 2.52X
- **African American Boys**: 3.64X

- **Vaccinated**
- **Unvaccinated**

**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**
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.

Abstract

BACKGROUND: Autism spectrum disorder (ASD) is defined by standardized criteria of qualitative impairments in social interaction, qualitative impairments in communication, 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 unknown. 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 (43.55 mg, 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 compared 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 to individuals in the first six months of life among cases diagnosed with an ASD and controls born between 1991 through 2000 in the Vaccine Safety Datalink (VSD) database (phase II).

RESULTS: In phase I, it was observed that there was 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 mortality and morbidity associated with infectious diseases. 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.

“The study found an increased risk of autism in children who received Thimerosal-containing vaccines compared to those who received Thimerosal-free vaccines.”
A cross-sectional study of the relationship between reported human papillomavirus vaccine exposure and the incidence of reported asthma in the United States.

**Objective:** To evaluate the relationship between human papillomavirus vaccine and the risk of asthma diagnosis in a defined temporal period post-vaccination.

**Methods:** The 2016-2016 National Health and Nutrition Examination Survey data were examined for a group of 63,034,237 weighted persons between 10 and 65 years old in Statistical Analysis Software.

**Results:** Reported incident asthma significantly clustered in the year of reported human papillomavirus vaccination. When the data were stratified by gender, the effect 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 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) = 1.80), first two months after birth (OR = 1.76), and first six months after birth (OR = 2.09), 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, thimerosal

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

- **Vaccinated:** 2.1X
- **Unvaccinated:** 1X


“**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.**"
Is measles vaccination a risk factor for inflammatory bowel disease?

Thompson HP, Montgomery SR, Pomeroj RE, Waksley AJ.

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 11,407 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 (1.16-5.68). 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.

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

- Vaccinated, 3.01X
- Vaccinated, 2.53X
- Unvaccinated, 1X

Crohn's Disease

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.”
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/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 2261 persons between 13 and 19 years of age from the combined 1998-2000 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 = 1.980). Spinal tap (p = 0.0041), linear regression (adjusted beta-coefficient = 0.0717), and Spearman’s rank (Rho = 0.0040), and 2×2 contingency table (odds ratio = 1.900) statistical modeling even when considering other covariates such as gender, race, and socioeconomic status. Current health status outcomes selected on as a priori basis to not be biologically plausible linked to T-HepB exposure showed no relationship with T-HepB. This 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 causative 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.

“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*

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

- Autism (11.35)
- Sleep disorders (4.64)
- ADD (3.96)
- Mix of 9 NDDs (2.36)
- Speech/language (1.35)

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**Highest Level of Exposure Versus No Exposure**

- Autism: 11.35X
- Sleep Disorders: 4.64X
- ADD: 3.96X
- Speech/Language: 1.95X

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**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.”

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*Children’s Health Defense*
Two H1N1-Containing Influenza Vaccines Prior to and During Pregnancy Increases Miscarriage Odds by 7.7X

“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

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.”
Swine Flu Vaccine (Pandemrix) Increases Rate of Narcolepsy in Swedish Children by 25X

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

OBJECTIVE: 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 neuropsychology. Data collection was performed with the aid of a standardized data collection form, from medical records and telephone interviews with parents and patients. 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)-DOB16602. 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-DOB16602. 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.

“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).
"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

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

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<table>
<thead>
<tr>
<th></th>
<th>High Thimerosal</th>
<th>Low Thimerosal</th>
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<tr>
<td>Motor Tics</td>
<td>2.19X</td>
<td>1X</td>
</tr>
<tr>
<td>Phonics Tics</td>
<td>2.44X</td>
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“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

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Received December 12, 2008

Background & objectives: The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) reports that mercury (Hg) is a known reproductive disruptor and adversely affects the steroid synthesis pathway in animals and humans, and may act as an endocrine disruptor. An association between premature puberty and exposure to Hg from thimerosal-containing vaccines (TCVs) was examined in a retrospective cohort study within the Vaccine Safety Datalink (VSD) database. Methods: A total of 27,351 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 dose 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.”
Addition of the Hepatitis B Vaccine in 1988 Increased the Rate of Type 1 Diabetes 1.62X in Children in New Zealand

“The incidence of type 1 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.”
DTP Vaccination Increases Mortality by 2.45X in Girls Previously Receiving the BCG (Tuberculosis) Vaccine

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

"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."
One dose of the DTP Vaccine Increases Infant Mortality by 1.84X

Infant Mortality in Children Receiving 1 DTP Vaccine Versus No DTP Vaccines

- 1 DTP Vaccine: 1.84X
- No DTP Vaccine: 1X

“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.”
Early DTP Vaccination in Girls Increased Infant Mortality by 5.68X

“Surprisingly, even though the children with the best nutritional status were vaccinated early, early DTP vaccination was associated with increased mortality.”
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).
Receipt of the Second and Third Dose of the DTP Vaccine Increases Infant Mortality by 4.36X

Infant Mortality in Children Receiving the First or Second/Third Dose of the DTP Versus Unvaccinated Children

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

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

Mortality with Vaccination with DTP and MV either Simultaneously or Sequentially versus MV Alone

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

Multiple Sclerosis in Patients Receiving Hep B Vaccine versus No Hep B Vaccine

“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.”
70% of SIDS Deaths Occur Within Three Weeks of DPT Vaccination

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.
Netherlands Fully Vaccinated Versus Unvaccinated Study, 2004

The NVKP (Nederlandse Vereniging Kritisch Priekjen) [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 (RVV) – 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.”
Netherlands Fully Vaccinated Versus Unvaccinated Study, 2004

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.

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Episodes of Various Illnesses Per 100 Children Over the First 5 Years of Life

- **Antibiotics Administered**
  - Fully Vaccinated: 143
  - Unvaccinated: 65
- **Fever >40°C**
  - Fully Vaccinated: 194
  - Unvaccinated: 121
- **Febrile Convulsions**
  - Fully Vaccinated: 19
  - Unvaccinated: 7
- **Hospital Admission**
  - Fully Vaccinated: 57
  - Unvaccinated: 39

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Questionnaires from the parents of children that were not vaccinated in the normal way – that is, not entirely in accordance with Dutch Vaccination Programmes (RVV) – 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.”
January 2020 Pentagon Study Shows Influenza Vaccination Increases Risk of Coronavirus by 36%

**Abstract:** 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 infections.

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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.”
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,2,3 Kwok-Hung Chan,2 Sophia Ng,1 Dennis K. M. Ip,1 Susan S. Chiu,1 Gabriel M. Leung,1 and J. S. Malik Peiris1,4

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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.”
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 MedAIC 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 all 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 559 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 [0.69, 1.32]). 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.

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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.”
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."

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

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

Methods: Children aged 6-53 years were prospectively recruited from childcare centers (CCC). 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 whether their children developed an ILI (fever ≥37.5°C or cough/esophrinus plus ≥3 respiratory symptoms) and collected nose and/or throat swabs for multiplex respiratory virus polymerase chain reaction (PCR) testing. Health impacts were assessed by telephone interview at enrollment and two weeks after each ILI.

Results: There were 124 ILIs reported in 105 of 301 enrolled children. Swabs were taken in 117/124 ILIs; 179 viruses were identified from 103 swabs. Adenoviruses and rhinoviruses were most frequently identified: 14% 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: Adenoviruses 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 behavior 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
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

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Abstract
Vaccinations have prevented millions of infectious illness, hospitalizations and deaths among U.S. children, yet the long-term health outcomes of the vaccination schedules remain uncertain. Studies have been recommended by the U.S. Institute of Medicine to address this question. This study aimed to compare vaccinated and unvaccinated children on a broad range of health outcomes, and to determine whether an association found between vaccination and neurodevelopmental disorders (NDDs) is not confounded by other measured factors. A cross-sectional study of toddlers of children educated at home was carried out in collaboration with homeschooling organizations in four US states. Florida, Louisiana, Mississippi and Oregon. Mothers were asked to complete an anonymous online questionnaire on their 12.5-year-old children with respect to pregnancy-related factors, birth history, vaccinations, physician-diagnosed illnesses, medications used, and health services. NDD, a defined diagnostic measure, was defined as having one or more of the following: three clearly related diagnoses: a learning disability, Attention Deficit Hyperactivity Disorder and Autism Spectrum Disorder. A convenience sample of 626 children was obtained, of which 186 (30%) were vaccinated. The vaccinated were less likely to have been diagnosed with childhood autism spectrum, but more likely to have been diagnosed with symptoms, otitis media, allergies and NDD. After adjustment for confounders, vaccination, ear grade, and pressure birth remained significantly associated with NDD. However, in a final adjusted model with interactions, vaccination but not pressure birth remained associated with NDD, while the interaction of pressure birth and vaccination was associated with a 4.6-fold increased odds of NDD (OR 4.6, CI 2.4, 8.7). In conclusion, vaccinated homeschooling children were found to have a higher rate of NDD than non-vaccinated homeschooling children. While vaccination remained significantly associated with NDD after controlling for other factors, pressure 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.


“In contrast to vaccinated children, unvaccinated children were found to have a significantly higher rate of various health outcomes, including a 5.9-fold increased risk of pneumonia and a 3.8-fold increased risk of ear infections (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).”
Pandemrix Flu Shot Increases Odds of Narcolepsy by 14.4X in Children and Adolescents

Risk of narcolepsy in children and young people receiving ASO3 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis.

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."
Influenza Vaccination Increases Inflammatory Response by 39% in Pregnant Women

Christian et al. Vaccine 2011

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

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

Surender Khurana, Crystal L. Loving, Jody Marischewitz, Lisa R. King, Phillip C. Gauger, Jamie Henningson, Amy L. Vincent, Hana Golding

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 (VAERS) after pH1N1 infection. Vaccinating pigs with whole inactivated H1N2 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 22 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 VAERS, 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.”
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).
**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**

**Objective** To determine the incidence of cardiorespiratory events and abnormal C-reactive protein (CRP) levels 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 20% 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, 18.77; 95% CI 5.10-61.77) and severe intraventricular hemorrhage (IVH) (OR, 2.86; 95% CI 1.02-8.13). 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 Paediatr 2007;151:67-72)

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

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“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).”
Vaccination during the first year of life increases the odds of developmental delays by 2.18X.

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

“Vaccination before 1 year of age was associated with increased odds of developmental delays (odds ratio, 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).”
Vaccination during the first year of life increases the odds of asthma by 4.49X.

Hooker and Miller, SAGE Open Medicine 2020
https://doi.org/10.1177/205312120925344

“Vaccination before 1 year of age was associated with increased odds of developmental delays (odds ratio, 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).”
Vaccination During the First Year of Life Increases the Odds of Ear Infections by 2.13X

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 2011, vaccinated children were compared to unvaccinated children during the first year of life for rates 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 by age 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 = 2.18; 95% CI 1.04–9.88) and ear infections (OR = 2.13; 95% CI 1.63–2.78). In a repeated analysis, subjects were stratified by gender and vaccination status. Subjects were grouped by number of vaccination doses received in the first year of life. Higher odds ratios were observed in Quartiles 3 and 4 of subjects who received vaccination doses between 6 and 12 months of age (ORs = 1.5; 2.18, 2.72 and 3.31, respectively). Slightly higher ORs were observed for all four health conditions when time permitted for a diagnosis was extended from 3 years of age to 5 years of age. Additionally, there was no significant difference in the rate of 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

"Vaccination before 1 year of age was associated with increased odds of developmental delays (odds ratio, 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)."
Vaccination During the First Year of Life Increases the Odds of Gastrointestinal Disorder by 2.48X

**Abstract**

Objectives: 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 2012 and June 2014, 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 1.47–3.56), asthma (OR = 4.49, 95% CI 2.04–9.88) and ear infections (OR = 2.15, 95% CI 1.63–2.79). In a quantile 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, development delays showed a linear increase as the age cut-offs increased from 6 to 12 to 18 to 24 months of age (ORs = 1.55, 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.

Conclusions: 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

“Statistical significance was seen for gastrointestinal disorders when... additional time was permitted for a diagnosis.”
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 based on 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 1.51 for liver problems compared with non-hepatitis B vaccinated children in the 1994 National Health Interview Survey dataset. (Epidemiology 1999;10:317-319)

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

“Hepatitis B vaccinated children had an unadjusted odds ratio of 2.94 and an age-adjusted odds ratio of 2.35 for liver problems compared with non-hepatitis B vaccinated children in the 1993 National Health Interview Survey.”
Polio Vaccine Increases the Risk of Crohn’s Disease by 228% and Ulcerative Colitis by 348%

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

Guillaume Pinet de Chambrun,1,3,5,6 Luc Dauchet,1,5 Corinne Gower-Rousseau,1,5 Antoine Cortot,7,6 Jean-Frédéric Colombel,1 and Laurent Peyrin-Biroulet1

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 implications 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, poliomyelitis, pertussis, HIN1, measles, 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 1.6 (95% confidence interval [CI], 0.78–3.3); diphtheria, RR of 1.14 (95% CI, 0.88–1.49); tetanus, RR of 1.77 (95% CI, 0.97–3.28); smallpox, RR of 1.68 (95% CI, 0.78–3.57); poliomyelitis, RR of 1.79 (95% CI, 0.38–8.46); mumps, RR of 1.31 (95% CI, 0.92–1.86). In cohort studies, and RR of 0.85 (95% CI, 0.64–1.10) 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 HIN1 vaccination was 1.34 (95% CI, 0.97–1.82).

CONCLUSIONS:
Results of this meta-analysis show no evidence supporting an association between childhood immunization or HIN1 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.

Incidence of Crohn’s Disease and Ulcerative Colitis in Polio Vaccinated versus Unvaccinated Children

- 228% Relative Risk for Crohn’s Disease
- 348% Relative Risk for Ulcerative Colitis

- 100% Relative Risk for Unvaccinated Children

“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).”

Pinet de Chambrun et al., Clin Gastroenterol Hepatol 2015
http://dx.doi.org/10.1016/j.cgh.2015.04.179
Vaccination in non-Persian Gulf War Veterans Increases Odds of Neurological and Pain Symptoms

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

Loa 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 1,546 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 deployed the region prior to the war (5%) and most prevalent among those who deployed 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.

Steele, Am J Epidemiol 2000

"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."
Vaccination Increases Odds of Gulf War Illness 260%

Unwin et al., The Lancet 1999

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**Health of UK servicemen who served in Persian Gulf War**

Catherine Unwin, Nick Bitchley, William Coker, Susan Ferris, Matthew Hotspur, Lisa Hule, Khalela Iamal, Ian Palmer, Anthony David, Simon Nossley

**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=42,409) and all personnel (army, navy, air force) deployed to the Bosnia conflict (Bosnia cohort; n=42,409). We asked about deployment, exposures, symptoms, and illnesses. We analysed men only. Our outcome measures were physical health, functional capacity (SF-36), general health, the presence of any health problem, which we defined as a complaint lasting more than 6 months.

**Findings** There were 8132 (6.3%) valid responses. The Gulf War cohort reported symptoms and disorders significantly more frequently than those in the Bosnia and Iran cohorts, which were similar. Perception of physical health and ability to work were significantly worse in the Gulf War cohort than in the other cohorts, even after adjustment for confounders. Gulf War veterans were more likely to report health problems than those in the Bosnia cohort to have subclinical fatigue (odds ratio, 2.2; 95% CI 1.9–2.6).

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**Incidence of Gulf War Illness for Multiple Vaccines Received**

- **Gulf War Illness**
  - Greater than 7 Vaccines: 260%
  - 3 - 6 Vaccines: 140%
  - Unvaccinated: 100%

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"Vaccination against biological warfare and multiple routine vaccinations were associated with CDC multisymptom syndrome in the Gulf War cohort."
Multiple Vaccination During Deployment Increases Odds of Gulf War Illness 500% and Fatigue 340%

Role of vaccination as risk factors for ill health in veterans of the Gulf war: cross sectional study
Matthew Hooper, Anthony David, Lisa Hull, Khulthu Ismail, Catherine Unwin, Simon Wesely

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 20.4% (n = 3284). Of these, 258 (8.2%) 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 pentamidine 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 Zuurda suggested that deployment was a stress which would in itself lead to increased circulating corticosteroids, and this too would influence cytokine profiles. 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. We found increased rates of ill health for all health outcomes in those who served in the Gulf. Among many other things we found that those who served in the Gulf were more likely to have received multiple vaccinations before deployment than those who served in Bosnia. We still found an association between multisymptom illness and receipt of multiple vaccines before deployment; however, after adjustment for prolonged exposure to stress, the association was no longer significant.

Incidence of Gulf War Illness and Fatigue for Multiple Vaccines Received During Deployment

0 100 200 300 400 500 600
Incidence relative to unvaccinated

Gulf War Illness
Fatigue

- Greater than 5 Vaccines
- Unvaccinated

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

Hotopf et al., BMJ 2000

Children’s Health Defense