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## **Vaccine Safety: Examine the Evidence**

The safety and effectiveness of vaccines are under constant study. Because vaccines are designed to be given routinely during well-child care visits, they must be extraordinarily safe. Safety testing begins as soon as a new vaccine is contemplated, continues until it is approved by the FDA, and is monitored indefinitely after licensure. The American Academy of Pediatrics (AAP) works closely with the Centers for Disease Control and Prevention (CDC) to make recommendations for vaccine use.

Over the past decade, questions have been raised regarding a relationship between autism and vaccines. Along with general safety concerns, parents have wondered about:

- too many vaccines overwhelming the immune system;
- the measles, mumps, rubella combination vaccine (MMR); and
- the preservative thimerosal, which was never present in MMR but was present in several vaccines used in the 1990s, but has since been removed from all routinely used childhood vaccines with the exception of flu.

Research has been conducted on all of these topics, and the studies continue to find vaccines to be a safe and effective way to prevent serious disease. This document lists those studies and provides links to the publications to allow parents and all those who administer or recommend vaccines to read the evidence for themselves. These studies do not show any link between autism and MMR vaccine, thimerosal, multiple vaccines given at once, fevers or seizures. This is not an exhaustive list- vaccine safety studies are constantly being conducted and published and may not be reflected here.

Please examine the evidence for yourself. If you have any questions, speak with your pediatrician.

STUDIES ABOUT GENERAL SAFETY AND NUMBER OF VACCINES

<b><u>Study Citation</u></b>	<b><u>Summary</u></b>	<b><u>Author Conclusion</u></b>
<p><b>Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism</b></p> <p>DeStefano F, Price CS, Weintraub ES. <i>Journal of Pediatrics</i>. 2013;  <a href="http://jpediatrics.com/webfiles/images/journals/ympd/JPEDSDeStefano.pdf">http://jpediatrics.com/webfiles/images/journals/ympd/JPEDSDeStefano.pdf</a></p>	<p>This case-control study of more than 1,000 children compared the total exposure of antibody-stimulating proteins and polysaccharides in children with autism spectrum disorder (ASD), autistic disorder (AD), or ASD with regression to the total exposure in children who were not diagnosed with any form of autism. The children included in the study were aged 6-13 years, but authors studied their exposures from vaccines during the first 2 years of life. Results showed that the odds of developing any of the three forms of autism studied did not rise with increased exposure to antibody-stimulating proteins and polysaccharides.</p>	<p>The authors concluded that parents' concern that "too many vaccines too soon" could lead to autism is not supported. There was no indication that children with autism were more likely to have been exposed to more antigens through vaccines either in a single doctor's visit, in the first 3 months of life, the first 7 months of life, or the first 2 years of life than were children without any diagnosis of ASD, AD or ASD with regression. The authors also pointed out that while children today may receive more vaccines than the children in this study, some of the children in this study were exposed to far more antigens (by thousands) than children today. This is because whole-cell pertussis vaccine is no longer used.</p>
<p><b>On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes</b></p> <p>Smith M and Woods C, <i>Pediatrics</i>. 2010; 125(6): 1134-41  <a href="http://pediatrics.aappublications.org/cgi/content/abstract/125/6/1134">http://pediatrics.aappublications.org/cgi/content/abstract/125/6/1134</a></p>	<p>The study of more than 1,000 children born between 1993 and 1997 looked at their vaccination schedules up to 1 year of age, and studied their performance 7 to 10 years later on 42 different neuropsychological outcomes. Timely vaccination was associated with better performance on numerous outcomes. The less-vaccinated children did not do significantly better on any of the outcomes</p>	<p>This comparison of children vaccinated on time with children whose vaccinations were delayed or incomplete found no benefit in delaying immunizations during the first year of life. For parents who are concerned that children receive too many vaccines too soon, these data may provide reassurance that timely vaccination during infancy has no adverse effect on long-term neuropsychological outcomes.</p>

<p><b>Evaluation of Immunization Rates and Safety Among Children With Inborn Errors of Metabolism</b></p> <p>Klein N, et al., <i>Pediatrics</i>. 2011; 127(5), e1139-46</p> <p><a href="http://pediatrics.aappublications.org/content/127/5/e1139">http://pediatrics.aappublications.org/content/127/5/e1139</a></p>	<p>Researchers studied children in Northern California to determine whether 77 infants with inborn errors of metabolism who received vaccines were more likely to experience adverse events following vaccination, than 1540 matched controls (infants born without inborn errors of metabolism). Authors did not find any association between vaccination of children with inborn errors of metabolism and an increase in hospitalizations or emergency-department visits within 30 days of vaccination.</p>	<p>On-time receipt of vaccines is not associated with increased risk for serious adverse events in the 30 days after vaccination, even in children who have metabolism conditions. This should provide reassurance that children with inborn errors of metabolism who are vaccinated routinely do not experience adverse effects.</p>
<p><b>Measles-Containing Vaccines and Febrile Seizures in Children Age 4 to 6 Years</b></p> <p>Klein N, et al., <i>Pediatrics</i>. 2011; 129(5): 809-14</p> <p><a href="http://pediatrics.aappublications.org/content/129/5/809">http://pediatrics.aappublications.org/content/129/5/809</a></p>	<p>Researchers chose to perform cohort study and included 715,484 children aged 48-83 months of age who received a dose of MMRV, a dose of MMR on the same day as a dose of Varicella injected separately, or MMR alone or Varicella alone to determine the risk of post-vaccination seizure in these groups. Results showed that more fevers and seizures did occur in children who had received the MMRV vaccine, compared with children who had received MMR + Varicella, or MMR or Varicella separately, though this finding was not statistically significant. The study did not find any peak in seizure or fever activity in any of the study groups in the 7-10 post-vaccination period. Of the 4 febrile seizures observed in the 7-10 days in the post-vaccination period for children receiving MMRV, only one</p>	<p>Overall researchers found no increased risk of febrile seizures in any of the study groups within 6 weeks of vaccination.</p>

	febrile seizure could be confirmed, resulting in authors claiming the rate of febrile seizure after MMRV to be 1 in 86,750 doses.	
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**STUDIES LOOKING AT MEASLES, MUMPS, AND RUBELLA (MMR) VACCINE:**

<b><u>Study Citation</u></b>	<b><u>Summary</u></b>	<b><u>Author Conclusion</u></b>
<p><b>No Evidence for Measles, Mumps, and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-year Prospective Study</b></p> <p>Peltola H, et al., <i>Lancet</i>. 1998; 351:1327-8</p> <p><a href="http://www.freenetpages.co.uk/hp/ginger_nut/lancet/Finland%20May%201998.pdf">http://www.freenetpages.co.uk/hp/ginger_nut/lancet/Finland%20May%201998.pdf</a></p>	<p>Prospective study of 3 million adverse events in temporal relation to MMR vaccine. A form was filled and posted to the data collectors, followed by another form with further information 2-3 weeks later. Researchers traced subjects who developed gastrointestinal symptoms or signs lasting 24 hours or more at any time after MMR vaccination (apart from within the first hour). Researchers also checked hospital and health center records or interviewed the local public-health nurses.</p>	<p>Over a decade's effort to detect all severe adverse events associated with MMR vaccine could find no data supporting the hypothesis that it would cause pervasive developmental disorder or inflammatory bowel disease.</p>
<p><b>Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association</b></p>	<p>Researchers looked for a change in trend in incidence or age at diagnosis associated with the introduction of measles, mumps and rubella (MMR) vaccination to the United Kingdom in 1988. The study identified</p>	<p>Data do not support a causal association between MMR vaccine and autism. If such an association occurs, it is so rare</p>

<p>Taylor B, et al., <i>Lancet</i>. 1999; 353(9169): 2026-9</p> <p><a href="http://tinyurl.com/5bgvwwg">http://tinyurl.com/5bgvwwg</a></p>	<p>498 cases of autism (261 of core autism, 166 of atypical autism, and 71 of Asperger syndrome) in children born in the UK since 1979. There was a steady increase in cases by year of birth with no sudden “step-up” or change in the trend line after the introduction of MMR vaccination. There was no difference in age at diagnosis between the cases vaccinated before or after 18 months of age and those never vaccinated. There was no temporal association between onset of autism within 1 or 2 years after vaccination with MMR. Developmental regression was not clustered in the months after vaccination.</p>	<p>that it could not be identified in this large regional sample.</p>
<p><b>Mumps, Measles, and Rubella Vaccine and the Incidence of Autism Recorded by General Practitioners: A Time Trend Analysis</b></p> <p>Kaye JA, et al., <i>British Medical Journal</i>. 2001; 322:460-63</p> <p><a href="http://www.bmj.com/cgi/content/full/322/7284/460">http://www.bmj.com/cgi/content/full/322/7284/460</a></p>	<p>Study compared prevalence of measles, mumps and rubella (MMR) vaccination among children in the United Kingdom to rising prevalence of autism diagnoses for children.</p>	<p>The data provide evidence that no correlation exists between the prevalence of MMR vaccination and the rapid increase in the risk of autism over time.</p>
<p><b>MMR and autism: further evidence against a causal association</b></p> <p>Farrington CP, et al., <i>Vaccine</i>. 2001; Jun 14; 19(27): 3632-5</p> <p><a href="http://tinyurl.com/5lb3w7">http://tinyurl.com/5lb3w7</a></p>	<p>Data from an earlier measles, mumps and rubella (MMR) vaccine study (Taylor et al, 2000) were reanalyzed to test a second hypothesis.</p>	<p>Results provide further evidence against a causal association between MMR vaccination and autism.</p>
<p><b>Time Trends in Autism and in MMR</b></p>	<p>Scientists looked for correlation between increases in</p>	<p>These data do not suggest an</p>

<p><b>Immunization Coverage in California</b></p> <p>Dales L et al., <i>Journal of the American Medical Association</i>. 2001; 285(9): 1183-5</p> <p><a href="http://jama.ama-assn.org/cgi/content/abstract/285/9/1183">http://jama.ama-assn.org/cgi/content/abstract/285/9/1183</a></p>	<p>the rate of autism diagnoses and increases in the rate of measles, mumps and rubella (MMR) vaccination in children born between 1980 and 1994.</p>	<p>association between MMR immunization among young children and an increase in autism occurrence.</p>
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<p><b>Measles-Mumps-Rubella and Other Measles-Containing Vaccines Do Not Increase the Risk for Inflammatory Bowel Disease: A Case-Control Study from the Vaccine Safety Datalink Project</b></p> <p>Davis RL, et al., <i>Archives of Pediatric and Adolescent Medicine</i>. 2001;155(3): 354-9</p> <p><a href="http://archpedi.ama-assn.org/cgi/content/abstract/155/3/354">http://archpedi.ama-assn.org/cgi/content/abstract/155/3/354</a></p>	<p>A case control study of 155 persons with inflammatory bowel disease with up to five controls each. Neither past vaccination nor age at vaccination with other MCV was associated with increased risk for Crohn’s disease, ulcerative colitis, or IBD. Risk for Crohn’s disease, ulcerative colitis, or IBD was not elevated in the time immediately following vaccination with either vaccine.</p>	<p>Vaccination with MMR or other MCV, or the timing of vaccination early in life, did not increase the risk for IBD.</p>
<p><b>No Evidence for a New Variant of Measles-Mumps-Rubella-Induced Autism</b></p> <p>Fombonne E, et al., <i>Pediatrics</i>. 2001; 108(4): e58</p> <p><a href="http://tinyurl.com/5adckj">http://tinyurl.com/5adckj</a></p>	<p>Study compared 96 children with a pervasive developmental disorder (PDD) born between 1992 and 1995 and who had received the measles, mumps and rubella (MMR) vaccine, to PDD patients who did not receive MMR.</p>	<p>No evidence was found to support a distinct syndrome of MMR-induced autism or of “autistic enterocolitis.” These results add to the large-scale epidemiologic studies that all failed to support an association between MMR and autism at population level. These findings do not argue for changes in current immunization programs and recommendations.</p>

<p><b>Measles, Mumps, and Rubella Vaccination and Bowel Problems or Developmental Regression in Children with Autism: Population Study</b></p> <p>Taylor B, et al. <i>British Medical Journal</i>. 2002; 324(7334): 393-6</p> <p><a href="http://tinyurl.com/6oqsfc">http://tinyurl.com/6oqsfc</a></p>	<p>Population study of 278 children with core autism and 195 with atypical autism, born between 1979 and 1998. The proportion of children with developmental regression (25% overall) or bowel symptoms (17%) did not change significantly during the 20 years from 1979, a period which included the introduction of measles, mumps and rubella (MMR) vaccination in October 1988.</p>	<p>Data provide no support for an MMR associated “new variant” form of autism with developmental regression and bowel problems, and further evidence against involvement of MMR vaccine in the initiation of autism.</p>
<p><b>Relation of Childhood Gastrointestinal Disorders to Autism: Nested Case Control Study Using Data from the UK General Practice Research Database</b></p> <p>Black C, et al., <i>British Medical Journal</i>. 2002; 325: 419-21</p> <p><a href="http://tinyurl.com/csudoy">http://tinyurl.com/csudoy</a></p>	<p>Nested case control study of 96 children diagnosed with autism and 449 controls. The estimated odds ratio for a history of gastrointestinal disorders among children with autism compared with children without autism was 1.0 (95% confidence interval 0.5 to 2.2).</p>	<p>No evidence was found that children with autism were more likely than children without autism to have had defined gastrointestinal disorders at any time before their diagnosis of autism.</p>
<p><b>Neurologic Disorders after Measles-Mumps-Rubella Vaccination</b></p> <p>Makela A, et al., <i>Pediatrics</i>. 2002; 110: 957-63</p> <p><a href="http://tinyurl.com/6ybfjr">http://tinyurl.com/6ybfjr</a></p>	<p>Study of 535,544 1- to 7-year-old children who were vaccinated between November 1982 and June 1986 in Finland.</p>	<p>Data do not support an association between measles, mumps and rubella (MMR) vaccination and encephalitis, aseptic meningitis or autism.</p>



<p><b>A Population-Based Study of Measles, Mumps, and Rubella Vaccination and Autism</b></p> <p>Madsen KM, et al., <i>New England Journal of Medicine</i>. 2002; 347(19): 1477-82</p> <p><a href="http://tinyurl.com/5eob5k">http://tinyurl.com/5eob5k</a></p>	<p>Compared relative risk of Autism Spectrum Disorder (ASD) in children vaccinated with measles, mumps and rubella (MMR) vaccine and unvaccinated children born in Denmark between 1991 and 1998. Of the 537,303 children in the cohort, 82% had received the MMR vaccine. Researchers identified 316 children with a diagnosis of autism and 422 with a diagnosis of other ASDs. There was no association between the age at the time of vaccination, the time since vaccination, or the date of vaccination and the development of autism.</p>	<p>This study provides strong evidence against the hypothesis that MMR vaccination causes autism.</p>
<p><b>Prevalence of Autism and Parentally Reported Triggers in a North East London Population</b></p> <p>Lingam R, et al., <i>Archives of Disease in Childhood</i>. 2003; 88(8): 666-70</p> <p><a href="http://adc.bmj.com/cgi/content/abstract/88/8/666">http://adc.bmj.com/cgi/content/abstract/88/8/666</a></p>	<p>Study of reported age of onset of Autism Spectrum Disorder (ASD) among 567 children in northeast London born between 1979 and 1998. The age at diagnosis of ASD was estimated to have decreased per five-year period since 1983, by 8.7% for childhood autism and by 11.0% for atypical autism. There was some evidence that measles, mumps and rubella (MMR) vaccine was more likely to be mentioned as a trigger after August 1997 than before.</p>	<p>The data suggest that a rise in autism prevalence was likely due to factors such as increased recognition, a greater willingness on the part of educators and families to accept the diagnostic label, and better recording systems. The proportion of parents attributing their child's autism to MMR appears to have increased since August 1997.</p>

<p><b>MMR Vaccination and Pervasive Developmental Disorders: A Case-Control Study</b></p> <p>Smeeth L, et al., <i>Lancet</i> 2004; 364(9438): 963-9</p> <p><a href="http://tinyurl.com/8wlhfj">http://tinyurl.com/8wlhfj</a></p>	<p>Matched case-control of 1,295 people born in 1973 or later who had first recorded diagnosis of pervasive developmental disorder while registered with a contributing general practice between 1987 and 2001. Controls (4,469) were matched on age, sex and general practice. 1,010 cases (78.1%) had measles, mumps and rubella (MMR) vaccination recorded before diagnosis, compared with 3,671 controls (82.1%) before the age at which their matched case was diagnosed.</p>	<p>Data suggest that MMR vaccination is not associated with an increased risk of pervasive developmental disorders.</p>
<p><b>Age at First Measles-Mumps-Rubella Vaccination in Children with Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta</b></p> <p>DeStefano F et al., <i>Pediatrics</i> 2004; 113(2): 259-66</p> <p><a href="http://pediatrics.aappublications.org/cgi/content/abstract/113/2/259">http://pediatrics.aappublications.org/cgi/content/abstract/113/2/259</a></p>	<p>Study compared ages at first measles, mumps and 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.</p>	<p>Similar proportions of case and control children were vaccinated by the recommended age or shortly after (i.e., before 18 months) and before the age by which atypical development is usually recognized in children with autism (i.e., 24 months).</p>

<p><b>No evidence for links between autism, MMR and measles virus</b></p> <p>Chen W, et al., <i>Psychological Medicine</i>. 2004 April; 34(3): 543-53</p> <p><a href="http://tinyurl.com/5msou2">http://tinyurl.com/5msou2</a></p>	<p>Study compared 2,407 persons with autism born between 1959 and 1993; to 4,640 Down syndrome subjects born between 1966 and 1993.</p>	<p>No increased risk of autism was found following exposures to wild measles and vaccinations with monovalent measles, and Urabe or Jeryl-Lynn variants of measles, mumps and rubella (MMR) vaccine.</p>
<p><b>No effect of MMR withdrawal on the incidence of autism: a total population study</b></p> <p>Honda H, et al., <i>Journal of Child Psychology and Psychiatry</i>. 2005; 46(6): 572-9</p> <p><a href="http://tinyurl.com/d8f3lg">http://tinyurl.com/d8f3lg</a></p>	<p>Study examined incidence of Autism Spectrum Disorders (ASD) to age 7 for children born between 1988 and 1996 in Yokohama, Japan. The measles, mumps and rubella (MMR) vaccination rate in Yokohama declined significantly in the birth cohorts of years 1988-92, and no MMR vaccines were administered in 1993 or thereafter. In contrast, cumulative incidence of ASD up to age 7 increased significantly in the birth cohorts of years 1988 through 1996 and most notably rose dramatically beginning with the birth cohort of 1993.</p>	<p>MMR vaccination is not likely to be a main cause of ASD, and cannot explain the rise over time in the incidence of ASD. Withdrawal of MMR in countries where it is still being used cannot be expected to lead to a reduction in the incidence of ASD.</p>
<p><b>Immunization Safety Review: Vaccines and Autism</b></p> <p>Institute of Medicine, The National Academies Press: 2004</p> <p><a href="http://books.nap.edu/catalog.php?record_id=10997#description">http://books.nap.edu/catalog.php?record_id=10997#description</a></p>	<p>The IOM's Committee on Immunization Safety Review was convened in the fall of 2000 to provide an independent review of increasingly prominent vaccine safety concerns. The 15 committee members with expertise in pediatrics, internal medicine, immunology, neurology, infectious diseases, epidemiology, biostatistics, public health, risk perception, decision analysis, nursing, genetics, ethics and health communications analyzed over 200 relevant studies.</p>	<p>The committee rejected a causal relationship between the MMR vaccine and autism as well as a causal relationship between thimerosal-containing vaccines and autism.</p>

<p><b>Relationship between MMR Vaccine and Autism</b></p> <p>Klein KC, Diehl EB. <i>The Annals of Pharmacotherapy</i>. 2004; 38(7-8):1297-300</p> <p><a href="http://tinyurl.com/chdjrk">http://tinyurl.com/chdjrk</a></p>	<p>Ten articles that specifically evaluated the possible relationship between the measles, mumps and rubella (MMR) vaccine and autism were identified. Review articles, commentaries, and evaluations of a link between gastrointestinal symptoms in autistic children and MMR immunization were excluded.</p>	<p>Based upon the current literature, it appears that there is no relationship between MMR vaccination and the development of autism.</p>
<p><b>Is There a ‘Regressive Phenotype’ of Autism Spectrum Disorder Associated with the Measles-Mumps-Rubella Vaccine? A CPEA Study</b></p> <p>Richler, et al., <i>Journal of Autism and Developmental Disorders</i>. 2006; 36(3): 299-316</p> <p><a href="http://tinyurl.com/66gtk2">http://tinyurl.com/66gtk2</a></p>	<p>A multi-site study of 351 children with Autism Spectrum Disorders (ASD) and 31 typically developing children used caregiver interviews to describe the children’s early acquisition and loss of social-communication milestones. For the majority of children with ASD who had experienced a regression, pre-loss development was clearly atypical.</p>	<p>No evidence that onset of autistic symptoms or of regression was related to measles, mumps and rubella vaccination.</p>

<p><b>Pervasive Developmental Disorders in Montreal and Quebec, Canada: Prevalence and Links with Immunizations</b></p> <p>Fombonne E, et al., <i>Pediatrics</i>. 2006; 118(1): e139-50</p> <p><a href="http://tinyurl.com/5c27nu">http://tinyurl.com/5c27nu</a></p>	<p>Study of thimerosal and measles, mumps and rubella (MMR) vaccine uptake in 28,000 Canadian children born between 1987 and 1998, of whom 180 were identified with a pervasive developmental disorder.</p>	<p>The data rule out an association between pervasive developmental disorder and either high levels of ethyl mercury exposure comparable with those experienced in the United States in the 1990s or 1- or 2-dose MMR vaccinations.</p>
<p><b>Immunizations and Autism: A Review of the Literature</b></p> <p>Doja A, and Roberts W, <i>The Canadian Journal of Neurological Sciences</i>. 2006; 33(4): 341-6</p> <p><a href="http://tinyurl.com/ddnqq7">http://tinyurl.com/ddnqq7</a></p>	<p>Literature review found very few studies supporting an association between vaccines and autism, with the overwhelming majority showing no causal association between the measles, mumps and rubella (MMR) vaccine and autism. The vaccine preservative thimerosal has alternatively been hypothesized to have a possible causal role in autism. No convincing evidence was found to support an association between the vaccine preservative thimerosal and autism, nor for the use of chelation therapy in autism.</p>	<p>Literature review found very few studies supporting an association between vaccines and autism, with the overwhelming majority showing no causal association between the measles, mumps and rubella (MMR) vaccine and autism. The vaccine preservative thimerosal has alternatively been hypothesized to have a possible causal role in autism. No convincing evidence was found to support an association between the vaccine preservative thimerosal and autism, nor for the use of chelation therapy in autism.</p>
<p><b>No Evidence of Persisting Measles Virus in Peripheral Blood Mononuclear Cells from Children with</b></p>	<p>Peripheral blood mononuclear cells were isolated from 54 children with Autism Spectrum Disorders (ASD) and 34 developmentally normal children, and up to 4 real-time polymerase chain reaction assays</p>	<p>There is no evidence of measles virus persistence in the peripheral blood mononuclear cells of</p>

<p><b>Autism Spectrum Disorder</b></p> <p>D'Souza Y, et al., <i>Pediatrics</i>. 2006; 118(4): 1664-75</p> <p><a href="http://tinyurl.com/dcb79o">http://tinyurl.com/dcb79o</a></p>	<p>and 2 nested polymerase chain reaction assays were performed. No sample from either ASD or control groups was found to contain nucleic acids from any measles virus gene. In the nested polymerase chain reaction and in-house assays, none of the samples yielded positive results. Furthermore, there was no difference in anti-measles antibody titers between the autism and control groups.</p>	<p>children with ASD.</p>
<p><b>MMR-Vaccine and Regression in Autism Spectrum Disorders: Negative Results Presented from Japan</b></p> <p>Uchiyama T, et al., <i>Journal of Autism and Developmental Disorders</i>. 2007; 37(2): 210-7</p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/16865547">http://www.ncbi.nlm.nih.gov/pubmed/16865547</a></p>	<p>Study of 904 patients with Autism Spectrum Disorders (ASD). During the period of measles, mumps and rubella vaccine (MMR) usage, no significant difference was found in the incidence of regression between MMR-vaccinated children and non-vaccinated children. Among the proportion and incidence of regression across the three MMR-program-related periods (before, during and after MMR usage), no significant difference was found between those who had received MMR and those who had not. Moreover, the incidence of regression did not change significantly across the three periods.</p>	<p>The data do not support an association between MMR and autism.</p>
<p><b>Measles Vaccination and Antibody Response in Autism Spectrum Disorders</b></p> <p>Baird G, et al., <i>Archives of Disease in Childhood</i>. 2008; 93(10): 832-7</p> <p><a href="http://tinyurl.com/dn6yy8">http://tinyurl.com/dn6yy8</a></p>	<p>Case-control study of 98 vaccinated children aged 10-12 years in the UK with autism spectrum disorder (ASD) and two control groups of similar age: 52 children with special educational needs but no ASD and 90 children in the typically developing group. No difference was found between cases and controls for measles antibody response. There was no dose-response relationship between autism symptoms and antibody concentrations.</p>	<p>No association between measles vaccination and ASD was shown.</p>

<p><b>Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study</b></p> <p>Hornig M et al., <i>PLoS ONE</i>. 2008; 3(9): e3140</p> <p><a href="http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0003140">http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0003140</a></p>	<p>Researchers looked for measles virus in the guts of 25 children with both autism and gastrointestinal disorders, and another 13 children with the same gastrointestinal disorders but no autism. The virus was detected in one child from each group.</p>	<p>This study provides strong evidence against association of autism with persistent measles virus RNA in the gastrointestinal tract or with measles, mumps and rubella (MMR) vaccine exposure.</p>
<p><b>Lack of Association Between Measles-Mumps-Rubella Vaccination and Autism in Children: A Case-Control Study</b></p> <p>Budzyn D, et al., <i>The Pediatric Infectious Disease Journal</i>. 2010; <u>29(5): 397-400</u></p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/19952979">http://www.ncbi.nlm.nih.gov/pubmed/19952979</a></p>	<p>Researchers in Poland compared vaccination history and autism diagnosis in 96 children with autism, ages 2 to 15, as well as 192 children in a control group. For children diagnosed before a diagnosis of autism, the autism risk was lower in children who received MMR vaccine than in nonvaccinated children. A similar result was achieved for the single-antigen measles vaccine.</p>	<p>The study provides evidence against the association of autism with either MMR or a single measles vaccine.</p>

## COURT DECISIONS

<u>Case</u>	<u>Result</u>
<p><b>U.S. Court of Federal Claims decision in Omnibus Autism Proceeding</b></p> <p><a href="http://www.uscfc.uscourts.gov/node/5026">http://www.uscfc.uscourts.gov/node/5026</a></p>	<p>On Feb. 12, 2009, the “vaccine court” ruled in three test cases on the theory that MMR vaccine and the vaccine preservative thimerosal are linked to autism. The court found the scientific evidence is overwhelmingly contrary to this theory.</p>

**STUDIES LOOKING AT THIMEROSAL:**

<u><b>Study Citation</b></u>	<u><b>Summary</b></u>	<u><b>Author Conclusion</b></u>
<p><b>Association Between Thimerosal-Containing Vaccine and Autism</b></p> <p>Hviid, et al., <i>Journal of the American Medical Association</i>. 2003; 290(13):1763-6</p> <p><a href="http://tinyurl.com/5rtzjd">http://tinyurl.com/5rtzjd</a></p>	<p>Study of 467,000 children born in Denmark between 1990 and 1996 compared children who were vaccinated with a thimerosal-containing vaccine to children who received a thimerosal-free formulation of the same vaccine. The risk of autism and other autism spectrum disorders did not differ significantly between children vaccinated with thimerosal-containing vaccine and children vaccinated with thimerosal-free vaccine.</p>	<p>The results do not support a causal relationship between childhood vaccination with thimerosal-containing vaccines and development of autistic-spectrum disorders.</p>
<p><b>Thimerosal Exposure in Infants and Developmental Disorders: A Prospective Cohort Study in the United Kingdom Does Not Support a Causal Association</b></p> <p>Heron, et al., <i>Pediatrics</i>. 2004;114(3):577-83</p> <p><a href="http://pediatrics.aappublications.org/cgi/content/abstract/114/3/577">http://pediatrics.aappublications.org/cgi/content/abstract/114/3/577</a></p>	<p>The researchers monitored the thimerosal exposure of more than 14,000 children born in the United Kingdom between 1991 and 1992. The age at which doses of thimerosal-containing vaccines were administered was recorded, and measures of mercury exposure by 3, 4 and 6 months of age were calculated and compared with a number of measures of childhood cognitive and behavioral development covering the period from 6 to 91 months of age.</p>	<p>No convincing evidence was found that early exposure to thimerosal had any deleterious effect on neurologic or psychological outcome.</p>



<p><b>Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data</b></p> <p>Madsen, et al., <i>Pediatrics</i>. 2003; 112(3): 604-6</p> <p><a href="http://tinyurl.com/5omq4u">http://tinyurl.com/5omq4u</a></p>	<p>Analyzed data from the Danish Psychiatric Central Research Register recording all psychiatric admissions since 1971, and all outpatient contacts in psychiatric departments in Denmark since 1995. There was no trend toward an increase in the incidence of autism during that period when thimerosal was used in Denmark, up through 1990. From 1991 until 2000 the incidence increased and continued to rise after the removal of thimerosal from vaccines, including increases among children born after the discontinuation of thimerosal.</p>	<p>The discontinuation of thimerosal-containing vaccines in Denmark in 1992 was followed by an increase in the incidence of autism. The data do not support a correlation between thimerosal-containing vaccines and the incidence of autism.</p>
<p><b>Autism and thimerosal-containing vaccines: Lack of consistent evidence for an association</b></p> <p>Stehr-Green P, et al., <i>American Journal of Preventive Medicine</i>. 2003; 25(2):101-6</p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/12880876">http://www.ncbi.nlm.nih.gov/pubmed/12880876</a></p>	<p>Study compared the prevalence/incidence of autism in California, Sweden and Denmark from the mid-80s to the late 90s with average exposures to thimerosal-containing vaccines. In all three countries, the incidence and prevalence of Autism Spectrum Disorders began to rise in the 1985-1989 period, and the rate of increase accelerated in the early 1990s.</p>	<p>The data is not consistent with the hypothesis that increased exposure to thimerosal-containing vaccines is responsible for the apparent increase in the rates of autism in young children being observed worldwide.</p>

<p><b>Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association</b></p> <p>Andrews N, et al., <i>Pediatrics</i>. 2004; 114(3): 584-91</p> <p><a href="http://tinyurl.com/7rvj6m">http://tinyurl.com/7rvj6m</a></p>	<p>Study analyzed thimerosal exposure and possible development delays in 109,863 children born in the United Kingdom from 1988-97. Exposure was defined according to the number of DTP/DT doses received by 3 and 4 months of age and also the cumulative age-specific DTP/DT exposure by 6 months.</p>	<p>With the possible exception of tics, there was no evidence that thimerosal exposure via DTP/DT vaccines causes neurodevelopmental disorders.</p>
<p><b>Immunization Safety Review: Vaccines and Autism</b></p> <p>Institute of Medicine, The National Academies Press: 2004</p> <p><a href="http://books.nap.edu/catalog.php?record_id=10997#description">http://books.nap.edu/catalog.php?record_id=10997#description</a></p>	<p>The IOM's Committee on Immunization Safety Review was convened in the fall of 2000 to provide an independent review of increasingly prominent vaccine safety concerns. The 15 committee members with expertise in pediatrics, internal medicine, immunology, neurology, infectious diseases, epidemiology, biostatistics, public health, risk perception, decision analysis, nursing, genetics, ethics and health communications analyzed over 200 relevant studies.</p>	<p>The committee rejected a causal relationship between the MMR vaccine and autism as well as a causal relationship between thimerosal-containing vaccines and autism.</p>
<p><b>Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links With Immunizations</b></p> <p>Fombonne, et al., <i>Pediatrics</i>. 2006; 118(1); e139-50</p> <p><a href="http://tinyurl.com/5c27nu">http://tinyurl.com/5c27nu</a></p>	<p>Quantified thimerosal and measles, mumps rubella (MMR) vaccine uptake in 28,000 Canadian children born between 1987 and 1998, of whom 180 were identified with a pervasive developmental disorder.</p>	<p>The data rule out an association between pervasive developmental disorder and either high levels of ethyl mercury exposure comparable with those experienced in the United States in the 1990s or 1- or 2-dose measles-mumps-rubella vaccinations.</p>

<p><b>Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years</b></p> <p>Thompson, et al., <i>New England Journal of Medicine</i>. 2007; 357: 1281-92</p> <p><a href="http://tinyurl.com/5ndvpe">http://tinyurl.com/5ndvpe</a></p>	<p>Study compared early exposure to thimerosal-containing vaccines to 42 neuropsychological outcomes in 1,047 children between the ages of 7 and 10 years. Exposure to mercury from thimerosal was determined from computerized immunization records, medical records, personal immunization records and parent interviews.</p>	<p>The study does not support a causal association between early exposure to mercury from thimerosal-containing vaccines and immune globulins and deficits in neuropsychological functioning at the age of 7 to 10 years.</p>
<p><b>Mercury Levels in Newborns and Infants After Receipt of Thimerosal-Containing Vaccines</b></p> <p>Pichichero, et al., <i>Pediatrics</i>. 2008; 121(2): e208-14</p> <p><a href="http://pediatrics.aappublications.org/cgi/content/full/121/2/e208">http://pediatrics.aappublications.org/cgi/content/full/121/2/e208</a></p>	<p>Study assessed blood mercury levels of 216 healthy children prior to immunization with thimerosal-containing vaccines, and 12 hours to 30 days after. The blood mercury half-life was calculated to be 3.7 days and returned to prevaccination levels by day 30.</p>	<p>The blood half-life of intramuscular ethyl mercury from thimerosal in vaccines in infants is substantially shorter than that of oral methyl mercury in adults. Increased mercury levels were detected in stools after vaccination, suggesting that the gastrointestinal tract is involved in ethyl mercury elimination. Because of the differing pharmacokinetics of ethyl and methyl mercury, exposure guidelines based on oral methyl mercury in adults may not be accurate for risk assessments in children who receive thimerosal-containing vaccines.</p>

<p><b>Continuing increases in autism reported to California's developmental services system: mercury in retrograde</b></p> <p>Schechter and Grether, <i>Archives of General Psychiatry</i>. 2008; 65(1):19-24</p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/18180424?ordinalpos=44&amp;itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum">http://www.ncbi.nlm.nih.gov/pubmed/18180424?ordinalpos=44&amp;itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum</a></p>	<p>Study analyzed autism client data from the California Department of Developmental Services between 1995 and 2007. Even though thimerosal was absent from scheduled childhood vaccines after 2002, cases of autism continued to climb quarter by quarter</p>	<p>The California DDS data do not show any recent decrease in autism in California despite the exclusion of more than trace levels of thimerosal from nearly all childhood vaccines. The data do not support the hypothesis that exposure to thimerosal during childhood is a primary cause of autism.</p>
<p><b>Prenatal and Infant Exposure to Thimerosal From Vaccines and Immunoglobulins and Risk of Autism</b></p> <p>Price C, et al., <i>Pediatrics</i>. 2010; 126(4): 656-64</p> <p><a href="http://pediatrics.aappublications.org/cgi/content/full/126/4/656">http://pediatrics.aappublications.org/cgi/content/full/126/4/656</a></p>	<p>Researchers reviewed managed care organization records and conducted interviews with the parents of 256 children who were verified to have ASD according to a standardized personal evaluation. Children with ASD were further categorized as having autistic disorder or ASD with regression. Another 752 children without autism, matched to the ASD children by birth year, gender and managed care organization, were also studied. For none of the autism outcomes was prenatal or early life receipt of thimerosal-containing vaccines and immunoglobulins significantly greater among children with ASD than among children without ASD.</p>	<p>These results add to the evidence that thimerosal-containing vaccines do not increase the risk of autism.</p>

<p><b>Lack of Association Between Measles-Mumps-Rubella Vaccination and Autism in Children: A Case-Control Study</b></p> <p>Budzyn D, et al., <i>The Pediatric Infectious Disease Journal</i>. 2010; <u>29(5): 397-400</u></p> <p><a href="http://www.ncbi.nlm.nih.gov/pubmed/19952979">http://www.ncbi.nlm.nih.gov/pubmed/19952979</a></p>	<p>Researchers in Poland compared vaccination history and autism diagnosis in 96 children with autism, ages 2 to 15, as well as 192 children in a control group. For children vaccinated before a diagnosis of autism, the autism risk was lower in children who received MMR vaccine than in nonvaccinated children. A similar result was achieved for the single-antigen measles vaccine.</p>	<p>The study provides evidence against the association of autism with either MMR or a single measles vaccine.</p>
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**INVESTIGATIVE REPORTING:**

<u>Article Citation</u>	<u>Summary</u>
<p><b>How the case against the MMR vaccine was fixed</b></p> <p>Deer B, <i>British Medical Journal</i>. 2011; 342: 77-84</p> <p><a href="http://www.bmj.com/content/342/bmj.c5347.full">http://www.bmj.com/content/342/bmj.c5347.full</a></p>	<p>British journalist Brian Deer investigates Dr. Andrew Wakefield (the man who initially claimed a link between autism and the MMR vaccine), his practices during the study that was published on this alleged connection, and uncovers truths that lead to the revocation of Dr Wakefield's medical license and to the retraction of the article he published on the subject.</p>