

External Article Review of: Vaccination and neurodevelopmental disorders: a study of nine-year-old children enrolled in Medicaid

Peter C. Gøtzsche

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Review

In January 2025, a study was published in an online journal of 47,155 nine-year-old children, which reported that vaccination was associated with significantly increased odds for all measured "neurodevelopmental disorders," including autism spectrum disorder.¹

Apart from autism, the included diagnoses were hyperkinetic syndrome, epilepsy or seizures, learning disability, encephalopathy, and tic disorders.

For autism, there was a dose-response relationship. The more vaccinations a child had received, the greater the risk of autism, compared to children who had not been vaccinated. Children with just one vaccination visit were 1.7 times more likely to have been diagnosed with autism than the unvaccinated (95% confidence interval 1.21 to 2.35) whereas those with 11 or more visits were 4.4 times more likely to have been diagnosed with autism than the unvaccinated (2.85 to 6.84).

The authors discuss various limitations of their study but not the most important one, which is one that makes their study unreliable. The more often people visit a doctor, the greater the risk that they will get a diagnosis that many of us could get if we went to see a doctor. Moreover, the authors mentioned that African Americans comprised the largest group of unvaccinated children, thereby demonstrating that they did not compare like with like. People who don't get vaccinated at all are unlikely to see a doctor much for other issues.

The diagnostic criteria for autism and ADHD (formerly called hyperkinetic syndrome) are vague, and false positive diagnoses are therefore very common. At a dinner in my house, we discussed this and I tested my wife, daughter, her very laid-back boyfriend and myself with the test for adult ADHD,² and we all tested positive.

It is also wrong to say that ADHD is a neurodevelopmental disorder. It is just a name for a collection of symptoms that lie at one end of the normal distribution for such symptoms.³

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I agree with the authors that the overall impact of the vaccination schedule on children's health has been left unexplored. I am aware of only two researchers who have studied this. They did several studies and found that nations that require more vaccines for their infants have higher mortality rates in small children. This is alarming and should lead to other studies as a matter of urgency. Since observational studies will always be confounded, we need large randomized trials comparing few vaccinations with many.

Misinformation about vaccines

There is a huge amount of misinformation about vaccines, not only in social media , but also in scientific articles and in information from the authorities including the US Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration.⁵,⁶

In the USA, the misinformation is particularly pronounced.⁵,⁶Antivaccine circles celebrate one of the worst fraudsters in medical history,⁵ Andrew Wakefield, as a hero.⁵ He published a study in The Lancet claiming that the MMR vaccine (measles, mumps and rubella) caused autism.⁷ This claim has been debunked in the most reliable observational studies,⁵,⁸ and a cohort study from Denmark is particularly persuasive.⁹

Since the authors of the new study claimed that vaccines can cause autism,¹ I decided to investigate who funded them and who they are. This was revealing.

Who funded the study?

The study was funded by the National Vaccine Information Center (NVIC). As several commentators have pointed out, this name is misleading as it gives people the impression that it is a governmental body. For example, the United States Department of Health and Human Services has an advisory body named the National Vaccine Advisory Committee.

Who are the authors?

The authors, Anthony R. Mawson and Binu Jacob, declared that they have no conflicts of interest. They come from the Chalfont Research Institute, Jackson, Mississippi. I have not been able to find much about this institute, apart from it having assets of \$465 in 2021. Another website noted that they were "seeking investors to help develop a patented electronic device for treating pressure and diabetic ulcers and other chronic wounds." Such devices for such disorders never work. The idea is to maintain tissue oxygenation.

Conclusions

The paper by Mawson and Jacob should be forgotten.

Disclosures, Funding & Conflicts of Interest

None.

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Author Rejoinder

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Reponse to Gøtzsche from Dr. Anthony Mawson, DrPH and Binu Jacob, MPH

Submitted 02/25/2025

We thank the Editor of the Journal of the Academy of Public Health for the opportunity to respond to the review of our paper in Science, Public Health Policy, and the Law, "Vaccination and neurodevelopmental disorders: a study of nine-year-old children enrolled in Medicaid," by Peter C. Gøtzsche.

First, let me assure readers that neither I nor my co-author Binu Jacob are against vaccination ("anti-vaxxers"), as if critics of cars are anti-cars. We are both trained in public health and recognize the importance of vaccines. Our concern is with the safety of the current childhood vaccination schedule, which has increased nearly

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three-fold compared to the schedule in the 1950s. Just as cigarette smoking was once assumed to be safe, so today the safety of vaccination is taken for granted. A few cigarettes will not cause lung cancer, but it was shocking to learn that packs smoked per day were directly associated with the risk of lung cancer and heart disease in a dose-response relationship. In the case of vaccines, previous studies have focused on single vaccines, with inconsistent results. But the cumulative impact of all the scheduled vaccinations has been ignored, as Gøtzsche notes. This gap in the evidence led to our own research.

The new study, comprising 47,155 nine-year-old children who had been continuously enrolled in the Florida Medicaid program, found that: 1) visits involving vaccinations were associated with significantly increased odds for all measured neurodevelopmental disorders (NDDs); 2) children born preterm and vaccinated were significantly more likely to have been diagnosed with at least one NDD than those born preterm and unvaccinated; and 3) the relative risk of diagnosis with ASD increased according to the number of visits that included vaccinations.

These results suggest that the current vaccination schedule may be contributing to multiple forms of NDD; that preterm birth, an inflammatory condition (1), coupled with vaccination appears to be strongly associated with increased odds of all of the measured NDDs compared to preterm birth in the absence of vaccination; and increasing numbers of visits that included vaccinations were associated with increased risks of ASD.

Dr. Gøtzsche alleges that we did not discuss the most important limitation, that "the more often people visit a doctor, the greater the risk that they will get a diagnosis." In any study comparing vaccinated and unvaccinated children, the only expected outcome would be that the vaccinated were protected against the targeted infectious diseases. In our study, on the contrary, we reported significantly increased odds of several NDDs in the vaccinated compared to unvaccinated children. There is no doubt that some vaccinated children with NDDs unrelated to vaccination itself may have been so diagnosed simply because their condition was more likely to be recognized after increasing numbers of visits. Conversely, more unvaccinated children may have been diagnosed with an NDD if they had been seen at the office. However, it is implausible to suggest that our findings and the pattern of the findings on NDDs are due to numbers of office visits and greater exposure to being diagnosed, and that the absence of visits explains the lower frequency of NDDs in the unvaccinated. The implication is unreasonable that the parents of an unvaccinated child would not take their child to the doctor if his or her condition required it.

We stand by our study because the overall results, based on Medicaid claims data, closely match those of our 2017 pilot study based on mothers' anonymous responses to an online questionnaire on the health outcomes of 666 children and their own experiences in pregnancy (2). The new results replicate and expand on the findings of the pilot study: vaccination was significantly associated with NDDs (combining ASD, ADHD, and learning disorders); preterm birth coupled with vaccination was associated with increased odds of NDDs compared to preterm birth in the absence of vaccination; and fully vaccinated children had significantly higher odds of NDDs than the partially vaccinated.

Reproducibility is a key criterion of validity. The strong reproducibility of our results supports their validity and our conclusions. The organization Retraction Watch continues to post that our 2017 "pilot comparative study" paper was retracted twice. This is false. The paper was never retracted by any journal, and it remains online.

The fact that African Americans comprised the largest group of unvaccinated

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children reflects the demographics of the population and has no bearing on the validity of the overall results.

Gøtzsche further asserts that diagnostic criteria for autism and ADHD are vague and that people who don't get vaccinated are less likely to see a doctor for other issues This comment unfairly implies that many of the unvaccinated may have had NDDs but were not diagnosed because of parental neglect. However, almost any child with an NDD, regardless of their vaccination status, will require at least one health care visit due to the disorder, involving the use of a diagnostic code for billing. The chance of a totally missing diagnostic code for an NDD in the Medicaid billing and claims data is therefore virtually zero.

ADHD was known as Minimal Brain Dysfunction in the 1960s and was rare. It was not officially recognized in the Diagnostic and Statistical Manual of Mental Disorders (DSM) until the second edition in 1968, where it was listed as "hyperkinetic impulse disorder". In 2024, an estimated 7 million (11.4%) US children aged 3–17 years were diagnosed with ADHD, according to a national survey of parents using data from 2022 (3). Could this increase be due to greater recognition of the symptoms of ADHD in the general population? More likely it indicates a real increase in the prevalence of the condition.

We agree with Gøtzsche that the overall impact of the vaccination schedule on children's health has been left unexplored. The studies mentioned by Gøtzsche suggest that increasing numbers of required vaccinations are linked not only to death but to adverse health outcomes in general, including NDDs, as our study suggests.

Gøtzsche's suggestion to randomize children either to receive or not receive vaccines is a logical method in theory but it is universally rejected as unethical, since it would deprive some children of the needed vaccines. This restriction therefore requires observational studies comparing vaccinated and unvaccinated children.

Regarding Wakefield, he and his co-authors did not claim that the MMR causes autism. They wrote: "We did not prove an association between measles, mumps, and rubella vaccine and the syndrome described. Virological studies are underway that may help to resolve this issue"(4). It is also not true that the case-series study by 12 respected physicians was fraudulent (5). Importantly, it was the first study to draw attention to gastrointestinal issues in children with ASD.

The MMR vaccine is the last in a series of vaccinations in the first 12 months of life and could conceivably trigger ASD in susceptible children due to their net impact. Importantly, none of the cited studies compared outcomes in totally vaccinated children and totally unvaccinated children.

Chalfont Research Institute is a start-up medical research and development company, of which I am the president. Until recently, due to my employment as a professor, I have not had the time to devote to building the institute. The electronic device is being developed based on my research on patients with spinal cord injury, who are most at risk of pressure injuries due to impaired circulatory function. My research showed that electrical stimulation can increase tissue oxygenation levels at the sacrum into the normal range within minutes (6). The prototype device will soon undergo randomized clinical trials.

In summary, readers should take Gøtzsche's review with a large grain of salt.

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Peer Review of: External Article Review of: Vaccination and neurodevelopmental disorders: a study of nine-year-old children enrolled in Medicaid

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The authors fail to address my criticism and introduce new errors

Reviewer Closure from Peter Gøtzsche

Submitted 02/27/2025

The authors have not resolved the key flaw of their study, which is that the more often people visit a doctor, the greater the risk that they will get a vague diagnosis that many of us could get if we visited a doctor.

Astonishingly, the authors claim in their reply that "It is not true that the case-series study by 12 respected physicians at the Royal Free Hospital in London was

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fraudulent." To prove their point, they cite the fraudster, Wakefield, himself!

Wakefield's study was the basis for the false claim that vaccines can cause autism, but it was a horrendous fraud at many levels and there was also financial corruption.[1-9] When Wakefield refused to carry out the replication research requested of him by his employers, they fired him. In January 2011, BMJ's editor-in-chief called Wakefield's research "an elaborate fraud" and accused the Royal Free medical school and The Lancet of "institutional and editorial misconduct." [8,9] Although the GMC had found Wakefield guilty of some three dozen charges, The Lancet continued to cover up for him but ultimately retracted his paper.

Disclosures, Funding & Conflicts of Interest

None in relation to this paper.

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