

The Vaccine-Autism Connection: A Public Health Crisis Caused by Unethical Medical Practices and Fraudulent Science

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The Wakefield autism paper gained scientific legitimacy when published in the prestigious and widely read medical journal *The Lancet* in 1998.¹ In 2000, Wakefield published another article claiming that the measles, mumps, and rubella (MMR) vaccine was introduced into mass vaccination programs without sufficient safety testing.² Both papers garnered little interest until a medical charity, which promotes gastrointestinal research, held a televised press conference during which Wakefield outlined his reservations about the safety of the MMR vaccine and the connection between this vaccine and autism-enterocolitis.

The teleconference ignited a public health crisis in England and questions about vaccine safety in North America. In England, parents refused the MMR vaccine for their children, and the vaccination rates dropped precipitously from 91% in 1998 to below 80% in 2003.³ Measles, which had been eradicated in England, began to re-emerge. New cases of measles increased from 56 in 1998 to 1370 in 2008.⁴ Vaccination rates in England have never recovered to the levels necessary to protect a susceptible population (herd immunity).⁵ In contrast, the MMR vaccination rates in the US remained above 92% from 1998 to 2008, with approximately 100 measles cases per year.⁶⁻⁸

Underimmunization had a devastating effect on public health in the UK. Measles outbreaks began to occur in London, where less than 50% of children were immunized.⁹ The outbreaks quickly spread to Scotland and Ireland. In 2002, 100 children in Ireland were hospitalized with measles-associated bronchopneumonia or acute en-

In 1998, Dr. Andrew Wakefield, a British gastroenterologist, described a new autism phenotype called the regressive autism-enterocolitis syndrome triggered by environmental factors such as measles, mumps, and rubella (MMR) vaccination. The speculative vaccination-autism connection decreased parental confidence in public health vaccination programs and created a public health crisis in England and questions about vaccine safety in North America. After 10 years of controversy and investigation, Dr. Wakefield was found guilty of ethical, medical, and scientific misconduct in the publication of the autism paper. Additional studies showed that the data presented were fraudulent. The alleged autism-vaccine connection is, perhaps, the most damaging medical hoax of the last 100 years.

KEY WORDS: MMR vaccine, regressive autism, Wakefield.

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cephalitis. During this outbreak, 3 children died from measles encephalitis. Another child died of measles complications in England during a 2006 outbreak.⁹

Population Studies

Evidence supporting the autism-MMR connection began to unravel quickly. Seven controlled observational studies and 2 ecological studies on populations in the US, Great Britain, Denmark, and Japan failed to document an association between MMR vaccination and autism.¹⁰⁻¹⁸ Two studies in Finland reached the same conclusions.^{19,20} By 2004, the scientific community was united in the belief that vaccines did not cause or contribute to the development of autism.

Despite the overwhelming evidence of the safety and effectiveness of the MMR vaccine, the vaccine-autism connection gained traction on the Internet and was perpetuated by print and television media eager for increased circulation or higher ratings.²¹ Entertainment shows contributed to the controversy by offering vaccine-autism connection

proponents a platform to make their case, largely unchallenged.²¹ By 2009, 1 of 5 parents in the US believed that vaccines cause autism in otherwise healthy children. Moreover, 10% of parents in a study published in 2010 were refusing 1 or more newer vaccines for their children.²²

Evidence of Misconduct and Fraudulent Science

In February 2004, *The Lancet* editors were made aware that Dr. Wakefield failed to disclose conflicts of interest that could have affected the credibility of his 1998 paper.²³ In the 2 years prior to publication of that article, Dr. Wakefield received approximately \$670,000 in compensation as a consultant to attorneys representing parents of children allegedly harmed by the MMR vaccine.²⁴ After a cursory examination of the paper and request of an explanation from the senior author, *The Lancet* editors cleared Wakefield of misconduct, but stated that his failure to disclose conflicts of interest affected the suitability, credibility, and validity of the study.²⁵ Within a month, 11 of the 12 coauthors of the 1998 paper issued a formal retraction of the interpretation that there was a causal link between MMR vaccine and autism.²⁶

Because of the continuing controversy surrounding the Wakefield paper and its effects on public health, the British General Medical Council (GMC) initiated a formal investigation.²⁷ Three physicians and 2 laypersons spent almost 3 years (2007–2010) reviewing data sets and hearing evidence from witnesses on the 34 charges against Dr. Wakefield. The GMC found Dr. Wakefield guilty of a failure to disclose conflicts of interest, as well as medical and scientific misconduct.²⁸ In addition to his role as a consultant to attorneys, Wakefield failed to disclose that he was listed as an inventor on a patent for a new vaccine for the elimination of measles and was involved in a company that would produce and sell the new vaccine.^{28,29} The GMC also found that Wakefield and 2 coinvestigators were guilty of ethical and medical misconduct for performing a medical study that was not approved by a bioethics committee.²⁸ Moreover, Wakefield had acted “dishonestly and irresponsibly” with “callous disregard” for the children used in the study by performing invasive colonoscopies and lumbar puncture on children when it was neither clinically indicated nor germane to the study.²⁸ He was also found guilty of scientific misconduct. Wakefield and one of his coauthors biased the selection of children used in the 1998 paper in favor of families reporting an association between autism and MMR vaccine.²⁸ Based on the findings, a GMC Fitness to Practice Panel recommended revocation of Dr. Wakefield’s license to practice medicine in England.^{28,29}

In February 2010, *The Lancet* editors formally retracted the 1998 Wakefield paper from the published record based on the fact that the study was not approved by a bioethics committee and that the children were not randomly chosen

for inclusion in the study.²⁹ However, the narrow retraction criteria left open the possibility that the data and speculative conclusions were valid.

Subsequent examination of the data revealed that Wakefield had altered numerous facts about the children’s medical histories to support his claim of the new regressive autism-enterocolitis syndrome.^{30,31} None of the 12 cases he reported was free of misrepresentation, and medical histories could not be reconciled with diagnoses and histories described in *The Lancet*.^{30,31} Three of the 9 children reported as having regressive autism did not have a diagnosis of autism. Another 5 were not normal as described in the paper, and had preexisting developmental concerns.^{30,31} Moreover, the onset of autism symptoms occurred months after vaccination and not days after MMR vaccination, as reported in the article.^{30,31} Based on the data analyses, the editor of the *British Medical Journal* publicly declared that the Wakefield article linking the MMR vaccine to autism was fraudulent.³⁰

Although the Wakefield paper has been debunked and the vaccine-autism connection totally discredited based on scientific evidence, it is unlikely that these events will change the opinions of the lay public. The vaccine-autism connection provides a simple explanation to a complex problem while excluding the possibility of a genetic predisposition or in utero exposure to environmental agents as a cause of autism. It will be a challenge for public health officials to design targeted education programs that address parental concern about autism and vaccines.

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