

***The Ethics of the Scientific Community,  
Journals, Media and Public during the  
Recent MMR Controversy***

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## Introduction

MMR is the name of the vaccine against mumps, measles and rubella, which can be given in a single dose against all three diseases at ages between 12 and 15 months, with a booster to be given before going to school at around 3 to 5 years of age. This replaced the need to give separate vaccinations in 1988, which would require 6 separate inoculations and therefore making it easier and more likely that uptake of the vaccination would be taken by parents (Politics.co.uk.2010). All of these diseases can cause serious complications and even kill, and in the case of rubella, if it is contracted in the first trimester of pregnancy, there is a chance that this will cause damage to the unborn child resulting in miscarriage and still birth as well as other significant problems for the unborn child if it survives to the full term of the pregnancy. This paper will attempt to look at the facts surrounding the MMR scare initialised by Dr Andrew Wakefield *et al* in 1998 via research he undertook at that time, and the subsequent handling of the issue by the media, scientific journals and reaction by the public.

## The Facts and the Timeline

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|--|---|---|--|---|---|--|---|--|---|---|--|
| Original paper published by Wakefield <i>et al</i> in medical peer reviewed journal The Lancet | 14 year study in Helsinki by Patja <i>et al</i> | Wakefield & O'Leary (Dublin) have 'compelling evidence' of link | Wakefield claims MMR hasn't been properly tested | Prime Minister Tony Blair refuses to disclose whether son Leo was given MMR | MMR uptake reduced to 79% from previous 91% | The Lancet announce retraction of original paper | Japanese scientists Honda <i>et al</i> stating an unlikely link with MMR and Autism | 13 year old boy dies of measles first in 14 years. | GMC starts investigation into Wakefield | 2008 figures show 1000 cases of measles compared to 56 in 1998. 3 more deaths reported. | GMC find Wakefield unethical. Further hearings scheduled |
| 1998   | 2000  | 2000 (April)  | 2001   | 2001  | 2003  | 2004   | 2005  | 2006   | 2007                                    | 2009  | 2010   |
| <b>MMR Scandal Timeline</b>  |   |   |  |   |   |  |   |  |   |   |  |

In 1998, a paper was published in the medical journal, the Lancet by a team of doctors and lead by scientist Dr Andrew Wakefield from the Royal Free Hospital in London, describing research carried out which could link the occurrence of autism and bowel disorders (Wakefield *et al*. 1998). Meanwhile a study carried out in Helsinki and run by Patja *et al* (2000) followed 1.8 million individuals over 14 years from 1982-1996, who had received MMR vaccination stated in their report, that in view of the reported adverse reactions and after comprehensive analysis, that the indication that they were causally related to MMR vaccine was rare and would outweigh any risks of natural MMR disease. April 2000 saw Dr Wakefield and Dr John O'Leary (Coombe Womens Hospital, Dublin) that states there is 'compelling evidence' that there is a link. (Times Online.2010) In January 2001 there were claims made by Dr Wakefield that the MMR vaccine had not been tested properly and after being ostracised by the British medical community he and his family moved to America. (Times Online.2010) Tony Blair, the current Prime Minister who had previously supported the MMR vaccine refused to say if his son Leo had been given the vaccine in December 2001. (Times

Online.2010) 2003 saw a drop in the uptake of the MMR to 79% compared to a previous 91% in 1997 (Times Online.2010)

The Lancet in February 2004 announced that they were retracting the original 1998 paper issuing this statement from 10 of its original 12 authors, one of whom was unable to be contacted. *'We wish to make it clear that in this paper no causal link was established between MMR vaccine and autism as the data were insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract the interpretation placed upon these findings in the paper, according to precedent.'* (Murch *et al.*2004)

Further, Japanese scientists Honda *et al* published a paper in 2005 stating that Autism Spectrum Disorder (ASD) is most unlikely to have been caused by the MMR vaccination and that withdrawing from the MMR vaccination programme in countries where it is used would be unlikely to reduce the incidence of ASD occurring. In April 2006 a 13 year old boy dies from the measles, and is the first in 14 years. He had not been vaccinated with MMR. The GMC begins an investigation into Dr Wakefield in July 2007. Figures released in 2009 for 2008 show that in England there were well over 1000 cases of measles confirmed in comparison to 56 in 1998, with 3 more deaths reported. (Times online.2010)

Finally, in January 2010, the results of the GMC investigation into Dr Wakefield were released, after many delays. According to the GMC, Dr Wakefield abused his position, acted unethically and subjected the children to unnecessary investigations and brought the medical profession into disrepute. (BMJ.2010)

## **The Research and the Claims.**

The original research paper was carried out by Dr Andrew Wakefield *et al* (1998), in which 12 children were investigated via referral. The mean age of the children was 6 (from age 3 – 10) and 11 of those were boys. These children had shown normal development until they showed signs of loss of language and communication skills along with some gastrointestinal symptoms such as abdominal pain, diarrhoea, and some with food intolerance. These children were then subjected to intensive invasive investigative procedures including lumbar puncture, venepuncture, biopsy and ileocolonoscopy, as well as barium radiological procedures. Other procedures were performed such as magnetic resonance imaging (MRI), electroencephalography (EEG), as well as psychological, neurological and developmental assessments. The paper states that the behavioural problems had been noted by the parent to coincide with the administration of MMR Vaccine. All 12 had gastrointestinal problems. Of the behavioural problems, 9 had autism, 1 had disintegrative psychosis and 1 had possible post viral or vaccinal encephalitis. Accounts and records were accessed from parents, health visitors and GP's with regard to assessing the developmental progress of the children. Clinical examination showed no neurological abnormalities in any of the children. MRI, cerebrospinal fluid (CSF) analysis, EEG and radiological procedures revealed no abnormalities. Developmentally, all the boys showed normal early development with the one girl in the group reported to have developed on a slower level to her older sister. It was later discovered that she suffered from coarctation of the aorta for which she had surgery when she was 14 months old, when her developmental progress increased, and she learned to talk. This however was lost later. Of the 12 children 8 had had behavioural problems which were associated by the parents of the children or by their doctor to

the MMR vaccine. 5 of the 8 had an adverse reaction early on to the vaccine which caused them to suffer from rash, fever and delirium. 3 of those had convulsions. The average time it took to associate the behavioural problems with the vaccine was 6.1 days, between 1-14 days. It was less clear about a time span to link the intestinal problems by the parents as some of the children were not toilet trained.

The study was given ethical approval by the Ethics Approval committee at the Royal Free Hospital NHS Trust, London.

The study was accompanied by a press release and video news coverage. It received enormous attention from the media, as well as further attacks on the vaccine by Dr Wakefield and the media. (Deer.2010)

### **Was the Study Biased?**

The study itself might have had valid questions which could have been answered by a suitably designed investigation. However, there are some concerns over the methodology and seemingly aggressive investigations inflicted upon the children.

To begin with, any scientific investigation worthy of note warrants a large enough data set to ensure accuracy and non bias. This study had only 12 participants and as is stated in the discussion section of the paper, they were self referred all of whom had problems which could have come about with coincidence. (Wakefield *et al.*1998) The results from this study have never been replicated, and to deem a study viable one must be able to reproduce the results. Despite the attempts of scientists to do so, none have succeeded. Statistics showed that after MMR was introduced into the UK in 1988 that there were no significant in the increase in the occurrence of autism. Some scientists investigated the link with bowel disease through the study of virology, which wasn't shown to be the case. (Deer: Main points of investigation.2010)

Two years before any of this occurred; Wakefield was hired by a solicitor by the name of Richard Barr. He was attempting to bring a lawsuit against the companies who produced MMR. Wakefield's fee's which were paid by Barr happened to be raised from Legal Aid payments. These amounts added up to substantial payments and that alone could be indicative of bias in the study. (Deer: Summary.2010)

It was also reported in the Sunday Times in November 2004 (Deer.2004) by Brian Deer that Wakefield was developing a vaccine of his own against measles which would have been a rival of the MMR combined vaccine. Wakefield did not disclose any conflicting interests when criticising the MMR vaccine or casting doubt on its safety or effectiveness. Wakefield denied this; however, he did file a patent for such a vaccine in June 1997.

### **Conclusion**

There are some strong claims made by Wakefield *et al* regarding the safety of the MMR vaccine. These claims are well documented in the original paper (Wakefield *et al.* 1998) and seem to be little more than a

short study of **possible** links between MMR and autism as well as bowel disorders. The study shows that **these children** had indeed suffered from all of these disorders, but a study where there are only 12 subjects who were not handpicked for participation in the study, but were random referrals by the parents and their GP's. To make these claims defensible it would seem reasonable to call for further studies in this area rather than have stated on the evidence perceived that there was a definite link. The failure of the results to be replicated would also indicate that the evidence should not be relied on solely. Further scientific studies would require that a much larger group of subjects be investigated over a longer period of time, as well as a control study group. Such an undertaking would take time and planning to set the criteria and the parameters which should be measured.

Despite the seeming lack of scientific method in the original study, it was published by the Lancet, a major medical peer reviewed journal. It seems reasonable to assume that if the journal is peer reviewed, then all of the above factors must have been taken into account. Or were they? Who were the peers who reviewed the paper prior to publication, and even if they let it pass, why was none of this commented on before the decision was made by the editor to publish?

It would appear that perhaps the Lancet were a bit lax in their decision making policies as to what should be published.

As far as the handling of the story by the media, this all seemed to be fuelled by the press conference and a video news release which were held at the time of the publication. Is it any wonder there was so much interest in this story, given that it would have an effect on the lives of very many children and their parents? However, the media coverage could have been more objective rather than the tactless and often inaccurate method employed by some of the media such as the Mail Online. For example in a report published in the Mail Online in March 2003, Wakefield was reported to have been obliged to leave his work at the Royal Free Hospital as he felt it had been imperilled, giving the impression that he was being ostracised. (Mail Online 2003). Or headlines such as that used in the Sunday Express, "Jab as deadly as the cancer" which do little to inspire confidence among the general public. (Tabloid Watch.2009) Nevertheless, newspapers such as these remain to be among the highest read in the country despite other broadsheets giving a more informed and less emotional account of the issue at hand. On searching the Sunday Express website for the article related to the headline referred to in Tabloid watch, it returned a message "ARTICLE MISSING - The article you are looking for does not exist. It may have been deleted." (Article search.2010) The Mail published a story outlining the plight of one little girl who developed problems only two days after being vaccinated by MMR. (Ellise.2009). While this story is heart rendering it hardly provides proof that her problems were specifically linked to having had the MMR vaccine. In complete contrast to the tabloid sensationalism, there are the broadsheets such as the Telegraph who reported a more factual based account of the events to date using more explanatory headlines such as "MMR bowel disorder called into question" and "Mumps cases triple in a year" (MMR Vaccine search.2010). The former articles simply and briefly states that the link between the bowel disorder and the vaccine and that the pathologist who tested the bowel specimens described the tissue as normal despite the fact that the original Wakefield *et al* paper attributed them with having ileal-lymphoid-nodular hyperplasia, or non specific colitis. Headlines are a useful tool for the media which 'hooks' the reader into the story at hand. Tabloids exploit this by overstating and using scare tactics and emotional language in

order to pull in the readers and then misquote or distort the facts, if indeed the facts are laid out within the article.

The incident seems to have been mishandled on all levels. Firstly by the authors of the paper itself, in that it was not a complete scientific study and warranted more investigation. Secondly by Dr Wakefield in holding a press conference in addition to releasing a news video where he publicly doubts the safety of the MMR vaccine, and also the facts that later transpired regarding liaison with a lawyer looking to discredit the MMR production companies as well as Dr Wakefield himself planning to develop his own rival measles vaccine. The Lancet might have been more scrutinising over the article before it was published, and the media could have had less influence over the general public reaction had the tabloids not resorted to their scaremongering and fear fuelling tactics.

Had this been the case, then perhaps there would not have been the vast drop in parents having children vaccinated, which led to an upsurge of childhood diseases such as measles which can lead to debilitating and sometimes fatal consequences.

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