



Promoting Integrity as an Integral Dimension of Excellence in Research

Case study: Wakefield and MMR

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Case Study 1: The MMR Fiasco

Summary

This case study documents what is probably the most notorious and most publicised case of alleged research misconduct in the UK which led to a global public health crisis regarding the safety of the Measles, Mumps and Rubella (MMR) vaccination. The case follows a timeline of over 20 years, over which allegations and investigations regarding the research and the accused, Andrew Wakefield, have emerged. Whilst the research in this case was contentious amongst the scientific community from the outset, the work of the investigative journalist Brian Deer, the whistle-blower in this case, exposed more worrying issues about the integrity of the research. The outcomes of this case culminated in the longest ever medical fitness to practise investigation conducted by the General Medical Council (GMC)¹ which resulted in Wakefield being struck-off the medical register along with one of his co-authors Professor John Walker-Smith and the journal articles documenting this research were retracted. Whilst Walker-Smith has gone on to successfully appeal his removal from the medical register, Wakefield has not attempted to clear his name by appealing the GMC ruling. Nevertheless, throughout the entire case, Wakefield has remained belligerent, standing by his research and denying any wrong-doing. Fascinating is that he still continues his work, albeit in the US and retains a great deal of support amongst the public despite the scientific consensus that his theories are flawed and compelling evidence that he has committed research misconduct and acted unprofessionally and without integrity.

Methods

Evidence for this case study consists of documents that are publicly available via the internet. The evidence was gathered through a combination of on-line searches for relevant keywords (e.g. Dr Andrew Wakefield, MMR, misconduct, etc) using Google and Google Scholar. Furthermore, evidence was gathered through following a 'paper-trail' of citations and information from documents as they were collected. Table 1 below details the different types of data and sources below (also see references and bibliography for full details of sources used). Unfortunately, due to time constraints it was not possible to conduct interviews with any actors related to this case.

Table 1: list of evidence sources

Type	Source
Newspaper articles & online news articles	The Sunday Times, The Guardian, The Telegraph
Webpages	UCL, The Russell Group, Whistle-blower's website
Official documents	GMC Fitness to practice hearing, UCL Policy response, Wakefield v Channel 4 & others Libel case decision
Press releases	UCL, UKRIO
Personal & official correspondence	Letters of complaint to GMC by whistle-blower
TV programmes	Channel 4 Dispatches documentary by the whistle-blower

¹ Deer, B. The Lancet's two days to bury bad news. BMJ, 2011; 342:c7001.

	BBC Panorama BBC Horizon
Other Audio/visual	Vaxxed & video recorded interviews with the accused
Academic Journal Articles	The Lancet, BMJ, The open Vaccine Journal, The American Journal of Gastroenterology Molecular Pathology

Types of alleged misconduct:

There are a number of areas of misconduct that have been alleged in this case:

First it is alleged that the research itself is flawed and there is insufficient evidence for the conclusions drawn, this was later expanded to suggest that in fact the data was manipulated potentially including some falsification to make the findings favourable to the hypothesis of the accused.

Later investigations lead to accusations about unethical treatment of research participants, and deviation from the original ethical approvals obtained from Royal Free Hospital research ethics committee.

There is also accusation of conflict of interest in terms of the funding of the accused by a lawyer working on behalf of families seeking to take legal action against the manufacturers of the MMR vaccine. But also that the accused had business interests and patents for a single vaccine.

The academic institution employing the accused has been criticised for the handling of the case and its initial actions publically promoting the research and the views of the accused, leading to a media uproar about the research which greatly affected public trust in the government MMR vaccination programme, with public health repercussions world-wide.

Finally the Editor of The Lancet has been criticised for the role that the journal played in the case, allegedly failing to properly peer review the original research and allowing it to remain in the public sphere without full retraction for twelve years.

Background information of the Accused

Andrew Wakefield

Andrew Wakefield trained in Medicine at St Mary's Hospital Medical School where he qualified in 1981, later becoming a fellow of the Royal College of Surgeons in 1985 and specialising in Gastroenterology. He worked in Canada for several years in the late 1980s, before returning to work in the UK at the Royal Free Hospital in the 1990s, initially as a Senior Lecturer in the Departments of Medicine and Histopathology, followed by the role of Reader in experimental Gastroenterology from May 1997². In this role, Wakefield was an Honorary Consultant in Experimental Gastroenterology but his contract "*stipulated that he should have no involvement in the clinical management of*

² GMC Fitness to Practise Hearing, 28th January 2010 Available online, accessed 20/9/2017: <http://briandeer.com/solved/gmc-charge-sheet.pdf>

patients”³. Wakefield worked at the Royal Free investigating a controversial and now known to be unsubstantiated theory that linked the single measles vaccine to Crohn's Disease⁴. During this time, he was contacted by parents of children with autism who believed that the MMR vaccine may have caused the disease due to the onset of the disease post MMR, which also included intestinal problems⁵. Wakefield claims that it was these cases that triggered his interest in autism and the start of his work investigating a link of MMR to a syndrome with symptoms of inflammatory bowel disease and autism⁶.

As soon as Wakefield et al's research was published in The Lancet in 1998, it was controversial and heavily criticised amongst the scientific community for lacking any substantiated proof of a link between MMR and inflammatory bowel disease and autism⁷. Furthermore, the research had become extremely politically charged due to the huge media attention it received. The public health consequences of which, led to Dr Wakefield's mutually agreed resignation from his post at the Royal Free Hospital in 2001⁸.

After investigations by Brian Deer commenced in 2003, accusations of misconduct regarding the ethical conduct of the research and potential conflict of interests emerged in 2004⁹; by this time Wakefield had moved from the UK and was working in the US as Research Director of the International Child Development Rescue Center, run by Dr Jeff Bradstreet, a controversial figure, who claims to treat Autism with 80% success¹⁰.

Background information about the whistle-blower

Brian Deer

Brian Deer is a British investigative journalist who is known for working in 'social affairs journalism' since the 1980s, mainly for the Times and Sunday Times newspapers¹¹. His work has looked at a range of social issues, and has a large medical focus with investigations into the pharmaceutical industry and medicine where he has uncovered several cases of scientific misconduct, including Dr Andrew Wakefield, the accused in this case¹².

Deer initially conducts a four-month investigation of Wakefield's MMR research for The Sunday Times initiated in 2003 and culminating in the publication of an article on the 22nd February 2004¹³. His investigations into Wakefield continued and he reported on further allegations of wrong-doing in

³ Ibid.

⁴ BBC Horizon, 2005, Does MMR Cause Autism? 2005 available online, accessed 20/9/2017:

https://www.youtube.com/watch?v=VxFII53_qKY, <https://www.youtube.com/watch?v=3I-XaxJQNyA>,
https://www.youtube.com/watch?v=BUeJ7nyb_MA, <https://www.youtube.com/watch?v=Dh0CwtZ2pno>

⁵ Ibid; Wakefield, A, Dr Wakefield deals with allegations, 2016, Available online, accessed 20/9/2017:

<http://vaxxedthemovie.com/dr-andrew-wakefield-deals-with-allegations/>

⁶ Ibid.

⁷ BBC, Horizon, 2005

⁸ BBC Panorama, 2005

⁹ Deer, B, Revealed: MMR research scandal, 22nd February 2004, The Sunday Times, available online, accessed 20/9/2017: <http://briandeer.com/mmr/lancet-deer-1.htm>

¹⁰ Deer, B. Wakefield joins strange enterprise when “transfer factor” autism products fail [no date], available online, accessed 20/9/2017: <http://briandeer.com/wakefield/wakefield-quack.htm>

¹¹ Deer, B. Overview of website [no date] Available online, accessed 20/9/2017: <http://briandeer.com/deer-site-guide.htm>

¹² Ibid.

¹³ Deer, B, Revealed: MMR research scandal, 22nd February 2004, The Sunday Times

a Channel 4 Dispatches investigation aired on UK television in November 2004¹⁴. Deer also wrote to the General Medical Council (GMC) requesting them to investigate the professional conduct of Wakefield and also his colleagues Dr Simon Murch and Prof John Walker-Smith. Deer continued to explore the case and document the GMC hearings and finally published a feature series of articles in the BMJ in 2011 summing up the case.

The Institutional context

The Royal Free Hospital is part of the University College London (UCL) Medical School, a merger that occurred in 1998¹⁵. UCL is a prestigious UK university founded in 1826 and a member of the Russell Group, representing the top twenty four research intensive universities in the UK¹⁶.

At the time of Wakefield's employment at UCL and the Royal Free his boss and mentor was Professor Roy Pounder, Professor of Medicine at the Royal Free¹⁷. In 1999, Prof Mark Pepys takes over as head of the Medical School.

The research context

Dr Wakefield worked with other clinicians, all based at the Royal Free Hospital, part of University College London Medical School to conduct the case series of children exploring a new syndrome of bowel and developmental disorder, potentially linked to MMR, this research was reported in The Lancet in 1998. The clinicians came from the Inflammatory Bowel Disease Study Group, and the university departments of Paediatric Gastroenterology, Child and Adolescent Psychiatry, Neurology and Radiology¹⁸.

Prominent co-researchers of Wakefield in this case are:

Dr Simon Murch who was a Senior Lecturer in Paediatric Gastroenterology with an honorary consultant contract with the Royal Free Hampsted NHS Trust (1995-2004)¹⁹, who investigated inflammatory bowel disease, including the potential links to autism²⁰.

Professor John Walker Smith who was Professor of Paediatric Gastroenterology at the Royal Free Hospital School of Medicine with an honorary clinical contract with the Royal Free Hampsted NHS Trust²¹

Prof John O'Leary Trinity College, Dublin, who collaborated with Wakefield and the Royal Free research group during between February 1999 and 2003²².

¹⁴ Deer, B, Dispatches, Available online, accessed 20/9/2017:

<https://www.youtube.com/watch?v=7UbL8opM6TM>

¹⁵ MMR and the development of UCL's research governance framework, 13th September 2012, available online, accessed 29/6/2017: <http://www.ucl.ac.uk/news/news-articles/1209/13092012-Governance>

¹⁶ Russell Group, About our Universities: UCL [no date] available online: accessed 20/9/2017:

<http://russellgroup.ac.uk/about/our-universities/university-college-london/>

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¹⁸ Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A. RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. 1998, The Lancet, 637-641

¹⁹ GMC Fitness to Practise Hearing, 28th January 2010 Available online, accessed 20/9/2017:

<http://briandeer.com/solved/gmc-charge-sheet.pdf>

²⁰ BBC, Horizon, 2005

²¹ GMC Fitness to Practise Hearing, 28th January 2010

Timeline and discovery and accusation of misconduct

1998

Wakefield et al 'Early Report' paper was published in The Lancet²³. The paper reports on a case series of 12 children who apparently have a new syndrome linking "regressive autism" and "non-specific colitis" potentially caused by the MMR vaccine²⁴. However, the article makes no causal claim about a link to the MMR vaccine and the syndrome, something that Wakefield is keen to highlight in defence of the article to this day²⁵.

Wakefield claims that he had been studying the safety reports of vaccines and became concerned about the use of the MMR vaccine²⁶. His theory was (and still is) that the MMR vaccine could be the cause of the increase in cases of autism, and he claims that looking at the autism figures per country, there is a correlation of an increase in autism with when the MMR vaccine was introduced²⁷. His theory that was proposed in The Lancet article was that in some children with low immune systems the measles virus injected in the MMR shot stays in the body, causing a persistent infection in the gut causing inflammatory bowel disease which prevents efficient digestion, leading to a build-up of opioids that damages the developing brain, causing autism²⁸

There was a great deal of critical scientific response to the paper because the evidence of a potential link between MMR and inflammatory bowel disease and autism was highly speculative and not at all substantiated²⁹. Indeed, criticisms and concerns were voiced in correspondence about the article published in The Lancet³⁰, to which the Editor, Richard Horton replied: *"the paper by Andrew Wakefield and colleagues is an example of how researchers, editors, and those concerned with the public's health can work together to present new evidence in a scientifically balanced and careful way"*³¹.

Indeed, it seems fair to state that what really thrust the research into the public sphere was a press conference that was held at the Royal Free Hospital to launch the paper³². The press conference was organised by Professor Roy Pounder, Wakefield's boss at the Royal Free Hospital³³. During the press conference, Wakefield appears very confident about the results and conclusions of the research exclaiming: *"We would not have presented this paper to The Lancet had we not undertaken extensive virological studies already,"*³⁴ and stating: *"there is sufficient anxiety in my own mind about the safety of the MMR Vaccination, and I think that it should be suspended in favour of the single vaccine"*³⁵. Wakefield also claimed that it is *"a moral issue for me"* and *"I can't support the*

²² Deer, B, O'Leary denounces collaborator Wakefield as clouds gather over Dublin pathologist [no date] available online, accessed 20/9/2017: <http://briandeer.com/mmr/oleary-statement.htm>

²³ Wakefield AJ, Murch SH, Anthony A et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998; 351: 637-41.

²⁴ BBC Horizon, 2005; Deer, B. How the case against the MMR vaccine was fixed, BMJ, 2011, 342:c5347.

²⁵ Wakefield, A, Dr Wakefield deals with allegations, 2016

²⁶ Ibid.

²⁷ BBC Horizon, 2005.

²⁸ Ibid.

²⁹ BBC Horizon, 2005.

³⁰ Chen RT, DeStephano, F. Vaccine adverse events: causal or coincidental? Lancet, 1998; 351: 611-12.

³¹ Horton, R. Editor's reply. The Lancet, 1998; 351: 908.

³² Ibid

³³ Wakefield, A, Dr Wakefield deals with allegations, 2016.

³⁴ Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

³⁵ BBC Horizon, 2005.

*continued use of these three vaccines, given in combination, until this issue has been resolved*³⁶.

Thus, the comments made by Dr Wakefield at the press conference differed from the more tentative conclusions made in the article itself, triggering an explosion of media interest in MMR and, creating controversy about the use of the triple vaccination. Wakefield claims that Pounder was well aware of his views regarding MMR and yet insisted that he attend the press conference to discuss his research³⁷.

The media storm surrounding the research subsequently initiated a decline in uptake of MMR vaccination across the country and demands for the single vaccine³⁸. Nevertheless, right from the start there was disagreement with Wakefield amongst the scientific community: Dr Liz Miller (of the UK's Health Protection Agency) disagreed with Wakefield's claims and raised concerns about his suggestion, particularly since there was a scientific rationale for providing the triple vaccination, including ensuring that full vaccination has been obtained and preventing spread of Rubella that can be damaging to unborn children³⁹.

2000

Wakefield et al publish a paper in the American Journal of Gastroenterology which utilises data collected from the 12 patients from the 1998 paper published in The Lancet⁴⁰.

2001

In January 2001, it is revealed that the UK government is to spend £3 Million on an advertising campaign to inform the public and medical professionals that they deem the MMR vaccine effective and safe to use, due to a decrease in uptake of the vaccine in the UK⁴¹. On the 22nd January, the Chief Medical Officer for England, Prof Liam Donaldson called a meeting of medical professionals to appraise the MMR evidence⁴². A UK government press conference is also conducted, including medical experts aimed at reassuring people about the MMR vaccine and counter the concern raised by Wakefield⁴³. Strong criticism of Wakefield et al's research is evident at this stage amongst scientists, for example a member of the government advisory authority Medicines Control Agency, Stephen Evans, is reported as saying that the research was *"flawed, contained errors of fact and had not been completely peer reviewed"*⁴⁴. Nevertheless, there is also considerable support of Wakefield and criticism of the government by families of autistic children convinced of a link between MMR, inflammatory bowel disease and autism, with in excess of 500 families seeking to sue manufacturers of the vaccine⁴⁵.

³⁶ Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

³⁷ Wakefield, A, Vaxxed, 2016

³⁸ BBC, Horizon, 2005

³⁹ Ibid.

⁴⁰ A J Wakefield, A Anthony, S H Murch, M Thomson, S M Montgomery, S Davies, J J O'Leary, M Berelowitz and J A Walker-Smith, Enterocolitis in children with developmental disorders Enterocolitis in Developmentally Disabled Children, September 2000, *The American Journal of Gastroenterology* **95**, 2285-2295.

⁴¹ Hall, C, Campaign to persuade parents that the MMR jab is safe, 23rd January 2001, The Telegraph, available online, accessed 20/9/2017: <http://www.telegraph.co.uk/news/uknews/1319029/Campaign-to-persuade-parents-that-the-MMR-jab-is-safe.html>

⁴² Ibid.

⁴³ Barclay, Sarah, BBC Panorama, MMR the debate, 2002, Available online, accessed 20/9/2017: <https://www.youtube.com/watch?v=cpyjnys3Nf0>

⁴⁴ Hall, C, Campaign to persuade parents that the MMR jab is safe, 23rd January 2001, The Telegraph

⁴⁵ Ibid.

In March 2001, at a UK parliamentary committee investigating autism Andrew Wakefield is asked to present, and describes his current 'double hit theory' in which he claims that some children who have received 2 doses of MMR may go on to develop autism, to evidence this, Wakefield uses a case study of a child 'Christopher Walker'⁴⁶.

25th April 2001 – Wakefield attends congressional hearing into link between MMR vaccine and autism in the US in which *'Wakefield is seen as something of a hero'*⁴⁷. At this meeting, there is more sympathy and support for Wakefield than there is for the UK government representative researcher (Dr Liz Miller) who claims to have evidence that MMR vaccine does not increase the likelihood of developing autism⁴⁸.

In November 2001, Wakefield leaves the Royal Free Hospital 'by mutual agreement'⁴⁹, although it is reported in The Telegraph that Wakefield was forced out, with him claiming *"I have been asked to go because my research results are unpopular"*, stating that he agreed to leave with the hope that this would *"take the political pressure off my colleagues and allow them to get on with the job of looking after the many sick children we have seen"*⁵⁰. At this point in time, despite much criticism of his theories, there was no accusation that Wakefield had committed research misconduct, although the UK government and World Health Organisation (WHO) did not support the findings of Wakefield's research and maintained that children should be vaccinated with MMR⁵¹.

2002

A BBC Panorama documentary is aired – Dr Simon Murch expresses concern about the research linking MMR to autism, as a clinician he states that it is problematic because it threatens vaccine uptake and there is no hard evidence about the link⁵².

Prof Brent Taylor at the Royal Free criticises Wakefield for not utilising rigorous methods to investigate his hypothesis about MMR⁵³, he has not been able to reproduce the research nor has anyone else

The Panorama programme reports on findings of Prof John O'Leary, a specialist in detecting viruses based in Trinity College, Dublin. O'Leary collaborated with Wakefield to investigate whether the measles virus could be detected in gut and blood samples of autistic children. In the Panorama documentary, O'Leary states that the measles virus was detected in 82% of the autistic children: *"we've identified a persistent measles infection in the guts of these children, which is statistically significant as compared to normal controls"*⁵⁴. The findings were subsequently published in the

⁴⁶ BBC Panorama, 2002

⁴⁷ Ibid.

⁴⁸ BBC panorama, 2002

⁴⁹ BBC Panorama, 2002

⁵⁰ Fraser, L, Anti-MMR doctor is forced out, The Telegraph, 2nd December 2001, available online, accessed 20/9/2017: <http://www.telegraph.co.uk/news/uknews/1364080/Anti-MMR-doctor-is-forced-out.html>

⁵¹ Ibid.

⁵² BBC Panorama, 2002

⁵³ BBC Panorama, 2002

⁵⁴ Ibid.

journal Molecular Pathology⁵⁵ and the MMR controversy is reignited⁵⁶. Nevertheless, the wider scientific community remained sceptical⁵⁷, indeed Wakefield's team had not been able to find this evidence in their earlier investigations of the bowel tissue⁵⁸.

In the Panorama documentary, Wakefield claims that the research team have investigated around 200 cases of inflammatory bowel issues in children, finding *"a remarkably consistent disease"*⁵⁹. Furthermore, he defends making the link between MMR and autism, stating that *"Proof may be ten, fifteen years away in terms of definitive scientific proof... the proof was there, that the questions that the parents had raised were valid..."*⁶⁰

The BBC documentary also highlights that by 2002, uptake of MMR vaccine in some areas of the UK are well below that what is needed for herd immunity⁶¹, spurring the UK government to invest in an advertising campaign to push the message to parents that MMR is safe despite claims made by Wakefield⁶².

2003

Brian Deer is employed by The Sunday Times to investigate Andrew Wakefield and the Royal Free team's research.

2004

On the 22nd February 2004, Deer's investigation of Dr Wakefield's work is published in The Sunday Times. It is claimed that Wakefield deceived both his colleagues and The Lancet, by failing to mention a conflict of interest, exposing that at the time of the research, he was in receipt of funds from lawyer Richard Barr of Dawbarns Solicitors, Norfolk, to seek evidence to use against manufacturers of MMR⁶³. Deer made the link through reviewing an article about the MMR legal case involving Rosemary Kessick, reported in The Independent newspaper in 1996 which highlights the research conducted at the Royal Free Hospital, funded by Dawbarns Solicitors⁶⁴.

Rather than being a random sample, several families whose children were participants reported in The Lancet paper were clients of Lawyer Richard Barr, seeking to sue manufacturers of the MMR vaccine or had heard about Wakefield through 'Jabs' an MMR campaign group⁶⁵. However, unknown to the families involved in the research, was that Wakefield had been employed by Jabs Lawyer Richard Barr, who was utilising 'legal aid' funding from the UK government to bring a case against MMR manufacturers⁶⁶. Barr used some of his legal aid budget to employ Wakefield to

⁵⁵ Uhlmann V, Martin CM, Sheils O, Pilkington L, Silva I, Killalea A, Murch SB, Walker-Smith J, Thomson M, Wakefield AJ, O'Leary JJ. Potential viral pathogenic mechanism for new variant inflammatory bowel disease. Molecular Pathology. 2002 Apr; 55(2):84.

⁵⁶ BBC Horizon, 2005

⁵⁷ Ibid; BBC Panorama, 2002

⁵⁸ BBC Horizon, 2005; Deer, B, Dispatches,

⁵⁹ BBC Panorama, 2002

⁶⁰ Ibid.

⁶¹ BBC panorama

⁶² BBC panorama, 2002

⁶³ Deer, B. Revealed: MMR research scandal, The Sunday Times, 22nd February 2004.

⁶⁴ Deer, B, Rosemary Kessick's son was in lawyer's project which underlay vaccine scare [no date], available online, assessed 20/9/2017: <http://briandeer.com/wakefield/dawbarns-kessick.htm>

⁶⁵ Ibid; Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

⁶⁶ Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

explore any links between MMR and autism, funding his research and paying him £435,643⁶⁷. No mention of this funding or prior research agenda are made in the paper published in The Lancet⁶⁸.

In addition to the allegations of conflict of interests, Deer also questioned the validity of the ethical approval for Wakefield et al's research and their treatment of research participants⁶⁹. Deer alleged that the research conducted did not correspond to the approval sought from and subsequently provided by the Royal Free Hospital research ethics committee⁷⁰. Furthermore, Deer had reason to believe that the highly invasive procedures (lumbar punctures and intubations) which were conducted on some of the vulnerable children, were unwarranted because they were not approved by the ethics committee, but nor were they 'clinically indicated' investigations⁷¹.

The Editor-in-Chief of The Lancet, Dr Richard Horton, along with five other Lancet editors were informed about Deer's investigation at a meeting with Deer, three days before his article was due to be published in The Sunday Times⁷². During the meeting they were presented with "*confidential and embargoed material*"⁷³ about the investigation which Deer claims was breached by journal, who promptly issued a press release before Deer's article was published in collaboration with Murch, Walker-Smith, Wakefield and Professor Humphrey Hodgson, Vice-Dean at the Royal Free and University College School of Medicine⁷⁴.

The press release by The Lancet consisted of statements by Horton the editor, Murch, Walker-Smith and Wakefield and Hodgson⁷⁵. Horton explained that the statements published followed the Committee On Publication Ethics (COPE) guidelines to provide "*full disclosure and transparency concerning these allegations*" and goes on to claim that the "*allegations of alleged research misconduct have been answered by clarifications provided by the senior authors of this work*"⁷⁶. The accusations about improper ethical conduct of the research were strongly refuted by the authors but it was conceded that the potential conflict of interest arising from the Legal Aid funding should have been declared in the original article, because this could have affected appraisal of the work⁷⁷. In the statement provided by Hodgson, representing the Royal Free and UCL, it was concluded that they were "*entirely satisfied*" that the research had been subject to independent and "*rigorous ethical scrutiny*"⁷⁸. Needless-to-say, Deer was critical of The Lancet press release and annoyed that Horton had colluded with the others to publish statements concerning his work that had been provided in confidence, prior to it being published⁷⁹. What resulted was another "*media firestorm*", whereby Deer's article in The Sunday Times was one of many⁸⁰.

⁶⁷ Ibid.

⁶⁸ Deer, B. Revealed: MMR research scandal, The Sunday Times, 22nd February 2004.

⁶⁹ Deer, B. Letter of complaint to the GMC, 25th February 2004; Deer, B. The Lancet's two days to bury bad news. BMJ, 2011.

⁷⁰ Ibid.

⁷¹ Deer, B. Letter of complaint to the GMC, 25th February 2004;

⁷² Deer, B. The Lancet's two days to bury bad news. BMJ, 2011

⁷³ Deer, B. Letter of complaint to the GMC, 25th February 2004.

⁷⁴ Deer, B. Letter of complaint to the GMC, 25th February 2004; Deer, B. The Lancet scandal [no date] available online, accessed 20/9/2017: <http://briandeer.com/mmr-lancet.htm>; Deer, B. The Lancet's two days to bury bad news. BMJ, 2011

⁷⁵ Statement, The Lancet, 2004: 363: 820-824.

⁷⁶ Ibid.

⁷⁷ Ibid.

⁷⁸ Ibid pg.: 824.

⁷⁹ Deer, B. The Lancet's two days to bury bad news. BMJ, 2011

⁸⁰ Ibid.

In Deer's report three days later, the Editor of The Lancet is reported as stating that Wakefield's link between MMR and autism was "*entirely flawed*" and should not have been published⁸¹. Indeed, the then Editor of the BMJ, Dr Richard Smith also criticised the publication of the paper exclaiming: "*That MMR paper is the best example there has ever been of a very, very dodgy paper that has created a lot of discomfort and misery.*"⁸². Nevertheless, Wakefield publicly denied acting unethically and defended his research as being "*conducted in good faith*"⁸³; stating that the conflict of interest was "*a matter of opinion*"⁸⁴.

Wakefield's co-author, Dr Simon Murch claimed that learning about the legal aid funding was not something that he and his colleagues knew about, making it "*a very unpleasant surprise*" that had caused some anger⁸⁵. But, Murch also stated that he did not see the issue as "*personal corruption*", rather it was "*a clear conflict of interest — it was not declared to us and it was not declared to the journal, and it should have been.*"⁸⁶. However, another co-author Dr Peter Harvey defended Wakefield, claiming that there was no conflict of interest⁸⁷.

On the 25th February, Brian Deer writes a letter to the GMC (sent by email) requesting that they use their powers to investigate the conduct of Dr Wakefield in light of his investigation⁸⁸. In the correspondence Deer urges the GMC to investigate the conduct of Murch, Walker-Smith and Wakefield on grounds of the potentially dubious ethical conduct of the research, the issue of conflict of interest and scientific fraud.

On March 6th 2004, The Lancet publishes a partial retraction of the Wakefield et al, 1998 paper, whereby a 'retraction of interpretation' is made by ten authors of the original paper, only Wakefield and Peter Harvey do not support this retraction (and it was not possible to contact John Linnell)⁸⁹. The retraction of interpretation makes it clear that the 10 authors deem the evidence reported in the paper insufficient to make a causal link that the MMR vaccine causes autism and furthermore they retract the interpretation that there could be any such possibility in light of the public health concerns about the vaccine⁹⁰.

On the 1st July 2004, Brian Deer emails Tim Cox-Brown, Fitness to Practise Directorate at the GMC further to his previous request that Murch, Walker-Smith and Wakefield are investigated by the GMC⁹¹. In the email, Deer annotates his views in response to the statements written by all three doctors published in The Lancet on the basis of the documentary evidence he has gathered in his investigation of the research⁹². Again, Deer urges the GMC to investigate the professional conduct of all three doctors⁹³.

⁸¹ Deer, B. Revealed: MMR research scandal, The Sunday Times, 22nd February 2004

⁸² Ibid.

⁸³ Ibid; BBC News, Lead researcher defends MMR study, 22nd February, 2004, available online, accessed 20/9/2017: <http://news.bbc.co.uk/1/hi/health/3510721.stm>

⁸⁴ Deer, B. Revealed: MMR research scandal, The Sunday Times, 22nd February 2004

⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ Ibid.

⁸⁸ Deer, B. Letter of complaint to the GMC, 25th February 2004

⁸⁹ Horton, R. The lessons of MMR, The Lancet, March 2004; 363: 747; Murch, SH et al, Retraction of an interpretation, The Lancet; 363:750.

⁹⁰ Ibid.

⁹¹ Deer, B, email correspondence to Tim Cox-Brown, GMC, 1 July 2004.

⁹² Ibid.

⁹³ Ibid.

In November 2004, Channel 4 aired a Dispatches documentary ‘MMR: What they didn’t tell you’ based on Deer’s on-going investigations into Wakefield⁹⁴. The programme exposed that Wakefield’s laboratory had failed to find traces of the Measles virus in bowel tissue samples extracted from children with autism⁹⁵. This claim was corroborated by a former PhD student of Wakefield, Dr Nick Chadwick, who had developed a technique to test tissue samples and who co-authored a paper with Wakefield & Pounder regarding this method⁹⁶. Chadwick informed Deer that he had used method and found no vaccine strain measles virus in the gut samples of autistic children, and that apparently Wakefield was aware of this⁹⁷. But it is claimed that he ignores Chadwick’s findings since they are not compatible with his hypothesis and turns to another research team in Japan to validate his theory⁹⁸. Like the findings of the O’Leary work, it is argued that the presence of the measles virus is due to contamination⁹⁹

Another claim of the Dispatches programme is that prior to commencing the research Wakefield patents a range of products relating to a single measles vaccine (based on the controversial scientific ideas of Hugh Fudenberg), suggesting that Wakefield also had a commercial interest in discrediting the triple MMR vaccine¹⁰⁰.

2005

BBC Horizon documentary aired examining the evidence – Does MMR Cause Autism?¹⁰¹ The programme explores Wakefield’s claims about the potential link between MMR and inflammatory bowel disease and regressive autism, finding little basis for this assertion apart from anecdotal evidence of parents of children with autism¹⁰². It also reports on dozens of epidemiological studies that have been conducted, post-Wakefield, to explore his claims, which have found no link and conclude that the MMR vaccine is in fact safe and not responsible for rises in cases of Autism¹⁰³.

The programme debunks claims made by Wakefield, reported in the 2002 BBC Panorama programme: that is a ‘vulnerable subset’ of children are susceptible to autism triggered by MMR, who have the new and distinctive bowel disease identified by Dr Simon Murch (a member of the Royal Free Hospital team and co-author of the 1998 Lancet paper)¹⁰⁴. And, that traces of the measles virus had been found in the bowels of a ‘vulnerable subset’ of children with autism¹⁰⁵. It reports upon new clinical studies into that fail to replicate O’Leary’s findings and Dr Murch is featured, stating that the evidence now clearly demonstrates that there exists no link between MMR and Autism¹⁰⁶. Nevertheless, the programme highlights that Wakefield continues to believe that evidence will be found that proves his hypothesis and furthermore, documents continued support of

⁹⁴ Dispatches, MR, what they didn’t tell you, Channel 4, November 2004, Available online, accessed 20/9/2017: <https://www.youtube.com/watch?v=7Ubl8opM6TM>

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ Ibid.

⁹⁸ Ibid.

⁹⁹ Ibid.

¹⁰⁰ Ibid.

¹⁰¹ BBC Horizon, 2005, Does MMR Cause Autism? 2005 available online, accessed 20/9/2017:

https://www.youtube.com/watch?v=VxFII53_qKY

¹⁰² Ibid.

¹⁰³ Ibid.

¹⁰⁴ Ibid.

¹⁰⁵ Ibid.

¹⁰⁶ BBC Horizon, 2005, Does MMR Cause Autism? 2005

Wakefield's theories amongst parents of children with regressive autism, identifying that a lack of clinical research to investigate the issue has not helped to convince them otherwise¹⁰⁷.

2006

Wakefield takes Libel court action against Channel 4 Television Corporation, Twenty Twenty Productions Ltd and Brian Deer. The case is rejected by the judge The Hon Mr Justice Eady and Wakefield is instructed to cover legal costs.

2007

On 16th July 2007, the GMC fitness to practise tribunal against Dr Simon Murch, Prof John Walker-Smith and Dr Andrew Wakefield begins. The focus of the investigation is that the Doctors conducted unauthorised research upon the 12 children who were participants reported in the case series research published in The Lancet, rather than the validity of the findings of the research¹⁰⁸.

2009

On the 8th February 2009, Brian Deer reports in The Sunday times that none of the other twelve co-authors of the 1998 Lancet paper, were involved in preparing the data used¹⁰⁹. Deer claims that the his on-going investigation of Wakefield (including interviews with some parents of the children involved in case series and access to their medical records), combined with the evidence presented at the GMC hearing demonstrates that the findings of the Wakefield 1998 research were selectively reported and altered to assert a link between MMR and autism¹¹⁰. Significantly, timings of onset of symptoms reported by Wakefield et al, varied considerably from those documented in the medical records, as did diagnoses of both gut and behavioural problems¹¹¹. Indeed, Deer reports that seven out of the eleven children reported in the paper as having bowel problems did not according to other specialists at the Royal Free¹¹².

Importantly, Deer reports that in June 1996, prior to any of the children involved in the case series being examined by Wakefield and his collaborators, Wakefield and Richard Barr (the Jabs Lawyer) filed a document with the UK government's Legal Aid Board, claiming a 'new syndrome' for which they intended to seek evidence to legally represent families¹¹³. Thus, unknown to Wakefield's research participants or collaborators, the 'new syndrome' was already conceptualised and the purpose of the research was to retrospectively gather evidence to support his claims¹¹⁴.

The media report also highlights how Wakefield stands by his research, denies allegations made against him, and still works in Austin, Texas, conducting colonoscopies in children and touring the US giving anti-vaccination lectures, whilst still maintaining a loyal following (including several participants who were involved in the original case series)¹¹⁵. It highlights exasperation amongst scientists that despite the evidence of wrong-doing, failure to replicate Wakefield's findings and

¹⁰⁷ Ibid.

¹⁰⁸ Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

¹⁰⁹ Deer, B. Hidden records show MMR truth, The Sunday Times, 8th February 2009.

¹¹⁰ Ibid.

¹¹¹ Ibid.

¹¹² Ibid.

¹¹³ Ibid.

¹¹⁴ Ibid.

¹¹⁵ Ibid.

clinical and epidemiological work that has gone on to disprove any link to MMR and autism, the controversy and mistrust of the vaccination among many members of the public remains¹¹⁶.

2010

28th January 2010, The GMC fitness to practise hearing of Murch, Walker-Smith and Wakefield finally concludes after two and a half years, making it the longest ever GMC disciplinary hearing¹¹⁷, during which the panel examined documentary evidence, and listened to cross-examinations of the three doctors and evidence provided by 36 witnesses¹¹⁸. The GMC found Wakefield guilty of 30 charges which included dishonesty and causing children to subject to invasive procedures that were clinically unjustified, and found Walker-Smith to be irresponsible and unethical¹¹⁹.

On 10th May 2010 both Wakefield and Walker-Smith were 'struck off' the medical register, but Murch was cleared over his involvement by the panel¹²⁰. Later, after appeal, Walker-Smith is reinstated¹²¹. The GMC Panel concluded that Wakefield committed "serious professional misconduct" and described him as "dishonest", "unethical" and "callous"¹²².

Following the findings of the GMC hearing, on 2nd February 2010, The Lancet retracts the Wakefield et al, 1998 article in response to the concerns about the work underlying the paper raised during the GMC hearing which contradicts the earlier investigation of the work by the Royal Free and UCL Medical School that stated that the study had full ethical approval (reported in a statement by Prof Humphrey Hodgson, Vice-Dean and Campus Director at the Royal Free and University College School of Medicine, printed in the Lancet 2004)¹²³.

In May, the American Journal of Gastroenterology follows suit and retracts the Wakefield et al 2000 paper on the basis that it contained data from the 12 patients included in the retracted 1998 paper published by The Lancet around which there were concerns about bias of the sample, inadequate ethical approval and potential bias in the interpretation of the data¹²⁴.

In May 2010 Wakefield publishes the book: Callous Disregard: Autisms and Vaccines: The Truth Behind a Tragedy in which he claims that his removal from the medical register was a political move to silence his criticism of vaccine safety¹²⁵. In a review of the book, Joel Harrison states that the

¹¹⁶ Ibid.

¹¹⁷ Deer, B. The Lancet's two days to bury bad news. BMJ, 2011; 342:c7001

¹¹⁸ GMC Fitness to Practise Hearing, 28th January 2010

¹¹⁹ Ibid; Deer, B. How the vaccine crisis was meant to make money, BMJ, 2011; 342:c5258

¹²⁰ Deer, B. Andrew Wakefield erased after tribunal rules him "dishonest", "unethical" and "callous" [No date] available online, accessed 20/9/2017: <http://briandeer.com/wakefield-deer.htm>.

¹²¹ Ibid.

¹²² Ibid; GMC Fitness to Practise Hearing, 28th January 2010

¹²³ The Editors of The Lancet, Retraction - Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children, The Lancet, 6–12 February 2010, Volume 375, Issue 9713, pg.445, Available online, accessed 20/9/2017:

<http://www.sciencedirect.com/science/article/pii/S0140673610601754?via%3Dihub>

¹²⁴ AJG, 2010, Errata, Corrigenda and Retractions, May 2010, Vol 105, pg.: 1214, Available online, accessed 20/9/2017: <https://www.nature.com/ajg/journal/v105/n5/pdf/ajg2010149a.pdf>

¹²⁵ Harrison, JA. Wrong about vaccine safety: A review of Andrew Wakefield's "Callous Disregard". The Open Vaccine Journal, 2013; 6:9-25.

main themes of the book are to first, discuss the vaccine safety studies and approval process and second, to discredit Brian Deer and the GMC fitness to practise panel hearings¹²⁶.

2011

Deer publishes a feature series in the BMJ: “Secrets of the MMR scare” detailing his full investigations regarding the work of Andrew Wakefield, supplemented by the evidence presented in the GMC fitness to practise hearings. In a series of 3 reports in January 2011 Deer discloses allegations of data fabrication/manipulation, unethical research practices and conflicts of interest. It is revealed that in addition to Wakefield’s commercial interests in developing a single measles vaccine, the Medical School at the Royal Free were also involved in the development of the single vaccine product patents, including Prof Roy Pounder, the organiser of the press conference, launching the 1998 Lancet paper, which Deer argues boosted the commercial plans¹²⁷. Deer claims that the business scheme with the School disintegrates when a new Head of Medicine, Prof Mark Pepys took over in 1999 and that Wakefield was finally paid to leave UCL in 2001 and with the condition that UCL were gagged from making any critical comments about him¹²⁸.

Also mentioned in one of Deer’s reports, is that Brent Taylor (head of community child health at Royal Free), who reputedly frequently clashed with Wakefield and Walker-Smith, claims that Wakefield’s team would “*talk about how they would win the Nobel Prize for this*” (referring to the MMR research)¹²⁹.

2012

Wakefield is reported as filing a defamation lawsuit against Deer, Fiona Godlee and the BMJ for the accusations of fraud made against him in the Feature series about him published in the BMJ in 2011. The case is filed in Texas in the US and is later dismissed (3/8/2012) by the Judge Amy Clark Meachum¹³⁰.

In January 2012, the BMJ and COPE hold a meeting to discuss research misconduct, which highlighted that the UK needs to strengthen procedures for investigating research misconduct¹³¹

UCL publish MMR and the development of a research governance framework in UCL, a document reflecting upon the MMR fiasco and what UCL can learn from the incident¹³². UCL state that they learnt a lot from the Wakefield incident and sought advice from the UK Research Integrity Office (UKRIO) about how to conduct a full investigation and detailed review of UCL governance

¹²⁶ Ibid.

¹²⁷ Deer, B. How the Vaccine crisis was meant to make money, BMJ, 2011.

¹²⁸ Ibid.

¹²⁹ Ibid.

¹³⁰ Meachum, A, Travis County, Texas, 201st District Court, 3rd August, 2012, available online, accessed 20/9/2017: <http://briandeer.com/solved/slapp-jurisdiction-dismissed.pdf>

¹³¹ UCL, MMR and the development of UCL’s research governance framework, Press Release, 13 September 2012, available online, accessed 29/6/2017: <http://www.ucl.ac.uk/news/news-articles/1209/13092012-Governance>

¹³² UCL, MMR and the development of UCL’s research governance framework, Press Release, 13 September 2012, available online, accessed 29/6/2017: <http://www.ucl.ac.uk/news/news-articles/1209/13092012-Governance> ; UKRIO, UKRIO responds to ‘MMR and the development of a research governance framework in UCL’, 13th September 2012, available online, accessed 29/6/2017: <http://ukrio.org/ukrio-responds-to-mmr-and-the-development-of-a-research-governance-framework-in-ucl/>

procedures, however, it was concluded that such a review would not be feasible for several reasons¹³³:

1. UCL would not have sufficient authority to require potential witnesses to contribute, UCL would therefore be unlikely to get full co-operation from all the individuals concerned
2. There is no formal complaint or complainant to trigger the formal UCL process
3. The considerable time that has elapsed since the initial research means that there evidence will likely be affected by failings in memory and, it is unlikely that full documentary evidence (lab notes etc.) would still be available to scrutinise.

UCL explain that their research governance framework is encompassed in 3 documents: the code of conduct for research, the procedure for investigating and resolving allegations of misconduct in academic research and the declaration of interest policy¹³⁴. All three documents were present in 2004 but since then have undergone considerable review, and the policy documents are now overseen by the UCL Research Governance Committee, which did not exist in 2004¹³⁵.

UCL states that as a consequence of the Wakefield case it has introduced a revised research governance framework “that is robust and fit for purpose”¹³⁶. The institution states that this framework must now be adequately embedded into management infrastructure and remain dynamic and workable to reflect ‘best practice’¹³⁷. UCL argue that institutions need to be self-reflective and also collaborate with others to critically review their policies and procedures annually and ‘actively raise the profile of research governance issues’¹³⁸.

UKRO also made a press release, welcoming the statement by UCL and stating that other institutions should similarly evaluate their own research governance policies to ensure that they are adequate and ‘fit-for-purpose’, in addition to promoting UKRIO as a valuable source of support and advice¹³⁹.

2016

Vaxxed: From Cover-Up to Catastrophe, a documentary directed by Wakefield is released, the film claims Autism is growing exponentially and that this increase can be attributed to the MMR vaccine, and that there is evidence to support this¹⁴⁰. The film is a polemic and effectively claims that there is a conspiracy between the US Centre for Disease Control (CDC) and manufacturers of the MMR vaccine (who have financial interests in the CDC) and that there is effectively a ‘revolving door’ between roles in industry, academia and policy makers¹⁴¹. The CDC and Pharmaceutical companies are accused of covering up that the MMR vaccine can cause autism in some vulnerable children, which is evidenced by a ‘whistle-blower’ Bill Thompson from the CDC¹⁴². Wakefield and others in the film claim that the evidence shows that the vaccination schedule for MMR means that it is given at

¹³³ Ibid.

¹³⁴ Ibid.

¹³⁵ Ibid.

¹³⁶ Ibid.

¹³⁷ Ibid.

¹³⁸ Ibid.

¹³⁹ UKRIO, UKRIO responds to ‘MMR and the development of a research governance framework in UCL’, 13th September 2012, available online, accessed 29/6/2017: <http://ukrio.org/ukrio-responds-to-mmr-and-the-development-of-a-research-governance-framework-in-ucl/>

¹⁴⁰ Wakefield, A. Vaxxed, 2016

¹⁴¹ Ibid.

¹⁴² Ibid. Interestingly this ‘whistle-blower’ does not speak openly in the film, rather his evidence is provided in the form of audio recordings secretly obtained without his knowledge.

an age when children are vulnerable to developing “isolated autism” because of the vaccine, particularly amongst children of African American descent¹⁴³.

Critics of the film claim that it ignores the fact that Wakefield has been discredited and struck off the General Medical Council register, and that his research has been disproven and heavily criticised¹⁴⁴. Furthermore, the film criticised for being very biased, and going against scientific consensus by failing to acknowledge a wealth of research into MMR and autism that has found no link¹⁴⁵.

In an interview with Wakefield on the Vaxxed website, he attempts to explain some of the allegations levelled at him by Deer¹⁴⁶: Wakefield claims that involvement with the MMR litigation occurred after his research rather than before as Deer claims¹⁴⁷. He also states that allegations that the research was funded for and done for the purposes of the litigation are “*absolutely untrue*”, rather he claims that the legal aid funds were to pay for him acting as a medical expert on behalf of the parents bringing the litigation, and that the Lancet study was paid for by the NHS.¹⁴⁸ Furthermore, Wakefield claims that the editor of the Lancet was told a year in advance of the paper being published that he was working with the legal team representing children believed to be affected by MMR; but he failed or forgot to tell this to the GMC investigation whilst under oath¹⁴⁹.

In the interview and Vaxxed film, Wakefield portrays himself as a medical expert championing the cause of parents and children who have been affected by the MMR vaccine; standing-up against the powerful pharmaceutical companies who are so influential of mainstream medical opinion. He claims that Deer has ‘*come after*’ him and ‘*concocted a fairy tale*’ framing him as an ‘*evil Dr*’ out to profiteer from causing controversy¹⁵⁰. Wakefield claims that Deer’s investigation was a ‘public relations strategy’ to silence and discredit him¹⁵¹.

In response to the accusations that he planned to profit from the single vaccine market through discrediting MMR, Wakefield claims that this is not true and that the patent held by the University that he was linked to, was not a single vaccine product¹⁵².

Finally, Wakefield also makes some counter allegations about Brian Deer, claiming that he has a very ‘*intimate*’ and ‘*close*’ relationship with GSK the manufacturers of MMR. He also highlights that James Murdoch (son of Rupert, owner of The Times – Deer’s funder and publisher) was on the board of GSK¹⁵³

2017

Whilst MMR vaccine uptake has increased again in the UK, the controversy about MMR continues. Wakefield remains to be supported by anti-vax groups and parents who claim a link between MMR and autism.

¹⁴³ Ibid.

¹⁴⁴ Glenza, J, Vaxxed: an expert view on controversial film about vaccines and autism, 2nd April 2016, The Guardian, available online, accessed 20/9/2017: <https://www.theguardian.com/film/2016/apr/02/vaxxed-film-scientist-interview-vaccines-autism>

¹⁴⁵ Ibid.

¹⁴⁶ Wakefield, A, Dr Wakefield deals with allegations, 2016.

¹⁴⁷ Ibid.

¹⁴⁸ Ibid.

¹⁴⁹ Ibid.

¹⁵⁰ Ibid.

¹⁵¹ Ibid.

¹⁵² Ibid.

¹⁵³ Ibid.

Resolutions & conclusions

Wakefield was paid to leave his position at the Royal Free in 2001 with a gag on Royal Free Hospital making any critical comment about him.

GMC removes Andrew Wakefield from the medical register after the fitness to practise hearing

In response to the GMC ruling papers in The Lancet and the American Journal of Gastroenterology are retracted in full.

The BMJ and COPE held a meeting to discuss the research misconduct in 2012 that is attended by institutional leaders from across the UK and highlights the need to strengthen processes for investigating research misconduct in the UK.

Institutional response UCL publishes a press release and policy statement reflecting on the MMR fiasco, there is recognition that research governance issues are important and that institutions should be periodically reflect on the adequacy of internal policies and procedures, as well as work together to maintain best practice.

The UK government has fought a continued public information campaign to refute the link between the MMR vaccine and Autism and counteract the drop in uptake of the vaccine. Only recently are the numbers of people opting for the vaccine starting to get back to the pre-MMR scare levels

To this day Wakefield denies any wrong doing and remains belligerent about the accusations made against him. He retains considerable support among parents concerned about MMR and is champion of the ant-vax movement. Despite rejection of Wakefield's claims by mainstream scientific opinion, the controversy rages on in public debate.

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