HOW THE CASE AGAINST THE MMR VACCINE WAS FIXED

In the first part of a special BMJ series, Brian Deer exposes the bogus data behind claims that launched a worldwide scare over the measles, mumps, and rubella vaccine, and reveals how the appearance of a link with autism was manufactured at a London medical school.

When I broke the news to the father of child 11, at first he did not believe me. “Wakefield told us my son was the 13th child they saw,” he said, gazing for the first time at the now infamous research paper which linked a purported new syndrome with the measles, mumps, and rubella (MMR) vaccine.1 “There’s only 12 in this.”

That paper was published in the Lancet on 28 February 1998. It was retracted on 2 February 2010.2 Authored by Andrew Wakefield, John Walker-Smith and 11 others from the Royal Free Hospital and School of Medicine, London, it reported on 12 developmentally challenged children, and triggered a decade long public health scare.

“Onset of behavioural symptoms was associated by the parents with measles, mumps, and rubella vaccination in eight of the 12 children,” began the paper’s “findings.” Adapting these claims as fact, its results section stated: “In these eight children, it was revealed that six had diarrhoea and three had gastrointestinal symptoms.”

But then he pointed at table 2—headed “neuropsychiatric diagnosis”—and for a second time objected. “That’s not true.”

Child 11 was among the eight whose parents apparently blamed MMR. The interval between his vaccination and the first “behavioural symptom” was reported as 1 week. This symptom was said to have appeared at age 15 months. But his father, whom I had tracked down, said this was wrong.

“From the information you provided me on our son, who I was shocked to hear had been included in their published study,” he wrote to me, after we met again in California, “the data clearly appeared to be distorted.”

He backed his concerns with medical records, including a Royal Free discharge summary. Although the family lived 5000 miles from the hospital, in February 1997 the boy (then aged 5) had been flown to London and admitted for Wakefield’s project, the undisclosed goal of which was to help sue the vaccine’s manufacturers.

Wakefield’s “syndrome”

Unknown to Mr 11, Wakefield was working on a lawsuit,3 for which he sought a bowel-brain “syndrome” as its centrepiece. Claiming an undiscovered £150 (€180; $230) an hour through a Norfolk solicitor named Richard Barr, he had been confidentially put on the payroll for two years before the paper was published, eventually grossing him £435 643, plus expenses.4

Curiously, however, Wakefield had already identified such a syndrome before the project that would reputedly discover it. “Children with enteritis/disintegrative disorder [an expression he used for bowel inflammation and regressive autism] form part of a new syndrome,” he and Barr explained in a confidential grant application to the UK government’s Legal Aid Board,5 before any of the children were investigated. “Nonetheless the evidence is undeniably in favour of a specific vaccine induced pathology.”

The two men also aimed to show a sudden onset “temporal association”—strong evidence in product liability. “Dr Wakefield feels that if we can show a clear time link between the vaccination and onset of symptoms,” Barr told the legal board, “we should be able to dispose of the suggestion that it’s simply a chance encounter.”6

But child 11’s case must have proved a disappointment. Records show his behavioural symptoms started too soon. “His developmental milestones were normal until 13 months of age,” notes the discharge summary. “In the period 13-18 months he developed slow speech patterns and repetitive hand movements. Over this period his parents remarked on his slow gradual deterioration.”

That put the first symptom two months earlier than reported in the Lancet, and a...
month before the boy had MMR. And this was not the only anomaly to catch the father’s eye. What the paper reported as a “behavioural symptom” was noted in records as a chest infection.

 “Please let me know if Andrew W has his doctor’s license revoked,” wrote Mr 11, who is convinced that many vaccines and environmental pollutants may be responsible for childhood brain disorders. “His misrepresentation of my son in his research paper is inexcusable. His motives for this I may never know.”

The father need not have worried. My investigation of the MMR issue exposed the frauds behind Wakefield’s research. Triggering the longest ever UK General Medical Council fitness to practise hearing, and forcing the Lancet to retract the paper, last May it led to Wakefield’s suspension, and forcing the GMC to investigate the MMR issue exposed the frauds behind Wakefield’s research paper.

HOW THE LINK WAS FIXED

The Lancet paper was a case series of 12 child patients; it reported a proposed “new syndrome” of enterocolitis and regressive autism and associated this with MMR as an “apparent precipitating event.” But in fact:

- Three of nine children reported with regressive autism did not have autism diagnoses at all. Only one child clearly had regressive autism
- Despite the paper claiming that all 12 children were “previously normal,” five had documented pre-existing developmental concerns
- Some children were reported to have experienced first behavioural symptoms within days of MMR, but the records documented these as starting some months after vaccination
- In nine cases, unremarkable colonic histopathology results—noting no or minimal fluctuations in inflammatory cell populations—were changed after a medical school “research review” to “non-specific colitis”
- The parents of eight children were reported as blaming MMR, but 11 families made this allegation at the hospital. The exclusion of three allegations—all giving times to onset of problems in months—helped to create the appearance of a 14 day temporal link
- Patients were recruited through anti-MMR campaigners, and the study was commissioned and funded for planned litigation

Lawsuit test case

But Mr 11 was not the first parent with a child in the study whom I interviewed during my investigation. That was Mrs 2: the first of the parents to approach Wakefield. She was sent to him by an anti-vaccine campaign called JABS. Her son had regressive autism, longstanding problems with diarrhoea, and was the prime example of the purported bowel and brain syndrome—still unsubstantiated 14 years later. This boy would appear in countless media reports, and was one of the four “best” cases in Barr’s lawsuit.

I travelled to the family home, 80 miles northeast of London, to hear about child 2 from his mother. That was in September 2003, when the lawsuit fell apart after counsel representing 1500 families said that, on the evidence, Barr’s autism claims would fail. By that time, Mrs 2 had seen her son’s medical records and expert reports, written for her case at trial.

Her concerns about MMR had been noted by her general practitioner when her son was 6 years old. But she told me the boy’s troubles began after his vaccination, which he received at 15 months. “He’d scream all night, and he started head banging, which he’d never done before,” she explained.

“When did that begin, do you think?” I asked.

“That began after a couple of months, a few months afterward, but it was still, it was concerning me enough, I remember going back.”

“So sorry. I don’t want to be, like, massively pernickety, but was it a few months, or a couple of months?”

“It was more like a few months because he’d had this, kind of, you know, slide down. He wasn’t right. He wasn’t right. Before he started.”

“Not quicker than two months, but not longer than how many months? What are we talking about here?”

“From memory, about six months, I think.”

The next day, she complained to my editors. She said my methods “seemed more akin to the gutter press.” But I was perplexed by her story, since there was no case in the Lancet that matched her careful account.

According to the paper, child 2 had his “first behavioural symptom” two weeks, not six months, after MMR. This was derived from a Royal Free medical history (citing “head banging” and “screaming” as the start) taken by Mark Berelowitz, a child psychiatrist and a coauthor of the paper. He saw Mrs 2 during the boy’s admission, at age 8, after she had discussed her son’s story with Wakefield.

As I later discovered, each family in the project was involved in such discussions before they saw the hospital’s clinicians. Wakefield phoned them at home, and must have at least suggestively questioned them, potentially impacting on later history taking. But I knew little of such things then, and shared my confusion with Walker-Smith, who I met shortly after Mrs 2.

“There is no case in the paper that is consistent with the case history [Mrs 2] has given me,” I told him. “There just isn’t one.”

“Well that could be true,” the former professor of paediatric gastroenterology replied, disarmingly. He knew the case well, having admitted the boy for the project and written reports for Barr, who paid him £23 000.

“Well, so either what she is telling me is not accurate, or the paper’s not accurate.”

“Well I can’t really comment,” he said. “You really touch on an area which I don’t think should be debated like this. And I think these parents are wrong to discuss such details, where you could be put in a position of having a lot of medical details and then try to match it with this, because it is a confidential matter.”

It was not merely medically confidential, it was also legally protected: a double screen against public scrutiny. But responding to my first MMR reports in the Sunday Times, in February 2004, the GMC decided to investigate the cases and requisitioned the children’s records.

The regulator’s main focus was whether the research was ethical. Mine was whether it was true. So as a five member disciplinary panel trawled through the records, with five Queen’s counsel and three defendant doctors, I compared them with what was published in the journal.

Multiple discrepancies

The paper gave the impression that the authors had been scrupulous in documenting the patients’ cases. “Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records,” it explained, specifying that Diagnostic and Statistical Manual of Mental Disorders IV (DSM IV) criteria were used for neuropsychiatric diagnoses. “Developmental histories included a review of prospective developmental records from parents, health visitors, and general practitioners.”

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When the details were dissected before the panel, however, multiple discrepancies emerged. A syndrome necessarily requires at least some consistency, but, as the records were laid out, Wakefield’s crumbled.

First to crack was “regressive autism,” the bedrock of his allegations. “Bear in mind that we are dealing with regressive autism in these children, not of classical autism where the child is not right from the beginning,” he later explained, for example, to a United States congressional committee.

But only one—child 2—clearly had regressive autism. Three of nine so described clearly did not. None of these three even had autism diagnoses, either at admission or on discharge from the Royal Free.

The paper did not reveal that two of this trio were brothers, living 60 miles south of the hospital. Both had histories of fits and bowel problems recorded before they received MMR. The elder, child 6, aged 4 years at admission, had Asperger’s syndrome, which is distinct from autism under DSM-IV, is not regressive, and was confirmed on discharge. His brother, child 7, was admitted at nearly 3 years of age without a diagnosis, and a post-discharge letter from senior paediatric registrar and Lancet coauthor David Casson summarised: “He is not thought to have features of autism.”

The third of this trio, child 12, was enrolled on the advice of the brothers’ mother—reported in media as a JABS activist, who had herself “only relatively recently” blamed the vaccine. Child 12 was aged 6 at admission and had previously been assessed for possible Asperger’s syndrome at Guy’s Hospital, London, by a renowned developmental paediatrician. She diagnosed “an impairment in respect of language”—an opinion left undisturbed by Berelowitz.

Mrs 12 was a GMC witness at its mammoth hearing, which between July 2007 and May 2010 ran for 217 days. She explained that the brothers’ mother had made her suspicious of MMR and gave her Barr’s and Wakefield’s names. Mrs 12 approached them and filed a statement for legal aid before her son was referred.

“It was like a jigsaw puzzle—it suddenly seemed to fit into place,” she told the panel, describing how she concluded, four years after the boy was vaccinated, that MMR was to blame for his problems. “I had this perfectly normal child who, as I could see, for no apparent reason started to not be normal.”

The 12 children were admitted between July 1996 and February 1997, and others had connections not revealed in the paper, almost as striking as the trio’s. The parents of child 9 and child 10 were contacts of Mrs 2, who ran a group that campaigned against MMR. And child 4 and child 8 were admitted—without outpatient appointments—for ileocolonoscopy and other invasive procedures, from one Tyneside general practice, 280 miles from the Royal Free, after advice from anti-MMR campaigners.

In the case of child 4, who received the vaccine at 4 years, Wakefield played down problems, suggesting that early issues had resolved. “Child four was kept under review for the first year of life because of wide bridging of the nose,” he reported in the paper. “He was discharged from follow-up as developmentally normal at age 1 year.”

But medical records, presented by the GMC, give a different picture for this child. Reports from his pre-MMR years were peppered with “concerns over his head and appearance,” “recurrent” diarrhoea, “developmental delay,” “general delay,” and restricted vocabulary. And although before his referral to Wakefield his mother had inquired about vaccine damage compensation, his files include a report of a “very small deletion within the fragile X gene,” and a note of the mother’s view that her concerns about his development began when he was 18 months old.

“In general, his mother thinks he developed normally initially and subsequently his problems worsened, and he lost some of his milestones, but he subsequently improved on a restrictive exclusion diet,” wrote his general practitioner, William Tapsfield, referring the boy, then aged 9, after a phone conversation with Wakefield. “The professionals who have known [child 4] since birth don’t entirely agree with this, however, and there is a suggestion that some of his problems may have started before vaccination.”

Similarly with child 8, who was also described in the Lancet.
as having overcome problems recorded before MMR. “The only girl . . . was noted to be a slow
developer compared with her older sister,”
the paper said. “She was subsequently found to
have coarctation of the aorta. After surgical
repair of the aorta at the age of 14 months, she
progressed rapidly, and learnt to talk. Speech
was lost later.”

But Wakefield was not a paediatrician. He
was a former trainee gastrointestinal
surgeon with a non-clinical medical school contract.10
And his interpretation differed from that of
local consultants (including a developmental
paediatrician and a geneticist) who had actually
looked after the girl. Her doctors put the
coarctation side by side with the developmental delay
dysmorphism, and noted of her vocabulary
that, before MMR at 18 months, she “vocalised”
only “two or three words.”

“Child 8’s mother has been to see me
and said you need a referral letter from me in
order to accept [child 8] into your investigation
programme,” the general practitioner, Diana
Jelly, wrote to Wakefield at referral, when the
girl was aged 3 and a half years. “I would simply
re-iterate . . . that both the hospital and members
of the primary care team involved with [child 8]
had significant concerns about her development
some months before she had her MMR.”

The girl’s general practice notes also provide
insight into the background to the 12 children’s
referrals. After person(s) unknown told Mrs 8
that her daughter may have inflammatory bowel
disease, Jelly wrote: “Mum taking her to Dr
Wakefield, Royal Free hospital for CT scans/gut
biopsies ?Crohn’s—will need rel letter—Dr Wake-
field to me funded through legal aid.”

The child was “pale”
The remaining five children served Wakefield’s
claims no better. There was still no convincing
MMR syndrome.

Child 1, aged 3 years when he was referred
to London, lived 100 miles from the Royal Free
and had an older brother who was diagnosed
as autistic. Child 1’s recorded story began
when he was aged 9 months, with a “new
patient” note by general practitioner Andrea
Barrow. One of the mother’s concerns was
that her son could not hear properly—which
might sound like a hallmark presentation of
classical autism, the emergence of which is
often insidious. Indeed, a Royal Free history,
by neurologist and coauthor Peter Harvey, noted
“normal milestones” until “18 months or so.”

This boy was vaccinated at 12 months of age,
however. Thus neither 9 nor 18 months helped
Wakefield’s case. But in the Lancet, the “first
behavioural symptom” was reported to have occurred “1 week” after the injection, holding
the evidence for the lawsuit on track.

Step 1 to achieve this: two and a half years
after the child was vaccinated, Walker-Smith
took an outpatient history. Although the mother
apparently had no worries following her son’s
vaccination, the professor elicited that the boy
was “pale” 7-10 days after the shot. He also elic-
ited that the child “possibly” had a fever, and
“may” have been delirious, as well as pale.

“It is difficult to associate a clear historical
link with the MMR and the answer to autism,”
Walker-Smith wrote to the general practitioner,
with a similar letter to Wakefield, “although
[Mrs 1] does believe that [child 1] had an illness
7-10 days after MMR when he was pale, ?fever,
?delirious, but wasn’t actually seen by a doctor.”

Step 2: for the Lancet Wakefield dropped
the question marks, turning Walker-Smith’s
queries into assertions. And, although Royal
Free admission and discharge records refer to
“classical” autism, step 3, the former surgeon
reported “delirium” as the first “behavioural
symptom” of regressive autism, with, step 4,
A “time to onset” of 7 days.

So here—behind the paper—is how Wakefield
evidenced his “syndrome” for the lawsuit, and
built his platform to launch the scare.

“It is significant that this syndrome
only appeared with the introduction of the
polyvalent MMR vaccine in 1988 rather than
with the monovalent measles vaccine intro-
duced in 1968,” he claimed in one of a string
of patents he filed for businesses to be spun
from the research.23 “This indicates that MMR
is responsible for this condition rather than just
the measles virus.”

Three of the four remaining children were
seen in outpatients on the same day—in
November 1996. None of their families were
reported in the paper as blaming the vaccine.
Child 5, from Berkshire, aged 7 at admission,
had received MMR at 16 months. The paper
reported concerns at 18 months, but the medi-
cal records noted fits and parental worries at
11 months. Child 9, aged 6, from Jersey, also
had MMR at 16 months. His mother dated
problems from 18-20 months. Child 10, aged 4,
from south Wales, contracted a viral infection,
which was suspected by parents and doctors
to have caused his disorder, four months after
his vaccination.

“Behavioural changes included repetitive
behaviour, disinterest in play or head banging,”
said a question and answer statement issued
by the medical school, concerning the Lancet 12,
on the day of the paper’s publication.

Another discrepancy to emerge during the
GMC hearing concerned the number of fami-
lies who blamed MMR. The paper said that
eight families (1, 2, 3, 4, 6, 7, 8, and 11) linked
developmental issues with the vaccine. But the
total in the records was actually 11. The par-
ents of child 5, 9, and 12 were also noted at the

<table>
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<th>Non-specific colitis</th>
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Comparison of three features of the 12 children in the Lancet paper with features apparent in the NHS
records, including those from the Royal Free hospital.

See supplementary data on bmj.com for a version of this table with detailed footnotes.

*Recessive developmental disorder—autism.
†Royal Free hospital pathology service.
‡First behavioural symptoms ≤14 days after MMR.
hospital as blaming the vaccine, but their stated beliefs were omitted from the journal.

**Case selection**

The frequency of these beliefs should not have surprised Wakefield, retained as he was to support a lawsuit. In the month that Barr engaged him—two years before the paper was published—the lawyer touted the doctor in a confidential newsletter to his MMR clients and contacts. “He has deeply depressingly views about the effect of vaccines on the nation’s children,” Barr said.24 “He is also anxious to arrange for tests to be carried out on any children . . . who are showing symptoms of possible Crohn’s disease. The following are signs to look for. If your child has suffered from all or any of these symptoms could you please contact us, and it may be appropriate to put you in touch with Dr Wakefield.”

The listed symptoms included pain, weight loss, fever, and mouth ulcers. Clients and contacts were quickly referred. Thus, an association between autism, digestive issues, and worries about MMR—the evidence that launched the vaccine scare—was bound to be found by the Royal Free’s clinicians because this was how the children were selected.

Moreover, through the omission from the paper of some parents’ beliefs that the vaccine was to blame, the time link for the lawsuit sharpened. With concerns logged from 11 of 12 families, the maximum time given to the onset of alleged symptoms was a (forensically unhelpful) four months. But in a version of the paper circulated at the Royal Free six months before publication, reported concerns fell to nine of 12 families but with a still unhelpful maximum of 56 days.25 Finally, Wakefield settled on 8 of 12 families, with a maximum interval to alleged symptoms of 14 days.

Between the latter two versions, revisions also slashed the mean time to alleged symptoms—from 14 to 6.3 days. “In these children the mean interval from exposure to the MMR vaccine to the development of the first behavioural symptom was six days, indicating a strong temporal association,” he emphasised, in a patent for, among other things, his own measles vaccine,26 eight months before the Lancet paper.

This leaves child 3. He was 6½ and lived on Merseyside: 200 miles from the hospital. He received MMR at 14 months, with the first concerns recorded in his GP notes 15 months after that. His mother—who 4 years later contacted Wakefield on the advice of JABS27—told me that her son had become aggressive towards a brother, and records say that his vocabulary had not developed.

“We both felt that the MMR needle had made [child 3] go the way he is today,” the parents wrote to a local paediatric neurologist, Lewis Rosenbloom, 18 months before their son’s referral to London. They told him they wanted “justice” from the vaccine’s manufacturer and that they had been turned down for legal aid.

“Although it is said that the MMR has never been proven to make children to be autistic, we believe that the injection has made [child 3] to be mentally delayed, which in turn may have triggered off the autism.”

I visited this family twice. Their affected son was now a teenager and a challenge both to himself and to others. His mother said his diagnosis was originally “severe learning difficulties with autistic tendencies,” but that she had fought to get it changed to autism.

As for a connection with MMR, there was only suspicion. I don’t think his family was sure, one way or the other. When I asked why they took him to the Royal Free, his father replied: “We were just vulnerable, we were looking for answers.”

What was unquestionably true was that child 3 had serious bowel trouble: intractable, lifelong, constipation. This was the most consistent feature among the 12 children’s symptoms and signs28 but, being the opposite of an expected finding in inflammatory bowel disease,29 was nowhere mentioned in the paper. This young man’s symptoms were so severe that he was dosed at his special school, his mother said, with up to five packets of laxative a day.

“You always knew when his stomach was hard,” she told me, in terms echoed over the years by many parents involved with Wakefield.

“No case was free of misreporting or alteration. Taken together, the NHS records cannot be reconciled with what was published, to such devastating effect. "He would start headbutting, kicking, breaking anything in the house. Then he would go to the toilet and release it.”

For the Royal Free team, however, when reporting on these patients, such motility symptoms30 were sidelined in the hunt for Wakefield’s syndrome. In almost all the children, they noted commonly swollen glands in the terminal ileum, and what was reported as “non-specific colitis.”31 32 In fact, as I revealed in the BMJ last April,33 the hospital’s pathology service found the children’s colons to be largely normal, but a medical school “review” changed the results.

In this evolution of the gut pathology to what was published in the Lancet, child 3’s case was a prime example. After ileocolonoscopy (which GMC prosecution and defence experts agreed was not clinically indicated), the hospital’s pathologists found all colonic samples to be “within normal histological limits.” But three months after the boy was discharged, Walker-Smith recalled the records and changed the diagnosis to “indeterminate ileocolitis.”34

“I think, sadly, this was the first child who was referred, and the long-term help we were able to give in terms of dealing with constipation was not there,” he told the GMC panel. “However, we had excluded Crohn’s disease and we had done our best to try and help this child, but in the end we did not.”

So that is the Lancet 12: the foundation of the vaccine scare. No case was free of misreporting or alteration. Taken together, the NHS records cannot be reconciled with what was published, to such devastating effect, in the journal (table).

Wakefield, however, denies wrongdoing, in any respect whatsoever.35 He says he never claimed the children had regressive autism, nor that he said they were previously normal. He never misreported or changed any findings
MMR SCARE

Brian Deer journalist, London, UK

Funding: Brian Deer’s investigation, which led to the General Medical Council inquiry, was funded by the Sunday Times of London and the Channel 4 television network. Reports by Deer in the BMJ were commissioned and paid for by the journal. No other funding was received, apart from legal costs paid to Deer by the Medical Protection Society on behalf of Andrew Wakefield.

Competing interests: The author has completed the unified competing interest form at www.icmje.org/coiDisclosure.pdf (available on request from him) and declares no support from any organisation for the submitted work, no financial relationships with any organisation that might have an interest in the submitted work in the previous three years, no EOC investigation led to the GMC proceedings referred to in this report, including the charges. He made many submissions of information but was not a party or witness in the case, nor involved in its conduct.

Provenance and peer review: Commissioned; externally peer reviewed.

3. MMR and MR vaccine litigation: Sayers and others v Smith & kinase Beecham plc and others. - [2007] All ER (D) 30 (Jun).
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