

Education and debate

Suspected research fraud: difficulties of getting at the truth

Caroline White

When research misconduct is suspected and the researcher is working outside the jurisdiction of official research bodies, there is nowhere for editors to turn. If they want to investigate their concerns, they are invariably forced to go it alone—a lengthy, costly, and difficult process

In April 1992 the *BMJ* published a randomised controlled trial on the effects of dietary intervention to prevent further heart attacks in susceptible patients.¹ One of its key findings was that a year of a low fat, fibre rich diet almost halved the risk of death from all causes.

This study went on to become a “citation classic,” cited 225 times (at the time of writing), including in guidelines, and its lead author, Dr Ram B Singh, went on to publish many papers in other journals. During the process, he became the focus of a concerted, but informal, international investigation into suspicions of scientific misconduct and data fabrication, spanning well over a decade.

Suspicious are raised

After the publication of his paper in April 1992, Dr Singh submitted another study (manuscript 924479) to the *BMJ* in October of that year. The study was a two year follow-up trial of the influence of diet and moderate exercise on cardiovascular health (the Indian diet heart study).

The external reviewer pointed out the absence of deaths from other causes, which he deemed “would be incredible.” Many of the risk factors “appear to move significantly in the desired direction,” he observed, concluding that “this trial may be reporting a more striking total benefit than most previously reported trials.”

The editorial committee also had several concerns about the reliability of the data, which were based on “questionnaire reports and poorly described assessments of food intake.” The participants were “extremely heterogeneous,” and no attempt had been made to control for the effects of smoking.

Other aspects of the trial seemed to have already been published in the *American Journal of Cardiology* in 1992,^{2,3} raising the possibility of “salami publishing”—publishing many papers, with minor differences, drawn from the same study.

Importantly, no reference had been made to the paper already published in the *BMJ*, despite clear similarities between the two trials and the study participants. Singh was asked to clarify the degree of overlap between the two studies in January 1993. His lack of response prompted a further letter six months later.



P. WRIGHT/WHO

Data on the influence of diet on cardiovascular risk factors are under scrutiny

Doubts are compounded

In June 1993 Singh submitted another epidemiological study (manuscript 933348) to the *BMJ*. This looked at the impact of diet on cardiovascular risk factors in rural and urban populations in northern India.

The reviewer, Paul McKeigue, now professor of genetic epidemiology at University College Dublin, recommended rejection on the grounds that the errors were “so numerous as to cast doubt on the reliability of the findings.”

According to McKeigue, he and his colleague George Davey Smith, now professor of clinical epidemiology at the University of Bristol, already had “serious concerns” about Dr Singh’s work, after an informal review of his publications. They explained the reasons for their concerns in a letter to the *BMJ*s then editor, Richard Smith, in July 1993.

The “inconsistencies or unlikely results” in numerous recent papers in international journals, coupled with the “extraordinarily impressive nature of some of these results,” including those presented to the third international conference on preventive cardiology in Oslo in 1993, and Singh’s remarkable productivity, had aroused their suspicions, they wrote. They pointed out

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P+ A list of key events and a bibliography of Singh’s publications are on bmj.com

that Dr Singh had been the first author on 28 full articles between 1989 and 1993, and that he had published at least five large intervention trials within the space of 18 months.

A Medline search in June 2005 shows that Dr Singh was first author on 25 clinical research trials or case-control studies published between 1990 and 1994. High annual publication rates had characterised many of the international research misconduct cases, which had begun to come to light in the mid-1970s.⁴

Colleagues in India had also conveyed misgivings to the epidemiologists, they wrote, concluding that an investigation into the author's work was now needed, particularly because he worked at a private institution and therefore fell outside the jurisdiction of any official research body in India.

As the *BMJ* and the *American Journal of Cardiology* were among the most prestigious journals that had published Singh's work, McKeigue and Davey Smith suggested that these two journals should conduct a joint investigation, beginning with a thorough review of all Singh's published work. Richard Smith approached the *American Journal of Cardiology* that month for financial help to conduct an investigation. Although sympathetic, the editor refused the request on the grounds that the journal could not afford it.

Coincidentally, a few days after the letter from McKeigue and Davey Smith, Dr Teri Millane, then a senior registrar in cardiology at Manchester's Wythenshawe Hospital, wrote to the *BMJ*, expressing concerns about the paper it had published in April 1992.

During some research early in 1993 she had come across Singh's *BMJ* paper, she said, and was struck by the remarkable similarity between it and a Singh manuscript she had peer reviewed twice in 1992.

"The published *BMJ* paper describes 505 patients recruited over 3 years and followed up for one year. The unpublished paper reports on 342 patients with

the same inclusion criteria recruited over 2 years and followed up for 2 years," she wrote. "The timing of the submission of the two papers suggests that these are possibly the same patients. Whilst it is conceivable that the authors had access to two sets of patients over this time, the similarities of the data are so close as to at least raise the question."

As a junior researcher, she hesitated to criticise the work of others, she said, but the gravity of her concerns had compelled her to do so.

The need for an investigation

At this point Richard Smith became convinced that these collective concerns could not be ignored and now warranted an independent investigation.

In the past, when a reviewer alerted an editor about suspicious data in a paper, the paper would simply be rejected, on the grounds that editors had neither the time nor the money to investigate. But the International Committee of Medical Journal Editors, which decides policies on good practice for medical journals, had decided in 1988 that this position was no longer tenable. Editors had a duty to pass on their suspicions to an authority who was in a position to investigate.⁵

But there was no obvious authority to ask. Richard Smith therefore asked Professor Stephen Evans of the Royal London Hospital, a world expert in statistical fraud and a statistical adviser to the *BMJ*, to review the statistics on manuscript 933348 and a further paper submitted in July 1993 on the effects of commiphora mukal—an Ayurvedic treatment—in patients with high cholesterol (manuscript 933676).

The request for cooperation from Singh

Professor Evans felt that Singh should be asked to supply the raw data for both studies, to shed further light on the results given in the tables. Singh was asked to do this in August 1994, after another segment from his Indian diet heart study, on the effect of antioxidant vitamins on the risk of heart attack and death, arrived at the *BMJ* (manuscript 943543).

At the same time Dr Smith asked Professor McKeigue to undertake a detailed review of the three most recent manuscripts submitted to the *BMJ*, in addition to a systematic review of Singh's published research.

In November 1994, the editor of the *National Medical Journal of India*, Dr Samiran Nundy, asked Professor McKeigue to review a paper by Singh on the effect on high blood pressure of a low energy diet and weight loss.

In his reply, McKeigue wrote: "I have made a few checks on the consistency of the findings described in this manuscript, and I have uncovered an inconsistency in the results, which is difficult to explain if the data in the tables are correct and the study was carried out in the manner described."

Dr Nundy sent McKeigue's letter to Richard Smith in January 1995 and pointed out that two well known and respected colleagues in the field in India had also questioned whether Singh's research was genuine.

The same month, Richard Smith again asked Singh to provide the raw data for all three outstanding papers (933348, 933676, and 943543). Reams of data, written in pencil, for manuscript 943543 alone arrived in April

Box 1: Who is Singh?

Dr Ram B Singh is a private practitioner based in Moradabad, Uttar Pradesh, northern India.

He has published widely, principally on nutritional approaches to heart disease in Asians, and co-edits the *World Heart Journal*, published by Nova Science in New York (see bibliography on bmj.com).

In correspondence sent to the *BMJ* between 1992 and 2003, the letterheads identify Singh as honorary professor of preventive cardiology and nutrition. In an article on the Heartzine website, updated in June 2005, Dr Singh signs himself as Professor of Medicine at Halberg Hospital and Research Institute, Moradabad.

His address in Moradabad has variously been the site of the Heart Research Laboratory, the Heart Research Laboratory and Centre of Nutrition Research, the Centre of Nutrition and Heart Research, the Medical Hospital and Research Centre, and the International College of Nutrition.

Singh is a fellow and current secretary of the International College of Nutrition, which he says he founded with some of his friends in 1986.

Singh also co-founded the International College of Cardiology in 2000, and was its president until 2004. He says the World Heart Federation sponsors some of its meetings, but the federation says it has no record of this.

1995 and were sent to Professor Evans. Manuscript 933348 had been published, with some modifications, in the *International Journal of Cardiology* in January 1995, and 933676 had been published in *Cardiovascular Drugs and Therapy* in August 1994, although Singh didn't mention this in his covering letter.^{6,7}

The first report

In his report for the *BMJ*, submitted in March 1995, Professor McKeigue pointed out that the many inconsistencies and errors he had uncovered, although typical of fabrication, did not of themselves prove the case for scientific misconduct.

His analysis of the 1992 paper published in the *BMJ* was that it contained unlikely results: the one year death rates were unusually high for a secondary prevention trial, and the standard deviations for dietary intake variables were extraordinarily low. Baseline intake of fruits and vegetables also seemed to be too low. But the most glaring oddity was the reclassification of trial participants according to the amount of weight lost after 12 months—including 27 who had either died or been lost to follow-up. Three other papers by Singh, in the *American Journal of Cardiology* (1992), the *Journal of the American College of Nutrition* (1993), and *Cardiology* (1992), all reported on the same set of data, McKeigue pointed out.^{2,8,9}

He also recalculated the results of the three outstanding manuscripts submitted to the *BMJ* (933348, 933676, and 943543) and five other papers published between 1990 and 1992 in the *American Journal of Cardiology and Nutrition*.^{9,10-13}

Overall, he concluded that the P values recalculated from the means and standard deviations in the tables consistently failed to agree with those reported by the authors, as did the P values for the differences in proportions. Such discrepancies were not attributable to the choice of statistical methods used, he said. Several of the papers reported χ^2 values, when this method of calculation could not possibly have been used.

The standard deviations given in the tables for several dietary intakes were extraordinarily low: for example, the standard deviation given for the percentage energy from fat was less than 1%. It is usually about 6%. The author might have extracted plausible values from other published tables in which the standard error of the mean rather than the standard deviation had been used, suggested Professor McKeigue.

While there was no unequivocal proof that the data had been fabricated, McKeigue concluded: "I think that the level of inconsistencies and errors in these papers is sufficient to justify retraction by the *BMJ* and other journals of the papers from this source ... even if there is no direct evidence of misconduct." He went on to say that if the author was unable to provide the raw data, there would be reasonable grounds for supposing that the research had been faked.

Mounting concerns

Undeterred by the apparent absence of any decisions on his research, Singh submitted a study to the *BMJ* on serum cholesterol and coronary artery disease in December 1995 (manuscript 954962) and a

Box 2: Manuscripts submitted to the *BMJ* by Dr R B Singh

1992

Randomised controlled trial of cardioprotective diet in patients with recent acute myocardial infarction: results of one year follow up (published 18 April)

924479—The influence of fruit and vegetable enriched prudent diet and moderate physical activity on mortality and reinfarction in the Indian Diet Heart Study

1993

933348—Epidemiologic study of diet and cardiovascular risk factors in rural and urban populations of north India

933676—Hypolipidemic and antioxidant effects of commiphora mukal as adjunct to dietary therapy in patients with hypercholesterolemia

1994

943543—The influence of antioxidant rich diet on plasma antioxidant vitamins, myocardial infarction and mortality in the Indian Diet Heart Study

1995

954962—Serum cholesterol and coronary artery disease in populations with low cholesterol levels

1996

961005—Randomized double blind placebo controlled trial of spirulina as adjunct to dietary therapy in patients with mild to moderate hypercholesterolemia

962430—Association of trans fatty acids and Indian ghee with a higher risk of coronary artery disease

963269—Magnesium and antioxidant vitamin status and risk of ageing in an elderly urban population

randomised controlled trial of spirulina, an algal preparation sold over the counter, in patients with mild to moderately low cholesterol levels in February 1996 (manuscript 961005).

The spirulina paper was sent to Professor Tom Sanders at King's College, London, for review. He wrote: "I am very unhappy about this paper in that it is not consistent with the literature, it is poorly prepared and has a number of glaring omissions." The results indicated that spirulina was as effective as statins in lowering lipids—which, if true, would do much to boost the sales of spirulina, he said.

"Such an observation would, of course, be significant," continued Professor Sanders. "However, I have serious concerns whether this is a genuine report ... The issue of scientific fraud is at the back of my mind, but such an allegation may be quite unjustified."

While the *BMJ* was awaiting statistical evidence from Professor Evans before making any further decisions, Singh submitted a further paper in April 1996 (manuscript 962430). This time the paper, on the association of trans fatty acids and Indian ghee with a higher risk of coronary artery disease, was promptly rejected, on the grounds that it did not contain enough that was new.

Yet another paper arrived in June, this time on the association between magnesium and antioxidant vitamins and ageing (manuscript 963269).

The need to resolve the unanswered questions

Five years after his first paper was accepted by the *BMJ*, with no sign of further publication in the journal, Singh offered an editorial on the role of calcium in the pathogenesis of coronary artery disease, which, he said, he was jointly writing with a British researcher, formerly of the department of cardiology at the University of Manchester. The British researcher had not signed the covering letter.

Singh's offer was rejected, but two months later, in March 1997, a different editorial arrived—on affluence in South Asia and the implications for the risk of coronary artery disease, with several of Singh's own publications in the bibliography.

Paul McKeigue recommended rejection on the grounds that the editorial lacked originality and incisiveness. He reiterated the views expressed to him by colleagues in India, who had complained that Singh's conduct was undermining India's credibility in medical research. And he urged the *BMJ* to renew its efforts to try and "resolve the questions that hang over this author's work."

In his response to McKeigue, Richard Smith wrote: "To my mind this whole episode illustrates the great difficulties we have in investigating accusations of research misconduct. We obviously cannot make accusations of fraud without some evidence, but the gathering of evidence can be extremely difficult and expensive."

At the end of April 1997 Dr Singh "cancelled" [his term] manuscript 954962, for which he substituted a different paper on the same topic, and manuscript 963269. He also supplied the raw data for the randomised trial of spirulina (manuscript 961005), which were then sent to Stephen Evans. Because of the costs and time that had been involved to input the raw data for manuscript 943543, the raw data for manuscript 961005 were not analysed.

Manuscript 954962 was published in the *International Journal of Cardiology* in June 1998, and manuscript 963269 appeared, with some modifications, in the December 1996 issue of *Magnesium Research*.^{14 15}

In August 1997 Singh requested a definitive decision on all the outstanding papers by the end of September. Richard Smith replied in October, explaining that the *BMJ* would not be publishing any of his papers because of "severe doubts" about the validity of the data in these and previously published research. The delays had been caused by the investigations into these concerns, he wrote, adding that he soon hoped to have corroborative evidence to present to Dr Singh. The submissions to the *BMJ* stopped, but Singh continued to publish elsewhere.

Early in 1999, Professor George Davey Smith advised the *BMJ* that Singh had published a randomised controlled trial of fish and mustard oils in patients suspected of having had a heart attack.¹⁶ "They are getting less and less well done and more clearly implausible," wrote Professor Davey Smith, adding that this study had already been cited in the pages of the *BMJ* as evidence of the beneficial effects of a diet rich in oily fish.¹⁷

Singh is challenged

Part of the long awaited review from Professor Evans arrived in March 1999. Its delivery had been held up by the excessive amount of hand written data, which needed to be input electronically (at considerable expense), and also by a false start on the analysis.

The review provided a detailed comparison of the raw data for manuscript 943543 with the data described in the submitted paper. This paper, from the Indian heart study, was about the effect of antioxidant vitamins on the risk of heart attack and death.

Professor Evans concluded that there were a "considerable number of discrepancies" in the figures, as well as different patterns in the two groups that were randomised, which merited an explanation.

A more detailed statistical analysis of this manuscript is published in this issue of the *BMJ* (p 267).¹⁸ It ends: "We conclude that the data from the [Singh] trial were either fabricated or falsified."

In November 1999, Richard Smith confronted Singh by letter, enclosing Professor Evans's original report, and asked Singh to explain. Smith concluded his letter: "From our perspective, a likely explanation is that the data were generated in order to attempt to fit the values in the tables, rather than genuine measurements being made."

At the same time he sought guidance from the Committee on Publication Ethics (COPE), a recently established forum for editors struggling with cases of suspected research misconduct. It concluded that an investigation was warranted, and that this should be conducted by a national body as Singh was head of his institution.

The following day, Dr Smith sent a further letter to Dr Singh in which he expressed his concern that many of Singh's published papers and the manuscripts submitted to the *BMJ* might be fraudulent. He offered Singh the opportunity to respond to the allegations and warned that if a prompt response was unforthcoming, he would approach the National Human Rights Commission in New Delhi or possibly publish a piece in the *BMJ* about the matter. The commission has the powers of a civil court and can requisition any public record and summon the attendance of witnesses while investigating any complaints in respect of human rights violations. Richard Smith had approached the commission on a previous occasion when he had had doubts about an author's work.

Some allegations are denied

Singh replied promptly, but focused his response on Professor McKeigue, to whom he attributed the rejection of manuscript 943543, pointing out that he and Professor McKeigue did not see eye to eye over the risk factors for coronary heart disease in British Asians. He went on to admit that perhaps the statistical competence of his coauthor on this paper might not have been optimal, as he was a chemist by profession. He added that his records had been eaten by termites.

Singh explained that blinding had been abandoned in that study after around six weeks of follow-up because patients had repeatedly asked the treating doctor for dietary advice. But he said that the last available data for patients who had died or were lost to

follow-up had been used for the study, and he refuted the suggestion that the data had been generated to fit the values presented in the tables.

Singh did not answer all the questions raised in Richard Smith's letter, however. Instead, he said that he would be able to answer every query honestly, but that if the journal preferred to rely on the opinion of others, then he wished to withdraw 943543.

He was collaborating with universities in the United States, Japan, and Singapore, he said. And by way of a postscript, he informed the editor that his group had discovered that antioxidants could reverse renal problems in chronic renal failure, and would the journal like to consider the study if raw data were provided?

The Indian investigation

In December 1999 Richard Smith advised Singh that if there was not a more senior colleague who could take charge of an investigation at Singh's institution, then he would refer the matter to a national body.

Dr Singh replied, saying that the colleagues who had complained about his work had consistently opposed his views and did not believe in a preventive dietary approach to heart disease. The heads of his small centre were relatives, he said; therefore, any investigation they conducted "would not have sufficient weight." He suggested the presidents of the Hypertension Society of India, the International College of Nutrition, and the Association of Physicians of India.

Six months later, in June 2000, Richard Smith wrote to Singh advising him that he would be taking the matter up with the National Human Rights Commission rather than the organisations Singh had suggested. He enclosed a copy of his letter to the commission. In it he said: "It is very important for patients around the world, the scientific community, the many journals that have published the work of Professor Singh, and Professor Singh himself that a proper investigation is undertaken."

The submission included the reports of Professors McKeigue and Evans, a copy of the April 1992 *BMJ* paper, and three of Singh's unpublished papers sent to the *BMJ* (manuscript 943543, which Stephen Evans had analysed; manuscript 933676; and manuscript 933348).

The commission forwarded the complaint to the Indian Council of Medical Research in New Delhi, which is funded by the Indian government.

The findings

The council's report, sent to the *BMJ* in September 2000, said that the standard deviations for daily intake of nutrients and the coefficient of variation for fruit and vegetable intake were, respectively, "unexpectedly" and "unbelievably" low in the published *BMJ* paper. In a largely illiterate community, it would not have been feasible to have obtained the kind of detailed diaries outlined in the paper, the council said.

The council agreed that presenting information on study participants who had died was "definitely a serious mistake." But even more surprising, the council opined, was that a prestigious journal such as the *BMJ* should have published the paper in the first place.

The standard deviations in each of the other submitted manuscripts were also too low, the council said, adding that the reported P values in manuscript 943543 were incorrect. But it concluded that it was very difficult to form any definitive conclusions on the existing data without any information on the numbers and grade of staff at the institute, access to the raw data, or information on how the statistics had been applied.

Dr Smith wrote again in September to the director general of the Indian Council of Medical Research, querying whether all the material submitted with the original complaint had indeed been received. In the absence of any response, he wrote again in January 2001, and again in June 2002, expressing his concern that nothing much had been done. Substantial doubts had been left unresolved, he said, and he asked for assurance that some action would be taken.

A month later the council's director general, Professor N K Ganguly, responded, saying that it was not within its gift to take disciplinary action, because Singh did not work with, or for, the council. "The further action now rests with the Human Rights Commission who has taken up this issue," he wrote, adding that he intended to bring the matter to the attention of the appropriate authorities, without specifying who these might be.

This prompted Dr Smith in August to ask Professor Ganguly to explain what he meant. He warned that "we may have some ethical obligation to publish something in the *BMJ* on our severe anxieties if we cannot assure ourselves that a responsible body is taking steps to right what may be a considerable wrong."

In June 2005, a senior source at the council told a *BMJ* reporter based in India that the only other authority the council could have referred Singh to, following Richard Smith's complaint, would have been the doctors' regulatory body in India, the Medical Council of India. But the source added that it is rare for this body to take action against doctors suspected of wrongdoing. The ethics of scientific publishing have not been adequately debated in India, nor have national guidelines been produced, he said.

The reporter was shown a copy of a letter from Professor Ganguly to Dr Setalvad, secretary of the Medical Council of India, requesting that action be taken in respect of Richard Smith's complaint. It was dated 25 June 2005, although staff assured the reporter that an identical letter had been sent more than two years earlier.

The *BMJ* decides to go public

In October 2002, the *BMJ* Ethics Committee advised the journal to go public on the matter, a decision that was given added weight when a further Singh paper was published in the *Lancet* in November 2002.¹⁹

The paper, a randomised single blind trial, once again covered the effects of an Indo-Mediterranean diet on the progression of coronary artery disease in high risk patients. It was cited in the *New England Journal of Medicine* in June the following year, in an article about the growing body of scientific evidence that was now supplanting the myths surrounding the Mediterranean diet.²⁰

Richard Smith alerted the *Lancet's* editor, Richard Horton, who then commissioned one of the study's

coauthors to visit Moradabad and write a report. The report exonerated Singh of misconduct in relation to the *Lancet* paper, concluding it was not possible to judge Singh or his research facilities by the standards applicable in the developed world.

Calls for action

Dr Chittakkudam Raman Soman, chair of the non-governmental organisation Health Action by People, based in Trivandrum, Kerala, and retired professor of applied nutrition, wrote a detailed critique of the *Lancet* study in March 2004, a copy of which he sent to the *BMJ*. He queried the rate of recruitment in the trial and commented on the implausibility of the dietary habits attributed to the study participants.

Dr Soman also told the *BMJ* that Singh published a study (in the *International Journal of Cardiology*) that included his city.²¹ "The description of the city didn't conform to reality," he said. He highlighted inconsistencies and numerous statistical errors in the study in the same journal the following year²² but did not accuse Singh outright of scientific dishonesty. "You need a great deal of documentary proof for that, and that takes a lot of time," explained Dr Soman. "You cannot be seen as someone who is ungenerous, and who speaks ill of others in India. If you want to succeed, being open and blunt will get you nowhere. Ours is not a forthright and frank culture."

Dr Soman reiterated that Singh's work involving food diaries is implausible because literacy levels are so low, and there is no culture for keeping such diaries. "People might do it for a day, but not long term."

Srinath Reddy, professor of cardiology at the All India Institute of Medical Sciences in New Delhi, told the *BMJ* that he did not believe that doubts about Singh's publications would discredit other research efforts in India. But concerns about the quality of Singh's work make it difficult for Indian researchers to refer to it with confidence, he said.

"How do you conduct a thorough systematic review without mentioning his research," he asked, adding that a request to the Indian Council of Medical Research to conduct an investigation had not been accepted. "It would have helped us ascertain whether the work was the output of an outstanding scientist who deserves to be awarded and supported by the ICMR, or whether it represented a source of potential discredit to Indian medical research."

"He was quite prolific, and people started wondering how he was able to recruit so many people for so many studies from a small clinic in a small town," Reddy commented.

But one of Singh's frequent coauthors, Dr Shanti Rastogi, told the *BMJ*: "[Singh] has laboratory facilities and a good biochemist on staff. He also has animal experimentation facilities. He collaborates with local hospitals in India. That is how he is able to cite a large number of cases in his medical studies." He added: "There is no fabrication of data, no statistical jugglery ... Professional jealousy is at work."

Professor Reddy said that individuals taking Singh on in India would immediately face legal action. He believes the solution lies in a concerted international effort. But the initiative is unlikely to come from India

itself, he said, and would be seen as motivated by professional jealousy if it did.

There is a feeling on the part of the institutions in India, he added, that it is the responsibility of the international journals that have published Singh's work to take action, possibly under the aegis of the World Association of Medical Editors, as it is they who have secured his place in the canon of scientific research.

Professor Michael Meguid, editor of the journal *Nutrition*, to which Singh also submitted several papers and which recently retracted a paper by Professor Ranjit Kumar Chandra, a leading Canadian nutritionist (see p 288),^{23, 24} points out the difficulties of international collaboration.

In the case of Chandra, he said, the US Office of Research Integrity, which investigates cases of alleged scientific misconduct, would not intervene because Chandra was a Canadian resident, despite the fact that he had published in US journals. "This is not about [country] boundaries; it's about international ethical standards," said Professor Meguid.

Singh's response to the *BMJ*'s decision

The prospect of an article in the *BMJ* about its lengthy correspondence with him prompted Singh to send several emails to Richard Smith.

At the beginning of October 2003, he wrote: "I would like to know why Dr Paul McKeigue himself is not writing who is the person responsible, [for] making all the allegations ... My main concern is that studies conducted by [McKeigue] on South Asians and published in the *Lancet* [in] 1986 and 1991, [in] *Circulation* [in] 1993 and [in] *Diabetologia* should also be investigated by some impartial expert, once you have finally decided to blame us."

In a response to the *BMJ*, Professor McKeigue wrote: "The papers of mine referred to by Dr Singh are from the Southall study of diabetes and coronary risk, in which I had a lead role in the design, fieldwork, and writing up. If anyone wants to audit this project, I have no objection to this, as long as the usual requirements of confidentiality in relation to patient identities are met."

A few days later Singh contended that the investigation for the *Lancet* should have settled doubts. "Your major target for investigation, about my research [in] *The Lancet* paper, has been more thoroughly investigated ... than it could have been done by any other institution in India," he wrote.

During the course of the *BMJ*'s inquiries, Singh has continued to suggest that he cannot help because termites had destroyed his data, and sent copies of reprints of his 2003 paper in the *International Journal of Cardiology* as proof. The copies show evidence of damage to the edges of the pages.

In March 2004 Singh forwarded an email reference to the *BMJ* from Dr Franz Halberg, with whom he co-edits the *World Heart Journal*. Dr Halberg, who is director of the Chronobiology Center in Minneapolis and a retired professor of laboratory medicine and pathology at the University of Minnesota, wrote: "We value his [Singh's] integrity, diligence, competence and cooperation."

Contacted again by the *BMJ* in June 2005 and asked to explain why he either did not respond or failed to respond fully to queries raised by the journal

over the years, Singh renewed his attack on Professor McKeigue.

In response to the question why he did not respond to two letters from the *BMJ* in 1993 about his work, he said: "I do not remember why I did not but it is possible that Dr Paul McKeigue was the referee, so I thought not to respond ... I believe that I could guess that Dr Smith's mind is already corrupted by Dr McKeigue, so there is no point in responding."

And he did not comply with requests for raw data in 1995 because "the purpose appeared to me destructive rather than constructive and because it may have been prompted by Dr Paul McKeigue who was responsible for corrupting his mind against me."

Asked why he did not explain the errors and inconsistencies between manuscript 943543 submitted to the *BMJ* and the raw data he subsequently submitted for it, a concern highlighted by Richard Smith in a 1999 letter, Singh responded: "His questions were one sided and [the] aim appeared destructive, prompted by Dr McKeigue."

Singh concluded his emailed response: "[The] English are very impartial in general, but when it comes [to matters] between white and non-white, they always favour white. This has been proven in [the] case of Dr Chandra."

What can editors do?

The *BMJ* contacted some of the journals in which Dr Singh's work has been published, including those in which versions of the rejected *BMJ* papers had appeared.

Dr William Roberts of Baylor University Medical Center, Dallas, editor of the *American Journal of Cardiology*, confirmed that two or three of Singh's papers had been published in his journal in the early 1990s: "Singh's articles in the [journal] received good reviews." Once concerns had been raised by the *BMJ*, all subsequent manuscripts were declined, he said, but efforts to find out more about Dr Singh at the time were not successful.

Professor Lionel Opie of the Health Faculty of the University of Cape Town, South Africa, and former editor of *Cardiovascular Drugs and Therapy*, felt that Singh was guilty of disorganisation rather than any deliberate attempt to deceive.

Richard Horton, editor of the *Lancet*, believes that Western journal editors are so keen to publish research from developing countries, particularly if it offers cheap solutions to costly problems, that they tend to give the benefit of the doubt to aspiring authors.

Professor McKeigue says the *BMJ* is partly responsible for Singh's success. cursory checks would have indicated that something was wrong with the 1992 paper, he says. "Publication in the *BMJ* opened up the floodgates."

The difficulties of leaving things for a long time are that staff change, and papers slip through, McKeigue told the *BMJ*, citing the fact that concerns had already been raised with the *Lancet* about Singh under a previous editorship.

But the time lag also allowed Singh to polish up his presentation, he believes. "Every time the errors on [his] manuscripts were pointed out, they were cleaned up for the next submission. So in effect, the reviews

Summary points

The *BMJ* published a paper by Ram B Singh in 1992

Doubts were raised about that paper and subsequent manuscripts submitted by the same author

In the absence of answers from the author, the *BMJ* tried to find a legitimate authority to investigate and adjudicate on its concerns, and failed

The *BMJ* decided it had no option other than to publish an article documenting its efforts

were giving him a tutorial." This made it harder to detect any anomalies, he contends.

One option might be to require authors to deposit a copy of their dataset in a secure archive, so that the data could be audited if questions arise, McKeigue suggests. Another might be that journal editors should seek at least one reviewer who is familiar with the local environment in which the research was conducted.

Richard Smith, who left the *BMJ* in 2004, accepts that it has taken far too long to bring the case of Dr Singh to light. "It is shameful that this case has been left festering so long," he wrote to the journal after he had left. "The failure is in part mine."

In his defence, he says that he made concerted efforts to force an investigation on the part of organisations with legal legitimacy, to seek help from other publications, and to find answers from the author himself, all of which ultimately drew a blank. And the evidence needed careful analysis.

"All of this was in addition to my day job, which is why it has taken years. It couldn't be a priority," he wrote, adding that "the bigger shame lies with the scientific community that lacks means to investigate these international scandals and has to leave it to an individual journal."

And Richard Smith resolutely stands by the decision to publish the saga, principally on the grounds that many readers of Singh's work will be unaware that major questions hang over his research, research which could then be used to inform treatment and health policies, to the potential detriment of patients and communities.

"This story has to be told in order to alert the world to the severe doubts around Singh's work," he says. "More importantly, the story challenges the international scientific community to find a way to resolve cases like those of Singh and Chandra, where there are widely shared doubts about their work, but they simply go on publishing. The scientific community has an obligation to the public to do better."

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Investigating the previous studies of a fraudulent author

Richard Smith

This year, the journal *Nutrition* retracted a study by R K Chandra, and questions have been raised about the integrity of the rest of his work. Who has the responsibility for investigating previous work and if necessary punishing the researcher and correcting the scientific record?

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In February of this year, Michael Meguid, the editor of *Nutrition*, retracted a paper by the Canadian researcher R K Chandra, that it had published in 2001.^{1,2} The paper claimed to be a randomised double blind placebo controlled trial showing that physiological amounts of vitamins and trace elements would improve cognitive function in elderly people.¹ Meguid gave eight reasons for retracting the paper and said that Chandra had either ignored the reasons or failed to give an adequate response.²

Chandra's paper was submitted originally in 2000 to the *BMJ*, which had severe doubts about the paper: one reviewer said that the paper "had all the hallmarks of having been entirely invented."³ The *BMJ* asked Chandra's employers—the Memorial University of Newfoundland—to investigate its anxieties about the study. The university held an inquiry but found no serious problem. The *BMJ* was unconvinced by this response and raised further questions about the study. In August 2002 the university answered that Chandra had taken unpaid leave for the first four months of 2002 and failed to respond to any of its inquiries, including a request for raw data. Then in August 2002 he resigned.

Meanwhile, the *BMJ* had notified *Nutrition* about its anxieties over the study. Unfortunately *Nutrition* had already published the study. Chandra must have sent the study to *Nutrition* as soon as the *BMJ* began questioning it. The *BMJ* also notified the *Lancet*, which had published a closely related study by Chandra in



R K Chandra's paper in *Nutrition* was retracted; he resigned before the Memorial University of Newfoundland could investigate his previous studies

1992.⁴ Serious doubts were then raised about the 1992 study in a letter to the *Lancet* in 2003, which among other criticisms pointed out that "some of the standard errors were statistically impossible."⁵ There must be grave doubts about the *Lancet* study, which has been cited more than 300 times,⁶ and about the other 200 papers published by Chandra, many of which are randomised trials with him as sole author. Furthermore, investigations by the Canadian Broadcasting Corporation have raised many other questions over the integrity of Chandra, who is an officer of the Order of Canada and holds a patent for the supplement that is claimed to improve cognition.