

Newsletter no 28: January 1998

- Annabel Ferriman: [Pitfalls of medical journalism](#)
- "Slim trial" ad: complaint upheld
- [Homeopathy effect not all placebo](#)
- 1997 AGM: [Chairman's report](#)
- The [vitamin B6](#) controversy
- [Fraud in medical publications](#)
- Doctors in controversy over "[natural born healers](#)"
- [Are you serious...](#)
- - [Back to HealthWatch main page](#)

Pitfalls of medical journalism

Leading medical journalist Annabel Ferriman, winner of the 1997 HealthWatch Award, entertained members at HealthWatch's ninth Annual General Meeting in October when she explained the factors which can conspire against media reports being quite as accurate as health professionals would like them to be. Her talk is summarised here.

"Pitfalls include the pressure to produce, the need to be first, the search for simplicity, the media's dislike of neutrality and commercial and political pressures. I'm going to confess that I have fallen into all of them.

The Pressure to Produce

"Newspapers are not universities. They don't pay journalists to research into medical matters, fully inform themselves and then occasionally impart some of their wisdom to the British public. One day a journalist is a general reporter; the next, he or she is medical correspondent. From that day onwards, she's expected to understand the most complex issues and translate them into comprehensible language for the lay reader. Moreover; most of the time points are won only for disclosing information and producing copy, not for deciding that a story should not be published because it's without foundation or overblown. Experienced medical journalists who've seen dozens of breakthroughs and scares and who suggest to their news editor that the latest is not worth covering, are likely to be branded negative or stale or lazy.

"For me and others who work on weeklies, or who are feature writers rather than daily journalists, the problem comes when you sell an idea to the news editor or features editor that you then cannot "stand up". When you sell it, you have usually only half-researched it and often, on further research, you discover your first impressions were wrong.

"An example: I sold the idea to the medical editor of *The Independent* that it was a scandal that men were not being screened for prostate cancer; but discovered on further research that the issue was rather more complex. I could hardly then sell the idea that it was a good thing that we are *not* screening everyone for it, because that is a non-story.

"This is a well-known phenomenon in journalism known as the 'one 'phone call too many'. That is, you've made a 'phone call that has knocked down your whole story. What do you do? Suppress the knowledge and pretend you never made it? Sometimes that happens. Or include the qualifying statements in paragraph 24, so that it's not too obvious that your whole story is somewhat flimsy.

The need to be first

"This can result in dangerous half-truths. I have also been guilty of this: witness my piece on discovering the gene for schizophrenia. A chap at the Middlesex thought he had done so, I wrote it up and, as quite often happens, it was a false dawn.

The search for simplicity

"When I first started in medical journalism, I was told by Michael O'Donnell that there were only three medical stories: the major breakthrough, the major scare and the major scandal.

"The search for simplicity (usually based on the assumption that your reader has a 50-second attention span) often means that complicated stories are over-simplified to the point of nonsense.

"But this need for simplicity has another side to it. Editors and readers love nothing better than the story which suggests a lot of clever scientists have been working away for years to discover the key to a healthy life; or a cure for cancer; or the answer to multiple sclerosis. And then along comes a patient, or alternative medicine practitioner, who discovers that all that scientific research was quite unnecessary, that medics had been overcomplicating things and the answer was quite simple.

The media's dislike of neutrality

"Newspapers and television producers love to name the guilty men. Doctors, scientists and drug companies are often cast as the villains; the poor long-suffering patient as the hero or heroine. News editors don't tend to like stories that say: on the one hand this and on the other hand that. I was quite good at those, but they were usually put on page 10, so I didn't get many points for that.

"I recently discovered that the Hammersmith were planning to offer pre-implantation diagnosis for couples carrying the breast cancer gene. I tried to write a completely neutral story, but it ended up with the headline, 'Breast cancer embryos may be culled'.

Commercial and time pressures

"The fact is that most journalists are inundated with press releases every day, pushing this or that product, drug, cure, book or message. It is very easy, if you are up against a deadline, simply to reproduce a press release that you have been sent, without giving it the scrutiny that you should. I have seen press releases reproduced almost verbatim by journalists, for example a particularly idiosyncratic introduction to a Department of Health release on skin cancer was recently reproduced word for word in the Guardian. In this case, not many people would find it sinister. But it shows how easy it can be to manipulate the press.

"Some PR firms spoon-feed journalists and are rewarded by column inches. I had to produce a column very quickly for the Telegraph recently, and there happened to land on my desk a long press briefing about bedwetting. It even had the magic words, 'We have a case study which could be of some interest.' I am slightly ashamed to say that I used a great deal that was in the briefing, inter-viewed the case study and banged out 1,200 words in no time. My only defence is that I had very little time, and that I did include a lot of advice about behavioural ways of tackling bedwetting, as well as the fact that there is now a good pill available.

"In the light of the strong pressures working against good medical journalism, it is something of a miracle that medical coverage is as good as it is."

Annabel Ferriman

[Top of page](#)

"Slim trial" ad: complaint upheld

Newtons Traditional Remedies Ltd came under fire recently from the Advertising Standards Authority for their "continued disregard" of the Codes of Advertising Practice. The company's promotional activities have also been a source of concern for HealthWatch (see "The Vanishing Defendant", Health Watch [newsletter issue 24](#)).

The comment was made recently as the ASA upheld a complaint about a regional press advertisement headlined, "Slimmers Pre Clinical Trials Programme. Testers Urgently Wanted. Weightloss Tablets Free Offer". The ad invited people to take part in free testing of the tablets in question, and follow-up literature claimed the programme, "gives positive medicinal help to assist in shedding of excess fat and flab.. .safe to take. Effective."

Offer "not free"

Only in the follow-up literature was it made clear that, in order to receive a month's free supply of the tablets, it was necessary to buy a month's supply for £14.50. The ASA agreed that the ad had given the impression that the tablets were free, and noted that they "had already upheld complaints on an identical point against another company, Jacaranda Ltd, which had been run by the advertisers' proprietors and had since gone into liquidation".

Although the advertisers claimed their intention was to use the offer to fund "vitaly important clinical trials", they did not provide evidence of this and the ASA asked for this claim to be removed.

ASA Monitor November 1997

[Top of page](#)

Homeopathy effect not all placebo?

An analysis of 89 placebo-controlled homeopathy studies has concluded that there the clinical effects of the treatment may not be entirely explained by the placebo effect.

Homeopathy uses very dilute solutions to treat illness. The agent to be diluted is selected because it causes the same symptoms suffered by the person who is ill, the so-called, "principle of similars". Drops of the prepared solution are taken in a tiny sucrose pill. But these solutions may be so dilute they contain few or no molecules of the original drug.

Researchers at the National Institutes of Health's Office of Alternative Medicine combined the results from the 89 studies in which homeopathy was used to treat conditions including allergy, diarrhoea, migraines, seasickness, stroke, menopause, and labour pains. They report in the *Lancet* that the dilute solutions were found to be more than twice as effective as a placebo or "dummy" medication.

However, there was no benefit if the studies were examined alone. And when the researchers removed the more poorly designed studies, the 26 remaining reports suggested homeopathy solutions were only 1.6 times as effective as a placebo.

A detailed analysis of the trials suggests "that about two-thirds were methodologically poor; a third reasonable, and a tenth very good," the researchers wrote. Flaws include not following up on patients who dropped out of the study, or incomplete blinding - that is, patients knew if they were getting a placebo or an "active" medication.

But is it worth it? In an accompanying editorial Dr. Michael Langman, Birmingham University, commented, "The scientist must question whether the diversion of significant resources to support these trials can be justified when a rational basis for choice of homeopathy, or any particular modality of it, is lacking."

Reference: Linde K, Clausius N, Ramirez G, et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997; 350: 825, 834-43.

See also article by Dr Neville Goodman in [Newsletter 29](#)

[Top of page](#)

Health Watch 1997 AGM: Chairman's report

Health Watch Chairman, Professor John Garrow, addressed the Health Watch Committee and members at the ninth Annual General Meeting on 14th October 1997, at Regents College, London.

At the AGM last year it was noted that HealthWatch was becoming increasingly recognised by the media as a group of informed sceptics about methods for diagnosis or treatment, whether conventional or alternative. This trend has continued, as indicated by a BBC 2 [documentary programme](#) about Spagyrik which was broadcast on 15th July, and which featured three of our members.

I see it as one of the most important functions of HealthWatch to help journalists to achieve this objective.

There are many other organisations which have (at least on paper) objectives similar to those of HealthWatch. During the last year we have been trying to find out to what extent their objectives coincide with ours, and in what areas we can profitably cooperate. The HealthWatch Newsletter has carried transcripts of interviews with representatives of the BMA ([issue 25](#)), the Consumers' Association ([issue 26](#)), and the Royal College of Nursing ([issue 27](#)). Your Committee; and the newsletter's editor Mandy Payne would be very interested to hear from members about the organisations with which you think we should try to forge these links.

It is encouraging that this year the Newsletter has carried more readers' letters providing critical feedback on what has been published. We are most grateful to the members who have contributed orthodox or unorthodox views about health risks in their area of expertise, and Mrs Shirley Churchman who does sterling work in distributing the Newsletter and other documents which enable the membership and committee to keep in touch. Although we are making progress, a great deal remains to be done. [Newsletter issue 25](#) contained an all-too-typical report of a radio phone-in: listeners' personal anecdotes of miraculous cures were given as much credence as the best-designed clinical trial. Doctors are gradually learning that cherished beliefs based on personal experience can be cruelly misleading, but the public is learning this even more slowly. It is very difficult to be dispassionate about one's own strongly-held opinions.

I am also very grateful to Professor Vincent Marks and Mrs Sheila Smith for their work on the telephone Helpline. This is an important facility for providing information to enquirers, or guiding them to appropriate experts for advice.

A new development has been the establishment of an Internet site for HealthWatch, by courtesy of Dr David Bender at UCL. [Editorial note - since May 2000 HealthWatch has moved to a new web address: <http://www.healthwatch-uk>]. We exist to provide reliable information, so the world-wide-web is a means by which we can communicate with journalists and others who form public opinion of healthcare issues. However the Internet is also a means by which others transmit very unreliable information, so it remains to be seen if this will be an effective means by which we can further our charitable objectives.

Item 5 on our agenda this evening is the Treasurer's report. Probably few members appreciate what Michael Allen

has done as Treasurer since HealthWatch was first set up, and I am glad to have this opportunity to thank him for this very important work. We have weathered financial storms in the past, but this year our expenditure has exceeded income by some £2000. There is absolutely no waste on the expenditure side: our committee members are not merely unpaid, they are out-of-pocket, since legitimate expenditure (such as travel to committee meetings) is never claimed for reimbursement, and we meet in a room kindly provided (without charge) in the offices of our Vice-chairman Malcolm Brahams. Methods for increasing income are perennially debated: either by increasing membership or from sponsorship. If we doubled the membership we would roughly cover the costs of the Newsletter, but we would also double the work to be done by Mrs Deborah Bender and Shirley Churchman. We have applied (unsuccessfully) for an annual grant of about £2000 from the National Lottery Charities Board, and from PPP Healthcare Medical Trust. In the past we have accepted small donations from pharmaceutical companies, which has given our numerous opponents an excuse for accusing us of being a front for the pharmaceutical industry. I sincerely believe that the work done by HealthWatch needs doing, and is not being done by anyone else. I hope we can find a public-spirited source of finance which also takes this view. We welcome Mr John Hanford as our Treasurer-elect, and hope he will have success in finding an adequate and uncompromising source of finance.

It only remains for me to thank all the people who do so much to keep HealthWatch on the road: I hope it gives them as much pleasure to do so as it gives me.

[Top of page](#)

The vitamin B6 controversy

In June 1997 the Committee on Toxicity of the Department of Health reported on vitamin B6, having been asked by the Consumers' Association to re-examine the reports of nerve damage associated with high levels of intake of vitamin B6 supplements. As a result of this report, limits were set on the amounts of vitamin B6 that may be sold in supplements: up to 10 mg may be sold freely over the counter, as nutritional supplements; between 10 and 50 mg may be sold only through a pharmacy; above 50 mg may be provided only on prescription.

Here, two of the country's leading nutrition experts explain the science and give their personal views on this controversial subject.

I consider that in principle the action taken by DH and MAFF is to be welcomed, writes Dr David Bender. For the first time, a distinction has been drawn between nutritionally relevant levels of intake of a vitamin and levels of intake that are used to treat a medical condition, and which therefore should be considered like any other drug or medication. What is less certain is that the levels chosen are appropriate.

Nutritionally relevant levels of intake

Nutritionally relevant levels of a vitamin are up to five to ten times the normal human requirements, and for vitamin B6 would be up to 10 mg/day. But our knowledge of the human requirement for this vitamin is derived from a relatively small number of studies and our estimated average requirements are based on a best estimate from relatively poor data. There is a clear need for further studies to refine our estimates of requirements to prevent deficiency, and this is not purely an academic problem. A number of studies (2) have shown that up to 20-30% of the population of western countries show biochemical signs of marginally inadequate vitamin B6 status, despite apparently adequate intakes. This suggests that current estimates of requirements may indeed be too low.

Medicinal (pharmacological) levels of intake

The new principle introduced by DH and MAFF in June 1997 was the implicit definition of pharmacological levels of intake, when vitamin B6 is used not as a nutrient, but to treat a clinical condition. Here the interests of the scientist and consumer coincide - there is a need for evidence of both efficacy and safety if a substance is to be marketed for medical use.

The main uses of vitamin B6 supplements are to overcome the side-effects of oral contraceptives and menopausal hormone replacement therapy-the association with these arose during the 1960s, when use of the then current high dose contraceptives was found to be linked with abnormalities of the metabolism of the amino acid tryptophan that were similar to those seen in vitamin B6 deficiency - and to treat the premenstrual syndrome. The evidence for efficacy of vitamin B6 supplements in treating the premenstrual syndrome is poor. However; it is obvious that a considerable number of women believe that vitamin B6 supplements are beneficial. Therefore, it might be appropriate to permit sale of vitamin B6 supplements for treatment of premenstrual syndrome.

It is obviously not sensible to consider the formal (and very expensive) procedure involved in licensing a new drug to be applied to nutritional supplements. What is needed is some system of provisional Licensing by, or notification to, the Department of Health, so that such evidence of both efficacy and safety as is available can be scrutinised. After this, specified claims could be made for a medicinal product to be sold in pharmacies or other outlets where appropriately qualified professionals are available to offer advice.

Potentially toxic levels of intake

All compounds are toxic at a high enough level of intake. For many nutrients the range between requirements and toxicity is relatively small (perhaps only 5-10-fold). For medicines the toxic dose may be very close to the effective dose. However; there is a balance between the benefit in treating a disease and the hazard of toxicity. When an effective dose is close to the toxic dose, it is appropriate that the compound should be available only on prescription.

The problem with vitamin B6 is deciding the level of intake at which there is a risk of toxicity. The Department of Health committee considered a number of animal studies, showing clear evidence of nerve damage at very high levels of intake, and one report of seven people who developed nerve damage after taking supplements of the order of 1000-2000 mg of vitamin B6 per day for several months. In this report there was good neurological evidence of peripheral sensory neuropathy, which was partially, but not completely, reversed on cessation of the vitamin supplements.

The limit of 50 mg, above which vitamin B6 may be provided only on prescription, is based on the animal data, by the classical toxicological method of allowing a 100-fold safety margin, which is not appropriate for a medicine or nutrient, and the Dalton and Dalton report which has been criticised for its lack of neurological investigation. Therefore, while there is obviously a level of intake above which vitamin B6 should only be provided on prescription, for the treatment of defined conditions, it is far from certain that 50 mg is an appropriate limit. Again there is a need for further research.

David A Bender, Dept of Biochemistry and Molecular Biology University College, London

References

1. Bender DA. Oestrogens and vitamin B6 - actions and interactions. *World Rev Nutr Dietet* 1987; 51: 140-88.
2. Bender DA. Vitamin B6 requirements and recommendations. *Eur J Clin Nutr* 1989; 43: 289-309.

The health food industry is in high dudgeon, writes John Garrow. "Vitamin B6- what on earth does the government think it is doing?" demands Solgar Vitamins. "Regulatory mayhem" wails Berrydales. "B6 debate-based on shabby science?" reveals Quest Vitamins. Readers are exhorted to write to their MR call their local paper or radio station, complain to the Consumers' Association which gratuitously started the B6 witch hunt, or contact Consumers for Health Choice, a pressure group which will help you throw off the shackles of impending legislation.

What legislation? All this wrath has descended on the government because the much-heralded Minister for Food Safety, on 4th July 1997, acting on the advice of the Food Advisory Committee and Committee on Toxicology invited comment on the proposal that dietary supplements (which can be self-selected in a supermarket) should not provide a daily dose of more than 10 mg of vitamin B6. The reference nutrient intake is 1.4 mg/day, and the average intake organised from food is about 2.5 mg/day, so B6 deficiency is rare.

The problem is that some practitioners believe that a dose of 100 mg/day is helpful in treating the premenstrual syndrome (PMS). The evidence for the efficacy of this treatment was reviewed by Kleijnen *et al* who conclude "The existing evidence of positive effects of vitamin B6 is weak, and some well-designed trials with positive results would be needed to change this view." I have not found any such trials being reported.

Anxiety about safety arises because it is accepted by all concerned that daily doses of 500 mg or more over several months may cause a peripheral neuropathy (2,3). Between 10 mg/day (safe) and 500 mg/day (unsafe) there is a murky region of poor quality evidence. Central to the argument is a report by Dalton & Dalton (4). Dr Dalton was a private practitioner specialising in the treatment of PMS who believed that hormone treatment was appropriate, but B6 was not. When women came to her who had been taking B6 she advised them to have their serum B6 level estimated, and asked them if they had experienced any altered sensations in their limbs or skin, or if they had noticed muscle weakness or pains. Among 172 women who had high levels of B6 (> 18 ng/ml) 103 responded positively to these enquiries, and had "a neurological examination", the nature of which is not described. They had been taking 50 to 500 mg/day, and on stopping B6 the symptoms improved. The weakness of this experimental design is obvious, and the food supplement lobby rightly refers to it as "flawed research".

By way of counter-attack the Council for Responsible Nutrition (CRN) symposium at the Royal College of Physicians on 8th September, promising "new data" on the safety of B6. This turned out to be the result of a postal survey of 86 users which they had commissioned from Taylor Nelson ACB Healthcare between 26th June and 18th July. Over 10,000 questionnaires were mailed out, and 1671 came back saying that the respondents took B6 (mostly at a dose of 50 mg or more, but for an unknown period), and that they were very happy with their supplement. They did not report having neuropathy. Dr Ian Munro told us that in dogs a dose equivalent to 3 g/day in human subjects caused only minor neurological damage after 107 days. This was not altogether good news, because Schaumburg had shown that in man this dose caused severe damage, so clearly a dog is not a very sensitive indicator of toxicity. A paper by Dr Allan Bernstein reported that he did not find problems in patients with doses of 100 to 150 mg/day and commented that the neuropathy described by the Daltons did not correspond with true B6 neuropathy, so he thought that tablets up to 200 mg should be available without prescription.

All this illustrates that people (eg. buyers vs sellers) can look at the same set of indifferent data and come to opposite conclusions. The Minister is told that 1.4 mg/day of 86 is enough, so no-one needs a supplement which provides more than 10 mg/day. There may be danger in taking higher doses. On the other hand the supplement lobby claim that 100 mg/day does no harm, and may be helpful in the treatment of PMS and other conditions. Both views are tenable in the present state of knowledge, so which side should HealthWatch be on?

I think that Dr Bernstein is wrong to suggest that 200 mg tablets should be available off prescription, since the chance of someone taking several tablets per day and damaging their nerves is far greater than the potential benefit. The fact that B6 is a vitamin rather clouds the issue: if it is being used as a drug rather than as a nutrient then the permitted dosage should be judged on the basis of risk and benefit, as it would be for any other drug. The compromise that tablets between 10 and 50 mg should be sold only in pharmacies, and above 50 mg only on prescription seems reasonable from the viewpoint of safety, but what about the evidence of efficacy? It is hypocritical for Solgar to evoke "the vision of hundreds of thousands of premenstrual women marching on Parliament" because they cannot get their favourite PMS pill from the supermarket. If there is a market that large why are we not offered the "well-designed trials with positive results" called for by Kleijnen *et al* to show it is an effective treatment? The problem is not (as the CRN suggests) one of consumers being denied free choice, it looks more like one of producers making unsubstantiated claims.

John Garrow Chairman, HealthWatch

References

1. Kleijnen J, Ter Riet G, Knipschild p, Vitamin 86 in the treatment of the premenstrual syndrome-a review. *Br J Obstet Gynaecol* 1990; 97: 847-52.
2. Schaumburg H, Kaplan J, Windebank A *et al* (1983) Sensory neuropathy from pyridoxine abuse. *N Engl J Med* 1983; 309: 445-8.
3. Berger A, Schaumburg H. More on neuropathy from pyridoxine abuse (letter). *N Engl J Med* 1984; 311: 986-7.
4. Dalton K, Dalton MJT. Characteristics of pyridoxine overdose neuropathy syndrome. *Acta Neurol Scand* 1987; 76: 8-11.

See also letter from Linda Lazarides in [Newsletter 29](#)

[Top of page](#)

Fraud in medical publications

HealthWatch's chairman, Professor John Garrow, is also editor of the European Journal of Clinical Nutrition. He explains here how publishing fraud happens and how it might be reduced.

HealthWatch promotes the assessment and testing of treatments, whether "orthodox" or "alternative", preferably by means of valid clinical trials. Normally the channel by which the results of these trials are made known to the scientific community is by publication in a peer-reviewed journal.

The investigator (or, more commonly, a group of investigators) submits a manuscript in a prescribed format to a journal editor, who consults expert reviewers, and then decides whether or not the paper is worth publishing. If it is rejected the editor will try to explain why it was unacceptable, and if it is acceptable there are usually several points which can be improved or clarified, so the authors are invited to submit a revised version, which is in due course published.

The publication of a research paper does several things in addition to presenting new findings to the scientific community. If it is an exciting new discovery it enhances the promotion prospects of young investigators, the funding prospects of the institution in which the work was done, and the prestige of the journal in which the publication appears, so there may be conflicts of interest between the desire of both authors and editors to present a "breakthrough" and the need to present the whole truth, so the weaknesses as well as the strengths of the study are clearly set out. It is usually rather easy for the editor to resist overstatement of the value of a study, because his main interest is that his journal should be known to be reliable, and the reviewers who advise him are quick (sometimes too quick) to point out flaws in the research of rival investigators.

But what if the results presented are false literally too good to be true? This does not necessarily involve fabrication of non-existent data (although this does sometimes happen), because selection of the cases which support a hypothesis for publication, while negative results are suppressed, will easily generate a report which seems to show an effect where none really existed.

How often does this happen, and what can be done to stop it? These were the questions uppermost in a group of about 100 editors of medical journals who met near BMA house in London on 4th November, at which real but anonymous examples of "publication misconduct" were presented for discussion. The question "How common is publication fraud?" cannot be answered unless we agree a definition of "fraud", since there is a spectrum of misconduct ranging from fabrication of data (which everyone agrees is fraud, but which is rare) to what some editors count as fraud and others as little more than bad manners. For example in an ideal world investigators

would give full credit to others who prepared the ground for the research they did, and they would present their own results as concisely as possible. In practice this is often not done because it is not in the nature of investigators to search diligently for others with whom the credit for their discovery should be shared, and it may well seem to them that their work deserves to be published in several fragments (thus generating several citations for their curriculum vitae) rather than as a single report. However these are not trivial offences. Failing to acknowledge other work on which you have built is in effect stealing the work and representing it to be your own; this is called plagiarism.

Salami slicing of results, so your series of 18 patients with Whatsits Syndrome appear in four different journals, may mislead readers into thinking that there are 72 cases of this rare syndrome. The solution to this problem is that editors must be willing to print retraction notices when they learn that papers which they accepted in good faith are in fact republication of previously-published, but unreferenced, work. Editors are not always keen to do this: it does nothing for the image of their editorial process, which might have been expected to spot this flaw before accepting the paper.

Of course the most serious form of publication misconduct, which can cause the greatest harm to patients and to science, concerns data which have been tampered with to make the story seem stronger. It has recently been shown that editors can inadvertently contribute to this distortion of the evidence by giving preference to reports with a positive result over those of equal merit with a negative one. For example if an investigator presents a technically good report of a trial that shows that a supplement of vitamin XYZ significantly improves recovery from condition ABC (which is unexpected) the editor may well accept it. Why not? However a paper out of the blue saying vitamin XYZ had no effect on ABC would have no chance of publication: whoever thought it would have been any good? So the positive report (which may be genuine, but a chance finding) always gets a start over the negative reports which show that it was a chance finding. I see no cure for that: We editors cannot be expected to fill our journals with negative reports of improbable effects.

The most significant outcome of the editors' meeting on 4th November was a resolve that "whistleblowers deserve protection." This is crucial. If a keen investigator massages the results of a trial, so that some patients who do badly get forgotten while those that do well are written up, it is very difficult for the editor or reviewer to spot the fraud. But a colleague in the department may note that 53 patients entered the trial, of whom 4 died, yet the report lists only 50 patients, of whom one died. They have a duty to science to cry "foul", and many do so, but at considerable personal cost. Of course some whistleblowers are in fact malicious, and can cause great damage to honest investigators, but the subsequent career of genuine whistleblowers shows that they do not usually benefit from their public-spirited action just as the whistle-blower in Ibsen's play was judged to be an "Enemy of the people".

There is another solution, which is set out in a HealthWatch [Position Paper on the design of clinical trials](#). When trials are approved by an Ethical Committee a trial registration office (TRO) is set up. When a patient consents to enter the trial the investigator contacts the TRO (usually by telephone) and registers the basic data about this patient. The TRO then tells the investigator the treatment group (drug, placebo, etc) to which this patient has been randomly allocated, so there is no possible selection bias on the part of the investigator. When the trial is written up the TRO will check that all the patients who entered the trial have been accounted for. This would do a lot to improve the standard of medical scientific reporting, without requiring whistle-blowers to act as human sacrifices.

John Garrow, Editor of the *European Journal of Clinical Nutrition*

[Top of page](#)

Doctors in controversy over "natural born healers"

Partners at Southampton's Grove Medical Practice, who cooperated with the making of a recent programme on Channel 4's "Natural Born Healers" series on complementary medicine (presented by Dr George Lewith of the University of Southampton's School of Medicine), write to HealthWatch to express their concern at the finished programme:

The GP's involved believe the programme was seriously biased. It promoted Dr Lewith's organisation and showed his partner using unproven diagnostic methods, while denigrating orthodox clinical practice.

Dr Lewith has been an influential figure in the promotion of alternative medicine and was a spokesperson for the recent report promoted by the Prince of Wales. We raise our concerns because doctors are increasingly being asked to sanction such diagnoses and treatments from limited NHS funds.

In this programme (broadcast on 18th December 1997), a patient with chronic fatigue was assessed by electronic gadgetry by Lewith's partner, Dr Julian Kenyon. Multiple and changing diagnoses were made. These included malabsorption, liver deficiency, hypoglycaemia, candida infection, immune disturbance, parasite infection and deficiency of several vitamins and minerals. None of these was confirmed by conventional testing. Complex therapy involved vitamin injections, mineral injections, herbal remedies, homeopathic remedies and anti-fungal agents at a total cost of £1 ,240. Dr Kenyon claimed that they see 400 such patients every six

months.

Patient "no better"

The patient was registered at the Grove Medical Practice at Shirley Health Centre, and was reviewed by his GP Dr Peter May at the end of three months' treatment. He was found to be no better. The programme, however, which is narrated by Dr Lewith, claims the patient showed a 60% improvement. This claim was based on a consultation with the alternative practitioner which took place a month later, at which time his GP was not given an opportunity to assess him.

Dr May and his partners believe the film has seriously distorted the story.

In particular, the editor omitted discussion of:

- the lack of scientific validity of Dr Kenyon's diagnostic computer;
- extensive conventional tests which contradicted Dr Kenyon's diagnoses;
- an abnormality discovered by Dr May but overlooked by Dr Kenyon;
- counselling therapy that was conducted throughout the test period;
- the side effects of medication that could have caused key symptoms;
- a positive response to a trial of antidepressant therapy.

Fatigue "had recurred"

In addition, the film fails to show the reasons why the GP was unimpressed:

- the patient arrived in his surgery wearing dark glasses to relieve discomfort in his eyes, which the producer insisted he remove before filming;
- the patient claimed that his fatigue had recurred despite the treatment;
- during the final GP assessment the patient was so fatigued that he had to stop for a banana and a glucose drink before being able to finish the consultation.

Despite firm assurances to the contrary, the programme failed to discuss:

- the anecdotal value of a single case study;
- the need for properly constructed trials;
- the nature of the "placebo effect".

The partners of the Grove Medical Practice believe the result was a seriously biased programme which promoted alternative medicine.

"Unproven"

Dr Kenyon was practising unproven therapies, with Dr Lewith's approval.

Dr Lewith has been urging GP's to use their limited NHS budgets to pay for unproven therapies. Such expenditure would be a waste of public money.

All doctors who aim to practise evidence-based medicine should challenge the integration of such diagnostic and therapeutic methods into mainstream NHS healthcare.

[Top of page](#)

Are you serious...

Dr Andrew Herxheimer recently received an unsolicited e-mail from an American company who asked him, 'Are You Serious About Weightloss?'

The company, Planet New Medicine, were promoting their "Natural Alternative to Dangerous Weightloss Drugs". Their programme uses "Homeopathic Medicinal Nutraceuticals, with ingredients that are registered with the FDA, that work for you around the clock (24 hours), and have been used by thousands of satisfied customers.. All this with a no-risk, 60 day money-back guarantee". It is claimed to be "as effective as the prescription drug regimens.. without any of the side effects. Weight loss proceeds naturally, without feelings of deprivation (*sic*), depression and loss, increasing energy (without feeling the "jitters"), increasing positive mood and self confidence while naturally changing your appetite for more healthy foods."

Can it be true? Seems unlikely, and there seems little prospect of there being any effective way to control unrealistic claims made through the medium of the Internet.

Opinions expressed in letters and articles published in the HealthWatch Newsletter belong to the authors and do not necessarily reflect the views of HealthWatch. The editor reserves the right to amend text if necessary but will, where possible, consult the author to ensure accuracy is maintained. Letters and articles for publication are

welcomed and should be addressed to: *The Editor, HealthWatch Newsletter, HealthWatch, Box BM HealthWatch, London WC1N 3XX*

Letters and articles may also be sent to the Editor by e-mail to: newsletter@healthwatch-uk.org

Copyright © 1998 HealthWatch.

[Top of page](#)
