

## Newsletter no 27: October 1997

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## Are we being alarmed unnecessarily?

### *Dr Neville Goodman is disappointed by the media's doom predictions relating to how we're going to die*

"Every other Briton Will be hit by cancer" howled the *Independent* (25 June). It was not alone. Newspapers and the broadcast media alike were full of gloom and doom after a medical article appeared in which predictions were made for Britain 20 years from now. Predictions are important for the planners of health services, but this particular prediction should not have made it beyond the pages of the journal it was published in.

Experts popped up to be interviewed. A number of them criticised the statistics and assumptions of the prediction. Their criticisms were valid, though fully realised by the authors of the study. One of them, Dr T. W. Davies, Director of the East Anglian Cancer Intelligence Unit was clearly upset by the sensational response and wrote a letter to the *Independent* (28 June). The core of his complaint was the use of military analogies, of wars being lost. The *Guardian* took little notice. It admitted (*Guardian G2*, 1 July) that there were many success stories about cancer, but repeated that "New research says that in the next 20 years half the population will have cancer"

The criticisms were valid, but the correct public response to the story was, "So what?" The sensational headlines overlooked that we are living longer, and that life expectancy shows no signs of becoming less. Whatever way we die we nonetheless all will die. The numbers diagnosed with cancer would decrease dramatically if we brought back some of the more unpleasant infectious diseases, stopped the active treatment of heart attacks, and halted organ transplantation. A recent charity drive selling artificial red roses for heart research was based on the motto that heart disease is "Britain's Number 1 Killer". This is true and has the same logical flaw as the worry about the prevalence of cancer, but there is the subtle difference that it is always likely to be true. Heart disease-as a generic whole-will never be "solved".

People forget what has been before; they worry only about what they see. Dr Davies made the good point that people are mature enough to cope with predictions if discussed non-sensationally. The present intermittent hysteria about "the big killers" threatens to unbalance medicine in a more serious way than the occasional worries about rare diseases such as meningitis. What should most concern us are not the diseases that kill us, but the diseases that kill us before our time. Heart disease being so protean, it might well fit the bill, but there is a slight dishonesty seeking our money with the blunderbuss "One in three of us dies of heart disease"; we probably always will.

Vaidya and Mitra described an interesting way of bringing mortality into prediction: they expressed survival for patients with cancer not in terms of actual years but as a fraction of normal remaining life span. A similar approach to other fatal diseases (and other causes of death we can influence, such as road accidents) might bring some perspective. The preferred response of many is to worry about unknown factors: oestrogens are a current favourite (see, for example, Setchell *et al*). The writer of another letter in the same issue of the *Independent* asked whether environmental oestrogens were responsible for increases in breast, prostatic and testicular cancers. "All chemicals should be tested for their ability to give off oestrogens" because "to improve human health we must clean up the environment"-which overlooks (as most of these shrill cries do) that we are healthier now, and our environment cleaner, than ever before. It also overlooks that we seem unable to do anything about the common cancers whose causes we do know. Some of its victims might die later of other cancers, but lung cancer will remain for a long time the only common but largely preventable cancer.

Predictions of cancer deaths by epidemiologists are one thing, but pronouncements by government ministers

sometimes make one wonder whether anyone in real control of what happens in health will ever understand the realities. Ron Davies, the Welsh Secretary, has declared a target to halve lung cancer deaths in Wales within 12 years. The success so far of anti-smoking campaigns make it unlikely, for a disease that has a latency of 20 years, that this target will be even approached, let alone reached-unless lung cancer sufferers can be persuaded to move to England or to die of something else.

#### References

1. Setchell KDR et al. Exposure of infants to phyto-oestrogens from soy-based infant formula. *Lancet* 1997; 350: 23-7.
2. Vaidya JS, Mitra I. Fraction of normal remaining life span: a new method for expressing survival in cancer. *British Medical Journal* 1997; 314: 1682-4.

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## Blood and urine therapy is "quackery" conclude RPS committee

***A Gloucestershire couple who practised a therapy known as spagyrik, which involves boiling up samples of patients' blood and urine to make diagnosis and treatments, have been found guilty of misconduct by the Statutory Committee of the Royal Pharmaceutical Society, who concluded that they had been "practising quackery from the premises of a licensed pharmacy".***

The decision of the Statutory Committee was published on 14th August 1997. It concerned complaints made against Rosemary and Kenneth Spellman, whose company Signalysis Ltd runs a registered pharmacy from an address in Stroud. These premises, the Committee found, are "just about exclusively employed in the manufacture and dispensing of spagyrik therapy products." A second respondent was Jasmine Wells, Superintendent Pharmacist at the premises.

In the course of the investigation, Professor Rawlins, a professor of clinical pharmacology who has since 1993 been chairman of the Committee on the Safety of Medicines, made "the most withering attack upon the spagyrik therapy" and said he could find, "no pharmacological basis for the process." He refused to confirm whether the therapy was likely to be safe, and also said that, "it was simply impossible from its literature to replicate any of the results claimed."

### Expert witness "confused"

Signalysis Ltd's expert witness Dr Habel, a spagyrik practitioner and medical practitioner from Germany, was thought by the Committee to be "ill prepared, often confused. ..and apparently willing to make any claim that he thought he could get away with by obfuscation."

The Committee's conclusion, based on the evidence heard over the course of five days between 22nd May 1996 and 17th April 1997, was that "the spagyrik treatment and therapy has no pharmacological basis at all. It is not supported by any clinical trials. It is not scientific. It has no credible or respectable place in scientific literature." While conceding that Mr and Mrs Spellman "are well-intentioned and compassionate people concerned with the well-being of others" the activities conducted at their pharmacy were judged to be "reprehensible".

### "Serious professional misconduct"

Mrs Wells, as the Superintendent Pharmacist, was said to have had, "full responsibility to take care of all legal and ethical matters in that position, and in view of the situation that we have found to be so, she failed to do so." By her presence, the Committee added, she added credence to what it called, "the presence of quackery." The Committee concluded that she had been guilty of serious professional misconduct, rendering her unfit to be registered as a pharmacist.

The Statutory Committee wished it to be known "to any other pharmacist on the register that should they choose from now on to be associated as a Superintendent Pharmacist or in any other role with Signalysis Ltd (or any other company or body carrying on the spagyrik therapy) then this Committee will regard that association as misconduct and, subject to mitigation or explanation, would be likely to order the erasure of that pharmacist's name from the Register."

**See also article [below](#): HealthWatch doctors air views in documentary, and [Newsletter no 22](#)**

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## EMFs: tell the public the truth

***... argues Dr Neville Goodman, HealthWatch Committee member and Consultant Anaesthetist at Bristol's Southmead Hospital***

With the customary lack of media coverage, an article in the *New England Journal of Medicine* failed to find a link

between electromagnetic fields and cancer (HealthWatch [Newsletter issue 23](#), October 1996).

The investigating team enrolled 638 children with a form of leukaemia, and 620 controls. They looked at the fields from domestic wiring, distribution lines, and high-voltage cables.

It is time that an official statement was made. Even if a link is eventually described, it will be small enough to be ignored.

Millions of pounds and dollars are being wasted, which should be spent on more worthwhile questions of public health.

Reference: Linet MS et al. Residential exposure to magnetic fields and acute lymphoblastic leukemia in children. *New England Journal of Medicine* 1997; 337: 1-7.

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## Psychic healers: complaints upheld

***A clutch of psychic healers had complaints about their promotional material upheld by the Advertising Standards Authority last month.***

A particularly remarkable claim was among those made by a Mrs Sylvia Stevenson, in a leaflet in which she referred to herself as a "Psychic Spiritualist Root And Herbs Worker". Here, along with reuniting the separated, removing evil influences and healing the sick, it was said of her abilities that, "Childless couples become happy parents.. .100% Results Guaranteed within 30 days or money back". The advertiser, based in London, did not respond to the ASA's enquiries and was asked to withdraw the ad immediately.

There was more criticism in store for ads circulated by two other London-based healers. A leaflet headlined, "Sister Mary.. .Psychic House of Healing (sic)" offered "Guaranteed results" in areas that included, "bring back loved ones, end loneliness, stop jealousy, help with family, bring a better career, help with sickness and health, immigration, alcohol and drug abuse...". The ASA asked for immediate withdrawal of the ad.

Meanwhile another leaflet was being circulated with the headline, "The Strength of Psychic Knowledge... Mrs Adams... Spiritual Advisor, Healer and Spell Breaker". The copy read, "My guard, oils, candles, incense and prayers will do any job that needs to be done without fail.. .100% Fully Guaranteed Results." The advertiser defended the claims, saying they were true for those who believed in faith healing. The ASA, however, were concerned that there was not enough to substantiate the claims and asked that they should not be used again.

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## Candida: how much of a threat?

***Infection with the yeast Candida has been blamed for conditions ranging from chronic fatigue and irritable bowel syndrome to arthritis. Some alternative practitioners recommend drastic exclusion diets as remedies. But what are the facts? Dr Gillian Shankland, Principal Mycologist at the University of Glasgow's Department of Dermatology explains:***

There has been considerable speculation in the popular press in recent years as to the role *Candida* plays in a variety of complaints ranging from lethargy and allergy to systemic degeneration. Unfortunately a lot of theories reported are not based on peer reviewed scientific research and this has spawned many unscrupulous practitioners who prey on unsuspecting, debilitated individuals and expound pseudo science to add credence to their theories.

This is unfortunate for the individuals concerned but it is also making the job of those who try to investigate any of these allergy or overgrowth hypotheses, in a controlled scientific manner, just about impossible.

### What is Candida?

*Candida* is a genus of yeasts. Yeasts are single-celled fungi which reproduce by budding in their asexual state. There are several genera of yeast, the vast majority of which cause us no harm. Many, for example those from the genus *Saccharomyces*, enhance our lives by forming the basis of baking, brewing and wine production.

*Candida* is part of the normal human flora and everybody at some stage in their lives will carry *Candida* species in their mouth or gut where it will generally cause them no harm at all. There are some 200 species in the form genus *Candida*, all of which are associated with man and other warm blooded animals.

The overt presence of *Candida* infection always indicates an underlying problem. The species most often associated with both healthy and infected subjects is *C. albicans* but other species including *C. glabrata*, *C. tropicalis*, *C. parapsilosis* and *C. krusei* may also be implicated.

## Candida morphology

*Candida* is mainly present in the single-celled state but some species are dimorphic - that is, they may form themselves into a complex network called a mycelium; others can produce chains of elongated individual yeast cells termed pseudomycelium. Many *Candida* species are seen in all three forms *in vitro* as well as *in vivo*. Much of the crank literature says that the appearance of mycelia indicates the onset of pathogenic growth. This is not true. The ability of *C. albicans* to produce mycelium is certainly thought to be one factor contributing to its virulence (ability to cause infection) but both mycelia and the single-celled form are present in culture and when actively invading tissue as can be seen on histopathological examination. Moreover, *C. glabrata* is the second most commonly isolated species from the guts of healthy individuals and from cases of vaginal candidosis and it does not have the ability to produce either true mycelium or pseudomycelium.

## Candida terminology

The variety of ways in which *Candida* may be found in the body can be as diverse as the underlying conditions. They can be classified as:

- **Colonisation**, in which the organism coexists with other microbial flora in the mouth or gut.
- **Superficial infection** of the skin and nail where it can be detected by direct microscopical examination of specimens. These are infections of the non living keratinised layers.
- **Mucocutaneous infection** includes vaginal candidosis, oral thrush and pharyngeal infections. These infections can be quite severe in MDS patients.
- **Chronic mucocutaneous candidosis** is a complex disorder of recurrent *Candida* infection of the skin, nails and mucous membranes which is generally related to diseases of the immune or hormonal systems
- **Systemic infection** of the blood or internal organs can be localised or may become disseminated throughout the body. These tend to be infections of severely compromised individuals and may be fatal if not treated appropriately. The yeast may be present as a focus of infection such as endocarditis (heart) or endophthalmitis (eye) or become disseminated through the bloodstream and invade several tissues.

## Diagnosis

Conventional medicine uses culture and immunological methods to detect whether *Candida* is present. *Candida* is not a particularly fastidious organism and will grow on many of the routine media found in a general microbiology laboratory. There are also more specialised media which have been designed to enhance its growth, especially from blood culture. The amount of *Candida* isolated can be measured and the colony-forming units per gram or ml of specimen counted. It is details like this which are often lacking in the anecdotal descriptions of candidosis given in the popular press by alternative practitioners, and which does not allow for the proper evaluation of alternative therapies.

When an individual with a healthy immune system is infected, (and in some cases colonised) by *Candida*, antibodies to the yeast are likely to be detected. The levels of these antibodies can be used as a guide to the extent of involvement and progress of any therapy. There are some descriptions of *Candida's* toxic waste products in the alternative literature. Indeed diagnostic mycology laboratories use sophisticated methods such as HPLC and monoclonal antibody based latex and ELISA tests to "sniff out" *Candida's* chemical footprints in patients samples. The level of sensitivity of these tests is in the region of 2.5 ng/ml. Despite the millions of pounds spent to find an antigen (that is, a foreign material-usually a protein-produced by the invading organism that can trigger the body to produce antibodies that will fight it) specific to *Candida* infection there is still no test for candidosis. Research in this area is, however, discussed and published with the required controls in peer reviewed journals and tests are subjected to considerable investigation which is time consuming and expensive. This may be one reason therapies proposed by alternative practitioners are not so stringently investigated. Should anybody devise a test for Candidosis, based on concrete evidence, it would be welcomed.

## Treatment

The treatment of potentially fatal systemic infection by antifungal drugs is done under clinical supervision in hospital by the intravenous route predominately with the drug amphotericin B often in combination with 5FC. These patients have severely debilitating underlying conditions and have often undergone immunosuppressive therapy. There are several other families of drugs including the imidazole and triazole antifungals suitable for treating less acute *Candida* infections. The indiscriminate and inappropriate use of these drugs over time could lead to severe problems with the treatment of more acute cases or patients with long term recurrent problems. There is some evidence that antifungal pressure can cause pathogen shift within a hospital or ward after changing antifungal prophylaxis regimens.

That is, the organisms isolated change.

We saw the development of resistance to some antifungals in AIDS patients who were on long term high dose therapy for oesophageal candidosis. The species of *Candida* isolated after antifungal therapy may change, which is why it is important that the causative organism is isolated and identified to species. Selective gut decontamination by polyene antifungals is a recognised procedure before several hospital procedures and is a successful method for ridding the gut of commensal yeasts for a short time but there will be recolonisation by the

normal flora.

## "Alternative" diets

Diets recommended by some practitioners of alternative medicine can be very restrictive and unbalanced. There is no evidence published to support the use of these diets. The exclusion of alcohol, blue cheeses and bread are presumably made on the assumption they contain yeasts which then may inhabit the gut or release antigens to "irritate" the host's immune system. The bakers' and brewers' yeast *Saccharomyces cerevisiae* is from a different genus of organism and the *Penicillium* spp. associated with cheese production are very far removed phylogenetically. The exclusion of sugary foods would be beneficial to the teeth but the effect on *Candida* colonisation has not been investigated in controlled studies. Foods, even wholly natural foods, are chemically complex. Many of them will be broken down to simple sugars by the digestive system, which defeats the object of excluding sucrose in the first place.

## Conclusions

Candidosis does manifest itself in cases when the host is debilitated and undoubtedly the prolonged use of antibiotics and other medical treatments can contribute to the proliferation of *Candida* numbers. There may well be members of the population who could develop sensitivity to *Candida* but there is only anecdotal evidence that "crank" diets do anything to reduce *Candida* numbers. Until the claims of the sufferers and alternative approaches to cures are investigated in properly in controlled clinical trials then these claims cannot be substantiated. The trial designs should take into account the numbers of faecal organisms and also specific measurable parameters of the immune system. These should be closely monitored before and during any "treatment" and at follow up. People may put themselves at considerable harm by restricting the range of food and drink they consume as the body may not be receiving all its essential nutritional requirements. This may compound any underlying debility and increase the likelihood of prolonged colonisation with *Candida*. Any patient therapy, whether mainline or alternative, should undergo rigorous testing before being applied to patients.

Gillian S Shankland

See also article on *Candida* by Ursula Arens in [Newsletter no 8a](#)

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## HealthWatch doctors air views in documentary

***A recent BBC2 documentary featured several of HealthWatch's medically qualified members. Professor Edzard Ernst of Exeter University's Department of Complementary Medicine, general practitioner Peter May (introduced as a member of the "doctor's pressure group HealthWatch") and Charles Shepherd, medical adviser to the ME Association, were all given air time to voice their concerns about issues related to the practice of complementary medicine.***

The half-hour programme, part of the Home Ground series, was broadcast at 7.30pm on the 15th July.

It's main focus was on a curious treatment called Signalysis, or spagyrik, which has been the subject of a recent investigation by the Royal Pharmaceutical Society (see [above](#)) in which HealthWatch member Dr Charles Shepherd, who practises in Gloucestershire, was a key witness. The method involves boiling samples of a patient's blood and urine. Patterns of crystal residues formed are used to diagnose the conditions. Dr Shepherd commented, though, that there is no scientific evidence to support claims that this method can diagnose disease. The programme went on to explain that medicines are made from the steam formed during the process.

An elderly Cambridgeshire couple interviewed, who had sought help from Signalysis practitioners for relief from arthritis and ME, had been so desperate that they were undaunted by the fact that their GP refused to take blood samples for the Signalysis practitioners to use. It was an acupuncturist who eventually agreed to take the samples for them. But in retrospect the wife claimed her husband's condition had, if anything, deteriorated rather than improved after taking the treatment.

As well as drawing attention to the more extreme and unusual methods such as Signalysis, the programme highlighted the growing acceptability of complementary techniques amongst the medical authorities. An example is the Complementary Health Centre in Glastonbury which offers herbal medicine, acupuncture, osteopathy, massage and homeopathy as part of a five-year study funded by Somerset Health Authority. Nearby another NHS-funded enterprise is a healing clinic which has been so successful in terms of patient demand that it now has a waiting list for treatment.

While there are unexpected positive spin-offs to offering certain alternative methods - patients being seen at the healing clinic apparently spend less time with their GPs - the programme noted that complementary treatments are not free of adverse effects.

Amongst nearly 700 doctors who replied to a recent BBC survey, while 80% said they had recommended complementary therapies to patients, 87% of the same sample also said they wanted to see more regulation.

Even doctors who themselves practise complementary therapies were worried about the health claims made by some alternative practitioners where serious diseases are concerned.

At Exeter University a number of alternative therapies are being subjected to rigorous clinical testing. Professor Edzard Ernst commented that it is often difficult to persuade therapists to subject their methods to scientific scrutiny. "Nine out of ten withdraw when they realise the possibility of a negative outcome," he said.

HealthWatch member Dr Peter May said, "GP's have had extensive training in scientific medicine. It seems to me tragic that the state of the art of medicine won by hard work over hundreds of years is being ditched in favour of superstition."

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## Medical editors united against research fraud

***The Editors of the British Medical Journal, the Lancet and a number of specialist medical journals have united to combat research misconduct by establishing a Committee on Publication Ethics (COPE).***

The initiative came from Michael Farthing, editor of *Gut*, who encountered four cases of misconduct in his first year as journal editor. The move follows last week's decision by the General Medical Council to strike off John Anderton, former registrar and secretary of the Royal College of Physicians in Edinburgh, for faking data in a clinical trial.

Writing in the *British Medical Journal*, editor Richard Smith said that it is increasingly difficult to argue that British cases of research misconduct are rare but that, shamefully, we are leaving it to pharmaceutical companies, a private agency and the media to uncover cases of fraud. Dr Smith argued that the failure of medical schools and royal colleges to get to grips with the problem undermines the medical profession's case for self-regulation.

Dr Smith wrote that he hoped that the new Committee will encourage editors to respond more rigorously to possible research misconduct and ethical misbehaviour, rather than taking the easy option of simply rejecting questionable papers.

Reference: *British Medical Journal* 1997; 7102 (315): 201.

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## Nurses practising complementary therapies

***Growing numbers of nurses are choosing to practise complementary therapies. Are there adequate controls to protect patients from ineffective treatments? HealthWatch Chairman Professor John Garrow asked Miss Celia Manson, the Royal College of Nursing's Advisor in Nursing Practice (Complementary Therapies), in an interview at the RCN on 30th June 1997***

"Many nurses are enthusiastic about Complementary Therapies (CT) which the RCN endorses," John Garrow began. "Can you estimate what proportion of RCN members want to practise CT?"

*Manson:* The CT Forum was set up in 1994 and its membership is increasing rapidly to about 4,000 out of the total RCN membership of 300,000 plus, so it is still a small proportion of the total.

*Garrow:* In the literature you kindly sent me the RCN said it would provide indemnity for members who had "appropriate training" in CT. What does that mean?

*Manson:* The RCN really leaves it to the judgement of the individual member to decide if their training is appropriate for what they want to do. We inform members about courses at Diploma, Masters and Degree levels in various complementary therapies; these include acupuncture, therapeutic bodywork, homeopathy, herbal medicine, osteopathy, aromatherapy and reflexology.

*Garrow:* For some of these therapies, like osteopathy, there is good evidence that they are effective, but for others there is no such evidence. Does that affect the RCN attitude to providing indemnity?

*Manson:* Not really, because if the member has been trained we assume they are able to practice safely. But if someone asked our advice about taking a course in a therapy for which there was no evidence of efficacy we would point that out, but in the end the member must take the decision. We do not have either prescribed, or proscribed, lists of CTs. The UKCC position statement, 'in 1994, advised that nurses using complementary therapies should discuss this with other members of the health care team caring for a particular patient. They also say that it is vitally important that the introduction of any of these therapies to your practice is always in the best interests and safety of your patients or clients.

*Garrow:* What happens if a nurse uses a CT to diagnose, say, gall-bladder disease by iridology? What is she then going to do about it?

*Manson:* I am unaware that that has arisen, but I suppose the nurse would discuss the case with a doctor who might say either that he thought there was, or was not, a problem with the gall-bladder. But I agree it might cause difficulties.

*Garrow:* Then, to be blunt, the nurse is just playing at complementary medicine. The point of iridology, kinesiology, reflexology, etc. is that it enables the practitioner to diagnose disease which ordinary medicine cannot detect. If the nurse then backs off if the diagnosis is not supported by an orthodox medical doctor, doesn't that make the whole exercise rather pointless?

*Manson:* That situation would be terribly difficult, but so far as I know it has never happened. I do not think our organisation has really thought how we would cope with it if it did arise. The RCN considers people practicing within the context of nursing: if a member went off and did something other than nursing they could not look to the RCN for indemnity insurance, because they are not then functioning as a nurse. Even so, within nursing practice there have been problems, for example with adverse reactions to essential oils used in aromatherapy.

*Garrow:* Indeed, I understand that trying to combine the use of aromatherapy oils with barrier-type contraceptives has disastrous results, but perhaps you can trust a trained nurse who is familiar with the action of oil on rubber not to make that sort of mistake.

I would like to go on to another point in the RCN forum statement: that informed consent should be obtained from patients for complementary therapies, and records of this kept with the patients/clients care record. Does this actually happen?

*Manson:* I hope so, but suspect it is not done as often as it should be.

*Garrow:* Do you think it appropriate for senior nurses to remind their colleagues in CT that they have this duty? Nurses have a distinguished tradition of keeping their medical colleagues to the rules on such matters.

*Manson:* Yes, they should certainly advise their colleagues, but if this advice is disregarded what can they do? I suppose it would be a matter for the employers for nurses working in the NHS, but for nurses working on their own it is difficult to see how they can be effectively supervised.

*Garrow:* The RCN set up the Complementary Therapies in Nursing Forum, so I would have expected the officers of the Forum to collect information about any problems with obtaining or recording consent, and the results of evaluations of the therapy, which is another of their objectives.

*Manson:* Your questions highlight the fact that we do not at present have an effective monitoring system, and I think it will be one of the tasks for the newly-elected committee of the Forum to consider what should be done, but I do not think the committee can be expected to undertake a policing or inspection role-they do not have the resources to do that.

*Garrow:* Of course not, and HealthWatch does not have the desire or resources to undertake a policing role either. However we are very interested in the evaluation of therapies -whether complementary or orthodox-and it seems that nurses have a unique opportunity to contribute to this. Most CTs are done by practitioners who depend on CT to earn their living, so it is asking a lot that they should evaluate them objectively. Nurses who are using CTs within the NHS, but who do not depend on CTs for their livelihood, are therefore in an excellent position to keep records and see which therapies work for what conditions. Is there any way in which we in HealthWatch can work with the RCN Forum to obtain this information?

*Manson:* I think it would be very helpful if you spoke with the new Chairman of the Forum. It would be rather an exciting possibility to have a trial of CTs organised in the way you suggest, but I do not know how many nurses are using CTs as part of their NHS work, or how many are doing it part-time as an extra source of income. In principle I am sure the Forum would like to take any opportunity to show that this work was effective, and worth funding from NHS resources.

*Garrow:* I will send you two copies of the transcript of this conversation, and would be grateful if you would pass on one copy to the Forum. It would be great if we could combine to provide evidence about the efficacy of CTs in areas where such information is sparse.

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## Letter: Is this good science?

*George Lewith, Honorary Visiting Clinical Senior Lecturer at the University of Southampton's School of Medicine, writes:*

Dear Sirs

I received your recent magazine (HealthWatch [Newsletter issue 26](#), page 6) and was very pleased to note that you had quoted a study of mine which involved a properly controlled, double-blind, clinical trial on Arnica, indicating that Arnica was ineffective.

I was, however, quite appalled that you would attempt to draw any conclusions about any treatment on the basis of a single case study in one individual involving a relatively small number of stool samples ("Fat magnets come unstuck", HealthWatch [Newsletter issue 26](#), page 1). Surely it's Health Watch's duty to report and consider good science; had the treatment worked I am sure that you and I would have both felt that a single case study was an inadequate basis upon which to draw any conclusions.

Interestingly, one or two of my patients receiving Arnica actually did very well post-operatively, but the clinical trial as a whole showed Arnica had no effect. I am sure you would have felt it completely unreasonable and quite unscientific (as indeed would I) had I made any attempt to publish these one or two individual cases as proof that Arnica either did or did not work!

I am sure your readers will draw their own conclusions about your editorial policy.

Yours faithfully

George Lewith

***Professor John Garrow, Chairman of Health Watch, replies:***

Dr Lewith raises an important point concerning the appropriate size of clinical trials: he randomised 73 women in a study of the effect of Arnica on postoperative recovery following hysterectomy, and concluded that Arnica was not significantly better than placebo, although one or two of the patients on Arnica did very well. He is "quite appalled" that we should offer an n=1 trial to show that chitosan does not block the absorption of 12 times its weight of dietary fat.

The number of subjects needed in a clinical trial is affected by the relative size of the variation within a group on active or placebo treatment, compared with the effect which would be of clinical interest. In a group of women after hysterectomy there is a large variability in pain, etc. but even a small improvement in side effects would be of value, so it makes sense to do a large trial, which has the power to detect a relatively small effect.

However daily faecal fat excretion in a normal subject on a constant diet shows a variation of less than 2 g/day, so if, after taking 3 g chitosan, fat excretion had increased by about 36 g over a baseline of 4.1 g/day this would have been a basis on which to conclude that chitosan affected fat absorption. Conversely, since no increase was observed, it is a basis for concluding that the effect, if not zero, is too small to be of clinical interest. Of course it would have been better to do the chitosan trial on three or four subjects to see if any of them showed a clinically significant fat loss, but HealthWatch does not have the resources to do definitive trials on every questionable healthcare claim, nor is it our responsibility to do so. We demonstrated no effect in one subject, when the claimed effect was about 20 times greater than the normal daily variation. The onus is on those who promote chitosan to present their own data *in vivo* if they believe that our result is atypical.

Dr Lewith implies that HealthWatch is more willing to publicise negative than positive results on alternative therapies, but this is not true. Where results have been positive (as in chiropractic) we have given this due prominence.

Yours sincerely

John Garrow

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