

Newsletter no 54: July 2004

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WHO warns on alternative medicines

The World Health Organisation has issued a warning against the unregulated and often unsafe use of alternative medicines ranging from acupuncture to herbal medicines and food supplements. Studies in some countries have found products containing toxic heavy metals and even traces of narcotics to make the products addictive.

The United Nations agency has now issued guidelines aimed at helping national health authorities develop reliable information for consumers, especially those purchasing treatments over-the-counter without their doctor's advice.

Reports of adverse and even fatal reactions to so-called traditional or alternative medicines are on the increase as their use spreads in industrialised and developing countries.

Though WHO has no global statistics, the agency reports that in China there were 9,854 cases of adverse reactions reported in 2002 alone, more than double the number registered during the whole of the 1990s.

"It is not true that good, traditional medicines are good for everybody, every time in big quantities," said Vladimir Lephakin, WHO assistant director-general for health technologies and pharmaceuticals, at a news briefing on 22nd June. "There are a lot of examples of people who not only suffer but die because of drug interaction or non-proper use of traditional medicine," he said.

"There is a need for strengthening control of food supplements in all countries," Lephakin said.

The WHO website can be viewed on <http://www.who.int>

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UK centre "first" to promote evidence based surgery

The UK is now home to what is thought to be the world's first centre to help coordinate clinical trials into surgical interventions. The de Lotbinière Facial Surgery Research Centre, opened in June this year, aims to stimulate research and provide rapid answers to important questions about the value of surgical techniques.

Evidence-based assessment of surgical interventions is beset with difficulties. Funding for surgical trials is scarce compared to drug trials which can attract money from pharmaceutical companies. Furthermore, surgeons may in their working life see just a handful of patients with rare conditions requiring surgery. The new centre will help unite the experiences of surgeons around the country into effective collaborative clinical trials.

For the time being the centre will just support research into surgical interventions to treat conditions that affect the mouth and face. One study is to assess the value of radiotherapy after surgery for cancer of the salivary glands. On average a surgeon sees a patient with this type of cancer every three to four years. But by using the collaborative efforts of 40 surgeons in the United Kingdom the centre hopes to have results from enough patients to be statistically meaningful in five years.

DEBORAH BENDER

Many members of HealthWatch will have known Deborah Bender, who died on May 16th. She was Membership Secretary for many years, even if only because she was doggedly persistent in chasing up those whose subscriptions had not been renewed. Many people probably found it easier to renew than to resign.

Deborah was the youngest of the seven children of Berl and Rachel Swift, who came to Britain as refugees from the Ukrainian pogrom of 1904; she was born in 1918, and was married to Arnold Bender (a founder member of HealthWatch who died in 1999) for more than 50 years. Until the last few years she was a tireless voluntary worker in many areas. While my brother and I were at primary school she was an extremely active member of the Parent Teacher Association, raising money to buy the school its first radio, curtains for the stage, on which she and Arnold appeared in many pantomimes and serious plays—I especially remember her in a red muslin dress as "Fairy Mischief", and as the damsel in distress in a murder mystery set in a lift (the lift gates were painted in plywood in our back garden). The wig she knitted out of rug wool for Arnold to wear as an ugly sister was still returning to school jumble sales many years later, to be bought for another generation's dressing up box—as was the necklace made from laboratory plastic tubing that he also wore.

She was an indefatigable knitter, scorning the knitting machines that became popular during the 1950s, and when the family's wardrobes were full she knitted to order, to raise funds for the Jerusalem Baby Home and the local Liberal Association. No pattern ever defeated her, and I have what is probably the only example of an uncorrected mistake, in a ski sweater she knitted for me when I was at school—and she was willing to unpick almost the whole thing to correct one row. Almost as soon as she learnt to drive, and we had our first car, she began to drive people from St Cecelia's home for the blind, taking them for outings in Richmond Park and describing the view, or to visit relatives. Later she was active in the Ealing Association for Mental Health, the Britain-Nepal Society, and her local branch of the Arthritis and Rheumatism Research Council, as well as being President of the University of London academic wife's club.

When Arnold stood as Liberal candidate for Ealing North in the 1954 election, the campaign was run (by Deborah) from our dining room—in later election campaigns that he fought the campaign centre was away from home, but that did not stop her working determinedly. When Arnold returned to University life, in 1965, she took on the role of hostess and foster mother to the many overseas students taking the MSc in Nutrition. Indeed, for many years our house seemed to be the social centre of the department, and her hot buffet suppers for 20+ people were justifiably famous. When she was hospitalised in the 1970s the patient in the next bed asked her how many children she had, and by how many husbands, because of the large number of overseas students who visited, and all called her "mother".

Sadly, over the last five years she became increasingly frail, but it was only just over a year ago that she accepted that she could no longer cope on her own, and needed to move into a care home.

David A Bender

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NEWS IN BRIEF

The Netherlands is considering tougher laws on practitioners of complementary medicine, reports the British Medical Journal. A report from government health inspectors investigating the death from breast cancer in 2001 of the Dutch actress and comedienne Sylvia Millecam (see HealthWatch Newsletter issue 44, January 2002) severely criticised her treatment and has called for measures to protect the public against "dangerous quackery." Ms Millecam, who chose alternative over mainstream treatments, was treated by 28 different practitioners and institutions. The Dutch Healthcare Inspectorate has now reported six alternative practitioners to the public prosecution service, and has confirmed that three doctors are being investigated for possible disciplinary action, including two of the six practitioners.

British Medical Journal 2004; 328: 485.

An appreciable number of parents forget they have consented to allow their newborn babies to take part in clinical research, suggests a study in the Fetal and Neonatal Edition of Archives of Disease in Childhood. After 18 months, one in eight of 154 parents who responded to a survey could not remember being asked to consent to their child taking part in clinical research. A further 6% were unsure. Alternatives are being considered. But when asked if they would be happy to forgo consent if the trial had been passed by the institution's ethics committee made up of doctors and members of the public, more than 80% of parents said they would not.

Arch Dis Child Fetal Neonatal Ed 2004; 89: F321-324.

A north Wales hypnotherapist has been suspended from professional registers after he allegedly told a BBC reporter that he could stop cancer cells from growing, according to a report in the Daily Post (Conwy region). As part of an investigation by the BBC Wales consumer programme X-Ray, Bryan Evans of Caernarfon was filmed by an undercover researcher who posed as a woman awaiting the results of a mammogram.

Evans, whose hypnotherapy sessions cost around £50 an hour, allegedly told her that cancer can be triggered by an emotional shock and that, should a diagnosis of cancer be confirmed, he could use hypnotherapy to address the emotional conflict that had given rise to the disease.

BBC Wales report that Evans' membership of the NHS Trust Association's Directory of Alternative and Complementary Therapists, which GPs may consult when referring patients, has now been suspended pending further investigation of the allegations. The General Hypnotherapy Register, a professional body for hypnotherapists—which co-operates with the Department of Health—has also suspended Mr Evans from its listings.

In his local press advertisements Evans states that his methods "help my clients resolve the issues behind the significant emotional event that caused the cancer to grow. By working on and resolving the issues behind the trigger event we should be able to stop the cells from growing and allow the body to heal itself."

The programme was screened on BBC 1 Wales at 7.30pm on Monday 24th May

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MEDIA: FUTURE PROMISE, CURRENT HEADLINES

Attempts to make medical research interesting can end up generating false hopes, says Dr Neville Goodman. While new discoveries are exciting, scientists should not be blamed when early promise fails to produce hoped-for results

The human condition being what it is, as a group we look to a time when all disease will be conquered, although as individuals we are mostly realists. Paradoxically, while people tend to become suspicious of medical treatments once they are established, we are all fascinated and hopeful about treatments that are little more than speculation. And in general these speculations are informed by the basic science of Western preoccupations: the diseases that kill most people, i.e., cancer and heart disease; and reflections of our lifestyle, e.g., obesity and reproductive medicine.

Combining both preoccupations in one, research on cutting off the blood supply from cancer cells has been applied to fat cells and seems to work (Guardian, 10 May 2004). This is not done crudely, by cutting the blood vessels. Instead, a cellular regulator specific for fat cells is attached to a drug known to cause cells to self-destruct. It sounds a good idea, which indeed is all it is: the experiment was done on mice fed a high-fat diet.

At least the Guardian told us about the mice in the second paragraph. Reporting on another research study, the Weekly Telegraph's front page (17 March 2004) carried the headline "Scientists find way to beat menopause". Four-fifths of the article explained how new research is questioning the conventional idea that women are born with all the eggs (ova) they are going to have, commenting, "the textbooks may have to be rewritten." The research has been done in the Massachusetts General, one of the most famous hospitals in the world but unfortunately, as revealed in the penultimate paragraph, again only in mice. The textbooks can stay on the shelves for a while longer.

The mice's new ova originated, in the adult mice, from stem cells. There is always a promised treatment, and at the moment it's stem cells. We used to be in the age of the promise of genetics, but except for pre-implantation and pre-natal diagnosis genetics remains a promise. For all the information we now have about the human genome and the genetics of disease, little has made it to clinical medicine. A prominent hope is that drug treatment will in future be better tailored to individuals, especially in genetically complicated conditions for which many different drugs are prescribed. Hypertension is a good example. Black people are especially prone to hypertension, and also to its more unpleasant consequences. Drugs deemed globally helpful in hypertension may not be the best drugs for particular racial groups, and pharmacogenetics—as inevitably this branch of medical science is known—may help.

After the disappointment that the genetic hype has failed (Bill Clinton when he was President looked forward to a time when cancer was known only in history books), stem cells have taken over. Stem cells are 'pluripotent' cells: they can turn into many different kinds of cell and tissue, given the right stimuli. There are two types of stem cell: those derived from early embryos, which undoubtedly are pluripotent, but about which there are serious ethical issues; and those derived from adult tissues, which may not be as pluripotent as some experimenters think, but which are ethically uncomplicated. If adult stem cells really could be converted into other cells and tissues, it is theoretically possible for one's own cells to be harvested and injected back to repair damaged tissues. It is this theory that many investigators, and a lot of industrial money, are banking on.

Many recent basic science experiments, often published in Nature, have been reported in media stories as if

treatments will be on the shelf next Tuesday—until their last paragraphs with the inevitable, “It could be some time before...” Stem cells have been injected into damaged heart muscle (myocardium), mimicking a possible treatment for heart attacks. Claims that the stem cells formed new myocardial cells have been questioned by later experimenters, and the same has happened with work claiming that stem cells formed new brain cells (neurones) when injected into areas of brain damage. These experimental problems may just be teething problems as experimenters, impatient to substantiate their theories, are less careful with their technique than perhaps they should be; or they could be permanent barriers to the introduction of treatment with stem cells in the form currently imagined.

The science is genuinely exciting, whether or not the promise is fulfilled; and if it is not fulfilled that must not be a slur on the scientists. They must not be judged as having failed because they couldn't see the future. The media are right to get excited, but must take care not to blame the scientists for fostered disappointments.

Neville Goodman
Consultant Anaesthetist
Southmeads Hospital, Bristol

For anyone wanting to know more about stem cell research, there is plenty on the Internet, for example on: <http://www.stemcellaction.org/SCA/>

Could the media do a better job of reporting science and medicine? To what extent is accurate information sacrificed to the readers' demands for laughs and thrills? In the [next issue of the HealthWatch Newsletter](#), science writer and broadcaster Dr Geoff Watts shows us the other side of the coin when he explains how and why research reports get from the academic journals onto the news.

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FORUM: WATER FLUORIDATION—A STRONG CASE FOR ACTION TO IMPROVE DENTAL HEALTH

In [HealthWatch Newsletter issue 52 \(January 2004\)](#) Earl Baldwin of Bewdley argued that mass fluoridation of public water supplies had not been proven to improve dental health. Dr Nigel Carter (left), chief executive of the British Dental Health Foundation and himself a qualified dentist with 22 years' experience in clinical practice, argues here that a failure to fluoridate water supplies continues to put our children's dental health in jeopardy

In 1971 when the British Dental Health Foundation was formed, one in three people over the age of 16 had no teeth at all. Twenty years of the NHS had given the vast majority of the British population a nice new set of plastic dentures. Thankfully, the picture today is very different. The percentage of denture wearers has dropped to just 11 percent, and the majority of these are elderly people who already had dentures in 1971. Quite rightly, people now expect to keep their own teeth for life.

But what has caused this dramatic improvement in our expectations and dental health? The simple answer is fluoride. Fluoride was first added to toothpaste in the late 1960s, and by the early 1970s virtually all toothpaste contained fluoride at a level of around 1000 parts per million. This simple action has led to a reduction of around 50% in the levels of decay we experience. Brushing twice daily with a fluoride containing toothpaste remains the most effective measure to reduce dental decay.

However, for many, regular daily brushing is not a reality, or even an option. Clearly expenditure on toothbrushes and toothpaste is not a possibility or priority for many, and there are strong links between continuing high levels of decay and poverty and disadvantage. It is generally recognised that we should replace our toothbrush every three months, which should lead to a purchase of four toothbrushes per person every year. The reality though is that as a nation we only purchase around 1.2 toothbrushes each per year. This means that many people are using old ineffective brushes, sharing toothbrushes or simply not cleaning their teeth at all. This group are being denied the benefits of fluoride toothpaste and so continue to experience unnecessary high levels of dental disease, decay, tooth loss and dental pain.

So what can be done to improve matters and ensure that the whole population can benefit from the advantages that good dental health bestows? The answer is water fluoridation.

As a general dental practitioner I was fortunate to practise for much of my career in Birmingham, where the water was first fluoridated in 1964. Here I saw first hand the huge benefits of this simple cost-effective measure. Child dental decay was a rarity and the population could look forward to adult life with a fully functioning set of largely decay-free teeth. Early in my career my practice was on the border of fluoridated Birmingham and the then non-fluoridated Sandwell. It was possible with unfailing accuracy to tell from which side of the dividing main road a new child patient came from. If their teeth were free of decay they invariably lived in Birmingham, while those with decayed teeth, who were often in pain, came from Sandwell. Occasionally a child from Birmingham would present with decay but on questioning, it would transpire that they had recently moved from Sandwell. At that time Sandwell was near the bottom of the league when it came to levels of dental disease. Water fluoridation was introduced in Sandwell in 1987 and over the next few years they rapidly moved up the league table to rest in the top 10, despite being one of the poorest boroughs in the country! The argument is often put forward that

water fluoridation is no longer necessary now that we have fluoride in toothpaste, but these observations do not support this argument as virtually all toothpaste contained fluoride at the time.

Why then, does only 12% of the UK population, largely in the West Midlands and Northeast, benefit from the addition of fluoride at the optimum level of one part per million to their water supply? After all, this is despite the fact that surveys show over 80% of the population are in support of this important public health measure, and most cannot understand why, with such strong evidence in its favour, it is not already being added nationwide. The answer lies in the small and vociferous lobby who have denied the benefits of fluoridation to the bulk of the population for so long.

This evidence speaks for itself but what of the arguments so eloquently put by the anti-fluoridation lobby—fluoridation is unsafe, the case unproven, causes side effects, impinges on our freedom of choice and civil liberties?

Rarely has a public health measure been so widely examined and researched and yet none of this research supports the arguments of adverse side effects the anti-fluoridationists claim. In fact, quite the contrary. In the UK recent reports have been carried out by York University NHS Centre for Reviews and Dissemination (1), the Medical Research Council (2), the Forum on Fluoridation (3) (in Ireland, where virtually all water is fluoridated) and the Surgeon General in the United States (4) (where the majority of water contains fluoride, over 20 million more people having fluoride added to their water supply in the last 18 months alone). All these reports have come down largely in favour of continued or increased water fluoridation.

It is true that the York Review (1) found that some of the evidence in favour of water fluoridation was of a poor standard, but this is hardly surprising considering that many of the studies were carried out decades ago and, as such, do not meet the more rigorous standards of research imposed in the 21st century. Further research to modern standards is currently being undertaken and we can expect that the results of these studies will continue to support water fluoridation.

No support whatsoever has been found for the myriad claims of adverse affects on general health often put forward by the anti fluoridationists. Indeed in one area (that of increased hip fractures) there is evidence that there is in fact a lower level of hip fractures in areas with fluoridation.

Fluorosis of the teeth is also quoted as a problem with fluoridation. In severe cases this can lead to unsightly mottling of the teeth, commonly seen in areas of the world which contain natural fluoride at extremely high levels, such as parts of India. In practice, mild fluorosis will be seen in a significant proportion of children who receive fluoridated water. This occurs as an increase in opalescence of the teeth and is in many cases considered to give a more attractive appearance to the teeth. More unsightly cases are rare and very often due to over dosage, where a child has ingested fluoride toothpaste, been given fluoride supplements and also drinks fluoridated water. It is important in that children use only a pea-sized smear of toothpaste to avoid these problems and that fluoride supplements are only taken under the direction of a dentist.

The civil liberties issue is even harder to understand. Water fluoridation involves the adjustment of the level of a mineral—which occurs naturally in all water supplies—to the optimum level in order to provide protection against dental decay. I am not aware of any suggestion that adding chlorine to water supplies in order to purify it and prevent infection has ever been challenged on the basis of civil liberties—it is just taken as pure common sense, which is exactly what fluoridation is.

Last November, whilst considering the new Water Bill, the House of Commons took the major decision to force water companies to introduce water fluoridation following appropriate public consultations in each area. The last remaining barrier to many more of us enjoying the benefits water fluoridation has previously only provided to a few has been removed. We can look forward over the next few years to many of our children enjoying improved levels of dental health.

Dr Nigel Carter BDS Birm. LDS(RCS) Edin
Chief Executive of the British Dental Health Foundation

The British Dental Health Association website can be viewed on <http://www.dentalhealth.org.uk>

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Fluoride as found in nature

Mr Keith Isaacson, locum consultant in orthodontics at the North Hampshire Hospital in Basingstoke, wrote to comment on the fluoride issue:

Dear Sirs

Earl Baldwin introduces a little emotion into his argument against the fluoridation of water supplies ([HealthWatch Newsletter, issue 52 January 2004](#)). He suggests that a better public health measure would be to introduce statins into the water supply to control heart disease.

However, though statins may now be bought over the counter, they are a man made drug and should not be compared with fluoridation. The fluoride ions that are artificially added are the same as those fluoride ions that occur naturally in the water supply in many parts of the United Kingdom.

K G Isaacson

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Too much secrecy over Ethics Committees?

Two aspects of approval by Research Ethics Committees* have not been widely considered, says Dr Andrew Herxheimer—the quality of their work, and their isolation and secrecy. Scientific and medical journals that publish research could do much to bring about necessary improvements

The quality of the work done by Research Ethics Committees* varies enormously. Criticism has been muted, partly because their members are mostly hardworking unpaid volunteers. But by and large there are no independent checks of their work. Some of the issues they worry about seem irrelevant, as the recent correspondence on audit suggests.

It is not clear whether or how anyone other than an investigator or a sponsor of a study can appeal against one of their decisions. The basic difficulty is that an application, the discussion of the issues, and the decision approving it (or not) remain 'confidential', even after completion and publication of the study. This is against the public interest. In particular Research Ethics Committees (ECs) have an overriding responsibility to study participants, and these must be enabled, and indeed encouraged, to have direct access to the EC—not merely through the investigators.

The editors of journals and their advisers, the referees, often have questions about ethical aspects of work reported in papers they receive, and sometimes they ask the authors. But how often are authors asked to submit the formal letter of approval from the EC, together with the protocol that was approved and the information sheet that participants received? Such letters of approval would include the affiliation and contact address of the EC, which would make it possible to follow up particular points of concern.

I hope that journals will develop explicit policies of this kind, and publicise them. These are matters for most journals, not just for specialised bioethics journals.

Ultimately, of course, readers should be able to raise points of ethics, and they should not have to do so via the authors of the paper or the editor of the journal. The obvious solution is to publish the name and address of the EC that has approved the study as part of the paper. Then problems can be discussed, first privately, later in public if necessary.

Feedback to ECs about their work from study participants and from the scientific community at large would help them and us all to learn and improve practice. Secrecy is bad for our health.

Andrew Herxheimer
DIPEX Project, Oxford University
Emeritus Fellow, UK Cochrane Centre

*in North America, Institutional Review Boards

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EVIDENCE: Grey hair linked to heart disease and cancer

It is easy to sell with the words, "Research says" and "experts believe". Even heavily flawed research can be packaged to seem plausible to the layman, as John Garrow demonstrates here. But it's not just the laymen who are vulnerable: even the experts can be bamboozled by research whose design errors are not immediately obvious

It will not surprise any reader that people with grey hair are likely to have cancer or heart disease, because these diseases occur mainly in older people, and older people are more likely to have grey hair. They might, however, be surprised if they were to learn of research suggesting that hair colour is related to health, even among people of the same age (1).

If they were to hear, say, that a sample of 384 people (227 women and 157 man) who used a hair preparation called Trichotone were followed for nine years, and their incidence of heart disease and cancer monitored. Such a study would have been conceived because it has been shown that aniline dyes, which were often used in hair colorants, increase the risk of cancer, in particular cancer of the bladder. Trichotone is not a dye, but it stimulates the production of the natural melanin in the hair follicles, so even in older people the grey hair turns black again. The manufacturers were amazed that, when the incidence of heart disease and cancer in their customers was compared with the average values for people of the same age and gender, those using Trichotone had a significantly lower rate of these diseases. At a press conference Dr Sellers, the lead author of their report, said the reason for the health benefits were not clear but he could speculate that melanin, which has been shown to benefit travellers liable to jet lag, may have wider health benefits on the vascular system. He is now conducting clinical trials to test this hypothesis. He conceded that Trichotone was significantly more expensive than other preparations designed to restore hair colour, but thought many people would pay extra to have better health as well as a more youthful hair colour.

It would be unwise to continue with this exciting story, for fear of testing to destruction the goodwill of readers of this Newsletter, since they will be aware that the mission of HealthWatch is to promote proper testing of treatments, whether "orthodox" or "alternative". I would be very sorry if all our readers had not by now concluded that the evidence of benefit in the paragraph above is garbage, and they will be relieved to learn that it is also totally fictitious. However it is not unlike that which is often reported in the media about some therapeutic breakthrough. It is well known that the incidence of heart disease and cancer is inversely related to social class, and this is also reflected in, for example, more favourable smoking habits, body weight and intake of antioxidant vitamins². It is therefore probable that people who could afford the "significantly more expensive" Trichotone would have better health than the "average person of the same age" even if Trichotone had never been invented.

The warning signs of unreliable research in the fictitious example above are obvious. The "test" sample is small (384 people selected by the investigators) so we cannot be sure that they represent all people using Trichotone—it would have been easy for the authors to select those with especially good health. The authors were certainly biased—they had a commercial interest in producing results that favoured Trichotone. Finally, the research was published in *Acta Artefacta*, which is not a peer-reviewed journal (it is in fact non-existent), so the results have not been scrutinised by independent experts. Any "research" with these characteristics should be treated with great scepticism.

Unreliable evidence also occurs in real life. The March-April 2004 issue of a free magazine advertising dietary supplements contains articles written by "the UK's most eminent doctors and nutritionists". The health-giving potential of dietary supplements is extolled by doctors very well known in the media, but not necessarily expert in the field of nutritional supplements. There is clear evidence of bias to favour commercial interests.

But even highly expert non-commercial investigators, publishing in top-ranking journals, can draw conclusions from observational studies that are probably invalidated by flaws in trial design. For example, a very large study of the relation between plasma ascorbic acid (vitamin C) and mortality in men and women in Norfolk³ found that people with high vitamin C levels had significantly low 5-year mortality rates, even when the data were adjusted for age, systolic blood pressure, cholesterol, body mass index, smoking, diabetes and vitamin supplement use. However in another randomised placebo-controlled trial of antioxidant vitamin supplementation in 20,536 high-risk individuals⁴ no such protective effect was found. So what are we to believe about the efficacy of antioxidant supplements in preventing heart disease? Is one of these studies wrong? If so, which one, and for what reason?

Lawler et al (2) believe that randomised controlled trial (RCT) design is always superior to observational studies, so we should believe that antioxidant supplements do not confer this protection. They suggest that Khaw et al (3) reached the wrong conclusion because they failed correctly to allow for "social and behavioural factors acting across the life course". Certainly the Heart Protection study, and other RCTs of antioxidant supplements, fail to show the protection that we might expect from observational studies. Certainly those who promote antioxidant supplements on the grounds that "research has shown" that they protect are citing only one side of the research evidence. As Vandenbroucke (5) observes "...the health effects of lifestyles that people take up because of health concerns—dietary preferences, dietary supplements, or exercising—are notoriously difficult and maybe even impossible to study observationally". Unfortunately they are also notoriously difficult (and expensive) to study by RCTs. It would hardly be possible recruit a large number of people who were willing to be randomly allocated to either physical activity or a sedentary lifestyle for several years, and who would comply with this allocation for long enough to yield worthwhile information on the effect of exercise on health. Many years ago Miall and Morris showed that conductors of double-decker busses had far less heart disease than the bus drivers, who spent their working day sitting down. This is good evidence that exercise is good for your heart but, of course, it was an observational study. Some of the effect must have been because men with a weak heart would probably apply for a job as a driver rather than a conductor.

The clinical trial pundits will continue to debate the strengths and weaknesses of observational versus randomised controlled intervention trials, as issue 53 of this Newsletter showed. Meanwhile the passenger on a Clapham omnibus, when reading advertisements for health-promoting products or procedures, should bear in mind certain agreed rules about evidence of efficacy. Was the group testing the product similar to the control

reference group? Was the trial big enough to ensure that the reported benefit was not due to chance? Was the trial free from commercial bias? Were the results published in a reputable peer-reviewed journal? Any sensible person applying these rules would not rush out to buy Trichotone.

John Garrow
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EVIDENCE: MAGIC, OR MEDICINE IN SEARCH OF AN EVIDENCE BASE?

General practitioner Gus Plaut ponders the value of local injections or similar treatment for muscle pain

I am not the only one who has suffered from low back pain. The pain in my back became steadily more severe, in spite of simple analgesics, and I finally consulted my general practitioner. I am myself a retired general practitioner, and when I was in practice I often found local procaine injections for back pain dramatically successful.

I shall always remember a disappointed patient: He was relieved of the pain as soon as the injection was given. "Oh, doctor" he said "you have cured my back pain, and I had hoped you would give me a sickness certificate for a fortnight; now I shall have to return to work!" (At least he was honest.)

My own general practitioner told me that he "did not believe in injections for backache". He prescribed 50mg diclofenac (Voltarol) three times a day, and 10mg temazepam at night. My pain was not relieved even by this rather drastic pharmaceutical treatment. I visited the doctor again and this time he arranged for physiotherapy. I was treated with massage, exercises and ultrasound for six painful weeks. The physiotherapist had noticed a "lump" in the gluteal muscles on the right side. She contacted the general practitioner as she feared I had a neoplasm. I was sent for X-rays and isotope scans, but no neoplasm was found.

A non-medical friend, seeing me hobble along in pain, suggested I try his "Pain-Gone". It is, he told me, an instrument a little larger than a ballpoint pen and works by magnetism and electricity. I told him firmly that I was a supporter of HealthWatch and did not accept such magic. Nevertheless he persuaded me to try using this instrument, as "it could do no harm". Reluctantly, that evening, I carefully placed the nozzle over the "lump" in my buttock, and pressed the button on it repeatedly. The pain disappeared and from that evening I have not had to take diclofenac for back pain. Was it suggestion? I do not think I am subject to such suggestions, nor to magic.

As I had found benefit, I advised friends to try this method. Some refused to use such an "unscientific gadget". Others (twenty-three, up to the present) were prepared to see if it would help. Of these well over half found the instrument useful, the remainder did not derive any benefit. Among the successes is a friend who had limped and used a walking stick for many months. He was able to abandon the stick and now walks normally.

The gadget is, as mentioned, little larger than a pen. A button is at one end and a small metal point at the other. One is advised to push this metal point over the "lump" in the painful muscle and press the button about thirty times. Each time a small electric shock is experienced (clearly a high voltage, low wattage, discharge from a coil around a magnet is induced by pressing the button or the spring return.) I believe, though without any evidence, that the "lump" felt in the muscle is a localised spasm, producing local or referred pain. This spasm is relieved by the electric shock; it may be compared to defibrillation of heart muscle. (The makers, however, suggest that a nerve pathway is activated to send endorphins to the painful area.)

Injecting painful "fibrositic nodules" in muscle with local anaesthetic or steroids may similarly abolish muscle spasm. Perhaps the success of acupuncture reported by some (1) has a similar physiological basis. A report to the American Medical Association more than 50 years ago advocates injections of procaine into "trigger areas" for muscle pain, after applying a coolant spray (ethyl chloride) as local anaesthetic (2). My friend's electrical gadget may have a similar effect without a needle.

The manufacturers of the [Pain-Gone](#) state that it should not be used near the eye, by patients with epilepsy, those fitted with a cardiac pacemaker and similar contraindications (3).

So, can muscular or referred pain be alleviated by local injection or minor electric shock? Such treatment is often considered outside orthodox medicine, but I now wonder whether there might be evidence to show its effectiveness in suitable conditions. More research should be done to understand and evaluate this approach.

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Dr Plaut declares that he has no financial interest in any item or treatment mentioned.

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LAST WORD: BIO-DETOX...THROUGH THE FEET

A new method of removing toxins from the body involves putting your feet in a foot spa of warm water that contains a "Bio-Detox" unit, writes David Bender. According to the Holistic-Centre.org, "the unit causes electric dialysis by producing electromagnetic oscillations in the water. The water changes colour due to the release of toxic substances through the 2000 pores on the soles of each foot."

You immerse your feet in warm water within the Bio-Detox machine, according to the instructions on the website on http://fp.osteopath.plus.com/holistic-centre/serv/bio_detox.htm then, "We set the machine to the correct settings and ionisation levels. Then you sit back and relax for 30 minutes whilst Bio-Detox completes its cycle of treatment. You will see the excreted toxins in the water. The water will change colour and consistency—from orange, brown through to black. There may be lymphatic fat or mucous floating on the water—do not be alarmed as this is normal."

Their information continues by telling us that "Bio-Detox is an unusual therapy, based on the research of the medical scientist Dr Royal Rife and is a type of aqua detox. It aims to improve, among other things, liver and kidney function through an electro-magnetic detoxification process carried out on the feet." Then we are told that "the machine does not make the body detox, it bio-energetically stimulates the body to enable self detoxification and rebalancing of the body as shown in research using medically approved equipment." I am not quite sure I understand the difference between "making the body detox" and "stimulating the body to enable self detoxification".

According to the Talkabout network on www.talkabouthealthnetwork.com/group/alt.health.oxygen-therapy/messages/4280.html this wondrous-sounding apparatus is no more or less than a simple electrolysis of salt water with iron electrodes—something we probably all did in school chemistry lessons. The brown toxins that come out of your feet are actually rust from the iron electrodes. Just a slight note of caution—in the process hydrogen gas (explosive in air) and chlorine gas (irritant in low concentrations and toxic in high concentrations) are also produced.

For more on this see science journalist Ray Girvan's web site at http://www.raygirvan.co.uk/apoth/2004_05_01_arc.html#108575608 His home page <http://www.raygirvan.co.uk/apoth/index.htm> has a host of links to interesting sites—both alternative medicine and others.

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Some alternative therapy websites "can be dangerous"

A survey of 32 unregulated websites offering information on complementary and alternative medicines found that while most provided reliable and valuable information, many suggested unproven therapies and some were even deemed dangerous as they offered misleading advice. Three discouraged readers from using conventional cancer treatment.

The research, headed by Professor Edzard Ernst of the Peninsula Medical School, also highlighted two websites as excellent. These were [Quackwatch \(http://www.quackwatch.org\)](http://www.quackwatch.org), a 30-year-old American non-profit organisation formed to fight medical fraud, and [Bandolier \(http://www.jr2.ox.ac.uk/bandolier/\)](http://www.jr2.ox.ac.uk/bandolier/), an independent journal on

evidence-based healthcare written by Oxford scientists.

Guardian, 17 April 2004

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