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# HealthWatch

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## “VITAMINS FOR AIDS” LIBEL ACTION DROPPED

**A** VITAMIN entrepreneur who, it has been claimed, endangered the lives of Africans with Aids has dropped a year-long libel action against the *Guardian* newspaper. Matthias Rath, a qualified doctor said to be of German origin, had sued over three *Guardian* articles condemning his promotion of multivitamins to Aids victims in South African townships.

Rath, who is thought to have made millions selling nutritional supplements through his websites, had been operating in South Africa since 2004, where he was said to have distributed his multivitamin pills free while denouncing modern anti-retroviral (ARV) drugs as toxic and dangerous. Campaigners such as the Treatment Action Campaign believe that the activities of the Dr Rath Foundation have led to deaths, and doctors working for *Medecins Sans Frontières*—which opened the first clinic offering free anti-retrovirals in the country—testified that some patients had died. Rath was reportedly seen with the South African health minister, Manto Tshabala Msimang, who was later to back the healing properties of lemon, garlic and beetroot over ARVs.

Aids experts have welcomed the outcome of this libel action. Prof Brian Gazzard, one of the UK’s leading HIV/Aids experts, told the *Guardian*, “The widespread provision of anti-retrovirals in sub-

Saharan Africa is one of the most important public health measures of this century,” he said. The confusion caused by suggestions that giving undernourished people vitamins and minerals was an alternative to taking Aids drugs was “extremely harmful”. The high court awarded initial costs of £220,000 to the *Guardian*. The articles had appeared in January and February last year in Ben Goldacre’s weekly *Bad Science* column. In his blog Dr Goldacre, who won the 2006 HealthWatch Award for his entertaining and often daring exposés of science abuse, reported, “I am extremely pleased and—cheesily—proud that the *Guardian* fought this case.”

Last year Rath won a £100,000 legal victory over the *British Medical Journal* after successfully challenging a reporting error.

### Reference

*The Guardian*, 13th September 2008. View online at: <http://www.guardian.co.uk/world/2008/sep/12/matthiasrath.aids2>

## Award for FT’s Margaret McCartney

**G** LASGOW journalist GP Dr Margaret McCartney received the sixteenth HealthWatch Award at the 2008 AGM this month. Dr McCartney writes an influential weekly column for the *Financial Times* weekend supplement where she explores a wide range of clinical, research and consumer health issues. Her stance as a vocal and authoritative supporter of evidence-based medicine is well known.

She tackles complex and emotive issues such as health screening, drugs and infertility, as well as challenging commonplace received wisdom. Her recent *FT* columns covered issues ranging from the need for social justice in fighting global health issues to the evidence in favour of warming up before exercise (which, she says, is limited); she also writes incisively for the *British Medical Journal*.

McCartney qualified in medicine from Aberdeen University in 1994 and is a GP in a Glasgow partnership. She has written for a

variety of publications and her *FT* health column began in July 2005. Her main interests are the increased medicalisation of life, the certainty of uncertainty, and the ethics and dilemmas of medical research.

The award was presented at this year’s HealthWatch Annual Open Meeting and AGM. Dr McCartney spoke on the subject of “Evidence-based medicine in general practice”.

Read Margaret McCartney’s *Financial Times* columns at: <http://www.ft.com/comment/columnists/margaretmccartney>

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## JOHN GARROW ISSUES CHALLENGE TO CLINICIANS

**H**AVE YOU ever changed your clinical practice in the light of evidence that your current practice is wrong? On page 8 of this issue, under “Last Word”, we reproduce an article in which leading obstetrician Susan Bewley describes some of the obstacles she has encountered trying to get doctors to change their practice when the evidence runs counter to the obvious.

Professor John Garrow, on reading the original earlier this year in the *British Medical Journal*, asked himself the question, “How often have I changed my clinical practice in the light of evidence that my current practice is wrong?”

The answer, he says, is rather disappointing. “I was in clinical practice from 1952-1994 and the patients were all ‘malnourished’ over a wide range from severely undernourished infants in a third world country to vastly obese adults in the UK. Throughout I was employed by either MRC or a university as a clinical researcher, so it was my job to identify what was wrong with current treatment of such patients and change it for the better. From time to time our research indicated a need for change, so we changed, and published a paper recording the correction of our previous error. But I cannot remember ever making any change on the basis of clinical evidence provided by other researchers.

“Today, and in general medicine, things are very different. Clinicians are expected to follow ‘guidelines’ for the treatment of virtually any disorder and they hardly ever have the luxury of being able to test their own practice by their own clinical trials.

“HealthWatch promotes evidence-based over authority-based medicine. The doctor who follows his own clinical experience rather than the guidelines is rightly criticised. The guidelines are distillations of analyses or meta-analyses of published reports of controlled trials, and are the best evidence we have, but not always faultless. For example, in the field of nutrition controlled trials are mostly about the merits of particular nutrient supplements or slimming pills. The trials are almost always funded by the manufacturer of these products, so there is a conflict of interest. Clinical trials of lifestyle interventions are sorely needed, but prohibitively expensive, so guidelines on lifestyle changes are based on frail evidence.

“Susan presents an example where evidence should improve clinical practice, and she asks, why not? Why have the guideline makers not acted?”

Professor Garrow invites clinicians to send HealthWatch ([newsletter@healthwatch-uk.org](mailto:newsletter@healthwatch-uk.org)) their own answer to the question: Have I ever changed my clinical practice in the light of evidence that my current practice is wrong? The most interesting answers may be published in the *HealthWatch Newsletter*.

### news in brief

ANNABEL FERRIMAN, a past winner of the HealthWatch award for her outstanding medical writing while she was health correspondent for the *Times*, has now been voted jointly Health Editor of the Year in this year’s Medical Journalist Association’s awards. Ferriman, who now edits the *British Medical Journal*’s news pages, tied for first place with the *Times*’ health editor Hilly Janes. Annabel Ferriman has been senior news editor of the *BMJ* since 1998, before which she was health services correspondent at the *Times*. It was for her work there that she won the HealthWatch Award in 1997. The MJA awards invite journalists to vote for their peers in categories including medical journalist, health editor and medical publication of the year.

*BMJ* 2008; 337: a738

SESSIONS of Freudian analysis could soon be outlawed in the UK. “Talking therapies” such as counselling and psycho-analysis are to be subject to a regulatory regime which will require therapists to prove how they are tackling their patients’ symptoms. Unlike cognitive therapies, which tackle disorders such as depression with set outcomes, psychoanalysis may not have clear-cut outcomes. Under the new rules, to be introduced next year and to take effect from 2011, the UK’s 5,000 psychoanalysts will be regulated by the Health Professions Council (HPC), and subject to over 450 guidelines. There will be no “opting out” and those who fail to comply could face legal action.

*Daily Telegraph*, 21st July 2008

<http://www.telegraph.co.uk/news/newstoppers/politics/health/2298647/Freudians-having-bad-dreams-about-the-end-of-the-couch.html>

A NEW case-control study makes any link between autism and the MMR vaccine seem more unlikely than ever. In 1998 a well-publicised study first reported finding genetic material from the measles virus (MV RNA) in bowel tissue from children who had autism with gastrointestinal disturbances. Now US scientists writ-

ing in the online journal *PLoS One* report being unable to find any difference in the levels of MV RNA in gut tissues tested from children with GI symptoms whether autistic or not. The scientists also could find no link between the time of onset of symptoms and that of the children’s MMR vaccination.

*PLoS ONE* 3(9): e3140 doi:10.1371/journal.pone.0003140

<http://www.plosone.org/article/info%3Adoi/10.1371/journal.pone.0003140>

THE AUSTRALIAN Complementary medicines industry is to face stricter regulations and greater scrutiny of advertising claims. Nearly two-thirds of Australians used complementary medicines last year, compared to around one-third in the UK. Under Government plans for reform, the industry in Australia will be subjected to tougher regulation of advertising claims and expected to improve information available to the public.

<http://www.theage.com.au/national/alternative-remedies-face-review-20080731-3nzu.html>

TWO ALTERNATIVE medicine stories dominated the news pages this summer. The discovery that Radovan Karadzic, the former Serbian leader who was indicted for genocide and crimes against humanity—including the massacre of thousands of Muslims in 1995—had reinvented himself as a long-white-haired guru offering homeopathy, energy medicine and acupuncture, was followed the next day by the unrelated story of a woman who is now brain-damaged after following a “detox diet” in order to lose weight. Commenting in the *Guardian*, author Rose Shapiro highlighted new websites that catalogue stories of injury caused by unorthodox treatments: [whatstheharm.net](http://whatstheharm.net) and [skepdic.com/refuge/harmarchive](http://skepdic.com/refuge/harmarchive)

*Guardian*, 24th July 2008

<http://www.guardian.co.uk/lifeandstyle/2008/jul/24/healthandwellbeing.radovankaradzic>

# MEDICINE CHEST: COLLECTING TRADITIONAL REMEDIES AND FOLK WISDOM

**C**HANNEL 4 TV broadcast a series of four documentary programmes in January (repeated in July) in which “two young British doctors immerse themselves in radically different cultures in four of the most extreme places on earth. The doctors, who also happen to be identical twins, explore the mysterious world of tribal medicine to discover whether traditional forms of healing have anything to teach us about bodies, health and curing illness.”<sup>1</sup>

On the website associated with the programme<sup>2</sup> we are told that, “On their journey Chris and Xand discover a wealth of folk wisdom about healing and health. Medicine Chest is capturing just this kind of traditional know-how for posterity, before it gets lost or dies out. It is bringing together ideas from different places and cultures, across the UK and beyond.” This is followed by a request, “Please help by sharing knowledge and tips from your family, travels and other experiences.”

The Medicine Chest website (<http://www.medicinechest.info/>) then has a series of stories contributed by viewers about herbal and other traditional remedies. These are backed up by notes from the Royal Botanic Gardens at Kew with sound botanical information about the plants concerned, and their traditional uses. Each story is followed by comments from other people, and you are invited to click on a thumbs up or thumbs down icon to say that you have tried this and it either did or did not work for you. This is open to abuse. You do not have to log in or register to vote. I accidentally clicked on a thumbs down icon and saw the score change immediately to show that one more person had tried the remedy and found it did not work.

The laudable aim of this project is to collect traditional remedies and folk wisdom before they are lost. There are plenty of examples of traditional herbal remedies leading to the development of modern medicines—quinine, isolated from chinchona bark may no longer be the mainstay of malaria prevention, but curare (the alkaloid from South American arrow poison) is still used clinically. More recently, St John’s wort (*Hypericum perforatum*), traditionally reported to cause madness and mania, has been used for the treatment of depression<sup>3</sup>, and studies of the actions of *Rauwolfia serpentina*, used in Ayurvedic medicine as a treatment for mania, led to the amine hypothesis of depression and the development of rationally designed antidepressant drugs (see page 4 of this issue).

The Medicine Chest project parallels what the distinguished paediatrician and nutritionist Cicely Williams (1893–1992) did in what was then Gold Coast (now Ghana) between 1929 and 1936<sup>4</sup>. So far

from challenging the local traditional healer with her western medical knowledge she sent him the children she could not cure. When he effected a cure, she asked to be shown the plants they came from in order to identify them. Unfortunately she could not interest anyone in Britain to investigate her samples for active ingredients, and all her notes about this were lost when the Japanese invaded Malaya (she had been transferred there in 1936).

The difference between what Cicely Williams did in the 1930s and what the Medicine Chest project is doing now is that she looked for the evidence of efficacy first, then identified the plants used. The Medicine Chest is collecting anecdotes about remedies (with a very accident-prone way of collecting votes as to whether they work or not), and someone will have to look for evidence of efficacy later. It is difficult enough to investigate what are the likely active compounds in herbs for which there is evidence of efficacy, but a considerably larger task to try to identify potentially active compounds in remedies for which there is only anecdotal “evidence”.

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2. <http://www.medicinechest.info/> accessed 29/6/08
3. <http://nccam.nih.gov/health/stjohnswort/> accessed 29/6/08
4. Williams C. Witch Doctors. *Pediatrics* 1970; **46**: 448-55. There is a brief biography of Cicely Williams at <http://www.jamaica-gleaner.com/pages/history/story0037.htm>; and a review of a biography by Sally Craddock in *Archives of Disease in Childhood*, 1984; **59**: 392–394 or see <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1628679&blobtype=pdf> (accessed 29/6/08). She is mainly known for her work in identifying and describing kwashiorkor, the protein-energy malnutrition disease of children, and was the first head of the WHO Mother and Child Care unit.

## essential reading and listening

MY THANKS to committee member Caroline Richmond for pointing out a critical omission in last issue’s CAM bookshelf listing. *Healing, Hype or Harm*, edited by Edzard Ernst, is a collection of writings by scientists including HealthWatch’s John Garrow and Les Rose, as well as by well-known experts such as Michael Baum (top cancer surgeon and winner of the 2002 HealthWatch Award) and David Colquhoun (University College London’s distinguished professor of pharmacology). *Healing, Hype or Harm?: A Critical Analysis of Complementary or Alternative Medicine*. 178-page paperback published 2008 by Imprint Academic at £8.95.

Caroline also recommends journalist Nick Davies’ exposé of the corruption and misinformation that infects the news industry. *Flat Earth News: An Award-winning Reporter Exposes Falsehood, Distortion and Propaganda in the Global Media* by Nick Davies. Hardcover, 408 pages, published 2008 by Chatto & Windus at £17.99.

A remedy to journalists’ (and everyone else’s) mathematical illiteracy is the six-week summer statistics school on *BBC News Magazine* online. Michael Blastland’s essays are littered with examples relevant to the way we interpret health information in the media. Go to final lesson on <http://news.bbc.co.uk/1/hi/magazine/7605118.stm>, and scroll down to the central box titled “Missed past lessons?” for links to the other essays.

You can also log onto the BBC Radio 4 “listen again” service to hear Ben Goldacre’s two 30-minute programmes on the placebo effect, originally broadcast on the 18th and 25th August. Goldacre first looks at the growing body of research into the effect, then goes on to tackle questions such as: given the undeniable benefits of placebos can it ever be right to prescribe one without telling the patient? <http://www.bbc.co.uk/radio4/science/placebo.shtml>

Mandy Payne

## WHAT DON'T WE KNOW THAT WE NEED TO KNOW?

We often express uncertainty over treatments because there is “not enough research”. But even if there has been plenty we may still not know all we need to know. We can be misled by claims of benefits that are not supported by the research, or by the non-publication of unfavourable results. HealthWatch’s Chairman, David Bender, takes as examples two very different types of treatment. First he finds that meta-analyses which include the results of unpublished trials may tell a different story from those based on published trials only. Next he considers whether published research supports claims for the açai berry being “the world’s number one superfood!”



**Bernard Woolley** “But you only need to know things on a need to know basis.”

**Sir Humphrey** “I need to know everything! How else can I judge whether or not I need to know it?”

**Bernard Woolley** “So that means you need to know things even when you don’t need to know. You need to know them not because you need to know them, but because you need to know whether or not you need to know. And if you don’t need to know you still need to know, so that you know there is no need to know.”

*From an episode of the 1980s TV series “Yes Prime Minister”<sup>1</sup>*

**T**WO PAPERS published earlier this year suggest that quarter of a century on the question of what we don’t know we don’t know is still a problem, at least in so far as clinical trials are concerned. Both papers concern trials of antidepressant drugs. Kirsch *et al*<sup>2</sup> reviewed and re-analysed all the clinical trial reports submitted to the US Food and Drugs Administration for the licensing of four of the new generation antidepressants—the selective serotonin re-uptake inhibitors (SSRIs).

SSRIs can be considered to be the result of rational drug design—drugs developed as a result of basic biomedical science research since the 1960s that developed the hypothesis that the underlying cause of depression is an abnormally low concentration of the neurotransmitter serotonin in specific brain regions, and preventing its reuptake into nerve cells will increase the amount available to provide the chemical signals between nerves. The origin of this “amine hypothesis” of depression lies in studies in the 1950s of reserpine, the pharmacologically active compound in *Rauwolfia serpentina*, a herb that has a long history of use in Ayurvedic medicine as a treatment for mania. In healthy people reserpine causes a deep depression, and animal studies showed that it causes a severe depletion of two neurotransmitter amines, serotonin and dopamine. Further studies focussed on serotonin, and so the SSRIs were born, and became arguably the most widely prescribed antidepressants.

**When data was included from unpublished as well as published trials, “their meta-analysis showed that there was no significant effect in mildly depressed patients, and little effect in even severely depressed patients”**

Published trials of SSRIs reveal effects that are statistically significant but of marginal clinical significance. But when data from unpublished trials is included we find a difference of only 1.8 points between drug and placebo on the Hamilton Depression Rating Scale—in the UK NICE uses a drug-placebo difference of 3 points as the criterion of efficacy. Kirsch *et al*<sup>2</sup> obtained data from 47 trials (published and unpublished) from the Food and Drugs Administration (FDA). Their meta-analysis showed that there was no significant effect in mildly depressed patients, and little effect in even severely depressed patients. It was only among the most severely depressed that there was a clinically significant difference between drug and placebo.

Turner *et al*<sup>3</sup> obtained reviews from FDA for 74 studies of 12 antidepressant drugs, involving a total of 12,564 patients. Of these, 31% were unpublished. Thirty studies considered by FDA as being positive results were published, one was not. More worryingly, of the studies that were regarded by FDA as being negative, three were published, 11 were published in a way that suggested (to Turner *et al*) a positive effect, and 22 were not published. They conclude that according to the published literature 94% of trials were positive, whereas taking into account the unpublished studies this fell to 51%.

There are various reasons for not publishing negative findings. The most usual is that no journal editor wants to dilute the impact of his/her journal with papers that report negative findings and will not be cited. Conspiracy theorists will point out that pharmaceutical companies may try to suppress negative results, and according to Richard Smith, former editor of the *British Medical Journal* and winner of the 2004 HealthWatch award<sup>4</sup>, this is all too true in many cases.

All current and future clinical trials have to be registered in advance so that, like those of antidepressants analysed in these two papers<sup>2,3</sup>, all results—positive or negative—must be reported to the regulatory authorities. This is not true of older trials, and we may never know how many unreported trials of drugs for which there appears to be evidence of efficacy were negative.

Even though all trial results will be filed with regulatory authorities, it is unlikely that all negative trial results will be published, so if a future drug achieves regulatory approval (possibly on marginal evidence of efficacy) the published literature will show a considerably more positive effect than is truly the case. How then can we get to know what we don’t know we don’t know?

**W**HAT WE don’t know but can safely speculate is that the claims made for the açai berry are too good to be true. These unprepossessing little purple-black South American fruits are the latest “superfood”<sup>5</sup>, according to the technicolour e-mail that keeps pushing itself into my spam box. “Lose weight and flush up to 50 lbs!” it shouts. “Increased energy!”

“Loaded with antioxidants!”, “Flush out old food and pounds!”, “Get slimmer & feel great with the world’s #1 super food!”. It goes on to state that the açai berry is, “One of the most nutritious and powerful foods in the world!”, a statement attributed to one Dr. Nicholas Perricone.

We are told that açai berry is “as seen on CNN, ABC, CBS NEWS, NBC”—and Oprah Winfrey recommends it too.

According to Wikipedia<sup>6</sup>, “Nicholas Perricone MD is a dermatologist who has written several books, primarily on the subjects of weight loss and maintaining the appearance of youth. He is an Adjunct Professor of Medicine at Michigan State University’s College of Human Medicine, from which he received his MD. He has appeared in two special programs on PBS. He sells his own line of skin care products.” “Perricone has written five books. These all take a similar ‘three-tiered’ approach to skin problems. The three tiers are diet, supplements, and topicals. The books share some general recommendations, but each contains unique material.” “Perricone’s company, NV Perricone, MD Ltd, sells relatively high-cost topicals, as well as some dietary supplements.”

**“There is no mention in any of these papers of any possible or likely weight reducing action.”**

So what exactly is açai berry? It is the fruit of the açai (pronounced ah-sah’-ee) palm, *Euterpe oleracea*, from the Amazonian rain forest. The berries are an important traditional food of the Amazonian Indians, and the inner growing tip of the stem is eaten as heart of palm. (The inner growing stems of other palms are also eaten as heart of palm—a costly product since harvesting it involves killing the tree).

A MedLine search revealed ten papers on açai berry up to August 2008. Six report the nutritional analysis of the berry (it has a very high content of water-soluble antioxidants) and the oil from the seed. The other four report investigations *in vitro* and in cell culture of pharmacological actions that may or may not lead to clinical uses of berry extracts.

There is no mention in any of these papers of any possible or likely weight reducing action.

So, what we have is a berry that has long been an important food item for Amazonian Indians that is a rich source of antioxidants.

The berry does not store or travel well, and what is being marketed is freeze dried powder or bottled juices, often together with other fruits. So far, so good. There is a market in developed countries for exotic fruits, and harvesting açai berries provides a source of income for farmers—and indeed may help to preserve the Amazonian rain forest.

What is less justifiable is the hype that this “superfood” is not just a very rich source of antioxidants, which it is, but that it can increase energy (whatever that means, see Lewis Wolpert’s article on Scientific terms need protecting<sup>7</sup>) and “flush out old food” and cause weight loss.

A case, perhaps, of “we know what we don’t know, we know what they don’t know either but think they know, even though they don’t, and we can guess the rest.”

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## Check the evidence behind the health news stories

CHILDREN brought up in very clean homes are prone to developing diabetes in later life, reported a number of newspapers in September. A study of mice kept in a germ-free environment found that 80% developed diabetes. Some journalists also linked the findings of the study with the theory that lack of exposure to viruses and bacteria could make people more susceptible to illness.

But did the research justify the headlines? Not in the view of “Behind the headlines”, a handy online NHS source designed for health professionals and the public alike<sup>1</sup>. It offers, “an unbiased and evidence-based analysis of health stories that make the news.” It is up-to-date, responding to news stories the same day they appear in the media.”

This particular study, carried out by scientists in the US and in the UK, had appeared in the peer-reviewed journal *Nature*<sup>2</sup>. It was carried out in genetically modified mice prone to getting type 1 diabetes and which also lacked a part of the immune system

involved in bacterial response. The study found that 80% of mice given antibiotics to be kept germ-free, developed diabetes, and mice exposed to a mixture of normal gut bacteria developed substantially less diabetes. However, *Behind the headlines* concludes that these results have been over-interpreted by the newspapers, saying, “it is not clear whether these results are truly representative of the development of diabetes in humans. Resident bacteria are a normal part of the human body and would not be expected to be destroyed by maintaining a clean house.”<sup>3</sup>

Mandy Payne

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## CHECKING OUT THE LATEST GADGET

*Dr James May has been busy in his lunchbreaks. The Internet has made it easier than ever to investigate the evidence behind new developments in health technology*



**A FEW WEEKS ago one of my patients attended a same-day appointment brandishing a report from a “total body scan” for which she had paid a local pharmacist £60. The report was so bizarre that I had no hesitation in informing her that I thought it was worthless, and recorded as much in her notes.**

At coffee I passed the report under the noses of my colleagues who gave it equally short shrift, and encouraged me to pursue it further to put an end to what looked very much like a waste of money. What follows is a description of the process as it evolved, for the guidance of any readers who are inclined similarly to pursue apparently questionable devices.

The first and probably most important step was during the consultation to get hold of a copy of the report from the patient as well as asking a few pertinent questions, such as how long the scan took, how much it cost. The next step—to pop round and see the pharmacist—was initially delicate as I have a professional relationship with him. Two of my colleagues also visited to have a chat, as well as to have a peek at this wonderful machine. I asked the pharmacist about the machine, and explained my doubts. He said that it was FDA (the American Food and Drug Administration) approved, which seemed to me unlikely. It was clear to me that the pharmacist genuinely believed that the nutritional advice being offered was of benefit to his customers’ health and wellbeing. He also said that many pharmacists, as well as herbalists and nutritionists, use similar equipment and that he was offering a service that is fully supported by the Department of Health and welcomed by the general public. I suggested to him that he might contact the Royal Pharmaceutical Society of Great Britain (RPSGB, on [www.rpsgb.org.uk](http://www.rpsgb.org.uk)) to find out about the legitimacy of this machine. I then contacted the RPSGB myself.

Next I wrote a draft article for the *HealthWatch Newsletter* thinking that my job had been done. Members of the committee had other ideas, and suggested that this would be best pursued through UK Trading Standards ([www.tradingstandards.gov.uk](http://www.tradingstandards.gov.uk)). Trading standards were not easily persuaded. When I suggested that this was not an approved machine the officer replied that of course it was—even cotton buds have to be approved. I explained my reasons and he took it on but referred it to the Medicines and Health products Regulatory Authority (MHRA, on [www.mhra.gov.uk](http://www.mhra.gov.uk)) who are currently investigating the machine.

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**“When I suggested that this was not an approved machine the Trading Standards Officer replied that of course it was—even cotton buds have to be approved.”**

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The FDA claim intrigued me. Searches of the FDA website (see [www.fda.gov](http://www.fda.gov)) produced enormous impenetrable lists, in which I tried to find evidence in favour of the machine. Although I failed, I could not be sure that in doing so I hadn’t produced a false negative, and that I simply had not found it. Next, a twenty minute spell of Googling key words related to the scanner, seeing what came up, and following the links including a Wikipedia entry was very helpful and all the more intriguing. I could trace the gadget back to a company in Florida, I could find their address, and I could visualise a satellite image of their building on Google maps (not useful but fun). I discovered that according to their figures they are making in

the order of £4.5 million per year from the machine, and that the world-wide public is spending in the order of £100 million having their scans. If, like me, you are not good with the Internet, I find the following principle helpful: type into Google what you want and you will find it. Type in the name of the gadget followed by ‘FDA’ for example, or whatever words you think might be interesting—like ‘video’. I could find certificate numbers, registration codes and other registering bodies as well as a great film of the machine in use. Eventually I got back to the FDA website and sent them a message. Within 24 hours I had a reply telling me that the machine in question was registered but not approved. Essentially it has a registration number which puts it on a waiting list awaiting approval. I now had a correspondent at the FDA and mailed back asking what this meant—whether it could be leased out as to the pharmacist for example. I was told that it could not legally be sold, leased or even given away in the US.

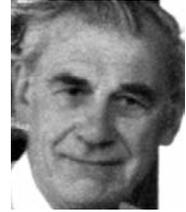
**G**IVEN the US connection I contacted Quackwatch, an American not-for-profit corporation run by Dr Stephen Barrett, which aims to expose and combat health-related frauds, myths, fads, fallacies, and misconduct ([www.quackwatch.org](http://www.quackwatch.org)). Within two hours I received a substantial and very helpful reply and we were soon exchanging e-mails updating each other on progress in our research of the scanner. They have since posted their own report on the subject and gave the following background in a recent e-mail update, “the scanning device ... is one of several dozen that work by applying a low-voltage current at various points on the skin, measuring the drop in voltage elsewhere on the skin, and interpreting the alleged significance of the drop with a meter or computer program. The FDA has cleared a few such devices for marketing as biofeedback devices, even though they are used for unapproved diagnostic purposes.” It seems that after the Seattle Times published a lengthy exposé on a similar device ([http://seattletimes.nwsource.com/html/localnews/2004020583\\_miracle18m2.html](http://seattletimes.nwsource.com/html/localnews/2004020583_miracle18m2.html)) the FDA banned importation of one device of this nature ([http://www.fda.gov/ora/fiars/ora\\_import\\_ia8006.html](http://www.fda.gov/ora/fiars/ora_import_ia8006.html)) and the House Committee on Energy & Commerce urged the FDA Commissioner to do more.

Back home, I e-mailed the UK branch of a company marketing a similar scanner here, asking for their evidence base. I was sent a lengthy technical text the same day and copied it to my growing list of interested contacts. Rather than answering my queries, it only served to feed the robust scientific response that is brewing. At around this time Quackwatch obtained a report from a scan by a gadget of this type and e-mailed me their brief verdict, the exact text of which our editor will not let me print in the interests of propriety but in which Quackwatch opined that the report was of no value to man nor beast.

I have not as yet pursued either the MHRA or the RPSGB, but am awaiting their responses. The gadget in question has now been referred to the FDA ‘compliance’ department. I could yet contact the European Commission, as per the advice given by MEP Dr

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## WAS IT REALLY A CONTROLLED TRIAL?



**T**HE ISSUE of the *British Medical Journal* dated 23rd August had a striking front cover. The text asked, “Alexander technique—can it help with low back pain?” A picture of two stacks of blocks represented two spinal columns: one was crumpled and collapsing but the other was straight and being hoisted up.

On pages 438–441 an article<sup>1</sup> appeared entitled, “Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain.” The authors’ conclusion is that one-to-one lessons in the Alexander technique have long term benefits to patients with chronic back pain. The Alexander technique, for those who are not familiar with it, involves a personalised approach to teaching patients to improve their postural tone and muscular coordination. It is an educational technique taught to be practiced by patients on their own and is not a form of exercise.

This report has many interesting features, but two that are, to me, the most important aspects are not mentioned by the authors, or by the writer of the associated Editorial.

### 1. Flow of participants through the trial

Back pain is a very common disorder, so it should have been easy to recruit enough suitable volunteers from the 64 participating practices. The trial was designed to test the efficacy of four treatments for back pain, alone or in combination, compared with “normal care” who were a control group. It was calculated that they needed about 70 volunteers in each of the 8 groups: in fact they found 579 people who matched their inclusion and exclusion criteria. To do so they invited 18,342 patients with a history of back pain. Of those invited only 4803 replied, and of those who replied only 1027 were potentially eligible. Further screening brought the available total down to 579, but we are not told which of the selection criteria was most important in disqualifying the 448 who were found to be ineligible at this stage.

The conclusions in the report about the effectiveness of the treatments for patients with chronic back pain assumes that those randomised in this trial are representative of all patients with chronic back pain, but this may not be true when the volunteers tested are a very small proportion (less than 3.2%) of those invited to participate.

### 2. Are the controls valid?

Ideally randomised controlled trials are designed so that the response of volunteers who are receiving the treatment under investigation can be compared with that of another group (controls) who are not receiving the active treatment, but a dummy treatment that

they cannot distinguish from the real one.

The ATEAM trial was not a randomised controlled trial in this sense. The response of the volunteers who had six lessons in Alexander technique, or 24 lessons, was compared with those who had none, but those people are not a valid “controls”. There was no “blinding” of the volunteers—everyone knew exactly what treatment they were having. This is a serious weakness of the design. Obviously those having 24 Alexander lessons were having much more contact with skilled therapists than (for example) those advised to take exercise. How do we know whether the better relief from back pain in the Alexander group is due to the patients’ practising the postural training they’d received, or the greater attention from the therapists, even if postural changes did no good whatever?

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**“everyone knew exactly what treatment they were having...this is a serious weakness of the design”**

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It is even possible that some of the volunteers started the trial with a belief that Alexander therapy was beneficial. If such a person were randomised to an Alexander group they would be pleased, but if they were randomised to a non-Alexander group they would be disappointed. This problem could be surmounted if the Alexander group were compared with another group who believed they were having Alexander therapy, and who had identical contact with the same therapists, but in fact it was a fake treatment resembling Alexander. There are those who argue that this is impossible, however such “fake” treatments have an important place in clinical trials to reduce patient- and observer bias, and trials can be designed accordingly. For example, sham acupuncture versus true acupuncture.

*John Garrow  
Emeritus Professor of Human Nutrition  
University of London*

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## Checking out the latest gadget

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Caroline Jackson on the front page of the last issue of the *HealthWatch Newsletter* (Issue 70, July 2008) which reported on the new EC-wide consumer protection laws. My earlier critique on the machine itself may now be revised and updated for a future issue of the *HealthWatch newsletter*. The whole process has taken about 20 hours and has been great fun for a good cause. One side effect is that I have found out about a lot more machines that are out there making similar claims.

What might have taken weeks of writing letters and trying to dig up information is made dramatically simple by the Internet. No longer are specialist teams required; investigation can now be done

during the lunch-break. Care is advised, however. Don’t rush into print or even on-line with your part-formed critique of any treatment, diagnostic or other health-related innovation without full evidence. Check with appropriate authorities such as the FDA, MHRA, Trading Standards Authority, for example. Your initial assessment could be incorrect or even libellous—and you could end up attracting a huge claim for damages.

*Dr James May  
HealthWatch Committee Member and GP  
London*

## EVIDENCE: GETTING TO THE BOTTOM OF IT

The following article by leading obstetrician Susan Bewley, who recently joined the HealthWatch Committee, first appeared in the British Medical Journal on 5th April this year and is reproduced with the journal's kind permission. The reference for the original is BMJ 2008; 336: 764.



**“WHICH way up should I put the suppository?” I’ve asked this question of countless junior obstetricians over the years as we administer rectal analgesia after a caesarean section<sup>1</sup>. Despite thinking it might be a trick question, they all want to insert the pointed end of the bullet shaped object first<sup>2</sup>. Surely that’s how they are designed, and it would be more comfortable?**

Well, no. A trial confirms that blunt end first is preferable<sup>3</sup>. Possibly because of the tapered shape and tone of the sphincter, fingers rarely need to be inserted into the anal canal (1% v 83%) as the suppository is “sucked” up and fewer suppositories are expelled (0 v 3%). There is 82% less invasive administration, and drug delivery and costs should improve by 3%. So, here is a simple, easy improvement to your practice. Or is it? At this point, I get an alarmingly familiar stare from the junior (is she right or completely barking?). “I don’t wish to practise authority based medicine,” I say. “If you don’t believe me, please check on Medline.” But only one has.

Good doctors, rightly, are risk averse and conservative. As individuals, we find change difficult. What is fascinating about the discourse of evidence based medicine is the psychological challenge it presents—of changing one’s practice from less effective to more effective. Changing on the basis of new evidence means accepting the uncomfortable notion that we did it wrong, or less well, before. Thus we have needlessly harmed people in the past. This is painful for health professionals, motivated by the urge to help and heal, even if our actions were unintentional or the evidence didn’t exist previously. Some find it easy to say, “Well, better stop harming now than carry on,” but denial is simpler, powerful, and comforting.

**W**HICH brings us back to the humble suppository as an excellent educational tool. The correct answer about mode of insertion is counterintuitive, the past harms are unpleasant (but relatively minor—not dead or damaged patients), and the lesson applies to nearly all NHS clinicians. Having failed to get a directorate-wide suppository guideline agreed, I decided to opt for a hospital-wide protocol. The chief pharmacist examined, and accepted, the arguments. We should indeed be inserting suppositories the other way, base first. The only problem was that all suppository packs contain the tradi-

tional, incorrect instruction, which would confuse patients. So, he concluded, it has to be an NHS-wide policy. I have written to the National Institute for Health and Clinical Excellence twice, but have had no reply and not found it on their programme of work. Why not? A 3% saving of the NHS suppository bill could be substantial.

The savings would be greater still if more attention was drawn to cheaper rectal drugs that might be used more frequently. A technique that doesn’t require finger insertion might help patient acceptability. The educational benefits of applying evidence based medicine for every doctor, nurse, midwife, health visitor, and patient in the UK would be phenomenal<sup>4</sup>. A problem remains in persuading the drug companies to change the patient information leaflets and potentially lose 3% profits.

In the meantime, don’t let the multinational, global political issues stop you reflecting on and changing your practice.

Susan Bewley  
Consultant obstetrician  
Guys and St Thomas’ Foundation Trust, London

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