



Health Watch

...for treatment that works

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MAGNETS ON PRESCRIPTION "MAY BE PLACEBO"

THE NHS Prescription Pricing Authority has ruled that a magnetic leg wrap is to be available for prescription by GP's. It is claimed that the device speeds wound healing. But many experts are concerned that the decision may have been based on inadequate evidence and that the device is nothing more than a placebo.

Magnets are commonly used to treat joint pains, sports injuries, backache, muscle soreness and period pain even though research suggests that applying small magnets to injured tissue can have no clinical effect. In an editorial in the *British Medical Journal* earlier this year US experts commented, "Patients should be advised that magnet therapy has no proven benefits."¹ However users believe they improve circulation because they attract the iron in blood towards them and, in doing so, increase the supply of oxygen to the wound.

4UlcerCare, a device comprising four magnets which are strapped to the leg, was devised by Derek Price who believes a magnetic collar he made for his dog, Kiri, relieved his pet's arthritis. His Bristol-based company Magnopulse has, according to the *Sunday Times*, sold more than a million therapeutic magnets since 1997 to treat arthritis, swollen ankles, period pains and varicose veins². The NHS will buy the treatments at £13.80 each, around half the normal retail price.

It is not clear what evidence was consulted in order to convince the NHS Prescription Pricing Authority to include it in the Drug Tariff, says the *Independent*³. A pilot trial was run on 26 patients in East Anglia by the London GP Nyjon Eccles and its results were published in the *Journal of Wound Care* early last year⁴. But even

as the NHS PPA gives a green light to magnets, the *NHS National Electronic Library for Health* website highlights numerous flaws in the East Anglia research and concludes that no firm conclusions can be made on the basis of this study alone⁵. Dr Ben Goldacre points out in the *Guardian* that the NHS PPA only assess based on cost-effectiveness and safety, but he speculates that, "this might be the first time something has been embraced by the NHS, with no compelling evidence of efficacy, knowing at the time that its effects may only be placebo"⁶.

HealthWatch's Michael Allen comments, "The normal minimum criteria for trials to confirm effectiveness of conventional treatments are concurrent results in more than one centre and a total of about 1,500 patients treated. This seems to be a case of different sauces for goose and gander and is very concerning."

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5. www.nelh.nhs.uk/hth/magnetic_bandages.asp accessed 15 March 2006.
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Separating facts from the fiction about chemicals

AN INVALUABLE 16-page briefing on chemicals, designed to counter misunderstandings and misinformation promoted in non-specialist "lifestyle" media, has been published by Sense About Science and is available to download from the Internet.

"Unfounded anxiety about chemicals is encouraging people to buy into ideas and 'remedies' that make little scientific or medical sense," says Tracey Brown, director of Sense About Science, in her introduction to their new publication *Making Sense of Chemical Stories*. This briefing document, she explains, flags up the more serious misconceptions that exist around chemicals and suggests straightforward ways for writers and presenters to present them. "It is intended to open a conversation that promotes a stronger connection between lifestyle commentary and chemical realities." Misunderstandings about chemicals are, she says, partly the result of intensive merchandising of 'alternative' products, lifestyle ideas and campaigns that play on misconceptions about chemicals and about how the body works.

In the new booklet leading chemical scientists identify and address six of the most prevalent misconceptions about chemicals. These include the ideas that man-made chemicals are inherently dangerous and that our exposure to a "cocktail of chemicals" is a ticking time-bomb. "The chemical reality is that, although the language of 'cocktails' and 'time bombs' is alarming, neither the presence of chemicals nor the bioaccumulation of them, in themselves, mean that harm is being done."

Sense About Science is an independent charitable trust that works to promote evidence and good science in public debates. View the document online on <http://www.senseaboutscience.org.uk/PDF/MakingSenseofChemicalStories.pdf>

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THE LORDS DEBATE HOMOEOPATHY

IN THE HOUSE of Lords on January 23rd Lord Taverne asked Her Majesty's Government, "whether they have any proposals to withdraw National Health Service funding for homeopathy?" The short answer from the Minister of State was that "decisions on the commissioning of complementary and alternative therapies, including homeopathy, on the NHS, are matters for primary care trusts. The Government consider that clinical decisions on the use of complementary or alternative treatments should be left to clinicians. However, there is further scope for the National Institute for Clinical and Health Excellence to include assessment of complementary therapies in its guideline work."

In the ensuing discussion it became apparent that some of the noble Lords who spoke were confused about the difference between evidence as to whether or not a treatment works, and knowledge of its mode of action. We were treated to the statement from one noble Lady that her consultant admitted that he does not know how paracetamol works, but he still prescribes it.

Leaving aside the problem of a consultant physician who has apparently forgotten the pharmacology he was presumably taught at medical school, ignorance of the mechanism of action of a drug or other treatment should not prevent its use - as long as it has been demonstrated to be effective.

Aspirin was used very effectively for almost 100 years before Sir John Vane elucidated its mechanism of action as an anti-inflammatory drug. Penicillin was used for two decades before its mechanism of antibacterial action was explained. We still do not really know

how the antidepressant drugs act. If they simply increase the availability of neurotransmitters in the brain, why is there a 2 - 3 week lag before benefits are seen? Chemical depletion of neurotransmitters leads to a deep depression within hours.

It is not acceptable to dismiss a proven treatment on the grounds that we do not know how it acts, but equally it is unacceptable to say that a treatment that has not been proven to work (or, as in the case of homeopathy, has been demonstrated not to work) should be used because we do not know its mechanism of action.

The full exchange can be read in Hansard at: <http://www.publications.parliament.uk/pa/ld199697/ldhansrd/pdvn/lds06/text/60123-02.htm>

David Bender
Chairman of HealthWatch

Public need education to support medical research

THE PUBLIC needs to know that advances in diagnostics and therapeutics are being held up by bureaucratic regulation designed to protect their privacy, said an Editorial in the 28th January issue of *The Lancet*. The call echoed that of contributors to an earlier *HealthWatch Newsletter* (issue 53, April 2004) which was dedicated to the issues raised by the EU Clinical Trials Directive that was passed in May of that year.

Large databases of patients' records are needed for important medical research, such as that into the causes of disease. But growing concerns about privacy have spawned laws and regulations governing the use of personal data, including the UK's Data Protection Act and the US's Health Insurance Portability and Accountability

Act (HIPAA), along with the EU Clinical Trials Directive. These complex regulations can be interpreted in different ways by researchers, which results in important and worthy projects being delayed or blocked entirely.

The Lancet commented, "When patients are convinced that their personal information is being used under rigorously controlled conditions and in accordance with best research practices, they are likely to agree to give up a small amount of individual privacy for the greater societal good that can come from population research. The future of our health depends on it."

The Lancet 2006; 367(9507): 275.

NEWS IN BRIEF

THE TREND towards open access publishing now includes the *Journal of the Royal Society of Medicine*. From March all research and original articles, as well as issues more than three years old, became available for free at www.jrsm.org. By early 2007 complete issues of the JRSM dating back to the first issue in 1809 will be available online thanks to support from the Wellcome Trust. HealthWatch members who browse the March issue will be interested to read the first article in a series by Richard Smith, ex-editor of the *British Medical Journal* and winner of the 2004 HealthWatch Award, on "The trouble with medical journals" (see *J R Soc Med* 2006; 99: 115-119).

A META-ANALYSIS has found no evidence that the hormone melatonin is effective in treating secondary sleep disorders or preventing jet lag. Melatonin - a hormone that is thought to play a part in controlling daily body rhythms - has been used increasingly to manage sleep problems. Researchers at the University of Alberta, Canada analysed trials of the effects of melatonin on secondary sleep disorders (sleep problems associated with medical, neurological or substance misuse) and sleep disorders arising from sleep restriction,

such as jet lag or shiftwork disorder. While there was evidence that melatonin is safe with short term use, they could find no evidence that it is an effective treatment for either class of disorder.

BMJ Online First, 10 February 2006. View full paper: <http://press.psprings.co.uk/bmj/february/melatonin.pdf>

JOURNAL EDITORS are proving slow to take steps to cut the risks of scientific misconduct and research fraud, suggest the results of a survey published in the *COPE Report 2005*. Although a spate of high profile cases of research misconduct have come to light over the past year, the survey found that almost two thirds of journals who responded to the questionnaire had no declared policies on pursuing research misconduct; six out of 10 had no declared complaints procedure and half had no published guidance for authors. COPE, the Committee on Publication Ethics, was set up in 1997 as an informal self-help group for journal editors. It now has a membership in excess of 300 international publishers and journal editors. The *COPE Report 2005* is published online only and is available from www.publicationethics.org.uk

VETERINARY HOMOEOPATHY - IT'S THE SAME ANIMAL

IN RECENT MONTHS a heated row has broken out within the ranks of the Royal College of Veterinary Surgeons (RCVS), regarding the provision of homoeopathy to animals. A senior vet, Dr Morag Kerr, jointly operates the tongue-in-cheek British Veterinary Voodoo Society (BVVS) on www.vetpath.co.uk/voodoo/. In May 2005, John Hoare, a veterinary homoeopath, happened upon the web site, took offence, and submitted a formal complaint to the RCVS alleging unethical conduct, and conduct disgraceful in a professional respect.

He claimed that Dr Kerr and colleagues had made "derogatory remarks" about veterinary homoeopaths, because the RCVS Guide to Professional Conduct discourages criticising one's colleagues. In fact the relevant strictures are phrased in the singular - "Veterinary surgeons must not speak or write disparagingly about another veterinary surgeon" and, "No veterinary surgeon should speak or write disparagingly of a colleague to a third party, since the effect is to undermine public confidence in the profession." We should however be aware of the context. The former quote is definitely talking about a client summarily taking his pet to a rival practice, and is intended to prevent vets in that situation from denigrating each other. The latter quote has a caveat in the following sentence: "This does NOT however apply to instances where professional negligence or misconduct may be involved". This suggests that members may criticise other members who are found wanting professionally, which makes it doubtful that these rules actually apply to this situation.

Mr Hoare objected to the BVVS writing, "disparagingly about other veterinary surgeons". Indeed the site also disparages the RCVS itself, by criticising sanctioning of homoeopathy as part of veterinary medicine. In fact that is really what the site is about (and about homoeopathic pharmacies and pharmacists). The force of the complaint was substantially reduced however by the inclusion in the evidence of external pages not part of the BVVS site. Mr Hoare particularly objected to the use of the spoof qualifications VetMFVoo and VetFFVoo. He demanded that, "The officers of the BVVS should be instructed to unwind their organisation. The use of the pseudo-qualifications should be stopped immediately", omitting to mention that neither VetMFHom nor VetFFHom is a recognised qualification.

"It is even illegal in Sweden for vets to practise homoeopathy (they can be struck off for it)"

Dr Kerr and colleagues, while being concerned at having their professionalism impugned, saw this as an opportunity to induce the RCVS to come to a decision about homoeopathy. The RCVS's first response was to tell Mr Hoare that there were no issues of professional conduct that could be pursued in this case. However, their letter to him also said that, "the College appreciates your concerns" and, "it could be argued that the sentiments on the website disparage the veterinary profession and reduce public confidence in it." Importantly, the RCVS did not notify the defendants before replying thus to Mr Hoare. This triggered a very heated reply by Mr Hoare, in which he objected to, "all homoeopaths being dubbed Quacks, Liars and Fraudsters" and, "the frequent use of the terms Quack, Fraud and Dishonest". But the fact is that the BVVS site does not address him or anybody else in those terms. The words do not appear anywhere in the pages from the site he submitted, and even on the rest of the site not in the context he alleged.

The BVVS site does state that, "any veterinary surgeon who makes therapeutic claims for ultradilute preparations, and/or administers such a preparation in preference to a licensed medicine, is guilty of gross professional misconduct", to which Mr Hoare also objected. This needs to be considered in the context of the 'Cascade' regulations, which require vets to use animal licensed medicines if such exist for the condition being treated. If

none such exist, then human licensed medicines may be used. Thus the BVVS statement is entirely in compliance with official veterinary guidelines.

In a further letter Mr. Hoare offered to drop the case if the defendants published a total retraction of their objections to homoeopathy (and to its spurious post-nominals), and disbanded the BVVS. Eventually, after three months of delay, the RCVS wrote to Dr Kerr and colleagues stating that, "the usage of the word 'Voodoo' in this context and your disparaging remarks against veterinary surgeons who practise homoeopathy bring the profession into disrepute." But the RCVS failed to consider the treatment of sick animals with placebos. Naturally the defendants responded in a robust manner, declaring that their web site represented justified criticism of a practice which was demonstrably inimical to animal welfare. Several important sources were cited in support. For example, the British Veterinary Association recently issued a position paper deeply critical of homoeopathy as being a threat to animal welfare. In its response to the MHRA's consultation on the proposed licensing of homoeopathic medicines, the BVA said that, "Wild extrapolation of a disproven human therapeutic modality to animals is an offence to animal welfare". The European Board of Veterinary Specialisation "only recognises scientific, evidence-based veterinary medicine which complies with animal welfare legislation. Specialists or colleges who practice or support implausible treatment modalities with no proof of effectiveness run the risk of withdrawal of their specialist status. No creditpoints can be granted for education or training in these so-called supplementary, complementary and alternative treatment modalities." It is even illegal in Sweden for vets to practise homoeopathy (they can be struck off for it).

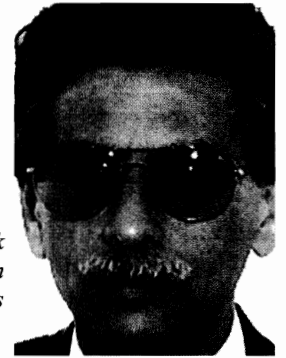
Dr Kerr and colleagues asked why, in the light of the responsible attitude of these European neighbours, the RCVS was prepared to condone the practice of homoeopathy, and asked that they should consider that the obligation to speak out against a practice which is demonstrably inimical to animal welfare over-rides any obligation not to appear to criticise a colleague. They also challenged the RCVS to address the matter of whether homoeopathy could justifiably be practised by vets.

On 15th February 2006, some nine months since the original complaint, the RCVS wrote to the defendants, dismissing the complaint on the grounds that their actions "could not amount to serious professional misconduct." There was absolutely no discussion of the merits or otherwise of homoeopathy, or whether vets could or should practise it. The evidence presented by Dr Kerr and colleagues on the proscription of homoeopathy by other veterinary organisations was not mentioned. Where does this leave the profession? On the one hand, it appears that vets are free to criticise other vets who practise it, but the latter remain free to carry on treating animals with unlicensed and ineffective "medicines" - in flagrant disregard of the evidence for efficacy. Hands up all those who saw this coming! But I am left with one question. If at least some respected veterinary organisations are prepared to proscribe homoeopathy in no uncertain terms, when are equivalent medical organisations going to do so? Or are their presidents more worried about getting their knighthoods and peerages?

Les Rose

Consultant clinical scientist and medical writer

NATURALLY SAFE?



While the public might believe processed foods are full of nasty chemicals, so-called "natural" foods can pack some pretty unpleasant surprises, explains Dr David Bender. The following article is adapted from his original in the Journal of the Science of Food and Agriculture, and is reproduced with kind permission of John Wiley & Sons Ltd on behalf of the Society of Chemical Industry. The original is in: J Sci Food Agric 2005; 85: 2511-2513.

A RECENT ADVERTISING campaign for a frozen food company in the UK suggested that their meals contain no nasty artificial additives. This is presumably a reference to two recalls of foods manufactured with spices that were contaminated with illegal dyes. In February 2005 more than 600 products were recalled because they had been made with a batch of chilli powder that was contaminated with Sudan I¹ and in May 2005 a further 69 products were recalled because they had been manufactured with cayenne pepper contaminated with Para Red².

It is difficult to see how two dyes that have industrial uses (Sudan dyes are used for colouring solvents, oils, waxes, petrol and shoe and floor polishes, and Para Red in printing), but no legal uses in foods, can accidentally contaminate spices. Indeed, although the UK Foods Standards Agency website talks mainly about "contaminated" spices, it does also state that "Sudan I was first discovered in adulterated chilli products in May 2003"³. Since July of that year all cargoes of dried and crushed or ground chilli and curry powders coming into any EU Member State have to be accompanied by a certificate showing they have been tested and found to be free of Sudan I.

An alternative interpretation of the claim that foods are free of nasty artificial surprises might be that they contain real, or natural, nasty surprises instead. For example, the pungent compound in chillies is capsaicin, which protects the fruit from consumption by herbivores. Birds are insensitive to capsaicin - presumably consumption of the fruits by birds will ensure wide dispersal of the seeds, while consumption by herbivores will not. At least one company markets seed for feeding wild birds that has been treated with capsicum oleoresin and ground cayenne pepper, under the trade name Pepper Treat, to deter squirrels³. Their website warns that you should wear rubber gloves when handling the products, and wash the gloves and your hands afterwards - anyone who has cut fresh chilli peppers and inadvertently touched a sensitive area of the skin will know that capsaicin stimulates pain receptors; indeed it has long been used by pharmacologists as a pain-generating agent for testing analgesics.

In the same way that many people have developed a liking for foods containing the pain-inducing agent capsaicin (often in quite large amounts), many Japanese people enjoy "dicing with death" and consider fugu (the porcupine or puffer fish) to be a delicacy. The gonads and viscera of fugu contain tetrodotoxin, and the fish must be prepared by specially trained and licensed chefs to avoid contamination of the flesh with the toxin, which is lethal even in small amounts^{4,5}. Tetrodotoxin selectively blocks sodium channels in nerves, leading initially to numbness and a (possibly pleasurable) tingling sensation, followed by increasing paralysis, and death within four to six hours if a sufficient quantity has been consumed. Between 1974 and 1983 there were 646 reported cases of fugu poisoning in Japan, with 179 fatalities, and it continues to affect between 30 and 100 people annually, mainly from home preparation of the fish⁴.

When a population of dinoflagellate algae develops rapidly, above a certain concentration it is termed a bloom. At higher concentrations the water can become discoloured, a so-called "red tide". The dinoflagellates produce neurotoxins which accumulate in molluscs feeding on the algae. Human beings eating the molluscs are at risk of paralytic shellfish poisoning, and toxic amounts of the

neurotoxin saxitoxin can accumulate in shellfish even when the total algal population is below the threshold for bloom formation if there is a relatively large proportion of the organism in the water^{5,6}.

Tapeworm fears from sushi?

There are fears that the increasing popularity of sushi and other raw fish dishes may lead to an increase in tapeworm infestation. Infection with tapeworms is a well known hazard of undercooked meat, but is nowadays rare in developed countries as a result of both rigorous meat inspection and sewage systems that break the cycle between excretion of eggs in human faeces and infection of the animal alternate host. The fish tapeworm, *Diphyllobothrium latum*, occurs in freshwater fish worldwide and was historically a major problem in the Baltic region with both human beings and bears providing a land-based host for the mature worm. Although infestation is no more severe than with any other tapeworm, and can be eliminated with a variety of drugs, *Diphyllobothrium* absorbs a very large amount of vitamin B12 (up to 80 to 100% of a test oral dose) and can lead to the development of megaloblastic anaemia and the neurological damage of vitamin B12 deficiency⁷.

"...there is a higher incidence of neural tube defects in areas where potatoes are eaten in large amounts⁸..."

A variety of toxins occur naturally in plant foods. Like capsaicin, they are secondary plant metabolites that have, presumably, evolved as protection against pests and predators. An example is the celery cultivar that was bred for resistance to pests and wilting (and so had a longer shelf life), but contained high concentrations of psoralens, which cause a photosensitive dermatitis on contact with the skin⁸. Its introduction was associated with photodermatitis among grocery employees.

It is well known that exposing potatoes to light leads to greening and the accumulation of potentially hazardous amounts of the bitter-tasting glycoalkaloids solanine and chaconine, both of which are glycosides of solanidine. Exposure to light is only one of the stress factors that lead to increased synthesis of glycoalkaloids: sprouting, mechanical damage and improper storage conditions, either of the tuber or after partial processing, are also important. The symptoms of mild solanine poisoning are acute gastrointestinal upset with diarrhoea, vomiting and severe abdominal pain. In more severe cases, neurological symptoms, followed by unconsciousness and, in some cases, death has also been reported. There is also some evidence that solanidine alkaloids may be teratogenic, and there is a higher incidence of neural tube defects in areas where potatoes are eaten in large amounts⁹. I note that the packaging on trays of loose

potatoes on display in my local supermarket states that they must be covered at night, although I would have thought there was more light exposure during the day than at night.

Broccoli and other Brassica species have been regarded as protective foods in recent years because of their high content of glucosinolates, which may protect against cancer by their action that limits the conversion of dietary procarcinogens to active carcinogens, and also by increasing the metabolic clearance of potential carcinogens and their metabolites by boosting the activity of certain enzymes^{10,11}. However, other compounds released during the metabolism of these vegetables can have a goitrogenic effect. There is no evidence that normal consumption of Brassica species has any significant effect on thyroid hormone status in human beings, but goitre can be a problem when cattle are fed large amounts of brassicas. In the long seafaring voyages of discovery in the fourteenth and fifteenth centuries, half or more of the crew often died from scurvy, but this was considerably less of a problem for Dutch explorers, apparently as a result of their consumption of large amounts of sauerkraut-fermented cabbage in which vitamin C is well preserved. The corollary of this was that iodine deficiency goitre, a condition traditionally associated with inland upland areas on thin limestone soil, was surprisingly common, partly as a result of poor absorption of iodide from the acid water-logged soil of the Rhine delta, and partly as a result of the high intake of glucosinolates. Because of this, iodization of salt was introduced in the Netherlands in the 1920s, second only to Switzerland's introduction of iodized chocolate to prevent deficiency in children.

"...it can be argued that organically produced food may be less safe than conventional produce."

Soya beans and other legumes have long been known to contain trypsin inhibitors which, being proteins, are denatured by cooking, and hence of little relevance in human nutrition. During the late 1970s slow cookers, in which the ingredients for a casserole could be left to cook at a low temperature throughout the day, became (briefly) fashionable. There were a number of reports of acute and severe gastrointestinal disturbance that was eventually traced not to bacterial growth in foods kept below boiling point for several hours, but to lectins in red kidney (and other) beans—proteins that are resistant to moderate heating, and require boiling for at least 10min to ensure denaturation^{12,13}.

In a debate about a definition of the term "natural" in relation to foods and food safety, someone once commented cynically that, "cyanide is natural, too". Indeed it is, and a large number of foods, including cassava, lima beans and bamboo shoots, contain significant amounts of glycosides that may yield cyanide when plant cells are disrupted. Probably more important than acute cyanide poisoning is the condition of tropical ataxia neuropathy, due to chronic cyanide intoxication in areas where the more highly cyanogenic bitter varieties of cassava are eaten¹⁴. Amygdalin, the cyanogenic compound in bitter almonds and apricot kernels, has been marketed as "laetrile" or (misleadingly) "vitamin B17", as a cure for cancer. The US National Cancer Institute notes that, "laboratory and animal studies have shown little evidence that laetrile is effective against cancer"¹⁵ but it is associated with signs of chronic cyanide intoxication. Despite the lack of evidence of efficacy, the obvious hazards, and the fact that it is not approved by the US Food and Drug Administration (FDA), laetrile is manufactured in, and sold from, Mexico.

Many consumers choose organic produce on the grounds of safety, but there is little evidence that organically produced food is either more or less safe than conventionally produced food. By definition, organic produce will contain much lower levels of agrochemical

residues than conventionally produced food, but there is no evidence that permitted levels of agrochemical residues are harmful. In contrast, it can be argued that organically produced food may be less safe than conventional produce. Use of manure rather than chemical fertilisers may cause contamination with pathogenic organisms. The varieties of plants that are most suitable for cultivation without the use of agrochemicals are those that produce large amounts of natural pesticides and other toxins, many of which have been shown to have carcinogenic or mutagenic potential¹⁶. The message to consumers is that neither "natural" nor "organic" means "safe".

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TACKLING PUBLICATION BIAS AND SELECTIVE REPORTING

WOULD YOU buy a house on the basis of a surveyor's report if you knew that the seller had not only hired the surveyor but could also edit the report before you saw it and remove anything dodgy? I doubt it. Yet, to some extent, that is the way decisions about health treatments are made because, until recently, many manufacturers released only the good news about their products while unfavourable results were never published.

Evidence-based medicine relies on techniques that combine results from several studies. The resulting systematic reviews or meta-analyses are regarded as the strongest evidence on which treatment decisions should be based. However, these reviews can be misleading unless they include all the studies that have been done. If studies were left out at random (some good, some bad, some large, some small) this would not matter so much. But when unfavourable studies are systematically omitted, this creates publication bias¹. The situation is sometimes made even worse when favourable studies are published more than once and included in reviews several times as if they were different studies².

Even when studies do get published, some findings may be omitted and, once again, there is a tendency to leave out the disappointing aspects³. This is termed selective reporting. Well-designed studies set out with a clear endpoint in mind and will have sufficient statistical 'power' to measure this reliably. Reports can be misleading if secondary endpoints or chance observations are presented as if they were the study's original aim.

"Ironically, trial registration has been compulsory in the United States for trials in 'serious and life-threatening conditions' since 1997 but this law has never been properly enforced"

Journal editors and people compiling systematic reviews have realised for some time that publication bias and selective reporting can seriously distort the medical literature⁴ but, until recently, there was little they could do about these problems. If you don't know a study has taken place, you can't pester the sponsor for the findings. And if you haven't seen the protocol (study plan) you cannot tell what the study was really designed to show. But there have recently been some important developments which should reduce both publication bias and selective reporting.

Members of the International Committee of Medical Journal Editors, which includes the editors of some of the world's most influential medical journals such as *The Lancet* and the *New England Journal of Medicine*, have demanded that details of a clinical trial must be entered onto a publicly-accessible register when the trial begins⁵. Their journals will now consider reports for publication only from properly registered trials. Other journals are following suit⁶.

Ironically, trial registration has been compulsory in the United States for trials in 'serious and life-threatening conditions' since 1997 but this law has never been properly enforced. However, the legislation has resulted in the trial register Clinicaltrials.gov which is run by the US National Institutes of Health. This, along with the UK-based International Standardized Randomized Controlled Trial Numbering (or ISRCTN) scheme, are an increasingly useful resource. As well as reducing publication bias and selective reporting, two further benefits of trial registers are (i) that research funds are less likely to be wasted on redundant projects, and (ii) that patients can discover what trials are taking place and can contact the organisers to see if they might take part.

Many major drug companies have publicly committed to registering their trials and, what's more, some have also agreed to make summaries of results available on the internet. This second step is

critical, as trial registers do not contain study findings, only their planned designs. Trial registration will make it easier for journal editors and researchers to check whether a study has been published before, or whether it remains unpublished. Register entries also enable reviewers to check that all the outcomes have been properly reported. However, if companies (or academic researchers) refuse to publish results, we are none the wiser and cannot be confident that healthcare decisions are based on firm evidence of all completed studies.

Guidelines on Good Publication Practice for Pharmaceutical Companies (GPP)⁷ call on companies to commit to publish results of all the trials they fund and, in particular, those that test marketed products. The GPP guidelines were recently endorsed by a House of Commons Health Select Committee. The guidelines also suggest the ways companies should work with doctors and scientists to ensure that studies are published responsibly. This relationship is vital to the proper conduct of clinical trials⁸. Reporting findings should be a joint responsibility of the sponsor and investigators, but there have been examples of companies trying to put a favourable 'spin' onto findings, denying investigator-authors access to the underlying data, and of preventing sufficient involvement of the named authors by having articles 'ghost-written'. The European Medical Writers Association (EMWA) has produced guidelines on the role of professional medical writers working for companies⁹. These guidelines aim to prevent the excesses of 'ghost-written' manuscripts and other situations in which sponsor companies have too much influence over the reporting of results.

If you are involved in clinical research sponsored by commercial companies, I urge you to look at the GPP and EMWA websites and to encourage more companies to endorse and follow these guidelines. If you are involved with academic clinical research and hope to publish in one of the major medical journals, you should check that your study has been registered. HealthWatch members can also support the move for trial registration by encouraging more journals to make this a requirement for publishing clinical trial results and to promote good publication practice for all trial sponsors.

If every trial is registered before it starts, and all companies and funding bodies agree to publish results of all the trials they sponsor, we will have made a significant step towards eliminating publication bias and selective reporting. This will mean that the information about drugs and medical devices available to healthcare professionals, patients and carers will be more reliable and we can be sure we are reading the whole story, not only the good news, about the medicines we take.

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Useful websites:
www.clinicaltrials.org
www.controlled-trials.com/isrctn
www.gpp-guidelines.org
www.emwa.org

For full references, see page 8 of this issue

ICM PUBLISHES CORRECTION AFTER PERSECUTION SLUR

THE INSTITUTE for Complementary Medicine has published a statement by past HealthWatch president Professor John Garrow to correct allegations that appeared in an earlier issue that suggested HealthWatch had “persecuted” an alternative health practitioner.

The November 2005 issue of the Institute’s e-mailed newsletter *Institute for Complementary Medicine Journal* featured a lengthy interview with Swansea man Roy MacKinnon¹. He explained to journalist Louise Mclean that, after studying Shiatsu, he had begun to treat patients using the “Dr Hulda Clark Protocol”, a de-tox programme devised by US-based physiologist Hulda Clark (one of whose books is titled, “The Cure For All Cancers”)². MacKinnon then described how he had been repeatedly pursued by the BBC and taken to Court for breaching the 1968 Trade Descriptions Act by claiming he could cure cancer, HIV and MS. He was subsequently acquitted. In the article he denied ever having made such a claim. He simply offers, he said, “to use the protocol of Dr Hulda Clark in order to unburden the immune system of its toxins and pathogens and thereby help the body to recover.” Mclean’s article reports him blaming the persecution upon HealthWatch, describing the organisation as, “effectively just a branch of the pharmaceutical multinationals”.

The following correction appeared in the February 2006 issue of the *Institute for Complementary Medicine Journal*³:

CORRECTION

Re: Persecution of alternative practitioner treating cancer in the UK, ICM Journal, November 2005

WE HAVE BEEN asked to clarify and correct some misrepresentation occurring in the report of an interview with Roy MacKinnon by Louise McLean, entitled “Persecution of alternative practitioner treating cancer in the UK”. The interview itself had been previously published by two publications and, since the ICM was not aware

or informed of any complaints about its contents, it was reprinted more or less unchanged.

However, Professor John Garrow, past Chairman of HealthWatch, has asked us to point out that Mr Mackinnon’s comments about possible connections between Healthwatch and the pharmaceutical industry are incorrect.

Prof Garrow has told the ICM: “The opinions expressed by MacKinnon [concerning links with the pharmaceutical industry] are not true. HealthWatch is a Registered Charity (No10003392)* so our audited accounts are available for public inspection. We are funded by the annual subscriptions of our members and by donations from registered charities or individuals who share our aims. We have no corporate sponsors and certainly no pharmaceutical companies. If you visit our website (www.healthwatch-uk.org) you will see that we are not ‘out to discredit alternative practitioners’, but do oppose anyone (orthodox or alternative practitioners, commercial or governmental bodies) if they make health claims unsupported by good evidence of efficacy.”

The ICM is happy to accept Prof Garrow’s correction and statement as to Healthwatch’s charitable status and independence from pharmaceutical industry support.

* NB: charity number given was incorrect. It should be 1003392.

References

1. The original article in the Institute of Complementary Medicine online newsletter appears on www.i-c-m.org.uk/journal/2005/nov/a03.htm
2. The Dr Hulda Clark Protocol is described on www.drhuldaclark.org
3. This and previous issues of the Institute for Complementary Medicine Journal can be viewed at www.i-c-m.org.uk

Cancer researchers’ fury at “miracle” report

A NEWSPAPER that reported a “miracle cancer cure” story has prompted a furious response from Australian researchers whose findings, they say, were subjected to “gross misrepresentation”.

The original study¹, published in the online edition of *Cancer*, the journal of the American Cancer Society, noted that many oncologists have encountered patients with proven non small cell lung cancer (NCLC) who received modest doses of radiotherapy to make them more comfortable and who then unexpectedly survived for more than 5 years; some were apparently cured. The authors used a large-scale prospective study to investigate this phenomenon and found that 1.1% of 2337 palliative RT patients survived for 5 or more years after treatment began, including 18 patients who survived progression-free for 5 years.

The study was reported in the *Independent* on 23rd January under the headline, “‘Miracle’ cures shown to work”, beginning, “Doctors have found statistical evidence that alternative treatments such as special diets, herbal potions and faith healing can cure apparently terminal illness, but they remain unsure about the reasons.” Although study author Professor Michael Mac Manus of the Cancer Institute of East Melbourne, Victoria is quoted saying, “It is important that the frequency of this phenomenon should be appreciated so that claims of apparent cure by novel treatment strategies or even by unconventional medicine or ‘faith healing’ can be seen in an appropriate context,” the article’s introduction and subsequent listing of

what it refers to as “unorthodox cancer cures” might have reinforced an impression that alternative therapies could have been implicated in the unexplained recoveries observed in the study.

Study author Michael Mac Manus, in a letter to the *Independent*, wrote, “We suggested that the patients might have tumours that were unusually sensitive to radiation but our paper contains nothing to suggest that any patients were cured by therapies such as, ‘vitamin C, laetrile extracted from apricot stones, or the Gerson diet of raw vegetables’. The *Independent* article has been widely quoted to give support to such therapies when it contains nothing to support them.”

The *Independent* published a correction on 17th February, which made it clear that the error was not the fault of the bylined author of the article.

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1. Mac Manus MP, Jane P. Matthews JP, *et al.* Unexpected long-term survival after low-dose palliative radiotherapy for non small cell lung cancer. *Cancer*. Published Online: 23 Jan 2006.
2. ‘Miracle’ cures shown to work. *Independent*, 23 January 2006. (Note: neither the original nor the 17th February correction are currently available from the *Independent* web site.)

SLIPPING THROUGH THE NET

LAST YEAR the *Telegraph* web site hosted an advertisement that would never have been allowed in their print edition. Alongside an article about autism were a few lines of text offering homeopathy as a treatment for the condition.

The link www.e-homeopathy.com/autism.htm led to a page headed, "Homeopathic Treatment of Autism" which went on to claim, "The Homeopathic approach... offers effective treatment for autism and related disorders." (It also asserted that homeopathy should be the therapy of first choice for tuberculosis, meningitis, gallstones and bedwetting).

Why would the *Telegraph* promote links to this madness on their web site, I wondered, filing my complaint on the Advertising Standards Authority website. Their reply was prompt, and disturbing. "In all probability the *Telegraph* is unaware of the advert's existence," wrote Matthew Morgan, ASA Complaints Handler. The advertisement, he believed, was an 'Ad by Google', an innovation by the US Internet company Google. "Neither the *Telegraph* nor Google will have pre-vetted the wording of the e-homeopathy.com advertisement. This type of advertisement is simply targeted to appear on relevant web pages: in this way, an advertisement for a treatment that claims to alleviate autism appears next to an article about autism." Furthermore such ads are not "fixed"; they do not always appear on the webpage in question and so are doubly difficult to trace.

And, finally, although the ad clearly breached the Code of Advertising Practice, my complaint could not be upheld because the advertiser is based outside the UK, so beyond the ASA's reach.

The idea that offensive advertisements from any source might be able to sneak unbidden onto otherwise respectable sites is alarm-

ing. Ads by Google is certainly a clever idea. There's no contact between advertiser and media. The advertiser is charged on a "cost-per-click" basis and, although the web site host may not be aware of the ad's existence, they will be aware that they're getting a cut of the cash, though Google will not disclose the exact revenue share that is passed to host web sites.

I asked Google Ads' customer services how ads are screened for possible offence. "Eric" replied, "The Google advertising program is managed by a set of policies which we develop based on several factors, including user and customer experience and legal considerations. We review our policies regularly and make changes to keep them current and effective. Our goal is to have policies that are fair, consistent, and adaptable." Well, they evidently don't keep out all misleading ads. Website managers can apply filters concerning the broad type of ads that appear, but it does seem that the only way to avoid the risk of carrying misleading ads would be not to carry Google Ads at all.

I twice e-mailed the *Telegraph's* press office to ask whether there was any concern felt about being paid for displaying advertisements that might mislead or offend, but received no reply. Perhaps businesses who cannot bring themselves to turn down such easy money could be persuaded to add a disclaimer to their website saying, "Sorry, we have no control over some advertising material on this website, which may be offensive and/or untrue."

Mandy Payne

TACKLING PUBLICATION BIAS AND SELECTIVE REPORTING

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4. Chalmers I. Underreporting research is scientific misconduct. *JAMA* 1990; **263**: 1405-8.
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Box BM HealthWatch, London WC1N 3XX Letters and articles may also be sent to the Editor by e-mail to: newsletter@healthwatch-uk.org

HealthWatch promotes:

1. The assessment and testing of treatments, whether "orthodox" or "alternative";
2. Consumer protection of all forms of health care, both by thorough testing of all products and procedures, and better regulation of all practitioners;
3. Better understanding by the public and the media that valid clinical trials are the best way of ensuring protection.

HealthWatch welcomes membership enquiries from those who share its aims. Membership costs £16.00 per year (£10.00 for students; £20.00 for those outside Europe). Questions about membership can be sent direct to Shirley Churchman at shirley.churchman@zoom.co.uk

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