



# HealthWatch

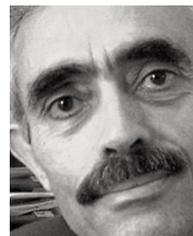
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Newsletter 83 October 2011

## DEPARTMENT OF EMBARRASSMENT



*Evidence-based practice embarrasses both the Department of Health and the General Medical Council, claims clinical research scientist Les Rose. He documents his battle to persuade the government to commit to evidence in healthcare*

**I**T STANDS TO REASON that, with the government planning a reform of the NHS that has the patient at the centre, its policy should focus on the use of treatments that work. I wasn't surprised to read that, earlier this month, 400 health professionals wrote to the Daily Telegraph warning that Health Secretary Andrew Lansley's proposals for NHS reforms will put patient safety at risk, waste money and damage trust in the medical profession. I would be interested to know if Mr Lansley's reply was much different from the ones that I have received in answer to my letters to his department warning of the damage to the health service threatened by their funding of unproven remedies.

While ministers pay lip-service to outcomes in health care, they are not prepared to define their expectations clearly. My correspondence with Earl Howe, Anne Milton, and their departments has reached an impasse. I have asked them why, before the general election, they stated clearly that treatments that lacked evidence had no place in the NHS, yet they still insist on funding unproven remedies. They consistently state that treatment decisions are for clinicians alone, while they refuse to set out what acceptable decision-making is.

In the Department of Health's response to the NHS Future Forum Report, there is a key statement:

"...we will support clinical commissioning groups to make high quality, evidence-based decisions, with information joining up to support integrated care."

### **Is it beyond the wit of the Dept of Health to say, "We expect clinicians in the NHS to follow evidence based practice in patient care"?**

But nowhere in the document is there a clear statement that in this brave new NHS, health care providers are expected to follow evidence based practice. So I asked the Department of Health. More than two weeks later I got the reply:

"We will publish an Information Strategy in due course, which will provide more detail about our plans to improve access to and the quality of information, including how commissioning can help to improve the collection and use of information and how we will ensure that information systems work together to support integrated care. I hope this reply has been helpful."

Well of course it isn't. Is it beyond the wit of the Department of Health to say, "We expect clinicians in the NHS to follow evidence based practice in patient care"? I suspect it is, because if they did

they really would have to close the homeopathic hospitals.

Rather than wait for another written response, I called the press office and asked to speak to someone about the NHS reforms. I began with, "Does evidence based practice by individual clinicians form part of the NHS reforms?" and was told once more that commissioning would be based on evidence. No, that isn't what I asked, I said, because I am interested in what the Dept of Health *expects* of clinicians when they are choosing treatments.

This went round in circles for a while, touching on NICE guidance, but I pointed out that NICE has not evaluated a great many treatments that are routinely used in the NHS. I was then referred to the NHS Constitution, which I was told contains the policy I was seeking. Apparently this sets out the standards of evidence based practice that are expected of clinicians. Well guess what, it doesn't. The word 'evidence' only appears once in the whole 12-page document. You can find it on page 6, in this section:

"You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you."

Of course, "local decisions on funding" are not in any way the same thing as whether a doctor is prescribing a treatment with no evidence that it works.

So if the government which pays for health services is unable to commit itself on standards of evidence, what about the medical regulator? Thus I asked the General Medical Council this question:

"This is a media enquiry on behalf of the charity HealthWatch, of which I am a committee member. I am prompted by the government's response to the NHS Future Forum Report. The government

*...continued on page 5*

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## news

### MMR WRITER BRIAN DEER RECEIVES AGM 2011 AWARD

BRIAN DEER spent much of seven years on a *Sunday Times* investigation of the MMR vaccine scandal. Ultimately the research which started it all was retracted; the researcher, Dr Andrew Wakefield, was struck off the medical register; and vaccination rates gradually recovered. Deer's project included a film for Channel 4 and, in January of this year, a three part series in the *BMJ*. In April he was named specialist journalist of the year in the British Press Awards. Judges described his work as, "a tremendous

righting of a wrong".

At HealthWatch's AGM on 18th October, Deer gave a personal view of the investigation, and revealed what he wished had turned out differently when he spoke about, "Regrets, I have a few. Inside the MMR investigation." A full report of Deer's talk to HealthWatch members at the Medical Society of London, along with news from the AGM, will appear in the January issue of the HealthWatch Newsletter.

### Power Balance® bracelet effect akin to a "carnival trick"

A CONTROLLED TRIAL of college athletes has found that wearing a Power Balance® bracelet did not enhance their performance. The bracelets, made of silicone and adorned with a small embedded hologram and sold for £30 apiece, are popular with sports enthusiasts. The California-based manufacturers originally marketed the bracelets by means of an exercise demonstration in which the wearer's strength and balance appeared to improve when the exercise was attempted a second time while wearing the bracelet.

In the study, sponsored by the non-profit organisation American Council on Exercise (ACE), 42 athletes completed trials wearing either a Power Balance® bracelet or a placebo rubber bracelet. No significant difference in flexibility, balance, strength, or vertical-jump height was found between the Power Balance® and placebo trials. The subjects did, however, do better in the second trial than the first, a phenomenon called the "order effect", attributed to the fact that the second time the athletes were more warmed up, or habituated to the task.

This would explain why in public sales demonstrations Power Balance® and similar performance-jewellery products appear to have beneficial effects on flexibility, balance and strength. In reali-

ty, these sales demonstrations are essentially little more than carnival tricks, said author Dr John Porcari.

In 2009, more than 2.5 million of the bracelets were reportedly sold in 30 countries. The UK website [www.powerbalanceuk.com/](http://www.powerbalanceuk.com/) currently claims the bracelets are, "used by many sports professionals, teams, coaches and trainers who tell us that they, or their clients and teams, have experienced improved gym and game performance when wearing Power Balance®." In December 2010, the Australia Competition and Consumer Commission (ACCC) challenged Power Band Pty Australia Ltd to produce scientific proof of the wristbands' so-called benefits. They admitted there was none, issued a public apology, and offered refunds to consumers who felt misled. In May 2011 the Australian company went into receivership, citing the effect of bad publicity on sales. Claims on other Power Balance® websites have been removed or substantially diluted.

Mandy Payne

#### Reference

Porcari JP et al. Power Balance or power of persuasion? March 2011. <https://www.acefitness.org/certifiednews/images/article/pdfs/ACEPowerBalanceStudy.pdf>

## NEWS IN BRIEF

SNAKEOIL is an interactive "balloon race" visualization of the scientific evidence for over 100 nutritional supplements. It shows at a glance which supplements are supported by evidence, by how much, and for what condition. This elegant and playful online representation is the result of work by a small group led by David McCandless, the London-based writer and designer behind the "Informationisbeautiful" blog, and is based on data from large, human, blind placebo-controlled trials only, sourced from Cochrane reviews and PubMed. Feedback from visitors to the Snake Oil web page helps refine future updated versions.

<http://www.informationisbeautiful.net/play/snake-oil-supplements/>

THE PUBLIC are being urged to "Ask for Evidence" in a new campaign from Sense About Science that aims to put a stop to misleading claims about science and medicine. Their new webpage has links to show how to get advice on asking for evidence, whether it is to question an advertisement, an MP or an article in the press. Over 5,000 scientists and hundreds of organisations are supporting the campaign, which also includes reports of evidence-hunting experiences for products ranging from detox shampoos to MRSA resistant pyjamas.

Ask for Evidence at [www.senseaboutscience.org/a4e](http://www.senseaboutscience.org/a4e)

WRITER Leslie Kenton has been told to take down her web advertisement for Cura Romana weight loss protocol. The ASA upheld complaints about claims that users could burn "inessential

fat stores at a rate of 1,500 to 4,000 calories a day while resetting your appetite and how your body handles foods." The ad referred to an original protocol involving injections of human chorionic gonadotrophin (hCG). Leslie Kenton told the ASA that, "the Essential Spray used in the Cura Romana programme did not contain hCG, and was physically nothing more than pure water and 25% ethanol... it was a vibrational essence that had itself been energised by several non-material vibrational essences including well known gem essences." Complaints that the ad promoted an unlicensed medicine, and made claims that were not compatible with good medical and nutritional practice, were upheld.

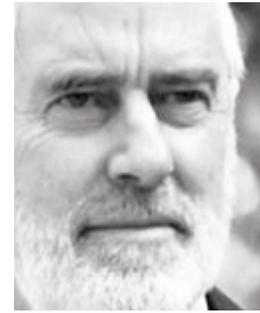
ASA Adjudications, 11 August 2011

BROCCOLI may undo diabetes damage, said one headline, while others claimed that chocolate lowers blood pressure. Some foods are said to be packed with chemicals that can ward off major killers such as cancer and heart disease. Not surprisingly, one in five appraisals covered by Behind the Headlines, the NHS Choices online guide to the science behind current news stories, is about food. A special 11-page report, Miracle foods: myths and the media, is a readable and informative digital publication aimed at the interested layperson and examines whether the news stories match the scientific evidence behind them. The report is downloadable free as a pdf file (2MB).

[http://www.nhs.uk/news/2011/02February/Documents/BTH\\_Miracle\\_%20foods\\_report.pdf](http://www.nhs.uk/news/2011/02February/Documents/BTH_Miracle_%20foods_report.pdf)

(all websites mentioned on this issue accessed 13 October 2011)

# THE SENSASLIM SAGA: THE UK FAILS TO ACT



**I**N MARCH this year a complaint I made to Australian authorities about the promotion of diet product SensaSlim set in train a series of extraordinary events. SensaSlim is an oral spray that the manufacturers say can help people lose more than two stone in a year. It is claimed to desensitize the taste buds (and hence suppress appetite) and administer ingredients linked with thermogenesis. SensaSlim retails online at USD\$69.95 for a 50ml spray (about £45).

My complaint was made to three authorities—the Complaint Resolution Panel (CRP), which hears complaints about alleged breaches of the therapeutic goods advertising code; the Therapeutic Goods Administration (TGA); and the Australian Competition and Consumer Commission (ACCC).

This complaint, along with at least seven further complaints from other people, alleged that the promotion of SensaSlim on the internet, TV and in shops breached numerous sections of the Therapeutic Goods Advertising Code.

In April, SensaSlim issued a claim in the NSW Supreme Court alleging that my complaint was defamatory and claiming “general and punitive damages for libel in the sum of AUD\$800,000”, plus costs.

This action had the effect of stopping the CRP from hearing all complaints about SensaSlim due to a regulation that says: “If, after a complaint has been made to the panel, a proceeding begins in a court about the subject matter of the complaint, the panel cannot deal with the complaint until the proceeding is finally disposed of.” SensaSlim reportedly sent out a newsletter to its distributors with an article in which Australian manager, Adam T Adams, stated, “This defamation action, which could be in the courts for a year or two or even longer, basically gives an iron clad protection that nobody can raise a complaint against SensaSlim to the CRP and hurt us.”<sup>1</sup>

The story broke in the media in May and the Australian media coverage has been extensive. The story was also picked up in the UK’s *Daily Mail*.<sup>2</sup>

In June, in response to submissions by the ACCC, the Australian Federal Court ordered SensaSlim’s bank account be frozen. In July, that court ordered the company to publish a notice on their website including a statement that they had been, “falsely representing that the SensaSlim Solution was the subject of a large worldwide clinical trial when in fact no such trial was conducted”.<sup>3</sup>

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**“the UK MHRA says it cannot investigate this matter because a breach of UK medicines regulations has not yet been shown”**

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Earlier this month, the NSW Supreme Court agreed to have the case against me struck out and costs awarded. Ironically, this appears to be a pyrrhic victory as the liquidator has said there is no money to award costs—and there are many other claimants. Nevertheless, a new defamation claim against me, similar to the first, has been filed in the Queensland Supreme Court by Peter O’Brien, a previous director of SensaSlim, this time for AUD\$1.075 million. Round two of this saga has begun.

SensaSlim International Limited has a registered address in Bristol, England, and a UK website with links to online product ordering (in USD\$).<sup>4</sup> In response to complaints about the site, the UK Medicines and Healthcare products Regulatory Agency (MHRA) has stated that it cannot investigate because a breach of UK medicines regulations has not yet been shown.

There are a number of lessons that can be drawn from this saga.

First, even if university-trained health professionals—in this case, including SensaSlim’s previous medical director, Dr Matthew Capehorn, and numerous Australian pharmacists—appear to support a product, this does not mean it is effective.

Second, the TGA should have responded to earlier calls to look more rigorously at complementary medicines before listing them on the Australian Register of Therapeutic Goods.<sup>5</sup> This type of scrutiny could save franchisees, stockists and consumers from losing money on unproven products.

Third, on receipt of well-documented complaints, the TGA could rapidly de-list products using the powers they already have under the Therapeutic Goods Act.

Fourth, regulations that suspend investigation of complaints while litigation plays out in the courts clearly encourage strategic litigation against public participation (SLAPP). These regulations must be repealed to protect whistle-blowers.

Fifth, until the penalties for unethical promotion of therapeutic goods are applied in a timely manner, and are greater than the financial returns, some promoters are unlikely to be deterred.

Sixth, the case taken against me shows again that the financial cost of defending a defamation action is now out of reach of the average individual. The cost of engaging lawyers and senior counsel to successfully defend the NSW case was AUD\$42,130.63, including a discount applied because of the public interest nature of the case. Indeed, at one stage, my legal team advised me to roll over and withdraw my complaints on the grounds that continuing to defend this action would be unaffordable.

Fortunately, due to the heart-warming moral and financial support of many people, including health professionals, I was able to see my first case through to a successful conclusion. For the second case, a large Australian legal firm (Maurice Blackburn Lawyers) have offered their services *pro bono*. This response by civil society sends a strong message to companies contemplating similar tactics against complainants—the publicity will be counter-productive and these cases will be fought to a successful conclusion.

Finally, this case shows the need for international cooperation with respect to Internet advertising offences that transcend the jurisdiction of one country. It seems ridiculous that UK authorities cannot act against a UK-based company and web site that continues to make claims for a product that Australian authorities have shown to be marketed in a fraudulent manner. Meanwhile, SensaSlim International has announced the launch of a new product<sup>6</sup> (though not, however, in Australia).

Ken Harvey

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La Trobe University, Melbourne, Australia

## References

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2. Daily Mail, 3rd July 2011. <http://www.dailymail.co.uk/news/article-2010727/Obesity-guru-paid-10-000-promote-fake-test-diet-spray-Sensaslim.html#ixzz1TjhGfGXJ>
3. Notice posted at <http://www.sensaslim.com.au/>
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5. Harvey KJ *et al.* MJA 2008; 188 (1): 21-25. View at [http://www.mja.com.au/public/issues/188\\_01\\_070108/har10522\\_fm.html](http://www.mja.com.au/public/issues/188_01_070108/har10522_fm.html)
6. Press release <http://www.prweb.com/releases/2011/9/prweb8771621.htm> (all weblinks above accessed 13 October 2011)

## media

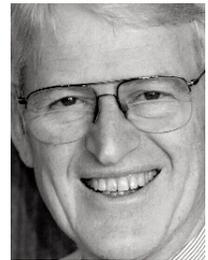
### IF IT WORKS FOR TIGER IT'LL WORK FOR ME!

**S**ports medicine is big business. Some conditions respond to conventional treatment, for example surgery to repair a torn Achilles tendon. But where there is no effective treatment, there's an attraction to methods that are not scientifically based. Some approaches, for example steroid injections for injured tendons, could even slow the healing process. The *International Herald Tribune*<sup>1</sup> recently highlighted the issue of sports celebrities giving credibility to expensive unproven treatments.

Tina Basle, a 44-year-old media consultant who runs marathons sustained a hamstring injury 18 months ago and has spent thousands of dollars on ultrasound and laser therapy, strength training, and finally \$1,500 on a PRP injection. PRP is the injection of platelet-rich plasma. Platelets secrete growth factors which in turn can help tissue heal. It is easy to extract a patient's own platelets by centrifuging a sample of blood. If they are injected into the injury site, the theory goes, they might speed recovery and, since it is the patient's own platelets, the treatment is unlikely to be harmful. In studies, however, results are no better than placebo saline injections. PRP's failure could result from the growth factors being quickly dissipated after injection. Or it could be linked to the fact that growth factors released from platelets need to make contact with cells that can respond—but most tissues in joints and tendons have very few cells.

In Ms Basle's case the result was not successful and she is now resigned to running at a much slower speed and with less endurance.

But celebrity athletes give unproven treatments "star appeal". Despite poor trial results, PRP is a classic example of what has been named the "orthopaedic triad": famous athlete+famous doctor+untested treatment. Two American football players claimed to have good results after having sprains treated. Then Tiger Woods had four PRP injections after knee surgery, and his doctor, Anthony



Galea (who, in July 2011, pleaded guilty to bringing unapproved drugs, including human growth hormone, into the United States in order to treat athletes), told the *New York Times* in December 2009 that within two days of his first injection Woods sent a text message, "He couldn't believe how good he felt".

Having a famous athlete report that a treatment works for them is like direct-to-consumer advertising. Dr Edward McDevitt, an orthopaedic doctor in Maryland, said that patients come and say, "I want the same thing that Tiger Woods had." McDevitt tells them that the treatment hasn't been tested but the patients respond, "I don't care I want it in any case."

The story took a new turn in May this year. New York Yankees' pitcher Bartolo Colon was treated for elbow injuries and a torn rotator cuff with PRP and "stem cells" from his own fat and bone marrow. Colon is said to have made an astonishing comeback, but no systematic study has yet been done of the treatment. That shouldn't stop it from becoming the next big thing.

Keith Isaacson  
Senior Consultant Orthodontist  
North Hampshire Hospital, Basingstoke

1. *International Herald Tribune*, 6 September 2011. View on <http://query.nytimes.com/gst/fullpage.html?res=9B0CEFD153DF936A3575AC0A9679D8B63>

### THE SEED AND THE SOIL

**D**RIVING ONE sunny autumn afternoon on my way to London Heathrow where I was to chair an International steering committee of a multinational clinical trial, I was tuned in to BBC Radio 4, my default station. Suddenly my full attention was grabbed having just completed the complex manoeuvre from the North Circular on to the A40 via the notorious Hanger Lane gyratory system.

I had been listening to an interview with Helen Browning, the new director of the "Soil Association". For those not in the know, the Soil Association is a lobby group promoting "organic food". HRH the Prince of Wales is one of their patrons. On principle I won't allow organic food in the house a) because it's more expensive than "inorganic food", b) their science that claims the food is healthier and tastier is dodgy, and c) I object to the word "organic" being hijacked to mean bullshit (used here both literally and figuratively).

Thanks to the BBC website (via the link here: <http://www.bbc.co.uk/i/b014qnlq/>) it's been possible to transcribe the exchange, from the 22nd September edition of *You and Yours*, here:

**Interviewer:** *As I said, you have said you want to embrace science and technology, and yet I also read that you treat your own farm animals with homeopathy, now I don't want to provoke a million e-mails from those who swear that homeopathy works for them, but the Commons Science and Technology Committee heard a great deal of evidence recently and concluded that it doesn't work beyond the placebo effect. So*

*you're not embracing science, are you?*

**Helen Browning, President of Soil Association:** *Well, the placebo effect is a very, er, powerful effect...*

**Interviewer:** *Even for cows?*

**Browning:** *Well, it does, it must be then because we have so many examples. I'm not going to be adamant about homeopathy but I know that when my staff are trained to use it, their animals tend to respond much better. That might be for a whole host of reasons that we don't yet scientifically understand ... and the cost of homeopathy is pennies, rather than hundreds and hundreds and thousands of pounds that you can end up spending on conventional drugs.*

I know, I know, science does not set out to prove anything but to falsify beliefs. I trust that after reading this short piece, members of HealthWatch will stop buying anything with organic in the title although I have to confess Duchy Originals are tasty biscuits with a fine stilton.

Michael Baum  
Professor Emeritus of Surgery and visiting Professor of Medical Humanities, University College London



## THE DEPARTMENT OF EMBARRASSMENT

...continued from front page

does not make it clear that evidence-based practice will be a component of the NHS reforms. Indeed ministers insist in correspondence that they will not intervene in clinical decisions, which they leave entirely to clinicians themselves. Could we have a statement please on the GMC's expectation in this regard? To maintain their registration, to what extent are doctors expected to adhere to evidence-based practice? Will the GMC engage with the government to ensure that evidence-based practice is increasingly followed in the NHS?"

I got a fairly quick reply:

"I would like to refer you to our core guidance for doctors, *Good Medical Practice* which in paragraph 3c states that a doctor must, when providing care, provide effective treatments based on the best available evidence. Doctors should abide by this guidance at all times in their practice."

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### **"don't miss the opportunity to be involved in the review of the GMC's *Good Medical Practice* by responding to the formal consultation when it is launched in October 2011"**

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Having been warned that this boilerplate reply was the GMC's usual ploy, I was ready with the next shot:

"I am interested in the phrase, 'Doctors should abide by this guidance at all times in their practice'. This presumably means that doctors who prescribe treatments for which there is no evidence, such as homeopathy, are in breach of their terms of registration? Please clarify. I should mention that the government's response to the Science and Technology Committee's evidence check report agreed that homeopathy is not effective."

This time the reply took rather longer—12 days:

"The GMC's role is not to evaluate the effectiveness of treatments but to set standards of good practice for doctors. Registered doctors have to apply our guidance to the situations they face and act in the best interests of the patient at all times.

"Our guidance does not require doctors to use only evidence based treatments, in any form of medical care, but we do expect doctors to do their best to ensure that any treatment they offer is in the patient's best interests. This will generally mean that any known risks of the treatment are outweighed by the potential benefits to the patient.

"We have not issued any advice about complementary and alternative medicine, as this is not within our remit."

So what about this, "at all times in their practice"? It has changed to "do their best to ensure that any treatment they offer is in the patient's best interests". I therefore asked whether prescribing a treatment that is known to be ineffective according to the evidence, is in the patient's best interest. After an even longer wait, here is what I got:

"Thank you for your inquiries about evidence based practice. Please accept my apologies for the delay in responding to you. As my colleagues have indicated, the GMC has not issued any advice about complementary and alternative medicine. However, all doctors have a duty to be familiar with and follow our core guidance, *Good Medical Practice* (2006), which describes what is expected of all doctors registered with the GMC. *Good Medical Practice* is guidance, not a statutory code; so doctors must use their judgement to apply the principles to the various situations doctors will face, bearing in mind that they must be prepared to explain and justify their decisions and actions.

"Specifically, we say that 'in providing good care [doctors] must provide effective treatments based on the best available evidence' (paragraph 3c of *Good Medical Practice*). Doctors must also be satisfied that any drugs or treatment provided serve the patient's needs.

In many cases this is straightforward as the evidence base for particular treatments is clear. Where there is little or no evidence to support a particular treatment, or where there is genuine uncertainty about the evidence base for a particular treatment, doctors need to use their clinical and professional judgement, and, working in partnership with their patient, make a decision about treatment options that will serve the patient's needs. As a result, doctors will not always only be providing evidence based treatments. We would not wish to stifle all innovation or unconventional approaches or prevent doctors from taking a patient's wishes into account. However, a doctor who believed that treatment, which would generally be regarded as outside the boundaries of conventional practice, would be of benefit to a patient should always:

"seek advice from at least one experienced colleague or ask a colleague to provide a second opinion.

"keep a detailed record of the decision making process.

"monitor the patient's condition and progress very carefully, and again keep a detailed record of the patient's response to the treatment, reverting to conventional therapies if the patient has an adverse reaction.

"In addition, our guidance, *Consent: patients and doctors making decisions together* (2008) requires doctors to give patients the information they want or need to make an informed decision about whether to agree to a particular treatment. This includes information about the 'purpose of any proposed investigation or treatment and what it will involve' and 'the potential benefits, risks and burdens, and the likelihood of success' of any treatment options offered. Regardless of whether a doctor is providing conventional or alternative treatments, they are expected to follow our guidance and serious or persistent failure to follow the guidance will put a doctor's registration at risk. We have imposed sanctions on several doctors in relation to their use of complementary and alternative treatments.

"WE ARE CURRENTLY undertaking a review of *Good Medical Practice* (2006) and we can further consider the advice we give on this issue as part of this review. In considering these issues, we are mindful of the recommendations of the Science and Technology Committee Report, *Evidence Check 2: Homeopathy*, and the Government's response to the Inquiry Report. In its response the Government noted that the commissioning of health services by Primary Care Trusts involved a range of considerations including, but not limited to, efficacy and outlined their continued position that local NHS services should continue to have responsibility for deciding what treatments to provide, including treatments such as homeopathy. I hope that you will take the opportunity to be involved in the review of *Good Medical Practice* by responding to the formal consultation when it is launched in October 2011 (you can keep up to date with developments by visiting [www.gmc-uk.org/gmp2012](http://www.gmc-uk.org/gmp2012))."

It seems to me that the policy has morphed from the previous "doctors must follow evidence-based practice at all times" to the present "if doctors don't follow evidence-based practice, they must tell their patients they are prescribing quackery and they must seek advice from a colleague" (I paraphrase). Would any of us be surprised if that colleague turned out to be similarly persuaded towards unproven treatments?

But I appeal to all HealthWatch members to take up the GMC's offer. We must not miss the opportunity to tell the GMC what good medical practice is, especially as they seem unclear themselves.

Les Rose

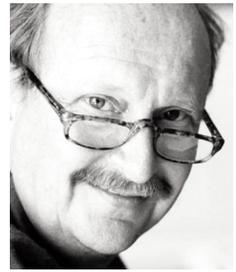
Freelance Consultant Clinical Scientist

Adapted with thanks from Les Rose's blog at <http://majikthyse.wordpress.com>

## homeopathy

# TIME TO CHALLENGE HOMEOPATHIC DENTISTRY

In the last issue consultant orthodontist Keith Isaacson questioned the use of homeopathy in dentistry. Now Edzard Ernst, professor of complementary medicine, weighs up the evidence



“**M**ANY HOMEOPATHIC remedies have been found to be effective for dental abscess, oral lesions, post-extraction bleeding and even medications to treat the anxious and nervous child”.<sup>1</sup> Quotes of this nature are not difficult to find in the dentistry literature. For decades, homeopathic dentistry had been a small yet largely undisputed branch of dental care. This situation might now be changing.

As reported in the last *HealthWatch Newsletter* (issue 82, July 2011), when a lecturer in ethics at the Dental School in Glasgow pointed out that “any homeopathic dentist is engaging in unethical practice to some extent...”<sup>2</sup> he provoked an angry response from two homeopaths who spoke about “vitriolic” opposition to homeopathy and insisted that, “clinical experience and evidence suggest that they [homeopathic remedies] are effective”.<sup>3</sup>

Many dentists might be puzzled by all this exchange as they are probably not even sure what the practice entails. Homeopathy was invented about 200 years ago by the German doctor Samuel Hahnemann. It is based on two axioms. The ‘like cures like’ principle holds that a substance which causes certain symptoms in a healthy person is effective for treating such symptoms when they occur in a patient. The principle of ‘potentiation’ assumes that, by a process of serial dilutions, the remedy does not become weaker but more potent. Both axioms clearly fly in the face of science.

Because of its biological implausibility and the now largely negative trial data,<sup>4</sup> many scientists have become outspokenly critical of homeopathy<sup>5</sup> and British doctors recently voted in favour of banning the practice from the National Health Service.<sup>6</sup>

Homeopathic dentists use homeopathic remedies as an adjunct to conventional dental care.<sup>7</sup> A recent audit showed that, in this way, they treat conditions such as abscess, tooth extraction, anxiety, sensitive cementum, post-surgical pain, gum swelling and pulpitis.<sup>8</sup>

The practitioners may well be convinced that their prescriptions

are effective, but is there any good evidence for such claims? Neither those who attack homeopathic dentistry<sup>2</sup> nor those who defend it<sup>3</sup> seem to base their arguments on much data from reliable clinical trials. The reason for this is very simple: there is very little such evidence.

Homeopathic arnica is frequently promoted for pain and swelling after trauma including tooth extraction. Thus it is popular in homeopathic dentistry.<sup>1</sup> The best available evidence, however, fails to demonstrate that it is more than a placebo.<sup>9</sup> Studies of other homeopathic dental treatments have also failed to generate convincingly positive results.<sup>10</sup> A recent study has confirmed what many experts had long believed: the positive experience of many patients with homeopathy is not due to the efficacy of the prescribed remedy, but due to the empathetic consultation.<sup>11</sup> This study was not in dentistry but there is little reason why its findings are not applicable to most clinical situations.

Homeopathy is not biologically plausible<sup>5</sup> nor is it based on sound clinical evidence.<sup>4</sup> Therefore it, “is ethically unacceptable and ought to be actively rejected by healthcare professionals”.<sup>12</sup> This applies to homeopathy in general and homeopathic dentistry should not remain an exception.

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## A fresh look at the Society of Homeopathy website

THE SOCIETY of Homeopaths is the professional organisation for most UK non-doctor homeopaths. It has an ethical code which few of its members seem to take seriously. One reason for this might be that the SoH has been shown to violate its very own ethical code.<sup>13</sup>

Recently I had a fresh look at the SoH's website.<sup>14</sup> To my amazement, I found that they continue to make unsubstantiated claims. Amongst others, they state that, for the conditions in the box (right), there is “sufficient research evidence”.

This list is too long to provide a comprehensive critical comment for each condition. Suffice to say that, in my opinion, this research evidence is NOT sufficient for any of the listed conditions.

In several cases, there is only a single study in support (those where I have put an asterisk). To claim that one study is “sufficient evidence” is in my view not responsible. In two cases, these were pilot studies (marked with a “p”) and in one case it was an observational study (marked with an “o”). The

*Allergies*  
*Upper respiratory tract infections*  
*Ankle sprain\**  
*Post-operative ileus*  
*Bronchitis\* (o)*  
*Childhood diarrhoea*  
*Chronic fatigue\**  
*Ear infection\* (p)*  
*Fibromyalgia*  
*Hayfever*  
*Influenza*  
*Osteoarthritis*  
*Premenstrual syndrome\* (p)*  
*Rheumatic diseases*  
*Sinusitis*  
*Vertigo\**

influenza claim was supported on the SoH website by a Cochrane review which has long been withdrawn. The fibromyalgia claim was backed by three randomised controlled trials and neglected our systematic review which concluded that “the effectiveness of homeopathy as a symptomatic treatment of fibromyalgia remains unproven”.<sup>15</sup>

For me, the post-operative ileus claim takes the biscuit. It rests on our meta-analysis of 14 years ago.<sup>4</sup> Our overall results were positive but the only reliable study was not. Thus our conclusions stressed the all-important fact that “several caveats preclude a definitive judgement”.<sup>16</sup> Sufficient research evidence? Heavens no!

When I first disclosed the fact that the SoH was in the habit of violating their own ethical code,<sup>1</sup> the SoH's chief executive was quoted as saying they were “grateful to Professor Ernst for highlighting his concerns” and promised the SoH “would be investigating the concerns and making amendments where appropriate”.<sup>17</sup> I think it is time for that again.

# THE HAZARDS OF HYPER-VITAMINIZING

*Vitamin supplements were in the news again this month when researchers reported that their use by older women was linked to higher rates of death. Professor David Bender here enlightens HealthWatch members*



**ARE VITAMINS killers? Recent news reports warned of higher death rates amongst older women using supplements. The research reported took the form of a long-term observational study, so there are many possible confounders, but the take-home message is that supplements do not save lives and may be hazardous.**

Previous meta-analyses of vitamin E and total antioxidant intervention trials have shown increased mortality among those taking antioxidants.<sup>2,3</sup> The increased mortality with iron supplements is interesting and perhaps predictable. Premenopausally, women are considerably less at risk of atherosclerosis and coronary heart disease than are men, and on average women have very low iron reserves compared with men, because menstrual blood losses are large and often cannot be met from dietary iron intake. Postmenopausally (and this study is in older, postmenopausal women), iron reserves increase because there is no longer the large menstrual blood loss, and female rates of atherosclerosis and coronary heart disease approach those of men with the same body weight, adiposity, etc.

There has long been controversy over recommended daily allowances (RDA) for iron, with some authorities wanting a very high level for women because of the prevalence of iron deficiency anaemia pre-menopausally, while the late Victor Herbert pointed out that 10% of the population are genetically at risk of iron overload, and so wanted more cautious iron RDAs. Iron overload—and perhaps even normal high (male) iron reserves—is associated with non-enzymic generation of free radicals which are a factor in atherosclerosis and cancer.

Therefore, I am not surprised that post-menopausal women taking iron supplements are at risk of increased mortality.

The vitamin D results are interesting and add weight to the arguments that considerably higher levels of vitamin D intake (or sunlight exposure) than are likely to be available from the diet are beneficial. There is a great deal of evidence accumulating that higher vitamin D status than has hitherto been considered appropriate for bone health and calcium metabolism is beneficial in lowering the risk of metabolic syndrome, type II diabetes, and some cancers.

The latest US and Canadian RDA for vitamin D in the elderly is 15µg per day, an amount that is certainly not achievable from food without supplements or fortification.

Interestingly, Finland is starting a programme of mandatory enrichment of foods (and especially infant foods) with vitamin D. I predict that in a few years time we will see reports of hypercalcaemia in Finnish infants and children. No-one seems to remember that in UK this occurred in the 1950s. At that time rickets was eradicated by widespread enrichment of infant foods, but a small number of infants are susceptible to hypercalcaemia, effects of which can include bone pain, constipation and kidney stones, at relatively modest intakes of vitamin D. Effectively the curves for requirement and toxicity for vitamin D overlap, so that at the (conventional) RDA a small proportion are likely to suffer toxicity. Lowering the RDA to below the toxic threshold leaves about 10% of the infant and toddler population at risk of deficiency, and every time someone does a study they find about 10% of toddlers in UK have sub-clinical rickets.

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## last word

# THE WINNING TOUCH

**L**AST WEEK I attended a pub-type quiz hosted by my local health authority. I had never won a pub quiz before but on this occasion our team won the tie breaker by most accurately guessing the length of the longest nose in history—7½ inches is the correct answer. The prize was a free hour of reflexology or an Indian head massage. No one (else) seemed to find it anything other than charming and lovely, that a 'health authority' employee should think that this was a good prize.



I was intrigued by the idea of receiving a 'therapy' as a prize. It is not how health services are normally distributed, rather the way luxury cruises are won. This was I suppose intended to be in the luxury cruise category, rather than the hip replacement box. It is a form of entertainment, of relaxation, or 'lifestyle' choice, not a scientific treatment modality. Certainly, no-one had done a pre-quiz diagnostic exercise to see if there were particular health needs that might be met by the prize.

I went home and discussed the predicament I found myself in with my wife. She felt that since I spend so much time lobbing in grenades from the outside, it might be prudent to 'experience' one of the therapies from the inside. I would not be funding this mumbo-jumbo since the deal had already been done, and arguably I would be using up their time, and so my ethical position would seem secure. As the outgoing chair of HealthWatch I would not wish any 'cash for quackery' scandal to sully my reputation. Who knows, I might enjoy it, might find it relaxing, and I might even feel 'better' afterwards. I might be able to speak with more authority about an experience that many people in our society value. There is every chance that I would find having my head or feet massaged pleasant and relaxing—it may well 'work for me'.

Touch is the most intimate of our sensations. It is the first sensation we experience when we are born, and often the last we experience as we die perhaps with a loved one holding our hand. Intentionally touching someone is normally a very intimate act. In England we often seem to find shaking hands with someone is more intimate than we can bear on first meeting someone. The Greeks persuaded us that sight was the most important and most objective of sensations, "you see?". However, even sight evolved from touch sensation developing light sensitivity.

One of the books I read my children is about a blind girl, and ends with this conclusion, "what really matters is not what you can see

with your eyes, but how you feel in your heart". This girl was apparently happy, despite being blind. However, this fashionable and charming conclusion omits to observe that the positive experiences of life which made her happy were nevertheless mediated through her other sensory organs. They are the membrane through which we interact with the real world.

Frankly I prefer a hug from my wife, holding my baby son, or being tickled by any one of my daughters to having my head rubbed by a stranger. Perhaps we live in an individualistic and consumer age where people are deprived of intimacy with loved ones and seek intimacy vicariously in a shop. In this sense perhaps massage is therapeutic for those who long for intimacy (I suspect an Indian head massage machine would not sell well), and so it is not surprising that people get confused between their personal and emotional needs and their physical functioning.

Relationships and intimacy are of course important, but so is the mechanical functioning of the body. A correctly functioning body is not the same as happiness, but it is crucial to facilitate engagement with other people and the world around. In critiquing quack medicine, we do not aim to undermine, but rather support people's happiness in life by using the appropriate tool of science to treat the body. It is a paradox that despite their inclusion under the umbrella of 'holism', such touching therapies are a poor substitute either for real relationships, or for treating the body. I believe a principal function of HealthWatch is to help people use the right tool for the right job, which is not to deny people's personal and emotional needs, rather to facilitate them.

In the end I have decided to use this hour for writing this article rather than having my head rubbed. But I have a coupon going if anyone is interested.

*James May  
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