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# HealthWatch

for treatment that works

Newsletter 74 July 2009

## HOMEOPATHY AND THE DEVELOPING WORLD: dangers and lessons



**I**N A LETTER to the World Health Organisation in June, a group of young scientists called on the agency to condemn the promotion of unproven homeopathic treatments for serious diseases—TB, HIV-AIDS, malaria and childhood diarrhea—in developing countries. One of the signatories, biochemist and medical writer Evelyn Harvey (above), has a background in TB research and has worked with Health and Development Networks, a TB and HIV communications non-governmental organisation. In India she reported on Community health in the Thar Desert. She writes here about her experiences exclusively for HealthWatch members.

The WHO takes a constructive view towards integrating traditional healers in the drive to improve public health. However, unlike many alternative medical systems, such as Indian Ayurveda, homeopathy is neither ancient nor traditional to the developing countries where it is being promoted—it was invented in 1796 by a German physician. And while herbal remedies contain active substances that affect the body's chemistry, homeopathic remedies are diluted to the point of containing not a single molecule of the substance on the label. Homeopaths in the West would shy away from claiming their remedies exclusively curative for TB, HIV, malaria and other serious diseases. I have found, sadly, that this is not the case in developing countries.

The dangers of unproven treatments in these regions are compounded by the hostility that is often shown towards allopathic medicines, demonstrated most corrosively by the AIDS denialists who advocate vitamins and vegetables as curative of HIV-AIDS. Third world homeopaths frequently denigrate proven drug treatments on the basis of side effects or inefficacy. (Homeopathic medicines are indeed without side effects, a predictable consequence of a remedy containing no active ingredients.) The dangers are manifold—patients can be persuaded to interrupt treatment, leaving them vulnerable to drug resistant TB, while someone with HIV might believe themselves cured and take no precautions against infecting others.

To me, the homeopathy issue demonstrates that public health programs can make great improvements to service delivery with the help of two relatively simple, low-cost interventions: accessible information and psychosocial support.

I believe that unpicking the scientific explanation and opening up the details of drug action and design in a way that people can readily understand, is the way to counter misinformation generated by alternative therapists. Merely stating the opposite will reduce people's decision to a judgment of trust, and on this factor homeopaths often win.

Why do people trust homeopaths and believe them but not doctors? Partly due to lack of understanding—scientific jargon and complexity can be intimidating, in contrast with the relatively simplistic explanations offered by homeopaths. It is also to do with the tendency of alternative practitioners to be more empathic, and they may have background or community in common with the patients. They offer, in effect, a form of psychosocial support that medical services would struggle to provide: a caring, sensitive and encouraging practitioner with time to talk over life in general, and who explains the disease in understandable (if incorrect) terms.

**"patients can be persuaded to interrupt treatment, leaving them vulnerable to drug resistant TB, while someone with HIV might believe themselves cured and take no precautions against infecting others"**

An appropriate level of communication is essential. People who have had no formal education are not stupid, but they will be alienated by medical jargon. I recall a medical educator manual, supplied by a western agency for use in Indian village health worker training, which suggested explaining that, "other STIs increase the risk of HIV transmission because lymphocytes are drawn to the inflamed area." Even the person doing the training didn't understand it!

Whereas when an open discussion was held on, "you know, THOSE diseases..." we got people coming up with good ideas. "So if a man comes to us, we should send the wife to the doctor too," for example. People in many cultures will not indicate when they have no idea what the speaker is talking about, instead sitting politely and silently through a meaningless session. On the other hand, once villagers I encountered were engaged and empowered in the discussion, there was no way to get a word in edgewise.

Cultural sensitivity is also extremely important. Discussing a

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## CHALMERS TO RECEIVE 2009 HEALTHWATCH AWARD

IAN CHALMERS has agreed to be the seventeenth winner of the HealthWatch Annual Award. Chalmers, who enjoys descriptions such as “maverick” and “troublemaker”, has spent the past 30 years trying to ensure that health professionals and patients have free access to unbiased evidence of the effects of medical interventions.

Currently editor of the James Lind Library, which documents the evolution of fair tests for treatments, he was a founder and director of the Cochrane Collaboration which promotes systematic review methods throughout medicine. Chalmers began his mission when, as a clinician in the 1970s, he realised that not everything he’d been taught in medical school had been correct, and patients were

suffering and dying for lack of reliable information on the effects of treatment.

Chalmers was knighted in 2000 for services to healthcare. The HealthWatch Award will be presented at the 2009 HealthWatch Annual General Meeting, to be held on Thursday 29th October. Further details will be sent to members in due course.

### Reference

Watts G. Iain Chalmers: maverick master of medical evidence *The Lancet* 2006; **368** (9554): 2203-2203. See: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(06\)69879-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06)69879-6/fulltext)

## Obama’s critics use UK NHS cases to strike fear

A US CAMPAIGN group is using tragic stories from NHS patients in its TV advertisements as a weapon to attack president Barack Obama’s healthcare reforms.

Obama hopes to contain America’s soaring costs of medical care while making treatment more accessible to the poor—45 million Americans have no health insurance. But in the broadcasts, by Conservatives for Patients’ Rights (CPR), Britons complain about waiting times, restrictions to operations and access to life-saving drugs on the NHS, says a report in the *Guardian*. In one ad cancer specialist Dr Karol Sikora, dean of the University of Buckingham’s

medical school, warns that a state-run system strips patients of control over their healthcare.

CPR says Obama’s plans will result in rationing of treatment and drug supplies similar to that overseen by the UK’s National Institute for Healthcare and Clinical Excellence (NICE). Britons are described as “trapped” by the NHS, with medical decisions made by bureaucrats, not doctors.

*Guardian, 13th May 2009*

[www.guardian.co.uk/world/2009/may/13/advertising-campaign-nhs-us-healthcare-reforms](http://www.guardian.co.uk/world/2009/may/13/advertising-campaign-nhs-us-healthcare-reforms)

## HOMEOPATHY AND THE DEVELOPING WORLD: dangers and lessons ...continued from front page

poster advertising a yogic cure for HIV-AIDS with a group of Indian villagers, it was clear that yogis command respect in their communities. So, while getting across the basic facts of HIV infection, and how to prevent it, I emphasised that although the yogi was only trying to help, there would come a point when the patient would need access to drugs and medical care.

Doctors in the developing world, with huge caseloads and limited resources, can’t always educate patients or cultivate personal connections, however much they would like to. However, community led education can be very successful and there’s a need for more operational research on the best strategies in this area. Too often, patient education and psychosocial support are afterthoughts. Yet the costs are minimal when compared to the investment need-

ed to develop and market a new drug, diagnostic or vaccine. It’s fundamental to the success of long-term public health strategy and is also the best defence against health programmes being undermined by proponents of unproven therapies.

*Evelyn Harvey*

[www.evelynharveymedicalwriting.com](http://www.evelynharveymedicalwriting.com)

### Further reading

For information about HDNet see [www.hdnet.org](http://www.hdnet.org)

To read about Voice of Young Science’s letter to WHO see: [www.senseaboutscience.org.uk/index.php/site/project/331](http://www.senseaboutscience.org.uk/index.php/site/project/331)

Media coverage: [www.guardian.co.uk/science/2009/jun/01/world-health-organisation-homeopathy-hiv](http://www.guardian.co.uk/science/2009/jun/01/world-health-organisation-homeopathy-hiv) and [www.timesonline.co.uk/tol/life\\_and\\_style/health/article6406213.ece](http://www.timesonline.co.uk/tol/life_and_style/health/article6406213.ece)

## news in brief

CHARGES HAVE been filed against nine French doctors for allegedly failing to disclose their ties to drug manufacturers, says a report by investigative journalist Jeanne Lenzer in the *British Medical Journal*. All nine are considered authorities in their fields. One, a professor of neurology, had chaired the Alzheimer’s disease working group of the France’s national health authority, which issued guidelines that recommend the use of specific drugs for Alzheimer’s. The charges were filed by the doctors group Formindep (Formation Independante) a French-based non-profit organisation that promotes independent medical information.

*BMJ* 2009; **338**: b2347

Go to <http://www.formindep.org/> for more information or to sign Formindep’s charter

HOMEOPATHY COST the NHS £11.89m between 2005 and 2008, according to figures released to More4 News under the Freedom of Information Act for a report that was broadcast in June. During this time there were 68,647 treatment “episodes” at an average cost per episode of £173. This breaks down to £151 for each outpatient treated, and £3066 for each inpatient. The biggest

spenders are the London primary care trusts—Camden PCT alone spent £1.86m.

<http://www.guardian.co.uk/society/2009/jun/10/complementary-medicine-nhs-more4>

<http://www.channel4.com/news/articles/uk/truth+behind+nhs+homeopathy+budget/3204562>

IN A REFERENDUM on 17th May Swiss voters approved a proposal to promote alternative medicines. Sixty-seven per cent of the electorate voted in favour of complementary treatments, including homeopathy, herbal and neural therapies as well as traditional Chinese medicine being paid for by the compulsory health insurance. However, the Swiss government says such treatments must be effective, reasonably priced and appropriate to be included in the list of paid health services. Opponents had unsuccessfully argued that including these forms of treatment would add to the financial strains on the health system.

[http://www.swissinfo.ch/eng/front/Therapy\\_supporters\\_roll\\_up\\_sleeves\\_after\\_vote.html?siteSect=105&sid=10716067&rss=true&ty=st](http://www.swissinfo.ch/eng/front/Therapy_supporters_roll_up_sleeves_after_vote.html?siteSect=105&sid=10716067&rss=true&ty=st)

# KEEP LIBEL LAWS OUT OF SCIENCE



**S**INCE 1993, when I was appointed professor of Complementary Medicine, I have researched chiropractic and have often been critical about aspects of this therapy. For instance, I have shown that it is associated with considerable risks and that the evidence for efficacy is frequently negative or unconvincing<sup>1</sup>.

Chiropractors often make claims far beyond spinal conditions. One example—asthma—may suffice. During October and November 2008, the following chiropractic organisations were promoting chiropractic as an effective therapy for asthma: American Chiropractic Association, British Chiropractic Association (BCA), Canadian Chiropractic Association, Chiropractic Patients Associations (US) and the International Chiropractors Association.

The three existing studies on this subject<sup>2</sup>, however, show quite clearly that chiropractic is not better than sham-treatment. In the light of this, promoting chiropractic for asthma is, in my view, irresponsible.

In the book I published recently with Simon Singh<sup>3</sup> we pointed out that the risk benefit balance for chiropractic is often not positive. Later, Singh wrote a commentary in the *Guardian* stating that the BCA was promoting chiropractic for several paediatric conditions, including asthma. Because his chosen phraseology might arguably have been taken to imply that he was accusing the BCA of being dishonest by backing treatments it knew did not work (even though he refutes this), the BCA sued for libel.

Over the last fifteen years, my work has attracted many unpleasant communications from chiropractors. Here are just a couple of examples. (Full texts are available on request):

**"EDZARD ERNST—sounds German—I fought against your race in the 2nd world war and my father in the 1st world war. Not a race to be trusted. Thank God I am an Englishman who plays fair."**

*From Tom Field, undated, in a private letter to E Ernst*

**"...you are basing your opinion on your own motivations, including maintaining job security for yourself and the other butchers..."**

*Jeff Sidman, in an e-mail addressed to Edzard Ernst, 22 March 2006*

Other people, for example Professor David Colquhoun, have had similar communications (see Colquhoun's website for more details on <http://www.dscience.net/>)

In healthcare, disagreements over evidence happen all the time, but it is wholly inappropriate to resort to personal attacks or the law court. To resolve them we must employ open discussions about the scientific facts. If this process is bypassed, we jeopardize free speech and medical progress. Readers who want to help preserve our ability to discuss science and medicine freely can sign the statement "Keep Libel Laws out of Science" on [www.senseaboutscience.org.uk/index.php/site/project/333](http://www.senseaboutscience.org.uk/index.php/site/project/333)

*Professor Edzard Ernst  
Director, Complementary Medicine  
Exeter*

## References

1. Ernst E. Chiropractic: a critical evaluation. *J Pain Sympt Man* 2008; 35(5): 544–562.
2. Hondras MA, Linde K, Jones AP. Manual therapy for asthma. The Cochrane Database of Systematic Reviews, Issue 2. Art. No.: CD001002. 2005.
3. Ernst E and Singh S. Trick or treatment? Alternative medicine on trial. Corgi Books, UK; 2009.

## Enjoy Quackometer but treat canards with caution

**F**OR SCEPTICS with a sense of fun, the Quackometer website is worth a look. It's simple: you enter any name (it could be a journalist, media personality, or even yourself) and the meter will return with a quackery score—a number of between 0 and 10 "canards" (the more canards scored the dodgier is that person's online presence). Try it for yourself on <http://www.quackometer.net>

But use with caution: a committee member recently observed that the name of *HealthWatch Newsletter's* own editor scored four canards. Consulting the site this week I found that it was true. But how? On close investigation I found that the quackometer had accidentally ensnared a completely unrelated Mandy Payne who'd published a lengthy letter recommending vitamin remedies for dogs on her Facebook page. That accounted for one of my canards. The other three had been dumped on me thanks to a naturopath who'd quoted on his website a passage from a short—and, I think, scientifically accurate—item I'd written for the *Sunday Times* some years back, then added some text of his own underneath so that my work seemed to lend credence to his own wacky ideas.

Quackometer's mastermind, Andy Lewis, was swift, gracious and apologetic when I e-mailed him. He explained, "The quackometer is doing little more than counting words in pages, there is not a great deal of sophistication going on. In some ways, this is

exactly my point about the quackometer. It is merely enough to be alarmed by certain words in health pages to start being sceptical about their claims. To get around the problem of avoiding referenced names looks like a hard problem to me. The sort that people ought to be good at, but computers not."

Lewis remarked that, notwithstanding the odd anomaly as in my case, the meter tends much more often than not to get things about right. "Where I want to take the engine is so that it automatically provides links to sites that can provide in-depth critiques of various techniques and practices—HealthWatch will be one of those sites. I think then, that the site will go beyond a bit of fun and an experiment into a fairly useful tool that will take a page, analyse it and then link to other pages that can challenge any spurious claims."

Quackometer is also worth bookmarking for its blog and its roundup of recent news stories related to treatments and evidence.

*Mandy Payne*

## DIETS THAT WORK, DIETS THAT DON'T

David Bender's assessment of diet fads below, taken from the latest edition of his *Dictionary of Food and Nutrition*, led to a spirited e-mail correspondence on the subject of whether and how diets work (or don't).

**I**N PRACTICE, it's almost impossible to measure the success or safety of diets people follow themselves, as we've no way of knowing exactly what they're eating in their own homes. But it can be done in a carefully controlled environment, and the results are not always what patients expect. John Garrow, the University of London's emeritus professor of human nutrition, explains, "For 17 years (1970–1987) I had the luxury of having complete control over three beds at the end of a ward at Northwick Park Hospital. We admitted obese patients from my outpatient clinic for three week periods, so each week one came in and one went out.

"So we had a closed ward where the patients never went out except when escorted by members of my research team, and everything they ate came from a metabolic kitchen, and whatever they left on the plate was analysed. We had the world's best calorimetry and body composition-measuring equipment and staff, and highly cooperative patients because they all believed that they had some unknown metabolic problem that made them fat even when they kept to prescribed slimming diets. They really wanted to show everyone that they DID gain weight on 1000 kcal a day, although no-one would believe them.

"For those three weeks we measured everything, and yes they did lose weight, and we knew the composition (fat and lean tissue) of the weight they lost—it is all published. However, when they went out with exactly the same diet prescribed which they had been fed in the ward, did they keep to it? No, and we knew they didn't because their change in weight and body composition did not follow the course it had done in the ward.

"But how do I know it was the diet that changed, and not their metabolism which had adapted to the longer exposure to the diet? Because in one very expensive experiment we had patients in for three weeks, then out for 20 weeks, and then back in for one week when they were given the same diet from our diet kitchen as they

had done before. We measured their energy expenditure and change in body composition, and we know that their metabolism had not changed (except that expected from the weight change—they came back having lost 20–30 kg).

"So we know for sure that what they ate at home was more than the prescribed diet."

It is often claimed that some people become obese because their resting metabolic rate is low. In fact the opposite is true, explains Garrow. "Quite consistently obese people have a higher resting metabolic rate than normal weight people of the same height, and if they get more obese it gets even higher. I even spent six months in Arizona studying the Pima Indians who were believed to have a thrifty gene so they got fat on a low energy intake, but their results were the same as for obese people in Harrow."

It has been speculated that one reason why high protein diets—such as the Atkins diet—are often successful might be because the body burns more calories running on protein than on carbohydrate. Theories of metabolism might seem to support this idea. "There's an absolute need for glucose for the brain and red blood cells," David Bender explains. "If there is little dietary carbohydrate, then

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### Diets that (probably) won't work: from A to Z

**ATKINS DIET** Originally proposed in 1972; a diet in which carbohydrate intake is severely limited (to 20–30 grams per day) but fat and protein are permitted in unlimited amounts, leading to ketosis. It is effective for weight loss, since ketosis reduces appetite, but as a long term strategy for maintaining weight loss it runs counter to all modern advice on a prudent diet. Excessive fat intake results in high blood cholesterol, leading to atherosclerosis and coronary heart disease. There are also suggestions that too much protein may be linked with the development of kidney disease and osteoporosis.

**BEVERLEY HILLS DIET** Based on the unfounded belief that enzymes from certain fruits (pineapple, mango, etc) are required to digest foods, and that undigested food in the gastro-intestinal tract leads to obesity.

**BLOOD GROUP DIET** From another unfounded belief, this time that blood groups evolved at different times, and the diet prevalent at the time a person's blood group evolved is optimum for health and weight control.

**CABBAGE SOUP DIET** Advocates consumption of large amounts of home-made cabbage soup with a very limited range of other foods; likely to be nutritionally inadequate in many respects.

**DETOX DIET** Based on the belief that weight gain is the result of accumulation of toxins in the body, and a period of fasting and strict avoidance of such supposed toxins as caffeine and food additives is beneficial. There is no evidence to support this.

**DUVET DIET** Followed from the observation that sleep deprivation leads to increased secretion of the hormones cortisol and ghrelin (which stimulate appetite) and reduced secretion of leptin (which

reduces appetite). By extrapolation it is suggested that increasing the time spent sleeping will reduce appetite and food intake, and so permit weight loss. There is no evidence it works.

**FOOD COMBINING DIET** A system of eating based on the—again unfounded—concept that carbohydrates and proteins should not be eaten at the same meal. It ignores the fact that almost all carbohydrate-rich foods also contain significant amounts of protein. In any case, in the absence of adequate carbohydrate, protein is oxidized as a metabolic fuel (i.e. to provide energy) and therefore not available for tissue building. Also called food combining or Hay diet.

**HAY DIET** This is a food combining diet (see above).

**MACROBIOTIC DIET** A system of eating associated with Zen Buddhism; consists of several stages, finally reaching Diet 7 which is restricted to cereals. Cases of severe malnutrition have been reported on this diet. It involves the Chinese concept of yin (female) and yang (male) whereby foods, and even different vitamins (indeed, everything in life) are predominantly one or the other and must be balanced.

**pH DIET** This involves balancing the intake of acid forming and base forming foods, but has little scientific basis.

**SOUTH BEACH DIET** Uses a high protein and low carbohydrate intake. A variant of the Atkins diet.

**ZONE DIET** Based on the belief that each meal should comprise a fixed proportion of macronutrients: 40% carbohydrate, 30% fat and 30% protein. There is no reason why this should be beneficial, let alone result in weight loss.

From *A Dictionary of Food and Nutrition* by David A Bender. Third edition published 29th January 2009 by Oxford University Press, Oxford. Paperback, 608 pages. Price £11.99 ISBN-10: 0199234876; ISBN-13: 978-0199234875

## BEHIND THE HEALTHWATCH STUDENT PRIZE

**A**NY HEALTHCARE professional has a duty to their patients to provide treatment which is based on sound scientific research. But how do you tell whether a given piece of research is reliable? In an attempt to encourage students of Medicine, Nursing and Complementary therapies to acquire the skills to assess research claims Health Watch launched the Student Prize in 2002. Its aim is to encourage students to learn how to read and critically appraise clinical trial protocols so they can assess the validity of research findings.

The gold standard of research in testing therapies remains the double-blind randomised placebo-controlled clinical trial. The Health Watch Prize is based on this. The students are invited to read four hypothetical protocols—which have been deliberately designed to contain flaws and omissions—and rate them in order of merit. The students have to explain in no more than 600 words the reasoning behind their ranking. They are asked to identify the flaws and how they could be modified to improve the quality of the protocol. Should a trial be fatally flawed this should be stated.

The protocols are usually written by one member of the committee; with input from colleagues if required. Some are based on actual published papers, others are completely fictitious. For the first five years Professor John Garrow was responsible for protocol writing. I dimly recall mumbblings at Committee meetings about the difficulty of the task which I rather stupidly dismissed as cries for sympathy, so when he wished to delegate in 2007 I volunteered. I very soon realised the difficulty of the task. It takes time and imagination to think of four scientific topics and write research protocols limited to one side of A4 each; to then try and deliberately weaken their design so as to have four studies of different merit is exhausting in the extreme! The best and the worst protocols are easy and a lot of fun can be had; particularly in composing the worst ever trial! The problem arises with the second and third worst; trying to make one “not too bad” and the other “really not very good” can be most frustrating.

**N**EXT, THE protocols are reviewed by the judges (and in my naivety I also volunteered for this!). Following a most difficult marking session a few years ago, in which a long standing friendship between two strong minded judges was quite severely tested, we decided to draw up a marking plan before the competition is launched. This involves identifying all the strengths and weaknesses of the studies and producing clear marking criteria to ensure a through, fair and reasonably straightforward assessment of the entries.

My first set of protocols produced a rapid response from a student

complaining that whilst he had had every intention of entering the competition the appalling scientific quality of the protocols together with their dreadful use of English grammar led him to complain rather than enter! I felt most demoralised but on review I am confident the science was correct even if the use of English left quite a lot to be desired!

In the last two years we have become increasingly worried that many students failed to identify the absence of ethics committee clearance or informed consent in some of the protocols. Last year we were most concerned since over 50% of entries had not commented on either of these essential components. We checked the undergraduate curriculum and have been assured that the students are taught the importance of both. It remains a mystery as to why students fail to comment on these vital research criteria.

The prize was initially advertised to students of medicine, nursing and complementary medicine but to date no student of complementary medicine has entered. We would still accept an entry from a student of complementary medicine but no longer advertise the competition in their unions or journal. Since we have started using the internet to advertise the prize awareness has risen and we have between 50 and 100 entries each year.

All members of the HealthWatch committee are grateful to the Ajahma Charitable Trust who has sponsored the prize for the last seven years. The Ajahma Trust was started in London in 1977. The Trust generally supports established charities and aims to balance donations between UK and international organizations. The Trust considers grants in the areas of women's issues, development, health, disability, poverty, family planning, human rights and social need. We much appreciate the Trust's interest in HealthWatch and are all most grateful for their support of The Student Prize.

Finally I would like to take the opportunity to thank Health Watch member Joan Gandy who has administered the prize from the outset and provided support to all involved.

Gillian Robinson

Associate Specialist in Sexual and Reproductive Health  
St Giles Hospital in London

## Diets that work, diets that don't

glucose will have to be made from amino acids produced by breaking down proteins. This is energy expensive, so—in theory—would increase metabolic rate, and hence weight loss. Also, there is evidence that at a high protein intake the rate of turnover of tissue proteins increases. Both synthesis and catabolism (breaking down) of proteins are energy expensive (synthesis much more so), which also might be expected to increase energy expenditure, metabolic rate and weight loss.”

But does this actually happen in practice? John Garrow has good reason to be sceptical. “One of the first papers I had published in a journal (the *British Journal of Nutrition*) was about the ‘specific dynamic action’ of dietary protein. Krebs (after whom the ‘Krebs cycle’ is named) had claimed that the increase in metabolic rate after eating a large protein load was due to the energy cost of urea synthesis.” So Garrow did a series of studies—on himself—which

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involved continuous measurements of his metabolic rate before and after a protein meal of either high biological value (of which little would be converted to urea) or low biological value (after which there would be much urea synthesis). Subsequent urine analysis confirmed that the urea output had changed in the required manner, but there was no measurable difference in the ‘specific dynamic action’. “Therefore even a giant of biochemistry predicted a change in metabolic rate on the basis of *in vitro* experiment which was not detectable by whole-body measurement *in vivo*,” Garrow concluded. “So I cannot be sure that the increases in metabolic rate due to changes in energy substrate will have much effect on whole body metabolism or, even if it did, that it would cause weight loss.”

Mandy Payne  
Editor, HealthWatch Newsletter

# CHOICE IS EVERYTHING—ISN'T IT?

**"What man wants is simply independent choice, whatever that independence may cost and wherever it may lead."**

*Fyodor Dostoevsky*



**I**T IS a largely unquestioned assumption which governs our thought life in the modern world—that choice is always and in all circumstances a good thing. The individual's freedom to choose has become ultimate reality in a generation charmed by the narcissism of the existential philosophy of Sartre whose axiom, "Man makes himself" is one we all buy into at some level—even if it is as trivial as an obsession with the interior design of our houses.

Thus in medical ethics the 'principle' of autonomy (the free choice of the individual) might be seen as trumping all other values where there is conflict. Those of us in General Practice are frequently being reminded that such and such a policy is part of the governments 'choice agenda'—polyclinics, 'choose and book', nurse prescribing, longer opening hours, NHS direct, pharmacy minor ailments schemes and so on *ad infinitum*.

I was recently privileged to be part of a 'round table discussion' as the background to a research project on 'choice' in medicine. Specifically we were discussing the choice patients have in the consultation regarding medications they are prescribed. I was among several research orientated academic GPs who were brainstorming from their experience in clinical practice what such patient choice might look like in the routine consultation.

The discussion was directed only by headings suggesting areas of relevance—in what sort of areas does choice occur, how is it limited, how is it facilitated and so on, but was otherwise left to flow freely. The clinicians recalled recent examples of clinical scenarios in which choice was or wasn't offered. It didn't take long before we discussed options in treating the menopause as a good example of where choice could be offered. There is after all so much to discuss, so many symptoms, so many treatment options on offer, including alternative therapies.

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**"If one is less concerned about supporting evidence, the choice is endless. The choice is however also pointless, and is actually not a choice at all, but the illusion of choice."**

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At this stage I began to wonder whether the Emperor had any clothes on. After all, surely a GP will best help the patient by advising which of the many remedies on offer might be most likely to benefit a patient with those particular symptoms. I felt obliged to say something. Is it possible that there are more options for treating conditions which do not have life-or-death consequences? Is it possible that there is more choice when one is less concerned whether or not there is any evidence supporting the choice? There are after all probably millions of herbs or homeopathic remedies which have no proven benefit in treating menopausal symptoms, and few people will have side effects from these treatments. The choice is therefore endless. The choice is however also pointless, and is actually not a choice at all, but the illusion of choice.

Patients are entitled to be sceptical of 'Western Medicine', came the reply. And so they might well be. But are GP's? Offering to replace the term 'Western Medicine' with the idea of 'medicine that

works' or 'evidence based medicine' prompted a comment that the demand for evidence was arrogant. Could it be that, even amongst academic GP's, choice trumps rational thought?

Reflecting later about the extent to which GP's might be expected to juggle decisions on treatment efficacy with the demand for patient choice, I came to musing about how the illusion of choice colours the language of estate agents, politicians and even these days among bankers. The ability to fill the air with descriptors of indeterminate significance—'a room with a view', a 'WMD', or a 'financial opportunity' belongs to those who are trying to hoodwink us into believing they can solve all our problems when actually they are solving their own problems. 'Choice' like this is the choice of the supermarket shelf on which the same product is repackaged and repackaged again until we finally succumb to temptation and buy it thinking (or at least hoping) it is something it isn't. This is the world we inhabit, and our consumer society buys into it with extreme naivety every day.

**I**AM NOT so cynical. I believe there is a place in the world for ethical estate agents, even ethical bankers. Am I naive to think that doctors have not yet moved so far from the light of Hippocrates that we need to appeal for ethical doctors? I am not sure.

If we are to remain the right side of the ethical line it seems to me that we need to understand what choice is, and what it isn't. The choice about the colour of socks I wear in the morning is a different sort of choice to whether or not I wear a seat belt on the way to work, or whether I drive within the speed limit. There are choices of taste, choices of wisdom, and ethical choices among others. For ethical choices at least we cannot pretend that it is always more important that someone can make a choice, than what it is that they might choose.

It is a widely held contemporary myth, derived from the likes of Sartre, that we create reality by the choices we make. This may be good enough for the world of postmodern art, but it isn't good enough in medicine. We have to make choices which are grounded in the reality of the world around us. That is why we need evidence, so that we know something about that reality. Is the demand for evidence arrogant? Or is it the humility of submitting to reality external to ourselves? Only with evidence can we make informed choices which are real choices rather than illusions, and which are therefore hopefully wise choices. That is the duty of both patients and doctors.

*James May*

*HealthWatch Chairman and GP  
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# HOW TO CHEAT IN RESEARCH



**T**HE DECEMBER 2008 issue of *The Biochemist* was devoted to ethics: forgery, fakery and fraud in science. In an article entitled *The golden age of fraud*, Walter Gratzer<sup>1</sup> quotes Charles Babbage “fulminating against the lax standards of probity set by the Royal Society, and the prevalence of intellectual malfeasance in English science generally.” Babbage identified “three sins”: forging, trimming and cooking.

## Forging data

This is obvious—the creation of fake experimental results and outright fabrication of data. Sometimes this is the result of a junior member of the research team trying to please the team leader; sometimes it is the result of desperation on the part of a junior or senior researcher. We believe that this type of fraud is rare, but the problem is that it will only come to light if:

- Someone who knows what is going on acts as a whistle-blower. A whistle-blower is in a very difficult position if he or she is a junior member of the research team, and despite the great service done to science may nonetheless wreck his/her career prospects.
- Other people try to replicate the work and cannot. In one example I know of, a former PhD student from Birmingham landed a very prestigious post-doctoral post in Germany. Others in his new laboratory could not replicate his results, and the head of the laboratory demanded that he perform the experiments in front of them. At this the post-doc broke down and confessed that he could not repeat the experiments because he had never performed them. Obviously his PhD was withdrawn, and his career wrecked, but, more tragically, his PhD supervisor had to retract several publications that had arisen from the student’s work, and was a broken man as a result.

Gratzer cites some of the more famous frauds, including Paul Kammerer; either he or an assistant injected Indian ink into the backs of midwife toads to provide “evidence” of his assertion that pigmented pads on the back of the female are an acquired characteristic that is inherited. Even more brazenly, in 1974, William Summerlin painted black patches on the fur of two white mice in an attempt to claim that he had performed a skin transplant.

One of the issues we are struggling with in medical education is the problem of student behaviour that gives concern about their future fitness to practice medicine. A liberal might say that students will always act like students, and undergraduate peccadilloes are unimportant. However, we have to record and investigate not only criminal convictions, but also police cautions. Perhaps this is right. Gratzer tells the story of the young researcher taken into Ephraim Racker’s laboratory at Cornell in 1981, who faked a set of results that (apparently) confirmed Racker’s theories. The fakery was discovered by another student in the laboratory, and Racker had to stand up before a major scientific meeting and withdraw the paper

he had been invited to present. On investigation it turned out that the student had forged not only his laboratory findings, but his references and a number of cheques.

Good laboratory practice now requires that proper experimental records are kept, and are signed off by the researcher and the head of the team. Of course, the problem remains of who verifies the results claimed by the team leader.

## Trimming data

This something that many of us may be guilty of—manipulating the data to show our results in the best light. This is also the one area where vigilant peer review should uncover inconsistencies, sloppy reporting of data and poor use of statistical analysis.

## Cooking data

Gratzer cites Gregor Mendel as a prime example of cooking data; his results for round and wrinkled, yellow and green, peas were, in the light of more recent experiments, too good to be true. It is likely that, consciously or unconsciously, he rejected those peas that were not exactly as he would have liked them. Such bias may well arise in clinical studies, especially where “soft” end-points (e.g. does the patient report feeling better, worse or unchanged?) are being assessed. It is all too tempting to ignore those responses that do not fall clearly into one category. In a well conducted clinical experiment the number of people entering should be reported, as well as the numbers meeting each of the outcomes—and, most importantly, the number lost to follow-up or who could not be classified. If the numbers do not add up then a vigilant referee should spot the discrepancy, and if too many people are unclassified then conscious or unconscious bias should be suspected.

In his address to the 2003 HealthWatch AGM, award winner Peter Wilmshurst<sup>2</sup> listed a number of cases of research misconduct in which data had been cooked in this manner.

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## Bottled water cancer scare (and other hoaxes)

IN BIG blue letters, the e-mail began, “Cancer update from John Hopkins” and explained that women should not drink bottled water that has been left in a car. “The heat causes toxins from the plastic to leak into the water and they have found these toxins in breast tissue...Please,” and here comes the clue, “pass this on to all the women in your life.” That’s right, it’s a hoax.

Countless chain letters are circulating warnings about health scares, computer viruses, even messages purported to be from emergency services advising how to protect yourself from new crime tactics. Some have been going round for years, and have been translated into dozens of languages. But if it ends with, “please pass

to everyone you know”, it’s almost certainly not true.

If you want to pass on useful information but don’t want to infuriate your colleagues with time-wasting hoaxes, check the message out first. Either enter key words from the e-mail’s title on a Google search, or—fastest—go straight to a chain-breaking site such as [www.hoax-slayer.com](http://www.hoax-slayer.com) or [www.breakthechain.org](http://www.breakthechain.org). These list currently circulating e-mails with a full explanation of their origin and whether there’s any truth in the text, while [www.snopes.com](http://www.snopes.com) is a fascinating catalogue of urban legends as well as junk e-mail. Bookmark them now.

Mandy Payne

## NEW ARNICA LABELS MAKE MHRA LOOK SILLY



**T**HE ANNOUNCEMENT appeared in the *Pharmaceutical Journal* in May<sup>1</sup>. The first homeopathic remedy has been approved for labelling with therapeutic indications. The product is Nelsons Arnicare KlikPak, and it is indicated “for the symptomatic relief of sprains, muscular aches, and bruising and swelling after contusions”.

Most readers will know that the new Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006 was slid quietly onto the statute book during that year’s summer recess, thus avoiding parliamentary debate, and caused a huge protest from scientific professional bodies (see HealthWatch’s position paper for more information<sup>2</sup>). No efficacy data are now required in order for a homeopathic product label to claim to be able to treat a medical condition, and the UK regulatory body (the MHRA) states that it allows these label claims to be based on traditional use only. In fact the MHRA also accepts data on homeopathic ‘proving’s’. Proving’s is a practice rooted in tradition and not in science, which has nothing to do with efficacy and is not even carried out on the finished product. Nevertheless, Nelsons’ chairman was reported in the *Pharmaceutical Journal* as saying, “The fact that therapeutic indications may now be included on the packaging of licensed homeopathic medicines not only opens the practice of homeopathy up to new users but also gives it added credibility as a safe and natural complement to conventional medicine.”

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**“The MHRA is not funded from taxation, but from fees, mostly from product licenses. Golden eggs and geese perhaps spring to mind...”**

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Responding in the same article the MHRA refuted Nelsons’ statements, adding that the rules were introduced, “to address the anomalies in regulating homeopathic medicinal products and enable consumers to make an informed choice”. This is a somewhat disingenuous stance, because in its consultation on the proposed rules the MHRA stated that to do nothing would, “inhibit the expansion of the homeopathic industry”. Why should the MHRA be worried about that? The answer may be simple. The MHRA is not funded from taxation, but from fees, mostly from product licenses. Golden eggs and geese perhaps spring to mind. At the time the MHRA argued that it was obliged to introduce the rules by a European

Directive, which was not quite correct as the Directive could have been satisfied by sensible legislation. For example, products on the market before 1971 (when the 1968 Medicines Act came into force) have licences of right which carry indications, and these could simply have been phased out and no new indications allowed. But then there would have been no new licence fees.

As it happens the actual clinical evidence for homeopathic arnica is well worth an examination. It is one of the most intensively researched homeopathic remedies, the outcome of which is—nothing. A systematic review of all eight randomised controlled trials of homeopathic arnica concluded as follows: “The claim that homeopathic arnica is efficacious beyond a placebo effect is not supported by rigorous clinical trials”<sup>3</sup>. It can be hardly any clearer that there is no effect. It seems ironic that a therapeutic indication can be awarded in the first instance to perhaps the most clearly ineffective remedy that could have been selected. As the review’s author, Edzard Ernst, professor of complementary medicine at Peninsula Medical School, Exeter, commented to HealthWatch, “This demonstrates just how silly the MHRA’s regulation really is.”

Let’s remind ourselves of what the MHRA says about itself: “We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe.”

Really? I will let readers judge the truth of that. Will they tell Nelsons not to make those statements? Don’t hold your breath...

Les Rose

Freelance consultant clinical scientist

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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.

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