

## Newsletter no 50: July 2003

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## SCREENING DEBATE CONTINUES

*The question of whether mass screening for breast cancer is justifiable continues to be argued in the medical press, and HealthWatch's chairman, Professor John Garrow, is making his voice heard. His recent letter (1) to the editor of the Journal of the Royal College of Physicians of Edinburgh appeared in their May edition virtually as submitted.*

Garrow was replying to a feature in the previous issue (2) in which the director of a breast screening service put a positive slant on the benefits of screening with an interpretation of the published data which, Garrow said, was misleading. The writer, he said, had been silent about the disadvantages, failing to point out the national screening programme's £50million cost per annum, the workload on health departments, and the anxiety caused to the 53 in 1,000 women screened who are recalled for re-examination. "Nor does she mention that an increasing proportion of the cancers detected by screening are DCIS—in other words they may never have caused illness..." yet such a diagnosis, however non-invasive, can be "a real handicap to any woman seeking life insurance, a mortgage or even a job."

Garrow called for more honest publicity on the subject in the HealthWatch Newsletter [Newsletter issue 45](#) (April 2002).

#### References

1. Garrow J. J R Coll Physicians Edinb 2003; 33(2): 143–147.
2. Anderson EDC. J R Coll Physicians Edinb 2003; 33(1): 10–11.

## Achievement award

HealthWatch is pleased to announce that Professor Garrow received an award for "Outstanding achievements in the field of nutrition" at the 48th Annual Scientific Meeting of the Caribbean Health Research Council held in Nassau, Bahamas on 1st to 3rd May 2003. At the final session, on Medical Education, Garrow presented a paper titled, "On what evidence should treatment be based?" An article taken from this presentation is scheduled to appear in the next issue.

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## UNTANGLING DOCTORS FROM DRUG COMPANIES

*Relationships between the pharmaceutical industry and patients' organisations must be at arm's length and transparent, and not affect the agenda and priorities of these groups, argued HealthWatch committee member Dr Andrew Herxheimer recently in a special theme issue of the British Medical Journal dedicated to exploring the relationship between doctors and drug companies.*

Herxheimer, an Emeritus Fellow of the UK Cochrane Centre for Evidence-based Medicine, explained that drug companies, prohibited from advertising direct to the public, often reach them indirectly by forming partnerships with self help groups and patients' organisations. While grants and joint projects with pharmaceutical companies can help such organisations grow and be more influential, they can also distort and misrepresent their agendas. More openness, less public relations flummery, and some modest public funding for patients' organisations should also be considered, suggests Herxheimer. More about the BMJ's theme issue [below](#).

BMJ 2003; 326: 1208–10. View the full paper on: <http://press.psprings.co.uk/bmj/may/edd1208.pdf>

## FAREWELL AND THANKS TO GEOFF WATTS

It is with regret that the HealthWatch committee has said farewell to a valued member, journalist and broadcaster Geoff Watts, who has stepped down as Vice-Chairman due to pressure of his many work-related activities.

Dr Watts, who presented BBC Radio 4's prize-winning Medicine Now programme for 17 years, was the first recipient of the HealthWatch Annual Award in 1993 (HealthWatch [Newsletter issue 13](#)). The committee would like to thank him for the work and commitment he has shown to HealthWatch in recent years and offer the very best wishes for the future.

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## Drug company-doctor relationship under the microscope

*A themed issue of the British Medical Journal at the end of May explored the extent of the doctor-drug company relationship, its effects on research, its influence on prescribing, and the consequences for patients. The result was a persuasive argument in support of the journal's view that doctors, drug companies, and most importantly patients would all benefit from greater distance between doctors and drug companies. Our report on Andrew Herxheimer's paper in that issue appears [above](#), here follow points from some of the other key reports:*

**Research funded by drug companies is biased.** It is more likely to produce results that favour the sponsor's product than research funded by other sources. These results apply across a wide range of diseases, drugs, and drug classes, over at least two decades and regardless of the type of research being assessed, say the Canadian authors.

BMJ 2003; 326: 1167-70. Full paper: <http://press.psprings.co.uk/bmj/may/ppr1167.pdf>

**Treatment decisions based on published studies are subject to bias.** Drug companies tend to publish studies with more favourable results, using duplicate publication, selective publication, and selective reporting to achieve desired effect. Without access to all studies, positive as well as negative, any attempt to recommend a specific drug based on published reports only is likely to be based on biased evidence, the Swedish authors conclude.

BMJ 2003; 326: 1171-3. Full paper: <http://press.psprings.co.uk/bmj/may/ppr1171.pdf>

**Weekly contact with drug reps is linked to unnecessary prescribing.** A cross sectional study amongst English general practitioners found that frequent contact with a drug industry representative was associated with a greater willingness to prescribe new drugs and to agree to patients' requests to prescribe a drug that is not clinically indicated; dissatisfaction with consultations ending in advice only; and receptiveness to drug advertisements and promotional literature from drug companies. GP's who saw drug reps most often tended to be singlehanded practitioners working in deprived areas.

BMJ 2003; 326: 1178-9. Full paper: <http://press.psprings.co.uk/bmj/may/gp1178.pdf>

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## Diary dates:

### CAM symposium;

The Royal College of Physicians, London will host the 10th Annual Symposium on Complementary Healthcare on 21st and 22nd November 2003. The meeting, run by Exeter's Department of Complementary Medicine, whose 10th Anniversary we report on in this [issue](#) is the longest running scientific meeting in its field. Closing date for abstract submission is 31st July 2003 and copies of the programme will be available by the end of August.

For further information or to register your interest in the symposium please contact Barbara Wider at the Department of Complementary Medicine, Peninsula Medical School, Universities of Exeter & Plymouth, 25 Victoria Park Road, Exeter EX2 4NT or telephone +44 (0)1392 424872. E-mail: [B.Wider@exeter.ac.uk](mailto:B.Wider@exeter.ac.uk)

<http://www.exeter.ac.uk/FACT/sympo>

### HealthWatch AGM

Don't forget HealthWatch's Annual General Meeting 2003 on Tuesday 28th October at the Medical Society of London, Lettsom House, 11 Chandos Street London W1. Reception begins at 6.30pm, followed by the meeting and presentation of the 2003 HealthWatch Award. Attendance is free, the buffet supper afterwards costs £25 per

person payable in advance. Please send cheques (made out to HealthWatch) to John Garrow, The Dial House, 93 Uxbridge Road, Rickmansworth, Herts WD3 2DQ.

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## How gullible are we?

A junior high school student won first prize at the Greater Idaho Falls Science Fair recently with a project which had urged people to sign a petition demanding strict control or a ban of the chemical he named "dihydrogen monoxide" on the grounds that:

- It can cause excessive sweating and vomiting
- It is a major component in acid rain
- It can cause severe burns in its gaseous state
- Accidental inhalation can kill you
- It contributes to erosion
- It decreases effectiveness of automobile brakes
- It has been found in tumours of terminal cancer patients

Of 50 people questioned, 43 supported a ban of the chemical, six were undecided, and only one knew that the chemical was water. The title of his project was "How gullible are we?"

Financial Mail, 2nd May 2003

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## Opinion: DISINTEGRATED MEDICINE

*On Sunday 10th August 1628 the Vasa sailed out of Stockholm harbour on her maiden voyage, writes John Garrow. She was, at the time, the world's mightiest warship, the flagship of King Gustav Adolphus, for whom this was a great publicity event. She carried 64 guns on two gun decks, and her forecandle was beautifully gilded. When she cleared the harbour she set full sail, fired a salute, heeled over and sank in view of the assembled crowds.*

In retrospect this disaster is easily explained. The ship was designed by the experienced Dutch shipbuilder Henrik Hybertsson, who based his calculations on water off the Dutch coast. But the salinity of the Baltic at Stockholm is about one tenth of that of the open sea, and consequently provides less buoyancy. It was politically necessary that this ship should carry heavier armament than any other contemporary warship, which meant that she floated lower in the water and was relatively top heavy. The lower gun ports were perilously near the water line, and when they were opened for the salute to be fired she heeled over in a freshening wind, many tons of water rushed through the open ports, and so she sank.

The National Health Service (NHS) has not sunk yet, but its seaworthiness is questionable, and I see parallels between its problems and those of the Vasa. The NHS is the flagship of our Welfare State, and consequently under intense scrutiny both from politicians, the media and the electorate. The politicians raise expectations, set targets, and announce new funding for high-profile services such as heart surgery. I see this as the analogue of gilding the forecandle, whereas the real problem concerns the buoyancy of the whole structure. The buoyancy of a floating structure of given size depends on the relationship between the load it is required to carry and the density of the supporting medium. Both these factors are inexorably changing in a direction that will sink the ship unless the trend is reversed.

It is obvious that the load the NHS is required to carry has greatly increased since I qualified in medicine 50 years ago, largely because there are far more old people (like myself) who need, and expect, to be provided with support that was not available 50 years ago. I looked up "prosthetics" in the index of the edition of the Encyclopaedia Britannica published in 1957, and was referred to a half-page entry about false teeth. Prosthetics is defined as "the substitution of artificial replacements for lost natural parts". Today such substitutes are available (at a cost) for almost every human body part, from an eye lens to a severed limb.

As patients' expectations rise, so does the financial penalty for failing to meet these expectations. The cost of litigation for medical negligence is now a significant part of NHS costs. The mantra "Prevention is better than cure" is often true, but it does not follow that screening for disease in apparently healthy people, and hence making an earlier diagnosis, leads to better or less expensive health care. It may, or may not, lead to better treatment: the screening itself is a financial burden, and may create "worried well" who increase the demand on healthcare services. Lifestyle changes (avoiding smoking, drug abuse or obesity, taking exercise, safe sex) may reduce health risks, but it is politically inexpedient to expect the electorate to bear the burden of preventive medicine while they are told that it is the duty of the NHS to do this for them.

Certainly the repertoire of effective drugs is far greater now than it was 50 years ago. Increasingly, the NHS doctor is seen to be a prescriber of drugs, and I see no prospect of this trend decreasing. The government

understandably wants the funding of the NHS to be "a partnership with industry" (so as to share the cost) and the only industry that makes large profits from the NHS is the pharmaceutical industry. Hence most of the research, and the public relations hype that goes with it, concerns drug research, or genetic research which (it is hoped) will lead to new drugs. So far we have been protected from Direct to Consumer (DtC) advertising of prescription drugs, that is permitted in some countries (and de facto on the internet). Recently HealthWatch has been invited to support an "Ask about medicines week", which is scheduled for 12th to 18th October 2003. The objective of this exercise is that "asking about medicines becomes the norm for patients and carers". This may, or may not, be a useful advance in healthcare. It is certainly desirable that patients should understand the medicines that have been prescribed for them, but it is certainly undesirable if some patients expect that consultations in primary healthcare should feature a seminar in pharmacology. It is still less desirable if the patient, dissatisfied with the information provided by the general practitioner, turns to pharmaceutical "helplines" which are, in effect, direct to consumer advertising. We shall have to see how this initiative develops.

I think this image of orthodox medicine as being drug-based has contributed to the rise of alternative therapies, that are seen as holistic and person-based. Prince Charles sponsored the Foundation for Integrated Medicine, so the benefits of modern drugs could be combined with the ancient healing wisdom of alternative therapy. He correctly identified a problem, but was wrong in his proposed solution. I agree that modern NHS medicine is "disintegrated medicine". Fifty years ago we had fewer drugs, and more time and inclination to consider (and try to improve) the lifestyle factors that contribute to disease. When I was a young doctor diet, exercise and environmental factors (at work and in the home) were considered legitimate concerns of orthodox medicine. Now advice on such matters is given by self-styled "clinical ecologists" who may or may not have a medical qualification. I am all for integrated medicine if it means that NHS doctors have the time, training and inclination to consider these wider issues. But I am not for it if it means that "clients" get a drug prescription from a medic in one booth, and then pass on to another booth to have their energy flows tweaked, or a "diagnosis" made by a charlatan applied kinesiologist.

So far I have considered some of the many ways in which, over the last 50 years, there has been an increase in the load which our flagship, the NHS, has to carry. In addition, as with the Vasa, there has been a dilution of the medium from which it derives support. I am not thinking here about formal NHS staff, but about the ever-dwindling number of people (mostly young women) who, 50 years ago, saw it as their social duty to care for their elderly infirm relatives at home. As I get older and more infirm I do not want my younger relatives to be unwilling unpaid home carers, but nor do I want to be committed to an old peoples' home. How can I achieve some degree of personal independence although there are some of the activities of daily living that I cannot reliably perform for myself? This is a fundamental problem in healthcare similar to the financial problem with pension schemes: as old people progressively outnumber young people it becomes more difficult, and eventually impossible, for the young to provide adequate support for the old.

So what is the solution to the problem? If I were Secretary of State for Health what would I do to make the NHS a more seaworthy craft? Probably I would (like the recent incumbent of this post) resign to see more of my family, but I would offer advice to my successor along the following lines:

Please respect and cherish the good features of the NHS, because in parts it is very good—such as in the management of acute injury and disease. But please do not make promises on its behalf that are impossible to fulfil, and then order an immediate enquiry whenever it fails to meet the unrealistic expectations you raised.

Yes, employees in the NHS are (like yourself) paid by the taxpayer, and must be held accountable for the job they do. There is now adequate machinery to weed out the health-carer who is lazy or clinically incompetent, so the majority are conscientious workers, and some are quite intelligent, well educated and loyal to the service. So consider the possibility, when they criticise the system, that they may be right and you may be wrong.

The NHS (like the Vasa) is overloaded to the point of being overwhelmed, so be very careful not to seek political kudos by imposing schemes (such as mass screening for cancers) that have modest benefits to health in relation to the human and material costs involved. When apportioning NHS money for treatment or research, please apply equal criteria of efficacy to orthodox and alternative methods of care.

Do not ignore the demographic time bomb concerning care of the elderly. In this matter I draw some comfort from the work done by Professor Heinz Wolff's group at Brunel University. In principle the bioengineering ingenuity that creates prosthetic limbs could create a prosthetic environment in the home of an old person. Artificial devices to replace lost natural abilities, such as sight, hearing, agility or dexterity might enable old infirm people to live independently in a suitably-instrumented home without exhausting the supply of young, able-bodied health carers.

But then, at my age, I would say that, wouldn't I?

John Garrow  
Emeritus Professor of Human Nutrition  
University of London

## Evidence: THE QUEST FOR THE TRUTH ABOUT COMPLEMENTARY MEDICINE: the first ten years

*It is now ten years since the Chair of Complementary Medicine was founded at what is now called the Peninsula Medical School, a joint School of the Universities of Exeter and Plymouth. Since 1993, when the Laing Chair in Complementary Medicine was founded by £1.5m donated from the Sir Maurice Laing Foundation, the Centre has published around 600 clinical papers resulting from research projects into safety and efficacy of a vast array of traditional and unorthodox treatments. Research is led by Professor Edzard Ernst, the United Kingdom's first and only professor of complementary medicine.*

When the Chair was established it was no doubt expected in many quarters that Complementary and Alternative Medicine (CAM) had entered the realms of orthodoxy and was heading for some kind of official seal of approval—routine GP referrals to alternative therapists, reflexology on the NHS, and the like might swiftly follow. Ernst, who qualified in medicine in Germany in 1978 and later received training in several areas of mainstream medicine and science as well as in acupuncture, herbalism, homoeopathy, massage therapy and spinal manipulation was not, however, the champion of unconventional therapies that some had hoped for. On the contrary, his unit has been unique in its mission to subject popular remedies to the most rigorous clinical testing, from a standpoint that is as untainted by vested interest as it is possible to be. The result? A vast and growing body of clinical research that has identified authoritatively many areas of CAM which are effective, others that are useless and some that are potentially dangerous.

Professor Ernst was the worthy 1994 recipient of the [HealthWatch Award](#) for promoting quality of information in health care, and the intervening years have not diminished his enthusiasm in pursuit of this goal. But his results have not pleased everyone. As HealthWatch Chairman John Garrow explains, "The problem, of course, was that the Chair was established in the hope that good research would establish the value and safety of complementary and alternative therapies, but rather often the outcome was that the therapy was neither very effective nor very safe. He has become unpopular with proponents of some of the less effective therapies, who seemed to believe that a Professor of Complementary Medicine should offer evidence as favourable as possible to Complementary Medicine."

Recent months have seen concerns over the department's future with falls in funding. "Ernst's loyalty to the truth has always been stronger than his loyalty to the interests of those who sponsored his research," says Garrow, "so it is not surprising that he is finding it difficult to find private sponsors. In these circumstances I would expect the Department of Health to step in with the necessary support, but their response has been disappointing." There has, however, been welcome news in recent weeks of a further £500,000 donation from the Sir Maurice Laing Foundation. This should reassure everybody who supports evidence-based assessment of health treatments.

### The Department and what it does

Exeter's Complementary Medicine Research Group is the largest of its kind in Europe with a sixteen-strong research team. Research is focussed on CAM treatments most prevalent in the UK, including herbal remedies, homoeopathy, healing, spinal manipulation and acupuncture. The group defines CAM as, "Diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine." (1)

Their research aims to answer the questions: is it effective? is it safe? does it save money? Its investigative tools are systematic reviews of published randomised controlled trials, clinical trials, surveys and other experimental studies. In addition, the Department publishes the journal *Focus on Alternative and Complementary Medicine (FACT)*, holds an annual CAM symposium (see [above](#) for details of this year's event), and runs conferences, lectures, courses as well as offering media comment.

### In the media

As the UK's most authoritative source of comment on the subject of complementary and alternative medicine, Professor Ernst and his colleagues are frequently sought by the media.

Last December, for example, CAM enthusiasts were pleased when Professor Ernst spoke out against the Committee on Safety of Medicine's proposals for a ban of the herbal tranquiliser Kava, used as a "natural" alternative to Valium, after it was linked to cases of liver damage.

"Kava is proven to be effective in treating anxiety and, looking at the total risk, it is safer than synthetic drugs," he said, adding, "the public is entitled to protection from dangerous and toxic treatments whether they are complementary or conventional. But it may be counter-productive to ban an efficacious medicine on the basis of criteria that seem to be harsher than those used to license conventional, artificial drugs." (2)

He was less enthusiastic, however, about the benefits of the popular homoeopathic remedy arnica, sold to control bruising and aid recovery after injury. When an Exeter University double-blind placebo-controlled trial of two

different homoeopathic Arnica dilutions failed to show benefits (3), Ernst commented, "I hope this research will help people to look for more effective treatments and save money by not buying homeopathic arnica."

While Ernst's team seems to be asking the right questions, it is not surprising that there are those who flinch at some of the answers. Two years ago, writing in the *Journal of Alternative and Complementary Medicine*, advocates of CAM accused the professor of bias against alternative medicine after his team's reviews of the evidence for therapies such as acupuncture and chiropractic concluded that the scientific case for efficacy is weak (4,5). The allegations were especially surprising in the light of another Exeter study published the previous year, in which the team now accused of undermining CAM had in fact brought to light important evidence of bias against CAM among editors of scientific journals (6).

## The future

Funding, says Ernst, is the biggest obstacle to CAM research in the UK. Surveys by the Department showed that in 1996 only 0.08% of the NHS research budget and only 0.05% of the medical charities' research budget was spent on CAM. The professor has described the CAM research funding situation in the UK as "dismal" compared to Germany, the USA and Switzerland where public money is ring-fenced for CAM research. The Department's experience of rejections of grant applications suggests, Ernst has speculated, that the people on the research application review panels often do not understand CAM.

An ideal for the future, Professor Ernst believes, would be a Department that embraced an education programme which taught CAM to undergraduates and to orthodox medicine professionals; an information programme linking up with journals, the media and the public to counteract misinformation; and a clinical service that would ensure that those in the unit continue to see patients, thereby maintaining vital contact with the very people that CAM is designed to benefit.

Mandy Payne  
Editor, HealthWatch Newsletter

## References

1. Ernst E et al. *British General Practitioner* 1995; 45: 506.
2. BBC News Online, 4 December 2002, see <http://news.bbc.co.uk>
3. Stevenson C, Devaraj VS, Fountain-Barber A et al. *J Royal Soc Med* 2003; 96: 60-5.
4. Micozzi MS. *J Alt Comp Med* 2001; 7 (1): 13.
5. Morley J, Rosner AL, Redwood D. *J Alt Comp Med* 2001; 7 (2): 127.
6. Resch KI et al. *J Royal Soc Med* 2000; 93: 164-7.

## Links

- Complementary Medicine at the University of Exeter <http://www.ex.ac.uk/cam/index.html>
- FACT <http://www.ex.ac.uk/FACT/index.html>
- Postgraduate Medical Schools of the Universities of Exeter and Plymouth <http://www.pms.ac.uk>

## Major reference text

Ernst E, Pittler MH, Stevinson C, White AR. *The desktop guide to complementary and alternative medicine*. Edinburgh: Mosby, 2001.

## THE RESEARCH: Amongst the areas which have come under the team's scrutiny are:

**Homoeopathy** Research in this area has, as for many areas of CAM, historically been characterised by poor methodology, rendering the results open to question. After a recent meta-analysis suggested homoeopathy might have clinical effects beyond placebo, the Exeter team re-analysed the original data, excluding all but trials of the highest methodological quality. The results suggest that homoeopathic remedies are associated with the same clinical effects as placebo. Research in this area at the Department is continuing.

**Herbal medicine** With increasing use of herbal remedies, the department aims to create a reliable risk-benefit profile of commonly used herbs. While our knowledge base is far from complete, there is useful data for some popular remedies:

- Ginkgo biloba, while of questionable use for memory loss and tinnitus, it has some effect on dementia and intermittent claudication.
- St Johns Wort is effective in mild to moderate depression, but there are concerns over drug interactions.
- Echinacea may help treat or prevent upper respiratory tract infections, but data is not fully convincing.
- Saw palmetto has been shown in short-term trials to help reduce symptoms of benign prostatic hyperplasia.
- Kava is an effective short-term treatment for anxiety.
- Ginseng has yet to be associated with evidence for its efficacy in the treatment of any condition.

**Aromatherapy massage** Evidence suggests that massage using essential oils has a mild, transient, stress-relieving effect, though not strong enough for it to be considered for the treatment of anxiety.

**Reflexology** From the few controlled trials of reflexology, in which foot massage is used to diagnose and heal conditions elsewhere in the body, there is little support for the notion that reflexology is associated with specific therapeutic effects, beyond perceived benefits that could well result from non-specific effects.

**Spinal manipulation** Techniques such as chiropractic and osteopathy can and have been subjected to placebo-controlled study using sham treatments. A review of a number of high quality studies of this nature could find no therapeutic effects beyond placebo.

**Acupuncture** None of the studies that had investigated acupuncture's efficacy—for applications including weight reduction, tinnitus, neck pain, smoking cessation, tension headaches—had yielded conclusive or particularly positive results, although there is some evidence in favour of the technique's ability to alleviate dental pain and back pain.

**Patient satisfaction, CAM vs orthodox medicine** A questionnaire was used to examine levels of patient satisfaction with CAM and orthodox medicine amongst arthritis sufferers who had experienced treatments by both types of practitioners. This research had found that CAM therapists were perceived as much more friendly, as having much more time to spend on the patient and the treatment, as giving more information on the treatment and on the disease, and even as giving slightly more efficacious treatments.

**Publication bias** CAM journals have been shown to have a strong bias in favour of publishing papers which had positive results for CAM as opposed to negative or neutral results for CAM. However in the case of orthodox medical journals other research found that a paper based on an orthodox medical treatment was more likely to be accepted for publication than an identical paper which provided the same results for a CAM treatment.

**Safety of CAM** A survey of CAM users found that users could remember side effects of homeopathy, herbalism, spinal manipulation and acupuncture. However a similar survey of GPs found they could only recall having seen side effects of spinal manipulation. Concerning the view that CAM is relatively safe when compared to the levels of iatrogenic disease caused by orthodox medicine, Ernst emphasises that one must always keep in mind the risk/benefit balance.

The unit's key personnel

- **Edzard Ernst** professor of Complementary Medicine
- **Max Pittler** research fellow with particular interest in herbal medicine
- **Joanne Thompson-Coon** research fellow, background in pharmacology
- **Peter Canter** research fellow presently conducting a study of healing
- **Jongbae Park** traditional Korean physician, special interest acupuncture

### Edzard Ernst: quotes

"Traditional use is always interesting but not compelling. And it is nonsense to suggest that traditional use can masquerade as evidence."

15 December 2000, Connected at <http://www.dailytelegraph.co.uk>

"If we are going to ban kava today, then we should have banned Valium twenty years ago."

4 December 2002, BBC News Online at <http://news.bbc.co.uk>

Would you buy a car that is safe but does not work? Why is the press attitude so often different with regard to cars than to medicine?

FACT, December 2001

### Some statistics

- There are approximately 50,000 CAM practitioners in the UK
- Approximately 10,000 statutory health professionals practise some form of CAM.
- Up to five million patients consult a CAM practitioner in the course of a year.
- A study of 461 general practitioners in the South West of England found that 55% had endorsed or recommended CAM in the last week, 25% had referred one or more patients to a CAM provider and 16% practised some form of CAM themselves.
- CAM therapies are especially attractive to patients with chronic conditions and those where conventional treatments have no ready answer. CAM therapies have been tried by 59% of adult asthma patients, 33% of arthritis patients, up to 69% of people with dermatological conditions and, according to some studies, as many as 64% of cancer patients.

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## Research focus: OUTCOMES THAT REALLY MATTER TO PATIENTS

*Andrew Herxheimer calls for a new dimension in the clinical research process in this article which originally appeared in the newsletter of the organisation Consumers for Ethics in Research (CERES newsletter Spring 2003;*

**33: 1–3). We reproduce it with their kind permission.**

***Conventional clinical trials are designed to answer clear scientific questions in terms of hard outcomes that can be measured objectively. In cancer trials, for example, these include death, tumour size, disease progression and tumour markers. Some subjective outcomes are often measured, such as pain, disability (for example, Karnofsky scores), and increasingly 'quality-of-life' (QoL). They all entail the use of a scale, which enables different people's subjective observations to be combined and compared.***

When trial results are published they are expected to fulfil two functions. Firstly they should help to inform the medical and scientific community about the value of the interventions tested; secondly they should enable clinicians to explain to patients what the interventions have to offer, and what drawbacks have to be considered, to give them a basis for deciding whether to accept a treatment.

But anyone who tries to explain treatments to patients in this way has to overcome two major difficulties. The first is to convey the scientific concepts and data in words that the patient can understand. That requires skill, time and, preferably, trial summaries written in lay language. The second is to explain what impact the treatment may and is likely to have on the patient's life. Unfortunately conventional reports of trials lack the information on which such an explanation could be based. The reason is that measurements of disability and QoL cannot be translated back into the individual experiences from which they are derived.

The purpose of such measurements is to compare the effects of interventions across groups—for example a treatment group with a control group. What the individuals in each group experienced matters to those individuals, but is not of primary interest to the scientists who did the trial or to the clinicians who use the report—if they learn about such experiences this tends to happen incidentally. The group results cannot be translated back: the individual observations and experience that underlie them remain hidden in the averages, and these cannot be interpreted for future patients. This problem has until now not been recognised. The following proposal is an attempt to clarify and to help solve it.

### **A proposal**

The first need is to collect the separate subjective observations and reflections from a sample of the individual participants in the trial in a form that describes what they meant to those individuals. The observations would cover many topics that rarely surface in trials, for example effects of the disease and of treatments on relationships with family members, work, social life, unwanted effects and inconveniences of treatment, and of participation in the trial.

The data can then be analysed to describe the range of experiences of the people who were exposed to the treatments in the trial, and also summarised for each treatment group as a whole, as is done conventionally. A patient's individual subjective experience is most reliably collected in an open unstructured interview, supplemented by some neutral prompts. The method is being used to collect individual illness experiences in narrative interviews in the DIPEX project (1). At about the same time the patient completes the standard instrument used to measure Health Related QoL, and also the Schedule for Evaluation of Individual QoL (SEIQoL), in which each patient in effect constructs a personal scale that gives most weight to the aspects of life that matter most to her/him (2). This will make it possible to illustrate particular scores on these measurement scales with the experiences of the individual concerned, so helping to solve the problem of back translation to make the findings comprehensible in everyday terms to both patients and clinicians.

**Benefits** This additional component of a clinical trial would have important benefits apart from the gains in knowledge and understanding and making back translation possible. It would almost certainly bring to light aspects of the treatments and of the trial that the researchers had been unaware of and that could influence the interpretation of the results. By enabling patients to express their feelings and opinions it would significantly enhance their role as active participants in the study—they would be less likely to feel that they were 'subjects' or 'guinea pigs'. And the rapport between patients and trialists would very likely be improved. Finally, the results of the trial would provide a broader base for use of the treatments in practice, and for future research.

**Numbers and logistics** In the pilot/initial phase of gathering experience with this method it would be sufficient to collect interviews, etc. on a modest 'maximum variety' sample of the patients who enter the trial. Such a sample would aim to include patients in every major subgroup of those recruited for the trial, for example young and old, men and women, with mild, moderate and severe disability, of differing educational attainments and ethnicity. For example in a trial aiming to recruit 200 patients, a sample of 20 to 30 might suffice. The minimum number might be 12 to 15. Each patient in the sample would be interviewed at least twice, the first time after agreeing to take part in the trial, before entering it, the second time after a fixed period in the trial, or on leaving the trial. Depending on the design and length of the trial a third interview may be desirable, since a patient's experience may well change with time.

**Costs** The budget of the trial would have to allow for the interviews, their recording, transcription and analysis, and the administration of extra measuring instruments. The interviewers would have to be trained, and the qualitative analysis requires an experienced social scientist, who would have to be a member of the clinical trial team and contribute to the report. The cost may be very roughly estimated at £800 per patient (two interviews, etc, each).

**Getting the most from a pilot study** The clinical trial team is in a special position to watch and experience what happens when a new dimension such as this is incorporated in a study. It would therefore be worth getting individual members of the trial staff to keep diaries of their own observations and reactions during the trial, with special reference to the collection of patients' experiences. It would also be desirable to supplement the diaries with individual interviews of team members during and/or at the end of the trial.

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2. Joyce CRB, O'Boyle C, McGee H, eds. *Individual Quality of Life: Approaches to conceptualisation and assessment*. Amsterdam: Harwood Academic Publishers, 1999.

With thanks to: CERES (Consumers for Ethics in Research)  
PO Box 1365, London N16 0BW <http://www.ceres.org.uk>

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## Letter to the editor: A SINGLE-HANDED CAMPAIGN AGAINST HEALTH MISINFORMATION

*Sid Rodrigues, a pharmacology undergraduate at King's College London, wrote to us about his one-man campaign against dubious remedies:*

Dear Sirs

I first stumbled upon the mysteries of complementary and alternative medical regimes during a part-time job at a large pharmacy chain. On researching the ingredients in some of the supplements sold there I concluded that many of these products were spurious or useless which led me to question the company's policy on recommending them. I decided to give the customers my honest opinion and as a result there were numerous complaints to my manager.

A month later the Medicines Control Agency published a list of possible interactions between the herbal remedy for depression, St John's Wort, and some types of pharmacy and prescription medicines. I felt vindicated, but only just. Though I advised patients with clinical depression, users of the oral contraceptive and the others listed not to take St. John's Wort until consulting their GP, my impression was they they would probably take it anyway. This worried me to the extent that I left my job.

Later, at a chiropractic open week I decided to test the claims of the experts. I'd recently had a fall and damaged my back, so I would be a perfect candidate. In the week the chiropractors were in residence I saw all three, they all found a number of "subluxations" independently and recommended that I come to their surgery for treatment. I noted that none of the "subluxations" were in the same place, and none in the area causing me pain.

Concerned by the lack of action taken by companies and authorities against ineffective therapies, I sent the Advertising Standards Authority (ASA) examples from my e-mail box of of junk advertisements for remedies promising penis extension, anti-ageing and cancer cures. They advised, though, that as the companies in question are not based in the UK, it wouldn't be possible to check the validity of their claims.

I am having more success now with UK companies. One that I contacted was offering coral calcium supplements with claims such as, "Taking good quality Calcium supplements may prevent or even reverse over 200 Degenerative diseases including Cancer, Heart Disease, Arthritis, Osteoporosis & MS." I e-mailed the company stating that the advertisement was misleading, inaccurate and should be changed. Their reply was almost vitriolic, and I was pointed to the large disclaimer at the bottom of each page of their web site and told that any reasonable person could come to a fair conclusion about their own nutritional needs. Try telling that to someone with one of two hundred degenerative diseases, if they are still reasonable.

It wasn't a complete lost cause, twenty minutes later I received a second e-mail completely agreeing with my point that there was misleading information and it would be changed. I'm still waiting for the amendments. I'll probably give the ASA another call.

SID RODRIGUES

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## Last word: INFORMED CONSENT AND PERSONAL BELIEFS

***Homoeopathy probably causes more argument among doctors who provide conventional therapies than any other type of alternative or complementary therapy. Every time the British Medical Journal publishes any article about homoeopathy there is a flurry of e-letters in which the same arguments are put by both sides in a complete lack of meeting of minds.***

We reported just such a flurry in our last issue (HealthWatch [Newsletter issue 49](#) April 2003), and there has been another in response to GP Kathy Ryan's admission in the BMJ's Career Focus section that she too was a sceptic but now practises homoeopathy (1). She writes, "Sceptics often slag off homoeopathy", illustrating the pejorative language that flavours exchanges. This phrase is the first in a section headed, "My conversion", an interesting choice of word with connotations of religion rather than science.

The GMC recently made a judgement about a GP whom they decided had, by using homoeopathy, put her personal beliefs before those of her patients. (She was suspended from the register for three months.) From the details published in their newsletter (2), the whole affair seems somewhat odd and illogical. Three cases are described, including a homoeopathic remedy selected by dowsing and another remedy offered to a patient at risk of suicide. None of the patients had requested homoeopathy, although they did at first accept the medication suggested. The reasoning behind the GMC's judgement was not that the treatments being offered were ineffective. The GMC "did not consider the merits of homeopathic medicine or any form of alternative medicine, as it is not within its remit to do so." The GMC suspended the doctor for failing to get informed consent.

This raises two questions. First, how do you get informed consent for treatments that a large body of opinion holds are useless? Do you have to admit as much to the patient? I think you would have to because, as the GMC quotes from its own guidance, "you should give a balanced view of the options and explain the need for informed consent". As part of the same quote the GMC advises that it is for patients to decide what is in their own best interest. The doctor can recommend, but "must not put pressure on patients to accept their advice".

Even when considering choices within conventional medicine this advice risks serious harm to patients. I can think of situations where I would use as much pressure, short of threats, as I could. In the end, patients can do what they like, but doctors are not required to do the bidding of patients if they believe patients will come to harm.

The second question is to what extent the GMC takes its pusillanimous attitude to alternative therapies. What if a GP held iridology sessions, or crystal therapy sessions—with fully informed consent for patients who came to the surgery requesting these treatments? I suspect the GMC would take a dim view, consent or not. In the heading to their story the GMC gives the game away: Doctors' personal beliefs must not prejudice medical judgement. Indeed not, but this implies homoeopathy is a matter of belief, not evidence. Without admitting it, the GMC just doesn't want to enter the debate about alternative medicine.

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### References

1. Ryan K. Working as a medical homoeopath. BMJ 2003; 326: S151.
2. GMCnews. April 2003; 17: 8.

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