

## Newsletter no 55: October 2004

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### Richard Smith to receive HealthWatch Award

*Dr Richard Smith, until recently editor of the British Medical Journal and a central figure in the world of medical and scientific publishing, will receive the 16th HealthWatch Award this month at HealthWatch's Annual General Meeting, to be held at the Medical Society of London.*

HealthWatch president Nick Ross will present the award to Dr Smith as recognition for his work as a champion of medical journalism and of ethics in research and publishing. He will address the meeting on a controversial subject, Are medical journals simply an extension of the marketing arm of pharmaceutical companies? (This topic is currently of key relevance to HealthWatch—see articles by [Michael Allen](#) and [Andrew Herxheimer](#), and [feature by John Garrow](#), in this issue).

In the last 13 years, as journal editor and chief executive of the BMJ Publishing Group, Dr Smith has enabled the group's research reporting to reach ever wider audiences and directed moves to raise ethical standards for researchers and authors, such as helping form the Committee on Publication Ethics. The winner of four awards for journalism and medical writing, Richard Smith has written, lectured and broadcasted widely to both lay and professional audiences in Britain and overseas. His advice is sought by government committees, and he is a member of three Royal College of Physicians working parties.

In July this year Dr. Smith announced his resignation from the BMJ to become chief executive of the European arm of UnitedHealth Group, the largest healthcare company in the United States.

### OCTOBER 19th: HEALTHWATCH AGM

HealthWatch's sixteenth AGM and Open Meeting, which is free and open to all, will take place on Tuesday, 19th October 2004 at The Medical Society of London, 11 Chandos Street, Cavendish Square, London W1M 0EB (nearest Underground: Oxford Circus). Reception is to begin at 6.30pm, followed by the HealthWatch Annual General Meeting at 7.00pm and award presentations. (Please note: while all are welcome at the meeting, only members can vote at the Annual General Meeting.)

As well as the HealthWatch Award, Nick Ross will present the HealthWatch Student Prize to the winners of this year's competition assessing the quality of clinical trial protocols. The meeting will conclude with Dr Richard Smith's address; a lively discussion is expected.

As usual, any present who would like to continue to debate the meeting's issues with committee members over dinner can join them in a buffet with wine at 8.45pm at a cost of £27. Bookings for the meal must, however, be made in advance. Please contact Michael E Allen as soon as possible on 0208 789 7813 to reserve a place at the buffet.

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## CANCER EXPERT ISSUES A ROYAL REBUKE

*The Prince of Wales came under fire from one of the UK's top cancer surgeons this summer after he commented publicly on the Gerson Cancer Therapy, a costly and unproven regime that involves taking regular coffee enemas and drinking substantial quantities of liquidised vegetables and fruit.*

*Michael Baum, professor emeritus of surgery at University College London and one of HealthWatch's founder members, rebuked Prince Charles in a stinging open letter that was published in the British Medical Journal and reported in the media worldwide.*

The Prince of Wales had addressed the UK's leading cancer charities in his capacity as president of his Foundation for Integrated Health, at a conference on "Complementary Therapies and Cancer Care" held at The Royal College of Obstetricians and Gynaecologists in London on 24th June 2004. The meeting aimed, he said, "to discuss, explore and develop new ways of integrating complementary therapies into the care of cancer patients". In calling for more research into the value of complementary therapies in cancer, Prince Charles claimed, "I know of one patient who turned to Gerson Therapy having been told that she was suffering from terminal cancer, and would not survive another course of chemotherapy. Happily, seven years later she is alive and well...many patients use and believe in Gerson Therapy, yet more evidence needs to be available as to who might benefit or what adverse effects there might be."

In an open letter to the British Medical Journal titled, "With respect your Highness, you've got it wrong", Professor Michael Baum begged the Prince to exercise "extreme caution when advising patients with life threatening diseases to embrace unproven therapies". He criticised in particular the use of anecdotes when discussing cancer, a disease with an unpredictable natural history. "With advanced breast cancer the median expectation of life might be 18 months, but many of my patients live for many years longer, with or without treatment."

The professor's outrage was shared by many leading commentators. Another HealthWatch Awardwinner Polly Toynbee, in an article in the Guardian (30 June), condemned the Prince's comments as "dangerous". The Gerson Therapy costs \$4,900 a week, Toynbee says, adding that "After 60 years it has failed to get mainstream authentication for its wild claims...the American Cancer Society warns it may be dangerous."

British Medical Journal 2004; 329: 118 (10 July)

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## New look for HealthWatch website and new email address for the editor

A website makeover has just been completed, giving the HealthWatch site a new and more modern look while making information even easier to find. The address remains the same, at <http://www.healthwatch-uk.org>

We have also set up a new dedicated e-mail address for the editor of the HealthWatch Newsletter. From now on, please send your letters and articles to [newsletter@healthwatch-uk.org](mailto:newsletter@healthwatch-uk.org) (The editor aims to acknowledge all correspondence within seven days).

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## NEWS IN BRIEF

Three out of five clinicians in Israel report using placebos—inactive treatment or drugs—on their patients. A survey of hospital doctors, head nurses and family doctors carried out from the Herzog Hospital and Hadassah School of Medicine in Jerusalem revealed that almost all—94%—believed placebos were effective to some degree. Placebos were prescribed for conditions ranging from anxiety and vertigo to asthma and even angina, says the paper, published on [BMJ Online First](#). While the use of placebo is officially disapproved of, the authors suggest that judicious use of dummy treatments may actually have a genuine role in treating patients. They call for an open debate on their effectiveness and the ethics of their application.

The Traditional Health Practitioners Bill, which would give formal recognition to 200,000 traditional healers in South Africa, was approved in the Parliament of South Africa's National Assembly in September. South Africa's traditional healers are all in private practice, and take on much of the demand for healthcare that would otherwise fall to the state to provide. But the bill raised concerns, one being that traditional healers would give patients leave to take an excessive amount of time off work. The legislation would make it illegal for anyone not registered as a traditional healer to offer treatment or a cure for HIV and Aids, though spokespeople pointed out that this is not to infer that registered Traditional Health Practitioners are able to offer a cure for Aids. The bill now goes to the National Council of Provinces for concurrence.

Sapa, 9 September 2004

### **“Cancer is preventable”: hurtful but not offensive?**

I can't think of a better cause than preventing cancer. However, the Cancer Prevention Research Trust has been admonished by the Advertising Standards Authority for the claim that “cancer is a preventable disease”. The ASA considered that the claim was likely to mislead and have sought the Trust's written assurance that it will be removed from their advertisements and replaced with a less categorical claim, such as “you could reduce your risk” or similar.

They failed to uphold a complaint that the claim was offensive, and indeed it would have been better if the complainant had said it was hurtful rather than offensive: it is no joke for a cancer patient to be told they needn't have contracted the disease, especially when it isn't true, which is usually the case.

The advertisement was in the front section of the 2004 Who's Who, where they list people who have died since the previous edition, and it solicits donations.

The CPRT seems an unusual organisation, and the advice on their website is a little odd (is a pet cat really carcinogenic?) but an Internet search shows that it funds some perfectly bona-fide postgraduate research.

A HealthWatch member, name withheld

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## **OPINION**

### **ASK ABOUT MEDICINES WEEK: can you trust the answer?**

*1st to 6th November this year is “Ask About Medicines” week. Michael Allen asks, is it more than just a clever way of circumventing rules on promoting drugs to consumers?*

There has been a great deal of interest in Direct to Consumer Advertising (DtCA) of prescription medicines over the last few years; two years' back Nick Ross and I drafted a Position Paper on the subject for the HealthWatch Newsletter ([issue 48, January 2003](#)). In this we pointed out that DtCA has never been permitted for prescription medicines within the EU where the physician was learned intermediary—only he or she was thought to be qualified to make judgements about which medicine was appropriate for a specific condition and which could be dangerous if misapplied.

We also noted how the relationship between doctor and patient has changed and that attempts of the former to intermediate may now be met with scepticism and hostility. We commented upon the value of the patient information leaflet (PIL) and Summary of Product Characteristics (SPC) which provide detailed information on the product to the patient and physician and on the many other ways that information on prescription products can get to the public. The Position Paper is on the HealthWatch [website](#).

At the time, the European Commission proposed a cautious experiment by permitting DtCA for a few categories of medicines; processes within the EU are always slow and this initiative has been further delayed by the European Parliament. Therefore, no progress has been made to alter the legal position within UK or the wider EU. Behaviour in each EU member state is different, reflecting local history and custom; UK is moving through a time of great change due to the need to control NHS expenditure. Initiatives such as making products previously prescription-only available through the pharmacy and studies of cost-effectiveness made by the National Institute

for Clinical Excellence (NICE) are symptoms of this struggle.

Meanwhile, the UK pharmaceutical industry has found interesting and effective ways to circumvent any prohibition on DtCA by their generous support for patient groups and through initiatives such as the Ask about Medicines week, the next being due in November this year. Here industry uses a different sort of learned intermediary, the educated patient, to carry their promotional message. The way this is done currently is a model of appropriate behaviour: the supportive role of industry is clearly stated, no specific product promotion is carried out and contact details of the patient groups are given. But industry gets access to explain the benefit of their new medicines to patients who have a vested interest in their early use and who then act as surrogates to take the promotional initiative that the industry cannot itself make. Involvement of the educated patient is certainly something of which I approve; they are concerned to get the best treatment available regardless of cost and thus act as a democratic counterbalance to NICE, where cost and benefit both must be considered.

We live in a world where the market rules; there would be little viable applied pharmaceutical research without a profitable industry. In HealthWatch [Newsletter issue 53](#) (April 2004) John Garrow reported on the difficulties put in the way of academic research. Now, one sees how easily governmental intentions on DtCA can be circumvented. I remain ambivalent; the process is currently honest, but may not be in the future. Will we always be able to trust the answer?

Michael E Allen  
Regulatory Consultant and Honorary Secretary, HealthWatch

A booklet describing Ask about Medicines week can be downloaded from <http://www.askaboutmedicines.org>

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## MORE TRANSPARENCY, MORE FREEDOM OF INFORMATION

*The influence of the pharmaceutical industry on medical practice and on the regulation of medicines is pervasive, overwhelming and relentless. So says Andrew Herxheimer, Emeritus Fellow of the UK Cochrane Centre in Oxford and a member of the HealthWatch Committee, in his evidence to the Health Committee of the House of Commons in September as part of its Inquiry into the Influence of the Pharmaceutical Industry.*

It is arguably the sheer size of this influence—rather than outright malpractice—that currently results in over-estimation of drug benefit and underestimation of drug harm, suggests Herxheimer. He calls for measures that might lead to greater transparency in this field and specifically freedom of information—including protection for whistle-blowers.

“The industry takes little pro-active interest in adverse effects of drugs; only legal or commercial concerns move it to do more than the regulators require,” Herxheimer claims. “The drug regulatory framework encourages this complacency by relying excessively on pre-marketing clinical trials in defining drug safety profiles.”

Competition is based far more on innovative marketing methods and public relations than on the effectiveness and safety of its products. One result is that drug treatments are uppermost in the minds of doctors and the public, and non-drug treatments (including non-intervention) are very often not adequately considered.

Another inevitable result is that the pharmaceutical industry must strive to control information—especially unfavourable information—about its products and its work. Current procedures for dealing with adverse effects once a drug is in use—known as pharmacovigilance—also come under criticism. “Companies rarely do more research on safety aspects unless they need to defend the product when a serious adverse effect is alleged or suspected, or to show that it is safer than a competing product. The design of studies performed in these circumstances is liable to be much influenced by legal and commercial considerations.”

Herxheimer goes on to highlight a specific danger: drug doses recommended by manufacturers are often higher than is medically necessary. “About one in six drugs have had dosage recommendations modified (generally downwards) at some time after licensing,” he says, calling for companies to be compelled to submit more detailed evidence on dose-related risks and benefits, and for publicly-funded research into the mechanisms of adverse effects.

## EVIDENCE

### Meta-analysts, public money and public trust

***Obesity is becoming the most serious threat to public health in the UK. Yet a publicly funded review of obesity treatments, published earlier this year, skims over the evidence for a number of effective weight-reduction methods while giving most emphasis to that from drugs. Professor John Garrow, HealthWatch Chairman and one of the country's foremost obesity experts, asks whether the public's money and trust are well-placed.***

We all agree that medical treatment should be based on sound evidence of efficacy. In his address when receiving the HealthWatch Award in 1996 Professor David Sackett said: "The problem is to distil the message buried in some 600,000 published randomised controls into a form which is accessible to clinicians when they need it."(1).

The solution to that problem is to fund groups of skilled meta-analysts who would search out all the published evidence relevant to a particular clinical condition, combine the results of the trials by arcane mathematics that gives different weights to the results of individual trials depending on the size and quality of the trial, and arrive at a single score that shows the best estimate of the benefit (or harm) of a treatment compared with the outcome of a control group who did not have the treatment. Old-fashioned reviews were written by individuals who might have axes to grind (e.g. citing excessively their own research) but the meta-analysis was to be a distillation of pure truth, derived from what was, by consensus, the best evidence.

For most of my professional life I have been concerned with the treatment and prevention of human obesity—a topic that has recently been given high priority by NHS health authorities. I was therefore eager to read a massive (A) meta-analysis, published in May 2004, entitled "Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvements" (2). The authors' Introduction said they would evaluate, for the treatment of adult obesity, "...all aspects of diet and lifestyle alteration, with or without pharmacotherapy, and in some cases surgery." I was therefore amazed, and deeply concerned, that the "Implications for healthcare" paragraph at the end of the Executive Summary (the part that healthcare providers would read, and on which they would base their planned expenditure) began with the sentence "Orlistat, sibutramine and metformin appear beneficial for the treatment of adults with obesity."

The sentence quoted is (to a degree) true: orlistat and sibutramine have been shown in large randomised trials to cause a statistically significant increase in the weight loss, compared with controls given placebo, after one year of treatment. But to give these drugs first place in a summary of effective treatments verges on the comical. The eight trials of orlistat involved a total of 3,885 obese patients (mostly women) who were, on average, initially more than 30kg overweight (B). Some were given orlistat and some a similar placebo capsule. They were all on a "slightly hypocaloric" diet (C) for 52 weeks. After a year of treatment those who had taken orlistat (trade name Xenecal) had lost 3kg more than controls on placebo. At the end of the year the controls (who had taken no orlistat) had lost about 6kg from baseline weight. These figures are average weight changes, but the variation within groups was huge, so some unfortunate participants, both in the orlistat and control groups, actually finished the year heavier than they were at the outset of the trial!

All these trials were sponsored by Roche, the makers of Orlistat, and three of the authors declared a competing interest in Roche. The results were analysed on an ITT (intention to treat) basis. In general this is good practice: if estimates of the efficacy of a drug is based only on those who complete the trial this usually yields too favourable a result, because it is the participants who are doing badly that are likely to drop out. However, in the orlistat trials some showed a statistically significant extra weight loss with the drug by ITT analysis, but not if completers were analysed! The dropout rate in all the trials varied from 24–42% in control groups, and from 15–36% in the drug groups. On one trial (3) there were 110 people on orlistat who lost 1.99kg more than the 108 people on placebo, which was significantly greater than zero by ITT analysis (P=0.016). However the 59 people who completed on orlistat lost 2.48kg more than the 61 who completed on placebo, and this failed to reach statistical significance (P=0.092). When calculating the weight loss of people who dropped out the last recorded weight was used as the final weight—so if someone lost 10kg in six months, then dropped out and regained 10kg in the next six months, this would count as a loss of 10kg. Furthermore, the differences between groups may have been statistically significant, but could not be considered clinically important in the face of the level of obesity of the trial participants.

If these drugs were really the most effective available treatment for obesity the situation would indeed be terrible, but there are much better options. Diet with behaviour therapy (D), or (for very obese people) surgery (E) is much more effective. Exercise itself does not cause much weight loss (4), but it probably prevents weight gain—an important topic not addressed in this meta-analysis. They chose to analyse only trials starting with obese people (F), not people who were trying not to become obese, or who have lost weight and want to prevent weight regain. Perhaps this decision relates to the fact that the drugs they recommend are only prescribed for people who are already obese. Perhaps it relates to the criteria that were used to judge the quality of the trials included in the meta-analysis; if the highest weighting is given to well-designed, modern drug trials, it would not be surprising if studies made with limited resources but which are none-the-less honest and relevant get a lower weighting. However, where obese people need to be managed in the real world, the results obtained by methods other than drug treatment should not receive such academic disdain.

I believe this is a situation in which a meta-analysis has been commissioned, using public money, and published under the imprint of HMSO. Readers are therefore entitled to expect that the conclusions are not only impartially derived from the available evidence, but are relevant to actual clinical practice and useful to guide the way generalists manage their obese patients. Unfortunately, for reasons given above, and others (G) I consider that the presentation of this report is skewed in a way that will promote the use of drugs of marginal benefit, so public money is wasted.

John Garrow  
Emeritus Professor of Human Nutrition  
University of London

## References

1. Prof David Sackett, [HealthWatch Newsletter 1996; 20](#): 1.
2. Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L Stearns SC, et al. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvements. *Health Technol Assess* 2004; 8: 21.
3. Finer N et al. One-year treatment of obesity: a randomised, double-blind, placebo-controlled, multicentre study of orlistat, a gastrointestinal lipase inhibitor. *Int J Obes* 2000; 24: 306–313.
4. Garrow JS, Summerbell CD. Meta-analysis: effect of exercise, with or without dieting, on the body composition of overweight subjects. *Eur J Clin Nutr* 1995; 49: 1–10.

## Explanatory notes

A. The hard copy of the report is a document of 194 pages. The 38 Appendices, on 264 pages, are not available as hard copy but on a CD, and the whole report can be downloaded from <http://www.ncchta.org>

B. The report does not state the initial weight of participants in the orlistat trials, but Appendix 8 gives the BMI of drug and control groups, which is approx 37kg/m<sup>2</sup>. Assuming their mean height is 1.65m this implies weight is approx 100kg. Since upper limit of desirable weight is a BMI of 25kg/m<sup>2</sup>, then their weight would need to fall to 68kg, so they are more than 30kg overweight.

C. The diet with 30% of energy from fat was designed to supply 600 kcal/day less than energy expenditure for the first 24 weeks, and was reduced by 300 kcal/day from the 24th week. This was described as a “slightly hypocaloric” diet.

D. The meta-analysis showed that, in the selected trials, a low-calorie diet with behaviour therapy was associated with a weight loss of 7.93kg greater than that of controls. For very-low-calorie diets the mean extra weight loss after 12 months was 13.40kg.

E. Surgery is not considered systematically in this report. In the Swedish Obese Subjects trial (Torgerson JS, Sjostrom L. *Int J Obes* 2001; 25 (suppl 1): 52–54) typically the weight loss (expressed as a percentage of the initial body weight) was 33+10% after gastric bypass, 23+10% after vertical banded gastroplasty, and 21+12% after gastric banding.

F. The study inclusion criteria were that: the trials should be RCT (randomised controlled trials); a full study report should be available; the follow-up should be at least 12 months; participants aged over 18 years; and the initial BMI > 28kg/m<sup>2</sup>. Appendix 10 lists over 200 RCTs on the treatment of obesity that were excluded because they failed to meet these selection criteria.

G. The inclusion criteria (mentioned in note F above) greatly favoured drug trials, and disadvantaged trials of

diet, exercise or surgery. In the drug trials the drug and control groups were on a slightly hypocaloric diet and placebo for a run-in period—usually 4 weeks. The participants who were compliant (i.e. who took > 75% of the placebo capsules) were then stratified and randomised to receive either drug or placebo for the rest of the trial. The weight change was then measured over 52 weeks following randomisation. Thus, if those randomised to placebo lost 3kg during the run-in, and another 4kg while on placebo as controls, this was counted as only a 4kg weight loss, whereas they had lost 7kg in all on diet alone.

There are some diet vs control (no treatment) studies accepted for analysis, and these showed efficacy of diet in reducing weight and disease risk factors that are somewhat better than the drugs (see note D above). However these receive no endorsement in the executive summary. Indeed the text tends to be rather dismissive: for example on page 123 a paragraph on “Dietary interventions” refers to “one small study” of VLCD which produced a weight loss of 13.40kg compared with untreated controls (95% CI. -18.43 to -8.37kg). It was indeed a small study (published in BMJ) with only 19 subjects in treatment and control groups. However with such massive weight loss you do not need a large study to achieve statistical significance.

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## MEDIA

### WHY TRIVIA WINS IN THE RATINGS WAR

*Picture this. Two press releases arrive simultaneously on the desk of the medical correspondent of the Daily Whatever, a mid-market national with a big circulation. One describes the findings of a five-year multi-centre MRC trial comparing two drugs used in the treatment of a common and life-threatening disease. It reports finding a modest difference between the two drugs—but because a large number of people take them, the practical implications are important.*

*The other story features a new treatment for another illness which, although equally dangerous and just as well known, is relatively rare. Bizarrely, this treatment relies on a chemical found only in the tear glands of crocodiles. Thus far just six patients have received it—but five of them are claimed to have responded quite dramatically.*

*The medical correspondent writes up both stories, each at 400 words, and sends them to the news desk. The news editor has space left for one piece only. He reads both, then makes his choice. Bye-bye MRC; hello crocodiles.*

Most doctors and scientists reading this brief fiction would say that the news editor had made a bad decision. The paper’s medical correspondent might agree. And if you rate worthy-but-unexciting above chancy-but-intriguing, the news editor is indeed wrong. But decisions about what gets into the media are influenced by much more than the objective importance of the facts themselves.

This can be a problem for any trialist who’d like his or her findings more widely disseminated. The difficulty is that the media are about real life—sometimes, admittedly, in a rather overblown form!—whereas randomised controlled trials are not. Real life is about opinion, emotion, prejudice, instinct, fashion, style and scores of other honourable or disreputable forms of human outlook and behaviour. Imagine the average newspaper stripped of all such attributes. Even a textbook on philosophy would make a more gripping read.

This is not, of course, to disparage the austerity and the intellectual clarity of clinical trials; but it does mean that their ethos is not one that sits particularly comfortably within the norms of journalism. It follows that even the most scientifically literate journalists may have difficulty selling stories about trials to their editors. Journalism thrives on black and white, not carefully modulated shades of grey. Like the fictitious MRC trial at the beginning of this piece, their results don’t have to be dramatic to be important. But if they’re not dramatic they’re less likely to be reported. And before we get too judgmental about this, we should ask ourselves why we select the paper we buy and the programmes we tune into. Can the news editor really be blamed for choosing the crocodile tear story instead of the MRC one? If his decision was indeed the wrong one, why aren’t more newspapers stuffed full of material of the kind he chose to reject?

And then there’s the source of the new drug: crocodile tears. Irresistible. Once again, before sneering at such base triviality, think of the practicalities of producing a newspaper or a broadcast news magazine that has to entertain as well as inform. Ask people which of two stories they’d be more likely to read: “Scientists today announced the results of a study on drugs derived from a rare tropical mollusc”; or “Scientists today announced the results of a study on drugs derived by entirely conventional methods from a lot of other chemicals with very long names”. It may be exceedingly foolish of us humans to find triviality so seductive. But though the media might play to this regrettable tendency, it was not the Sun or the BBC that invented this predilection.

Some stories, of course, do rely solely on facts that have virtually no inherent interest beyond their importance. But much of what appears in the media—including some of the best of it—is inspired by the personal and the specific as against the impersonal and the general. Unfortunately, the very essence of a clinical trial is to discount the exceptional. Its findings reflect the group response, but not necessarily that of any one individual. To the

scientist, individual experience by itself proves little or nothing; yet personal experience is the essence of much journalism. Hence the demand from journalists for illustrative cases: people who have individually benefited. And that mollusc story raises all sorts of interesting angles (Why a mollusc? How ever did they find out? Might other molluscs have equally interesting properties?) that the MRC report does not.

Accommodations can of course be reached, and trialists with sufficient nous will be sure to have identified representative subjects willing to recount their individual experiences to those hacks who need them. But other conflicts are more difficult. The probabilistic rather than definite nature of many trial conclusions, for example. And there's also the burden of trying to get others to see why such elaborate methods need to be devised to answer the simple question, does it work? Anyone who doubts that these things can be explained to a lay audience should take a look at the James Lind Library's web site and its excellent explanatory essays. The logic of the randomised controlled trial—the "fair test"—is spelt out in all its magnificence. The reader learns why researchers make such a fuss about doing them according to the book. But even without references and most of the examples, between them the essays come out at well over 6,000 words.

Space and time are the two commodities in shortest supply in the media. Half a column in a broadsheet might give a journalist reporting a trial the space to say who had been compared with whom, or what with what. But even if space was available, outlining the finer points of research methodology is not part of what the media see as their role. And as for a 25 second report on a news bulletin, it may have time to do little more than quote a single finding and its possible impact.

To cap it all, some journalists writing or broadcasting about medicine—and most of those making the final decisions about what gets used and what doesn't—are generalists who may share the fears and confusion of the wider public. Take part in a trial and swallow something that might harm me? I think not. Randomised? I want my doctor to choose the treatment that's best for me, and not by tossing a coin. Take my chance and maybe end up swallowing a dummy pill when I might have taking a real one? No thanks, I want to be treated, not experimented on.

Some trials do get reported. From time to time there are articles and programmes that even explain why they're important and how they work. Of course, we may see a radical change in the nature of journalism—or even in the human mind. Short of these things, there's more chance of hearing Prayer for the Day on Beijing Radio than witnessing all the media coverage that enthusiastic trialists might like to see.

Dr Geoff Watts  
Journalist and broadcaster

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## LETTERS TO THE EDITOR

### A SCIENTIFIC DEFENCE OF HAIR ANALYSIS

*Dr Ellen Grant is a physician and medical gynaecologist in private practice and a founder member of the British Society for Allergy, Environmental and Nutritional Medicine. She is also on the editorial board of the Journal for Nutritional and Environmental Medicine. Dr Grant wrote to HealthWatch Committee member Dr David Bender to question HealthWatch's view on hair analysis:*

Dear David Bender,

I am surprised your site considers hair analysis unscientific. Hair samples have been sent to poor quality laboratories in the USA which do not do repeated routine sample control tests.

However I have been comparing the results from Biolab of mineral analysis blood (serum white and red cells), sweat and hair in my patients since the 1980s.

The British Medical Journal in 1989 published the results of our trial of dyslexic children which showed zinc deficiency in sweat compared with controls (1). The hair zinc levels did not always correspond to the sweat zinc level for the obvious internationally accepted reason that in zinc deficiency hair growth slows and very high or normal hair zinc levels can be found. However, the results matched for lower chromium and higher copper and toxic metals in dyslexics in both sweat and hair.

The effect of progesterones and oestrogens in lowering zinc and raising copper levels (higher copper/zinc ratio) is clear in simultaneous sweat, hair and serum tests in my first paper in the Journal of Environmental Medicine (2) which contains the proceedings of a Symposium on the effects of exogenous hormones.

While I would prefer not to use hair analysis alone, it is clearly useful for toxic metals but hair analysis can mislead for the two commonest deficiencies, zinc and magnesium, if blood and/or sweat tests are not also done.

Nutritional Medicine is a most basic foundation for all Medicine and should be an important part of medical

education. Nutritional analysis for people is at least as important as an annual MOT for cars.

Ellen Grant

### **DR DAVID BENDER REPLIES**

Dear Dr Grant

One major problem with hair zinc analysis is that many shampoos may contain zinc, which is adsorbed onto the hair when it is washed. Joyce Treuherz read a paper at a Nutrition Society meeting some years ago, and showed a bimodal distribution of hair zinc—although it does not appear in the published paper (3) she admitted in discussion that this was almost certainly due to use of shampoos that did or did not contain zinc. At that time, some shampoos contained high levels of zinc, although this may no longer be the case.

A further problem is that sweat contains a large amount of zinc; this may or may not affect hair analysis, but it certainly affects toe-nail zinc analysis (another method that has been tested for assessment of zinc status). Some years ago I got involved with a podiatry student's research project and we measured zinc in different regions of the toe-nail, including the part that is normally under the skin. We found a considerable gradient of zinc concentration, increasing with the age of the section of nail, and a gradient across the nail corresponding to the direction that (I am told) sweat travels around the foot (4).

David Bender

### **DR ELLEN GRANT REPLIES**

Dear Dr Bender,

Zinc deficiency is one of the most important diagnoses in clinical medicine. The function of hundreds of enzymes are impeded when zinc is deficient. It is a great pity that the diagnosis of zinc deficiency has been hindered by lack of availability of the most reliable tests and confusion over the results of hair analyses.

In children serum zinc is often within the normal reference range even when zinc is very low in a passive sweat sample which has been collected for one hour from the skin of the back. Zinc deficiency can be confirmed from analysis of white blood cell concentrations. A sweat test can be repeated hourly or daily and repletion of severe deficiency can take up to 14 days, or longer if gut absorption is also impaired. (Although other labs have started to provide the sweat test it is very time consuming compared with WBC zinc so it is the latter that tends to be used instead by other good labs.)

If levels of zinc were very high in a hair sample, a source of contamination would be sought. At one time an anti-dandruff shampoo had this effect, although not in any of my research subjects or patients. Newly grown hair from the nape of the neck is collected as older longer hair gives different results.

Our studies in 1981 (5) and 1989 (1) found significantly higher concentrations of copper and cadmium in hair, and also in sweat in 1989, in dyslexic children compared with matched controls. Sweat zinc was severely deficient in the dyslexic children, being 66% lower than that for control children. Zinc deficiency allows accumulation of toxic metals which may be important causes of the increase in autism, asthma, dyslexia and hyperactivity in the past few decades (6,7).

Ellen Grant

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## BOOK REVIEW

### MMR and autism. What parents need to know by Dr Michael Fitzpatrick

Published by Routledge, London, June 2004. 218 pages with index. Hardback ISBN 0415321786 price £45.00; Paperback ISBN 0415321794 price £14.99

*The Observer, 11 July: 'Revealed: black market trade in mumps vaccine'. Thus do middle class parents put their children at real risk, and put money into the pockets of private clinics, to avoid the risk of MMR vaccine making their children autistic. Radio 4 Today programme, 8 July: John Humphrys interviews the epidemiologist, Professor Jean Golding, who has won funds to research the causes of autism. Aggressively, he concentrates on MMR, "Some scientists believe..." He keeps pressing Professor Golding on whether a link with MMR could emerge from her research.*

**She would have done well to have directed Mr Humphrys to Dr Michael Fitzpatrick's book.** He proceeds logically through the MMR story and identifies all the ironies, such as vested interests ruling out any orthodox view but not counting for the motives of private clinics, and the way MMR activists pour scorn on medical science unless it supports their beliefs. No rational person could read it and still hold any notion that MMR causes autism, although there's a problem with his sub-title. The book is indeed what parents need to know but the story has moved beyond the rational, and some of the evidence is quite complicated.

The book is a tour de force. Extensively researched (there are 18 pages of references) and impeccably argued, Fitzpatrick mostly eschews scorn, a scorn that I cannot help feeling for some of the major players. The book is up to date. While it was in the last stages of preparation, various retractions and statements appeared in the Lancet after researcher Andrew Wakefield was discovered to have had a conflict of interest. These are dealt with, entirely appropriately, as a postscript to the preface—a preface in which, for those who do not know, Fitzpatrick tells the story of his own son, who developed autism after being inoculated with MMR. But 'after' does not mean 'because of'—probably the most important reason for the public misunderstanding of science.

Fitzpatrick is critical of Tony Blair's refusal to say whether his son Leo received MMR, a crucial point in the story. It seemed to me clear, as it was to the middle classes at the time, that Leo had not been inoculated. Fitzpatrick cites the media research showing the astonishing proportion of the population who recall this incident.

Anyone who followed the frenzied e-letters in the BMJ that were prompted by the reviews of the television play Hear the Silence will realise that this book will have no effect whatever on those who believe (the word is apposite) that MMR causes autism. One e-correspondent described Fitzpatrick as evil. A common rejectionist position is that the question can be answered only by studying autistic children, in other words that epidemiology cannot answer it. Fitzpatrick will not persuade them. Another common position is to blame orthodox medicine for autism, because neither cause nor cure is known. Fitzpatrick has sympathy for them, but no solace other than to counsel constructive acceptance rather than destructive blame.

I have only one disagreement with Fitzpatrick. Although single vaccines are a poor substitute for MMR (another irony is that the single vaccines so sought after are less tested than MMR), I think that the situation would have been defused if the government had made them available. It would also have eased the government's two-faced posture of encouraging patient choice on the one hand while denying it for MMR. But I could be wrong, and there's no telling. We are where we are, and Fitzpatrick's last chapter shows just how far we have to go to get back to where we were.

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