

Newsletter no 51: October 2003

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FLUORIDATION: EFFICACY IN QUESTION

THE VALUE of fluoride in drinking water is being questioned in the face of moves which could give health authorities the power to compel water companies to add the chemical to water supplies, where health bosses and the public request it. The House of Lords voted in July this year to introduce the power as a new clause to the Water Bill. The Lords' amendment had its second reading in the House of Commons on 8th September and will be before a Standing Committee within the next few weeks.

There have always been those opposed to adding chemicals to public water supplies, but there has been little high quality evidence that fluoridated water poses serious risks to health. Recently, however, experts have raised a new question: does fluoridation actually work?

Studies of countries which have abandoned fluoridation found that rates of dental decay did not subsequently rise (and, indeed, continued to decline). In Western Europe, only England, Ireland and Spain still fluoridate some public water supplies. About 10% of the UK population receive water with fluoride added.

In December 2002, members of the government's last major study of the effects of water fluoridation (1) wrote to Hazel Blears, the public health minister, on the effectiveness of fluoridation in reducing caries, "We could discover no reliable, good quality evidence in the fluoridation literature worldwide. What we found suggested that fluoridation was likely to have a beneficial effect, but in fact the range could be anywhere from a substantial benefit to a slight disbenefit to children's teeth."

Water companies have had the power to add fluoride to water supplies since 1985 but have not done so for fear of legal action from those opposed to it. The amendment would give indemnity against legal action to water companies that add fluoride to their supplies, paving the way for the extension of fluoridation schemes throughout this country.

Reference

1. McDonagh M, Whiting P, Bradley M et al. A systematic review of public water fluoridation. NHS Centre for Reviews and Dissemination, University of York, 2000. ISBN 1 900640 16 3

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NEW FACES AT AGM

THERE WILL be new faces at this year's HealthWatch Annual General Meeting as members are invited to vote fresh blood onto the committee. Following the appeal in the last issue for potential new committee members, a number of prominent scientists and communicators have been put forward, including Professor Heinz Wolff, the journalist John Illman, and gynaecologist Gillian Robinson.

Tuesday 28th October 2003

at Lettsom House, 11 Chandos Street, Cavendish Square, London W1M 0EB

Reception 18:30

AGM 19:00

at 19:30 Nick Ross (HealthWatch President) will present the prizes to the winners of the second HealthWatch Prize for Clinical Research Protocol Appraisal. This competition, which is sponsored by a grant from the AJAHMA Charitable Trust, invites students of medicine, nursing and complementary medicine to spot flaws in the design of trials for a variety of fictitious complementary treatments.

- Aikaterini Denediou (UCL)
- Shirley Moore (Aberdeen)
- Runners Up: Mareeni Raymond (UCL), Donny Lim (Imperial), Kathryn Musgrave (Cambridge (Pembroke)), Simon Harrison (Bristol)
-

At 19:40 Nick Ross will present the HealthWatch Award to Dr Peter Wilmshurst; after the presentation Dr Wilmshurst will address the meeting on:

Obstacles to honesty in medical research

All members, non-members, and press are welcome to the AGM at the Medical Society of London, Lettsom House, 11 Chandos Street, London W1 on Tuesday 28th October. The reception begins at 6.30pm, followed by the meeting and talk by Dr Wilmshurst. Attendance is free, but anyone wishing to attend the buffet supper afterwards must inform John Garrow no later than the 23rd October and pay £25 per person in advance. Cheques (made out to HealthWatch) to MICHAEL E ALLEN, 12 Balmoral Close, Putney, London SW15 6RP.

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News: A FAREWELL TO “Dr HOPE”

AN ITALIAN physician who made his life’s work the promotion of an unorthodox cancer treatment has, on his death, been saluted by some of his country’s leading medics and politicians with fondness and admiration, despite the fact that his therapy could never be shown to work. Professor Luigi Di Bella of Modena, Italy passed away on 1st July at the age of 91.

In 1997 it was reportedly claimed that in the 25 years preceding, the professor had successfully treated more than 90% of 10,000 cancer patients. His method was to administer a cocktail of drugs including melatonin and somatostatin with vitamins, plus other drugs added according to the individual’s needs. Detailed results, however, were never released and his recipe remained a secret.

The Italian health authorities, backed by their then Health Minister Rosy Bindi, had understandably refused to pay for patients to receive the Di Bella treatment (costing up to \$5000 per patient a month) in state hospitals. When, however, a judge ordered that the government must pay on the grounds of “freedom of cure” the Health Ministry, under massive media pressure, began ten trials on 2,600 patients (1).

On 13th November 1998, an estimated \$20m later, Bindi called a halt to the research, which had found no positive effect. Though the professor claimed the trials had been rigged, media interest died rapidly, apart from isolated news reports of tragic cases in which individuals for whom all else had failed pleaded for what became known as the “miraculous cocktail”.

Di Bella was not forgotten by the press, however. His country’s national daily, La Repubblica (2 July 2003), devoted a full page to him the day following his death. He was remembered and admired widely for his compassion, humanity and the warmth of his relationship with his patients. Italy’s current Health Minister, Girolamo Sirchia, was quoted describing the professor as, “an honest person. The fact that his therapy could not be proven effective does not detract from the value of the man”. The headline saluted “Dr Hope”.

It is clear that Luigi Di Bella was no cynical exploiter of the sick and vulnerable—on the contrary he cared deeply about his patients and truly believed that his work, which he pursued tirelessly, was for the greater good of humanity. But was it? When researchers at Parma conducted a survey of patients’ expectations and reactions early in the Di Bella trial they concluded, as one might expect, that campaigns for unproven treatments can actually harm expectations, with psychological consequences for the patient (2,3). HealthWatch members will recall John Garrow’s report of questioning Di Bella as part of a TV studio audience (HealthWatch [Newsletter issue 31](#), October 1998) and his headline at that time, “Sincerity is not enough” is, sadly, still the case.

References

1. Italian Study Group for the Di Bella Multitherapy Trials. *BMJ* 1999; 318: 224–28.
2. Passalacqua R, Campione F, Caminiti C et al. Patients' opinions, feelings, and attitudes after a campaign to promote the Di Bella therapy. *Lancet* 1999; 353 (9161): 1310.
3. Remuzzi G, Arrigo Schieppati A. Lessons from the Di Bella affair. *Lancet* 1999; 353 (9161): 1289.

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NEWS IN BRIEF

WHILE MOST people would rather avoid anything that is highly radioactive, one Greek holiday promoter is using the high local radioactivity levels as an attraction for health tourists. The website, which praises the hot springs on Ikaria island, says, "Ikaria's abundant therapeutic radioenergised spring sources have been identified as amongst the best in the world in terms of healing qualities, radioenergy and water supply," quotes New Scientist, who found the website on <http://www.island-ikaria.com/nature/springs.asp>

New Scientist, 27 September 2003

MAGNETS don't relieve pain after all, reports the Journal of the American Medical Association. Devotees and manufacturers have long claimed that the application of magnets to various parts of the body can dispel pain, despite the lack of plausible explanation. However doctors from the prestigious Mayo Clinic report that their randomized, double-blind, placebo controlled trial of 101 adults diagnosed with plantar heel pain found no significant difference in levels of relief between those using active or sham magnets.

JAMA 2003; 290: 1474-1478.

THE BANNING of barley straw, reported recently in a snippet from the Weekly Telegraph, is intriguing. According to the report the sale of barley straw patches, currently found in garden centres and used to clear murky pond water, will be forbidden under a European Union directive unless their mode of action can be explained and lack of harm proven. No-one knows how they work, and it would be too costly to investigate scientifically, so by default they must go, it seems. One wonders if the directive (not named in the report) also covers health products. But perhaps the ban only applies if, like barley straw, they actually work?

Weekly Telegraph, 24 -30 September 2003

OUR THANKS and apologies to those who pointed out an error in issue 50. We referred incorrectly to the "UK Cochrane Centre for Evidence-Based Medicine". The correct name is, simply, the UK Cochrane Centre.

PLEASE NAME THE SOURCE

THE EDITOR acknowledges with thanks the many press cuttings and leaflets sent by members and others interested in HealthWatch. However many of these are sent anonymously. In order that senders can be contacted for further information if required, it would be greatly appreciated if they could include a brief note with their name and contact details.

As always, articles for the HealthWatch Newsletter and letters to the editor are welcome. Correspondence, which should be sent to the address on the right, will always receive a reply, though publication cannot be guaranteed. The editor can also be contacted by e-mail at newsletter@healthwatch-uk.org and aims to reply to all e-mails received within seven days.

Opinions expressed in letters and articles published in the HealthWatch Newsletter belong to the authors and do not necessarily reflect the views of HealthWatch. The editor reserves the right to amend text where necessary but will, where possible, consult the author to ensure accuracy is maintained.

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Opinion: PATIENT PACKS AND MEDICINE QUALITY

The UK lags behind the rest of the European Union when it comes to the labelling of drugs dispensed to the public, leaving patients vulnerable to the dangers of ineffective or even harmful counterfeit products, says Michael E Allen, a pharmacist with 26 years' experience in Drug Regulatory Affairs.

WHEN I STARTED my retail apprenticeship long ago, I was considered deeply weird by my apprentice master for objecting to counting out tablets on my sweaty palm before shoving them loose into a cardboard tablet skillet. I obtained a hygienic tablet counter; then, as technology improved, moved up to a 9 to 1 balance; then to an electronic tablet counter.

This improved hygiene, but did nothing to reduce the possibility of cross-contamination or human error, which had to be minimized by care and cross-checking. The practice of dispensing tablets and capsules in cardboard skillets long persisted before pharmacists could obtain payment from the Ministry of Health to purchase humidity-resistant containers and, with patients likely to store medicines in the bathroom cupboard and re-use them years later, many a useless or dangerously deteriorated product must have been taken. Information on the medicine dispensed was considered too dangerous to be shared with anyone as ignorant as the patient; much time was spent removing all identity marks from packs, to be replaced with "The Tablets—Take as Directed by your Doctor" or a similar message.

With agreement throughout the European Union, quality of product and of information provided to the patient has been transformed, but at the point of delivery of medicines to the patient the UK has lagged behind the rest of the EU. The usual suspect—cost saving by the National Health Service—is responsible. The UK has adopted Directive 92/27, now incorporated into Directive 2001/83/EC, which decrees that a prescribed medicine should be dispensed in clearly labeled original patient packs and should be accompanied by a patient information leaflet (PIL) specific to the product. However, it is estimated that 30% of medicines may currently be dispensed in the UK without a PIL or not in a patient pack (1). The Department of Health has suggested a stratagem to ensure a PIL is given to the patient when medicines are dispensed from bulk packs: this involves offering to pay pharmacists to have a photocopy machine so they can copy them in the pharmacy. Such an approach is patently flawed: copyright law and product liability issues are involved should another company's PIL be attached to a product and this would not in any case achieve the target of improving quality assurance at dispensed level.

The easiest way that quality and identity of product can be assured and the correct PIL attached is to adopt the system of patient pack dispensing, as have the other EU member states. Benefits of patient packs include:

- identification of medicine and manufacturer, with complete batch data;
- details of dosage form constituents, allowing problems with allergic response to be identified;
- instructions on dosage and storage of the product;
- retention of the manufacturer's packing, designed to protect the product and keep it from deteriorating.

The detailed case for quality improvements, including but not exclusively focusing upon the issue of patient packs and PILs, is made by a Norwegian pharmacist (2); his paper's title is perhaps an example of Scandinavian irony. He points out that, while quality standards for UK retail pharmacy were once far ahead of those of other professions, today consumer goods including Coca-Cola, cornflakes and toilet paper are better labeled and easier to trace backwards from consumer to manufacturing batch than UK prescription medicines.

He identifies these problems as current for the UK:

- pharmacy labels obliterating important information when patient packs are used and over-labeled;
- the extensive use of parallel imports so that patients are presented with badly re-labeled product of varying appearance (a matter also subject to bitter comment by representatives of patient groups (3,4));
- failure to ensure that batch identity information gets beyond the pharmacy and is provided to the patient; and
- failure to provide critical information to the patient in a coherent manner.

Much progress has been made by manufacturers despite the lack of leadership by the Department of Health and most products are issued in patient packs. However, this does not apply to all generic products. When I am issued with re-packaged medicines which have no clear identity or specific PIL attached, I return them to the pharmacy concerned. If the pharmacist does not agree to provide a properly identified product, I take back the prescription and go elsewhere. I recommend that everyone do this in order to put pressure on the system at the pharmacy level. However, not everyone is aware of the issues or able to argue their case, so there is an obligation for the DoH to take responsibility, even if this does increase the cost marginally.

In addition to the problems discussed in the Pharmaceutical Journal articles cited, I believe that parallel importation and the use of products with inadequate identification may facilitate illegal import of products that have not gone through the proper regulatory approval. This opens the way for counterfeit or poor quality products which will not act as intended or may be harmful.

Michael E Allen
Regulatory Consultant and Honorary Secretary, HealthWatch

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1. Mahadevaiah K. Clear benefits for patient safety and better use of pharmacy resources—the Royal Pharmaceutical Society's view. *Pharmaceutical Journal* 2003; 270: 686.
2. Lyftingsmo S. Let the UK be a forerunner in the user-testing of patient pack labels and leaflets—a European perspective. *Pharmaceutical Journal* 2003; 270: 753.
3. Thorpe T. Clear and accurate information needed in order to keep patients informed—the Parkinson's Disease Society view. *Pharmaceutical Journal* 2003; 270: 724.
4. Mitchell S. Patients are struggling with the daily realities of an unsatisfactory system—the Epilepsy Action perspective. *Pharmaceutical Journal* 2003; 270: 723.

The *Pharmaceutical Journal* has collected relevant papers (including those cited) in their patient pack campaign. These can be found on www.pjonline.com/noticeboard/series

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Evidence: DETOX DIETS: DO THEY WORK?

The popularity of "detox diets" persists even though the evidence for their efficacy is somewhat shaky.

Nutritional biochemist and HealthWatch Committee member David Bender passes a scientist's eye over some of the diet books currently available. He is not convinced that we would benefit from following their advice.

ONE OF the trends (I hesitate to call it a fad) over the last decade is the detox diet—various diet regimes intended to clear the body of toxic waste material. Some of these are designed as part of a weight reducing diet, others are a matter of “life style”, making no claims about weight loss. What they all have in common is the mistaken belief that the body accumulates large amounts of toxic waste that it cannot deal with.

This waste is, it is said, responsible for ailments ranging from tiredness, bad circulation, high blood pressure, headaches, dizziness, dry and wrinkled skin, back pain, stress, weight gain and indigestion to slow thought processes, a sluggish metabolism and a weakened immune system. To quote Belinda Viagas (1), “To detox is to trust that your body’s innate intelligence and homeostatic mechanisms will win through, and to give yourself the right internal environment for this to happen.” She tells us that we should “Spring clean our bodies—like our homes”.

There are three main themes running through the various detox diet plans:

- accumulation of toxic waste in the body (and especially in the intestines);
- accumulation of environmental toxins in the body tissues, overwhelming our capacity to metabolise them;
- a “spiritual” or mystic dimension, tracing detox diets back to ancient oriental mystics. Savill and Hamilton² tell us that detox is based on “highly sophisticated methods of cleansing” developed by “ancient yogis” thousands of years ago

Accumulation of toxic waste in the body

Savill and Hamilton (2) tell us that, “if the digestive tract is not working properly then the cellular waste like worn out cells, deactivated hormones and cholesterol, and exogenous toxins like pharmaceutical drugs, can’t be removed effectively via the liver and bile..., this starts to put more strain on the other elimination channels and perpetuates a condition where the body as a whole becomes overloaded with toxins...” and, “the liver stores toxic material if the body’s cleansing channels as a whole are overloaded.” They go on to tell us that one of the principles of detox is to, “remove old residues from the digestive tract”. Therefore you may have diarrhoea; this is hardly surprising if you are consuming their diet based on large amounts of soluble fibre and fruit juice.

I am worried by the thought that there are old dead cells and residues of undigested food in my intestine that appear to have been lurking there for many months or years. There seem to be two ways of dealing with this problem: a detox diet (which may last for as little as one day up to several weeks) and colonic irrigation.

The various detox diets range from fasting for a day, or eating only one type of fruit (but as much as you like) for a day, through a range of more or less sound diets, all of which are based on high consumption of fruit and vegetables, and juices. Being high in fibre, all of these will increase the volume and softness of faeces, and will indeed “flush out” the content of the gut. All the diets also recommend drinking 1.5 to 2 litres of water a day (the next issue of this newsletter will include a scientific article on the subject of how much water you actually need to drink)—sometimes this must be pure water, other authors permit tap water or fizzy mineral water, and most ban tea and coffee.

Some detox diets make much of the fact that fruits and vegetables yield an alkaline residue or ash, while meat and dairy produce yield an acidic ash; while this is correct chemistry, it has little physiological relevance. Most make use of a variety of herbs for their presumed health-giving properties. Not all of these are exotic herbs: “Beetroot is a great tonic for the liver...pineapple and grapefruit help the gall bladder to release its store of fat busting bile into the digestive process” (1). Others recommend additional supplements to enhance intestinal health, including fructo-oligosaccharides (there is indeed evidence that they enhance the growth of beneficial intestinal bacteria), probiotic supplements (again there is evidence that regular intake of *Lactobacillus* has beneficial effects on intestinal bacteria), and supplements of the amino acid glutamine which is said to be, “highly beneficial for leaky gut ... can also help with cravings for sugar, stimulants and alcohol and it’s beneficial for the lymphatic system” (2). There is little or no scientific basis for this.

A number of authors make much of the virtues of raw fruit and vegetables (and juices made from them)—they have a high “life force potential” (whatever that is) and contain enzymes. This last is true, but unfortunately the enzymes will be denatured and inactivated in the acid conditions of the stomach, so will have no more beneficial effect than any cooked protein. I am also unsure about the advice to chew your fruit and vegetable juice to “make sure it is properly mixed”—surely it will have been well mixed in the juicer, not to mention while pouring it into the glass.

Some diets go further, and ban wheat and dairy produce—they may permit yoghurt made from goat or sheep milk, but not cow milk. This seems to be mixing in a different set of problems. Allergy to the wheat protein gluten (coeliac disease), and allergies to cows’ milk proteins are not uncommon, but it is hardly fair to suggest that most of us are intolerant of these foods. However, there is a body of (largely anecdotal) evidence that eliminating wheat and dairy foods from the diet may be beneficial in treatment of autism and schizophrenia.

Colonic irrigation is a “therapy” that is essentially an enema—installation of water into the large intestine to

cause diarrhoea, and so clear the gut of its contents (these uneliminated gut contents are, of course, the cause of all our ills). Scrivner (3) tells us that colonic irrigation is "an internal bath that helps to cleanse the colon of accumulated poisons, gases, faecal matter and mucus deposits", and the after effects are "a feeling of wellbeing, lightness, mental clarity, loss of any bloated feeling, relief from constipation (that's correct at least) and clearer glowing skin". Isherwood (4) gives an amusing account of his introduction in California in the 1940s to the yoga technique of washing out the intestines, and Scrivner (3) gives a comforting description of how "the modesty of the client is observed through the treatment" by a practitioner. However, apart from as a treatment for chronic constipation there is no scientific basis for its use.

Equally, I am not convinced that brushing my skin (with a dry natural fibre brush, as recommended by Belinda Viagas (1) to remove dead cells) will enable it to eliminate waste more effectively, so easing the burden on my liver and gut. However, she tells us that "The skin can become clogged with dead cells and this reduces your ability to eliminate through the skin ... when your skin is not functioning well the strain has to be taken up by the body's other eliminating routes and organs" ... "Regular skin brushing also stimulates your lymphatic system—the body's waste collection service" (I am not sure what this means, it is not in my text book of physiology). However, she seems to be convinced there is an effect of skin brushing, since she warns us, "Do not skin brush if you suffer with nervous irritation or any major pelvic disturbances".

Accumulation of environmental toxins in the body

In addition to endogenous toxins and accumulated waste, some authors are concerned about the accumulation of environmental toxins in our bodies. It is certainly correct to say that over the last century we have been exposed to a wider variety of environmental toxins than at any previous time, but it is not correct to say, as do some authors, that our bodies cannot metabolise them—most can be metabolised, although a number are indeed carcinogenic. The recent decision by the European Commission to ban a large number of chemicals that have not yet been tested to modern standards will doubtless fuel the arguments of those who claim that they are hazardous, and can be eliminated by detox diets—they will claim that because they have been banned they must be harmful, whereas they have been banned because they have not yet been tested adequately rigorously.

Among those damning "synthetic chemicals" is Dr Paula Baillie-Hamilton (5), who contributes the concept of "chemical calories". These are environmental toxins said to disturb the body's normal weight control mechanism, and cause us to gain weight regardless of food intake. Lettuce (14 kcal /100g) grown using "synthetic chemicals" is, according to Baillie-Hamilton, more fattening than avocado (134 kcal /100g). I find the evidence offered in support of this theory unconvincing, as does my colleague Professor John Garrow (see his review of her book in HealthWatch [Newsletter 46](#), July 2002 and Dr Baillie-Hamilton's reply in [issue 48](#), January 2003). The solution offered, of course, is a detox diet, based on 2 to 3 litres per day of pure water (which flushes out toxins in sweat and urine) and organic fruits and vegetables, supplemented with charcoal, soluble fibre and bentonite to adsorb the toxins that are released from adipose tissue and excreted in the bile, and vitamin, mineral and amino acid supplements to "feed the body's detoxication system".

Many authors recommend organic rather than conventionally grown fruits and vegetables because they are supposed to be free from toxins, and therefore safer. Magkos et al (6) argue that there is little evidence that organically produced food is either more or less safe than conventionally produced food. By definition, organic produce will contain very much lower levels of agrochemical residues than conventionally produced food, but there is no evidence that agrochemical residues (at permitted levels) are harmful. By contrast it can be argued that organically produced food may be less safe than conventional produce. Use of manure rather than chemical fertilisers may cause contamination with pathogenic organisms. Organically grown fruit and vegetables may contain higher levels of natural toxins, produced by the plant in response to stress from pests and fungi, than conventionally grown produce. Indeed, the varieties that are most suitable for cultivation without the use of agrochemicals are those that produce large amounts of natural pesticides and other toxins, many of which have been shown to have carcinogenic or mutagenic potential. They conclude that the message to consumers is that "organic" does not mean "safe".

The spiritual dimension

Many authors include in their accounts of detox concepts such as "energy" and "life force", and attempt to trace detox back to ancient religious and mystical cleansing regimes. ("Energy" here has nothing to do with chemical or physical energy, but is psychic or spiritual energy—see Lewis Wolpert's letter on this topic in HealthWatch [Newsletter issue 45](#), April 2002).

It is certainly true that most religions have periods of self-denial, ranging from prolonged fasting in some oriental religions, through the Muslim holy month of Ramadan, when food is not eaten during daylight, and one-day fasts in Judaism, to abstinence from meat during Lent in Eastern Orthodox Christianity and abstinence from meat on Fridays in the Roman Catholic tradition. I doubt that any of these religions devised periods of abstinence as a means of eliminating toxic chemicals or waste from the body—rather they were (and by the orthodox still are) regarded as providing a means of freeing oneself from the concerns of the body (finding, preparing and eating food) to concentrate on prayer and reflection, or simply as a way of making the foods more appreciated afterwards.

During prolonged fasting (or prolonged intake of a very low calorie diet) many people experience a sense of lightheadedness, or dizziness. To the mystic this might signal divine revelation; to the proponent of detox as a way of eliminating toxins from the body it signals the release of toxins from storage, ready to be eliminated; to the scientist it simply reflects the physiological response to starvation—decreased blood glucose and elevated ketone bodies.

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4. Isherwood C (1980) My guru and his disciple. Methuen, London.
5. Baillie-Hamilton P (2002) The detox diet: eliminate chemical calories and restore your body's natural slimming system. Michael Joseph, London.
6. Magkos F, Arvaniti F & Zampelas A. Putting the safety of organic food into perspective. Nutrition Research Reviews 2003; 16 in press.

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Meeting report: ON WHAT EVIDENCE

Professor John Garrow, HealthWatch's Chairman, 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 earlier this year. At the final session on Medical Education Garrow presented a paper titled "On what evidence should treatment be based?" from which the following is taken.

GARROW went to the new University Hospital in Jamaica in 1952 as a newly-qualified and, he says, very naïve doctor. He believed that advice in clinical textbooks was a reliable guide to good treatment. His clinical experience soon taught him that orthodox teaching was often wrong. For example, at the time, it was taught that normal adults required 70 g of protein daily to maintain good health, and that severely malnourished infants should be treated with intravenous infusions of aminoacids. However he was involved in nutrition surveys that discovered very healthy adults eating only half the "required" amount of protein, and observed that aminoacid infusions were more likely to kill, than to save the lives of, malnourished children.

Today, medical students are taught to apply "evidence-based medicine". Ideally a treatment should have been shown to be effective by randomised controlled clinical trials, but this also presents difficulties. There never have been (or will be) randomised controlled trials to show the effect on the health of adults of eating only 35 g protein a day, or infusing aminoacids solutions into severely malnourished children. Therefore treatment in such cases must be guided by less highly-regarded indicators, such as clinical experience.

Yet even in the case of the placebo-controlled randomised trial, evidence must be carefully evaluated. Garrow invited the audience to comment on a report of a placebo-controlled trial of orlistat (1), which showed the weight loss in one year of a group of patients on orlistat, or a placebo control. The text said "Weight loss was 68% greater on orlistat than placebo ($P < 0.001$)". This was obviously true, since the diagram showed the orlistat group lost 10.3 kg, and placebo group only 6.1 kg, and the 4.2 kg difference between mean in drug and control group at 52 weeks was clearly highly significant. This is the type of evidence on which decisions to licence a drug are based, but Garrow claimed that the way the data were presented were highly misleading in several respects.

- It may have been a placebo-controlled trial, but it was not double blind. Thirty-one per cent of those on orlistat complained of oily/fatty stool, so they could have guessed their treatment group.
- The patients' initial mean weight was around 100 kg. An extra 4.2 kg weight loss in a year may be a statistically significant difference, but is not clinically significant in patients who must lose in the region of 35 kg to achieve normal weight.
- Of the orlistat weight loss of 10.3kg, approximately 4kg was lost during the 4-week run in period on placebo. So the actual weight loss on orlistat was only in the region of 6.3 kg
- In the first year 80 patients on placebo and 59 on orlistat dropped out, yet the analysis was on the 340/343 who started. For those who dropped out the last weight was carried forward for analysis, so those who dropped out and then regained weight are not shown in the analysis. This means a too-favourable impression is given of both groups' weight loss.
- Taking into account the variation within each group, the weight loss among 66% of the orlistat group after one year ranges from 1 kg to 20 kg, with the remainder losing either less or more than that range. Amongst the placebo group, in 66% their weight change was in the range of +3 kg to -16 kg. Therefore there is far more overlap in the weight loss of the two groups than the figures given imply.
- Orlistat induces weight loss is by reducing absorption of dietary fat, however no data are (or have

subsequently been) given concerning faecal fat excretion in the two treatment groups.

This example shows that, even in trials by distinguished investigators reported in prestigious peer-reviewed journals, it is still necessary to interpret critically the evidence of efficacy provided by very large and expensive placebo-controlled randomised trials.

The "gold standard" of reliable evidence is now a meta-analysis of all the available evidence from trials of the treatment being considered. In the last part of his talk Garrow considered the apparently contradictory conclusions arising from recent meta-analyses of the efficacy of mammography screening to reduce deaths from breast cancer. Olsen & Gøtzsche (2) concluded that "there is no reliable evidence that breast cancer screening reduces mortality". The report of the IARC Working Group (3) concluded "National reduction of breast cancer mortality may be of the order of 10 to 20%". A review article by EDC Anderson (4) concluded "the reduction of mortality ... in women who participate in screening programmes is about 35%". He asked the audience: is it possible that all three estimates of efficacy of screening (0%, 10 to 20% and 35% reduction in mortality) are correct?

His answer was that, according to a recent review (5), the number of women who need to be screened to prevent one death from breast cancer after 14 years observation is 1224 (95% confidence interval 665 to 2564). The reason we get three different estimates is that the three papers seek answers to different questions.

- Olsen and Gøtzsche ask: Can the possible number of lives saved, in meta-analysis of trials of good quality, exclude zero? To this question the answer is NO.
- The IARC Working Group ask: What is your best guess at the percentage of lives saved by good screening programmes, in favourable populations? They answer: 10 to 20%
- Miss Anderson asks: What is the decrease in breast cancer mortality among the enlightened women who comply with breast cancer screening programmes? She answers: 35%.

The final message of Garrow's talk was that evidence-based medicine is excellent, provided that there is good evidence from randomised controlled trials that are relevant to the problem. Often there is no such evidence, or what appears to be good evidence is presented in a biased manner so it is misleading. Those who seek to use evidence-based medicine must not simply accept the claim that "Clinical trials show...", but must be willing and able to evaluate the evidence. Evidence-based medicine based on bad evidence is bad medicine.

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Letter to the editor: THE ETHICS OF INFORMED CONSENT

John Mew, specialist orthodontist and Clinical Director of the London School of Facial Orthotropics, writes:

Dear Sirs,

I WAS interested in Neville Goodman's article in the last issue of the Health Watch Newsletter ([issue 50](#), July 2003). He suggests that it would be justifiable for a doctor to "use as much pressure short of threats" to discourage a patient from accepting an inappropriate treatment. This is fine if the doctor is a reasonable man but not all are and yet all have to equip their patients with the information required to give informed consent.

Modern specialisation requires high levels of technical knowledge and there is a risk that inexperienced clinicians will accept the current rules and colour the information offered in order to save patients from accepting treatment they deem inappropriate. An example of this is the application of therapies involving dental extractions within orthodontic training and practice to the extent that non-extraction techniques are often ridiculed. Even if teeth are not extracted at the start of treatment, extraction will usually be precipitated later. There is no clear evidence to justify one approach over the other and both extremes have been orthodox, at different times over the past decades.

It can be dangerous to be sure you are right, certainly in the case of Informed Consent.

Yours faithfully
John Mew

NHS Initiatives: THE EXPERT PATIENT WILL SOON BE HERE

THESE ARE encouraging reports of a plan to harness a vast and previously untapped body of expertise in the field of healthcare. It is high quality, readily available, requires no new technology and will almost certainly save money as well as improving the care of the chronically ill. Often disregarded or even treated with contempt in years gone by, the expertise of individual patients in the field of their own chronic illness is at last to be recognised and incorporated into England's health services.

Patients with chronic diseases often know more about their condition than their own doctor does. Certainly they are experts in the big picture—what it is like to live, day to day, with the disease, and how effectively (or ineffectively) each health professional in the team contributes to their overall care. Increasingly, patients are also undertaking their own research into the condition, an activity that used to be regarded as more of a threat to their doctor's authority than an aid to their condition's management.

Furthermore, the number of patients with chronic diseases is on the increase, an inevitable result of the population living longer. Thankfully, our increasingly overstretched NHS has recognised that its patients' knowledge base can no longer be ignored.

Launched by the Government in September 2001, "The Expert Patient—a new approach to chronic disease management for the 21st century" set out recommendations for the development of a programme which would allow such patients to have more control over their own care. A seminar held at the Royal Pharmaceutical Society on 19th May this year favourably reviewed the initial anecdotal results (1).

The first stage of the Government's Expert Patients Programme (EPP) began in May 2002 with the launch of pilot courses for patients, who are trained to manage their conditions better on a daily basis. The programmes involve a two-and-a-half hour workshop session held weekly for six weeks, in which from eight to 16 participants are trained in topics such as pain management, medication, diet, exercise and communication.

At first only 25 primary care trusts were involved but latest figures from the Department of Health show over 200 PCT's have agreed to take part and at least 100 have already run at least one course. While formal evaluation is not yet complete, initial feedback from the pilot stage which will run until 2004 is encouraging.

Speakers at the RPS seminar included Dr Stuart Eastman, a general practitioner in Wiltshire, who reported on the change in an osteoarthritis patient after attending a self-management course. "She has become less dependent on me, her physiological well-being has greatly improved. The doctor-patient relationship has become one of mutual co-operation rather than one of dependency and I have seen this trend repeated with other EPP course patients."

Multiple sclerosis patient Tom Stebbings, an early EPP course participant and now a course tutor, commented, "There are hundreds of chronic conditions but the four things that emerge during the sessions time and time again are mobility, pain, depression and loss of self-esteem. We teach people how to manage them. You may have to downsize your aspirations but it isn't all doom and gloom."

Support for the scheme came also from outside the UK. Dr Malcolm Battersby of Finders University, Australia talked about the new international interest in what is known elsewhere as "self-management". He talked about results from a similar programme, called "Partners in Health", for which a pilot gave the following results: 70 per cent of patients who took part felt better able to cope with life, and 50 per cent of general practitioners had substantially changed their management of patients as a result of taking part.

We look forward to reading the full results of the EPP pilot trials and congratulate the Government on a promising new initiative. We may not have to wait much longer before we encounter a scene in a waiting room in which the door opens and a nurse says, "Doctor, your patient will see you now."

Mandy Payne
Editor, HealthWatch Newsletter

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Information about progress of the pilots can be found on <http://www.doh.gov.uk/cmo/progress/expertpatient>

Last word: FROM CROCODILES TO "MIRACLE DRUG"

A RECENT e-mail circular (August 24th 2003) was advertising a new miracle drug called "the Antidote". According to the web site that promotes it (<http://www.biologalmiracle.com/>), "The miracle healing powers of the Antidote can now be used to fight all known human viruses and bacteria. The common cold is a thing of the

past, even serious infectious diseases such as Cancer, AIDS, SARS and many other life threatening diseases can be made dormant by the massive power of the Antidote."

The Antidote is so valuable that you can only order four bottles (each a 5 ml dose) to any one delivery address—at \$49.95 per bottle. The on-line fact sheet tells us that the Antidote is taken orally as a single 5 ml dose taking 48 hours to become effective.

The compound was discovered as a result of a BBC TV documentary "The Secret Life of Crocodiles", filmed in Australia, and first shown on BBC TV on May 31st 2000. The producer, Jill Fullerton-Smith, wondered why it is that despite the "horrendous injuries" that crocodiles inflict on each other, their wounds rarely get infected, and she enlisted the aid of Gill Diamond at New Jersey Medical School in the USA. Diamond isolated a peptide from crocodile blood that had potent antibacterial action, and coined the name crocodillin (1). (It should be made clear at this point that there is no evidence that Fullerton-Smith or Diamond are in any way connected to the claims made in the above website).

Neither MedLine nor the US Food and Drug Administration web site gave anything at all on searching for "crocodillin"; a MedLine search under "crocodile" and "antibacterial" yielded one paper, a brief note by an Israeli team, published in 1999, reporting the presence of antibacterial peptides in blood and tissue samples from a variety of birds and crocodiles (2). A Google search for "crocodillin" yielded a number of press releases and home pages about crocodiles and infection, but no scientific research at all.

So, I have been offered as a miracle antiviral drug a compound that apparently has antibacterial (but not antiviral) action, although there is no published research to support this claim. Furthermore, it is a peptide, and hence likely to be broken down to its constituent amino acids in the stomach and small intestine, yet I am supposed to take it by mouth. I will let someone else have my ration of four bottles.

David Bender
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BAD SCIENCE EXPOSED

One of the most entertaining columns around at the moment has to be Ben Goldacre's "Bad Science" on Thursdays in the Guardian which exposes Press and Internet examples of careless, unsubstantiated or ridiculous science and health information. Goldacre, whose knuckles are no doubt raw from being rapped by his papers' legal advisers, brazenly names perpetrators (who, one speculates, might refrain from issuing retaliatory libel suits out of sheer embarrassment).

Recent columns have reported on a website which advises anyone travelling with homoeopathic remedies not to put said remedies through airport security x-rays, "as it will render their healing properties less effective"; reports of comfort eating in sheep; and a recently published book which claims depression can be controlled by a method which involves constricting the anal muscles 100 times a day.

For those who have missed them, previously published columns have been installed on the Guardian website, log on to <http://www.guardian.co.uk/life/badscience/>

You can send your own examples of bad science to Goldacre at bad.science@guardian.co.uk

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