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Newsletter no 23: October 1996

Melatonin could disrupt sleep patterns

Melatonin, a natural hormone which has been hailed as a cure for conditions ranging from jet-lag to ageing, could distort sleep patterns, say scientists from the University of Surrey's School of Biological Sciences and the Ministry of Defence.

By law, melatonin is available in this country only on prescription, although a report in the August issue of *HealthWhich?* claims that melatonin capsules are still widely available.

In a letter published in *The Lancet* (1) Benita Middleton, Barbara Stone and Josephine Arendt report data to support their assertion that "in some circumstances melatonin may have deleterious effects on sleep".

Two experiments detailed in the letter took the form of double-blind crossover trials of melatonin. In both studies, healthy young men were kept for periods of between 11 and 16 days in a closed environment in constant dim light. The men took either 15 mg melatonin, or placebos, every day and were told to eat and sleep when they wished.

While most subjects treated with melatonin retained a normal 24-hour sleep-wake cycle, the researchers found that in each experiment a minority of the men displayed highly irregular sleep patterns. One subject interspersed very short sleeps with much longer sleeps.

"The effect," say the authors, "may be theoretically explicable if melatonin acts primarily on the timing mechanisms of sleep".

> "Whatever the mechanism, it is clear that indiscriminate use of melatonin could lead to undesirable effects."

Reference 1. Middleton B, Stone B, Arendt J. Melatonin and fragmented sleep patterns. *Lancet* 1996; 348: 9026.

See also letter from Dr Andrew Herxheimer in Newsletter 24

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Mobile 'phone fears groundless?

The publicity scare surrounding power lines seems to have been replaced by a new panic with even less science to support it. Dr Neville Goodman searches - in vain - for grounds to believe that mobile phones might cause disease.

All has been quiet in the media for some months, but I do not expect for one moment that the power line cancer

scare *(Newsletter 21, April 1996)* has gone away.

The *British Medical Journal* quoted from a recent review in *Occupational and Environmental Medicine* (1) that "the evidence is not strong enough to support the putative causal link between residential exposure to magnetic fields and adult leukaemia, brain tumours, or breast cancer".

Those familiar with the British and (especially) US legal systems will know that evidence must never be allowed to get in the way of apportioning blame for misfortune. Have a look at Peter Ruber's book (2) if you doubt this. Angell's excellent review (3) of the silicone breast implant story touches on all the points that Huber makes. Most frightening is her telling that, "Several jurors..., as well as the head of a powerful advocacy group, have publicly said that the results of scientific studies did not matter to them.. medical research was irrelevant. All that mattered was what they believed, never mind why they believed it." Anyone who holds these views is simply unfit to be a juror (or a judge) in any court case that includes scientific evidence.

Unsurprisingly, the newspapers that have previously emblazoned details of the power line scare across their front pages did not publicise the findings of the recent review in *Occupational and Environmental Medicine.* But they may be getting bored, especially as there is a new scare. What is more, the new scare has the enormous advantage that there is as yet no evidence at all, only speculation.

"Mobile phone users 'face cancer risk' *(Times,* 3 June 1996). The *Evening Standard* the same day mentioned links with severe headaches, skin irritation and blurred vision and previewed a BBC Watchdog programme linking mobile phones with asthma, Alzheimer's disease and cancer. (Isn't it odd how so many putative health scares are for these same diseases?)

Which? (June 1966) was reassuring, and highlighted the concerns of the Alzheimer's Disease Society about the quality of the research being used to market a shielding device for users.

A brief search of Medline revealed only two scientific papers of relevance: one a news item titled "Brain cancer scare hits US phone manufacturers" (4); the other an article (5) in which it was claimed that 3 minutes' exposure to electromagnetic fields caused alterations in a number of neurotransmitters and cancer-related proteins. The abstract mentioned "Bi-Digital O-Ring Test Dysfunction Localization and Molecular Identification Methods" for detecting these substances, one of which, acetylcholine, is as far as I am aware undetectable in humans under the conditions of the experiment.

Asking Lycos on the Internet for 'phone' AND 'cancer' produced as the first document an NCI summary stating quite baldly that case-control studies were now being done, but that there was no evidence of a link between mobile phones and cancer.

Perhaps the media should be forced to republish John Paling's 'Richter scale' of risk *(Observer* 2 June) every time they report a health scare. How many people know that the yearly risk of needing emergency treatment in hospital for an injury from a sink or toilet is greater than 1 in 10,000? More seriously, this same figure is the yearly risk of dying while driving. The risk for mobile phone users is certainly increased-by not paying attention to the road ahead; brain tumours are not part of the equation.

However, I do have evidence that mobiles addle the brain. In a London bar, I overheard a woman (it was impossible not to) negotiating the release of her car from a wheel clamping company by giving her credit card details, home address, and other personal information over the phone.

See also Newsletter no 32

Neville Goodman, Consultant Anaesthetist, Southmead Hospital, Bristol

References

1. Li C-Y, Thenault G, Lin RS. Epidemiological appraisal of studies of residential exposure to power frequency magnetic fields and adult cancers. *Occupational and Environmental Medicine.* 1996; 53: 505-510.
2. Huber PW. Galileo's revenge: junk science in the courtroom. Harper Collins, 1991
3. Angell M. Shattuck lecture - Evaluating the health risks of breast implants: the interplay of medical science, the law, and public opinion. *NEJM* 1996; 334: 1513-8.
4. Anon. *Ann Oncol* 1993; 4: 260-261.
5. Omura Y, Losco M. Electro-magnetic fields in the home environment (truncated) *Acupunct Electrother Res* 1993; 18: 33-73.

See also Newsletter 26

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Regulate dietary supplements, says CA

The Consumers' Association has called for a stricter framework to control the sale of dietary supplements such as guarana, aloe vera and products containing hydroxycitric acid (promoted as a slimming aid).

Forty per cent of people taking dietary supplements believe they are medicines, says a survey of 500 supplement users published in *Which?* magazine. In the eyes of the law; however, pills and potions which do not carry a medical product licence are classed as foods and banned from making medicinal claims. Despite these regulations, more than half of people questioned took supplements for a specific health problem, the survey found. Some companies are able to bypass the need to make explicit labelling claims by using suggestive product name and pack design or editorial-type advertisements.

For some ingredients, such as ginseng, there is evidence to support certain health claims. But ingredients may also produce adverse effects or be contraindicated in particular people and currently the rules governing sale of dietary supplements do not demand adequate information on these.

The Medicines Control Agency has powers to act on producers who make medicinal claims for their products, but only if they receive a complaint. The agency does not actively monitor the market.

The association proposes setting up a central register for all products including a list of acceptable claims; tighter controls on labelling; warnings of adverse reactions; quality assurance standards and a review of how the market is monitored and policed.

Which? September 1996; *Health Which?,* August 1996

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"It demolished my rolls of fat"… advertising watchdog disputes claim

Complaints continue to be upheld against slimming companies who make misleading claims in their advertisements.

The Advertising Standards Authority received five objections to mailshots produced by a Guernsey company called Natural Choice Ltd promoting Orthosiphonia and Camilia capsules. The material featured "before-and-after" photographs of a female slimmer alongside claims that included, "The first week I lost l0 lb. . .8 lb the second week.. .7 lb the third week... it demolished my rolls of fat."

The mailing went on to claim that these products could cause quick, large-scale, safe and permanent weight loss without changes to eating habits.

The ASA concluded that neither Orthosiphonia nor Camilia had proper weight reducing properties beyond their action as diuretics (causing water loss); nor had the advertisers substantiated their claim that the products were safe to use.

The company was asked to withdraw the mailing immediately.

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Some food supplements contain ephedrine

The standard mainstream drug ephedrine (which has an effect similar to adrenaline) is present in some health-food supplements and could pose a substantial hazard to certain unsuspecting consumers, a panel of experts convened by the US Food and Drug Administration have warned.

The FDA has received about 800 reports of adverse reactions to herbal products containing the drug. Heart attack, stroke, angina and irregular heart beats have most commonly been linked to the drug's use, according to the FDA, and people may not know they are at risk.

The panel do not yet have enough data on the substance to determine what would constitute a safe level of the drug. The FDA is expected to review the arguments presented by panel members and make a decision at some point in the future.

In the UK the ephedrine-containing herb ephedra, otherwise known as Ma Huang, cannot be legally sold as part of a dietary supplement. However the Consumers Association recently reported that supplements containing the herb are still available for sale.

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Improving the standards of RCT reporting

Guidelines just published aim to produce greater consistency in the reporting of randomised controlled trials, or RCTs, and are being adopted by major UK medical journals.

The CONSORT statement, which appeared at the end of August in the *Journal of the American Medical Association*, is the result of an extensive collaboration between epidemiologists, biostatisticians investigators and editors. The work was prompted by a number of reviews of published RCT's which have found deficiencies in the way they are reported - raising concern that what has been held as the "gold standard" for the assessment of medical interventions may not always be relied upon.

The CONSORT statement insists on the inclusion of the word "randomised" in the report's title, and a properly structured summary. For the guidance of authors and editors the statement also gives a checklist of 21 items to be included in the report, along with suggested subheadings within the methods and results sections of the paper. The published report will additionally help readers by including a trial profile, or flow chart, showing the number of participants eligible and the numbers that were randomised and who completed the trial, accounting for losses along the way.

Triallists are encouraged to follow the statement's recommendations immediately, but they will not become a requirement until 1st January 1997.

The recommendations of the CONSORT statement are supported and will be adopted by the *British Medical Journal*, the *Lancet*, the *Journal of the American Medical Association* and some other journals.

Reference: Begg C, Cho M, Eastwood S, Horton R, Moher O, Olkin I, et al. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996; 276: 637-9.

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More power ... Less cancer ... More confusion?

A recent study looking for a link between electromagnetic fields and cancer has come up with an unexpected result which will surely confound those who are convinced we are at mortal risk from overhead cables.

Electromagnetic fields around power lines and transformer stations have been blamed for causing childhood leukaemias but evidence supporting a link is sparse. This has not, however, prevented elements of the media from indulging in the occasional alarmist report, a matter HealthWatch has remarked upon recently in some detail (HealthWatch Newsletter 21, April 1996).

Because it is difficult to measure an individual's cumulative exposure to electromagnetic fields, proving cause and effect directly is not easy. Now Dr Shigeru Sokejima and colleagues from Toyama Medical and Pharmaceutical University in Japan have looked at the problem from a new angle - instead of trying to measure electromagnetic fields, they related electric power consumption within designated administrative regions to death rates from leukaemia in those regions.

In a recent letter to the *Lancet,* they detailed their findings that there was indeed a relation between power consumption per person in each region and deaths from leukaemia in boys (but not with death rates from other causes). But the association they found was the opposite to that expected: areas with the *lowest* power consumption per capita had the *highest* rates of leukaemia and, in fact, all cancers. The researchers admit their study does not necessarily demonstrate a direct relation, albeit an unexpected one, but suggest their findings may help explain why other studies have reached contradictory conclusions.

Sokejima's work may or may not be a vitally important piece of the power line puzzle. But it will be interesting to see how much media interest is generated by these surprising results. We suspect there will not be a great deal, but if the news is picked up no doubt we can expect the formation of a pressure group which will attempt to persuade us to use more electricity in order to protect everyone from cancer.

Reference: Sokejima S, Kagamimori S, Tatsumura T. Electric power consumption and leukaemia death rate in Japan. *Lancet* 1996; 348: (9030): 821-2.

See also Newsletter no 24

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Alternative interior design

A leaflet promoting new alternative medicine books has come our way, which gives details on texts advising on health and.. decor

New titles from the Green Library, London, include Man-Ho Wok's *The Feng Shui Kit.* The blurb asks, "Have you ever wondered why you feel at home in some places but not others?. . The illustrated book tells you how to use the specially designed compass and ruler to learn how to reveal forces and colours for every room and situation."

Geopathic Stress, by Jane Thurnell-Read, is introduced on a similar theme. "Sometimes when you go into a building you feel uncomfortable - a deep instinct warns you of unpleasantness, perhaps even danger - a feeling

all recognise... in fact, whole streets can have a history of illness and emotional upsets."

New books on candida include a *Practical Guide* to the subject by Jane McWhirter, whose blurb describes the condition as a "debilitating complaint... a silent epidemic of the nineties.. which is, as yet, not generally recognised by GPs".

"…the success of many activities in daily life is subject to natural rhythms and the phase and position of the moon", reads the introduction to Moon *Time,* by Johanna Paungger and Thomas Poppe.

And Cassandra Eason has produced a book with the interesting title, *Every Woman a Witch.*

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Complaints upheld against computerised treatment systems and magnetic fields

Complaints have recently been upheld against advertisements for some extraordinary therapies.

Equestrian Innovations Ltd offered horse owners portable magnetic field therapy for "Fresh Splints, Tendonitis, Pulled Muscles, Suspensories, Back Shins, Bowed Tendons, Most Fractures, Sinusitis, Open Wounds, Breathing Problems", claiming, "Magnetic Field Therapy is already universally used and is an accepted method of therapy in human and animal care. This type of therapy is designed for soft tissue and bone damage conditions."

While the ASA conceded there was some demonstrable effect of magnetic field therapy in some specific conditions in humans, the advertisers could not substantiate claims for the product's effect on either horses or the conditions listed.

Warwickshire Trading Standards Department objected to a leaflet offering an "automated computerised treatment system" listing treatments including homeopathy, Flower Remedies and Minerals and claiming, "A startling new way of using energies to provide 260,000 treatments.. acts treats all conditions and enhances other forms of treatment, optimising the natural healing of the body and boosting the immune system".

The ASA asked for claims that the system could treat conditions, aid healing or boost the immune system to be withdrawn.

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A degree of scepticism

American students will soon be able to enrol on a course that should qualify them as sceptics, says a recent report in the science journal *Nature* The Center for Inquiry Institute - a branch of the Committee for the Scientific Investigation of Claims of the Paranormal (CSICOP) - has launched a three year academic programme leading to a certificate of proficiency in "science and the paranormal" and "humanistic studies".

The course aims to train those prepared to challenge the "rising tide of irrationalism" - 48% of Americans believe in unidentified flying objects, with 29% convinced that contact has been made with aliens.

The academic programme was announced last month at the First World Skeptics Congress, held at the State University of New York at Buffalo, on CSICOP's twentieth anniversary. The course will include training in communication skills and manners, to help sceptics convey the science message more effectively.

A Council for Media Integrity on Science is also being set up, says the report.

Nature, 18 July 1996

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Magnetic "Breakthrough for pain sufferers"

Sufferers with "arthritis, migraine, frozen shoulder, sciatica, rheumatism, cramp, tennis elbow, swelling, white finger or other painful condition" are being targeted by Tyrian Services of Bradford, in a leaflet promoting BIOFLOW; a "break-through for ionisation by magnetic induction".

This gadget, available by mail order at the price of £29.99 is worn on an elasticated band attached around the wrist, leg, arm or waist. It is claimed as, "the naturally better way to maintain a healthy life. Users feel better because their blood haemoglobin carries larger amounts of Oxygen *(sic)* and nutrients".

The leaflet goes on to say, "Your body's requirement for a static magnetic field was highlighted when early pioneers in space suffered from what became known as space sickness. By providing the astronauts with a

magnetic field space sickness was prevented."

The product features a "combination of neodynium magnets and Central Reverse Polarity".

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Vitamin Pushers

Professor Arnold Bender looks with dismay at the hype and misinformation generated by certain elements in America's nutrition industry and asks, could it happen here?

The recent spate of advertisements for dietary supplements is partly fuelled by food scares but particularly by the enormous sales potential "if only we behaved like the Americans". For many years the "latest from America" was considered a good selling point but nowadays it is more often a warning.

One hundred million Americans take vitamin preparations and the sales of "health" supplements are, per capita, some 5 - 10 times greater than in the UK.

US advertisements ask whether you work under pressure, travel frequently, become tired. If you do, and especially if you are under stress or smoke or drink, then you are robbing your body of vitamins and minerals and therefore need supplements ("strenuous exercise can actually knock essential minerals right out of your system"(!))

It is illegal in the US to print medical claims on the label of a food supplement because this would make the product a drug and liable to drug regulations but there are some 36 publications "philosophically aligned" with the health food industry, 22 newsletters and 3 newspapers in which unsubstantiated claims can be made (1).

A 1993 survey by the US National council Against Health Fraud found that 286 out of 618 listings in the "nutritionists" section of "Yellow Pages"' were spurious and Barrett and Herbert (1) traced bogus professors, PhDs, and DScs with bogus qualifications.

It is possible to obtain "degrees"' in nutrition and to join high-sounding professional organisations by mail order and Dr Victor Herbert enrolled his poodle as a professional member of the American Association of Nutrition consultants and it has a certificate in the name of Sassafras Herbert to verify the fact. Not to be outdone his cat, Charlie Herbert, joined the International Academy of Nutritional Consultants (combined cost $100).

Some of the claims made for "health"' supplements in the US are so ludicrous that we might be tempted to assume that "they could not happen here". For example, it was claimed that flower pollen produced loss of weight, permanently alleviated allergies, reversed the aging process, cured, prevented or alleviated sexual dysfunction and also served as an antibiotic. The company involved eventually agreed to pay $200,000 to settle charges of false representation.

Another company reached "consent agreement" with the Federal Trade Commission whereby they agree to pay $2.4 million to settle charges of falsely advertising 41 products.

Another paid $1.45 million to settle. An American TV programme reported in 1960 the virtues of Doc Willard's Wonder Water - "catalyst-altered water". Although no trials were reported the programme included testimonials from people who claimed that it successfully treated emphysema, dandruff, pink-eye and burns.

The US Food and Drug Administration ruled the product illegal and although Willard himself died in 1991 the product was still being marketed in 1994 at $2 - 3 per ounce with a long list of unsubstantiated health claims.

Apparently many companies sell health-related products by turning their customers into salespeople. Multi-level marketing, also called network marketing but more commonly known here as pyramid selling is a form of direct sales in which independent distributors not only sell products but can make money by recruiting other people as salespersons. The more you sell and the more distributors that you recruit the more money you make, because you get a proportion of their sales.

It does not always work out though - one pair of distributors found that their sales patch had become saturated so they moved elsewhere. But that area was already saturated. To maintain sales volume they kept buying the products themselves, placing phantom orders in the names of inactive distributors-then they went bankrupt and joined a $75 million class-action lawsuit against the company.

Let's hope it can't happen here.

Arnold Bender Emeritus Professor London University

Reference: Barrett S, Herbert V. The Vitamin Pushers (How the "Health Food" Industry is selling America a Bill of Goods). Prometheus Books, 1994.

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Has cancer research wasted millions chasing viruses and vaccines?

Not only the human race, but all vertebrates - from dinosaurs and dromedaries to toads and terns - have inherited a mechanism by which micro-organisms and other foreign substances can be resisted and, hopefully, destroyed. At least 99% of infections are effectively dealt with by our natural body defences without any help from antibiotics.

These days many people are aware of this so-called immune response. They know that vaccination has saved countless lives by promoting it. And that when the immune response is damaged, as in AIDS, numerous infections may take hold.

But is there something sufficiently foreign about cancer cells that they could be resisted in a similar way? The idea is so appealing that enthusiasm for it has come in waves all through the 20th Century, only to be dashed by contrary evidence or disappointing results. Now Michael Milken, a wealthy American who has himself been treated for cancer, has funded at the John Wayne Cancer Institute in California a vaccine against malignant melanoma. This is a cancer that is much more serious than other skin cancers, but not as deadly as many believe, at least forty out of every hundred patients being alive and well many years later.

At this clinic the vaccine is being given only in cases where the disease has spread and is "out of control", but many nevertheless look well and feel well, as is not unusual in this kind of cancer. Several hundred have now had the vaccine and a recent BBC Horizon television programme (dramatically entitled 'A Miracle for Cancer?") followed two of the thirty-four UK patients who have spent a lot of money flying out to California once a month for their treatment.

What are the chances that it will help them? Interviewed by HealthWatch, Dr Harold Hewitt, a veteran cancer research worker who became well known 20 years ago because of his steadfast refusal to go along with fashionable convictions on this subject, explained that he has had to put up with many accusations of being too negative, but still finds it hard to believe that such treatment can ever have any important effect. He feels that there are just too many arguments stacked against it.

For a long time more than a quarter of the articles in leading cancer journals were concerned with tumour immunology. Are we now going back to this? The primitive idea of all ills, but especially cancer, being due to malevolent external influences has always had a great appeal to the public on whom the big cancer charities largely depend for funding. So when Harold Hewitt protested that this approach to cancer, involving so much effort over so many years, was wasting millions - it was being over promoted and ought to have been stopped sooner and the money directed elsewhere - he was not very popular with the cancer research establishment.

Among the points that Hewitt has made for many years is the fact that in animal experiments rejection of a tumour by an immune response has in general been demonstrated only in tumours that have been artificially induced by powerful carcinogens, or that are artificial in other ways. Cancers that naturally and spontaneously occur in these animals have *not* been successfully rejected. And while in human cancer there may be some fluctuation and remission, very seldom do tumours disappear completely without some kind of treatment. Convincing self cure without any treatment is very common with infections, but very *uncommon* with cancer. This argues strongly against any idea of the body mounting a significant immune reaction against cancer of the type that it mounts against infection by micro-organisms.

Closely related to the idea of the body rejecting cancer cells as something foreign is the idea of cancer being caused by a virus that the immune response would attack as it attacks other viruses. This idea, too, has absorbed a vast amount of money that might have been better employed in other directions. It is true that in 1910 Peyton Rous demonstrated that in chickens it was possible to transmit a sarcoma (a cancer arising from connective tissue) without transmitting any cancer cells and there seemed little doubt that a virus must be responsible. Half a century later-at the height of the cancer virus bandwagon - he got a Nobel prize for it. But the sad fact is that in human cancer there is very little evidence either for a virus causing more than a very few cases, or for any natural immuno-surveillance system for resisting cancers.

When the immune response is depressed as it is in AIDS (or in organ transplant patients who have had to have their immune response deliberately suppressed to prevent rejection of the transplant) only a few cancers of an uncommon kind show increased prevalence. And immuno-deficient mice may get less cancer, not more. Even with leukaemia - a favourite subject for the virus concept - babies born to mothers suffering from advanced leukaemia have not contracted the disease; and nor have patients after being inadvertently transfused with leukaemic blood.

As for vaccines, Hewitt points out that when used against known virus infections these may be very effective in prevention (for example in poliomyelitis) but are of no value in established disease, so that even if it were true that a malignant melanoma was caused by a virus, such a measure would come too late.

What a tragedy that this melanoma project in California is being done without a comparable series of patients being currently treated in some other way. Of course, they already have the usual quota of grateful patients now "living longer than expected". Patients doing far better than average occur in any cancer series, but especially in

certain types-of which melanoma is one. What matters is whether such cases occur *more often* after this vaccine. And that is something that - as HealthWatch never tires of saying - will never be known unless a valid comparison is made, preferably by randomising patients for one policy or the other.

This is something that becomes even harder to organise than it is already after television programmes like this one, with talk of possible miracle cures and no mention of the need for the proper comparing of results. But it should not be impossible. The need for it has to be carefully explained, together with appropriate stress of the unknown risks in any new and experimental treatment. And then the new treatment must be available *only* to those willing to be randomised, knowing that they may either get this vaccine or they may get other treatment which may well be just as good.

At present the media do little or nothing to explain this. Far too often they prefer the language of death sentences and miracles.

Thurstan Brewin

Reference: Hewitt H. *European Journal of Cancer Prevention.* 1992; 1: 187-9.

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Book review: Evidence-based General Practice: A Critical Reader

by Leone Ridsdale, WB Saunders Company Limited, 1995

Like all doctors I want to do the best for my patients and think when I make diagnoses and formulate management plans that these are based on knowledge and experience.

In obstetrics, we have witnessed many changes in practice and, thanks to the National Perinatal Epidemiology Unit and the Cochrane Database, now have an enormous wealth of data on which to base decision making. Many Labour Wards have on-line computer facilities to this database for midwives and resident doctors to access. I am a passionate believer in randomised controlled trials and yet find that I have some residual sympathy with dinosaur colleagues of the "doctor knows best" school that still relies on text book teaching from 25 years ago. Not because I agree with them, but because the studies, critical research and epidemiologists often do not speak to me personally in my job in the Ante-Natal Clinic, on Labour Ward or in a Protocol Committee.

I, too, had my suspicions about the evidence-based medicine gurus until I read this book which both demystifies evidence-based medicine and humanises it at the same time. Dr Ridsdale takes the most holistic doctor we have, the general practitioner, who lives with the most uncertainties, and examines her practice with a critical eye.

The success of the book is that it is based on patients and never strays too far away into the academic wars in ivory towers. Ridsdale starts with a description of a couple of days in the life of a general practitioner, describing patients with common problems and using these patients to introduce the themes of the subsequent chapters. For example, her first chapter starts with a familiar extra patient who was "slotted in" leading to delays for all the patients with booked appointments. She reviews the literature about patients' views on their doctors and their levels of satisfaction, as well as experiments that have been performed with changing appointment times, offering patients variable appointment times, and the effect of these on doctors in terms of communication, stress levels and practice costs. I had been idly flipping through the pages of the book on a friend's shelf but by page 17 was hooked and read it all in one sitting.

The next few chapters are on minor illness and why patients present when they do, their ideas about illness and how this affects absenteeism and compliance. Ridsdale examines the psychological distress that is brought, often in a hidden way, to general practice; and GP's communications skills (theories and skills and how they have been measured and influenced in individuals).

By her choice of simple vignettes to introduce each chapter Ridadale keeps the reader close to the heart of the problem. Instead of feeling battered by the ideologues and their mean analyses, the reader is drawn into the delight of new discoveries and the application to clinical problems, thus fostering a sense of self-criticism that feels good.

In later chapters she looks at the process of innovation and change and the effect of different skill mix in the primary care team. With her chapters on screening and critical appraisal, particularly directed to the MRCGP exam candidates who have a critical reading paper, we are drawn into the real-life application of statistical and scientific methodology.

A chapter on medical ethics works less well as the patients become mere ciphers. She tried too hard to cover the different schools of ethics with the problem of a dementing patient continuing to drive and a 44 year old woman wanting fertility treatment on the NHS. The references are more theoretical and are not evidence-based research on doctors' ethical values.

In some ways the book is a quirky collection of topics, with huge areas of practice left out. Nevertheless it

achieves two main aims: Firstly, it enlivens "evidence-based medicine", by revealing it as a set of attitudes or approaches to the clinical, social and psychological problems of patients; Secondly, it answers the elusive question of what is general practice? Not one thing, but many disciplines and theories that compete and overlap. A good buy.

Susan Bewley, Director of Obstetrics St Thomas' Hospital, London

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Book Review: Complementary Medicine and the Law

by Julie Stone and Joan Matthews, Oxford University Press £30 hardback, £12.99 paperback

This is a book which most HealthWatch members would approach with some reserve. Firstly because of a natural suspicion of anything which seems to legitimise some of the wilder practices of complementary or alternative medicine, secondly because anything approaching legal textbook is something of a a turn-off for non lawyers.

The first reservation has some justification. Joan Matthews, the co-author; is a complementary practitioner. Certainly it is no part of the book's mission to debunk complementary practices. The need which HealthWatch constantly emphasises for impartial assessment of results through randomised trials is dismissed as largely inappropriate for alternative therapies. However it would be a pity if the second reservation discouraged non-lawyers from reading the book. The relatively short list of cases and statutes betrays the fact that this is not a heavyweight legal tome.

On the contrary it is, rather, a thoughtful and well written account of where regulation of "conventional" medicine has got to in the UK and an examination of why the model of the GMC and the various Medical Acts may not be the best way of regulating these new procedures. The authors frequently emphasise that the legal framework should be different because the relationship between the alternative practitioner and the patient is quite different with the practitioner being relatively less expert and the patient having a greater input into his or her treatment.

The way the common law of negligence creates a duty of care is explained in relation to complementary therapies and the authors make the point that the law of contract will almost apply since almost all alternative therapists are in the private sector

The authors accept that it is alternative therapies which claim to be complete systems of medicine that have the greatest potential to harm the patient. However they also claim that there is very little evidence of alternative therapies doing harm and almost no case law to that effect. It would be interesting to pursue the question of why this is so. Is it because most therapies are relatively harmless and even their most fervent supporters resort to a doctor when things go wrong? Or is it because those who resort to aromatherapy, acupuncture, reflexology and the like know they are basing their decision on faith rather than reason and therefore tend to blame themselves rather than the practitioner if the expected miracle does not occur?

The message of the book is that the huge increase in the practice of complementary medicine requires a regulatory structure but that the nature of such therapies demands a novel system based on self-regulation with a strong ethical basis. This proposition is well argued but the cynic might still say "why go to the trouble of setting up an elaborate regulatory structure unless and until the efficacy of the treatment has been established?"

Read the book by all means. You will be informed by much of the material and provoked by some of it. What a pity the question "does it work?" has such a low priority.

Malcolm Brahams, Solicitor, Vice-Chairman of HealthWatch

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Book Review: Essential Oil Safety: a Guide For Health Care Professionals

Robert Tisserand and Tony Balacs, London: Churchill Livingstone, 1995.

This is a rather strange book Why strange? Because it is so coy about being concerned solely with aromatherapy. Both authors work at the Tisserand Institute (in Hove, Sussex) and I think we can take it that the first author has given his name to his institute rather than called himself after it.

In the same vein the second author is described as a *"Lecturer in Essential Oil Science at the Tisserand Institute".* Once again there is no immediate or obvious mention of aromatherapy. So I phoned and it was explained to me that the whole institute was concerned with aromatherapy.

The detail in the book is astonishing. There are 280 pages between hard covers and no fewer than 537 references. And note that all this is concerned only with the *safety* of some 311 essential oils used in aromatherapy, not with indications for their use or with claims for their benefits.

The information given has the seal of approval from John Caldwell PhD, Professor of Biochemical Toxicology at St Mary's Hospital Medical School in London, who says in his forward that, "This collection of safety data, presented at a level suitable for the general public, is unique."

At times the book may seem to some of us a bit like safety precautions for those lighting candles in mystical patterns to ward off sickness or evil, but if all this information is accurate and if it all makes aromatherapy even safer than it is already, what can we do but welcome it?

Thurstan Brewin

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Letter

Dr David Peters, Trustee of the British Holistic Medical Association, Royal Shrewsbury Hospital South, writes in response to HealthWatch Chairman Thurstan Brewin's comments in an editorial on the BHMA, issue 21 (April 1996):

Dear Sir;

I am broadly in agreement with what Dr Brewin says about the BHMA: holistic medicine is far too important for us to let it be pushed to the margins as some superstitious activity. I believe, as he appears to, that the continuing emphasis on (and sometimes the BHMA Newsletter's bordering on promoting) the most 'fringe' complementary therapies has to be commented on. Although there is nothing inherently holistic about these sorts of therapies a recent issue featured crystal therapy, the one before, urine therapy. It seems Dr Brewin was outraged not only because these therapies are so 'unscientific', but also because the Newsletter was misrepresenting holistic medicine. On both counts I have to say that he is correct.

Whatever the underlying rationale for crystal or urine therapy-and they would be very different rationales-it cannot be the same as the precise biotechnical concepts of pathology and treatment which underlie conventional medicine. They are not in this sense 'scientific'. Then are they holistic? It may be that people seek new kinds of therapy because they need to approach aspects of life through ritual and symbol; or because these therapies represent what the medical anthropologist Mary Douglas refers to as the more 'spiritual' and gentle' extremes of a spectrum of therapeutic activity. People who choose them perhaps do so in preference over approaches at the other extreme, which they experience as mechanical and alienating; perhaps they feel uncomfortable with conventional medicine because they identify it with these attributes. Possibly, as Mary Douglas and other writers have suggested, the unconscious appeal lies in traditional systems being underpinned by cosmologies that connect inner and outer "subtle orders". Unfortunately none of these issues was addressed. Nor, though holistic medicine acknowledges the profound influence that culture, beliefs and inter-personal relationships exert on well-being, in the articles the therapies were dealt with as though they were medical activities, when in actuality they are far better understood as sociological phenomena.

Nonetheless they are interesting and if they were, for example, made the focus of a medical anthropological paper then neither I - nor, I suspect, Dr Brewin - would raise any objection. It is their being offered as implicit examples of holistic medicine, that has raised our hackles. Curiously, for a growing number of people, the often strange beliefs and practices of non-conventional medicine seem to meet the need for new ways of defining illness and of enacting the therapeutic process. I think Dr Brewin recognises that this is a serious and important phenomenon of our time but feels - as I do - that this significant social trend ought not to be trivialised. His indignation should remind us that the term holistic medicine is emblematic of an aspiration for better health care, and that it was because of this aspiration that the BHMA was founded.

The BHMA's original understanding of holism had nothing to do with outré therapies, but with a wish to enquire into a broader, interdisciplinary, humane, patient-centred mainstream for health-care. In the early 1980's relatively few doctors in the mainstream were looking for new ways forward; very many now find they are in tune with these original aims. Moreover, the complex interaction of mind, body and spirit and its influence on health has over the past decade become an area for both scientific research and philosophical interest. So it would be a lost opportunity if the BHMA appeared to be a voice representing only an irrelevant 'outlaw' territory For though I can see that 'alternative therapies' convey an important message about changing needs and beliefs, and that a magical dimension has always played a part in therapeutic activity these are marginal concerns. No doubt the BHMA's Newsletter sometimes needs to be a vehicle for discussing non-conventional approaches. Over-emphasising them might appeal to therapists and their patients who understand holistic medicine to be about 'energy.. vibrations.. subtle bodies', but it will definitely alienate potentially friendly practitioners who are struggling with everyday practice. For them the relevant issues have more to do with political policy, education, nutrition, lifestyle, the psychological and social factors determining susceptibility and coping, inter-professionalism, the therapeutic relationship, and professional stress.

If the BHMA Newsletter does not also give a voice to these themes then it will not be surprising if Dr Brewin and other thoughtful colleagues fail to realise that the BHMA's concerns are not with mumbo jumbo, but rather for the promotion of practical bio-psychosocial options for health care in the mainstream.

Yours sincerely

David Peters

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Letter

Dr Gene Feder, Senior Lecturer on the East London Clinical Guidelines Project, St Bartholomew's and the Royal London School of Medicine and Dentistry, writes in response to a book review by Professor John Garrow, issue 22 (July 1996):

Dear Sir;

I would like to question a point made by John Garrow in his review of *Chiropractic: the Victim's Perspective* in your July newsletter. While randomised controlled trials are useful for testing the efficacy of treatments conventional or complementary, they are not the right method for judging the safety of treatments. Unless an adverse effect of treatment is common it will not be detected with the sample size of most randomised controlled trials. Other methodologies are needed such as case control and cohort studies. The argument in favour of randomised controlled trials for the assessment of complementary therapies is undermined by claiming that it can answer questions about safety.

By the way, manipulation is likely to be more effective in acute than in chronic back pain contrary to what is claimed in the review (1).

Yours sincerely

Gene Feder

Reference: 1. Shekelle PG, Adams All, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low-back pain. *Ann Intern Med* 1992 Oct; 117(7): 590-8.

Professor John Garrow replies:

Dear Sir,

I accept Dr Feder's point that the safety of a treatment is not well judged from randomised controlled trials unless adverse events are very common. However it is not well assessed by anecdote either; since the adverse event may have had some other cause. Ideally for all treatments there should be a centrally-held register of adverse events (like the Committee on Safety of Medicines' "yellow card" which records details of adverse events, and other drugs, etc, which might be involved). We understand from the Research Council for Complementary Medicine that unfortunately there is no such register for complementary therapies.

The conclusion of the meta-analysis by Shekele *et al* is that spinal manipulation "is of short-term benefit in uncomplicated acute low-back pain" but that data for chronic low back pain are insufficient for analysis. The studies by Meade et al (to which we refer in Newsletters 5 and 19) show that after three years follow-up "those treated by chiropractic derive more benefit and long-term satisfaction than those treated by hospitals". The point I was making in this brief book review was that there is evidence of efficacy of chiropractic for certain types of low-back pain, but there is no good evidence of efficacy, and anecdotal evidence of severe harm, for neck manipulation as a treatment for problems in visceral organs.

Yours sincerely

John Garrow

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Letter

Dr G S Plaut of Halstead, Essex writes with reference to the Health Watch position paper on Health Screening, issue 22 (July 1996):

Dear Sir;

My impression on "Checkups" in my general practice was as follows: if a patient said he wanted to see the doctor because of; say, a cough or bowel trouble, he thought that he might be considered a baby, BUT if he went for a "check-up" he would be thought a wise person!

Yours sincerely

G S Plaut

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