



# Health Watch

...for treatment that works

Newsletter 57 April 2005

## EXPERTS ATTACK PRINCE CHARLES' HEALTH BOOKLET

**A**TTACKS on the Prince of Wales's foundation's new complementary healthcare booklet have continued since its release early in February. HealthWatch's chairman John Garrow recently joined the growing number of concerned experts voicing their fears in the media, when he was the subject of a detailed interview that was screened at a peak viewing time on BBC 2.

*Complementary Health Care: a guide for patients* is published by the Prince of Wales's Foundation for Integrated Health and advises readers on how to find practitioners of the 12 most popular complementary therapies, including reflexology, homoeopathy, craniosacral therapy and healing. The 45-page book, part-funded by the Government, is being distributed free to all GP surgeries.

The British Medical Association has already expressed its concern that the booklet promotes treatments without adequate evidence to support their benefit. There has been further criticism from Edzard Ernst, Professor of Complementary Medicine at the Peninsula Medical School and holder of Britain's only academic chair in the field, who reportedly described an early draft as "hair-raisingly flimsy, misleading and dangerous", revealing to the *Independent* newspaper that his repeated offers to correct the text free of charge were rejected<sup>2</sup>.

Professor John Garrow appeared on the BBC News 24 programme screened on BBC 2 on the morning of 12th February, where he was invited to describe HealthWatch's views on the new booklet. In an interview lasting over three minutes Professor Garrow vented his anger over its content. "In conventional medicine we are subject to extremely tight rules about how to do research. The Prince of Wales's Foundation has now said that for complementary medicine these rules don't apply." He pointed out that the new booklet has little information on efficacy. "There are complementary medicines that work and HealthWatch is keen to

support them. They're not keen to have NHS money spent putting out a booklet which simply tells you how to get it without establishing whether it works or not."

### Ernst lashes out

Now in a stinging article in the *Guardian* (22nd March 2005)<sup>3</sup>, Professor Ernst has lashed out at again at the new booklet, calling it a "scandalous waste of public funds." In an article titled "Double Standards", he protests that complementary medicines seem to have escaped the rigorous evaluation to which other medical treatments are subjected by the National Institute for Clinical Excellence (NICE).

"The guide is the most spurious I have seen for years," he says. "It reads like a promotional booklet. The problem is not that a lobby group is indulging in promotion; it is that the government is repeatedly supporting a lobby group to do the work of independent experts," he writes.

### References

1. *Complementary Health Care: a guide for patients* is now on sale for £5.99 and can be ordered, or downloaded free of charge, from the web site <http://www.fihealth.org.uk>
2. *Independent*, 6 February 2005, view on the Internet at: [news.independent.co.uk/uk/this\\_britain/story.jsp?story=608226](http://news.independent.co.uk/uk/this_britain/story.jsp?story=608226) (charge of £1 payable to non-subscribers)
3. <http://www.guardian.co.uk/g2/story/0,,1442930,00.html>

## Sunlight and vitamin D: debate in this issue

AS CANCER Research UK highlights the dangers of getting too much sun, warning that rates of deadly skin cancer are set to treble\*, some cancer experts fear that staying in the shade could be even more harmful, according to a feature in the *Independent*. Even in sun-soaked Australia there is now concern that some people may get too little sun to maintain vitamin D levels, says the report.

In this issue of the *HealthWatch Newsletter* medical journalist

Oliver Gillie, author of *Sunlight Robbery*, explains the possible health risks of being too sun-shy, while Sara Hiom of Cancer Research UK defends the charity's advice to take care in the sun. (see pages 4, 5 and 6 for reports and full references).

*Independent*, 22 March 2005

\*<http://info.cancerresearchuk.org/pressoffice/pressreleases/2005/march/70331>

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## TRIALS DIRECTIVE—ONE YEAR ON



**O**NE YEAR ago, in Issue 53 of this Newsletter, we presented differing views about the merits and dangers of Directive 2001/20/EC from the EU concerning the conduct of clinical trials involving administration of a “medicinal product” to human volunteers. The Directive was intended to improve the quality and safety of trials to test new drugs, but the term “medicinal product” is open to a wide interpretation.

It was generally agreed that the Directive would increase both the cost, and the amount of form-filling, required from the trialists. In particular it was feared that only wealthy sponsors (such as pharmaceutical companies) could afford to comply with the new regulation. If this happened it would be very serious for clinical research because, as Richard Smith showed in his address at the 2004 HealthWatch Award, pharmaceutical companies manipulate trials to give more favourable results than results obtained in trials of the same drug, but with independent non-commercial sponsors.

It is too soon to be certain about all the effects on academic clinical trials, but there is strong evidence that the Directive causes three important problems, which are briefly described below.

**1 Documentation** Anyone who thinks this is a trivial problem should visit the website [www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk) designed by the MRC and Dept of Health to guide trialists through the bureaucratic labyrinth. There are three “route maps”: these apply to trials that on 1st May 2004 were about to start, or already running, or about to finish. In each case there are at least ten points at which the trialist must submit a document, obtain a permission, and/or produce evidence that some action has been taken. It is difficult to estimate the cost, in time and money, of all this documentation, but my former Medical College (Barts, London & St Mary’s Westfield) needed to appoint three extra staff to cope with it.

**2 Sponsorship** Every trial must now have a Sponsor who indemnifies those involved in case of injury. For commercial trials this is not a problem: the drug company indemnifies participants and recoups the cost from sales of the drug when it is licensed. But for trials sponsored by a consortium of non-profit institutions (eg. MRC, Wellcome, and other charities) which one should provide indemnity? The chief financial sponsor may not be the employer of the lead clinician for the trial, who is responsible for seeing that all the safety measures are observed. Obviously, it is desirable that everyone involved in a clinical trial should be appropriately insured, but this requirement will make academic institutions and minor charities wary of sponsoring clinical trials of non-commercial products.

**3 NHS co-operation** Academic clinicians are usually employed by Universities, but have honorary contracts to treat patients in NHS hospitals. Formerly this was a symbiotic relationship: the NHS had the services of a specialist whom they did not pay, and the University had access to the clinical facilities that they did not fund. Today, hospital managers have a conflict of interest: they are under intense pressure to use the clinical facilities they control as profitably as possible, but releasing beds or nurses to facilitate clinical trials will not gain them credit with inspectors

from the Healthcare Commission on whom their star rating, and hence their future level of funding, will depend. For certain types of research, such as gene therapy, very special facilities are needed: For example, clinical waste from patients given genetically modified agents must be decontaminated on-site, instead of the normal, and much less expensive, removal to a designated waste site for decontamination. Bamford and colleagues observe that to meet such requirements “requires a significant ideological, organisational and financial commitment” from the NHS managers, who have no incentive to do so unless the sponsor of the trial is able to supply a massive financial inducement.

The objectives of the Directive are commendable, but there are clear indications that its implementation may unintentionally stifle independent academic clinical research, especially the small, locally financed research projects on which the research clinicians of the future cut their teeth. Clinical research is now a field in which only the big battalions can compete, but many important advances in the past have been made by small groups of dedicated researchers. Where will future generations look for such researchers?

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*“clinical research is now a field in which only the big battalions can compete”*

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To save independent researchers from extinction some steps are required. Academic sponsors must be funded so they can afford the clerical and indemnity cost of the new regulations. HealthWatch has written to the Healthcare Commission to suggest that one of the criteria of assessment under the “Standards for better health” section should be that hospitals are given credit for the extent to which they provide essential facilities for non-profit clinical trials. (The full text of this letter is available on our website [www.healthwatch-uk.org](http://www.healthwatch-uk.org)). This short note is an inadequate sketch of the problem. In Brussels on 10 – 11 May 2005 there will be an international forum discussion among experts about the good and bad effects of the Directive on clinical research of different kinds in Europe and elsewhere. We hope to provide an overview of the proceedings of that Conference in the next issue of the HealthWatch Newsletter, and would welcome comment from readers who have experience of the good or bad effects that have arisen from the implementation of the Directive.

Please watch this space.

*John Garrow*

*Emeritus Professor of Human Nutrition, University of London  
and Chairman of HealthWatch*

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1. Bamford *et al.* *Q J Med* 2005; **98**: 75–86.

## What has really changed? A researcher’s view

MANY ISSUES, now said to result from the Directive, were present many years ago when I was in active research.

Applications to Ethics Committees and University bodies were onerous then; there is an obvious increase in documentation required with the involvement of the regulatory authority. My research was sponsored by a charity, but conducted within the NHS. Co-operation was problematic: administrators were correctly concerned that liability should not fall on the uninsured NHS and the

charity as sponsor had to obtain insurance cover; it also purchased materials, paid for staff and rent and defrayed other costs.

So what has changed? Difficulties I experienced decades ago have certainly increased, but now they are attributed to the Directive. In fact, they represent increasing attention paid to human rights and to accountability of researchers and would be present regardless of the Directive.

*Walli Bounds*

# DESIGNING CLINICAL TRIALS

**ONE OF THE principal objectives of HealthWatch is to promote the testing of treatments and the conduct of clinical trials. There are three false arguments used to claim trials are unnecessary for certain types of treatment.**

1. If patients feel better after the treatment, nothing else matters.
2. Trials of truly holistic treatment are impossible: there can never be a control patient with whom the result can be compared because each patient is different and the treatment is tailored to the individual.
3. Clinical trials cost huge sums of money that small independent practitioners cannot afford.

We believe that due to a lack of proper testing, patients are offered treatments that are less effective, less safe and more expensive than they need to be, both in conventional and alternative medicine.

If a patient feels better after a treatment, it is very satisfactory but does not mean the treatment is effective. The patient might have improved without any treatment, or there might have been even more improvement with a simpler, cheaper or safer treatment. The best way to find out, almost always, is to do a suitable clinical trial.

Every good practitioner, whether conventional or alternative, should practise holistic medicine; treatments should always be chosen to suit the whole patient in their particular circumstances and environment, and not simply the pain or lump that they may have. Similar pains or lumps may be treated differently in different patients. Despite this, it is still possible to do valid clinical trials using the guidelines set out below.

The onus of providing evidence of efficacy is on those who promote a treatment and not, as is sometimes stated, on the scientific community in general. It is true that large scale multi-centre drug trials can be very costly, but most of the expense is in administration and in the biochemical tests that are not an essential part of the comparison, but are to check for any unexpected harmful effects of the treatment.

Some minimum conditions for a proper trial to compare two treatments:

## ***Protection of research subjects***

It is illegal to conduct any research involving human subjects without the prior approval of a Research Ethics Committee. It is the duty of these committees to check that the research is properly designed, and that previous research on the topic to be studied has been adequately considered. Any conflict of interest (e.g., the research is sponsored by an organisation with a commercial interest in treatment being tested or the researchers have a financial interest such as company shares) must be declared. Any possible harm to trial participants must be as little as possible, and volunteers must be given a clear description of what the trial involves and what other treatments might be, so they are able to give fully informed consent that they are willing to participate. They need to be told that they are free to opt out of the trial at any time, without giving any reason and without suffering any detriment.

## ***Choice of treatments***

If there is no treatment that is known to be safe and effective for the condition under study, then a new treatment may be compared with a placebo treatment. If, on the basis of existing evidence, two (or more) treatments are equally appropriate and it is not known which is better, they should be compared, using a group of patients for each treatment. If the new treatment is to be compared with one of several

already established treatments, the best should be selected as the comparator treatment. Each treatment should be clearly described, including its formulation, dose, route and frequency of administration, full product characterisation and details of manufacturer.

## ***Aims and objectives of the trial***

These must be adequately described, e.g., to compare the effectiveness of two treatments for a specific medical condition, over a given period of time, in a specific group of patients. The measurements of the desired treatment effects (outcome measures) must be appropriate, precisely defined and, where possible, objective and reproducible.

## ***Patient allocation***

To be as sure as possible that the groups are otherwise similar, and to avoid the researchers choosing which patient is given which treatment (avoidance of selection bias), allocation of patients to treatment groups must be random. Assigning patients by alternation or by dates of birth is not acceptable. Ideally, true randomisation is best achieved with the aid of a third person not directly involved in the trial (often contacted by phone) who, after having checked that the patient meets the entry criteria, allocates the randomly selected treatment group for that patient.

## ***Registration of Clinical Trials***

The trial should be on a register. This ensures other researchers working in the same field are aware of its existence and means the results will be available for review even if the outcome is unfavourable to the procedure or product. Registration reduces the trend for positive trials to be published and hence available to reviewers, while negative trials are not, thus avoiding publication bias. The register held by the European Medicines Evaluation Agency (EMA) of the European Union could form a part of such a register, but must be freely available to researchers and not maintained 'Commercial in Confidence' as it currently is.

## ***Methods***

This should include a clear description of the types and characteristics of patients eligible to take part (entry criteria), their previous treatments or medication(s), details of who will administer the treatments and how, and how the treatment effects will be recorded. For example, in a trial comparing methods of pain relief, one needs to devise a method of scoring the intensity of pain, which can then be compared with the intensity of pain before treatment and between treatments. Ideally, to prevent any possible bias, neither the patient nor the person who assesses the effects of treatment should know which treatment is being used (known as blinding), though this is not always possible. Other factors that could influence the effects of the treatment being tested, such as diet, exercise and other medications, need to be recorded, as do side effects and reasons for dropping out of the trial.

## ***Data analysis***

Patients who fail to complete treatment for any reason should not be excluded from the final analysis, as comparisons should usually be on an intention to treat (ITT) basis. In some trials it is necessary

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## CHARITY ADVICE PUTS LIVES AT RISK

Award-winning medical journalist Oliver Gillie is the author of *Sunlight Robbery*, an independent report into the health risks of inadequate exposure to the sun. Here he argues that government-sponsored advice on sun protection, as is currently being issued by Cancer Research UK as part of its SunSmart publicity campaign, could claim more lives than it saves.

**OUTDATED ADVICE to avoid exposure to the sun is putting the public at risk of a number of serious diseases including cancer. Ironically, this advice—to cover up and avoid bright sunlight—is part of a programme called “Reduce the Risk” which has been devised by Cancer Research UK, Britain’s premier cancer charity.**

Tragically the charity’s well meant advice will increase the risk of cancer. Cancer Research UK, and government which has underwritten their campaign with more than £1 million so far, has overlooked the fact that exposure of the skin to sunlight is necessary to obtain vitamin D, and that vitamin D is essential for normal growth and protection against cancer. Vitamin D is needed, not only to make strong bones, but for the healthy functioning of more than 30 different tissues or organs in the body.

Two recently published scientific studies<sup>1,2</sup> provide a profound challenge to the established ideas of skin cancer specialists who advise against exposure to the sun. These two studies have found that people with a greater exposure to sunlight have a lower risk of developing melanoma, the most serious form of skin cancer, and a lower risk of dying from it. This is consistent with other studies suggesting that the risk of 16 or more different types of cancer are reduced by exposure to the sun<sup>3</sup>. These cancers are generally much more common in the northern states of America or in the northern countries of Europe than in southern states or southern countries where people generally receive more exposure to the sun.

Other studies<sup>4</sup> using different methods (“case-control” or “cohort” studies) have confirmed that the risks of lymphoma, and cancer of the breast, colon, ovary and prostate, increase when sun exposure is reduced. The most recent of these studies, published in December 2004 and January 2005<sup>5,6</sup>, have shown that lymphoma is less likely to occur in people who have a high exposure to UV light as a result of sunbathing, foreign sunshine holidays or use of sunbeds. The reduction in lymphoma associated with UV exposure was found to be as much as 30–40 per cent—a startling result which suggests that a major reduction in these cancers could be achieved by a reversal of Cancer Research UK’s sun-avoidance policy. Similar reductions might be obtained for a number of other cancers if sunbathing was actively encouraged, instead of discouraged, by Cancer Research UK’s policy on sunlight<sup>1</sup>.

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***“It is tragic that this distinguished charity is in the position of endorsing advice which has no proper scientific basis”***

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The charity’s advice is intended to prevent skin cancer. It has of course been devised with the very best intentions but it originated from a consensus statement that never had a secure scientific basis. This mistaken advice, presented to the public as the SunSmart programme, assumes that sufficient vitamin D can be obtained by casual exposure of the hands and face to the sun during normal activities.

Cancer Research UK has said that its advice is supported by the National Radiological Protection Board, among others. The NRPB endorsed the “hands and face assumption” in a report<sup>7</sup> published in 2002, although the assumption was not supported by any comprehensive scientific evidence. But late last year, realising that the evidence was flawed, NRPB officially withdrew its support for the “hands and face assumption” leaving Cancer Research UK’s sunlight policy without a reasoned basis for safety<sup>8</sup>.

The SunSmart programme, which was originally developed in Australia where casual exposure to the sun is very much greater than in the UK, recommends putting on a high factor sunscreen 30 minutes before going out. It also advises against going into the sun for four hours around midday. At other times of day sunlight is rel-

atively weak in the UK because the sun is low in the sky and UV light is filtered out by the atmosphere. So the SunSmart advice effectively blocks any useful synthesis of vitamin D in the skin.

The injunctions of Cancer Research UK against sunlight are endorsed by government and more specifically by the chief medical officer Sir Liam Donaldson. Together they are responsible for the fact that anyone following their guidance will obtain insufficient vitamin D and put themselves at risk of a number of chronic diseases including cancer itself. It is tragic that this distinguished charity has got itself into the position of endorsing advice which has no proper scientific basis. It can only be hoped that Cancer Research UK will redeem itself by a rapid reversal of policy before the coming summer.

The consequences of insufficient sunlight and vitamin D go much further than increasing the risk of cancer. Insufficient vitamin D is also associated with a number of quite different chronic diseases including multiple sclerosis, diabetes (types 1 and 2), raised blood pressure, inflammatory bowel diseases, polycystic ovary disease, infertility and resistance to certain infections as well as the classic bone diseases<sup>4</sup>.

It may seem difficult to believe that one vitamin could be necessary for the healthy function of so many different parts of the body. But vitamin D is now known to have profound effects which involve not only regulation of calcium metabolism, but the switching on and off of genes which cause cells to differentiate, to mature, and to die by organised cell death (apoptosis). Vitamin D also has hormone actions which may alter growth signals to cells, inhibit growth of blood vessels and modulate activity of the immune system<sup>4</sup>.

The action of vitamin D is particularly important during pregnancy which ends with a rapid growth of the baby’s bones. At this time the mother’s body may become acutely short of vitamin D with long term consequences for the baby which include multiple sclerosis or other nervous system problems developing in later life. People born in northern latitudes, in Canada, Great Britain and Scandinavia have a risk of developing MS that is significantly increased—by 8% above average—if born in May, that is at the end of winter when vitamin D in the mother’s body is lowest. And the risk of MS is decreased by 8% below average if born in November, at the summer’s end when vitamin D reserves in the body are highest<sup>9</sup>. This seasonal birth of people with MS has been found to be most marked in Scotland, possibly because the poor weather there does not encourage sunbathing while in Scandinavia, which is at a comparable latitude, sun-bathing and sunbed use are popular.

The cost of diseases which might be prevented by increased exposure to sunlight runs to billions of pounds in the UK. The direct cost of hip fractures alone is £1.7 billion in the UK<sup>7</sup>. A number of studies have shown that vitamin D not only prevents fractures by strengthening bones, but also prevents falls through its effect on the nervous system<sup>7</sup>. William Grant, an independent researcher based in San Francisco, has calculated that increased sun exposure and fortification of food with vitamin D could reduce deaths from cancer in the UK by about 20%, saving some 30,000 lives a year and very large sums of money at present spent on complex treatments<sup>3,10</sup>.

Over the last ten years melanoma and several other cancers have been occurring with increasing frequency in the UK. This increase in incidence of melanoma has been blamed on foreign holidays

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## WHY IT'S STILL SMART TO COVER UP IN THE SUN

Sara Hiom is Head of Health Information in Cancer Research UK's Policy and Communication Directorate. Her background is in research, including six years at the MRC's National Institute for Medical Research. She explains why the SunSmart Campaign should continue.

**P**UBLICATIONS indicating a protective role for sunlight and vitamin D in several diseases, including some cancers, continue to spark debate and controversy. This often prompts a media response encouraging increased sun exposure. So it is no wonder that the public is uncertain about the authority of health messages that warn against too much sun exposure.

Since the 1980s skin cancer prevention campaigns, in countries with predominantly white populations, have been set up because of rising incidence in all skin cancers and belief that most could be prevented by moderating sun exposure. Solar radiation is classified as a Group 1 carcinogen, known to cause cancer in humans<sup>1</sup>. It is accepted as being the major environmental cause of skin cancer and excessive exposure to ultraviolet radiation (UVR) is estimated to cause about 90% of non-melanoma skin cancer (NMSC) and at least two thirds of melanomas<sup>2</sup>.

NMSCs are very common with an estimated 100,000 cases diagnosed each year in the UK<sup>3</sup>. These are rarely life threatening but can involve disfiguring surgery and place a great burden on health services. Malignant melanomas are more often fatal, causing more than 1,600 deaths in the UK in 2002<sup>4</sup>. Although still relatively rare, incidence rates have been increasing rapidly for several decades in all Caucasian populations<sup>5,6</sup>. In Britain, melanoma is the third most common cancer in 15-39 year olds. Age standardised incidence grew by 49% over the ten-year period 1991-2000 and since the 1970s rates have risen faster than for any other major cancer<sup>7</sup>. Rising incidence trends look set to continue<sup>8,9</sup>.

Intermittent sun exposure<sup>10</sup> and a history of sunburn<sup>11</sup> are linked to increased risk of melanoma, whereas low-level, chronic and cumulative exposures are not<sup>12</sup>. Exposure to intense sunlight and sunburn in childhood significantly increases risk<sup>10,13</sup>. Skin cancer prevention advice is therefore to advise against sunburn by avoiding the summer sun between 11am and 3pm, covering up with suitable clothing and using a high factor sunscreen when shade or clothing are not practical options. These messages—together with a reminder to take extra care of children—form the basis of Cancer Research UK's SunSmart campaign.

Public health campaigns should have a firm scientific evidence base. All new research must be regularly evaluated to inform any changes to policy or messages. Recently there has been a call for SunSmart to be abandoned<sup>14</sup>. The author asserts that, "Advice should only be given to the public to reduce sun exposure if it can be shown that this is likely to do no harm and to provide substantial benefit." But, despite the increase in publications claiming a

role for sunlight/vitamin D in the reduction of incidence and mortality from certain cancers, the data are still incomplete and the mechanisms underlying the observed associations are yet to be defined. In contrast, evidence for a link between sun exposure and skin cancer is solid.

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*"since the 1970s rates of melanoma incidence in Britain have risen faster than for any other major cancer"*

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The studies described in reference 14, and elsewhere, are mainly based on observations of cancer incidence and mortality variations with latitude in the United States. Increased rates for prostate, colon and breast cancers were observed with increasing latitude (distance from the equator) and these results taken as further confirmation of a protective role for sunlight. But applying this hypothesis to a comparison of rates of these cancers in Australia and New Zealand with those in the UK is less successful. The annual ambient solar UV radiation in southern Australia and New Zealand is about two to three times that in Great Britain<sup>15</sup> and studies of individual exposure to sunlight demonstrate that average doses in Australia are significantly greater than those measured in a similar cohort of subjects in England<sup>16</sup>. So we can conclude that people living in Australia and New Zealand are exposed to considerably more solar UV radiation than those living in the UK. This is borne out by a comparison of the rates of melanoma. Both incidence and mortality rates are higher in Australia and New Zealand than in the UK<sup>17</sup>. But rather than indicate a protective effect for sunlight, the data for prostate, colon and breast cancer rates show that mortality rates do not vary significantly between countries. Incidence data imply generally higher rates for these cancers in Australia and New Zealand, but it is likely that mortality data are more reliable due to possible differences in diagnosis.

The beneficial effects of sun exposure in maintaining adequate vitamin D levels to protect against bone disease are well documented. The vitamin D hormone plays an essential role in increasing calcium absorption. However, the exact amount of sunlight necessary to achieve optimal vitamin D levels is uncertain and will vary

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## THE PROBLEM OF VITAMIN D

Dr David Bender comments on our state of knowledge concerning bodily requirements of "the sunshine vitamin"

VERY FEW foods are good sources of vitamin D, and most of our requirement is met by synthesis in the skin following sunlight exposure. In UK we have reference intakes only for infants and the (house-bound) elderly; for this latter group the reference intake of 10µg/day is estimated on the basis of an intake that will maintain the same plasma concentration as is seen in younger adults at the end of winter—a time when their reserves are depleted after the dark winter months. This level of intake is adequate to prevent clinical deficiency disease, but it was established before the importance of vitamin D in controlling insulin release, immune sys-

tem function and cell differentiation and turnover (and hence its importance in preventing cancer) was known. The need to revisit requirements for vitamin D for optimum health, as opposed to absence of deficiency disease, has been acknowledged by the most recent call for research proposals by the Food Standards Agency. For details see pages 30 to 31 at <http://www.food.gov.uk/multimedia/pdfs/rrd16.PDF>

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## CHARITY ADVICE PUTS LIVES AT RISK

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and careless sun exposure. In fact the tragic SunSmart policy and its advice to avoid exposure to the sun may be in part responsible for the increase in several kinds of cancers. The government should halt the SunSmart programme immediately and promote a new policy of safe sunbathing instead.

Oliver Gillie  
Medical Journalist

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## WHY IT'S STILL SMART TO COVER UP IN THE SUN

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depending on skin type, latitude, time of day, time of year, cloud cover, clothing, sunscreen usage, amount of skin exposed and age. Once a person's vitamin D requirement is met, any additional vitamin D is converted to inactive substances in the body<sup>18</sup>. So, increasing sunlight exposure, resulting in tanning or burning, does not improve vitamin D status while having increased carcinogenic effects on the skin. In the UK, vitamin D levels are known to decrease over the winter. But, normal plasma levels built up during the summer should be sufficient to last through the winter without experiencing vitamin D deficiency<sup>19</sup>. An important proponent of the beneficial effects of sun exposure has indicated that exposing about 10% of body surface several times a week to the amount of UV necessary to induce a slight reddening of white skin (the minimal erythemal dose or MED) from spring to autumn is easily sufficient<sup>20</sup>.

Further research is necessary to elucidate the exact role of sunlight and vitamin D in the prevention of diseases, the extent to which the population is vitamin D deficient and how any such deficiency can be addressed safely. Changing health behaviours is a slow process, and while evaluations show that knowledge of effective sun protection is increasing, the requisite action to reduce skin cancer risk is yet to be widely adopted in the UK. Those receiving insufficient sunlight for good health are likely to be avoiding sun at greater levels than current policy suggests. However, if there are people who might benefit from slight increases in casual exposure, then the nature of this exposure is crucial. The desire to tan, regardless of skin type, surely leads to the type of sun exposures that are most likely to increase melanoma risk.

In the current climate of concern about vitamin D deficiencies set against a backdrop of relentlessly rising melanoma rates, research must be constantly reviewed to ensure that health messages are appropriate. The weight of scientific evidence in this debate lies with a causal role for sun exposure in the development of malignant melanoma and non-melanoma skin cancers. The link between sun exposures, vitamin D levels and bone disease is also well established. Although a growing number of ecological studies indicate a possible protective effect of sunlight for certain internal cancers, these data are inconsistent and further exploration is necessary before current policy on sun exposure is overturned. In the meantime the challenge will be to promote a sensible attitude to sun exposure that safely balances the inherent risks and benefits.

Sara Hiom

Head of Health Information, Cancer Research UK

Cancer Research UK's SunSmart campaign is funded by UK Health Departments. Its advisory board includes representatives of the National Radiological Protection Board, British Association of Dermatologists, International Commission on Non-Ionising

Radiation Protection, EUROSkin, UK Skin Cancer Working Party and the British Photodermatology Group. For further information please go to [www.sunsmart.org.uk](http://www.sunsmart.org.uk)

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### CHOICE, TEMPERAMENT AND ALTERNATIVE THERAPIES

Medical journalist Caroline Richmond writes from London on what makes some people choose the irrational:

Dear HealthWatch Newsletter editor,

I HAVE a lot of sympathy with Debbie Kings, who is watching with mounting frustration as her male friend with breast cancer spends huge sums of money on crackpot treatments including 'alkaline water' at \$400 a shot, and the Hay Diet. She doesn't say whether he eschews conventional treatment, but she implies that he does.

I used to be equally irritated and frustrated when friends and acquaintances did this; now I am not so sure. People have to make their own journey, and there are always people who seem to want the irrational. Indeed, many of them will grab hold of a pick'n'mix of therapies with mutually incompatible philosophies, with the only common theme being irrationality. Also, you can't blame the Internet; these therapies have always been around, and some people have always sought them out.

I often wondered if I would be tempted to try the untested

and bizarre if I were confronted by the grim reaper. Then, in December 2002, my long-standing and low-malignancy non-Hodgkin's lymphoma spawned a high-malignancy non-Hodgkin's lymphoma. They do that sometimes. Over the following twelve months I was to have many hospital admissions, mainly for surgery or chemotherapy (including high-dose chemo and a stem cell transplant). I also had emergency admissions with septicaemia, breathing emergencies because of fluid round my lungs, and other problems. My chance of survival was under 4%, and I found myself able to accept this without difficulty. And I found I wasn't attracted by the idea of wacky therapies; indeed, it was the last thing I wanted to do with what time I had left. So I think it boils down to a matter of temperament.

I survived, despite a poor prognosis. I attribute this to good science, marvellous care, and the luck of the draw. One of my friends, a former national-newspaper medical correspondent, attributes my survival to a will to live.

Yours,  
CAROLINE RICHMOND

### EYE MOVEMENT THERAPY FOR TSUNAMI TRAUMA CASES

A DEPARTMENT of Health advisor has reportedly recommended that GPs treating patients traumatised in the aftermath of the tsunami disaster consider a form of therapy which many experts rate as akin to placebo.

William Yule, professor of child psychology and an expert in childhood trauma at the Institute of Psychiatry in London, who is also a member of the National Institute for Clinical Excellence (NICE) committee, was quoted in the *Daily Telegraph* as saying, "We will also draw the attention of GPs to two techniques—trauma-focused cognitive behavioural therapy and eye movement desensitisation therapy. We now accept that these make a big difference for some people." While the former therapy is proven useful, evidence for the latter—full name Eye Movement

Desensitisation and Reprocessing (EMDR)—is strongly contested. In EMDR an individual is asked to create and hold in their mind a picture of the worst moment during the disaster, while following the movement of their clinical psychologist's fingers with their eyes. The psychologist instructs the patients to "let the image go freely where it wants to". Some proponents believe it has the power to unlock traumatic memories.

However a panel of psychologists and psychiatrists from the British False Memory Society (BFMS) have confirmed that EMDR is "akin to a placebo with no evidence basis for treatment," adding that it has parallels with Mesmerism.

*Daily Telegraph*, 14 January 2005  
*BFMS Newsletter* 2005; 13 (1): 1. See website [www.bfms.org.uk](http://www.bfms.org.uk)

### Position Paper: DESIGNING CLINICAL TRIALS

...continued from page 3

to report results both based on ITT analysis and also using only completers. It is always necessary to report how many patients refused consent, how many patients met the entry criteria, how many were randomised to each of the two (or more) comparison groups, and how many dropped out from each of the treatment groups and their reasons for doing so, if known. Any apparent differences in results must be analyzed to determine the probability of their arising by chance. A probability of less than one in twenty is often regarded as a reasonable indication of a real difference. For this reason, the more patients who enter a trial, the smaller the differences that can be detected. Small numbers can reliably detect only big differences, and make it more likely that the two groups are not properly comparable in important respects other than the treatment.

This is a very simple summary of essential features of a well-designed clinical trial. HealthWatch is very willing to give advice to anyone seeking to evaluate the efficacy of any method of treatment and or type of benefit or side effect.

#### Further reading about trial design

From trial outcomes to clinical practice. *Drug & Therapeutics Bulletin* 1996; 34: 38–40.

Randomised controlled trials in single patients. *Drug & Therapeutics Bulletin* 1998; 36: 40.

Excellent advice on the reporting of clinical trials can be found on [www.consort-statement.org](http://www.consort-statement.org)

*This position paper was revised by John Garrow and Walli Bounds and endorsed by the executive committee of HealthWatch on 12 January 2005. To view HealthWatch Position Papers on other issues see the HealthWatch website on [www.healthwatch-uk.org](http://www.healthwatch-uk.org)*

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## THE CRYSTAL TRUTH ABOUT IONISED WATER



**S**HOULD YOU buy a water ionizer? In *HealthWatch Newsletter* issue 56 (January 2005) a concerned nurse expressed her despair over a friend who seemed to think an expensive ionizer available on the Internet might cure her husband's cancer. David Bender checked the claims being made on the website. Could it cure...or is it just another way to wash money down the drain?

The website [www.detox.eu.com/](http://www.detox.eu.com/) promotes the new Microlite JP-107, "a high performance filtration system that changes normal tap water into purified, energised, alkaline water." This machine, priced at £390, appears in fact to be a water filter that also heats the water somewhat, and performs electrolysis. The simplest interpretation is that the device makes a dilute sodium hydroxide solution to drink.

But why would you want to? The site claims, "The hydroxyl ion, OH-, has an extra electron with a negative charge which turns it into a potent liquid anti-oxidant that scavenges free radicals throughout the body". No. Negative ions do not neutralise free radicals. Free radicals have an unpaired electron, and can only be neutralised by reacting with another radical so that the unpaired electrons become paired.

We are then told that, "Ionized alkaline water contains only five to six water molecules per cluster instead of ten to thirteen of conventional water." I doubt this. "Its smaller hexagon-shaped molecular structure is similar to our DNA." Nonsense. "This compatibility promotes cell health and resistance to aging. This 'reduced' water is more hydrating than conventional water and is extremely detoxifying". I think not.

The need for alkaline water seems to be because "when people are born, their bodies are predominantly alkaline. During growth...the body acquires and stores excess acid wastes that may build up to alarming levels and begin to destroy body tissues and organs. This is in fact the cause of most adult diseases ... Maintaining an alkaline pH 8.5 to 1.5 (I presume they mean 10.5) makes it difficult for degenerative diseases to thrive ... ionized alkaline water will eventually flush out acid wastes." If blood pH rises above about 7.5 you are in trouble—8.5 is simply not possible.

Conditions helped by drinking alkaline water (microwater) ("from research and testimonials") are listed as: "high blood pressure, morning sickness, diabetes, osteoporosis, poor blood circulation, hyper-acidity, constipation, diarrhoea, common cold, muscle aches after exercise, hangovers, urea stones, water retention, body odor, induces faster healing, obesity, chronic fatigue,

migraines". I would agree that drinking water (any water) helps with a hangover, but what are urea stones?

Following these explicit and implied claims for health benefits, there is a disclaimer: "Water Ionizers", incidently (sic), are approved as 'medical instruments' by the Korean and Japanese Ministries of Health and Welfare. However, no such claim is made outside of these areas".

The web-site also reports on an experimenter who photographed crystals formed from water that had been exposed to different types of music before being frozen. Classical music of various kinds reportedly gave different, but beautiful, crystals, whereas heavy metal music gives an amorphous mass of ice. At last I understand why I dislike rock music. But wait, the imaginative investigator went even further. He taped words and names onto glass bottles of distilled water. The waters were then frozen and photographed. Kind words and the name of Mother Theresa gave beautiful symmetrical crystals, whereas words of hate, and the name of Adolf Hitler, gave unpleasant asymmetrical patterns. Amazing.

As far as the health benefits claimed for alkaline ionised water are concerned, these seem to be based on some serious misunderstandings of chemistry and physiology. I also do not believe that your thoughts, and the music you play, will affect the water you drink. However, the photographs of the ice crystals might justify a visit to the web-site.

If this product were on sale in the UK, I would go to my local trading standards officer and complain that I have been misled. As it is being sold from overseas, there is nothing they can do—and Customs are unlikely to be interested in preventing me importing something that, while useless, cannot be classified as material that might be used for terrorist or other illegal purposes.

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1. The assessment and testing of treatments, whether "orthodox" or "alternative";
2. Consumer protection of all forms of health care, both by thorough testing of all products and procedures, and better regulation of all practitioners;
3. Better understanding by the public and the media that valid clinical trials are the best way of ensuring protection.

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