

Newsletter no 20: January 1996

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The need for evidence-based medicine

At the Annual General Meeting of Health Watch at Regent College, London this year we were delighted to welcome guest speaker Professor David Sackett from the Oxford Radcliffe Hospital. The professor's compelling talk described his team's important work on the need for accurate and up-to-date information in making clinical decisions

Doctors need new clinical information up to 100 times a week but are unlikely to receive it because their textbooks are out of date, and their journals disorganised. Yet this dearth of accurate information could influence eight important decisions every day. So began Professor David Sackett, visiting professor at the University of Oxford, when he addressed the 7th Annual General Meeting of HealthWatch on 23rd October 1995.

By questioning a group of general practitioners while they saw their patients, Professor Sackett's team identified up to 16 needs for new, clinically-important information in just half a day, of which a quarter were related to diagnosis.

However, only 30% of these information needs were met in the doctor's workplace, and most of these by asking colleagues.

The literature shows that doctors' ability to obtain the information they need is limited by out-of-date textbooks, journals that are too disorganised to be useful, and by simply not having enough time to read. Even the keenest GPs spend only one hour a week reading the medical literature, and this is clearly not enough to keep pace with therapeutic advances.

The net effect of this unfulfilled need for important new information is that it can lead to progressive declines in clinical competency. It has been shown repeatedly that there is a negative correlation between a doctors' knowledge of up to date care and the years that have elapsed since completing formal training. For example, in one study of clinical behaviour, the decision to start antihypertensive drugs was more closely linked to the number of years since medical school graduation in the doctor than to the severity of target organ damage in the patient.

It is clear, said Professor Sackett, that doctors need far readier access to clinically-important information. The problem is to distill the message buried in some 600,000 published randomised controlled trials into a form which was accessible to clinicians when they needed it, and on which they would be able to base their treatment decisions.

Critics of conventional medicine, said the professor, have claimed that fewer than 15% of medical interventions are supported by solid scientific evidence, leaving between 80 and 90% in the realms of quackery. A more reassuring picture emerged when the professor's team reviewed the diagnoses made and interventions performed upon 121 patients admitted during April 1995 to the John Radcliffe Hospital.

He found that the vast majority - 82% - of interventions were justified on the basis of evidence-based medicine, and in 53% of all cases that evidence came from randomised controlled trials. In only 18% of cases were treatments performed for which there was not substantial clinical evidence, and Professor Sackett found that these involved mainly non-acute disorders for which there are no known effective treatments.

The professor went on to outline how clinicians can practice evidence-based medicine for themselves as a life-long, self-directed learning process. The discipline involves:

- converting information needs into answerable questions;
- tracking down efficiently the best evidence with which to answer them;
- critically appraising that evidence for its validity and usefulness;
- applying the results and evaluating performance.

Research in Canada has shown that when equipped with these skills, graduates not only made more accurate diagnostic and management decisions, but they retained a high level of clinical competence and stayed more up to date than their traditionally trained peers as long as 15 years after graduation.

HealthWatch award

After his talk at the HealthWatch 7th Annual General Meeting Mr Nick Ross announced that Professor David Sackett was the unanimous choice of the committee for the Third Annual HealthWatch Award. Professor Sackett was presented with a handsome silver-plate comport-a dish for dessert, raised on a stem-inscribed with these words:

Annual Health Watch Award 1995

To Professor David Sackett in recognition of his distinguished contributions to medical research, education and the reliable assessment of treatment.

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"Complementary medicine carries risks," says *Health Which?*

The myth that complementary therapies are safe because they are natural overshadows the risks of injury or even death, says the latest issue of the consumer magazine HealthWhich?

Hundreds of cases of adverse effects worldwide, including some deaths, have been linked with complementary therapies. Some Chinese herbs, for example, have been found to contain toxic chemicals-and treatments such as osteopathy, chiropractic or acupuncture could, in the wrong hands, cause physical damage.

In a Consumers' Association survey of 2,635 people who had tried complementary therapies, three per cent said they had had a bad experience or wanted to complain. Very few actually did so, however, and none of those interviewed got satisfaction from therapists' professional bodies.

Twelve people had suffered physical injury-a nerve was pierced in one woman 5 arm during her first acupuncture session.

One woman had her lung punctured when receiving an injection from an osteopath. Other cases suggested (at best) inexperienced or (at worst) incompetent practitioners.

"Most people who go for complementary medicine are happy with their choice. However, there are risks-and if things do go wrong, you may have a fight on your hands," says David Dickinson, Editor of *Health Which?* "Complementary medicine is big business, yet it's still possible to set up and practise without any qualifications or training.

"Our work suggests a pool of unvoiced complaints-and it's clear that the professional bodies need to raise their public profiles so people are aware of how to complain."

Health Which?, December 1995

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Health tips from "green" books

A recent mailing from the Green Library in Fulham includes a list of books for which the promotional copy makes some interesting health claims.

Here is a selection of claims made for some of the books advertised:

"The author notes that while conventional medicine denies arthritis has a cure, he himself has successfully treated patients from the ages of 9 months to 95 years."

"Kinesiology is the science of testing muscle response to gentle pressure to find where imbalances in function or energy blocks are located in the body..."

"The Mayr method... has been found particularly useful for digestive disturbances, constipation,

dyspepsia, stomach, liver gallbladder and intestinal complaints; poor blood profiles.. obesity. . heart problems, Type II diabetes, and back problems; rheumatism and gout. "

"...a natural holistic way to keep cats and dogs healthy."

And, finally, an intriguingly named book, *Solved: the Riddle of Illness* is said to tell "... the fascinating medical detective story that traced seemingly unrelated ailments to their root in the malfunctioning of the thyroid gland."

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Music therapy?

Music lovers with an interest in astrology can now order classics "to unlock the secrets of each individual star sign".

The new "Astrology Collection" appears in the Christmas catalogue of EMI's Classic FM Music Store telephone ordering service. The blurb reads "each of us knows our star signs and how they influence our individual personalities.. Popular classics by the great composers born under your star sign put you in touch with your innermost feelings.

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HealthWatch AGM: Chairman's report

Chairman Dr Thurstan Brewin addressed the Health Watch committee and members attending the Annual General Meeting at Regent College, Regents Park, London on Monday 23rd October

Thank you for electing me to be your chairman for a third year. As you know, I took over from John Garrow two years ago as he had completed three years. Under our constitution no chairman can serve for longer than this, so this will be my last year.

We continue - I think fairly successfully - to let our views be known and to have as many people as possible at least thinking a little about what we say; and hopefully considering it quite carefully. We do this especially through the media (who get in touch more and more without any prompting from us); through our quarterly newsletters; and through our attendance at meetings and conferences, both mainstream and alternative.

For example, our point of view was put to a well attended meeting of the Medical Journalists Association in Bath; we were invited to take part at a meeting organised in London by the Ciba Foundation and attended by influential speakers from overseas, including the Netherlands and the USA; and we have given written evidence and views to the Health Education Authority, to the Vice Chancellors of Universities and to the Minister of State for Education.

In a nutshell these views, as we all know; are first that there ought to be far more clinical trials done both in mainstream medicine and in fringe medicine. We think that what most people want to hear about is not theories, but results. A valid and reliable comparison of results (which, of course, should always include risks and side effects as well as benefits) gives some idea as to which treatment for most people is best and which is second best. Then each person can make an informed choice.

We must also never forget that the failure to compare results properly has led mainstream medicine in this century to carry out many needlessly drastic procedures, especially in certain kinds of cancer, where we now know that something simpler is just as good.

Second, we are concerned about the ever increasing enthusiasm, sweeping across Europe, for treatments based not on any reliable evidence of their value but on such things as ancient mystical theories; perhaps on an anti-science feeling (often based on a caricature of what science is all about); or perhaps on no more than the personal convictions of someone who has founded what often seems no more than a health cult. To show the trend here is part of an advertisement that appeared in the Daily Mail of September 12th and was spotted by the eagle-eyed Andrew Herxheimer:

"Train for a new career... Start your own stress clinic... Correspondence diploma courses on aromatherapy, reflexology; iridology (*followed by a list of 14 other similar subjects*).

The almost totally uncritical stance of the BMA and the Royal Medical Colleges, apparently mainly from fear of sounding arrogant or giving offence, has led many to suppose - wrongly we think and hope - that the medical profession is now convinced of the value of such things.

As to our newsletter; I wrote on your behalf to Aisling Irwin to thank her for her splendid work as editor; and I'm glad to welcome here this evening her successor; Mandy Piggot, who has considerable experience in writing, editing and publishing. Two others I'd like to extend a specially warm welcome to this evening are Mrs Barbara Searle, a most generous supporter of HealthWatch for some years; and Dr Roy Macgregor, a London GP with wide

experience on radio and television, who we feel will be a very valuable additional member of our committee.

Finally, it is a great pleasure to thank-both personally and on your behalf-not only the whole committee but especially Vincent Marks, our information officer; and his secretary Sheila Smith, who handle the 'phone calls; Deborah Bender; who carries the considerable load of being Membership Secretary; Shirley Churchman who does selfless, unpaid secretarial work from her home; and Malcolm Brahams, my Vice Chairman, who now provides a meeting place for us in Fleet Street.

Thurstan Brewin, Chairman of HealthWatch

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But why can't complementary medicines be subjected to RCT?

The question arose in the course of correspondence with Dr Iain Smith, Senior Lecturer in health services research at the Nuffield Institute for Health in Leeds. In a BMJ editorial earlier this year he noted that many authorities are commissioning complementary treatments costing up to £20,000 a year, and called for research to show evidence for efficacy of complementary procedures.

At HealthWatch we applaud his view, expressed in that editorial, that "the burden of proof should be no greater, or less, than for mainstream medicine."

We were unconvinced, however, by a comment further on in the piece which suggested that randomised controlled trials (RCT) "may fail to allow for the holistic effect that is central to the philosophy of most complementary therapies," and that, "the beneficial effects are often so obvious, the side effects so rare and mild, and the duration of effect so variable after even a single exposure that perhaps the observational studies may be enough to prove benefit."

HealthWatch invited Dr Smith to suggest examples of complementary therapies which cannot be tested by RCT's for those reasons.

His reply intrigued us, particularly where he reported that complementary organisations and practitioners comment that "their specific therapy, by virtue of its very nature, is not readily amenable to a traditional RCT" and suggests that because "their therapies have a high benefit : risk ratio," for some low risk therapies the "burden of proof could be shifted toward either observational evidence or alternate research analysis."

So should different rules apply when assessing the effectiveness of treatments because they happen to be low risk? We think not. Yet in a recent paper by Long and Mercer (1995) which Dr Smith enclosed, the view is expressed that "It is critical that complementary therapies are evaluated in their own terms whilst not compromising the need for rigour and control of bias.... Blinding of patient and/or practitioner.. is improbable and problematic within any evaluation of complementary therapies undertaken in their own terms -especially as complementary therapists seek to exploit any 'placebo effect'".

So this is not at all a level playing field: to show efficacy in mainstream medicine it is necessary to use blinding to control for bias and to correct for a placebo effect, yet in complementary medicine bias can be avoided *without* blinding (how?), and any placebo effect is credited to the therapy! How would that go down in mainstream medicine?

The placebo effect can, of course, be magnified if the placebo is offered with total assurance that it will be effective. Which begs the question: where do we draw the line between enthusiastic psychotherapy and fraud?

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Trading standards prosecute after "cancer relief" claims

A man who claimed magnetic healing equipment he was selling could help treat cancer has been found guilty of contravening the rarely used Cancer Act 1939.

On 21st November 1995, at Camberwell Magistrates Court, Southwark Trading Standards Service brought the case against Rolf Gordon Dohm of London after receiving a letter of complaint from Dr Charles Shepherd, who is an adviser to the Myalgic Encephalomyelitis (ME) Association.

Mr Dohm, whose company is named Dulwich Health Society, claimed that the equipment known as the MagneTech can be used beneficially by people undergoing radiotherapy and chemotherapy. He was fined £3,500 and ordered to pay costs of £200.

The MagneTech is used to apply a magnetic field to parts of the body and ranges in price from £80 to over £200. The promotional literature calls it "an entirely painless method of dealing with most illnesses, injuries and other ailments without creating side effects." It claims that the equipment "can be used.. to eliminate the side effects of medical drugs and radiotherapy"; that "significant benefits" are experienced on "bone structures, such as.. .bone tumours"; and that a certain lung cancer patient "could not sleep due to pain nor cough up impurities without using the MagneTech on a daily basis." Other medical claims made related to rheumatoid arthritis, stroke, multiple sclerosis and varicose veins.

The Chairman of the Magistrates, after hearing expert medical evidence, told Mr Dohm that his offences were extremely serious and they therefore had to impose a heavy fine.

In mitigation, Mr Dohm said that he believed that the Magnetech, which he has sold worldwide, worked.

He was also found guilty of using the word "Society" in his company's name without the required permission from the Department of Trade and Industry.

Chair of Southwark's Regeneration and Environment Committee, Councillor Nick Dolezal said, 'We are very pleased with the outcome of this case because we felt it was our duty to protect vulnerable members of our community who may be suffering from cancer and the effects of its medical treatment from being misled into buying unproven but expensive treatments.'

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Testing times for Chinese medicines

Over 600 clinics offer Traditional Chinese Medicine (TCM) in the UK, and it has been estimated that over 1 million TCM prescriptions were dispensed here over the last year, says Hannah Patrick of the National Poisons Unit in a recent editorial in the Journal of the Royal Society of Medicine.

There are very few studies that test the effectiveness of TCM, says Patrick. Chinese remedies for eczema that had proved relatively unresponsive to conventional treatments have been tested and found effective, though more work is needed before doctors can confidently recommend that their patients invest in TCM.

Most of the remedies dispensed in the UK are imported directly from China or Hong Kong. A single remedy may contain 10 to 15 different herbs, and the quality may vary. Unrecognized contamination by other herbs, drugs or chemicals and improper processing are hazards.

Adverse reactions can also occur between TCM and drugs prescribed by Western practitioners, which may not come to light because patients who do not view TCM as 'drugs' fail to mention them to their doctor

Regulation exists but it is not all-encompassing and rules for herbal remedies are currently under review. The Medicines Act of 1968 covers herbal medicines, but has specific exemption from licensing requirements for herbal practitioners and herbal remedies. Herbs that form part of a product for which a medical claim is made must be licensed, but can be sold over the counter

The Register of Chinese Herbal Medical Practitioners sets standards of training and practice but membership is not compulsory and many UK practitioners are not members.

Reference

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TV review: Doctors in the Dock

Malcolm Brahm reviews the media examination of the fates of two doctors, struck off for very different reasons, in the first two programmes of the BBC2 series "Doctors in the Dock"

The first programme in the BBC2 series, "Doctors in the Dock", portrayed the downfall of Nicholas Siddle, a gynaecologist and obstetrician whose forays into keyhole surgery went seriously wrong. He was first suspended and then dismissed from his post at University College Hospital. Shortly afterwards he suffered the ultimate indignity of being struck off the Medical Register.

The programme carried comments by his colleagues and superiors but also gave Mr Siddle a good deal of screen time speaking directly to camera. At first I thought the programme was slanted in his favour and depicted him in a rather sympathetic light. At the end of the thirty minutes I felt they had given him enough rope with which to hang himself.

It is true that he expressed regret for his patients' suffering-in one case after another he had damaged various organs in a series of keyhole operations. However, he appeared to lack insight into his shortcomings and never to

express true remorse. There was also the suggestion that he paid insufficient attention to the need for the kind of post operative care which would have minimised his patients' sufferings.

By comparison, the patients of Dr David Corden, a Reading GP, were very satisfied with their doctor. The second programme of the series relates how Dr Corden was struck off for developing a relationship with a patient. She was also his receptionist and he subsequently married her.

Dr Corden had taken pity on her when her earlier marriage was in difficulties. When she felt she could not stay with her husband, he offered her a roof over her head. But their relationship developed and it was when she became pregnant some months later that her husband reported Dr Corden to the GMC. He was struck off and despite later having his registration restored, he has been unable to resume his medical career. To this day he can not understand what "vile crime" he has committed and says he would do exactly the same again.

The programme showed a number of established medical figures in a literally unflattering light. The manner in which former GMC member David Bolt was lit from below made him look like a vampire! He explained that doctors are in a position of trust. Unfortunately the profession has to be hard on doctors like Dr Corden who barely overstep the mark in order to protect patients from the genuinely unscrupulous. Of course Dr Corden should have known this and acted within the rules. Nevertheless it was hard not to be sorry for Dr Corden who, like Mr Siddle but in a different way, could not really see how he had erred.

On balance, I felt the first two programmes were a bit dismissive of the need to uphold standards but they did give enough information to allow the viewer to make up his or her own mind and for that I was grateful.

The spectacle of the downfall of a professional man or woman is not edifying and the rest of us may feel, "There but for the grace of God go I." But if standards slip, we all pay. The programmes left me regretting that a degree of expertise and many years training was going to waste and wondering how such shortcomings might be picked up and corrected before the real damage is done.

Malcolm Brahams Vice-Chairman of HealthWatch

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Are we selenium deficient?

A recent survey has shown that the average daily intake of selenium (Se) in the UK has decreased to 34 µg (1/30,000 g). The Department of Health (DoH) expert committee in 1991 advised that a suitable average intake for an adult man (or woman) would be 75 (or 60) µg /day, and that the Lower Reference Nutrient Intake (LNRI) for both sexes was 40 µg/day. The definition of LNRI is "an amount of a nutrient that is enough for only the few people in the group who have low needs". So are most of us not getting enough Se, and does it matter?

The answer to this question depends on the experts you consult. The Se intake of a population depends on the concentration of the mineral in the soil on which cereal crops and vegetables are grown. In China, where there are both high-Se and low-Se soils, there is evidence of a disease of heart muscle (Keshan disease) where intakes are very low (12 ~g/day) but not where it is 19 µg /day (1). At the other end of the scale there is evidence of toxicity, shown by irregular nail growth, where intakes are 900 µg/day, so the DoH advises that the safe upper limit is 450 µg/ day.

New Zealand is the country in which there have been the most intensive studies of the consequences of Se deficiency, since the soil is very low in Se, and Se deficiency impairs the health and wool-production of sheep. Among New Zealand adults the average Se intake is about 25 ~g/day, and there is no evidence of Se-deficiency diseases among New Zealanders (2). Over the last 20 years the Se intake in the UK has decreased, as we have eaten less high-Se Canadian wheat and more European wheat with a lower Se content. Over the same period the Se intake in New Zealand has increased as they imported more Se-rich wheat from Australia, and they now show a saturation of the Se-dependent enzyme glutathione peroxidase (3). However there has been no detectable trend in Se-related diseases in either country.

So what should we do to be selenium-safe? Go to a Health Shop and buy supplements? I shall not do that since the supplements typically contain 100 to 200 µg Se per capsule, which rapidly takes you into toxic levels. It is lucky that the general healthy eating advice (eat more cereals, fresh vegetables and fish) also ensures that your selenium intake would be in the desirable range of 50 to 100 µg/day. Why not do that?

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“Miracle” ads could offend, say ASA

The Advertising Standards Authority has recently upheld complaints against advertisers which have claimed to slim with fruit extract ... and heal by the power of God.

Nineteen objections were received to posters and advertisements promoting the evangelist Morris Cerullo's "Mission to London" meetings at Earl's Court, London. One poster featured a photograph of a boy holding a pair of crutches and with a football at his feet, beneath the headline, "They said I'd never stand on my own two feet!" A press advertisement claimed, "SALVATION. HEALING. MIRACLES ... THE BLIND SEE! THE DEAF HEAR! THE LAME WALK!"

In upholding complaints, the ASA commented that the posters might raise the hopes of many people. While the advertisers asserted that the miracles had indeed happened they submitted no evidence and were asked not to repeat the claims in future.

Over 70 people nationwide complained to the ASA about a direct mailing from Moore Laboratories of Guernsey. It featured "before" and "after" photographs of a woman with the claims, "I went from 17 stone to 9 ½ in 3 months," and "Citra-Slim CONTAINS A NEW NATURAL INGREDIENT THAT BURNS UP EXCESS FAT AND CONVERTS IT INTO ENERGY. YOU CAN EAT YOUR FAVOURITE FOODS AND STILL LOSE WEIGHT.. The main ingredient is a fruit extract from the dried rind of Garcinia Cambogia - a rare fruit found in the jungles of Asia.. average weight loss during this week was between 28 lb and 91 lb."

The advertisers did not provide evidence to support their claims, and were asked by the ASA to withdraw the mailing immediately.

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Snake oil on the internet

Dr Neville Goodman has been busy surfing the information superhighway and has come across some astonishing examples of misinformation. Medical rumour on the Internet is rife, he says. Should it carry a health warning?

"Compound X is a unique formula that has reached through time, over several hundred years, to meet the needs of an ailing civilisation today.. the 14-day regimen.. .has been used for internal malignancies of the liver, kidneys, colon, prostate, female sex organs, breasts, lungs and throat areas. Also for a variety of viral conditions, yeast infections, fungus, 'flu, colds, strep throat, mouth diseases, parasites, constipation, ulcers, venereal diseases, lupus and much more."

There is nothing unusual about this nonsense. Except one thing: it came from the Internet. The Internet has been dubbed the "information super-highway" though in truth the information superhypeway is more like it. As a source of information it is often slow, frustrating and remarkably inconvenient, but it *is* all there. With a computer; a modem, a 'phone line and a good deal of patience, it is possible to get information on all sorts of things: magnificent photographs taken by the space shuttle, the expenditure of various departments of the French government, and an enormous amount of misleading medical information.

The Internet is a great, sprawling network of interconnected computers. It has three components. One, it serves as a vast library Two, it can be used to send electronic messages to anyone else whose E-mail address you know. Three, people with common interests set up "bulletin boards" on a system called USENET. Whenever you want, you can drop in electronically to see what has been posted since you were last there.

I downloaded the above information about Compound X from a USENET group called alt.support.cancer. There is nothing to stop anyone joining these groups and, unless the group has a "moderator" checking all the postings, nothing to stop anyone posting anything. Anybody can attach comments to a posting, but there is no guarantee that this unofficial moderation will be read. I've been watching alt.support.cancer for some time, and when I saw the cryptic message, "New cure for cancer". I requested more information.

One response came from a David Mitchell from New Mexico, who claimed that "Hundreds of thousands of people are dying needlessly from cancer every year just because the medical profession refuses to admit that anyone else could know anything useful." Mitchell, who practises healing, described a 70-year-old man with "a large pancreatic cancer". He claims to have "carried out all of the energy healing work in this case remotely from about 1,800 miles distance." In only two weeks, "by my sensing, his cancer had shrunk to about 1 inch in diameter [and] his organ functions had risen to the 50% range."

Another download was titled "Natural anti-cancer remedies" and included advice such as "Do NOT take this bath

within a few hundred miles of a thunder storm or within three days of a full moon," and "Cancer cells can NOT live in a strong NORTH MAGNETIC FIELD, especially if it is pulsating on and off"

Misinformation can also be found in the library function of the Internet. All good libraries need some sort of indexing and searching procedure, and on the Internet one of a number of so-called search engines is called Lycos. It searches all Internet documents for terms of interest, and assigns them a score for relevance to your terms. On the 31st August I asked Lycos to search for "breast cancer". The first document, with the highest rating of 1.0 is an unsensational but excellent description of breast cancer from the National Cancer Institute, with details of current treatments and reviewed each month by cancer experts.

Unfortunately, there's no need to go far down the list to find more dubious offerings. The fourth article, rated 0.92, is titled "Integrated healing: breast cancer's call to action". Much of the document is the transcript of a talk given when, "as part of a vision of integrated and conscious living, the service branch of the Inspiration Community took on the mission of transforming the way we approach healing breast cancer; hoping not only to accelerate the healing of the breast cancer epidemic, but to demonstrate a prototype for healing issues at all levels of society." Anything that speaks of a cancer "epidemic" (unless it is lung cancer; but it never is) is usually hyperbole, and there is nothing yet convincing that we can cure or prevent breast cancer.

The Internet contains the same sort of misguidance - some mischievous, some innocently deluded - as you will find on the shelves of the popular health sections of any large bookshop. The difference is that for those with access this misguidance is effectively free. Used sensibly; by sensible patients, the Internet will save doctors much time in explanation. But used wrongly, by desperate patients, which document will they want to believe? The document that Lycos puts at the top of the pile will not have the same ring as "Compound X is a unique formula that has been used for internal malignancies".

There have always been snake oil merchants; now they are electronic. We must keep an electronic eye on them.

Neville W Goodman Consultant Senior Lecturer in Anaesthesia, University of Bristol and Southmead Hospital

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Evidence-based old wives' tales

Michael Allen applauds the company which was brave enough to subject its natural product's medical claims to a randomised controlled trial and asks why others do not follow their lead.

What is special about the structured summary below? It is in standard Vancouver format, it describes a randomised double-blind trial, it refers to a placebo, it is written in the standard, frankly boring style of the serious scientific article. Routine. But look again and note that the test material is neither an established nor potential pharmaceutical product, but **Cranberry Juice**. Read it carefully, please, before I make further comment.

Objective

To determine the effect of regular intake of cranberry juice beverage on bacteriuria and pyuria in elderly women.

Design

Randomized, double-blind, placebo-controlled trial.

Subjects

Volunteer sample of 153 elderly women (mean age, 78.5 years).

Intervention

Subjects were randomly assigned to consume 300 mL per day of a commercially available standard cranberry beverage or a specially prepared synthetic placebo drink that was indistinguishable in taste, appearance, and vitamin C content but lacked cranberry content.

Outcome Measures

A baseline urine sample and six clean-voided study urine samples were collected at approximately 1-month intervals and tested quantitatively for bacteriuria and the presence of white blood cells.

Results

Subjects randomized to the cranberry beverage had odds of bacteriuria (defined as organisms numbering 2105/mL) with pyuria that were only 42% of the odds in the control group ($P = .004$). Their odds of remaining bacteriuric-pyuric, given that they were bacteriuric-pyuric in the previous month, were only 27% of the odds in the control group ($P = .006$).

Conclusions

These findings suggest that use of a cranberry beverage reduces the frequency of bacteriuria with pyuria in older women. Prevalent beliefs about the effects of cranberry juice on the urinary tract may have micro-biological justification.

So what of the oft-quoted principle that the randomised, placebo-controlled clinical trial has no application outside of new medicines research? Maybe it is not so much principle as self-interest. I once proposed to two businessmen who wanted to promote a food substance for a medical indication how easily they could establish a programme of research to prove their point. The kinder of the pair interrupted me to say: "We have taken up this product to make money, not to spend it".

I would like to address three things in this article.

Firstly, my admiration for the sponsor. This research was funded through a research grant from Ocean Spray Cranberries, Inc, but a footnote makes it clear just how independent the research was:

"The sponsor had no role at all in the development of the experimental design, analysis of the data, or interpretation and presentation of findings. No author serves as a consultant to Ocean Spray or has any financial relationship to the company."

Unlike the businessmen I met in my youth, this sponsor was prepared to enter an essentially risky relationship with the research team at the Brigham and Woman's Hospital, Boston, Massachusetts in order to gain respectable proof of their conviction.

Secondly, why do we find that other sponsors endlessly assert that the scientific method cannot be applied to their product/situation? Could it be they lack faith in their product's ability to perform as claimed? Or do they just believe that scientific proof is expensive and unnecessary in a world where it seems anyone will believe anything (as long as it is not a doctor that says it)? There is no doubt that the research done by Ocean Spray Cranberries was expensive, but the benefit is obvious. And actually the downside is small. Good negative research might not even get published, let alone be widely disseminated, while the sponsor has an obvious right widely to quote this successful outcome.

Third, rather importantly, money. Ocean Spray Cranberries, Inc is a growers' cooperative and the placebo was a synthetic juice made without cranberries, but of similar smell and flavour. Perhaps they saw the possibility that such a synthetic product could be produced by rivals and sold. But there is no way they can protect their research from use by growers outside the cooperative.

However, within the pharmaceutical market an originator can protect unpatentable industrial property rights to their expensive research. In the EU medicines control system a new "Proprietary Medicinal Product" is protected by EU Directive against copies for a period of 6 or 10 years in various Member States before a simplified registration procedure can be used to bring an "essentially similar" product to the EU market. This means that a generic (copyist) company must repeat the research if they want to make the same claims the original sponsor is able to make on the basis of their scientific research. This method is open to any company.

It must be admitted that scientific freedom of expression is somewhat impeded when this path is followed because to keep information that might be valuable to competitors out of the public domain, the originator of the research needs to be economical with the details. However, balance this disadvantage against the considerable value to be gained if more products, currently sold by innuendo and suggestion in health food shops, went down the path of evidence-based assessment and were able to profit from the operation.

Michael E Allen, Treasurer of Health Watch

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