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GOOD EVIDENCE SAVING LIVES

PRESENTING the 2009 HealthWatch Award, Nick Ross said, “Iain Chalmers has saved more people’s lives than anyone else I can think of.” Iain Chalmers, editor of the James Lind Library, has for the last 30 years championed the need for health professionals and patients to have access to unbiased evidence on which to base clinical decisions. His talk on the development of fair tests of treatments in health care was illustrated with examples going as far back as 1500BCE, all taken from the James Lind Library’s extensive and publicly searchable online archives. More details and a summary of the talk appears on pages 4 and 5 of this issue, while a fuller version can be found on the HealthWatch website www.healthwatch-uk.org.

Some fifty members of HealthWatch and its committee were present at this year’s Annual General Meeting, held on 29th October at the Medical Society of London.

There was a warm welcome back for Peter Wilmshurst, the cardiologist who had received the HealthWatch Award in 2003 for his courage in challenging misconduct in medical research. Dr Wilmshurst is currently being sued over his criticisms of an American trial of a heart implant (see *HealthWatch Newsletter* issues 72, 73 and 75 from the past 12 months). Dr Wilmshurst’s case has been featured in the national press recently along with calls for reform to England’s libel laws. Referring to his courage in speaking out for science, HealthWatch’s president Nick Ross described Wilmshurst as, “on the side of the angels.” (See page 2 of this issue for more about Peter Wilmshurst).

There was good news for medical students this year. The generous grant from AJAHMA, which has supported the HealthWatch Student Prize since its inception six years ago, will soon run out so it was with great pleasure that Walli Bounds announced that the Medico-Legal Society has agreed to take over funding of the annual award. The HealthWatch Student Prize encourages healthcare undergraduates to learn how to critically evaluate clinical research protocols. It invites students to rank four trial protocols in order of merit and to identify and explain their strengths and flaws. This year’s winner was Suzanna Jefferson, a student of medicine at



Nick Ross (left) presents the award to Iain Chalmers

Queen Mary’s University of London. Suzanna’s entry showed, according to Nick Ross, “a very good understanding”. She is pictured below, second from left, with runners-up Simon Rowland (Imperial), Lauren Ewington (Imperial), Rohit Narayan (Birmingham) and Ross Mirvis (Imperial). Suzanna received a cheque for £500, the runners-up each received £100.

Although the competition was originally open to students of nursing and complementary medicine, most entries—and certainly by far the highest quality ones—been from medical students. “We’ve been impressed with some well-reasoned entries,” said Walli Bounds.

Mandy Payne



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CONCERN OVER EU'S NEW DRUG AD PLANS

IT IS EXACTLY six years since HealthWatch published its position paper on Direct-to-Consumer Advertising of prescription medicines (DTCA). Its author, the late Michael Allen, described it as, "a bad idea". Now the latest EU "Information to patients" Directive is attracting criticism from health care professionals, scientists, and groups representing consumers and patients who fear that, if approved, it could lead to that "bad idea" becoming a reality in Europe.

Worldwide the only countries that currently permit advertising of prescription drugs direct to consumers are the USA and New Zealand. The US experience has shown that more advertising leads to more requests for advertised medicines, and more prescriptions². It has also included tragedy. Merck's painkiller Vioxx (rofecoxib) was withdrawn in 2004 after being found to increase cardiovascular risk, resulting in deaths. It had been heavily promoted through DTCA.

A "pharmaceutical package" put forward by the European Commission in December 2008 includes suggested amendments (affecting Articles 86 and 88, Directive 2004/27/EC) which would permit certain exceptions to the current pharma advertising ban in Europe. For example, direct information by the producers may be permitted if medicines are presented in appropriate context and if the information does not go beyond the approved labelling. Its supporters argue that quality drug information should be available to counter online misinformation. But the proposal has so far been shelved by EU member states amid concerns that the measures proposed would open the door to

direct advertising of prescription drugs.

At an expert meeting at the European Parliament in Brussels on 2nd December 2009, attended by nearly 100 patient group representatives, policy-makers, pharmaceutical companies, and health professionals, Dr Barbara Mintzes of the University of British Columbia showed evidence that even when drug companies advertise within the suggested guidelines, "disease-mongering is common". Jorg Schaaber, President of the International Society of Drug Bulletins, gave examples of selective use of trial data in pharmaceutical company websites aimed at patients, and called instead for support for the high quality independent information sources that already exist in Europe.

Some participants argued against the proposed amendments, others suggested improvements. All who spoke agreed that the new proposal was far from meeting patients' needs in its current form.

Michael Allen had prepared HealthWatch's 2003 Position Paper in response to earlier EC proposals that were, ultimately, rejected by the European Parliament. In the light of the new developments his work remains relevant.

Mandy Payne

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Scuba divers rally round to support Peter Wilmshurst

MEDIA INTEREST in cardiologist Peter Wilmshurst's libel case continues to grow after his conversation with Justice Secretary Jack Straw in November, who subsequently announced plans to reform England's libel laws. (Read *The Times*' report on <http://business.timesonline.co.uk/tol/business/law/article6932252.ece>).

Readers may not be aware that Dr Wilmshurst also has a dedicated following among the scuba diving community. As a medical referee on the UK Sport Diving Medical Committee, the cardiologist at the Royal Shrewsbury Hospital has published widely on diving-related clinical problems. Forums on diving websites are littered with comments of thanks and appreciation from those who have

benefited personally from his work.

The February issue of *Dive* magazine plans to publish a letter from Graham Fisher, of Leeds, which says, "Along with many other divers, I have reason to be grateful for diagnosis and advice from Dr Wilmshurst following dive related problems," and asks members to show their support by contributing towards Dr Wilmshurst's legal case via the HealthWatch website. Scuba diving websites and local diving newsletters are echoing Fisher's comments of support. Look out for www.divemagazine.co.uk or Google "Wilmshurst, diving".

Mandy Payne

NEWS IN BRIEF

THE INSTITUTE for Science in Medicine (ISM) is a new international policy group that aims to alert the public and policy-makers to the dangers of ignoring scientific validation of medical interventions. Many of ISM's leaders, who include Edzard Ernst, professor of complementary medicine at the Peninsula Medical School in Exeter, and David Colquhoun, professor of pharmacology at University College London, are already prominent bloggers on the subject.

<http://www.scienceinmedicine.org/>

A BOOK co-authored by HealthWatch's vice-chairman Keith Isaacson was highly commended at the BMA Medical Book Awards this year. The British Orthodontic Society's Radiology Guidelines was described as, "...an excellent, well written and concise write-up on the background of clinical dental radiographs and indication for radiographs in clinical orthodontics. It is a must read for all clinical dentists especially those treating children" Keith Isaacson is consultant orthodontist at the North Hampshire

Hospital in Basingstoke. He is one of four experts in dental and maxillofacial radiology who authored the book. It is available for £15.00 (inc p&p) online from www.bos.org.uk or by telephoning 020 7353 8680.

THE LIBEL REFORM COALITION was launched on 10th December 2009 by science and free speech groups including Sense About Science and Index on Censorship. Raymond Tallis, emeritus professor of geriatric medicine and 2007 HealthWatch Awardwinner, commented, "I think the public must now know that they should be afraid, very afraid, of the way the libel laws are being used to suppress challenges to dangerous and fraudulent scientific claims." A new petition calling for reforms such as a cap on legal costs and damages, and stronger public interest defences to libel, has begun on www.libelreform.org

The Times, 10th December 2009. View on www.timesonline.co.uk/tol/news/science/medicine/article6951054/ece

ACTIVITIES, CHALLENGES AND SUCCESSES

At the 21st HealthWatch Annual General Meeting, held on 29th October at the Medical Society of London, chairman James May reported on the activities that HealthWatch has done, the challenges faced and the successes achieved.



BEGINNING WITH HealthWatch's many activities of 2009, I am personally very grateful for all the hard work of the committee. Keith Isaacson is our vice chairman, Gillian Robinson our secretary, Anne Raikes looks after our finances, and other members are David Bender, Susan Bewley, Walli Bounds, Diana Brahams, Malcolm Brahams, John Garrow, John Illman, Caroline Richmond, and Les Rose. Two student members Alison Myers and Ashley Simpson have also attended regularly throughout the year. In addition we are very grateful to Ken Bodman our membership secretary.

The standard of the Newsletter has been very high in the past year. We are profoundly grateful to our editor Mandy Payne and to Caroline Addy, the barrister who proof reads the text for libel. The newsletter is circulated to journalists and members of HealthWatch.

The Student Prize is awarded for the ranking of clinical protocols to promote skills in evidence based medicine amongst medical and nursing students. We are very indebted to Walli Bounds and Gillian Robinson for producing the protocols and for deciding on the winning entries. Our thanks are also due to Joan Gandy who publicises the competition and collects and sorts the correct entries.

The HealthWatch website is well used, averaging 1,200 hits per day. It contains an archive of previous newsletters as well as position papers on various subjects.

The Google Group is increasingly one of the main ways of developing ideas and strategies and keeping each other up to date. Members can join the group discussions by contacting David Bender on david.bender@btinternet.com

Challenges

The Pittilo Report on the regulation of traditional medicine: The Department of Health is currently consulting the public regarding the Pittilo recommendations for the regulation of Acupuncture, herbal medicine, Traditional Chinese medicine, and other traditional medicines. HealthWatch is concerned that the recommendations focus on regulating the side-effects rather than the supposed effects of these therapies. We encouraged our members to complete the online consultation questionnaires before the 2nd November deadline, in which activity they were helped by guidance available on David Colquhoun's website: www.dscience.net/?p=2310

RCP 'Integrated Health Committee': The Royal College of Physicians has an 'Integrated Health Committee' which seems under heavy influence of CAM and the Prince's Foundation for Integrated Health. We have expressed our concerns in writing and personally to the chair of the committee, Mike Cheshire. This is against the declared purpose of the college to protect the public from misleading health claims. We feel that the association of the College with conferences that promote CAM will be interpreted as the College's support for CAM. We plan further responses but are encouraged that the College seems to recognise our concerns.

NICE Guidelines on Back Pain: NICE have produced guidelines for the management of chronic lower back pain recommending that acupuncture, osteopathy and chiropractic be used as an adjunct to conventional therapies. We are concerned that the evidence base for this is very thin for acupuncture and non-existent for the manipulative therapies. Three members of HealthWatch, along with Tracey Brown from Sense about Science, have met with Sir Michael Rawlins, chairman of NICE, to express our concerns, and are pleased that he seemed receptive to them.

Whistle-blowing: We have a Whistle-blowers' support fund set up to help Peter Wilmshurst in his libel case against NMT medical. John Garrow wrote a summary of his case in the last newsletter

(*HealthWatch Newsletter* issue 75, October 2009). Peter is a previous winner of the HealthWatch award for his whistle-blowing activities and may yet win it again if he carries on like this. Details of how to contribute to the support fund are available on the HealthWatch website.

Simon Singh: The science writer Simon Singh has won his right to appeal the ruling against his use of the word 'bogus' in reference to the British Chiropractors association. In recent months Edzard Ernst has been prolific in writing articles in journals and magazines regarding the lack of evidence for claims previously made by the British Chiropractors Association.

'Integrative Medicine' Editorial in BMJ: HealthWatch was concerned that this editorial (1st September 2009) was really promoting CAM and avoiding questions of efficacy by muddling the physical effects of a treatment with the interpersonal skills of the clinician. HealthWatch members contributed the majority of over 50 rapid responses to this article online.

New BMJ group journal "Acupuncture in Medicine": HealthWatch will be keeping a close eye on developments with this new journal which on one hand should encourage good research to be done, but on the other hand seems to give undue recognition to a field which so far can only claim limited evidential support.

Successes

WHO has responded to homeopathy concerns: The Voice of Young Scientists wrote an open letter to the World Health Organisation expressing their concern about the use of homeopathy in the developing world (see *HealthWatch Newsletter* issue 74, July 2009). WHO responded by saying that it DOES NOT recommend the use of homeopathy for treating HIV, TB, malaria, influenza and infant diarrhoea.

Homeopaths under pressure: In a German journal a Director of the Society of Homeopaths, Lionel Milgrom, published a long article entitled 'Homeopathy in the UK and its detractors'. This was explicitly about the pressure homeopaths are feeling in the UK.

Chiropractic under pressure: Chiropractors are also under considerable pressure, principally as a result of their libel action against Simon Singh. Ben Goldacre has reported in the Guardian about the substantial media attention, international petitions, and the work of bloggers that have resulted from this case. Around 1,000 chiropractors have been reported to Trading Standards for making claims that cannot be substantiated. There has also been made public a statement leaked from one chiropractic group, which they sent to all their members warning them to take down their websites in case they were caught advertising services that had no evidence to support them.

This is a summary of the highlights of the last year.

*James May
HealthWatch Chairman and GP Principal, London*

THE DEVELOPMENT OF FAIR TESTS OF TREATMENTS IN HEALTH CARE



Iain Chalmers has devoted the last 30 years to efforts to help ensure that health professionals and patients have access to unbiased evidence on which to base their treatment decisions, most famously through his work as one of the co-founders of the Cochrane Collaboration. He was at the first ever HealthWatch meeting back in 1992, and since then he's been a friend and valued critic, and prepared to make a pointed comment if he ever believes HealthWatch has failed to apply to itself the standards it expects of others. "It's important to be even-handed, for us all to be judged by the same rules. If we depart from this, then we'll be open to the accusation of double standards," he said by introduction to his talk at the 2009 HealthWatch AGM. Chalmers, who received a knighthood in 2000 for services to healthcare, applies his passion for fairness now as editor of the James Lind Library¹, created to help people understand fair tests of treatments in health care.

A FEW journalists—among them Nick Ross—understand evidence based medicine, and are prepared to battle against the stereotypes. On the 2nd April 2001 Nick was amongst fifty people who met to consider how to get the public to appreciate randomised controlled trials. There's a problem with the name: it has so many negatives associated with it. "Randomised" suggests haphazard. "Controlled" implies controlling. "Trials" has legal connotations. It was Nick Ross who suggested, "why not call them fair tests?"

James Lind, a pioneer of fair tests, was a naval surgeon in the 18th Century and a member of the Society of Naval Surgeons (whose members went on to found the Medical Society of London). Like many who favour quantifying outcomes, he was something of an outsider. It's harder to ask the question, "Is the Emperor wearing clothes?" when you're a member of the Emperor's establishment. It's a problem that remains with us today. No matter how fair the test itself, the interpretation of science continues to be distorted by those who have a vested interest in the results, other than the well-being of patients.

The James Lind Library was launched by the Library of the Royal College of Physicians in Edinburgh in 2003. It has an online archive of illustrative records, from 1550 BCE to the present, illustrating how fair tests developed². These make clear that many of the principles of fair tests that we still use today go back hundreds, even thousands of years.

Conceptualising fair tests of treatments

In an extract of a letter written in 1364³, the Italian poet Francesco Petrarca wrote, "I solemnly affirm and believe, if a hundred or a thousand men of the same age, same temperament and habits, together with the same surroundings, were attacked at the same time by the same disease, that if one half followed the prescriptions of the doctors of the variety of those practising at the present day, and that the other half took no medicine but relied on Nature's instincts, I have no doubt as to which half would escape."

Treatments with dramatic effects

Even earlier, we have a surgical papyrus dated from around 1550 BCE which has been translated to reveal an explanation of how to reduce a dislocated mandible. It describes exactly what we do today, yet it was written more than 3,000 years ago. You don't need carefully controlled trials to prove a treatment which is so clearly effective.

Recognizing the needs for controls

In the 10th Century CE, the Baghdad doctor Abu Bakr Muhammad ibn Zakariyya al-Razi (Rhazes), wrote on his experience of treating meningial inflammation, noting the characteristic symptoms of photophobia, neck stiffness and headache. He wrote, "So when you

see these symptoms, then proceed with bloodletting. For I once saved one group [of patients] by it, while I intentionally neglected [to bleed] another group. By doing that, I wished to reach a conclusion." If this sounds rather barbaric remember it's the way of thinking that's important—he realised that he needed an untreated group in order to make an inference about the effects of his treatments.

Prospective experiments

The James Lind Library records a 16th Century example of a within-patient prospective controlled trial. "A kitchen boy fell into a cauldron of almost boiling oil..." wrote the French royal surgeon Ambroise Paré in 1575. "I went to ask an apothecary for the refrigerant medicines that one was accustomed to apply to burns. A good old village woman, hearing that I was speaking of this burn, advised me to apply for the first dressing raw onions crushed with a little salt... I was agreeable to trying the experiment and, truly, the next day, the places where the onions had been had no blisters or pustules, and where they had not been, all was blistered."

During 18th Century naval campaigns more sailors were being killed by scurvy than by the fighting. One of several recommended treatments at the time was vitriol (sulphuric acid), which was favoured by the Royal College of Physicians of London. Of one of the earliest known reports of a clinical trial, the naval surgeon James Lind wrote in 1753, "...I took twelve patients in the scurvy... Their cases were as similar as I could have them. They all in general had putrid gums, the spots and lassitude, with weakness of their knees. They lay together in one place, being a proper apartment for the sick in the fore-hold; and had one diet common to all." Lind allocated two sailors with scurvy to each of: "a quart of cider a day; twenty-five gutts of elixir vitriol three times a day; two spoonfuls of vinegar three times a day; a course of sea water... half a pint each day; two oranges and one lemon every day; the bigness of a nutmeg three times a day." The most sudden and visible effects were seen amongst the seamen taking the fruit.

"Blinding" assessment of outcomes

The report of the homeopathic salt trials in Nuremburg in 1835 contains a detailed description of a randomized double-blind experiment in which participants were given either a homeopathic salt solution or pure distilled snow water. The details of which num-

bered bottles had contained which liquid were kept sealed until the end of the experiment. The experiences of the participants in the two groups were indistinguishable. One should bear in mind that homeopathic care in the late 18th and early 19th century was almost certainly safer than the bleeding, purging and use of heavy metals by orthodox practitioners.

Recognising the “law of large numbers” and the “limits of oscillation”

The idea of using numerical data to justify conclusions about treatments goes back at least three centuries. Pioneering work on how to apply inferential statistics to therapeutic data in order to make critical judgments on the value of therapies was published in Paris in 1840 by Louis-Dominique-Jules Gavarret. According to his beautifully written *Principes Généraux de Statistique Medicale*, “Average mortality, as provided by statistics, is never the exact and strict translation of the influence of the test medication but approaches it all the more as the number of observations increases. To be able to decide in favour of one treatment method over another, it is not enough for the method to yield better results: the difference found must also exceed a certain limit, the extent of which is a function of the number of observations.” Hence, the need to estimate what he calls “the limits of oscillation” (confidence intervals).

“Moore estimated that at the peak of their use in the late 1980’s, these widely-used anti-arrhythmic drugs killed as many Americans every year as were killed during the whole of the Vietnam war”

Confidence in results can be increased by examining the results of multiple trials. A key paper in the history of meta-analysis is Karl Pearson’s 1904 report in the *British Medical Journal* on “certain enteric fever inoculation statistics” which looked at correlations between typhoid and mortality and the inoculation status of soldiers serving in various parts of the British Empire.

In the early 20th Century important advances in study design were implemented in the USA in a programme of research to assess serum treatments for pneumonia. The trials in the programme demonstrated many of the important features of fair tests, involving large numbers of patients, allocation to treatment or control groups using an unbiased process (alternation), an assessment of the likelihood that observed differences could be explained by chance, and meta-analysis of the results of similar studies.

Recognising reporting bias

The English philosopher and statesman Francis Bacon, in his 1620 “New Instrument for the Sciences” commented, “It is a proper and perpetual error in Human Understanding, to be rather moved and stirred up by affirmatives than by negatives...” This is still as true today, and it can kill. Dr Cowley and his colleagues wrote in 1993 how, in an unpublished study done 13 years before, nine patients had died among the 49 assigned to an anti-arrhythmic drug (lorcainide) compared with only one patient among a similar number given placebos. “We thought that the increased death rate that occurred in the drug group was an effect of chance... The development of the drug was abandoned for commercial reasons, and this study was therefore never published; it is now a good example of ‘publication bias’. The results described here...might have provided an early warning of trouble ahead.”¹⁴ In his 1995 book *Deadly Medicine*, the American author Thomas J Moore estimated that at the peak of their use in the late 1980’s, these widely-used anti-

arrhythmic drugs killed as many Americans every year as were killed during the whole of the Vietnam war.”

Recognising the need for a cumulative science

In 1884 Lord Rayleigh, professor of physics in Cambridge and President of the British Association for the Advancement of Science, said, “If, as is sometimes supposed, science consisted in nothing but the laborious accumulation of facts, it would soon come to a standstill, crushed, as it were, under its own weight... The work which deserves, but I am afraid does not always receive, the most credit is that in which discovery and explanation go hand in hand, in which not only are new facts presented, but their relation to old ones is pointed out.”

In 1965 the English epidemiologist and statistician, Austin Bradford Hill, framed the four questions to which readers want answers when reading reports of research: Why did you start? What did you do? What answer did you get? And, what does it mean anyway?

An example that lives up to Bradford Hill’s expectations is the CRASH research into the effects of systemic corticosteroids in acute traumatic brain injury. The research was started because practice varied and a systematic review of existing studies (some of which had never been published) revealed important uncertainty about whether systematic steroids did more good than harm. To address this important uncertainty a large publicly-funded, multi-centre randomized trial—called the CRASH trial—was organised. The results, which were published in the *Lancet* in 2004⁶ revealed that this treatment had been killing people since it was first used nearly 40 years previously.

The report of the CRASH trial is exemplary because it referred to current uncertainty about the effects of a treatment, manifested in a systematic review of all the existing evidence, and in variations in clinical practice; it noted that the trial was registered and the protocol published prospectively; it set the new results in the context of an updated systematic review of all the existing evidence; and it provided readers with all the evidence needed for action to prevent thousands of iatrogenic deaths.

In summary, science is cumulative, so researchers must cumulate scientifically, using methods and materials to reduce biases and the play of chance. Because researchers still do not do this routinely, people continue to suffer and die unnecessarily.

Iain Chalmers
Editor, James Lind Library

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MUCK AND MAGIC WIN FARMERS' PRIZE



THE BBC FOOD and Farming Awards Farmer of the Year is an “award for someone who has risen to the challenges of farming in the 21st century and is an inspiration to anyone interested in food production and the countryside”¹. The awards for 2009 were presented by HRH the Prince of Wales at a ceremony on November 25th, and the winner was Andrew Dennis of Woodlands Organic Farm in Lincolnshire.

Woodlands Organic Farm is a mixed farm growing cereals, fruit and vegetables and raising livestock, all in an organic way, using manure from the livestock to fertilize the fields.

Some organic food certainly tastes better than intensively reared animals or intensively grown crops. This may be because the food is fresher (especially from a local farmers’ market or farm shop). It may also be because many organic farmers also raise rare breeds of livestock, which may grow more slowly (and so are less profitable for conventional farming, but have a better flavour). The same is true of fruit and vegetables—many of the traditional varieties grown by organic farmers have a better flavour than higher yielding and faster growing crops.

But is organic food “better for us” or more nutritious? The Food Standards Agency² has summarised the evidence and concluded that there is no nutritional difference between organic and conventional foods, and for safety there are strict legal controls on pesticide and herbicide residues in food. The nutrient yield of fruits and vegetables varies widely, even between individual fruits of the same variety grown in the same soil. Indeed, the fruit from one side of a tree may have a better flavour and more micronutrients than those on the other side of the same tree.

Magkos and coworkers³ note that “some organic foods can be expected to contain fewer agrochemical residues and lower levels of nitrate than conventionally grown alternatives. On the other hand, environmental contaminants are equally present in foods of both origins. With regard to other food hazards, such as natural chemicals, microbial pathogens and mycotoxins, no clear conclusions can be drawn.” They suggest that the use of animal manure on salad crops may increase the risk of food-borne infection, especially from *E. coli*. Their conclusion is that, “it is difficult...to weigh the risks, but what should be made clear to consumers is that ‘organic’ does not equal ‘safe’”.

My problem with this awardwinner is that Andrew Dennis describes himself as a biodynamic farmer, using special biodynamic preparations (which he described on radio as being “like homeopathic fertilisers”) to his soil and plants. The Woodlands’ website has a link to the Biodynamic Agricultural Association⁴, which tells us that “the practice of the biodynamic method...embraces the idea that the whole earth is a living organism...The biodynamic farm is self-sustaining, depending largely for its manures and feedstuffs on its own resources and thereby benefiting and harmonising rather than exploiting it. A biodynamic farm is a mixed farm, with an appropriate balance of animals and crops, a system of recycling and benign methods of pest and disease control. *Implicit is the use of specific biodynamic preparations added in minute quantities to soil, compost and growing plants.* Establishing and maintaining a balanced biodynamic farm or garden...takes into account the whole environment: the underlying rock strata, the soil, the atmosphere, the local flora and fauna and *above all, the cosmic forces acting upon them*” (my italics).

Among the biodynamic preparations offered on the Biodynamic Agricultural Association website are:

- Horn manure: “a specially fermented cow manure preparation... It encourages healthy root growth, assists the plant in finding nutrients and mediates the terrestrial forces of life. Under drought situations it encourages deep rooting”.

- Horn silica: “finely ground quartz meal energized through spending the summer in the soil inside a cow horn. It is sprayed as a fine mist directly on to the growing plant at specific stages in its development. It helps to stabilize growth and plant metabolism and enhances qualitative development. It also benefits the ripening process in all kinds of crops”.

We are told that, “one unit of horn manure (20 ml) or one unit of horn silica (1 ml) stirred in 10–15 litres (3 gals) of water, is enough for one acre.” Surely you need more than 20 ml of cow manure per acre to do any good? And I doubt that any useful amount of silicon will dissolve in water no matter how finely the quartz has been ground or how long it has been buried in a cow horn.

We are also offered preparations we can place into a compost or manure pile, which “radiate their effects throughout the material”:

- Yarrow preparation, which “is connected to the potassium and sulphur processes of the soil and helps draw in substances, finely distributed in the atmosphere and beyond to replenish soil grown tired through many years of cultivation.” I’d be worried if my compost drew in substances from beyond the atmosphere!
- Oak bark preparation, which “is rich in calcium substance. It helps to ward off so-called plant diseases and fungal attacks”. Does this imply that plant diseases are a figment of our imagination, and what is “calcium substance”?
- Dandelion preparation, which “is connected with living silica processes, activates light influences in the soil and enables the interrelationships of nature to become fully effective”. What are “living silica processes”? What are “light influences in the soil”?

Then there is Three Kings Preparation. This is sprayed on January 6th “as a gift to the elemental world. It also has a harmonising effect.” A set, which includes 15 g each of gold (D2), frankincense and myrrh along with an instruction sheet and 25 ml of glyc-erine, costs £10.

Wikipedia⁵ says that the founder of biodynamic farming was Rudolf Steiner (1861–1925), “an Austrian philosopher, social thinker, architect and esotericist. He gained initial recognition as a literary critic and cultural philosopher. At the beginning of the twentieth century, he founded a new spiritual movement, Anthroposophy, as an esoteric philosophy growing out of European transcendentalist roots with links to Theosophy.” He seems to have had no qualifications in chemistry or agriculture.

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SHOULD YOU STILL TAKE ASPIRIN REGULARLY?



A new report in the Drug and Therapeutics Bulletin¹ warns that the benefits and risks of taking daily aspirin may be more finely balanced than previously thought. Millions of over-50's could be self-medicating in the belief they are reducing their risk of cardiovascular disease. Are they in danger? Keith Isaacson considers the evidence.

For many years now a daily low dose of aspirin has been recommended as a method of helping to prevent cardiovascular disease, heart attacks or even strokes. Aspirin affects platelets by making them less sticky and less likely to form a thrombus. The official guidelines of NICE², and also Scotland's equivalent body, the Scottish Intercollegiate Guidelines Network³, have been advising a regular daily dose of 75mg. As a result large groups of people, maybe millions, are probably taking a daily dose.

The patients for whom a regular daily dose of aspirin is recommended fall into three groups.

- *Those who have already had some cardiovascular event: a mild heart attack, angina or a mild stroke. For these groups aspirin is indicated for secondary prevention of any recurrence.*
- *Those patients who are at a higher risk of getting cardiovascular disease, including ones with Type II diabetes who are over 50 years of age, and patients with hypertension, provided their blood pressure has been brought under control.*
- *Patients over 50 who have a risk factor of getting cardiovascular disease of over 20% in a 10 year period. (There are tables which can calculate the risk factor for an individual which are based on three factors. Firstly, whether the patient smokes or not. Secondly whether they have a raised systolic blood pressure and, thirdly, a calculation based on the levels of two types of blood cholesterol).*

The dose of aspirin one might take for a headache is 600mg up to four times a day, whereas the prophylactic dose is an eighth of that once a day. You would think, wouldn't you, that taking prophylactic aspirin is harmless? Not so. Not only does aspirin reduce the tendency of the blood to clot, which may result in intra-cranial bleeding, but it can also cause gastric damage *directly* because it is an irritant and *acts* indirectly as a result of its pharmacological effects on the gastric mucosa. Either may occur as a result of long term use or single dose treatment with aspirin.

There have been a number of studies and meta-analyses. One published in 2002 looked at 195 randomised trials of aspirin compared with no aspirin⁴. This made a total of over 130,000 patients. Serious vascular events occurred in 10.7% of the patients who were taking the aspirin compared with 13.2% of patients who were not. As a result it was considered a good idea to take aspirin routinely. However this particular study did not differentiate clearly between patients who had already had a cardiovascular event and patients who had none.

A more recent publication of randomised controlled trials, involving a total of 95,000 patients, looked at the relative benefits of aspirin for primary prevention in apparently healthy people i.e. primarily at low risk⁵. It found:

- *Reduction in serious vascular events was very small and there was little difference between those patients who were taking aspirin and those who were not.*
- *The rates of any cause of death due either to coronary heart disease and/or stroke did not differ between the aspirin and the non-aspirin groups*
- *There is an increased likelihood of having major gastro-intestinal or other extra cranial bleeding as a result of taking aspirin.*

Another meta-analysis looked at the difference between males and females using aspirin for just over 6 years⁶. This produced an average benefit of 3 cardiovascular events prevented per 1000 women and 4 cardiovascular events prevented per 1000 men. But this was offset by an additional 2.5 major bleeding events per 1000 women and 3 major bleeding events per 1000 men.

What about patients with diabetes? Well, again some recent work has cast doubt on its value even for such patients. A Scottish trial which lasted for six years comparing patients not taking aspirin with those taking aspirin 100mg daily found there was no reduction in the proportion of patients with diabetes either getting coronary heart disease or stroke, or dying from heart disease or stroke⁷.

The *Drug and Therapeutics Bulletin* (the doctors' excellent "Which" equivalent guide to medicines) has considered this very carefully. There is no doubt that for patients who have had a cardiovascular incident, the use of aspirin as secondary prevention is established and continues to be appropriate preventive treatment. However current evidence for its prophylactic use in primary prevention suggests that the benefits and risks of aspirin are more finely balanced than previously thought—even in individuals thought to be at increased risk of experiencing cardiovascular events, including those with diabetes or elevated blood pressure. "Low dose aspirin prophylaxis should not be routinely initiated for primary prevention", they conclude.

The *Drugs and Therapeutics Bulletin* draws attention to the fact that aspirin can be bought over the counter and there may be many patients doing this in the belief that it is helping them without having been assessed by their GP. So, the advice for any over 50's self-medicating with a small daily dose of aspirin is, admit to being over 50 and get an appointment to talk to your GP about it. Have your blood pressure checked too. Those already taking low dose aspirin on medical advice for primary prevention should discuss with their doctor whether to continue or not.

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A RANT AGAINST UCL'S CANCER APPEAL

Medical journalist and HealthWatch committee member Caroline Richmond was so furious when asked to donate to her hospital's "healing garden" that she had to protest.

UNIVERSITY COLLEGE Hospital and its now-deceased partner, the Middlesex, has looked after my lymphoma for fifteen years. When I sprouted a high-grade lymphoma they saved my life with high-dose chemotherapy and stem cell rescue despite my poor prognosis. Most of the hospital has now been rebuilt. The oncology department hasn't but plans are afoot. It includes a "healing garden" and a "wellness centre". I've just had an appeal from UCLH cancer services appeal. I have sent this rant to my oncologist, who certainly doesn't deserve to be ranted against.

Grrr. Is a healing garden one that doesn't have any fungi or bacteria in the soil? I think not.

Or which grows poisonous plants (Vinca, Taxus, etc) from which anti-cancer agents are extracted, and which we patients can chomp on as we wish? Again, I think not.

And what is a "wellness centre"?

When a hospital offers discredited therapies, it pleases alternative practitioners no end because it convinces patients that maybe there's something in reiki and reflexology, after all. Bah! Humbug!

During my 17-week stretch after the transplant in 2003 I was too weak to cut my own toenails, and a nurse couldn't because of some

regulation (though another nurse did them anyway when no-one was looking). Yet I was offered reflexology, which is foot massage with hokum thrown in. Words failed me.

If the oncology department want to offer tender loving care to patients, fine. Hairdressing, to those lucky enough to have hair. Massage, manicures and pedicures. Music, art. The Chelsea and Westminster is awash with marvellous art, and it makes me feel great. When I was in their day unit having a blood transfusion, a barbershop quartet came in and sang "I love you Peggy Sue". Terrific.

If the new dept has a garden I'll enjoy using it, but if they call it a "healing garden" it will enrage me so much I'll be unable to set foot in it.

I'm not sending any money for a new oncology-with-quackery centre, but will gladly contribute money for art, preferably by living British artists.

I know the hospital has someone in charge of art. If they launch an appeal, I'll contribute.

Caroline Richmond

Catch up online, video clips for news and entertainment

WHEN PAUL BENNETT, professional standards director for Boots, told a committee of MPs recently that the pharmacy chain stocks homeopathic remedies for no other reason than that they are popular, BBC News invited GP Sarah Jarvis to discuss with Professor George Lewith, of the Integrated Medicine Research Group at the University of Southampton, the question of whether homeopathy works. See <http://www.youtube.com/watch?v=mFtJgCzPgL0>. (The comments that prompted the piece can be read in the Daily Telegraph, 26th November, on <http://www.telegraph.co.uk/finance/newsbysector/retailandconsumer/6658864/Boots-we-sell-homeopathic-remedies-because-they-sell-not-because-they-work.html>)

Loretta Marron, who reported from Australia for the October

issue of the *HealthWatch Newsletter*, has sent in one of her recent exposes. Watch her in action on <http://blip.tv/file/2747331>.

For light relief, Susan Bewley has sent the classic nine minute philosophy on aspects of misrepresentation from Harry G Frankfurt on <http://www.youtube.com/watch?v=ISbI8MtUN0>. Comedian Dara O'Briain expounds on his views on alternative therapies on <http://www.youtube.com/watch?v=VlaV8swc-fo&feature=related>.

Some web clips may include unfortunate language and HealthWatch cannot be held responsible for any offence caused (neither for any injury resulting from uncontrolled laughter).

Mandy Payne

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