



Health Watch

...for treatment that works

Newsletter 59 October 2005

LANCET ISSUES CHALLENGE TO NICE ON HOMOEOPATHY

THE *LANCET* has called upon the Department of Health and the National Institute of Health and Clinical Excellence (NICE) to consider developing guidelines on the use of homoeopathic remedies as “a matter of urgent public concern”. The request comes after the publication of research¹ that labelled homoeopathy “no better than placebo”.

The research involved a review of 110 randomised, placebo-controlled trials of homoeopathy. When the analysis was restricted to large trials of high quality, said the team from Berne in Switzerland, there was no convincing evidence that homoeopathy was any better than a placebo (see page 3 of this issue for Neville Goodman’s comments on this report).

Richard Horton, the *Lancet*’s editor, has shared with the media his 31st August letter to Professor Sir Michael Rawlins, Chairman of NICE, in which calls for guidance on the use on homeopathic remedies on the NHS. Dr Horton writes, “The formulation of guidance based on an appraisal of homoeopathy’s effects would help to promote the best possible improvement in patient care for the given NHS resources available. NICE guidance would add substantially to the debate about whether and to what extent homoeopathy should be available on the NHS. There is now a sufficient evidence base on which to decide such guidance. Moreover, there is strong reason to believe that, in the absence of such guidance, there will continue to be inappropriate practice throughout the NHS.”

The *Lancet* action will be add substantially to the growing pres-

sure upon NICE and the Department of Health to answer concerns from the medical profession over double standards in requirements for evidence of safety and efficacy of treatments. According to a recent *Guardian* article², around 42% of GPs in England will consider referring patients to a homoeopath, while in Scotland as many as 86% are said to be in favour of the 250-year-old holistic therapy. As Horton writes in a hard-hitting editorial³ that coincided with his letter to NICE, “The more dilute the evidence for homoeopathy becomes, the greater seems its popularity.”

Reference

1. Shang A, Huwiler-Müntener K, Nartey L, *et al*. Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet* 2005; **366** (9487): 726–32.
2. Boseley, S. As a fourth study says it’s no better than a placebo, is this the end for homeopathy? *Guardian*, 26 August 2005. www.guardian.co.uk/medicine/story/0,11381,1556831,00.html
3. Horton, R. The end of homoeopathy. *Lancet* 2005; **366** (9487): 690.

A warm welcome to new HealthWatch treasurer

AFTER eight years of careful and conscientious money-management, HealthWatch’s treasurer John Hanford has now stood down in order to enjoy his retirement. He has the committee’s thanks and appreciation, not just for the professional manner in which he handled our accounts but also for his enthusiasm and willingness to contribute with ideas and suggestions in many other areas.

We are confident that HealthWatch’s funds will remain in good hands, with the appointment of Anne Raikes as our new treasurer. Anne is an Oxford maths graduate who qualified as a Chartered Accountant and has since acquired fifteen years’ experience as a

fund manager for Merrill Lynch Investment Managers, specialising in asset allocation mainly for international corporate clients. In her spare time she is a keen choral singer who also enjoys skiing, tennis and walking.

We look forward to welcoming our new treasurer formally onto the committee at this year’s HealthWatch Annual General Meeting (see page 2 for more details).



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PATIENTS “AT RISK” FROM OTC STATINS

INADEQUATELY TESTED cholesterol-lowering drugs are being sold over the counter—lawfully—at possible risk to patients, say doctors. UK medicines regulators apologised in June after the editor of the *Drug and Therapeutics Bulletin* (DTB) claimed publicly that evidence behind last year’s decision to offer Zocor Heart-Pro for sale through chemists was flawed. Yet the drug remains on sale, and now a HealthWatch committee member adds his concerns to those of the journal.

DTB’s editor Dr Ike Iheanacho first warned in April¹ that last year’s decision by the Medicines and Healthcare products Regulatory Agency (MHRA) to reclassify the cholesterol-lowering drug simvastatin as the over-the-counter product Zocor Heart-Pro (for heart attack prevention) was not based on robust evidence of clinical benefit. No trials, said Iheanacho, have assessed Zocor Heart-Pro’s long-term effectiveness in its target group—people likely to be at moderate risk of having a heart attack. The lack of such research, he said, raises serious questions about whether people are unknowingly wasting their money—around £170 per year—on a treatment that might not be doing them any good.

HealthWatch’s Keith Isaacson, a consultant in orthodontics, feels strongly about the potential risk to patients. Since people can be sold Zocor Heart-Pro without a proper examination including blood pressure and cholesterol level measurement, some could be wrongly classed and treated as being at only moderate risk of a heart attack, when in reality their risk is very much higher. “I’m concerned for patients might buy this drug when they don’t really need it,” says Isaacson. “But what about patients who may have high blood pressure that is not recognised? And those think that by taking Zocor Heart-Pro they are protected and don’t need to

alter their diet? Also, patients are at greater risk from cardiovascular events if they stop taking statins than if they had not taken them at all.”

DTB also claimed in April¹ that they had evidence that the MHRA wrongly reported last year’s public consultation that preceded the drug’s reclassification. After initially refusing to accept the journal’s analysis, the MHRA admitted in June that they had made an “administrative error” and said, in a letter to Iheanacho, that it would review procedures following its inaccurate reporting of the consultation². Dr Iheanacho, however, has called on the Government to appoint a truly independent medicines regulator with an unambiguous remit to protect public health³.

References

1. Simvastatin over the Counter. *Drug and Therapeutics Bulletin* April 2005; **43** (4): 25–28.
2. *Which?* press release, 8 June 2005. www.which.net/press/releases/health/050608_heart_nr.html
3. *Which?* press release, 1 September 2005. www.which.net/press/releases/health/050901_drug-regulation_nr.html

Prince to tell NHS “complementary therapies save money”

AN “OUTRAGEOUS and deeply flawed” report commissioned by the Prince of Wales is expected to arrive on ministers’ desks this month in an attempt to persuade the Government that billions of pounds of taxpayers’ money could be saved by providing complementary therapies on the NHS.

The report, which was seen in draft form by the *Times*, has been prepared by a former chief economics adviser to Barclays Bank who has no medical expertise. It reportedly includes claims that up to £480 million could be cut from the prescription drugs bill if ten per cent of GPs were to offer homoeopathy as an alternative to standard drugs, and that £38 million could be saved by switching

ten per cent of depression patients to the herbal remedy St John’s wort. Evidence offered, however, is said to be highly selective.

Edzard Ernst, Professor of Complementary and Alternative Medicine at the University of Exeter, who had been interviewed for the report has asked that his contribution be withdrawn from the final document. He was highly critical of the draft, telling *The Times* that it was based on hair-raisingly poor science and that the recommendations flew in the face of evidence which shows that providing alternative therapies incurs higher, not lower, costs.

Times, 24 August 2005

<http://www.timesonline.co.uk/article/0,,2-1748270,00.html>

Diary note: don’t miss the HealthWatch AGM

EUROPE’S FOREMOST authority on the subject of complementary and alternative medicine (CAM) will address HealthWatch’s seventeenth AGM and Open Meeting later this month.

The HealthWatch Award is to be presented to Professor Edzard Ernst, who holds the Laing Chair in Complementary Medicine at the Peninsula Medical School, a joint school of the Universities of Exeter and Plymouth. He will speak on, “Complementary and alternative medicine: the good, the bad and the ugly”.

The meeting, which is free and open to all, will take place on Thursday 20th October 2005 at The Medical Society of London, 11 Chandos Street, Cavendish Square, London W1M 0EB (nearest Underground, Oxford Street). The reception is to begin at 6.30pm, followed by the HealthWatch Annual General Meeting at 7.00pm

and award presentations. (Please note: all are welcome at the meeting, only members can vote at the AGM).

Nick Ross will present the HealthWatch AJAHMA Student Prize to the winners of this year’s competition assessing the quality of clinical trial protocols. The meeting will conclude with Professor Ernst’s address and discussion.

As usual, any present who would like to continue to debate the meeting’s issues with committee members over dinner can join them in a buffet with wine at 8.45pm at a cost of £27. Bookings for the meal must, however, be made in advance. Please send a cheque (made out to HealthWatch) to John Garrow, The Dial House, 93 Uxbridge Road Rickmansworth, Herts WD3 7DQ (or contact Michael Allen on 0208 789 7813) to reserve a place at the buffet.

BOLDNESS, HONESTY...AND HOMOEOPATHY

FIVE YEARS ago a double-blind trial of homoeopathy and placebo published in the *British Medical Journal* found in favour of homoeopathy in allergic rhinitis¹. Homoeopathic practitioners were pleased. Many of them responded, not just in letters to the journal (which can still be read on its website) but also in the popular media.



A few years before, I had been at a meeting on peer review held by the journal. In the course of a discussion on the impartiality of referees for medical journals, I admitted that I would not be able to referee papers claiming to show benefit from homoeopathy. My view was that homoeopathy cannot work, and thus any alleged benefit could mean only that the study was in some way flawed, or that the result was simply chance. A weakness of evidence-based medicine is its insistence that clinical evidence trumps all else, and it was clear to me at the meeting that many in the audience were hostile to my view that clinical evidence should be rejected if not consistent with the wider implications of pathophysiology.

Now, ten years after I explained my views on homoeopathy in the *HealthWatch Newsletter*², there is a real and substantial challenge to homoeopathy. In the *Lancet* of August 27, there appeared a comparative review³ by Shang and others of 110 homoeopathy trials and 110 matched trials of conventional medicine, plus an editorial and a comment piece. Feeling itself on firm ground, the *Lancet* issued a press release and a challenge to the Department of Health and to NICE (National Institute for Clinical Excellence) to issue guidance to the NHS “based on an appraisal of homoeopathy’s effects”, i.e. there are none that can’t be explained by the placebo effect. Despite safeguards, in the end no one can stop people buying whatever sorts of treatments they want, if they use their own money. But homoeopathy is available on the NHS, and the gauntlet has now been thrown down.

“Letter writers drew attention to work with animals and human infants, and one writer even claimed that homoeopathy was successful during cholera epidemics in the 19th century. But it really won’t do. When all the evidence is put together, homoeopathy is found wanting.”

Funnily enough, homoeopaths happily accepted the investigation of homoeopathy by conventional controlled trial when Taylor and colleagues’ paper was favourable. Now, suddenly, unfavourable evidence produced the standard objection that homoeopathy cannot be tested in this way, because it is such an individual treatment. Letter writers drew attention to work with animals and human infants, and one writer even claimed that homoeopathy was successful during cholera epidemics in the 19th century. But it really won’t do. When all the evidence is put together, homoeopathy is found wanting.

The sad thing is that Shang’s comparison was needed at all. It would be an extraordinary piece of luck or genius that enabled homoeopathy’s inventor, Samuel Hahnemann, to put forward a system of medicine that held more or less unchanged since he first wrote about it in 1796. In 1796, the idea that greater dilution produced more effective medicine might have been a reasonable one, but surely not in the 21st century. Reading Oliver Wendell Holmes’ 1842 analysis of Hahnemann’s ideas⁴ should convince anyone that homoeopathy can have no effect. Petr Skrabenek and James McCormick⁵ used an 1879 quotation to describe homoeo-

pathic dilutions: “one grain of salt dissolved in a volume of diluent which would fill 10 thousand billion spheres, each large enough to contain the whole solar system”. Yet doctors with modern training in physiology and pharmacology are still gathering to support homoeopathy. Well, now we shall see. Perhaps by the time this newsletter appears, the *Lancet* will have had an answer from NICE.

THE *Lancet* declared in an editorial accompanying Shang’s paper, “Now doctors need to be bold and honest with their patients about homoeopathy’s lack of benefit, and with themselves about the failings of modern medicine to address patients’ needs for personalized care.” Which is, of course, what it is all about. Modern medicine is rushed, starved for resources, impersonal. As Ben Goldacre wrote⁶, “...in many cases homeopathy does seem to help, as a complex intervention, laden with branded cultural meaning, at least better than “doing nothing”. So the question is whether the modern NHS, in a high-tech society, should be doing more than nothing for people who need not medicine, but personal attention or social support.

And as Goldacre also astutely pointed out—something that had not occurred to me but should have—allopathic doctors have been accused both from outside and inside the profession of paternalism, of not explaining things to patients and not giving them choice. Yet alternative practitioners are the ultimate paternalists: “the didactic, paternalistic, authoritative, mystifying mantle has passed to the alternative therapist”⁶. There is no doubt that many of the practitioners use it wisely and to good effect, but it is ultimately dishonest. The NHS must not countenance dishonesty.

Neville Goodman
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References

1. Taylor MA, Reilly D, Llewellyn-Jones RH, McSharry C, Aitchison TC. Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *British Medical Journal* 2000; **321**: 471–6.
2. Goodman NW. Opinion: homoeopathy. It may be popular, but does it work? *HealthWatch Newsletter* 1995 (October); **19**: 7.
3. Shang A, Huwiler-Müntener K, Nartey L, *et al*. Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet* 2005; **366**: 726–32.
4. Wendell Holmes O. Homeopathy. In: Stalker D, Glymour C. Examining holistic medicine. Buffalo, NY: Prometheus Books, 1989, pp 221–243.
5. Skrabenek P, McCormick J. Follies and fallacies in medicine. Glasgow: Tarragon Press, 1989, pp 115–9.
6. Goldacre B. A tonic for sceptics. *Guardian* 20 August 2005, p 16.

VACCINES AND AUTISM: THE LIMITATIONS OF PARENTAL EXPERTISE



Dr Michael Fitzpatrick is a London GP and the author of the acclaimed handbook, *MMR and Autism: What Parents Need to Know*. Dr Fitzpatrick writes occasionally for the *Lancet* and is a frequent contributor on medical matters to the news review web site, Spiked Online (www.spiked-online.com). He has an autistic son.

THE TRAGIC death of a five year old British autistic boy in the USA following mercury chelation¹—a treatment now being promoted by groups of parent activists on both sides of the Atlantic—has thrown the possible dangers of alternative therapies back into the spotlight.

Abubakar Tariq Nadama lived with his family—of Nigerian origin—in Batheston in Somerset until his mother took him to Portersville, Pennsylvania, where the Advanced Integrative Medicine Center offers to eliminate mercury from the body through the intravenous injection of the chelating agent EDTA. A growing number of campaigners believe that autism is the result of mercury toxicity caused, at least in part, by the mercury-based preservative thiomersal (thimerosal in the USA) formerly used in childhood vaccines. Many parent activists claim that chelation therapy has produced dramatic improvements in their children. Shortly after his third course of treatment, Abubakar sustained a cardiac arrest and died. A post mortem proved inconclusive and it could be several months before investigations are complete.

“The experience of having a child with autism qualifies you to speak authoritatively on your experience as a parent of a child with autism: it does not give you any particular insights into the science of autism.”

In 2004 the US Institute of Medicine systematically examined—and rejected—claims that vaccines (MMR as well as those containing mercury) may cause autism². The US drug regulatory agency, the FDA, approves chelation therapy only for acute mercury poisoning: there is no scientific evidence of its benefits in autism and little information about its risks.

Yet, despite the categorical dismissal of the mercury-autism theory by medical and scientific authorities, the anti-mercury campaign has continued to gather momentum. Earlier this year, David Kirby, a New York journalist, published *Evidence of Harm*³, a book promoting the anti-mercury cause, which has received widespread publicity. Defeat Autism Now!—a network of parents and doctors who offer a range of unorthodox treatments (including mercury chelation)—is staging a conference in Scotland this month.

Though the death of Abubakar Nadama has caused widespread shock throughout the world of autism, it seems not to have deterred the anti-mercury campaigners. In the same angry tones in which campaigners blame the medical establishment for poisoning their children with vaccines, they repudiated their critics in the US media:

“We are not desperate parents willing to try anything. We are educated, caring parents who have done thousands of hours of research and administered dozens of medical tests on our children

under the care of knowledgeable physicians.”⁴

Parent activists challenge mainstream scientific expertise with the evidence of their own experience and with the results of their own painstaking researches. But both these sources of knowledge may be misleading and relying on them may have damaging consequences for children with autism and their families.

Parents sometimes say “we know our children” better than any doctor or scientist. I would say that we know our children in a different way. It is a familiar experience with children who are not autistic that they sometimes behave very differently at home and at school; parents and teachers know them differently. With children with autism the problem is more profound. I obviously know my son with autism well; yet, in some ways I feel that I do not know him at all—that is the nature of the disorder. He is thirteen years old and I have never had a conversation with him and I have very little idea what is going on in his mind, try as I have to work it out. I fully accept that somebody who has studied the subject intensively and has clinical experience of a large number of people with autism might well know something more about my son than I do.

The experience of having a child with autism qualifies you to speak authoritatively on your experience as a parent of a child with autism: it does not give you any particular insights into the science of autism. Indeed one of the problems of being the parent of a child with autism is that it gives you little time or energy to study the wider aspects of the subject. In recent years, however, some parents have devoted much time to reading scientific papers on autism. But, when such parents demand to be heard—and are heard—in scientific controversies it is important that the limitations of parental experience and study are recognised.

MODERN scientific knowledge in any discipline is complex and highly specialised. The professional understanding of research scientists and clinicians is the product of a long process of study, training and experience. Such knowledge and expertise cannot be acquired through reading journals, downloading information from the internet and attending occasional conferences. At best, parents can acquire a “narrow-band competence” that may allow them to select information supporting some pre-conceived conviction, and presenting this may be effective for campaigning purposes. But a narrow and selective approach can lead to the sort of dogmatic outlook expressed by the anti-vaccine campaigners which is inimical to scientific inquiry and discussion.

In relation to autism research, there are important differences in the perspective of parents and scientists. Whereas parents’ central

concern is with their own children, scientists have to take account of the problems of all children with autism. Parents are interested in practical applications of scientific advances; and, watching their children fall ever further behind their peers, they are impatient for short-term results. Researchers are all too aware that, given the limitations of the current state of scientific knowledge of autism, practical applications are likely to be the long-term outcome of advances in the basic understanding of the condition. Parents, whose knowledge about autism is likely to date from the diagnosis of their child, are inclined to jump at novel theories or interventions. Scientists, who base their judgements of new developments and plans for research projects on years of familiarity with the field and on the experience of past studies and experiments, are likely to proceed more cautiously. Scientists are well aware that they may pursue many leads that turn out to be dead ends before they make some headway. Though parents may be impatient, they need to be careful they do not short-circuit the scientific process and take their children on journeys that lead to disappointment.

“When scientists appeal over the heads of their peers directly to a public lacking in scientific expertise there are dangers of manipulation.”

The closer relationship between parents’ groups and scientific research into autism may give rise to a number of problems. One is that, under pressure from parents desperate for rapid results, scientists may circumvent the procedures that have been established to ensure adequate standards and to safeguard the public. These procedures require that scientific work is reviewed by peers before publication, that provisional results are confirmed or replicated before claims of significant findings are made, that therapies are subjected to rigorous trials before they are recommended for public consumption. It is unfortunate that in the network of parents promoting chelation and other unorthodox therapies, it has become commonplace for all these safeguards to be violated. Scientists who identify with this approach release unpublished data and make claims of unconfirmed findings at public conferences. Parents seize upon provisional reports that appear to confirm some aspect

of the unorthodox approach or to validate some therapeutic intervention. There are clear dangers that such prematurely released results are unlikely to be confirmed and that therapies promoted in this way will turn out to be ineffective or to have harmful side-effects, or both.

WHEN scientists appeal over the heads of their peers directly to a public lacking in scientific expertise there are dangers of manipulation. I have attended conferences at which speakers have addressed parents in scientific jargon so dense as to be incomprehensible. Though the object of this exercise appears to be to demonstrate the intellectual authority of the speaker, it means using science to impress rather than to explain and it often leaves parents bewildered and confused. There is also a danger that scientists whose work is not of adequate quality to satisfy the standards of mainstream academic institutions may be able to secure recognition—and increasingly funding—from parent groups. The danger of abuse is greatest when there are links among scientists, parent groups and commercial interests, providing diagnostic tests, specialised dietary requirements, food supplements and medications. The common feature of all these interventions is that they are inordinately expensive and may constitute a substantial financial burden for some families with autistic children, whose resources are already severely stretched.

Michael Fitzpatrick

MMR and Autism: What Parents Need to Know was published by Routledge in 2004 (see review by Neville Goodman in the HealthWatch Newsletter issue 55, October 2004).

References

1. Smith L. Autistic boy, 5, dies after US therapy. *The Times*, 26th August 2005. www.timesonline.co.uk/article/0,,2-1751753,00.html
2. Immunisation Safety Review: Vaccines and Autism. Institute of Medicine, 2004.
3. David Kirby, Evidence of Harm: Mercury in Vaccines and the Autism Epidemic: Medical Controversy, New York: St Martin’s Press, 2005.
4. A statement from Generation Rescue regarding the tragic passing of Abubakar Tariq Nadama. www.generationrescue.org/tariq/html (accessed 5 September 2005).

GEARIN-TOSH DIES, BUT NOT FROM CANCER

THE OXFORD don, Michael Gearin-Tosh, died on July 29 2005 aged 65. HealthWatch members will remember the colourful Australian less for his brilliance as an English teacher or for his renowned generosity, than for the eccentric cancer treatments he embraced and later wrote about.

His book, *Living Proof—A Medical Mutiny* (2002), describes his fight against multiple myeloma (cancer of the bone marrow) which he had been diagnosed with eight years earlier. Given six months to live, Gearin-Tosh rejected the chemotherapy that he was told could give him at best another two years of life, and that at worst could itself kill him. Instead he embarked upon an exhausting regime based on the Gerson therapy, which subjected him to 12 freshly-made vegetable juices a day, high-dose vitamin injections, acupuncture, raw garlic, coffee enemas, Chinese breathing exercises and the visualisation of his immune cells attacking the tumour.

The extent to which this regime and the various other alternative treatments he tried were responsible for keeping him alive for the

next 11 years will continue to be a subject of debate. He died this summer, not from the myeloma, but from a systemic infection following a tooth extraction.

The Gerson therapy received publicity last year when prominent doctors castigated the Prince of Wales for promoting it despite lack of evidence of efficacy and concerns about the dangers to patients who abandon orthodox treatments to follow it. The regime was developed by the German physician Max Gerson, originally to treat his own migraine headaches and later used to treat cancer patients. He died in 1959 and his method is now promoted, not only by royal patrons, but through the Gerson Institute (www.gerson.org).

TAMOXIFEN AND THE SINGING VOICE

A SHORT news item in the last issue, which reported on a recent article by HealthWatch committee member Andrew Herxheimer, has generated letters. We reported on his recent article in the online journal PLoS (HealthWatch Newsletter July 2005, issue 58) and referred to a controversial example in order to illustrate his assertion that some side-effects of drug use that have a real impact on patients' lives might be ignored or considered trivial by health professionals. The example offered—that of a possible voice-deepening effect of the breast cancer drug Tamoxifen—attracted concerned attention from prominent advocates of research and patient information who argued that this was an anecdote whose repetition was leading to it being wrongly perceived as evidence. Dr Herxheimer has now sent to PLoS and the HealthWatch Newsletter a note amending the point he made in the original piece. His note, and some of the resulting correspondence, now follows.

Voice changes: evidence less clear than implied

Andrew Herxheimer writes:

MY REMARK in this essay¹, that deepening of the voice occurs with long-term use of tamoxifen for breast cancer, needs qualification.

Several colleagues have rightly pointed out that the evidence for the effect is less clear than I implied: it comes from women who have experienced it², but there have been no controlled studies. A change in voice was looked for and not found among effects spontaneously reported in large trials of tamoxifen, but this was not specifically asked about and might well have been missed. It is also recognised that the voice sometimes becomes deeper at or after the menopause, in the absence of tamoxifen.

To convey the uncertainty of the facts, I wish to amend my statement as follows:

"The irreversible deepening of the voice that has been reported to occur with long-term use of tamoxifen for breast cancer is an example of a side effect that prescribers, manufacturers, and drug regulators seem to have considered trivial and have not investigated."

ANDREW HERXHEIMER

References

1. Herxheimer, A. Communicating with Patients about Harms and Risks. *PLoS Medicine* 2005; **2** (2): e42 DOI:10.1371/journal.pmed.0020042
2. Goodare H (1992) Tamoxifen and singing. BCMA (Breast Cancer and Mastectomy Association) Network Spring 1992: 2.

Single anecdote versus a mountain of data

Hazel Thornton, Hon DSc (Leicester), is an independent advocate for quality in research and healthcare; Professor Michael Baum was principal investigator of the CRC tamoxifen and ATAC trials. They responded:

WE ARE PLEASED to note that Andrew has modified the statement made in his PLoS essay¹ and thank him for his acknowledgement. We feel it might be helpful for everyone if we provide some indication of steps that researchers take to explore and record side-effects. You may then appreciate why we have to disagree with his assertion that prescribers and manufacturers found this a "trivial" matter that has not been "investigated".

Thousands of patients have been studied in the NATO, CRC, IBIS and ATAC trials. The latest results in the ATAC trial with over 9,000 patients set up for registration of anastrozole with the FDA and with monitors employed for "good clinical practice" (GCP) is a good example of how clinical researchers leave no stone unturned in their search for any anticipated or unexpected adverse effects of drugs. The protocol of this study allowed for any "adverse event" (AE) described anecdotally in the case records to be captured blinded to treatment allocation².

To suggest therefore that the researchers were insensitive to any AE of importance to the individual participant in the trial, expected or unexpected is absurd. In addition, the confounding factors of concurrent chemotherapy and the psy-

chological stress of the diagnosis and surgical treatment of the cancer need to be taken into account when undertaking analyses. Aside from this, it is well known that lowering of both the singing and speaking female voice can occur at the time of the natural menopause that frequently coincides with the diagnosis of the disease. Furthermore a detailed quality of life study was carried out with 1,000 patients in the ATAC trial: this problem was not identified.

Any patients who experience side effects have opportunity to use the Cochrane Library's feedback system to submit criticisms of relevant reviews. The 'yellow card system' is also now open to patients to report side effects³.

HAZEL THORNTON

<http://www.le.ac.uk/press/press/bestinformedpatient.html>

MICHAEL BAUM

References

1. Herxheimer, A. Communicating with Patients about Harms and Risks. *PLoS Medicine* 2005; **2** (2): e42 DOI:10.1371/journal.pmed.0020042
2. ATAC trialist group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of post-menopausal women with early breast cancer: first results of the ATAC randomised trial. *Lancet* 2002; **359**: 2131–2139.
3. McCartney, M. Doctor's notes. *The Guardian: Health*, 8 Feb 2005, page 9.

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Proven effectiveness the only way to a “Club Class” NHS

Retired consultant surgeon David Crosby OBE LLM FRCS of Cardiff took issue with John Garrow's analogy between complementary medicine and flying “Club Class”.

Sirs,

PROFESSOR John Garrow writes interestingly in issue 58 of the *HealthWatch Newsletter* about his attendance at the “Integrated Health: coming of age” meeting at the Royal Society of Medicine, sponsored by the Foundation for Integrated Health which in turn is sponsored by Prince Charles. Professor Garrow appears to conclude from it that if the NHS could afford to provide complementary and alternative medicine (CAM) in addition to everything else it is trying to do, the result would be a Club Class service rather than Economy. In my view he has either gone native, or latched onto an inappropriate analogy.

Sir Iain Chalmers is right to castigate those who have not informed themselves about previous research, and to consider whether a given treatment may be doing more harm than good; and also to point out that much so called orthodox treatment is unsupported by sound evidence. You do not have to be a genius to identify a considerable number of such services including counselling, many screening programmes, and much of physiotherapy. But none of that in my opinion justifies the addition of more “therapies” to NHS provision, in the absence of sound evidence that they exceed the placebo effect, in which event, they should of course be regarded as orthodox.

The NHS already delivers several billions of pounds worth of CAM, most of which appears to have wormed its way into the system without the awkwardness of having to provide evidence of its effectiveness. Homoeopathy, aromatherapy, and much of acupuncture are good examples. And, as is well known, removing something that has already been provided “free” is extremely difficult. Now politicians—aided and abetted by Prince Charles and others—wish to add to it, whilst at the same time treatment of well-proven efficacy remains in short supply. Sheer madness, surely.

There can be no denying that the placebo effect is well worth having for many patients. Archie Cochrane himself said so more than thirty years ago:

“It is important to distinguish the very respectable, conscious use of placebos. The effect of placebos has been shown by randomised controlled trials to be very large. Their use in the correct place is to be encouraged. What is inefficient is the use of relatively expensive drugs as placebos”.

Were he still on the scene I feel sure he would have agreed to add “therapies which are relatively expensive”, because they are usually labour intensive. Since the population already spends willingly many billions of pounds of its own money on CAM, as it is fully entitled to do, the transfer of this commitment to the NHS would be disastrous despite the much increased funding by the present government. The notion that “free” CAM would divert public demand from the more expensive funding of orthodox treatment is at best ingenuous.

There is also the present day issue of “informed consent”. If the pseudo scientific nonsense and psychobabble of much of CAM is to be explained to recipient patients under current NHS guidance, this may pose difficulties for properly trained doctors to explain honestly.

It is reasonable to speculate where and why the continuing thrust to include CAM in NHS provision is coming from. My own view is that it includes politicians (votes), CAM providers (increased income), Royal Patronage (bias and blandishments), and many doctors who perceive it as an escape route from hypochondriacs, “heart sink” patients, and the “worried well”, rather than deal with these unfortunates themselves.

To return to Professor Garrow's reference to “Club Class or Economy?”, surely we should be aiming for an NHS that only provides treatment of proven effectiveness. If achieved, and other forms of wastefulness excluded, it would mean Club Class for everyone. Unfortunately this seems to be getting further off than ever.

Yours,
DAVID CROSBY

Reference

1. Effectiveness and Efficiency: Random Reflections on Health Services. A L Cochrane. The Nuffield Provincial Hospitals Trust 1972, p31.

Tamoxifen and the singing voice: last word?

Andrew Herxheimer concludes:

In response I would like to explain why I wrote that the effects of tamoxifen have not been investigated. Indeed I believe that the protocol of the ATAC and the other trials not merely allowed, but required adverse events described in the case records to be included for analysis. However only a minority of adverse events are recorded anecdotally, in trials as in practice. Voice change is gradual, no one is looking for it, and few women or their family members would think it might have to do with tamoxifen. The ATAC detailed quality of life study would not have found it without asking specifically about the voice.

The only way to establish reliably how often the voice changes is to look for it prospectively, asking women directly whether they have noticed any change, to describe it, and to say if it mattered. That's what I mean by “investigate”. No such investigation followed Heather Goodare's alert many years ago, suggesting that those who could have built it into

a trial thought it unimportant.

This general point applies to all clinical trials and systematic reviews, but has until now been very widely neglected. The methods used to ascertain and assess adverse effects are far less reliable than those for evaluating effectiveness. Until they are properly and critically used, conclusions on the benefit-harm balance of many treatments are likely to remain rosily biased.

This is discussed at length in *The Cochrane Handbook for Systematic Reviews of Interventions*, ed 4.2.5 [May 2005], in a new Appendix 6b on ‘Including Adverse Effects’.

ANDREW HERXHEIMER
Co-founder DIPEX www.dipex.org

Reference

1. Goodare H (1992) Tamoxifen and singing. BCMA (Breast Cancer and Mastectomy Association) Network Spring 1992: 2.

INFECTED BY MISINFORMATION

ONE OF THE many insidious ways in which the Internet is spreading medical misinformation is through health warnings that circulate by e-mail. Have you had one? Coming via a genuine friend, containing some hot new health news that you or I (but not most members of the public) would immediately suspect is no more than a piece of discredited research whose proponents won't allow to die, or some daft but superficially plausible health scare that's too wild to make it into the respectable media.

To call this circulation of misinformation an "infection" is apt—the way in which it travels could be described as "viral", being transmitted from one vulnerable person to all their personal contacts, who then pass it on to theirs, as you would the common cold.

One such message appeared on my laptop the other day. Though the sender had herself received it from a—doubtless—equally honest and concerned friend, the age and original source of the message was, of course, impossible to discover. How far worldwide it has already circulated, and how many women have been scared witless by it, can only be guessed at. As this particular e-mail came in at a quiet time, I decided to investigate.

Here's how it went.

Subject: FW: Breast Cancer

THIS IS INTERESTING

A friend of mine who has received Chemotherapy and is now receiving Radiation at Princess Margaret Hospital for breast cancer phoned me to tell me what they have now found about causes of breast cancer.

The person with the cancer has been told by the hospital to only use deodorant rather than an anti-perspirant.

The reasons are outlined in the letter below.

Sometime ago, I attended a Breast-Cancer-Awareness seminar. During the Q&A period, I asked why the most common area for breast cancer was near the armpit. My question could not be answered at that time. I have since found out that the leading cause of breast cancer is the use of anti-perspirant.

A concentration of toxins leads to cell mutations, a.k.a. cancer. Most of the products out there are an antiperspirant/deodorant combination. Deodorant is fine, anti-perspirant is not.

The human body has a few areas that it uses to purge toxins from the body; the toxins are purged in the form of perspiration. Anti-perspirant, as the name clearly indicates, prevents you from perspiring. Instead, the body deposits them in the lymph nodes.

Additionally, men are less likely (but not completely exempt) to develop breast cancer prompted by anti-perspirant usage because most of the anti-perspirant product is caught in their hair and is not directly applied to the skin. Women who apply anti-perspirant right after shaving increase the risk further.

PLEASE pass this along to anyone you care about.

It took ten minutes to run a Google search on "antiperspirant, breast cancer" and scan enough information to back up my impression that the message was a lot of nonsense. Not surprisingly the major cancer charities had already seen similar e-mails—they've been circulating since the 1990's—and had whole pages devoted to the subject. Cancer Research UK's reassurances are written in clear and simple language on <http://www.cancerhelp.org.uk/help/default.asp?page=3943>. Breast Cancer.Org write in some detail about the many limitations of a small study published last year that could have given new life to the rumour, in which chemicals called parabens (used in foods, medicines and cosmetics as well as deodorants) were found in breast tumour samples. See http://www.breastcancer.org/research_deodorant.html. Elsewhere *New Scientist* reports (January 2004) on a US epidemiological study linking breast cancer, antiperspirant use and under-arm shaving, saying it had too many weaknesses to be regarded as definitive. See <http://www.newscientist.com/channel/health/cancer/dn4587>.

The "Antiperspirant/breast cancer" headline also appears on a fascinating list titled "MOST COMMON COMPUTER HOAXES" on www.stiller.com, the website of a computer software R&D firm that specialises in virus protection. Their page <http://www.stiller.com/cancer.htm> reproduces a years-old e-mail warning which is in many details identical to the one I received days ago.

Naturally, I sent all this information back to my friend with the plea, "Please pass THIS along to anyone you care about!"

Mandy Payne

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