



HealthWatch

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REMEDIES TO STAY, LABELS TO CHANGE?

THE GOOD news from July's announcement on homeopathy from the UK Department of Health—that they are calling for a review of how homeopathic remedies are labelled—was somewhat diluted by the news that they have no plans to withdraw funding for NHS supply of the discredited therapies,¹ a position that has drawn an outcry from medical professionals. But more recent developments suggest that wider support for the government's stance may also be on the wane. In September a Scottish NHS trust announced it was to reconsider its own policy on the practice after a local homeopath claimed on TV to be offering the remedies in place of the MMR vaccine;² and even London's famous homeopathic hospital dropped the word "homeopathic" from its official title (see page 2 of this issue) amidst "witchcraft" jibes from a doctors' organisation.

Health secretary Andrew Lansley issued a statement in July which acknowledged that although, "the evidence of efficacy and the scientific basis of homeopathy is highly questionable" the products should remain available, "to provide patient choice."³ The coalition government's statement did, however, recognise that patient information supplied under the National Rules Scheme could be clearer, and said, "The Medicines and Healthcare products Regulatory Agency (MHRA) will review the labelling requirements under the National Rules Scheme to ensure that these deliver clarity as to the status of the products and their composition." The MHRA has told the *HealthWatch Newsletter* that its review is currently in progress and its findings are expected to be available towards the end of 2010.

The health secretary's statement was a response to February's 275-page report of the House of Commons Science and Technology Committee (HCSTC), which had called upon the government to stop funding homeopathy on the NHS.³ Lansley's words roused Professor Michael Baum, breast cancer surgeon and a founder member of HealthWatch, to comment in a letter in the *Lancet*, "It beggars belief that a modern NHS that prides itself on evidence-based medicine should fly in the face of the Science and Technology Committee, which concluded that homeopathy is nothing other than an elaborate placebo and involves deceiving the patient every time it is prescribed."⁴

James May, HealthWatch chairman and London GP, was one of many doctors to complain in writing directly to the health secretary. The Department of Health's Customer Service Centre replied, "Decisions on the provision and funding of any treatment will remain the responsibility of the NHS locally... The Department of Health would not intervene in such decisions." James May commented, "We are under considerable pressure from patients to provide CAM treatments. The government will be able to say to those demanding homeopathy, 'We have made it available'." The therapy, he said, gets undeserved credibility, making it harder for doctors to say "no".

February's HCSTC report examined the British government's policies on providing homeopathy through the NHS and the licensing of homeopathic products by the MHRA. The report recom-

mended that the government should stop paying for homeopathic consultations; remove funding for homeopathic hospitals; end the routine prescribing of placebos; and that the MRHA should withdraw its discrete licensing schemes for homeopathic products. It questioned the ethics of providing placebos and drew attention to the risk to patients' health, describing the government's position on homeopathy as, "confused". Evan Harris, a former Liberal Democrat MP who sat on the science select committee during the inquiry, told the *Independent* that the government's decision to continue funding homeopathy is not a good start for the new health secretary. "How does the Government justify allowing treatments that do not work to be provided by the NHS in the name of choice, when it allows medicines which do work to be banned from NHS use?"⁵

NHS Highland is considering withdrawing funding for homeopathy after an Inverness practitioner claimed on TV that she gave patients a homeopathic potion to replace the MMR vaccine. "Magic or Medicine—Homoeopathy and the NHS" was broadcast on BBC One Scotland at 19:30 on 13th September 2010.

Mandy Payne
Editor, HealthWatch Newsletter

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news

ARE OUR MEDICAL JOURNALS REALLY HAUNTED?

WHEN IS a medical writer a ghostwriter? The open access journal *PLoS Medicine* threw the issue into the spotlight in September by publishing an academic analysis of 1,500 documents relating to alleged ghostwriting, which had entered the public domain as part of the court case brought against Wyeth by around 14,000 patients who developed breast cancer while taking the hormone replacement therapy Prempro.

PLoS Medicine, acting with the *New York Times*, had argued successfully in court that sealed documents identified during the discovery process for the court case, which demonstrated the practice of ghostwriting, should be made available in the public interest.

In this particular case, writes Dr Adriane Fugh-Berman of Georgetown University Medical Center, Washington DC, dozens of ghostwritten reviews and commentaries published in medical journals and supplements were used to promote unproven benefits and downplay harms of menopausal hormone therapy (HT), and to cast competing therapies in a negative light. Specifically, ghostwritten articles were said to have been used “to mitigate the perceived risks of breast cancer associated with HT, to defend unsupported cardiovascular ‘benefits’ of HT, and to promote off-label, unproven uses of HT such as the prevention of dementia, Parkinson’s disease,

vision problems, and wrinkles.”

Commenting on the article, representatives of the European Medical Writers Association (EMWA) made the distinction between anonymous “ghostwriters” and professional medical writers who work within published guidelines, and who are appropriately named and acknowledged in the resulting publication. “While using ghostwriters to insert unwarranted marketing messages into papers is unacceptable...there is no evidence to suggest it is common,” wrote Adam Jacobs and Andrea Palluch.

Mandy Payne

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Fugh-Berman AJ. The Haunting of Medical Journals: How Ghostwriting Sold “HRT”. *PLoS Med* 2010; **7(9)**: e1000335. See: <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000335>

Diary date: HealthWatch AGM and 18th Award

THIS year’s HealthWatch Open Meeting and AGM will feature “How the web has turned the tables on pseudoscience”, a presentation from David Colquhoun, professor of pharmacology at University College London and the winner of the 18th HealthWatch Award. Nick Ross will also present awards to the winners of the annual HealthWatch Student Prize, for whose sponsorship this year we gratefully thank the Medico-Legal Society.

The meeting will be held on Thursday 28th October at The Medical Society of London, 11 Chandos Street, Cavendish Square,

London W1M 0EB (nearest Underground is Bond Street) starting with reception at 6.30pm. The meeting is free and open to all, but only members may vote at the AGM, which begins at 7.00pm. The meeting will be followed as usual by a buffet dinner with wine at 8.45pm, at £35. Booking forms being sent to members should be returned by 17th October, cheques made out to HEALTHWATCH. Any late applicants for the dinner should contact membership secretary Kenneth Bodman on kenneth.bodman@btinternet.com

NEWS IN BRIEF

AS OF September 2010, the Royal London Homoeopathic Hospital has been renamed the Royal London Hospital for Integrated Medicine. The change is said to better reflect the hospital’s methods, though critics have speculated that the new name is designed to make it look “less flaky”. The hospital in Great Ormond Street, part of the University College London hospitals, came under fire recently from the British Medical Association’s junior doctors committee, whose deputy chairman Dr Tom Dolphin said: “Homeopathy is witchcraft.”

London Evening Standard, 16 September 2010.

See: www.thisislondon.co.uk/standard/article-23878782-homeopathic-hospitals-name-change-is-dishonest.do

VICTIMS of England’s libel laws—cardiologist Peter Wilmshurst, and science writers Simon Singh and Ben Goldacre—are asking 1,000 supporters to donate £10 each to help engineer a more effective libel reform bill. The Government is writing a new defamation bill to be published in the New Year. Campaigners say the inject of cash at this crucial stage will help ensure the government fulfils its pledges and reduce the risk of the new bill being watered down by vested interests. Donate at: www.justgiving.com/libelreform

THE WORK of the above libel reform campaigners was recognised in the Medical Journalist Association’s awards this year.

Simon Singh won Health Campaigner of the Year, while the charity Sense About Science (which has been co-ordinating the campaign) took Health Charity of the Year, in the MJA’s 2010 Awards. Ben Goldacre received a commendation in the Freelance Journalist category.

See: www.mjauk.org/

THE ADVERTISING Standards Authority (ASA) will soon give consumers much wider protection from misleading advertising on the Internet. From March 2011, the ASA’s code of advertising practice will apply in full to marketing material on advertisers’ own websites, as well as in non-paid-for space under their control, such as social networking sites like Facebook and Twitter. Journalistic and editorial content will continue to be exempt. However websites originating outside the UK, even if directed at UK markets, also necessarily fall outside the net. New sanctions include removing ads that link to the page hosting the non-compliant marketing communication; and the ASA’s placing of paid-for search advertisements online to highlight an advertiser’s continued non-compliance. The ASA have received over 3,500 complaints since 2008 about marketing communications on websites that couldn’t be dealt with under the current system but which would be actionable under the new rules.

See: www.asa.org.uk/Media-Centre/2010/ASA-digital-remit-extension.aspx

WHISTLEBLOWING AND THE ABUSE OF LIBEL LAW: A VIEW FROM FRANCE

ENGLAND IS NOT the only country whose libel laws can be abused to silence scientific debate. In 2006, medical researcher Pierre Méneton became the first French healthcare professional to be sued for libel.¹ Méneton had been trying to implement national recommendations for dietary salt intake in line with worldwide guidelines. The Comité de Salines, France's agent for the salt industry, sued the researcher over his claims that consumers were being misinformed by salt industry publicity.

Méneton triumphed—in early 2008 the court dismissed the case, pointing out that a critical opinion proposed by a scientist is not a libel. However Méneton was not actively protected by his employers (INSERM, France's national institute for health and medical research). His country's equivalents of the General Medical Council, the Department of Health and the healthcare watchdog (Haute Autorité de Santé or HAS) also remained silent. Fortunately he received help and funds for the suit from *Prescrire*, France's famous independent drug bulletin.

The second French healthcare professional to be sued for libel is, as far as we are aware, Gérard Dubois, professor of public health at Amiens University Hospital and a 2008 recipient of the Legion d'Honneur, France's highest civil and military honour. Dubois was sued in autumn 2009 by the Confédération des Buralistes (the French tobacconists' union) after he stated on French TV² that cigarettes kill two smokers a year for every tobacconist. He won but the case has gone to appeal. The irony is that in June 2009 Professor Dubois received a "Knowledge for the World" award in the US from the Johns Hopkins Alumni Association for making the very same claims.³ Dubois' efforts to protect the French public from the dangers of tobacco are well known. In 1991, Dubois and four colleagues (collectively dubbed "the Five Wise Men") drafted a report that resulted in France's first major anti-tobacco law, named the Loi Evin, of 1991. Among other measures, Evin's Law regulated tobacco advertising, smoking in public places, and excluded tobacco from the retail price index. Dubois' 2003 book, *Le Rideau de Fumée* (The Smoke Screen),⁴ exposed tobacco industry documents. He secured a two-phase regulation which banned smoking in the workplace in 2007 and, the following year, in all public places. Now the professor is fighting his libel case with help from the Comité National Contre le Tabagisme (the National Committee Against Smoking, an NGO). His university, however, remains silent.

In France, very few people can translate the term "whistleblowing" into their own language, and even fewer can name someone who has successfully drawn the authorities' attention to a practice over which they had concerns. The Conseil d'État, France's highest administrative court, judges that servants must remain silent ("duty of confidentiality"), implying that whistleblowing is an offence.

"In France, very few people can translate the term 'whistleblowing' into their own language"

In the minds of French medics, the journal *Prescrire* stands out as being one of the few organisations prepared to push its head above the parapet. The following example is one among many: since 2005 it was making yearly calls^{5,6} for the banning in France of benfluorex, a derivative of fenfluramine marketed for diabetes and weight loss (fenfluramine and most of its derivatives were withdrawn from the US and many other markets worldwide in 1997). Indeed, after the withdrawal of benfluorex's marketing authorization in April 2003 in Spain for serious adverse effects (valvular heart disease) the ban rapidly spread among European countries. But not to France. Despite international isolation, the French National Health Scheme was still reimbursing the cost of benfluorex in 2006, as noted in a

formal evaluation by the "Transparency Committee" of the HAS' drug assessment committee. What's more, in 2009 two generics of the same drug appeared on the market. This was the same year that the European Medicines Agency recommended revoking marketing authorisations for medicines containing benfluorex from all EU markets because of poor efficacy and links to heart valve disease.⁷ It was not until 30th November 2009 that the withdrawal of benfluorex in France was finally implemented.

In the UK, in contrast, whistleblowing is an important part of an organisation's safety culture, and those who raise concerns in the public interest are protected in law from dismissal and victimisation by the Public Interest Disclosure Act of 1998.⁸ Introducing new guidance for National Health Service employees issued in June 2010, the UK's secretary of state for health stated, "It is vital that staff in the NHS feel empowered and expected to speak up whenever patient safety may be compromised or errors occur."⁹ The British Medical Association's own guidance on whistleblowing,¹⁰ issued last year, advises, "Every doctor has an obligation to protect fellow colleagues, patients and themselves from unprofessional conduct or acts of clinical negligence. Speaking up is an act of conscience, knowing that inaction, while an easier option, may lead to harm to others."

THIS IS IN sharp contrast to the experience of Dr Alain Braillon. He had, since 2005, been a senior tenured consultant in Professor Dubois' unit at Amiens, until his surprise sacking last December when his position, as head of the regional body for the assessment of professional practice, was abolished by a vote of the hospital board. Known as a "high profile expert on public health",¹¹ Braillon had been in charge of several regional programmes (e.g., hepatitis B prevention, smoking cessation in pregnancy, suicide prevention) which were subsequently terminated. (François Bourdillon, chairman of Société Française de Santé Publique, the French Public Health society, later told the *BMJ* "This is the first case of the sacking of a public health expert that I have heard of."¹¹). France's National Management Centre (the counterpart of the UK's Department of Health) investigated only after the event to confirm Braillon's sacking, and did so without hearing evidence from him. A large majority of the members of the National Statutory Committee objected to the sacking, however the National Management Centre overturned the advice. Both facts are unusual, accordingly their coincidence is exceptional.

The French General Medical Council remain silent but many professionals, leaders and organizations from various specialities are publicly supporting Braillon in the French media. Denise Silber, the CEO of the healthcare IT company Basile Strategy, was one of the first to blog in support of Braillon.¹²

Health care administrators have the impossible task of extracting more from less. French public hospitals now have to comply with "tariff by activity" (or T2A)—they receive funding per activity carried out. Time-consuming public health programmes, which can be expensive to run and with benefits only seen in the long term, are hard to justify. The shift of decision-making from doctors to administrators makes this a serious concern in France as in many countries. Sadly, the three most frequent avoidable causes of death and illness have

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public health

ON SECURING THE SUPPLY OF EFFECTIVE DRUGS, AND EATING CHILDREN

Corticosteroids, prescribed to mothers delivering pre-term babies, are among the most effective and life-saving drugs that we have. But the supply chain is fragile and doctors may have to ration supplies to the most vulnerable patients. Susan Bewley reports on repeated threats of shortages and how they affect hospital care.



RECENTLY I SHARED a lift in my centre of excellence with a person wearing a hospital badge stating “Cancer Centre Complementary Therapist”. On the same day I received the following e-mail about a vital drug shortage (our pharmacy alerts relevant clinicians but HealthWatch members may be unaware of the extent of the NHS’s problems):

“There are at present and for the next few weeks national shortages of all brands of betamethasone and dexamethasone injection that we stock. Given the national nature of this shortage, it is unlikely that we will be able to purchase any other brand in the short term. Could the neonatologists please advise which babies they would consider most at risk (the Preterm Guideline states, “those at risk of imminent delivery”) so that prescribing for administration to the mothers can be prioritised...”

I have received several similar e-mails in the last two years.

These two corticosteroids, dexamethasone and betamethasone, improve fetal lung maturity when babies are at high chance of premature delivery.¹ Some clinicians are also using these drugs for babies having elective caesarean section.² They are given as a “one-off” course of two injections 12-24 hours apart. The Cochrane review states that, “a single course of corticosteroid, given to the mother in preterm labour and before the baby is born, helps to develop the baby’s lungs and reduces complications like respiratory distress syndrome (RDS). Furthermore, this treatment results in fewer babies dying and fewer common serious neurological and abdominal problems, e.g., cerebroventricular haemorrhage and necrotising enterocolitis, that affect babies born very early. There does not appear to be any negative effects of the corticosteroid on the mother. Long-term outcomes on both baby and mother are also good.”

Unlike many drugs used to prevent or treat heart disease, stroke or cancer, antenatal corticosteroids have a very low “number needed to treat”. We only have to prescribe them to a handful of pregnant women at risk of premature delivery to be sure of saving one baby’s life or long-term health. Not bad compared to lots of other best-selling medications! Corticosteroids’ benefits, and their data for quality-, or disability-adjusted life years, are far superior to those for new chemotherapeutic agents, for example. It’s great being an obstetrician, as so many of our (admittedly few) treatments really work.

Yet recently, the NHS has repeatedly run short of standard obstetric medications. A couple of years ago we couldn’t prescribe methyl dopa for a little while (a safe drug still used for pre-eclampsia). Later, the pharmacy had to scabble around to keep the small amount of the hospital’s supply of intravenous labetalol (used in severe stroke-threatening pre-eclampsia) reserved for the labour ward as there were concerns about the use of the alternatives in pregnancy. Then there was a problem obtaining betamethasone so we switched temporarily to dexamethasone. Now it was both corticosteroids at the same time.

After pointing out that obstetricians were better placed than neonatologists to advise which babies were at risk of being born, my colleagues rallied round; some suggested that we limit steroids by gestation, particularly if the mother was having a non-labour caesarean, others that we might use a research fibronectin test that more accurately predicts pre-term delivery in women with uterine activity and threatened premature labour. The pharmacists managed

to source a supply of dexamethasone from another nearby hospital. Notices went up regarding the proposed change in drug, dose and volume to be drawn up from the ampoule. Two days later another memo circulated:

“Pharmacy have been able to obtain a supply of our normal dexamethasone injection today and there is still betamethasone injection (e.g., on Antenatal Ward) and some dexamethasone available on the unit so steroids should continue to be given for all usual indications at present although supply is still very fragile...”

So, the short-lived crisis was averted and we went back to our usual recommended prescribing unlimited by supply. But for how long?

The risk is that patients will not receive effective, timely medication and be endangered as a consequence. I am unaware of any harm that occurred from any of these shortages, but they necessitate work, use up valuable pharmacy and clinician time dealing with the continuing problems of changing drugs and dosages and must lead to confusion. The Royal College of Obstetricians and Gynaecologists has communicated with the Department of Health on several occasions, as this has affected medications with a long history of effectiveness in pregnancy. A number of the shortages are fed down to pharmacy through national channels but unfortunately they come across the majority on an ad hoc, reactive basis. I was told that if our medical director contacted the DoH for an explanation each time there was a problem in our large Trust, he would be making ten calls a day, as pharmacy had hundreds of order lines outstanding.

“We only need to prescribe these corticosteroids to a handful of pregnant women at risk of premature delivery to be sure of saving one baby’s life or long-term health.”

Why the shortages in vital obstetric drugs? The politics are complicated, but various reasons have been proffered including: the fall in the value of the pound compared to the Euro, supply problems with limited numbers of producers, producers giving up unprofitable “old drugs”, manufacturing problems, and on one occasion a factory fire in Eastern Europe. *Chemist & Druggist* magazine’s latest stock survey shows that supply is a continuing problem for many branded medicines,³ but our problem is a complete absence of the effective drugs, even generics. The national problem was well documented as, it was alleged, being due to the exchange rate leading to exporters moving to Europe, but the betamethasone situation was different as there were manufacturing problems with one particular batch; pharmacy were waiting for the next batch to clear all processes. They could have imported betamethasone from abroad in the meantime, but it would have been a different formulation to that we were used to at four times the cost and with a time delay, hence

the option to swap to dexamethasone.

It's so ironic considering how difficult it was to get obstetricians to change their practice in the 1990's on the basis of the evidence from randomised trials and reviews from the 1980s. I recall resistance in 1994 to a unit-wide protocol for steroids from older colleagues who chose not to believe the evidence nor the warnings about the litigation problems of failing to use corticosteroids.⁴ A friend told me of influential senior clinicians who spoke out against the evidence, such that it was just not possible to prescribe corticosteroids in certain cities in France. One evidence-based protester dared to write the graffiti "Bokassa II" on the wall of a maternity building (referring to the African president with close suspicious links with France who was accused of eating children).⁵ The fact remains that many premature babies died or were avoidably damaged by the slow implementation of evidence into clinical practice.

There is a steady stream of high-value medico-legal negligence cases that turn on the year a mother was in premature labour or her pregnancy was ended for preeclampsia and whether there would have been time for corticosteroids to have been administered and have effect. We use so few effective medications in pregnancy it seems scarcely credible that these powerful life-saving drugs are now imperilled by a fragile supply chain.

PROBLEMS look set to continue. Professional guidance is thus required for prescribers: for obstetricians, this might include how to avoid early delivery or prioritise those babies at risk of RDS. The Royal Colleges of Midwives, Obstetricians and Paediatricians might work together with national pharmacy bodies regarding what to say to those pregnant women who will, or will not, get steroids or antihypertensives during the next shortage. This would be transparent, fair and protective of patients, whilst also enabling wider discussion of why these shortages occur and recur.

There is no evidence that complementary therapy is effective against cancer but corticosteroids do save life and prevent hand-capping brain haemorrhage in premature infants. In my hospital the first is available (a charity pays) and yet the supply chain of the second is insecure. Should patients and the general public be informed about real threats to the prescription of treatments that work, or would that be too unsettling? In times of recession, difficult choices and backdoor rationing, maybe it would be good to return to an explicit, old-fashioned health policy principle of "women and children first". When my turn comes I'd willingly forgo my chance of receiving an Alzheimer drug or toxic treatment for metastases,⁶ in favour of premature babies starting out life more healthily. I believe most parents and taxpayers would agree. Antenatal corticosteroids don't even cost much. Ah, but maybe therein lies the problem? My

accountant sister always tells me to, "watch where the money goes" and reminds me that pregnant women are not a powerful economic force. Homeopathy remains available both on the NHS and for those who'll pay for it. Politicians are determined that voters should be able to choose ineffective complementary medicines. Maybe the dilemma could be solved by giving women at imminent risk of premature birth a homeopathic pill or placebo injection of water? It would just be a shame for the babies with life-threatening complications that remedies containing nothing don't work so well.

Susan Bewley

Consultant Obstetrician & Honorary Senior Lecturer

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Footnote It was the New Zealand physiologist, Sir Graham "Mont" Liggins, who first conceived the idea of using corticosteroids in premature labour. He died on 25th August this year aged 84. His obituary in the *Guardian* of 6th September describes the fascinating story of how he developed the life-saving treatment after observing the deaths of premature lambs at a neighbour's farm. See: www.guardian.co.uk/society/2010/sep/06/sir-graham-mont-liggins-obituary

Herbal remedies linked with bleeding after dental surgery

A DOCTOR in Manchester has reported the unusual case of a man who presented at an Accident and Emergency department because his gum would not stop bleeding after a tooth extraction. The phenomenon was attributed to long-term use of herbal remedies.

The letter in the *British Dental Journal* explains that the 46-year-old man had had a routine extraction of an upper molar earlier the same day but when the wound continued to bleed he went to the city's Royal Infirmary. Doctors there found the tooth socket had not clotted properly was gently oozing blood. They stopped the bleeding with stitches and dressings but were puzzled as to the cause.

On further questioning the patient revealed that he had, for a number of years, been taking a range of vitamin and herbal remedies including Ginkgo biloba, ginseng, garlic and ginger. Dr Patel, the letter's author, notes that there have been case studies linking

herbs such as Ginkgo to post-operative bleeding, but few involved dental surgery.

Ginkgo, often taken to improve memory and circulation, is known to have an anti-coagulant action. The case highlights the potential for post-operative complications and drug interactions in patients taking herbal remedies. Dr Patel writes that many patients do not feel they need to inform health professionals of herbal remedies when giving their drug history but that herbal and vitamin supplements may well be medically relevant.

Mandy Payne

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research

EVIDENCE BY NUMBERS

TWO YEARS AGO I gave a brief account of a DIY low-cost method for testing the reliability of methods of diagnosing disorders (*HealthWatch Newsletter 70, July 2008*). I used Applied Kinesiology, referred to here as AK, to test for food allergy. But it can be used for any diagnostic test such as iridology or reflexology where the presence of disease anywhere in the body is indicated by changes in distant points, such as the pupil of the eye, or sole of the feet.

The score card for the test is shown on the right. Glass phials containing twelve common antigens (milk to grasses) were tested on 20 consecutive patients. Their positive reactions are shown by an X on the upper part of the chart. Among the 20 patients tested there were 43 positive reactions.

Every patient was then tested again using another set of 12 phials that were coded A-L. These contained the same range of antigens as in the previous testing or, in some cases, only saline. In this "blind" testing there were 79 positive reactors.

Analysis of the data on the card shows that on only 6 occasions did the patients give reactions consistent with the allergy diagnosis made by AK, and that on 73 occasions the reactions were false (i.e., positive when they should be negative, or vice versa). Since correct responses were observed in only 6 out of 79 this is well within the proportion that would be expected on the basis of chance.

Here, then, is the evidence that this version of AK cannot diagnose food allergy. But, just to be sure, I decided to subject the results to a standard analysis and for this I acknowledge with thanks the help of statistician Tim Greene, who did the maths and, furthermore, undertook to explain its significance to us in wonderfully plain English.

Tim said, "Given the results from the first round of 'labeled' tests, the expected number of correct guesses is shown in the table below, along with the actual re-test results. The expected numbers are calculated separately for each substance, and then summed.

"This shows that the re-test results are very similar to those one would expect to get purely by guesswork: in terms of correctly identifying samples which had tested positive when openly labelled, 8 out of 50 were correctly identified, while guesswork would produce, on average, 9 correct results. However in terms of correctly identifying samples which had tested negative at the open label stage, 126 out of 150 were correctly identified, slightly more than the 121 one would expect to get, on average, by chance.

OPEN LABEL SAMPLES

Patient no.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	total
Milk	X	X								X	X		X	X							6/20
Cheese		X	X				X	X		X											4/20
Candida	X	X		X	X	X					X			X	X			X			9/20
Maize		X								X					X		X				4/20
Yeast															X		X		X		3/20
Ethanol		X						X													2/20
Beef			X				X							X		X					4/20
Lamb					X										X	X					3/20
Pork				X																	1/20
Cod																X					1/20
Orange		X																			1/20
Grasses	X	X				X	X										X				5/20
Total +ve	1	6	4	1	2	1	2	4	1	2	2	1	1	1	3	4	1	4	1	1	43/240

CODED LABEL SAMPLES

PATIENT no.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	total
Correct	0	3	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	1	0	0	6
False	3	6	7	4	4	1	4	4	1	4	6	3	3	3	4	7	1	2	3	3	73
Total	3	9	7	4	4	1	4	4	1	5	6	3	3	3	5	7	1	3	3	3	79

Responses of 20 patients to 12 labelled antigens and 12 code-labelled antigens (X denotes positive response)

"Total expected agreement would be 65.4% by chance alone, and the agreement actually observed was 67.0%. This gives a kappa (chance-corrected agreement) value of 0.05, with a 95% confidence interval for kappa being -0.14 to +0.23. Although the interpretation of Kappa is problematic, values below 0.2 are generally considered to indicate 'Poor' agreement, while values in the range 0.2 to 0.4 indicate 'Fair' agreement." So, is predicting allergic reactions using Applied Kinesiology more reliable than making predictions by chance? "The results for this test show there is no evidence of even moderate, let alone good, agreement," that predictions made by AK are more reliable than those made using chance alone.

*John Garrow
Emeritus Professor of Human Nutrition
University of London*

	Expected if guessing	Actual re-test results
Correct blind positive response	9.32 (4.7%)	8 (4.0%)
False blind negative response	42.68 (21.3%)	42 (21.0%)
False blind positive response	26.52 (13.3%)	24 (12.0%)
Correct blind negative response	121.48 (60.7%)	126 (63.0%)
Total	200 (100.0%)	200 (100.0%)

COPE didn't receive complaint about eCAM

IN THE LAST issue Les Rose wrote of his disappointment as a peer reviewer for the journal *Evidence-Based Complementary Medicine (eCAM)*, and said that his complaint to the Committee on Publication Ethics (COPE) was not actioned. Liz Wager, chair of the COPE, was concerned and contacted Les to say that she had not received his complaint and invited him to re-submit it.

Les responded, "It seems that my message to COPE disappeared into the ether somehow. I completed the contact form on the website, got confirmation that it had been received, and then nothing.

Technical problem? Not sure, but I can certainly trust Liz when she says she never saw it. It emerges that *eCAM* has not signed up to the COPE standards, so is not bound by them. Looking at the standards, it would be amazing if *eCAM* could accept them. Interestingly, the journal is leaving Oxford University Press in January 2011 and will be published by Hindawi. Meanwhile I will chase up OUP again while I have the chance. So I am grateful for Liz Wager's intervention and advice."

Mandy Payne

“NHS Evidence” or NHS evidence-spinning?

MOST READERS will know “NHS Evidence”.¹ It aims to allow healthcare professionals “to access a wide range of health information to help them deliver quality patient care”. It has 34 specialist collections, one of which is “NHS Evidence—complementary and alternative medicine”. This collection is in the hands of a project team drawn from the following three organisations: the Royal London Homeopathic Hospital; the Research Council of Complementary Medicine; and the University of Westminster (CAM group).



It has six academic consultants (I am one of them), seven associate editors and an external reference group of 35 individuals. It is worth your while having a look at all these names to find out whether you see more than one person who is remotely critical of CAM.

On 14 June, “NHS Evidence—complementary and alternative medicine” published the “2010 Annual Evidence Update on Homeopathy”.² It aims to “identify, organise and present all relevant systematic reviews and RCTs published between May 2009 and May 2010”. I was delighted to see one of our articles included. Here is what they said about it:

“The SR on the efficacy of homeopathy included four RCTs [randomised controlled trials]. Two of these involved individualised homeopathy, but with a limited range of homeopathic medicines, versus placebo, one used fully individualised homeopathy also controlled against placebo. The fourth looked at “care by a homeopath”, including the consultation and medicine, compared to normal care alone. The conclusion was that all RCTs reported evidence supporting the effectiveness of homeopathy compared to placebo or to usual care. But there were important caveats including small sample sizes, lack of replication and lack of placebo control in one study.”

This summary of our work is puzzling, because it does not correspond to our conclusion which stated: “...the effectiveness of homeopathy as a symptomatic treatment for fibromyalgia remains unproven.”³

Equally disappointing is the fact that another systematic review

authored by me⁴ was not mentioned at all in the annual update, even though it was published in the reporting period. I do wonder whether this had anything to do with its conclusions:

“The findings of currently available Cochrane reviews of studies of homeopathy do not show that homeopathic medicines have effects beyond placebo.”

I am sure that “NHS Evidence” is a splendid service. I am, however, far less certain about its “specialist collection” focusing on complementary and alternative medicine. We all know that evidence requires critical appraisal, and it seems that the team responsible for “NHS Evidence—complementary and alternative medicine” are not very good at that particular task nor at coping with cognitive dissonance.

*Edzard Ernst
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Whistleblowing and the abuse of libel law: view from France ...continued from page 3

strong links with industry (tobacco, alcohol, bad diet). There is a fear that financial interests could lead to the downplaying of health and safety concerns. Braillon has taken a high profile stand on several public health issues, criticising a law passed in July which allowed the advertising of alcohol on the internet, and taking the French Association for Urology to task for promoting the prostate specific antigen screening test for prostate cancer, despite professionals outside France questioning its usefulness.¹³ His ex-employers deny that this activity has any bearing on his sacking.

The considered response to the problems of industrial and health-care lobbies must be principled, concerted, evidence-based and Europe-wide. Very few countries have experiences of whistleblowing that are as positive and constructive as in the UK, where a “safety culture” is growing within a comprehensive framework. Will Europe grasp the nettle? The British have a long tradition of being cynical about Europe’s barminess and meddling (not without reason—EEC No 1677/88 set up an “extra class” for cucumbers having a bend of 10mm per 10cm of length). But on the matter of whistleblowing, it may be down to the UK to lead the way in contributing to directives that can have a meaningful effect on public health and those who strive to protect it.

*Alain Braillon and Gérard Dubois
Amiens, France*

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last word

MIRACLES? ALL YOU NEED IS LOVE



POPE BENEDICT XVI's visit to the UK last month has brought the subject of miraculous healing back into the news. As Peter May explained in our last issue (*HealthWatch Newsletter 78, July 2010*), controversy still surrounds US deacon Jack Sullivan's mysterious recovery from spinal debility that led Pope Benedict to beatify Cardinal John Henry Newman on 19th September.

Whether the good deacon's recovery was a miracle or not, TV viewers could be forgiven for thinking that the Catholic Church does not have the monopoly on miracles.

A BBC3 programme shown earlier this year was an example. Jodie Kidd, TV personality and fashion model, presented a documentary all about her attempt to gain a better understanding of Spirits. She did not want to find out if there are Spirits (because, she said, she knows they do exist, some good and some bad) but she wanted to know how to establish rapport with them so they were for her rather than against her.

Her gifts—she is very good looking, and has a charming manner—are helpful for a model, but not for a researcher. She did not set up hypotheses and seek to verify them, but instead noted events and then reviewed the past to identify possible causes for the event. She was not at all into comparisons between test and control groups. It is not in her nature to try to replicate observations. Indeed it was almost all about *her* and what *she felt*. There was no mention of her family, friends or even the cameraman who followed her every footstep.

The first miracle related to the recovery of a severely autistic young boy who was treated by a shaman. To get a closer experience of Spirits she went to ever more distinguished shamans, who explained how spiritual factors affected her own life. To get to the really top shamans she went (with cameraman) to Nepal. They miraculously diagnosed her as having anxiety. (Since this was all done through an interpreter we do not know what the shaman actually said.)

The climax was a long hard climb in the Himalayas, with lots of drum beating and not much food or rest. She had a strange feeling that she interpreted as spiritual activity (but my guess was more towards hunger, exhaustion, and possibly the effect of altitude). All through the night there was more drumming, and a chicken was sacrificed to the Spirits. She was told she had something bad inside her, of which she was not aware. This turned out to be another miracle, because as she was on her way to the station to go home she had severe abdominal pain, and attributed this to the miraculously diagnosed “bad thing”.

Back in England she met a lady who had ovarian cancer, had an operation, but it spread to all her body. She was told she would soon die, but she went to a shaman and was told that if she had hope it would go away. She did have hope and 12 months later it had indeed gone away. She was still seeing her doctor regularly, but it was not clear what therapy she was having from him. Finally we see the formerly autistic child initially being afraid to get on a horse, but on being coaxed to do so he rode happily down to a beach. Another miracle!

In conclusion it was implied that the benign spiritual power was love. Who would have thought it?

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“I believe in miracles” was broadcast on BBC3 on 2nd February 2010 at 9pm.

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