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Newsletter 72 January 2009

LIBEL SUIT AGAINST CARDIOLOGIST

DR PETER WILMSHURST, cardiologist and a past recipient of the HealthWatch Award for his courage in challenging misconduct in academic medical research, is being sued for libel and slander by the US manufacturers of a medical device he was involved in researching. The case revolves around comments he reportedly made about the trial at a scientific meeting.

The case is being brought by NMT Medical of Boston, Massachusetts, which makes the STARFlex septal repair implant. Wilmshurst, a consultant cardiologist at the Royal Shrewsbury Hospital, was one of two principal co-investigators in the Migraine Intervention with STARFlex Technology (MIST) trial in the United Kingdom. The trial aimed to test whether using the device to close a hole between the right and left atriums of the heart (patent foramen ovale) would reduce the incidence of migraine, particularly migraine with aura.

The published results of the trial were negative. Dr Wilmshurst, who had initially supported the idea that closing such shunts might affect migraine, later put forward several ideas why the results were negative, with which the company disagreed. Along with another member of the steering committee, Simon Nightingale, also of the Royal Shrewsbury Hospital, Dr Wilmshurst was not listed as author of the study. They had refused coauthorship because they had not had access to the whole data set.

Wilmshurst was interviewed by a journalist for *Heartwire*, a US

online news service for cardiology specialists (www.theheart.org), at the transcatheter cardiovascular therapeutics meeting in Washington, DC, in 2007 and the resulting article appeared in October 2007. In his 90 page defence to the libel action, which has been filed at the High Court in London, Dr Wilmshurst admits making some, though not all, of the comments attributed to him but says that his statements were true and made in the public interest.

Dr Wilmshurst is being sued in a British court. The Medical Defence Union (MDU) are not providing financial help for his defence. Neither is his NHS Trust, despite the fact that the Trust received money from the trial, whose research he was contracted by his hospital to do. For more information please see www.healthwatch-uk.org

Mandy Payne

Reference

1. Dyer C. Cardiologist is sued for comments on potential migraine device. *BMJ* 2008; 337: a2412. View online at: www.bmj.com/cgi/content/full/337/nov03_4/a2412

Prize winning students at HealthWatch AGM

JOANNA SMEETON of King's College Medical School won the 2008 HealthWatch student prize for the critical appraisal of clinical research protocols. She is pictured here receiving her £500 award from Professor John Garrow at HealthWatch's 2008 Annual General Meeting, held in October.

Among the five runners up was Ashley Simpson, below left, of Queen Mary's University of London. Ashley and Joanna have been welcomed as student representatives to the HealthWatch Committee. The other runners up were Charity Santeng, Yasser Madani and Khalil Hassanally, also from Queen Mary's University of London, and Antonia Bull of Brighton and Sussex Medical School. They each won a cheque for £100. The annual HealthWatch student prize for evaluation of clinical research protocols is generously supported by a grant from the Ajahma Trust and is open to medical and nursing students.



Glasgow journalist GP Margaret McCartney received the 2008 HealthWatch Award for her efforts to promote evidence-based medicine; her full presentation appears on pages 4 and 5 of this issue.



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EVIDENCE ONLINE AND IN PRINT

TO MARK the 40th anniversary of the Medicines Act (1968), Sense About Science have launched an “Evidence Based Medicine Matters” online opinion board featuring stories from medics, scientists, patients, the media and members of the public about why evidence-based medicine matters to them. Go to www.senseaboutscience.org.uk and select “Evidence-based medicine”.

After browsing these you can also download a free copy of their new booklet, “I’ve got nothing to lose by trying it”, a guide to weighing up claims about cures and treatments for long-term conditions. Select from the home page, on the right hand panel.

Every year over 200,000 new research articles are published in over 40 medical specialities. The British Medical Journal Group have just announced their new Evidence Centre on <http://evidencecentre.bmj.com/> which aims to improve decision making in health care by making it easier for professionals to access this growing evidence base.

At the same time, the Group is parting with the editorial director of its “Knowledge” division. Dr David Tovey, who has been responsible for the *BMJ*’s “Clinical Evidence” and its sister product “BestTreatments”, has been appointed Editor-in-Chief of the Cochrane Collaboration. Health information and systematic research reviews at the Cochrane library can be accessed on

www.thecochranelibrary.com.

Another launch due for the new year, again from the BMJ Group, is a medical journal on acupuncture. The quarterly *Acupuncture in Medicine*, currently self-published by the British Medical Acupuncture Society, will become the Group’s first complementary medicine title.

This last news release coincided with publication in the journal *Human Reproduction* of a randomised controlled trial designed to test the efficacy of acupuncture used to improve outcome of *in vitro* fertilisation¹. The intriguing result was that, “placebo acupuncture was associated with a significantly higher overall pregnancy rate when compared with real acupuncture.”

Mandy Payne

Reference

1. *Human Reproduction* 2008; 1–8. View pdf of full paper at <http://www.oxfordjournals.org/eshre/press-release/freepdf/den380.pdf>

news in brief

THE GOVERNMENT has failed to give a clear answer to the recent e-petition that called for a ban on NHS funding of homeopathy. The 134-word response says that it is up to local NHS organisations to commission healthcare services and treatments, and that clinical and cost effectiveness, safety and availability of suitably qualified practitioners are all to be taken into account. But why the woolly answer? It refers to, “clinical effectiveness”—so shouldn’t that be, “Yes, right away!”? However the conclusion, that, “PCTs will be expected to support practices that are innovative and entrepreneurial, and which extend patient choice.” might suggest otherwise.

See www.number10.gov.uk/Page17457

THE CATHOLIC Church is under fire for its plans to use psychological screening to weed out those with “deep-seated homosexual tendencies” from amongst candidates for the priesthood. The Congregation for Catholic Education in the Vatican, in its new “Guidelines for the Use of Psychology in the Admission and Formation of Candidates for the Priesthood” recommends psychological evaluations to be used whenever there is a suspicion of personality disturbances. Controversially, it’s been made clear these should be used to screen out homosexuals, even if they are celibate, because homosexuality is, “a type of deviation” that disqualifies a priest from exercising “spiritual paternity”. However a psychologist with experience in the area of psychometric testing commented to HealthWatch, “It is highly unlikely that there are any such tests, certainly not that would be robust on an individual predictive basis... Such proposals are usually made by people with little experience but much faith in the methods.”

Belfast Telegraph, 8th November 2008. Read report on:

www.belfasttelegraph.co.uk/news/world-news/catholic-church-to-set-gay-test-for-new-priests-14046126.html

“CONTINUOUSLY tap on the Gamut point (point on the back of the hand, between and just below knuckles of the 4th and 5th finger) while performing each of these 9 actions: (1) Eyes closed (2) Eyes open (3) Eyes up (4) Eyes down (5) Eyes left and right (6) Roll eyes in circle (7) Roll eyes in other direction (8) Hum 2 seconds of a song (9) Count to 5 (10) Hum 2 seconds of a song.” Party game? No—it’s an extract from a manual promoting Emotional Freedom Technique (EFT) which Leeds consultant psychiatrist Karel de Pauw found accompanying the agenda for a local com-

munity team away day. E-mail the editor at newsletter@healthwatch-uk.org to get your own copy and send us your comments so that Dr de Pauw can share them with the Leeds Partnerships NHS Foundation Trust.

PLANS to incorporate the traditional remedy Hoodia into diet drinks have been abandoned, reports the *Financial Times*. This plant extract, believed to suppress appetite, has been purified by the British pharmaceutical company, Phytopharm, who acquired the patent rights. Unauthorised Hoodia products are widely sold on the internet without regulatory approval and no guarantee of quality (see David Bender’s article on Hoodia patches in *HealthWatch Newsletter* 65, April 2007). Phytopharm entered into an agreement with Unilever with the plan to introduce Hoodia extract in liquid form as part of their SlimFast weight reduction plan in 2009. Unfortunately the extract was found to be too bitter, caused nausea, and was also metabolised too quickly thus reducing its efficacy. Unilever have now abandoned the project. Phytopharm is looking for a new commercial partner to help incorporate Hoodia into a solid dietary food.

Financial Times, 15th November 2008. Read report on:

www.ft.com/cms/s/0/0be8dc00-b2a2-11dd-bbc9-0000779fd18c.html

THERE ARE two new books to look out for. *Defeating Autism: A Damaging Delusion* is by Michael Fitzpatrick who is a London GP, journalist and himself father of an autistic child. Campaigns promising to defeat or cure autism, argues Fitzpatrick, are not only unscientific, but they risk dehumanising and stigmatising affected children and their families. Published in October 2008 by Routledge, paperback version £19.99. Meanwhile medical ethicist Donna Dickinson’s powerful exposé of the global market in human body parts is soon to appear in paperback. In *Body Shopping: the Economy Fuelled by Flesh and Blood* (first published 2008 by Oneworld, hardback £16.99, paperback from April 2009 at £9.99), we learn that in law we cannot own our own bodies. Using case history, thorough research and intelligent analysis Dickinson explores public scandals and secret horrors as organs, tissues and even individual cells become marketable commodities.

Reviews for both titles are planned for the next issue of the *HealthWatch Newsletter*.

WHAT DOES HEALTHWATCH DO AND HOW DO WE DO IT?

Outgoing chairman David Bender addressed the 2008 HealthWatch annual general meeting at the Medical Society of London on 14th October last year with his summary of the year's activities and an explanation, for new members, of what HealthWatch does

WHAT WE do is (I hope) well known to members, but perhaps not so well known to others. One of the student prize winners at the HealthWatch annual general meeting commented that he had little idea of what HealthWatch does until he heard my speech. Our website is full of information, but until his comment did not open with a clear statement of our activities. I hope I have done something to rectify that now.

What HealthWatch does

- We publish this quarterly newsletter, which goes to all members, plus a considerable number of journalists. Our heartfelt thanks go to Mandy Payne, the editor, who always manages to produce an interesting newsletter, and Caroline Addy, the barrister who reads the proofs to check for possible libel—a valuable help to us, especially as she does so free of charge.
- We produce position papers on matters of interest. All of these are on the website as a resource for members, visitors and journalists. It is perhaps pleasing that our position paper on trans-fatty acids came to the same conclusions as the Foods Standards Agency, in a much shorter paper and produced earlier (and, no, I was not a member of the FSA expert group).
- From time to time we write open letters, e.g. to the Medicines and Healthcare products Regulatory Agency, Medical Royal Colleges, the Royal Pharmaceutical Society, etc., concerning the promotion of unproven complementary and alternative therapies, with the aim of publishing their responses.
- We run the student prize for critical appraisal of clinical research protocols, to help medical and nursing students to develop their skills. Hitherto this has been generously supported by a grant from the Ajahma Trust. They have indicated that they can no longer support the student prize, and we are seeking alternative sponsorship. Our thanks are due to Walli Bounds and Gillian Robinson for their work in drafting the protocols for the students to appraise, and to Joan Gandy who undertakes all of the work of publicising the competition to students, collecting and collating the entries, and selecting those that have ranked the protocols appropriately to send to Walli and Gillian.
- We make the annual HealthWatch Award to an outstanding medical scientist, practitioner or journalist who has made a significant contribution to public understanding of evidence-based medicine. This year's awardee, Dr Margaret McCartney, is both a practising GP and also a columnist for the Financial Times.

How we do it

There are various ways that things get started:

- Sometimes a member of the committee will bring a press cutting, advertising leaflet, magazine or transcript of a radio or TV programme to a committee meeting to start discussion of what we should do about it, and who will do it.
- Sometimes (increasingly commonly) there is a flurry of emails between committee members, which may result in an article for the Newsletter, a new position paper, or, occasionally, a radio or TV appearance.

We heard about the homeopathic AIDS conference last December in advance, and with help from the Terrence Higgins Trust and

Sense About Science we mounted a media blitz, as a result of which HealthWatch committee members were interviewed on national radio and television. In one radio interview a spokesperson for the homeopaths referred to a document containing a summary of the evidence for the efficacy of homeopathy. We obtained a copy. It contained summaries of a series of published meta-analyses of trials of homeopathy that apparently demonstrated efficacy. I read the papers they cited, and my re-analysis was published in the April 2008 *HealthWatch Newsletter*. I did not reach the same conclusions as the homeopaths, because the papers they cited did not provide evidence of efficacy.

“The scan purported to highlight medical concerns, when in fact there was nothing wrong with her.”

James May, our new chairman, is a GP. One of his patients came to his surgery with a report from an “electro-interstitial scan”, for which she had paid £60 at a local pharmacy. This purported to highlight medical concerns, when in fact there was nothing wrong with her. James wrote an interesting account in the October 2008 *HealthWatch Newsletter* of how he followed this up, and there will be more to come, since he has been in correspondence with the manufacturers of the device and the Royal Pharmaceutical Society. There is also on pages 7 and 8 of this issue my own analysis of what is implied in the manufacturers' information about the device and whether it can do what it seems to claim.

The chairman is only as good as his committee, and I have to thank all those committee members who have done so much more than I have to further the aims of HealthWatch: Gillian Robinson who acts as committee secretary, and Walli Bounds, who also takes notes at meetings, Anne Raikes, who manages our (meagre) finances admirably, John Garrow, who has been vice-chairman for the last three years and is a constant source of information and inspiration, Susan Bewley, Diana and Malcolm Brahams, Neville Goodman—who retires from the committee at the AGM—John Illman, Keith Isaacson, James May, Caroline Richmond and Les Rose; and our student representative, one of last year's prize winners, Alison Myers. I also have to extend our heartfelt thanks to Kenneth Bodman, who took on the job of membership secretary two years ago, little knowing that no sooner had he sorted out the membership list, and cajoled more members into gift-aiding their subscriptions, than he would have the task of getting members to update their standing orders for the new subscription rates that were agreed at last year's AGM.

I am confident that HealthWatch is in good hands as I hand over to James May as the new chairman, and Keith Isaacson as the new vice-chairman.

David A Bender

EVIDENCE-BASED GENERAL PRACTICE



Margaret McCartney is the 2008 winner of the HealthWatch Award. She is a GP in Glasgow who writes a stimulating and often provocative weekly medical column in the Financial Times Weekend section. She received her award at October's Annual General Meeting. Here is the presentation she made on acceptance.

I AM MOST certainly 'for' evidence based general practice. But evidence based general practice is not necessarily good general practice, and has brought a lot of new problems. What we surely want is not just any old EBM, but thoughtfully applied, professionally delivered, evidence based general practice. And while I do try and do my best to achieve this, I am not sure that I manage to. Bearing that in mind, I want to try and explain the problems and issues that EBM have led to in general practice, especially given the set of circumstances that medicine is now practised in.

I have a few personal guiding principles. More in medicine does not always mean better. Second, the most potent things about medical practice are not easily measurable. And last, harm is always possible.

'Patient choice' has been decided to be a good thing by politicians, and GPs are meant to offer choice to patients, for example, in where to be referred to for hospital care. GPs now spend large amounts of time discussing what clinic to send patients to, when perhaps what is of more importance lies elsewhere. The National Institute for Clinical Excellence offers to assess the evidence for treatment interventions and to try and measure its worth in terms of cost effectiveness. Yet NICE is often regarded as an enemy preventing people getting access to expensive interventions.

"Statination is a word I use to describe the mechanism by which GPs currently seek to turn most people over the age of 50 into patients via prescribing a cholesterol lowering drug."

We have also seen the rise of the guideline. Guideline based medicine usually offers a distillation of evidence, but they are often used with a similar distillation of the limitations and uncertainties of that evidence. Guidelines have become goalposts, not necessarily a good thing.

GPs are usually independent contractors to the NHS. The GP contract essentially measures 'Quality and Outcomes Framework points'. All sorts of things are measured. How many times blood pressures have been checked, how often people have been told to stop smoking, how many peak flows have been measured annually in people with asthma. Some have some evidence behind them—for example, there is a detectable decline in smoking where doctors offer help to quit. However, even here, it is still possible to do harm. For example, there are people who avoid their doctor because they are afraid that they will be chastised for being smokers still.

And of course doctors themselves are changing. GPs, and not just the female ones, are increasingly wishing to work part time. 'Cradle to grave' care is evaporating. Doing evening and weekends is in most places optional.

It is with these circumstances as the backdrop that a lady comes to see me. Statination is a word I use to describe the mechanism by which GPs currently seek to turn most people over the age of 50 into patients via prescribing a cholesterol lowering drug. Since her husband died three years ago, this lady has had episodes of anxiety and low mood which have been treated. She is an ex-smoker. Her high blood pressure is now in a satisfactory range. And she took up

an offer to have her cholesterol checked for free at a high street chemist. The pharmacist was concerned. By the time my lady came to see me, she was agitated and worried. I went through her notes, and found that she had wanted to try a statin five years ago for a cholesterol of 6.9. There was a note about our discussion on lack of evidence for treating women in these circumstances. She had muscle pains and fatigue on taking the statin which resolved when she stopped it. We had decided then to concentrate on lowering cardiovascular risk overall via diet and exercise. This lady was now worrying that a heart attack was imminent. Have we really done her any favours?

As we know, there is good evidence and there is evidence which we can—and should—pick holes in. But even where evidence is favourable, it does not mean that we should necessarily start using the intervention. Statistical significance does not imply clinical significance.

What about the harms from something as commonplace as cervical screening? Every week or two I get a phone call from a lady who is distressed at being recalled for colposcopy. In fact the chances of being recalled unnecessarily—false positive—are far more likely than having a true positive. We should not underestimate the damage that this can do, both psychologically and in its wider effect on a woman's family.

In recent years GP's have been finding that smear results may include the additional information that the smear has shown 'features consistent with HPV infection'. HPV has been in the news a lot recently because the new vaccination against it is now available. But when women have their smear test, the issue that signs of HPV might be reported in the smear result is not raised. When the result is available, GPs have a duty to share the information with the woman. But what then? The reason why we don't know about the stress and damage caused by being told you have an untreatable infection which may—may—cause cervical cancer is because we have not adequately addressed the prospect of causing harm by our intervention. Yet such harm is witnessed in primary care and is most certainly done.

THERE ARE people in the audience who know much more about breast screening than I do. We have all seen on buses and billboards that the chances of getting breast cancer are 'one in nine'. However this is not the case; this is only the risk if a woman is over 85, and most UK women don't live that long. But this statistic wasn't just used by breast cancer charities which, while they may have a useful role, also have an interest in getting media attention. I interviewed Julietta Patnick, the head of NHS screening for a piece in the Financial Times recently¹. I was asking her why the publicity for the NHS

breast screening programme also uses the one in nine figure, and this is what she said. “I’ll tell you what happened: we were debating what to put on the leaflet and I was going to work, following a bus. And there it was, ‘1 in 9’, on an advert on a bus. I realized that if we didn’t put it on, we were going to confuse like mad.”

We know that women overestimate their chances of getting breast cancer, underestimate the benefits of treatment, and do not realize that the risk of breast cancer increases with age. It could be said therefore that all the breast cancer ‘awareness’ months as well as the NHS information have been associated with damage rather than benefit. When staff from the breast screening service published research last year showing that women are not aware that the risk of breast cancer increases with age, they did not suggest that their information should be improved—only that GPs should be more aware of the lack of knowledge.

Breastfeeding is another example of damage being done by well intentioned doctors. GPs are meant to encourage breast feeding, even at the pre-conception stage. If staff in the practice all agree that they will encourage women to breast feed then you can get a special certificate to put up on the wall. Yet we know that breastfeeding rates, despite the enormous publicity, haven’t actually changed that much in the UK over the last decade. And we have not looked adequately for evidence of harm that these campaigns have done. I see many women who are struggling to breast feed and feeling desperately unhappy if they stop. I have also been concerned that women who have had problems and stopped breastfeeding become reluctant to seek medical advice about other matters because they are afraid of being scolded; and I am concerned that ‘failure’ to breast-feed could fuel postnatal depression. But apart from my anecdotes, I have no definitive evidence—because no one has looked for the harms of the relentless drive to push women towards breast feeding.

Even the benefits of breast feeding may have been overemphasized by health professionals. There is a good Cochrane review showing that the benefits from breastfeeding are overall small gains. These are important—but we should also be aware of the harms our enthusiasm can do.

“...we have a suggestion in a problem page that ‘GPs are not trained to deal with skin problems’ which is news to me; however it seems that the private clinics listed are.”

One of the problems of ‘disinterested’ information giving is that it is sometimes used as an excuse to stop being interested in the patient at all. An article in the New York Times a couple of years ago demonstrates this quite nicely.

“Awash in information, patients face a lonely, uncertain future”. “We’re in the outer reaches of medical knowledge,” he said, “and none of us knows what you should do. So you have to make the decision, based on your values.” Ms Gaines, bald, tumour ridden, and exhausted from chemotherapy, was reeling. “I’m not a doctor—I’m a criminal defence lawyer. How am I supposed to know?”

It is the word ‘lonely’ that gets to me. Of course doctors must acknowledge and attempt to reduce uncertainty—even the GMC says so—and doctors must be able to explain why they have done certain things. But ‘evidence’, or lack of evidence, is sometimes used as a way of abdicating professional responsibility. ‘No evidence’ can say, ‘no evidence for what I have to offer being of benefit’ but it is also used as meaning, ‘not my job’. This is increasingly seen where protocols are used to decide who might benefit from a particular intervention. But if you don’t fit the protocol, who is

going to look after you, and help you make difficult decisions steeped in uncertainty? I think it is telling that there are ‘advocacy services’ now who seek to get better medical care for patients. ‘Advocacy’ used to be firmly in the doctor’s job description. Sadly, this is not now the case.

Neither are doctors seen as being ‘in charge’ of informing people about health and disease. To a degree this is a welcome destruction of medical paternalism. But the void has been filled by other sources who are arguably even more ‘interested’.

A prostate cancer charity produces a leaflet aimed at women, encouraging them to persuade their man into having a ‘prostate check up’. It suggests that they, “leave information leaflets lying around in the bathroom, remote control or car seat” and has a guide to how to, “tug at his heartstrings”. I’m not even going to start on the misinformation there. Or we have a suggestion in a problem page that, “GPs are not trained to deal with skin problems” which is news to me; however it seems that the private clinics listed are. Then we have another company offering ‘MOTs’ via CT scanning, with nothing about the risks of radiation, or false positives or negatives, but which they tell us ‘could save your life’.

SO WHO do we trust to support us through illness, to advise us fairly about preventive health services, and to give balanced information with due regard for risk as well as benefit? This should be the job of professional healthcare workers, but to do this, we have to put our own house in order. General practice is in a mess, because we are conflicted thanks to the GP contract. We are still in servitude to the pharmaceutical industry with our reliance on them for postgraduate medical education—pharma estimates it provides half. Physicians with private rooms may be guilty of using the media to stoke a market. Our correct enthusiasm for independent and unbiased evidence based medicine has not been accompanied by a similar need to be independent and unbiased ourselves.

Healthcare workers need to ensure that evidence based medicine is applied professionally as well as honestly and fairly. General practice can do more than provide fair information and advocacy. Everyone here will know about the benefits of the placebo effect, but also that using placebos are riddled with ethical conundrums. However, if we are to regard the psychologically mediated effects of good healthcare as ‘placebo like’ effects, there are lots which we can gainfully and ethically use. For example, in general practice, continuity of care, longer consultations, and confident professionals all improve measurable health outcomes. One intervention for COPD—pulmonary rehabilitation—uses peer support and graduated exercise to improve quality of life and reduce hospital bed days. It seems to me that these kind of ‘evidence based’ interventions are the ones which are underutilized and under acknowledged and yet which bridge the gap between a professional health service which cares about individuals and the unafraid application of evidence based practice. I think there is hope for evidence based general practice yet, but if all patients are going to gain from it, we need to be heightened in our sensitivity to harms, and to deliver that medicine with professionalism, compassion and care.

Margaret McCartney
Glasgow

Reference

1. McCartney M. Reality check on breast cancer. *Financial Times*, 27th September 2008. View online at: http://www.ft.com/cms/s/0/3f714b0a-893c-11dd-8371-0000779fd18c.html?ncllick_check=1

DOES YOUR PHARMACIST PROMOTE EBM?

We trust pharmacists not only to issue our medicines but also to give clear and honest advice, sometimes even diagnosis. They certainly regard themselves as part of the family of clinicians, along with doctors, surgeons, nurses and radiotherapists; and pharmacists have been lobbying to take on more responsibilities. But can they be relied on?



A RECEPTION hosted jointly by Sense about Science and the Royal Pharmaceutical Society of Great Britain (RPSGB) was about the importance of medicine based on sound evidence. In a welcoming speech the President of the Society stressed the big contribution that pharmacists had made to evidence based medicine.

The Society was setting up new regulations concerning continuing professional development and assessment of fitness to practice. It was generally accepted that pharmacists would take on a greater role in advising the public about healthcare, and in particular the choice of OTC products.

But are standards high enough? To call yourself a pharmacist you must be on the RPSGB register. In the old days the Society had a Code of Practice that said a pharmacist must not “purchase, sell or supply any medicinal product where the pharmacist has any reason to doubt its safety, quality or efficacy.” The high street chemist was highly regarded as the learned intermediary who would help the public to make sound judgements about over-the-counter medication. Indeed I was dismayed to discover that my late mother-in-law believed he was a greater authority in this field than either her daughter or son-in-law, both of whom were registered medical practitioners.

“Pharmacists must come clean about the differences between goods they stock as retailers and real medical products”

The RPSGB has now replaced the old code with a 13-page “Code of Ethics for Pharmacists and Pharmacy Technicians”. The current version (published 1 August 2007) no longer requires the pharmacist to believe that the product being offered for sale is effective. This somewhat undermines the status of the pharmacist as a learned intermediary if the customer wants to know if a product is good value for money. I asked my local pharmacist about a product new to me called LIPObind. According to the website (www.lipobind.com) LIPObind™ contains a fibre complex of organic plant source made from 100% natural dehydrated cactus leaves, which binds to undigested fats in the body. It is suggested that to lose weight between 2 and 4 tablets are taken after each meal for at least 6 months, or until weight target is achieved.

LIPObind has a recommended retail price of £24.95 for 60 tablets, so if a person takes 2 tablets 3 times a day this costs £2.50 per day. I asked the pharmacist, “Would you advise me that this is good value for money?” She replied, “Well, we sold a lot of it during the summer.” I repeated the question, and she replied, “I haven’t taken it myself, but I know a person who did, and she said it was good.” I pressed her: “So are you advising me to buy it?” There was a pause, and then she said, “Yes, I think I am”.

I am not impressed with this performance as a learned intermediary, but it seems she did nothing that might cause her to be struck off the RPS register. Her evidence of efficacy was based entirely on anecdote. Of course it would be unfair to stigmatise all pharmacists on the basis of one interview in one small pharmacy, though it would be interesting to have some ‘mystery shopper’ trials to see whether this lack of regard for evidence is common or not. Undoubtedly the pharmacists and pharmacologists in trials of major prescription drugs work at a much higher scientific level. However even in reports published in premier medical journals the results may be presented in a rather misleading way.

Orlistat (marketed by Roche as Xenical) is a drug that reduces the

amount of fat that can be absorbed from the diet. It was hailed as a major advance in obesity treatment, because in tests¹ those on orlistat lost 68% more weight in a year than the placebo controls. That is the good news that received the publicity, but there were aspects of the research that were not so good.

First: the starting body weight of the volunteers was about 100 kg, so they all needed to lose about 30 kg. After a year those on placebo lost on average 6 kg, and orlistat had lost on average 10 kg, which is indeed 68% more. However, to put the same data in a different way, after a year those on placebo still had 24 kg to lose while those on orlistat had 20 kg to lose, (which is only 17% less) and both groups were, on average, still seriously overweight.

Second, the range of weight change within each group was huge. Each group contained about 370 individuals. The standard deviation of weight loss in each group was about 10 kg. So, instead of saying, “the orlistat group lost 10 kg”, one could more accurately say, “The mean loss for the orlistat group was 10kg, plus or minus 10 kg.”

Third, while on average the orlistat group lost 10 kg from the baseline weight, they actually lost 3.5 kg in the 4-week run in while taking placebo, so they lost (on average) only 6.5 kg on orlistat.

There are many other examples of a blurred line between efficacy and profit. Most pharmacists will stock a range of cough medicines that purport to be most effective for tickly coughs, with others for dry ones or loose ones, but whose active ingredients are similar (and sometimes identical). How can we count on a profession which is essentially a sales machine?

IF PHARMACISTS are going to be entrusted with a greater role in advising the public on healthcare matters then the RPSGB must be able to assure the public that all members understand the importance of scientific trials and are qualified to give advice about efficacy that is based on sound and unbiased evidence. Truth and integrity cannot be adulterated to suit the harsh realities of the high street. That is not to deny that retailing is a tough and highly competitive business, and without clever marketing a lot of pharmacies would go out of business. However pharmacists must come clean about the differences between goods they stock as retailers and real medical products which they can honestly endorse on the basis of sound research evidence. If a pharmacist is directly involved in selling untested products then he or she should be expected to say clearly that the product has not been tested to the standards normally required of pharmaceuticals.

Pharmacists are highly trained and generally do a very good job, in fact health services would struggle desperately without them. But they cannot have their cake and eat it, or one day the NHS, the medical profession, and indeed the customers, will rumble them.

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

Reference

1. Sjöström L, Rissanen A, Andersen T *et al*. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. *Lancet* 1998; **352**: 167–173.

THE ELECTRO-INTERSTITIAL SCANNER: can it do what I think it claims to do?



IN THE LAST issue of this newsletter (*HealthWatch Newsletter* issue 71, October 2008) James May told how he investigated an electro-interstitial scanner (EIS) after one of his patients came to him with a detailed report for which she had paid a pharmacist offering the service £60. On request, the manufacturers sent him an 18 page booklet about the scanner, complete with 70 references to the scientific literature. James passed me this with the question, “Can the EIS do what it seems to be claimed to do?”

So, what is it claimed to do? The manufacturer said in an email, “The EIS system has a number of applications. It can be used by practitioners to get a picture of the functioning of the organs of the body allowing them to direct further examination as necessary. I would stress that the system in itself is not a diagnostic. It is also useful to monitor the effectiveness of treatment and adverse side effects. It is also a very valuable tool to guide patients to make necessary lifestyle and nutritional changes and to monitor the effect of these changes.”¹

In subsequent emails the manufacturers have again stated that the EIS is not licensed for diagnostic use, and no-one to whom they sell or lease the machine should use it for diagnosis. The information in the booklet states that the scanner has been used to monitor acid-base balance, tissue oxygen, and the effects of chemotherapy; as a marker for unipolar depression and underactive thyroid; screening and follow-up and monitoring of various pathologies including diabetes, hepatitis, circulatory problems, duodenal ulcer, chronic bronchitis and asthma, and cancer. So, while it is clearly not intended to be marketed as a diagnostic tool, I could be forgiven for misinterpreting the information—if it can be used to monitor these conditions, might it not also be useful to diagnose them?

“I doubt that you could differentiate between the liver, pancreas and gall bladder, or indeed between the large and small intestines, with only six electrodes”

There is an impressive list of clinical trials of the EI scanner for monitoring and follow-up of various conditions, but we are not given any results or references to these trials. The manufacturers’ booklet contains some good sound (text-book) physiology on interstitial fluid volume, but most of this is not relevant to the scanner. Likewise, on following up the references cited in the booklet, while most were to peer-reviewed medical and scientific journals, few were actually relevant to the scanner.

However, let’s come back to the original question: whether it can do what it claims to do, not what I think it might claim to do.

The underlying principle of the scanner is that it measures the electrical conductivity of the body. This is well-established as a means of measuring body fat. Electrolytes (sodium, potassium, chloride, bicarbonate and phosphate, etc) in lean tissues conduct an electric current, fat does not. For body fat determination a low voltage high frequency (typically 50 kHz) alternating current is used, and the impedance (equivalent to resistance) between the hands and feet is measured. The greater the impedance, the more fat is present. Such devices are widely used in nutrition research, and have begun to appear in gyms for people to use themselves.

A high frequency alternating current penetrates all body water compartments: the bloodstream, intracellular water and water between cells (the interstitial fluid). The EIS, by contrast, uses a low voltage direct current, which the manufacturers state only measures

interstitial fluid electrolytes and the volume of interstitial fluid. Unfortunately they do not cite a reference for this so it is not clear whether research supports this use of direct rather than alternating current in this application.

The EI scanner uses six electrodes, attached to the left and right forehead, and both hands and feet. Readings are taken using 21 different pairings of the electrodes as a way of modelling the body. The manufacturer’s booklet and website² suggest that sophisticated mathematical analysis of the results permits estimation of the volume and contents of the interstitial fluid in discrete organs and tissues. I cannot follow the mathematical arguments in the paper cited³ but I doubt that you could differentiate between say the liver, pancreas and gall bladder, or indeed between the large and small intestines, with only six electrodes—even in 21 different combinations.

We are given a series of references to papers showing that, with suitably placed electrodes, conventional bio-electric impedance can be used for estimating cardiac output, confirming the results of mammography (because of the very different composition of normal breast and tumour tissue) and monitoring hydration during and after surgery, etc. All very sound, but not actually relevant to the EI scanner.

We are then referred to papers on electrochemical measurement of various compounds in interstitial fluids. This is all good sound chemistry, and with suitable equipment, and techniques including spectrophotometry and electrochemical detection, it is indeed possible to measure different compounds, both electrolytes and non-electrolytes such as glucose, and individual small hormones (e.g. thyroid hormone) and neurotransmitters. But not, however, simply by using electrodes placed on the skin.

There is some discussion of the pH of tissues, and especially of cancerous tissue. Again, pH can be measured using electrodes placed in tissues or the blood vessels supplying and draining them, but not by using electrodes on the skin. There are references to two papers on tumour pH. One is a fluorescence microscopy study in rabbit ears with implanted tumour cells⁴, and the other⁵ involves NMR spectroscopy and magnetic resonance imaging of human tumour cells grown in mice. I presume these are supposed to provide a theoretical basis for how changes in pH claimed to be found on EIS are related to the presence or absence of cancers.

IN CONCLUSION, it is difficult to decide quite what the EI scanner is supposed to do. The manufacturers are clear that it is not a diagnostic tool, yet all the information in their booklet suggests that it can be diagnostically useful. I am not clear from the booklet whether it purports to be able to measure glucose, cholesterol, proteins, individual ions, oxygen and carbon dioxide or not. There is a table showing values for these in different body fluids, but there is no claim that they are measured. However, James May’s patient came to see him with an eight-page report with what appeared to be a full biochemical breakdown, advice about the function of all organs, and advice about recommended foods. The manufacturers say that this report should not have been produced. I

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THE TIGER THAT ISN'T: SEEING THROUGH A WORLD OF NUMBERS

by Michael Blastland and Andrew Dilnot

Published by Profile, 10 July 08. £7.99 Paperback. ISBN 978 1846681110

WHEN I WAS a child, my bedroom had a swirly beige-and-white wallpaper. I often thought I saw faces and even tigers (how did the authors know?) in the random swirls; nowadays, fundamentalist Christian parents in the USA play their teenagers' pop records backwards and fancy they can hear the antichrist.

Chaque un à son gout. Ignorance and a keen imagination can take a person along some strange paths. Blastland and Dilnot are, respectively, creator and presenter of Radio 4's statistics series *More or Less*. And their book comes with endorsements: Rory Bremner says it made statistics far, far too interesting, and David Dimbleby says it explains to lay people how to make sense of numbers and how we can avoid having the wool pulled over our eyes. New Scientist considers that every journalist should get paid leave to read and re-read this book until they've understood how they've been spun.

I agree. This book is written with wit and pizzazz. There are chapters on the pitfalls of the distortions of spin-doctors. Mrs Thatcher's governments changed the definition of 'unemployed' 23 times (or was it 26? accounts differ). The *Daily Telegraph* screamed that one boy in four is a job when boys were asked if they had injured anyone, however slightly, by hitting or jostling, including their family and school-friends. Labour apportioned £300m for childcare over five years. Is that a bonanza? Well, divide by a million—the number of pre-school children—and you get £300 a child. Over five years, that's £1.26 per child per week. How much childcare can you buy for that?

Around midnight on bonfire night 2003 in Wishaw, West Midlands, a mobile phone mast came down. It had been carefully unbolted first,

and next day villagers prevented T-mobile from re-erecting it. In the twenty houses within 500 metres, there had been nine cancer cases, and to the villagers the cause was obvious. And that is one reason why it's important to understand clustering, a natural phenomenon.

Then there's regression towards the mean, which means that extremes (of temperature, rainfall, behaviour, or many other things) are likely to be followed by something more average. So, is it better to reward good performance or to criticise or punish bad performance? It is easy to conclude that punishment works better, as it is more likely to be followed by improvement.

This book is entertainingly written and a pleasure to read. It takes many examples from healthcare spinning, including manipulation of NHS waiting lists; and from crime statistics—the police reported a drop in violent crime but hospital A&E records showed that this was an artefact. The book will stay on my shelf alongside the classic *Innumeracy* by John Allen Paulos (he uses his middle name to avoid being taken for the late Pope), *Reckoning with risk* by Gerd Gigerenzer (Penguin 2002), and *Irrationality* by the late Stuart Sutherland, republished in 2007.

Caroline Richmond
Medical journalist and author, London

THE ELECTRO-INTERSTITIAL SCANNER: can it do what I think it claims to do?

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agree with them. They do not claim that these measurements are made, and I very much doubt that the EI scanner could make them.

David A Bender

Senior Lecturer in Biochemistry, University College London

References

1. E-mail from Roddy Macdonald of Biomedical Technology Ltd to James May, 29th August 2008.

2. Manufacturer's main company website www.Idteck.com
3. Bryan K, Numerical recovery of certain discontinuous electrical conductivities. *Inverse Problems (Institute of Physics)* 1991 7: 827–40.
4. Martin GR & Jain RK. Non-invasive measurement of interstitial pH profiles in normal and neoplastic tissue using fluorescence ratio imaging microscopy. *Cancer Research* 1994; 54: 5670–4.
5. Reference to a 1979 PhD thesis by Gillies RJ, linked to Prof Gillies' home page <http://bmbc.biology.arizona.edu/gillies.html> (accessed 16/11/08).

Published by HealthWatch

Press enquiries to Professor John Garrow: 01923 710665
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