



# HealthWatch

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Newsletter 89 April 2013

## £50,000 FUND LAUNCHED TO SUPPORT EVIDENCE-BASED MEDICINE RESEARCH

**H**EALTHWATCH IS launching a £50,000 research fund to promote evidence-based medicine, thanks to a donation by a private supporter. The HealthWatch Research Fund will back projects that further our aims and objectives. Chairman Keith Isaacson has publicly welcomed the donation, saying: "This is one of the most exciting developments for HealthWatch in our 22 year history. We've supported small projects, but this is the first time we've been able to support more ambitious research projects."

Applications for the first funding round, which closes on June 1st 2013, will be assessed by a subcommittee of HealthWatch trustees. Individual applications may be for sums of up to £10,000, although is anticipated that most bids will be for smaller amounts.

The HealthWatch Research Fund's private donor has no links with, nor any financial interest in, any healthcare or pharmaceutical

companies.

Parties who wish to apply for funding will find full details and application forms at <http://www.healthwatch-uk.org> under "Research" tab.

Media enquiries for the research fund are being handled by David Bender at [enquiries@healthwatch-uk.org](mailto:enquiries@healthwatch-uk.org)

## Kings College lecture success is "celebratory milestone" for HealthWatch

**T**HE INAUGURAL HealthWatch lecture, in conjunction with King's College, London, was a celebratory milestone in the history of (to quote our president Nick Ross) "a small charity with a big ambition" to make evidence based medicine an integral part of healthcare.

The lecture explored the question: "The direction of Medical Research: Top Down or Bottom Up?" The predominantly young, 150-strong, audience at King's College on 13th March will remember it for the outstanding quality of two internationally acclaimed speakers and because it made them laugh and have fun as well as address issues of life-saving importance to the healthcare of billions of people. Even the amazing attributes of snails got in on the act. Robin Ince, stand-up comedian and co-presenter with physicist Brian Cox of BBC Radio's The Infinite Monkey Cage, introduced the speakers.

The current model for drug approval "is probably unsustainable", because most new drugs were "completely unaffordable" for the seven billion people, seven-eighth of the world population, who live in lower and middle-income countries, said Sir Michael Rawlins, the first speaker. Some new cancer drugs cost up to \$10,000 a month per patient.



Sir Michael Rawlins, left, with Professor Steve Jones

Speaking 18 days before ending his 14-year tenure as founder chair of the National Institute for Health and Clinical Excellence (NICE), Sir Michael outlined the possible "lean" benefits of an alternative model known as "adaptive licensing".

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## news

# THOUSANDS PLEDGE SUPPORT FOR TRIAL DATA TRANSPARENCY

**M**ORE THAN 200 organisations—including HealthWatch—and 40,000 individuals have so far signed the AllTrials' petition in support of transparency in the reporting of clinical trial results. Meanwhile, across the Atlantic a free-to-view article<sup>2</sup> has been published online in the March 18th issue of the *Journal of the American Medical Association* calling for a new era of open science through data sharing.

Behind the AllTrials campaign is Ben Goldacre, together with Sense About Science, Iain Chalmers of the James Lind Initiative (and Cochrane founder), Fiona Godlee (editor in chief of the *British Medical Journal*), and Carl Heneghan (director of the Centre for Evidence Based Medicine at Oxford) and Richard Stephens (patient advocate). Goldacre has reported in his book, *Bad Pharma*, that the best currently available evidence estimates that around half of the trials for the treatments we use right now haven't been published, and this has never been adequately addressed by legislation or codes of conduct.

The list of organizations who have so far signed to show commitment to changing this dangerous status quo includes more than a hundred patient groups, NICE, academic funders such as the Medical Research Council and the Wellcome Trust, Royal Colleges, the Royal Pharmaceutical Society, the British Pharmacological Society and the Faculty of Pharmaceutical Medicine. The pharmaceutical giant GlaxoSmithKline added its endorsement to the campaign on 5th February, declaring its intention "to publish CSRs [clinical study reports] for clinical outcomes trials for all approved medicines dating back to the formation of GSK." This news

prompted Goldacre to declare in his "Bad Science" blog,<sup>3</sup> "while I will always wait for the proof in the pudding—I do not believe this is mere lip service" concluding, "I couldn't be any happier. This is huge, and internationally huge."

The *JAMA* article was more cautious in its enthusiasm. The authors, doctors Joseph Ross and Harlan Krumholz, both of Yale, described the wall around the clinical trial research enterprise as crumbling, albeit slowly, with a gathering momentum towards open science through data sharing. They suggest, "The full potential of the clinical research enterprise can be realized by creating a culture that promotes sharing and provides credit to those who do—and consequences for those who do not."

Mandy Payne  
Editor, HealthWatch Newsletter

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1. The petition can be found on: [www.alltrials.net/](http://www.alltrials.net/)
2. Ross JS, Krumholz HM. Ushering in a New Era of Open Science Through Data Sharing: The Wall Must Come Down. *JAMA* 2013;(0):1-2. See: <http://jama.jamanetwork.com/article.aspx?articleID=1668313>
3. Ben Goldacre's blog is on: [www.badscience.net/](http://www.badscience.net/)

## NEWS IN BRIEF

"COURAGE IS a much needed commodity in medicine, and few have shown it with such persistence as Peter Wilmshurst." So wrote the *BMJ*'s Minerva column about the Staffordshire cardiologist who has been awarded the first ever *BMJ* Editor's Award, "for courage and persistence in speaking truth to power." Peter has repeatedly spoken out against wrongdoing whatever the personal cost, and endured a lengthy lawsuit after highlighting research misconduct at the company whose device he was evaluating. In an online "rapid response", Dr Wilmshurst said he felt honoured to receive the award, and gratefully acknowledged the support of his colleagues at HealthWatch.

*BMJ* 2013;346:f203.

See: <http://www.bmj.com/content/346/bmj.f203>

THE 2013 HEALTHWATCH student prize for the critical appraisal of clinical research protocols is now open. As usual, there will be a first prize of £500 and runner-up prizes of £100 in each of the two main categories. The student prize this year is possible thanks to the generous support of John Garrow.

See: <http://www.healthwatch-uk.org/student-prize/>

INTERNET SEARCHES on health symptoms are a rich data source for drug safety monitoring, say US researchers in a brief communication published online in the *Journal of the American Medical Association*. Microsoft's researchers in Washington used the anonymised search logs of 82 million US web users to analyse queries which combined drug names and the symptoms of high blood sugar. At the time of the study, it was not yet public knowledge that the two drugs being monitored caused hyperglycaemia when taken together. Yet researchers found that

people who looked up both drugs online were almost twice as likely to search for terms associated with high blood sugar as were those who looked up the drugs separately.

White RW, et al. *J Am Med Inform Assoc* 2013;0:1-5

IMAGINE A WORLD where healthcare professionals can receive educational material guaranteed free from industry influence. Conflict Free Conferences is an initiative set up by a group of British doctors and medical students. The aim is to create an accreditation scheme to certify medical education that is delivered without industry funding and by individuals without ties to companies with a commercial interest in the topic under discussion.

See: [www.conflictfreeconferences.com](http://www.conflictfreeconferences.com)

PLACEBOS are commonly offered by GP's in the UK. The results of a web-based survey published in March in *PLoS ONE* suggest that 97% of GP's have prescribed an 'impure' placebo at some time in their career, with 77% claiming to offer them at least once a week. The study described 'impure' placebos as treatments prescribed for ailments where their efficacy is unknown or unproven, and ranged from nutritional supplement for conditions unlikely to benefit from them, through antibiotics for suspected viral infections, peppermint pills for pharyngitis, to non-essential physical examinations. It is more encouraging to read that 'pure' placebos, interventions such as sugar pills that have no active ingredient, were prescribed regularly by only 1% of UK GP's. The study was carried out by the University of Oxford and the University of Southampton.

See: <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0058247>

## THE PRINCE AND THE PAUPERS: his thoughts on healthcare for the masses



**I AM NOT OF THE OPINION that medical journals are the preserve only of doctors. Health is of interest to all, and I fervently defend the principle of free speech. Nevertheless, it does not follow that all world views are equally valid. Whatever we wish to say must be open to challenge, and to demands for evidence if claims are being made. Hence, I welcomed the opportunity to read the Prince of Wales' article<sup>1</sup> in which he described his vision for health care.**

The title certainly piques interest. 'Post modern medicine' is not defined in the text, but would be something I'd wish to avoid if it resembled post-modernist sociology, as the 'anything goes' approach to evidence does not attract me. But this provides an explanation for how it has crept into the Prince's rhetoric. Such sociologists maintain that there is no such thing as objective truth: anyone's idea of truth is as valid as anyone else's. That closely fits with the movement to dismiss evidence-based medicine and to allow unproven treatments into routine clinical practice. This is exactly what the Prince has campaigned for over many years, as he states clearly in the very first line.

Again we are encouraged to respect 'ancient wisdom'. Assuredly the ancients had wisdom the ancient Greek philosophers were well versed in logic and ethics (for their time). But did the 'ancients' have knowledge relevant to health care today? Let's consider Galen, a giant of medicine in his day, but he was wrong about the cardiovascular system, believed in the four 'humours', and was an enthusiast for bloodletting. Galen's inaccurate drawings caused the stagnation of the study of anatomy for more than a thousand years. So if the Prince means wisdom, then yes there was some, although we have advanced in ethical standards today. If he means knowledge, then few really want to be treated by physicians using 2000-year-old methods.

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**"While the Prince does not dismiss scientific medicine outright, he seems to think that science somehow endangers caring. I cannot see how care is enhanced by inventing stories about how the body works."**

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It is a puzzle as to why something ancient should necessarily be venerated. Antiquities interest me for their artistic qualities, and for what they say about long dead civilisations. I think it very unlikely that the 'ancients' had any better knowledge about anything than we do now. People then were closer to nature because they had to be—nature 'red in tooth and claw' governed their lives rather more than it does today. They were not better off for that. Nature is not inherently benign, it is cruel and heartless. For natural selection to work, less competitive organisms have to suffer and die. Yet we know that is how we came to be the dominant species.

The Prince also defines integrated medicine as including mind, body and spirit in the health care mix. He seems to assume that we are all agreed as to the definitions of mind and spirit, as if they are clearly separate entities from the body. There are many who would argue that such distinct compartments do not exist. What is 'spirit'? Does he mean the soul as envisaged by theologians? Is the mind separable from the brain? These are questions which he needs to address but does not.

I do not dispute his sentiments regarding the role of context and environment in health. But the Prince seems to think that only he and his acolytes have noticed this. In reality, this is why health and social care are moving towards integration, a process informed by scientific studies. He reminds us of his long campaign against a mechanistic approach to health. The reality is that, over the thirty years to which he refers, the more science looks at health and disease, the more mechanisms are uncovered. The concept of vitalism

was abandoned by thinking people a very long time ago, and it is now possible to construct living organisms in the laboratory. Of course health is much more than just the body, it involves all the interactions that we have with a host of other factors. The Prince is right to emphasise that these are part of health care, but they are also mechanisms and amenable to scientific study. In other words, we need evidence in support of whatever effects these interactions are claimed to have.

A further misunderstanding in the article, and a frankly inexcusable one, is that conventional medicine only treats symptoms. This is a ridiculous idea widely believed by the anti-science community. It is rather at odds with the objection to scientific medicine. Understanding mechanisms means that doctors are not simply treating symptoms, they are modifying the very mechanisms that cause disease. That is what modern medicine is all about. However, go to any ten alternative medicine practitioners and they will give you ten different causes of your disease—they can't all be right, and the conclusion has to be that they do not have any idea of the truth. It is they who are treating symptoms, especially in the case of homeopaths for whom the 'symptom picture' is paramount. While the Prince does not dismiss scientific medicine outright, he seems to think that science somehow endangers caring. I cannot see how care is enhanced by inventing stories about how the body works.

It is interesting to note how often in his speeches and writings the Prince uses the phrase "it seems to me", and how rarely the phrase "the evidence tells us". This reveals what really informs his thought. He does cite some research in support of integrating external factors into the health care picture, such as sociological and environmental ones, but this is what is happening anyway. Doctors are trained intensively to take a full patient history that includes all such factors, because science has told us that this is important, yet he suggests that this training is severely lacking in medical schools. That is simply not true today.

He also appears poorly informed as to the huge amount of research into the doctor-patient relationship. It is very well known that the effectiveness of treatments depends on empathy between the parties, which is why it gets so much attention at medical schools. The piece ends with yet another plea to combine traditional and modern health care. By 'traditional', does he mean shamans, witch doctors, medicines containing parts of endangered species, and the like? I do not think he has ever spoken against toxic Chinese herbal medicines, or homeopaths selling ineffective vaccines.

I normally avoid hearsay, but the following anecdote is particularly relevant. A friend told me about an encounter at a royal reception. A senior scientist was trying to explain the evidence about some pet topic of the Prince's, who abruptly turned on his heel and walked away. An aide sidled up and said, "One does not disagree with His Royal Highness". It is rather hard to listen with equanimity to a lecture about inequalities, from someone so privileged from birth. I am forced to ask whether the editor of the *Journal of the Royal Society of Medicine* applied the usual high editorial standards and would have published the same article had it been written by a commoner.

*Les Rose, freelance consultant clinical scientist*

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1. HRH The Prince of Wales. Integrated health and post modern medicine. *J R Soc Med* December 2012; **105(12)**: 496-8.

## media

# LESSONS FROM HORSEMEAT AND PORK

**M**ANY YEARS AGO the late Ben Oser, who ran a private analytical laboratory in New York, asked me a question. I am sure that this was an attempt by a very eminent senior scientist to engage a very junior one in discussion after he had asked me for my first impressions of his city. (My response to that was amazement at the graffiti on buses, I had never seen the like before, and the dense smog that obscured the view across the river from the round Manhattan boat trip.) His question was: how would I go about determining if hamburger beef had been adulterated (diluted) with cheaper soya protein? My response was that I could only do the opposite, and tell him if soya protein had been adulterated with meat, by measuring a specific amino acid (methyl-histidine) which is found only in muscles.



Technology has advanced considerably since then, and we can now determine the species of meat in any product by DNA analysis. This would probably not answer Oser's question, since isolated soya protein does not contain DNA, although the ratio of DNA : protein would be lower than expected if soya protein had been added to the meat.

The recent scandals of traces of pork in supposedly Halal beef products, followed by the discovery that some manufactured meat products labelled as beef were up to 100% horse meat, raises questions that are relevant to nutritional and other supplements. I can accept that traces of pork in beef products could be accidental contamination, although cross contamination of this sort in a factory that handles both beef and pork raises questions of food hygiene, of thoroughness of cleaning of machines between batches of meat, and good manufacturing practice. It is more difficult to accept that very high levels of horse meat in 'beef' products are the result of anything other than deliberate adulteration—fraud and deception.

**"... some of these products do not contain any hoodia extract.<sup>4</sup> This is perhaps comforting, since hoodia is an endangered species ..."**

The question that we now need to answer is who should be responsible for ensuring that the product contains what it says it does? If I buy a supermarket's own brand product then I expect the supermarket to have its own quality control facilities, checking the products and inspecting the factory where they are made. When Marks & Spencer first began to branch out into selling food, they set up what were, by the standards of the day, extremely rigorous conditions for their suppliers, and did indeed inspect their premises. (One innovation was a laboratory coat that had a double thickness panel at the back instead of the conventional split—an interesting idea for hygiene in a food factory). However, if a supermarket is selling a branded product then they (and the consumer) should be able to rely on the manufacturer's quality control mechanisms.

So, should the food processors trust their suppliers, or should they test each batch of meat they receive? In a radio interview<sup>1</sup> Lord Haskins, the former CEO of Northern Foods, a major food processing company, said that he would want to see the whole piece of meat *before* it was minced, not just the minced product.

This is where the lessons that we will learn from the 'horsemeat scandal' are relevant to nutritional supplements. If I buy a supplement or herbal preparation, I am entitled to believe that it contains what it says on the label. I am also entitled to believe that it does not contain undeclared ingredients. There is evidence that a number of protein supplements marketed to sportspeople contain undeclared steroids and other compounds that are illegal in competitive sports.<sup>2</sup> Someone could be banned from international sport after quite innocently taking a protein supplement that contained a banned substance, but that was not declared on the label. It is not relevant to my argument here that protein supplements are, in fact, of little, if any, use to athletes and sportspeople.

Towards the end of the last century there was great excitement about the South African succulent plant *Hoodia gordonii*, which has

traditionally been used by the San people of the Kalahari as an appetite suppressant.<sup>3</sup> A potential active compound was isolated and, controversially, the plant was patented by the South African Council for Scientific and Industrial Research in 1996. A licence to exploit hoodia was granted to a UK company, Pharmachem, who collaborated with Pfizer, then later Unilever, to develop slimming products based on the plant. Both Pfizer and Unilever gave up their licences, after considerable investment, citing difficulties in ensuring the quality and consistency of the plant extracts. There is, in fact, no evidence from human studies that hoodia extracts have any useful appetite suppressant actions, although there are a few positive animal studies. Nevertheless, a quick web search reveals a number of companies selling hoodia extract for slimming. It is doubtful that they have overcome the problems of quality control experienced by the major companies who abandoned their research and development on hoodia. Finally, there is evidence that some of these products do not contain any hoodia extract.<sup>4</sup> This is perhaps comforting, since hoodia is an endangered species and is protected under the Convention on International Trade in Endangered Species.

Seaweed patches for slimming are sold on the basis that iodine deficiency leads to hypothyroidism and weight gain, and over-activity of the thyroid leads to weight loss. It is irrelevant to the manufacturers that if you are not iodine deficient, providing additional iodine will not increase your production of thyroid hormone, so the patches cannot possibly have any effect on body weight. Perhaps more importantly, in at least one court case the patches were shown not to contain any detectable iodine at all.<sup>5</sup>

If I buy a supplement from a reputable manufacturer, I can be reasonably sure that they have good quality control and laboratory facilities, analyse each batch of ingredients bought from suppliers, and can trace each batch of ingredients into each batch of their final products. By contrast, if I go online to buy my supplements, while I may be lucky, the chances are that I will buy from a company that does not have its own laboratory facilities, and does not keep precise records of each batch of ingredients and products. They will be buying from their suppliers in good faith, but they could be buying horse meat labelled as beef.

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## MAKING MONEY OUT OF MISERY

**T**HE MOMENT I heard about Neon Roberts' I felt fairly sure there was an alternative medicine root to the tragic story which hit the national media in the run up to Christmas. I have encountered similar, if slightly less dramatic, cases before.



Seven-year-old Neon had a brain tumour. This information alone strikes fear into the heart of any parent, not least because even the best possible outcome would presumably have involved opening up the child's skull and removing the tumour from within the brain.

Of course even this is cleaner than the reality which also probably involves stereotactic radiation surgery or other radiotherapeutic options. It is the stuff of nightmares. Who wouldn't want their child to have an alternative to this? I have four children, and as I write this the oldest is going to be eight years old tomorrow. I do understand.

According to the *Sunday Times*, Neon's mother Sally Roberts believed that there were alternatives to the treatments the doctors were offering, including light and photodynamic therapy (PDT). The Court later ruled<sup>2</sup> that despite his mothers' preferred options, it was in Neon's best interests to undergo surgery and radiotherapy.

On the 23rd of December my family were visiting my parents in Southampton for Christmas when I came upon another *Sunday Times* article<sup>3</sup> reporting on their undercover investigation into a certain Dr Julian Kenyon who is now based up the road from Southampton in Winchester. (In a former time Dr Kenyon was a partner of George Lewith at the Centre for Complementary and Integrated Medicine, a private practice with clinics in Southampton and London's West End.)

The undercover reporter posed as a relative of a cancer sufferer, and Kenyon reportedly told him that he was one of the worldwide pioneers of a treatment that could kill cancer with light and ultrasound. It could even offer the chance of a cure, saying, according to the *Sunday Times* reporter: "We get significant tumour cell death in 80% [of cases of late-stage cancer]. We do get some long-term survivors and we call those 'complete response'. They are now cancer-free."

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**"Promoted as natural, non-invasive therapies that use non-toxic light-sensitive substances such as chlorophyll, the claims made by the private clinics in Mexico and China which charge typically £10,000 per treatment, are *not* supported by scientific evidence."**

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Let's be clear. Nowhere is it implied that he said explicitly that his patient was alive as a result of receiving this treatment. But I believe that isn't good enough. What a desperate patient hears is not necessarily the words that are actually said.

As a GP I am constantly trying to explore, not simply what I have said to a patient, but what they have understood. I know that patients do not have a good understanding of the relative benefits of anecdotal evidence or randomized controlled trials. It is potentially highly misleading to tell the relative of a cancer sufferer that a patient who took such and such a treatment is still alive. Few patients think to ask the questions which come naturally to a doctor—might that patient have survived anyway, were they on other treatments for their lung cancer, is the tumour slow growing so that actually they are still going to die of it but just not yet. And so on.

The anxious relative hears only the unsaid words—"the patient survived because of this treatment"—a success rate of 100%!

Who wouldn't hand over their life savings for such a wonder cure? And who would subject their child to the risks and possibly devastating after-effects of brain surgery and radiotherapy (which may well not even cure the condition), with the prospect of a wonder cure on offer?

To many people, alternative therapies seem a romantic reaction to the age of industrialization, a return to the natural and pure. The reality is much tougher—it is about money. The Department of Health Website NHS Choices recently posted an alert<sup>4</sup> warning the public of the dangers of, "unproven, unlicensed versions of PDT sold by some private clinics in the UK and overseas". What is not well understood by many people is that PDT is an effective, licensed cancer treatment that has been proven effective in some cancers and skin conditions, including early-stage lung cancer, oesophageal (gullet) cancer and Bowen's disease. This does not apply, however, to the so-called 'advanced' or 'next-generation PDT' (NGPDT) and 'sonodynamic therapy' (SDT). Promoted as natural, non-invasive therapies that use non-toxic light-sensitive substances such as chlorophyll, the claims made by the private clinics in Mexico and China which charge typically £10,000 per treatment, are *not* supported by scientific evidence. There is no convincing data to support the idea that ultrasound used in this way is effective in the treatment of primary tumours and multiple metastases. Put simply, they cannot, and do not, work.

Another recent and tragic case illustrates their warning. In June 2012, seven-year-old Olivia Downie from Aberdeenshire travelled to a clinic in Mexico to receive SDT to treat her neuroblastoma (a rare cancer of the nervous system). The NHS could do no more for her, and this was her last hope. The treatment didn't work. The child was put on a life-support machine and transferred to a private Mexican hospital. Her parents were forced to appeal for money to fly her home in an air ambulance. Olivia died within 48 hours of her return. Her mother deeply regrets making the trip.

As the NHS Choices warning concludes, "Health experts believe that people running such clinics are either misguided or exploiting the public for commercial gain."

And that, sadly, is the truth that patients need to hear.

James May  
GP Principal, London

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## research

# CAM arthritis remedy shows promise

**A NEW TRIAL** showing positive results on a complementary treatment for osteoarthritis<sup>1</sup> has been described as “impressively sound” by Edzard Ernst,<sup>2</sup> ten years after his own review found the available evidence for the dietary supplement to be “not entirely convincing”, noting at the time that the only long-term trial to date showed a negative result.

For the ERADIAS study, French rheumatologists conducted what Ernst, emeritus professor of complementary medicine, has described as a “massive research effort” into the efficacy of the supplement, avocado-soybean-unsaponifiables (ASU). The prospective, randomised, double blind, parallel group, placebo controlled trial involved almost 400 patients and lasted for three years. The results, published in *Annals of the Rheumatic Diseases*, showed that treatment with ASU reduced the speed of narrowing of joint space width, indicating a potential structure modifying

effect in hip osteoarthritis. Ernst described the trial as rigorous, well-reported and cautious in its interpretation of the results.

*Mandy Payne*

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## Kings College lecture success a “milestone” for HealthWatch

*...continued from front page*

Sir Michael, professor of clinical pharmacology at the University of Newcastle, since 1973, explained that adaptive licensing could involve three phases, just like the current system. The first two would continue as now. Phase I studies would confirm an agent’s pharmacodynamics and identify appropriate doses and unacceptable adverse effects. Phase II studies would provide a preliminary assessment of efficacy and safety<sup>3</sup>, and some indication of magnitude of benefits.

Phase III would depart from conventional strategy. At present, in effect, a newly licensed therapy moves from being an *experimental* into an *approved* treatment. Thus, after only being available to a relatively small trial population, it may become available to millions of “real world” patients. Under adaptive licensing, Sir Michael explained, the drug would become available significantly sooner to a wide patient population, while continuing to be investigated in a formal observational study.

### “Adaptive licensing ... would go a long way towards responding to the unsustainable costs of developing cancer drugs”

He added: This would allow the manufacturer to recoup at least some of its R & D expenditure. The purpose of this stage would be to assess the extent to which the product achieved its initial promise—not in the setting of a randomized controlled trial, but observationally—in a real world setting.”

“There would have to be caveats. The drug would need to be used strictly in the terms of its ‘conditional license’. There could be no ‘indication creep’ (off label use). The fate of the patient would need to be carefully documented—which would be greatly facilitated by electronic medical records.

“Some agreement would need to be reached between payers and the manufacturer about reimbursement—including what to do if the drug’s promise was unfulfilled, as well as over-fulfilled.”

Adaptive licensing, he added, would not solve all of the problems, but it would go a long way towards responding to the unsustainable costs of developing cancer drugs and those in other therapeutic areas.

Addressing the central theme of the lecture, Sir Michael advocated using both bottom up (basic sciences) to discover new targets and top down (clinical studies) to confirm the predictions of early science. But basic science had its limits. For example, the glitazones (for Type 2 diabetes mellitus) had been found to cause adverse cardiovascular effects despite in vitro and in vivo screening. The antidepressant SSRIs (selective serotonin reuptake inhibitors) were associated with suicidal thoughts in children and

adolescents.

Professor Steve Jones, of University College, London, geneticist, prize-winning author and broadcaster said that it was impossible to disentangle bottom up (nature) from top down (nurture). His students became glum when he told them that two out of three of them would die because of their genes. He cheered them up by saying that if they’d been living in Shakespeare’s time, two out of three of them would probably have been dead already, many from starvation, violence, cold and cholera.

The strong genetic components of today’s big killers, such as heart disease, cancer and diabetes, made people think that they were enslaved by their DNA; and probably encouraged the most dangerous idea in genetics that there was a single gene for everything from a sweet tooth to obesity to premature ejaculation. Phrases beginning “the gene for” were meaningless. Genes only assumed meaning within an environmental context.

Quoting height, the most heritable human attribute as an example, he explained: “When I was a student in Edinburgh, Scottish men were on the average about half a cm shorter than English men. Last year Scottish men were two cm shorter than English men.”

Tall people tended to be healthier than shorter ones because of how they live, not what they inherit. Professor Jones said: “Scottish men now live more than a year less than Englishmen – and within Scotland the figures are shocking. In the poorest district of Glasgow, men are five cm shorter on the average than men from the richest suburb in Glasgow, Lenzie.

“This might seem trivial, but there is a 28 year difference in life expectancy between men born in inner city Calton and those born in Lenzie, just five miles away.”

A key message was that you couldn’t change the biology, but that you could change the environment. Genetics could help to identify people at risk, but there were large shortfalls in knowledge. For example, a large study had identified about 200 genes affecting human height, but science may need to identify 1000 to 2000 more height-related genes to understand all genetic-driven variations in height. (Humans are reported to have some 23,000 genes.)

Professor Jones added: “Genetics has always been the science of extremes. People who are either remarkably tall or extraordinarily short frequently have shifts in a particular gene, say a growth hormone gene. These are generally well understood, but the general picture is more complicated.

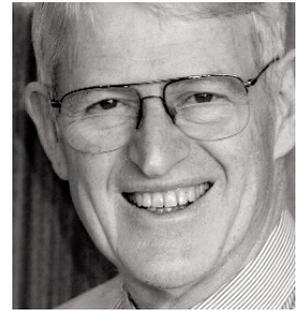
*Thanks not only to our distinguished speakers and compere, but to the organisers, led by HealthWatch committee member Professor Debra Bick, and the KCL events teams, including the student ambassadors*

*John Illman*

*Medical journalist, London*

## INNOVATING IN MEDICINE

**F**OR ANYONE who doubts that the world of evidence and science can still be a source of rich and creative invention, the Medical Innovations Summit<sup>1</sup> is held twice-yearly by the Royal Society of Medicine. At the first summit of 2013, held on 16th February, their central London headquarters hosted eleven presentations by experts from all over the world. Professor Christopher DeGiorgio, a neurologist from Los Angeles, began the day by demonstrating a pad which, worn during sleep, could replace drugs for many epileptic patients.



His device involves external trigeminal nerve stimulation. It produces a high frequency stimulus of about 60Hz, and is applied as a form of neuromodulation. An (albeit small) randomised controlled trial found that over 40% of patients experienced reductions in symptoms. It is now available in the United Kingdom on prescription. Because almost a third of epileptic patients become drug resistant this could, if larger scale trials support the results of the pilot work, give us a potentially useful non-invasive treatment.

Another Californian, the microbiologist Professor Chris Contag, is using micro-endoscopes for examining the oesophagus, stomach and intestine. By placing an absolutely miniscule microscope at the end of a very fine fibre optic cord, he has given pathologists a technique that lets them examine the living patient just below the tissue surface in what he described as “point of care” pathology. The images he showed gave the effect of actually peering through the thickness of the mucosa. The pictures compared very favourably with the traditional stained specimen of the same area.

A device that can extend the quality and length of life for the diabetic patient came from Dr Breanne Everett from Canada. She has an innovative plantar sensory replacement system a pressure-sensing insole for patients with diabetes or peripheral neuropathy. It enables patients who have lost normal feeling to be aware of sensations in their feet. This can reduce the incidence of diabetic ulceration which, if untreated, can lead to the need for amputation.

Innovative uses for mobile phones came next. Of particular note was Dr Yacov Geva’s medical smartphone which includes quick and accurate high quality medical sensors powering seven health tests. Users were able to measure and track various health and vital signs. All the data can then be collected and viewed later online or on the phone and shared with the health provider or family member.

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**“This 15-year-old boy produced a pancreatic cancer test which is 168 times faster and cheaper than the standard in the field.”**

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There were more endoscopic images from Professor Eduard Gratacos of Barcelona, these were astonishing pictures taken during the world’s first lung surgery on a foetus. Because the foetus is always on the move in its fluid-filled environment, access is extremely difficult and any interference with the unborn child’s position in the womb can risk significant damage. Surgery has to be carried out as quickly as possible. Professor Gratacos demonstrated a case of successful surgery for a pulmonary tumour. His pictures of the child as a 2-year-old in his parents’ arms produced a round of applause from the audience. He explained, however, that there are only a few rare conditions for which surgery can be considered in view of the high risk associated with the procedure.

Not all the speakers were from overseas. Professor Judith Hall of Cardiff University has developed a system of colour-coded interlocking couplings designed to reduce the risk of mistakenly injecting the wrong substance intravenously, with potentially fatal consequences.

At Churchill Hospital Oxford urological surgeon David Cranston is using high intensity focus ultrasound, in which the sonic energy produces local heat that can be used to destroy diseased or damaged

tissue. He explained that it is sufficient merely for the tissue to be brought up to 55°C for 1 second. It has been tried in a number of patients with liver cancer. Results are less satisfactory with the kidney and the pancreas, for the latter it can only be used for pain relief. However the whole procedure is time consuming, requiring a general anaesthetic and taking up to two hours.

On a totally different tack, scientists from Proctor & Gamble UK have developed a water purification process to be used in developing countries and anywhere that flood damage or other natural disasters prevent access to clean tap water. Globally, 80% of disease is water related. Although boiling the water kills organisms, it can soon get contaminated again. This innovation is an inexpensive product that clarifies and disinfects the water. Not only does it remove organisms, it also removes heavy metals and it contains chlorine so the water stays safe. So far it has been used in Kenya, Pakistan, Liberia, Guatemala and in Haiti following the earthquake. Result? A reported 50% reduction in incidents of diarrhoea. The invention has won P&G’s research scientists Philip Souter and Greg Allgood a Social and Economic Innovation Award from *The Economist* magazine. In view of its humanitarian benefit Proctor & Gamble UK are making this product a non profit venture

To make certain that the audience stayed to the end of the afternoon, the final speaker was 15-year-old Jack Andra, a young American who is passionate about medicine and science. He was a very competent speaker, although his accent was very strong and at times difficult to follow. Jack explained that after a relative died of pancreatic cancer, he had done some research. He found that pancreatic cancer cannot usually be detected until it is too late to halt the progress of the disease. He felt certain that it must be possible to identify in the blood stream some early markers and to be able to demonstrate their presence at a much earlier stage of the disease. Much of his work was carried out using Google and he eventually came up with a system which he believed would facilitate earlier detection. He wrote to 200 Universities in America. Of those, 199 rejected his findings or totally ignored him. However an academic at Johns Hopkins University was intrigued. He invited Jack to come and speak to senior academics and they quizzed him for over an hour. Eventually the schoolboy was allowed the use of space in a laboratory in order to prove his system. This young boy did exactly that, and has produced a pancreatic cancer test which is 168 times faster and cheaper than the standard in the field. He has now applied for a patent for the test but anticipates it will be some years before it will be marketable.

When Jack Andra was asked whether he was worried that, having sent his idea round to so many people, somebody else might develop it, he responded that this would not matter as it was for the benefit of humankind. When he finished he received the roundest applause of the day.

The whole day was very smoothly and efficiently run and of course hosted by our patron, Professor Sir Mike Rawlins.

*Keith Isaacson, Senior Consultant Orthodontist  
North Hampshire Hospital, Basingstoke*

### Reference

1. RSM Medical Innovations Programme website. See: <http://www.rsm.ac.uk/innovations/> (accessed 16 March 2013).

## last word

# TEACHING CAM IN GENERAL PRACTICE

**A** SA DOCTOR working as a final year GP trainee I am fortunate to have almost weekly teaching arranged by the local deanery. We have a larger teaching every other month with all the GP trainees in the area. This can be on a wide variety of topics but I was surprised to see that for a recent session there was an entire morning timetabled for homeopathy and chiropractic.

The homeopathy talk was by Dr David Owen, Principal Clinical Teaching Fellow at the University of Southampton, my alma mater. Dr Owen is a Fellow of the Faculty of Homeopathy, and he had given us a bit of reading to do beforehand. This was a chapter from his book "The Principles and Practice of Homeopathy". In these pages, he introduced some concepts about health models. He also discussed 'vitality' and the likelihood of getting various diseases.

His presentation was clearly aimed towards the medical end of the spectrum. Being a qualified doctor and registered with the GMC he described how, during his training, he had been dismayed that the patient and their experience were not being addressed. He said that he enjoyed talking to people and found this somewhat lacking in his medical education.

Thankfully things have now changed.

Modern GP training is now very much focused towards the treatment of the patient as a whole and within their social environment. The need to take into account their ideas, concerns, and expectations about their condition, is now drummed into us. You certainly cannot pass your RCGP exams if you do not take this approach. What's more, it makes consultation easier.

David Owen described how he looks at all the factors in a patient's life and considers whether there is a root psychological cause for it. This is very much what a GP does anyway, although homeopaths don't have to worry about any organic disease as this will have been screened for by the conventional doctor anyway. The main difference is that, unlike the regular GP, Dr Owen has a lot more time and then prescribes a placebo at the end.

There was very little content about the actual treatment given. He even stated that he didn't believe in all the theories about how homeopathy worked, suggesting that the tablets acted like "ideas". His slide about evidence was sparse and he covered this with a line stating that he didn't have enough time to talk about this, prompting a cynical chuckle from the audience. Unfortunately, he only offered enough time for one question. I suspect that having given

this talk to medics before, he has rather fine-tuned it, the lack of time to accept questions being an indicator of this.

The talk from the chiropractor was more interesting. He was from a family of doctors and seemed to pride himself on practising quite a medical model. He did, however, mention a number of times that what he practised wasn't what all chiropractors did, and that some of his colleagues had some more alternative views to his. He reviewed the NICE guidelines on back pain and focused on how these had now changed to suggest people are referred to "Any Qualified Providers" i.e., chiropractors and osteopaths, as well as physiotherapists. Essentially chiropractic is trying very hard to become an accepted conventional therapy. But the standardisation of care is going to be difficult given the variability in what is offered by these providers.

He allowed a little more discussion and questions. However, when asked about the risk of carotid artery dissection, a documented, if rare, danger of chiropractic, he was very dismissive. He claimed there had been no proven link between neck manipulation and this serious adverse event. "Do they have the dissection before they visit the chiropractor, given they are attending for neck pain anyway?" He said it wasn't widely recognised except by internet bloggers and Professor Edzard Ernst.

I wasn't sure about the thoughts of the other GP trainees as there hadn't been much time for discussion. Luckily I had the chance a few weeks later when my presentation slot came up in our smaller teaching group. I chose to use the time to appraise what was said, talk about some of the pros and cons, and to stimulate some discussion. It turns out I was preaching to the converted as the willingness to use any of these therapies was low in our group. Generally we appreciate that patients can get some benefit from such therapies but we are concerned about the money spent and risk of patients being exploited. It's not anything that we would ever recommend.

*Alex Rose*

*GP Registrar, Alresford, Hampshire*

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