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HealthWatch

SAATCHI DEBATE ENERGISES

THE SECOND HealthWatch public debate asked the question: “This house supports the Medical Innovation Bill”. Four distinguished and passionate speakers were masterfully chaired (and, occasionally, refereed) by Peter Bazalgette, and an educated and engaged audience packed the Kings College lecture theatre. An hour of passionate argument included many moving and thought-provoking contributions before the motion was put to the vote.

The Medical Innovation Bill (known as the Saatchi Bill) was a private members’ bill sponsored by Lord Maurice Saatchi, introduced in 2013 in a bid to address what he sees as doctors’ aversion to trying new treatments because of fear of litigation, by enabling them to innovate in cases of terminal cancer and other diseases safely and responsibly. But many believe such a law is unnecessary, and could permit irresponsible experimentation. Shortly before the HealthWatch Debate we learned that the Bill’s Second Reading, due for 27th February, had been put back to 6th March. The timing was perfect for HealthWatch to argue the Bill without knowing its destiny.

The stage was set then, for the debate at Kings College London’s Waterloo Campus, on 4th March. Sir Peter Bazalgette, chairman of Arts Council England, gave each speaker eight minutes to put their case. First up was Sir Mike Rawlins, chair of the MHRA and patron of HealthWatch. His speech in support of the motion described Dravet Syndrome, a rare and catastrophic form of childhood epilepsy, for which some sufferers have been helped by the compound cannabidiol. Doctors in this country, he said, cannot prescribe it because it is not licensed for the condition. Rawlins acknowledged having had initial reservations about the Saatchi Bill but, he said, it had been revised to address them. “Don’t throw the baby out with the bathwater” he concluded.

Opposing the motion was HealthWatch’s president, journalist and broadcaster Nick Ross, who said that not one penny of the £1.6bn claimed annually against the NHS is because of innovation. Innovation already happens within the current legal framework, but he warned against “confusing innovation with improvisation”—as an example of the latter, the untested practice by which thousands of premature babies, among them the musician Stevie Wonder, were blinded by oxygen treatment intended to help their lungs develop.

Seconding Rawlins was parliamentary lawyer Daniel Greenberg who claimed Ross’s concerns did not apply in the Bill’s latest version. Weighing into the battle of the lawyers, Nigel Poole QC argued that the Bill could create even more problems for doctors through new, untested principles of law.

Speeches over, views were invited from the audience, who included students, medics and lawyers, as well as HealthWatch members. Cancer surgeon Michael Baum described how he had innovated extensively within the current system without legal impediments. An A&E consultant fresh from theatre told of a life he



Nick Ross opposes the motion, with proposers Daniel Greenberg (centre) and Sir Michael Rawlins (right). Photo by Mandy Payne

saved recently by a spur-of-the-moment intervention, again without fear of litigation. Barrister and physician Pete Feldschreiber warned that the Bill would bypass the protection of existing benefit-risk assessment frameworks, and could prove extremely dangerous. Others called for sensitivity in helping the families of the dying to deal with their situation, rather than seek more and more medical treatments. A lawyer, observing that the Bill resulted from Saatchi’s passionate and well-intentioned desire to find a way to spare others the suffering his wife Josephine had endured, suggested that, had his wife died as a result of, say, medical negligence, we might be looking at a very different Bill. There was concern at the pain that was inflicted on the bereaved Maurice Saatchi when he saw that his own wife’s oncologist had signed a letter in *The Lancet* opposing his Bill—should that doctor have refrained out of compassion?

The motion was defeated by 90 votes to 3, with 13 abstaining. This judgment was echoed in Parliament a few days later—no MP moved the Bill at its Second Reading, so it will progress no further.

Mandy Payne

The debate can be viewed in full online at <http://www.healthwatch-uk.org/debate-on-the-saatchi-bill-march-4th/>

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Headache doctor trial verdict criticised

HHEADACHE EXPERT Andrew Dowson, of King's College Hospital London, has received a temporary suspension from the UK medical register for a "serious breach of professional standards" in clinical trial conduct.

Two charges of dishonesty were found proven against Dowson, the headache specialist who co-led the MIST (Migraine Intervention with STARFlex Technology) trial, but the decision to allow him to return to research post-suspension has come under criticism. Dowson was joint principal investigator with the cardiologist Peter Wilmshurst, who was later sued for defamation by STARFlex' manufacturers after he publicly aired his concerns about inaccuracies in the trial results.

The Medical Practitioners Tribunal Service panel ruled in February that Dowson had been dishonest in signing a "materially false" statement in a clinical trial agreement and in not telling a research ethics committee that he had breached the research protocol of a previous trial. After reaching its conclusions on the facts, a

fitness to practice hearing later that month suspended Dowson from the Medical Register for four months.

On hearing the verdict, Peter Wilmshurst told HealthWatch: "I am surprised that despite this being the second time that a Fitness to Practise Panel has found him guilty of misconduct in a clinical research trial (the first time was in 2006 and concerned unrelated research), they have made no ruling prevent him undertaking research when he gets back onto the Medical Register."

Mandy Payne

Reference

1. Dyer C. Migraine doctor is suspended for serious breach of professional standards *BMJ* 2015;**350**:h982
<http://www.bmj.com/content/350/bmj.h982>

NEWS IN BRIEF

HOMEOPATHY HAS been written off as a treatment for medical conditions by Australia's government working group. The National Health and Medical Research Council announced on 11th March that "there is no good quality evidence to support the claim that homeopathy is effective in treating health conditions." After assessing more than 1800 papers, NHMRC could find no good quality, well-designed studies with enough participants to support the idea that homeopathy works better than a placebo, or causes health improvements equal to those of another treatment. The Australian advocacy group Friends of Science in Medicine (FSM) are calling on the Australian government to stop subsidising unproven alternative therapies such as homeopathy through student loans for homeopathy and similar courses.

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

IT'S TIME to nominate an individual who has promoted sound science and evidence in the public interest for the 2015 John Maddox Prize for Standing up for Science. Emphasis is on those who have faced difficulty or hostility, especially if they have yet to receive recognition. The winner receives £2000, the presentation is at a reception in November.

<http://www.senseaboutscience.org/pages/maddox-prize-2015.html>

A ONE DAY educational event on Overdiagnosis will be held on Tuesday 12th May at The Education Centre, Royal Surrey County Hospital, Guildford. Speakers will include Iona Heath, John Yudkin and Richard Lehman. It's open to anyone with an interest, is non-profit making (£40 registration to cover costs) and there will be no sponsorship. Information and registration at <http://www.fromhealthtosickness.org/>

BAD MEDICINE was published back in 2007 but, now available on Kindle, it's still worth a read. By David Wooton, and subtitled "Doctors doing harm since Hippocrates" it asks, just how much good has medicine done over the years? And how much damage does it continue to do? Published by Oxford University Press.

THERE ARE LOTS of organisations that fact-check online, scrutinising everything from politicians' speeches to adverts to news-

paper headlines—and health is a ripe source of misconceptions. Fact Check Central is Sense About Science's new myth-busting website which collates info from fact-checking blogs such as Full Fact, the Health and Safety Executive Myth Busters Challenge Panel, NHS Choices 'Behind the Headlines', and SAS's own 'For the Record' series. Just browse down the list of headlines, then find the evidence in the links at <http://factcheckcentral.org/>

MEET YOUR fellow travellers on the journey of questioning, at the 16th European Skeptics Congress this September 11-13, at Goldsmiths College, London. HealthWatch committee members James May and Susan Bewley will be on the 'Skepticism and Medicine' panel at the congress. Edzard Ernst, formerly Professor of Complementary Medicine at the University of Exeter, past HealthWatch Award recipient, and current blogger at <http://edzardernst.com/>, will present a critique of integrative medicine. There will be talks on science, complementary medicine, parapsychology, magic and 'satanic panics'; and a Skeptics in the Pub event in which psychologist Gustav Kuhn will give a presentation (with demonstrations) on the Science of Magic. Register at <http://euroskepticscon.org/>

DOCTORS IN England are writing fewer prescriptions for homeopathy. In 2014, the number of NHS prescriptions for homeopathy fell for the eighteenth consecutive year, this time by over 21%, according to an analysis by the Nightingale Collaboration, using data publicly available from the Health and Social Care Information Centre. The number of prescriptions written for homeopathic remedies is just 6% of its 1996 peak, says the report.

<http://www.zenosblog.com/2014/10/an-idiots-guide-to-understanding-nhs-homeopathy-prescription-data/>

A SURVEY from Aberdeen found almost two-thirds of Scottish women reported using complementary and alternative medicine in the third trimester, despite uncertainty about their safety and effectiveness. Oral herbal drugs were the most commonly taken, with 40 different products identified. Having a university education was one factor that made the practice more likely, reported Pallivalapila and colleagues.

Obstet Gynecol 2015;**125**:204-11

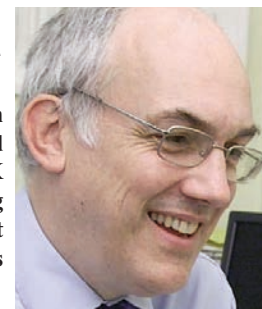
HRT and expert conflicts of interest

SINCE THE Women's Health Initiative trials^{1,2} confirmed that combined estrogen and progestogen hormone replacement therapy (HRT) increases the risk of breast cancer, heart disease and stroke, and that estrogen-only HRT increases the risk of stroke, most independent experts, including the UK Medicines and Healthcare Products Regulatory Agency (MHRA), and the US Federal Drug Administration, have advised that it should be limited to treating symptoms only, and used in the lowest dose, for the shortest time possible, and never for health promotion. Most doctors accept this advice, pass it on to their patients, and follow it.

But a small number of menopause "experts" with documented ties to HRT manufacturers, regularly write editorials and reviews casting doubt on the WHI trial results, playing down their implications, and claiming that HRT might even reduce heart disease when started soon after the menopause. This "timing hypothesis" is not born out by independent analysis of all the trials of long term HRT use, e.g., the latest Cochrane review.³ It also ignores the well documented cardiovascular harms seen in trials of short term HRT in younger women, which for many years were concealed by the manufacturers.^{4,5}

A few years ago the conflicts of interest for the most prolific of these authors came under the spotlight^{6,7} and the number of obviously biased review articles fell slightly, but they continue to promote their ideas via other routes; at congresses, and via the "documentary" film Hot Flash Havoc.

The 14th World Menopause Congress was held in the resort city



of Cancun, Mexico between 1st and 4th May 2014. Many keynote lectures on HRT had titles which, in themselves, and by their repetitive nature, suggested the speaker was biased. In case they forgot to mention them, their publicly available conflicts are listed in table 1, below left.

The "documentary" film Hot Flash Havoc directed by Marc Bennett and released in March 30, 2012, is regularly shown to women's groups, and at menopause meetings. Its message is summarised on its website. <http://www.hotflashhavoc.net/>

"HOT FLASH HAVOC is the most provocative and revealing documentary ever made about menopause. For the first time this documentary sets the record straight about the U.S. government sanctioned Women's Health Initiative (WHI) study released in 2002, which misrepresented that the hormonal replacement therapy being used by millions of women to treat the symptoms of menopause, could actually increase the risk of heart attacks and cancer.

This misinformation caused confusion, hysteria, and fear among women as well as healthcare providers, endangering the health and wellbeing of millions of women, many of whom flushed their hormones down the toilet.

This film not only sheds insightful light on the confusion stemming from a decade of misguided facts, but conveys poignant stories shared by real women and in-depth interviews with the world's most noted experts. HOT FLASH HAVOC provides compelling information about menopause that will empower women for the "Second Act" of their lives."

Most of the "world's most noted experts" are self-styled pundits, TV doctors, complementary therapists and the like. However they include five apparently reputable professors with expertise in the menopause, none of whom list any conflicts of interest on the Hot Flash Havoc website. They are listed in table 2 below.

It is of course possible that these "experts" came to their idiosyncratic opinions through careful personal review of the evidence. Perhaps they flew to Cancun to speak at their own expense. Maybe

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Table 1. Keynote lecture titles related to post-menopausal HRT, speakers, and their conflicts of interest at the 14th World Menopause Congress in Cancun, Mexico 1-4 May 2014

WHI: An Evolving Understanding of the Clinical Evidence. BMS Recommendations on Menopause & HRT. The optimal new way confirmed by KEEPS - Nick Panay <i>Nick Panay has received consultancy fees from Pfizer, Bayer, Abbott (click here) plus Baxter, Schering, Eli Lilly, Galen, Janssen Cilag, Merck, Novo Nordisk, Novogen, Organon, Orion, Procter & Gamble, Se-cure, Servier, Shire, Solvay, Storz, and Wyeth</i>	been paid lecture fees by Berlex, Merck, Pfizer, Novo Nordisk, and Organon
State of the art HRT - David Sturdee. <i>Dr Sturdee has had financial support from Amgen, Theramex, Procter & Gamble, Wyeth, Bayer Schering and Novo Nordisk.</i>	Efficacy and safety of low dose E2/DRSP in postmenopausal women - David Archer <i>David F Archer has consulted for Agile Therapeutics, Bayer Healthcare, Merck, Novo Nordisk, Warner Chilcott, and Wyeth Laboratories (Pfizer), and received honoraria from Bayer Healthcare, Merck, and Wyeth Laboratories (Pfizer)</i>
HRT—Route of administration, dose, age at initiation and duration of therapy. Strategies to optimize cardiovascular health with HRT. Hormone therapy and cardiovascular disease—what is the risk? - John Stevenson <i>Dr Stevenson has financial conflicts with Schering Plough, Wyeth/Pfizer, Bayer, Meda and Merck/Theramex.</i>	What if WHI had just used Transdermal Estradiol and Oral Progesterone instead? - James A Simon <i>James A Simon has been on the advisory boards of Allergan, Amgen Inc., Ascend Therapeutics, Bayer, BioSante, Boehringer Ingelheim, Concert Pharmaceuticals, Concept Therapeutics, Inc., Depomed, Inc., GlaxoSmithKline, KV Pharmaceutical Co., Lipocine, Inc., Medtrina Pharmaceuticals, Merck, Merion Pharmaceuticals, Nanma/Tripharma/Trinity, NDA Partners LLC, Novo Nordisk, Novogyne, Pear Tree Pharmaceuticals, QuatRx Pharmaceuticals, Roche, Schering-Plough, Sciele, Solvay, Teva Pharmaceutical Industries Ltd, Ther-Rx, Warner Chilcott, and Wyeth</i>
Cardiovascular Effects of Estrogens: Evidence and Hypotheses from Epidemiological Findings - Rogerio A Lobo <i>Rogerio A Lobo "has provided consulting services for many large pharmaceutical laboratories"</i>	Menopausal hormone therapy and osteoporosis: have we completed a full circle? - Tobias De Villiers. <i>Tobias de Villiers has received consultancy fees from Adcock Ingram and Pfizer; speaker's fees from Servier, and travel support from Amgen, Pfizer, and Bayer</i>
Relevance of cardiovascular diseases in menopausal women and their implication for clinical practice. A cardiovascular guide for menopause physicians—An update - Peter Collins <i>Dr Collins has served as a consultant to Eli Lilly, Berlex, Merck, Pantarhei, and Pfizer, and has</i>	

Table 2. Expert advisers to the film "Hot Flash Havoc"

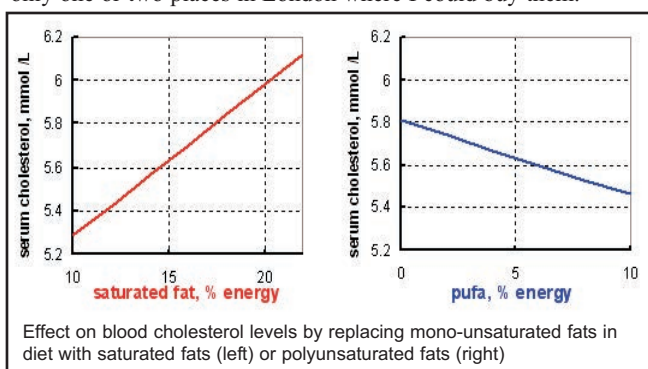
Dr Anita H Clayton, Professor of Psychiatry & Neurobehavioral Sciences at the University of Virginia Consultant, speaker, research support from Boehringer-Ingelheim, Bristol-Myers Squibb, Eli Lilly, Novartis, Pfizer, Wyeth and Sanofi-Aventis
Dr Sheryl Kingsberg, Chief of Behavioral Medicine, and Associate Professor Departments of Reproductive Biology and Psychiatry, Case Western Reserve School of Medicine Financial relationships with Novo Nordisk, and Pfizer
Dr James A Simon, Clinical Professor of Obstetrics & Gynecology, George Washington University in Washington, D.C Consultant, speaker, on advisory boards of: Bayer, Boehringer Ingelheim, GlaxoSmithKline, Merck, Novo Nordisk, Roche, Schering-Plough, Solvay, and Wyeth
Dr Leon Speroff, Professor of Obstetrics and Gynecology, Oregon Health & Science University School of Medicine Consultant and research support from Warner Chilcott, Organon, and Wyeth
Dr Wilf H Utian, Professor Emeritus of Reproductive Biology, Case Western Reserve School of Medicine Consultant or advisory board for Bayer, Bionovo, Merck, and Novogyne

ADVICE ON FATS: evidence flawed?

A WIDELY PUBLICISED paper in the journal *Open Heart*¹ in February said that the current dietary guidelines to reduce total fat intake to no more than about 30% of energy intake, and with no more than 10% of energy from saturated fats, were not supported by randomised controlled trials, and should not have been introduced.

There is a problem here. Any randomised controlled trial (RCT) of interventions to prevent death from atherosclerosis and coronary heart disease will, of necessity, involve people already at risk: middle-aged men who already have significant atherosclerosis. This is unavoidable if there is to be a result within, say, 5–10 years. However in such a population the best that can be expected of a successful intervention is a slowing in the worsening of their condition, something that is unlikely to have a statistically significant effect in such a short-term study. Middle-aged men with atherosclerosis are probably too late to benefit from dietary changes.

The ideal study would involve young people, followed for a lifetime, with half consuming one diet, and half the other. This is obviously not achievable. In Britain we have a series of cohort studies, the oldest of which is still following every person born in the second week of March 1946. There is much fascinating information here, but any information on diet and health in later life is not relevant to people born 15–20 or more years later. In 1946 food was still rationed, and rationing continued for several years after that. As I recall, the last rationing, of sweets, ceased in time for the coronation in 1953. I still remember the surprise of going into the sweet shop and being told that I could have anything my tuppence pocket money would buy, without needing ration coupons. There have been enormous changes in the range and amount of food available since the 1950s and 1960s. Many foods that are now commonplace were unknown in my youth. I first tasted yoghurt when my parents brought a bottle back from a trip to Paris. I was 13. I ate my first pizza in Italy at the age of 18. During my gap year in Israel I developed a taste for green peppers. On my return I found that there were only one or two places in London where I could buy them.



We have known for many years that elevated serum cholesterol is a major factor in the development of atherosclerosis and coronary heart disease, and that the total amount of dietary fat, and the type of fat, are important determinants of serum cholesterol. The figure above shows that progressively replacing mono-unsaturated fats with saturated fat results in a proportionate increase in serum cholesterol, while replacing with polyunsaturated fat similarly decreases serum cholesterol. This is based on admittedly relatively short-term feeding experiments on young people, but together with animal experiments they provide the real experimental evidence for the guidelines on fat intake.

An interesting intervention was carried out in Mauritius. A single government-controlled factory produced cooking oil for the whole country, and in 1987 they changed from using palm oil (high in saturated fats and low in polyunsaturates, to one based on soya bean oil (low in saturated fats and high in polyunsaturates). Five years

later, in 1992, there was a significant fall in the population's serum cholesterol.

However, when the results were published in 1996², it was noted that there had been no decrease in death from coronary heart disease. This is not surprising. The people dying from coronary heart disease in 1996 were middle-aged, and had established atherosclerosis. We may have to wait another 20–30 years to find out what happened when the people who were fed the soya-bean oil as children reach middle age.

Experts have refuted the claims made in the *Open Heart* paper. Christine Williams, professor of human nutrition at the University of Reading is quoted on the Science Media Centre's website,³ saying "The claim that guidelines on dietary fat introduced in the 1970s and 80s were not based on good scientific evidence is misguided and potentially dangerous." Tom Sanders, emeritus professor of nutrition and dietetics at King's College London, said "This report summarises six small trials conducted more than 30 years ago, which were of short duration and lacking sufficient statistical power to show any effect on mortality rates. In my view, the authors are wrong to suggest that advice to decrease total and saturated fat should not have been introduced. Their conclusion fails to take into account the totality of the evidence."

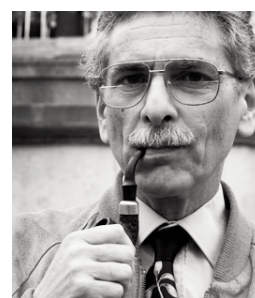
Kevin McConway, professor of applied statistics at the Open University concurs that the study shows the introduction of dietary fat guidelines in the US and the UK, well over thirty years ago, could not have been based on evidence from randomised controlled trials, but adds: "This does not mean that the guidelines were not supported by any evidence at the time. Trials are not the only source of evidence for policy changes like this. The new report itself points out that evidence for the guidelines came from other sources as well, in particular from population studies. This new research tells us rather little about what the overall evidence base for the recommendations actually was. So it really doesn't help us much in deciding whether or not the decisions made all those years ago were properly grounded in evidence."

So, we cannot conduct appropriate RCTs to test the hypothesis that changing dietary fat intake will reduce the risk of atherosclerosis and coronary heart disease. Nevertheless, we do know that diet and lifestyle changes over the last 30 years have coincided with a decrease in death from coronary heart disease. It is likely that this is cause and effect, but the best we can say is that the advice is prudent, and may be beneficial. At the very least, following the dietary guidelines will reduce the prevalence of obesity.

David A Bender
Emeritus Professor of Nutritional Biochemistry
University College London

References

1. Harcombe Z, Baker JS, Cooper SM, et al. Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-analysis. *Open Heart* 2015;2:e000196
2. Uusitalo, U. et al. Fall in total cholesterol concentration over five years in association with changes in fatty acid composition of cooking oil in Mauritius: cross sectional survey *BMJ* 1996;313:1044
3. Expert reaction to study looking at historic UK and US dietary advice on fats. Science Media Centre website, 9 February 2015. At: <http://www.sciencemediacentre.org/expert-reaction-to-study-looking-at-historic-uk-and-us-dietary-advice-on-fats/> (accessed 31 March 2015)



Are the NICE guidelines on adult overweight and obesity scientific?

Will the NICE guidelines for weight control¹ in adults prove any more effective than predecessor documents? Or will they, like the recommendations they replace, do more harm than good? There is some new awareness—of stigma as a hazard, of the need to monitor adverse effect and recognition of a role for multi-dimensional health measures.



But these are not enough to redeem them, and notwithstanding the sincere intent of the Professional Development Group, it is neither scientifically valid nor clinically meaningful and a far cry from the “fully engaged scenario” envisioned by Wanless in 2002.² The fact is, that telling people to eat less and move more hasn’t made us any thinner, healthier or happier as a population. I suggest we need a new map spanning health inequalities, metabolic syndrome and public health nutrition that promotes equity, self-care and body respect for all.

Anyone with a background in the eating disorders field will note the lack of analytical rigour in the NICE guidance. It cautions against weight stigma, then adopts the approach the Binge Eating Disorder Association warns against because: “Extensive evidence-based research has found that focusing on weight and dieting instead of health does more harm than good, resulting in an increase in eating disorders, weight gain, lower self-esteem, and bullying...”

When this incongruence is raised in stakeholder comments NICE upholds allegiance to scope, sacrificing the scientific method—and ultimately people’s lives—to institutional expediency. The fact that the evidence they looked at “identified no adverse effects of the type mentioned” and that “the considerations section highlights that the approach is to do no harm,” suggests flaws in process and logic. Willing something to be does not make it so, and ignoring potential harm is unethical.

The way the evidence reviews for NICE are conducted means that it is possible to comment on whether approach X is more effective than approach Y in achieving short term weight loss, while overlooking evidence that people following both X and Y will likely gain weight from baseline in the longer term. The systematic review of randomised controlled trials of weight loss studies with results at two years by Mann *et al*³ is the best relevant evidence available. This concludes that: “The benefits of dieting are simply too small and the potential harms of dieting are too large for it to be recommended as a safe and effective treatment for obesity.”

“Any guidelines that seemingly support weight reduction as effective necessarily rely on poorer quality reviews”

NICE is not alone in using review methods that overlook this high quality, longterm data to justify weight management recommendations. Any guidelines that seemingly support weight reduction as effective necessarily rely on poorer quality reviews: the British Association of Cardiac and Pulmonary Rehabilitation⁴ use a study where over 60% of studies included were 4 months or less; the British Dietetic Association⁵ choose a poor quality self-report study and the NHS Care Pathway booklet⁶ cites a review including a study with 9 participants.

The cherry picking methodology passes for science when we start with policy and build up a pseudo-evidence base around it: the NICE scope assumes that lifestyle weight management programmes are effective, and so only collates evidence that buttress-

es this assumption. The NICE decision protects existing belief by ignoring failure and minimising potential danger, such as concerns about weight cycling, which gets presented rather differently in Scottish guidelines⁷: “Weight cycling is a common condition as only a minority of people who lose weight through weight management interventions are able to maintain their weight loss ... Weight cycling is a risk factor for all-cause mortality and cardiovascular mortality (hazard ratio (HR) approximately 1.8 for both).”

This phenomenon of self-fulfilling philosophy has a parallel in the treatment of stomach ulcers. Medics and researchers who questioned the dominant belief that stomach ulcers were caused by acid struggled to be heard when they suggested a role for the bacterium *Helicobacter pylori*. Once ridiculed and vilified, their work earned several Nobel prizes and led to a radical shift in understanding of the treatment and aetiology of stomach ulcers. The paradigm shift needed in conceptualising “obesity” makes similar demands on us: it is imperative that we cast doubt on what we think we know.

EVEN SO, questioning a goal of weight loss as a premise for wellbeing can seem far-fetched. Until we consider that fatter people who change eating and activity patterns can improve wellbeing whether or not they lose weight. Weight loss may occur, then again, it may not. It is the pursuit of weight loss as a goal that I am interrogating. Let’s consider people attending diabetic clinic. Bill sees a dietitian for weight loss and sure enough loses weight. At six months he’s eating more regularly and enjoying cooking for his family, is more active and his HbA1C (glycated haemoglobin, monitored in diabetes) has improved. This suggests Bill benefited from taking time to think about what he was eating and receive some nutrition education. For every Bill, there are innumerable patients who have long histories of dieting, who go to bed calibrating their self-worth in terms of the scales, who wake up fearing food and dreading the day ahead. Their blood glucose is poorly controlled, their mood and self-efficacy low.

This history tells us that a weight-loss target can be ineffective and harmful, and it follows it would be unethical to recommend this. Now we switch our focus from weight loss to health-gain. Bill changes his lifestyle, gains health—and loses weight. The other patients are offered a way out of the diet roller coaster. They too have the opportunity to experience long term improvements in health behaviours, physiological and psychological measures in chronic dieters that are independent of weight change and arise from moving away from weight-loss targets. This approach is the essence of Health At Every Size®, or HAES®, a movement which promotes a focus on health that embraces equity and respect for all. Alongside switching the focus from weight-loss to health-gain, the HAES philosophy teaches compassionate self-care that in turn fosters a sense of agency and supports people to develop a healthy relationship with food. Contrast this with the traditional weight-centred approach teaching cognitive restraint where the battle with food is seen as inevitable and on-going, so much so that the British Heart Foundation⁸ lists driving past takeaways, feeding your children and being home alone as triggers to be planned for. This approach encourages the sort of food avoidance behaviour

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THE US NCCIH: WHAT IS IT?

AMERICA'S NATIONAL Centre for Complementary and Alternative Medicine (NCCAM) recently changed its name.¹ It replaced the words 'Alternative Medicine' with 'Integrative Health', to reflect both the 'growth of integrative health care within communities across the US' and its research focus. Originally the Office of Alternative Medicine (OAM), set up in 1991, it went on to be re-established as NCCAM, making NCCIH its third name. Is this just another attempt to give 'alternative medicine (AltMed)' the appearance of legitimacy?

Established by the US Congress in 1998,² as part of the National Institutes of Health (NIH), it has been shaped by politics, not by science. NCCAM was "set up to study alternative therapies and how they could be integrated into conventional treatment". NCCIH and its predecessor agencies have spent nearly \$2bn,³ much of it on research into implausible interventions such as acupuncture, prayer, homeopathy, therapeutic touch and energy medicine.

Comprising more than 1,000 interventions,⁴ the AltMed industry is worth \$100bn per annum worldwide,⁵ including \$4bn in Australia. It is an assortment of implausible and expensive interventions which are "exuberantly promoted to a scientifically naïve public".⁶ AltMed has origins outside scientific medicine and supposedly works on the immune system and (non-existent) 'energy' systems. However, while patients "feel better for a little bit",⁷ AltMed does not address underlying disease processes and therefore cannot change the course of any disease.

NCCAM funded over 3,800 research projects on complementary medicines and AltMed.⁸ Its primary purpose was to "investigate and validate alternative approaches",⁹ not to determine if they work or not. They consistently produced research of lower quality than that of other NIH Institutes, and they have even published worthless research.¹⁰ It was structured by its charter in a manner that "precludes an independent review of its performance".² The NCCIH now reportedly argues that "a treatment is valuable if patients report that it helped them, even if others receiving sham treatment said the same".¹¹ According to their Director, "most in the mind and body area have actually shown impact".¹²

Integrative Medicine (IM) is an umbrella that includes a range of AltMed. It refers to the "blending of conventional and evidence-based complementary medicines and therapies with the aim of using the most appropriate of either or both modalities to care for the patient as a whole".¹³ Some proponents of IM claim to be experts in 'nutritional and environmental' medicine. They might use unproven diagnostic tests on hair, blood or urine or so-called 'functional pathology', to 'diagnose' heavy metal levels and 'nutrient deficiencies'. Based on the results of these invalid tests,¹⁴ they might recommend chelation (for heart disease and heavy metal detox—costing up to \$5,000), and other unproven interventions, such as megadose vitamin infusions, hyperthermia, acupuncture, homeopathy, naturopathy, 'natural'/bio-identical hormone therapy, genome-based personalised healthcare programs, 'mind-body' interventions and complementary medicines.

SET UP to prove that AltMed works, the NCCAM has done the opposite.⁹ AltMed research is driven by faith, hope and ideology, rather than by science, and the interventions have failed when tested. Although NCCAM has not demonstrated efficacy for any AltMed, they have not informed the public of methods that are of no value. The recent Australian National Health & Medical Research Council (NHMRC) Natural Therapies Review into 17 popular interventions concluded that there was insufficient evidence that any of them worked for any illness!¹⁵

The NCCAM's failure is evidenced by the small number of their 'trials', scrutinized by unsuitable reviewers, that were published in peer-reviewed medical journals. Nearly two decades after its inception, NCCAM has made no AltMed discoveries which would justifi-

fy its existence.² The NCCIH will, however, continue to fund and promote such treatments. "Political pressures and the Center's charter would seem to make this inevitable. Ethics and the public interest are compromised."¹⁶

Its name change does not represent progress. It is a deceptive use of language and is no more than re-branding to enable it to continue its pointless research and its useless, sometimes dangerous, and always expensive, promotions. NCCAM consistently produced research of lower quality than that of other NIH, and they have conducted research that is not worthy of serious consideration.¹²

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References

1. NCCIH news release. January 16, 2015. <https://nccih.nih.gov/about/offices/od/nccam-new-name>
2. National Center for Complementary and Integrative Health. http://en.wikipedia.org/wiki/National_Center_for_Complementary_and_Integrative_Health
3. NCCIH Funding: Appropriations History. <https://nccih.nih.gov/about/budget/appropriations.htm>
4. International Institute for Complementary Therapists. <http://www.iict.com.au/membership/approved-modalities>
5. Top alternative medicine market studies and statistics. January 2014. <http://www.reportlinker.com/ci02242/Alternative-Medicine.html>
6. Atwood KC. The Ongoing Problem with the National Center for Complementary and Alternative Medicine. September 2003. http://www.csicop.org/si/show/ongoing_problem_with_the_national_center
7. ABC Radio, January 13, 2015: <http://www.abc.net.au/7.30/content/2015/s4161774.htm>
8. NCCIH news release. May 16, 2014. <https://nccih.nih.gov/about/offices/od/comments/transcript>
9. Senator Tom Harkin: NCCAM has "fallen short" because it hasn't validated enough woo. March 9, 2009. <http://scienceblogs.com/insolence/2009/03/02/maybe-nccam-isnt-so-bad-after-allnahhh/>
10. Atwood KC et al. *Medscape J Med* 2008;**10(5)**:115. <http://www.medscape.com/viewarticle/570625>
11. Good money following suspect medicine. December 18, 2011. http://www.cleveland.com/business/index.ssf/2011/12/good_money_suspect_medicine.html
12. Chicago Tribune, December 11, 2011. http://articles.chicagotribune.com/2011-12-11/health/ct-met-nccam-overview-20111211_1_cancer-treatment-alternative-medicine-breast-cancer-researcher/2
13. Royal Australian College of General Practitioners. <http://curriculum.racgp.org.au/statements/integrative-medicine/>
14. Friends of Science in Medicine recommendations for pathology tests in Australia. October 2013. <http://www.scienceinmedicine.org.au/images/pdf/pathologyrecommendations.pdf>
15. The Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies. Australian Department of Health. February 20, 2015. <http://www.health.gov.au/internet/main/publishing.nsf/Content/phi-natural-therapies>

Are the NICE guidelines on adult overweight and obesity scientific?

... continued from page 5

that is a diagnostic feature of eating disorders. The review methods used in NICE have fabricated a document that is theoretically threadbare.

IT'S TIME to take the science seriously. When weight science is not filtered through the "lose weight be healthy" lens it clearly shows that a focus on weight leads to size stigma and disrupts people's relationship with food and their embodied self. Moreover, the emphasis on individual lifestyle change means we take our eye off the ball of social determinants. Any health policy designed to reduce heart disease, hypertension, diabetes and other nutrition-sensitive conditions that eclipses the metabolic and psychological injury of living with poverty and oppression leads ultimately to a victim blaming agenda that further entrenches the thinking and policy that builds inequitable societies. Social gradients in heart disease in the UK cannot be explained by genetics, BMI or lifestyle alone. The Health of Minority Ethnic Groups Report of 2004⁹ found no association between fatness and risk of diabetes, stroke or heart disease in the groups studied; the Whitehall studies show that lifestyle accounts for only a fraction (5%-25%) of the social difference in health outcomes. Nowhere is this science apparent in the NICE guidelines. While there is some awareness of the social determinants of health (SDH), there is considerable theoretical confusion such that the SDH is erroneously used as synonymous with the socially distributed ability to eat well, keep active and access health services. SDH doesn't stop at health behaviours or medical care—the non-material impact of living with the stress of oppression, trauma and shame has very real, embodied consequences. We only have to look at work¹⁰ on racialised hypertension to realise that a weight-centred lifestyle narrative whitewashes the evidence.

The bottom line is that the focus on lifestyle, and within that, weight management, increases health inequalities and is detrimental to self-care and social justice. A new paradigm approach to public health nutrition and health inequalities written from a socio-politically aware reading of the evidence would find in favour of interventions fostering compassion, criticality and connectedness, hallmarks of the HAES approach. HAES is still at the stage of attracting ridicule and vitriol from some quarters, but if you don't mind ruffling a few feathers in the name of sound knowledge translation you might like to suspend incredulity and read on.^{11,12}

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Lucy Aphramor was a member of the NICE Policy Development Group for the guidelines referred to. She is co-author (with Linda Bacon) of "Body Respect", published by BenBella Books, September 2014.

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References

1. Managing overweight and obesity in adults – lifestyle weight management services. NICE guidelines [PH53], May 2014.
2. Wanless D. Securing our future health: taking a long-term view. Final report. London: HM Treasury, 2002.
3. Mann T *et al.* Medicare's search for effective obesity treatments: Diets are not the answer. *Am Psychol* 2007;**62**(3):220-233.
4. Standards and Core Components for Cardiovascular Disease Prevention and Rehabilitation. BACPR, 2012. (See Ref 49, Shaw *et al.*, 2006)
5. Grace C *et al.* The Dietetic Weight Management Intervention for Adults in the One to One Setting. Is it Time for a Radical Rethink? DOMUK, 2008.
6. Reddy S. Care pathway for the management of overweight and obesity. (See Van Gaal LF, Waunters MA and De Leeus IH (1997) The beneficial effects of modest weight loss on cardiovascular risk factors. *Int J Obes Relat Metab Disord* 2006;**21**:5S-9)
7. Management of obesity. A national clinical guideline. Scottish Intercollegiate Guidelines Network, 2010. (See page 18)
8. So You Want to Lose Weight...For Good. BHF, 2009.
9. The Health of Minority Ethnic Groups (2005) NHS Health and Social Care Information Centre, Public Health Statistics. Health Survey for England, 2004.
10. Krieger N and Sidney S. Racial discrimination and blood pressure: the CARDIA Study of young black and white adults. *Am J Public Health* 1996;**86**(10):1370-1378.
11. Tylka TL *et al.* The Weight-Inclusive versus Weight-Normative Approach to Health: Evaluating the Evidence for Prioritizing Well-Being over Weight Loss. *J Obes* 2014;**983495**.
12. Bacon L and Aphramor L. Body Respect: What Conventional Health Books Leave Out, Get Wrong, or Just Plain Fail to Understand about Weight. BenBella: USA, 2014.

HRT and expert conflicts of interest

... continued from page 3

they advised the film makers quite independently of any money they received from the HRT drug manufacturers. But women reading their articles, watching Hot Flash Havoc, and considering whether to take post-menopausal HRT, might reasonably wonder whether they are entirely disinterested.

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Further details and links available on Dr Thornton's blog at www.ripe-tomato.org

References

1. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. *JAMA* 2002;**288**:321-333.
2. Writing Group for the Women's Health Initiative Investigators. Effects of conjugated equine estrogen in postmenopausal women with hysterecto-

my: the Women's Health Initiative randomized controlled trial. *JAMA* 2004;**291**(14):1701-12.

3. Marjoribanks J *et al.* Long term hormone therapy for perimenopausal and postmenopausal women. *Cochrane Database of Systematic Reviews* 2012; Issue 7. Art. No.: CD004143. DOI: 10.1002/14651858.CD004143.pub4.
4. Hemminki E, McPherson K. Impact of postmenopausal hormone therapy on cardiovascular events and cancer: pooled data from clinical trials. *BMJ* 1997;**315**:149.
5. Hemminki E, McPherson K. Value of drug-licensing documents in studying the effect of postmenopausal hormone therapy on cardiovascular disease. *Lancet* 2000;**355**:566-569.
6. Tatsioni A *et al.* Partisan Perspectives in the Medical Literature: A Study of High Frequency Editorialists Favoring Hormone Replacement Therapy. *J Gen Intern Med* 2010;**25**(9):914-919.
7. Fugh-Berman A *et al.* Promotional Tone in Reviews of Menopausal Hormone Therapy after the Women's Health Initiative: An Analysis of Published Articles. *PLoS Med* 2011;**8**(3):e1000425.

Memoirs of a rebel with a cause

A Scientist in Wonderland by Edzard Ernst. Published by Imprint Academic, Exeter, 2015. £14.95. ISBN 9781845407773

IN THIS EMINENTLY readable little book (just under 200 pages), subtitled “A Memoir of Searching for Truth and Finding Trouble”, Edzard Ernst tells his story from being a child in post-war Germany through a psychology course in Munich (which may well have caused his abhorrence of pseudoscience), to medical school, and on through various clinical appointments in Munich, London, Hannover and Vienna, and finally to two decades as Professor of Complementary Medicine in Exeter.

Reading the first chapter I wondered whether, had I been a member of the interview panel for Munich Medical School, I would have offered him a place. His school grades were not outstanding, and his school reports referred to his disruptive behaviour (he managed to get himself expelled from a boarding school, apparently deliberately, because of his behaviour). He was more interested in playing jazz than in studying. Indeed, the fact that both his father and grandfather were doctors suggests that his interest in studying medicine might have been more genetic than personal. His mother’s ambition was for him to become the medical director of the hospital she managed.

Nevertheless, he did graduate in medicine, at the age of 30, and his first appointment was in the Munich Homeopathic Hospital. He says that his “theoretical knowledge of homeopathy was close to zero. At medical school, homeopathy had rarely been mentioned, but I had, of course, heard from our professor of pharmacology that this ... was complete and utter nonsense.” He then proceeded to read about homeopathy, and gives a clear account of its supposed theoretical basis. After a time working in a psychiatric hospital in London he secured a post in a research laboratory at St George’s Hospital Medical School. This sparked his love of science and laid the foundations for his belief in evidence-based medicine, and was followed by his appointment as Professor of Rehabilitation Medicine in Hannover (only 10 years after graduating), and then a prestigious appointment in Vienna. He is scathing about the vast amount of administration and internecine warfare in Vienna, which left him no time for research.

Disillusioned with Vienna, he replied to an advertisement in *New Scientist* inviting applications for the new chair of Complementary Medicine at Exeter—to general disbelief that he would forsake the prestige of Vienna Medical School and take a considerable cut in salary. Many people expected the new professor to promote complementary medicine. They were disappointed. He embarked on a

series of rigorous clinical trials with the philosophy that if it works and is safe, then it should become part of mainstream conventional medicine. If it does not work, or is unsafe, then it should not be offered to patients. There is an amusing description of how he designed a clinical trial of psychic healing with the help of psychic healers. Unsurprisingly, the results showed that there was no difference between “real” psychic healing and either placebo psychic healing performed by an actor or between a psychic healer in a separate room and an empty room adjacent to the patient. This is followed by a delightfully clear explanation of what is involved in a randomised controlled trial, and the importance of double blinding.

During his two decades at Exeter, Ernst’s team produced a prodigious amount of quality scientific research into a wide variety of complementary therapies, earning him a sound academic reputation and the undying hatred of complementary therapists. He disagreed publicly with the Prince of Wales about so-called “integrative medicine”, and this led to over a year of internal investigation by the University authorities and threats of disciplinary action and dismissal from the then Dean of Peninsula Medical School. His last years at Exeter were not happy. The University reneged on its promise to raise funding to match the original endowment of the department, and the department closed down after his retirement.

Perhaps this book should have been subtitled “Rebel with a Cause”. In addition to his pursuit of scientific rigour in medicine, Ernst also unearthed many unpleasant facts about the role of the German medical establishment in the horrors of the Nazi era. This stemmed from his childhood experiences when no-one would talk about what had happened in the decades before his birth, and even Germans born after the war were regarded, at best, with suspicion by many people.

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