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What is the impact of the US president's belief that 'Vaccines Cause Autism'?

Andrew Wakefield's¹ infamous *Lancet* article proposed the combined Measles, Mumps and Rubella vaccine is a causal factor in autism. It was later retracted on grounds of 'data distortion' and Wakefield was struck off the medical register. Following the spread of Wakefield's 'vaccine autism meme' (VAM), parental fear that vaccines cause autism is one underlying reason why some parents in the USA seek exemption from compulsory vaccination laws.² Haberman³ traced the roots of an anti-vaccine movement in the USA to Wakefield's article. Although some say 'America sneezes and Britain catches a cold' this story confirms two-way 'cognitive contamination'.

From the public health perspective high uptake of vaccination is essential to provide a level of immunity at population level (sometimes known as 'herd immunity'). Research has shown that parental knowledge, trust and information about vaccination relies, not only on health messages from health professionals, but also those from the media, who have become increasingly influential in decision making, hence increasing 'vaccination hesitancy'.

Such hesitancy has no veracity base. Research reveals no scientific evidence for any causal association between any vaccine and autism.⁴ Nevertheless, Donald Trump, apparently convinced by the VAM, said⁵ during his electoral campaigning:



'Autism has become an epidemic. Twenty five years ago, thirty five years ago, you look at the statistics, not even close. It has gotten totally out of control. I am totally in favour of vaccines, but I want smaller doses over a longer period of time. Because you take a baby in, and I've seen it, and I've seen it, and I had my children taken care of over a long period of time, over a two or three year period of time. Same exact amount. But you take this little beautiful baby and you pump, I mean it looks just like its meant for a horse not for a child. And we've had so many instances. People that work for me. Just the other day: two years old, two and a half years old, the child, the beautiful child, went to have the vaccine and came back and a week later got a tremendous fever, got very, very, sick, now is autistic. I only say it's not. I'm in favour of vaccines given over a longer period of time. Same amount. Just in, in, little sections. I think, and I think you're gonna have, I think you're gonna see a big impact on autism.'

Donald Trump's recognised official Twitter account posted on this topic in 2012 and again in 2014. At the time of writing, these posts remain published and in the public domain:

- 'Massive combined inoculations to small children is the cause for big increase in autism...'⁶
- 'Lots of autism and vaccine response. Stop these massive doses immediately. Go back to single, spread out shots! What do we have to lose.'⁷



By Mike Sutton (top of article, right), Linda Gibson and Matt Henn (above left and right) of the School of Social Sciences, Nottingham Trent University

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- ‘Autism rates through the roof--why doesn't the Obama administration do something about doctor-inflicted autism. We lose nothing to try.’⁸
- ‘If I were President I would push for proper vaccinations but would not allow one time massive shots that a small child cannot take - AUTISM.’⁹
- ‘Healthy young child goes to doctor, gets pumped with massive shot of many vaccines, doesn't feel good and changes - AUTISM. Many such cases!’¹⁰
- I am being proven right about massive vaccinations—the doctors lied. Save our children & their future.¹¹
- I'm not against vaccinations for your children, I'm against them in 1 massive dose. Spread them out over a period of time & autism will drop!¹²
- ‘No more massive injections. Tiny children are not horses—one vaccine at a time, over time.’¹³
- ‘So many people who have children with autism have thanked me—amazing response. They know far better than fudged up reports!’¹⁴
- ‘“@P01YN0NYM0U55: @jamandatrtl #vaccines #Shills insist #Autism starts in utero or genetic, but parents insist sudden onset after #vaccine.”’¹⁵

Busy citizens leading complex lives in uncertain times often have little choice but to invest their trust in the guardians of representative democracy; they expect politicians to make well-balanced and evidence-based judgments on matters of critical public policy, and to do so in the public interest.¹⁶ As Pitkin¹⁷ states: ‘In modern times, almost everyone wants to be governed by representatives ...; every government claims to represent.’ Thus when prominent politicians offer unequivocal pronouncements on complex policy questions, citizens need to feel confident that their faith in those same democratically elected representatives is not misplaced. The question, to which we currently have no answer, is: ‘Do politicians also influence the decision making of the electorate when they use media to broadcast their beliefs about health issues?’ What we do know however, is that the modern citizen is becoming increasingly wary of politicians who are perceived as using their elected positions to promote their own issue-interests rather than governing as representatives of the people.¹⁸

Although we have established here that presidential dissemination of VAM exists, we don't know whether it

represents a probable public health risk. To answer that question requires a research project to measure whether or not Trump's specific VAM publishing and broadcasting activities have impacted immunization decision making by parents in the USA and elsewhere. We recommend such a study be undertaken in the interests of public health.

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News

Deborah Cohen, investigative journalist, to receive HealthWatch Award at our 2017 AGM

The 2017 HealthWatch Award will be presented to the *BMJ* Investigations Editor Deborah Cohen, in recognition of her courageous reporting of medical issues in the face of attack from vested interests.

She has written about drug and medical device regulation, access to clinical data, cost of medicines, research integrity and conflicts of interest, as well as collaborating on documentaries with the BBC Panorama

and Newsnight, Channel 4 News and Dispatches. Her recent BBC Panorama investigation ([“Inside Britain's Fertility Business”](#)) exposed private fertility clinics selling costly “add-on” tests and treatments of doubtful efficacy.

Deborah will receive her award from HealthWatch's president, the author and broadcaster Nick Ross, at our annual general meeting on Tuesday 17th October at the Medical Society of London. The evening starts with a reception at 6.30pm, and is free to attend and open to all, although only members may vote at the AGM. The after-meeting buffet, at £45 a head, must be pre-booked – links

for the booking site will appear nearer the time on our website www.healthwatch-uk.org

New online membership system

We've just launched our new online membership system that allows new members to join from our website and existing members to renew theirs.

If we had an email address for you in our records, you should have received an email telling you all about it and how to log in to your account.

If you didn't receive an email, we may not have your email address or we may have an old one. Please email Alan on membership@healthwatch-uk.org with your name and address so we can sort it out.

You can pay by any of the usual methods and the email we sent gives you all the details. Those who have been paying by Standing Order can continue to do so, but please check you are paying the correct amount of £30 a year.

"Self regulation of integrity in research has largely failed" – the evidence

Great harm has been done to patients, and huge amounts of resources have been wasted, by professors and other senior doctors who have been found to have committed research misconduct in the UK. But institutions and regulators are often slow to take action. Before Parliament was dissolved for the general election (it seems a long time ago), the Science and Technology Committee had begun an inquiry into research integrity. Experts, including cardiologist Dr Peter Wilmshurst, had submitted written evidence which was accepted and published. "They had asked me to give oral evidence, but the oral hearings were cancelled when Parliament was dissolved," explains Peter. It is not certain whether a new Committee will carry on with the same inquiry. However, the published evidence stands, and has Parliamentary privilege, so is available online and citeable. Anyone interested in scientific integrity will be fascinated – and aghast – to read Peter's evidence and the catalogue of research misconduct he has exposed, at enormous personal and financial cost to himself. "I suspect that the more people that show interest, the greater the likelihood of the Science and Technology Committee taking it up again." Please view and share.

<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/research-integrity/written/68813.pdf>
<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/research-integrity/written/68813.html>

HealthWatch study published by Trading Standards' journal

Our latest research study into consumer protection was the subject of a major 6-page report in the Trading Standards Review, the quarterly magazine for members of the Chartered Trading Standards Institute.

A two-year HealthWatch investigation led by Les Rose exposed what really happens when consumers blow the whistle on false claims about healthcare products. They found that pursuing a complaint is cumbersome and lengthy; most complaints do not result in enforcement; and approaches to enforcement vary widely between trading standards offices. The

research has ruffled feathers among the professionals tasked with enforcing the Consumer Protection from Unfair Trading Regulations 2008, and exposed how underfunding has left them struggling to keep traders in line.

Bailey C. Mind the cracks. TS Review. April 2017. pp18-23.

The full research report is at <https://www.healthwatch-uk.org/cpr2>

Consultation by charity regulator

HealthWatch was among the many concerned organizations and citizens who made submissions to the charities regulator, calling on them to require charities promoting complementary and alternative medicine to supply evidence of efficacy. HealthWatch committee member Les Rose, and groups such as the Good Thinking Society, encouraged the government's Charity Commission for England and Wales to hold the consultation. The several hundred UK charities promoting complementary and alternative medicines may lose their charitable status if they can't prove their therapies work. A final decision on the standard of evidence needed to gain charitable medical status will be issued later this year.

New Scientist, 16 May 2017.

<https://www.gov.uk/government/news/charity-regulator-consults-on-its-approach-to-organisations-promoting-complementary-and-alternative-medicines>

Touching tributes to John Garrow

It is one year since the death of Professor John Garrow, founder member of HealthWatch and lifelong friend of integrity and evidence, and some obituaries have been published since those reported in our last issue.

A tribute has been uploaded by the Royal College of Physicians to their fellows roll, known as the Munk's Roll, and written by his children.

The British Journal of Nutrition published an obituary by his fellow HealthWatch founder, Caroline Richmond, which is openly accessible from the link below.

Royal College of Physicians Munk's Roll : Volume XII :

John Stuart Garrow

<http://munksroll.rcplondon.ac.uk/Biography/Details/7266>

Richmond, C. (2016). John Garrow, nutritionist. British Journal of Nutrition, 116(11), 1993-1994.

doi:10.1017/S0007114516003421

Gongs for evidence heroes

This year's Queen's Birthday Honours recognised three of our heroes. Professor Sir Michael Rawlins, chair of the Medicines and Healthcare products Regulatory Agency (MHRA) and patron of HealthWatch, was appointed Knight Grand Cross of the Order of the British Empire (GBE) for services to the safety of medicines, healthcare and innovation. Tracey Brown, director of the charity Sense About Science, received an OBE for services to science. Professor Ken Harvey of Melbourne's Monash University, a dogged battler against unproven alternative healthcare claims, and a leading light of Friends of Science in Medicine, received a Member (AM) in the general division of the Order of Australia for significant service to community health and the pharmaceutical industry.

Ben Goldacre, who received our own HealthWatch Award in 2006, is now this year's winner of the *BMJ* award for Outstanding Contribution to Health. The author

of *Bad Science* and *Bad Pharma* was behind the AllTrials campaign to ensure that all trial results are published.

Evidence-based audio

Susan Bewley, HealthWatch member and professor of complex obstetrics, was one of the experts interviewed in a BBC Radio 4 documentary by Fi Glover about the normalization of egg freezing as a means of prolonging fertility. The 28-minute programme is not available as a podcast currently but can be heard online.

Also worth listening to – Trust the Evidence is a podcast series of eight conversations with individuals interested in improving healthcare through the use of better evidence. Carl Heneghan, director of the Centre for Evidence-Based Medicine, conducts a series of 10-15 minute interviews with evidence heroes including some past HealthWatch Award winners. The first is with Professor Sir David Spiegelhalter, Winton Professor for the Public Understanding of Risk at the University of Cambridge.

The Great Egg Freeze, BBC Radio 4, 20 March 2017

<http://www.bbc.co.uk/programmes/b08j9z4s>

CEBM Trust the Evidence

<https://soundcloud.com/cebxford/sets/trust-the-evidence>

Training young bullshit detectors

Children can become remarkably skilled in sniffing out misleading healthcare information, even in the poorest of

schools. A study published in *The Lancet* describes the results of a trial of 10,000 primary school children in central Uganda, in schools with large student to teacher ratios and few resources, who were given lesson plans and textbooks specially devised to teach critical thinking skills. The 10-12 year olds were naturals at creating randomized controlled trials. There is more information about the initiative at <http://www.informedhealthchoices.org/>

Nsangi A et al. The Lancet, May 19, 2017

Private screening raises GPs workload

GPs are increasingly faced with counselling patients who have paid to undergo bogus and in some cases potentially harmful tests, says a report in the GP magazine *Pulse*. Their survey of 1,170 GPs revealed that nearly half reported their workload has gone up in the past year due to patients wanting to discuss results from non-evidence based health screening tests they have paid for privately. Margaret McCartney, Glasgow GP, author and HealthWatch patron is calling for a levy on private companies to pay the NHS for work they create through tests the health service does not recommend.

Just what the doctor didn't order: the rise of private screening. Pulse, 6 March 2017.

<http://www.pulsetoday.co.uk/clinical/just-what-the-doctor-didnt-order/20033987.article>

Want to know more? The HealthWatch Googlegroup is a source of breaking news and lively debate on topics to do with science and integrity that don't always make it to the newsletter, because of its longer lead time. It's exclusive to HealthWatch members and completely secure (i.e., no junk mail resulting). You can be a silent spectator or join in with your own comments. Sign up if you haven't already, by e-mailing Alan Henness on membership@healthwatch-uk.org

Consumer protection

Alkaline salts – a continuing challenge

On January 19th the BBC news website¹ carried the story of Naima Houder-Mohammed, a Captain in the British Army who suffered an apparently terminal recurrence of breast cancer in 2012. Refusing to give up, she came across the work of Robert O Young in California, and travelled to undergo his alkalising treatment at a cost of \$77,000. Her treatment consisted of intravenous infusions of sodium bicarbonate (baking soda). After three months her condition worsened and she returned to England to die. Young was arrested in January 2014 and convicted in 2016 on charges of theft and practising medicine without a license.² He has now been sentenced to three years and eight months in prison.³

Young's alkaline diet treatment is very loosely based on the fact that different foods leave an acid or alkaline residue after metabolism. Sodium, potassium, magnesium and calcium are alkali forming, while phosphorus, sulphur and chlorine are acid forming. Which of these predominates in foods determines whether the residue is acidic or alkaline; meat, cheese, eggs and cereals leave an acidic residue, while milk, vegetables and some fruits leave an alkaline residue. However, this will have a negligible effect on the pH of the blood, which is tightly



regulated except in cases of severe metabolic or respiratory disease. What will change is the pH of urine, as excess acid or alkali is excreted. It is a step too far to suggest, as Young did, that excess acidity of the blood is a factor in cancer and other diseases, and that administration of alkaline salts (such as sodium bicarbonate) will remedy this non-existent problem.

Nevertheless, Robert O Young is named as a "pioneering health researcher" on the UK website of Energise for Life, which claims to be "the biggest alkaline

optimum nutrition and lifestyle resource and shop in the world”, promoting the “alkaline diet” and selling its accompanying supplements, guides and products. HealthWatch committee members Les Rose and David Bender undertook a detailed critique of the claims made on the Energise for Life website and in the published research they listed in support of their claims for the benefits of alkaline salts that they sell.⁴ None of the papers supported the claims made, and the statement that the European Food Standards Authority supported their claims was also incorrect. EFSA permits a number of nutritional claims for potassium and magnesium (as the minerals themselves, not as alkaline salts). However, the EFSA approval of nutritional claims does not involve testing, simply a review of the published literature in support of a claim.

Rose and Bender then submitted a complaint to Northamptonshire Trading Standards (TS) (because Energise for Life is based in that county). They went directly to TS because the complaint was long (10 pages) and not suited to the Citizens' Advice on-line complaint form.

A week later no response had been received. A telephone call to Northamptonshire Trading Standards triggered a cascade of six automated menus, ending with a connection to the Citizens Advice Bureau. They of course knew nothing about the complaint, but took details for forwarding to Trading Standards. Two days later the latter emailed to say that they were aware of Energise UK Ltd, and that “After some advice they are in the process of changing their web content, however due to circumstances beyond their control they've not been able to complete this yet”. We pointed out that delaying tactics are common in this field of commerce, and that all that was necessary was for the misleading page to be deleted.

Within the following week the page concerned had disappeared, with only a “404 not found” error showing. The home page's link to “Shop for products” is also dead. We subsequently received this from Trading Standards: “... due to the long term illness of the owner and his inability to spend the resources necessary to amend the varied problems with the website they will sell what remaining stock they have and become an ‘information only’ site and so remove themselves from the remit of the Nutrition and Health Claims Regulations.”

It is rather ironic that the owner claims on his website that alkaline salts have transformed his health for the better. So it appears that Energise UK Ltd will carry on with publishing misleading information (and there is a lot more on the site), but not actually sell anything. Without income we wonder how long that can go on.*

This exercise demonstrates that it is actually possible to engage usefully with Trading Standards when dangerous health claims are being made. It did however entail a lot of work. We had to read 11 papers and check whether they supported the claims. It seems likely that this is what

triggered Trading Standards into prompt action. In our experience, simply asking the trader for evidence, and complaining to Trading Standards when none is received, prompts a different approach, as officers usually say that they will have to prove a claim false. This entails hiring expert witnesses, which costs money. In this case, we fulfilled the ‘expert’ role in advance. We do not think that, at least in this context, the public has “had enough of experts”, but the majority of complaints will be made by ordinary consumers, and hence less likely to trigger regulatory action.

Trading Standards initially advised us to report the website to the Advertising Standards Authority (ASA). This is because the ASA is regarded by government as ‘established means’ of enforcing consumer law. We do of

course have long experience of doing this, and the ASA is a highly efficient and rigorous regulator. But it applies only a voluntary code, and

has no concrete sanctions to impose. It can now refer non-compliant advertisers to Trading Standards, which can apply criminal sanctions, but this can be a very long process. Such advertisers are placed on the ASA non-compliers list and might stay there for a year before referral. It therefore creates a circular process if Trading Standards then suggests using the ASA as the means to doing their job. The whole area of consumer law enforcement with respect to health claims is confusing and fragmented, so it is all the more gratifying to have achieved a measure of success in this case.

Les Rose, retired Clinical Research Consultant; and David A Bender, Emeritus Professor of Nutritional Biochemistry, University College London

We do not think that, at least in this context, the public has “had enough of experts”

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* UPDATE: Evidently, that state of affairs did not last very long. At the time of publication, the Energise For Life website links had been restored, with new misleading content. Les has since been able to speak to Northants Fair Trading Department, who agreed to pass on the information to someone appropriate. Les has also reported this to the ASA, on the advice of Trading Standards, with no response so far, as of two months.

Nutrition

Lowering blood cholesterol doesn't save lives – or does it?

Elevated serum cholesterol is a risk factor for atherosclerosis and coronary heart disease. So, it might seem obvious that lowering serum cholesterol in people who have unacceptably high levels should cut their risk of coronary heart disease. But what do we mean by the term 'risk factor'? It is a specific jargon term used by epidemiologists to indicate something that can be measured as a marker of likely risk or hazard. It does not imply cause and effect.

Some years ago I came across the statement in a textbook of paediatric nutrition that “lack of indoor plumbing is a risk factor for infant malnutrition”. Obviously, installing water and sewage pipes does not feed underfed children – but before setting out on a lengthy study of infants in an underdeveloped region, a quick and easy way of assessing the likelihood of infant malnutrition is to check on the availability of indoor plumbing.

That being said, we have excellent biological mechanisms to explain how elevated levels of cholesterol (referred to as low density lipoprotein, or LDL) circulating in the bloodstream is a causative factor in atherosclerosis. The liver only takes up LDL from the circulation when it has a need for cholesterol. So, when it is already well supplied, the liver receptors that remove LDL from the circulation become less active. This increases levels of LDL circulating in the blood, so it is swept up by white blood cells. These lipid-engorged cells then migrate into the walls of the blood vessels where they are killed by the cholesterol they have released from engulfed LDL. The result is the laying down of cholesterol-rich fatty streaks in blood vessels – atherosclerosis. This growing fatty plaque occludes blood vessels, and when it ruptures leads to more or less complete blockage of the artery. When this occurs in coronary arteries, the result is a myocardial infarction, leading to death of the cardiac muscle cells supplied by the blocked artery – if severe enough, this can prove fatal.

So, from a biochemical and physiological viewpoint, lowering blood levels of LDL-cholesterol might indeed be expected to lead to a reduction in atherosclerosis and coronary heart disease (CHD). The perceived wisdom of the last half century is that reducing total fat intake, and especially saturated fat, and increasing mono- and poly-unsaturated fat intake, will reduce our blood levels of LDL-cholesterol, and hence the incidence of atherosclerosis and CHD. Mono- and poly-unsaturated fatty acids are considerably better substrates for esterification of cholesterol in the liver than are saturated fatty acids – and it is free, not esterified, cholesterol that leads to down-regulation of the liver's LDL receptors. Total fat intake is also important, because the remnants of the dietary fat breakdown in the bloodstream are also taken up by white blood cells, so contributing to the development of atherosclerosis. The more fat that is consumed, the more fat remnants will be in the circulation.

The conventional diet-heart model has been challenged in a re-evaluation of the data from the Minnesota Coronary Experiment (MCE) of 1968-73 and a review of other intervention trials.¹ The authors state that in the MCE “the intervention group had a significant reduction in serum

cholesterol compared with controls ... [but] showed no mortality benefit for the intervention group”. In five randomized controlled trials involving 10,808 people, they¹ state that “these cholesterol lowering interventions showed no evidence of benefit on mortality from CHD or all-cause mortality”.

So, we have a problem. Randomized controlled trials (RCTs) are the pinnacle of evidence; should we ignore them or discard the biochemistry and physiology? Should we abandon the dietary advice offered for half a century? Should I now increase my fat intake, abandon poly-unsaturated-fatty-acid-rich oils and spreads and not persuade my friends to eat more salmon, trout and herring?

While the results of the RCTs clearly show that reducing serum cholesterol does not affect mortality, it is noteworthy that all of the RCTs cited by Ramsden *et al.*¹ were relatively short term, and many were conducted on middle-aged people, in whom we would expect to see significant atherosclerosis anyway.

In 1996, Uusitalo and coworkers² reported an interesting experiment in Mauritius. Because of concerns about the high rate of CHD, the government of Mauritius decided in 1987 to change the composition of the cooking oil produced by the one (government owned) factory in the country, from one based on palm oil (and hence high in *saturated* fatty acids) to one based on soy bean oil, and therefore high in *poly-unsaturated* fatty acids. Five years later (1992) there was the expected significant reduction in mean serum cholesterol, but no mention of CHD mortality. The WHO Noncommunicable Disease Country profile for Mauritius in 2014³ shows a significant fall in CHD mortality starting in 2003 and continuing to 2012 (the last year for which the data were available). Overall from 2003 to 2012 there was a 32% reduction in CHD mortality among men and 40% among women.

The 16-year time lag between the start of the intervention and the beginning of the decrease in CHD mortality can be explained. During the early years, older people with significant atherosclerosis, and therefore already at risk of death, did not benefit from the dietary change – it was too late for them. It was only as younger people, who had been exposed to the improved oil from early adulthood, reached middle age that there was evidence of benefit; they had accumulated less atherosclerotic plaque throughout their lives.

This highlights a key problem in research on the effects of diet on health – if we want to see survival and improved health into our 8th or 9th decade, we are looking at long-term (life-long) experiments. Obviously these cannot be RCTs or other intervention trials. Perhaps in due course

we will learn a great deal from the 1946 birth cohort study,⁴ in which every child born in the second week of March 1946 in Britain has been, and still is being, followed. It will be for a future generation of researchers to analyse the dietary and other information from the oldest survivors of this cohort. Perhaps in 20 years from now we will begin to see analyses of the differences in diet and lifestyle of those who reach their 9th decade compared with those who died in middle age. Of course, many things have changed in the 70 years since this cohort was born, and much dietary (and other) data from the 1950s and early 1960s will be irrelevant to those born later – just compare the enormous range of foods available now in supermarkets now with the meagre offerings of the Co-op of my youth – even after rationing ended.

In summary, the current advice on dietary fat remains sound – and is especially important for young adults who

can be expected to benefit from lower CHD mortality in their middle age.

David A Bender

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Declaration of interest:

The author deeply regrets that he was born just 3 days too late to be included in the 1946 birth cohort.

Dentistry

Can I have straight teeth in six months?

Following easing of the restriction on advertising, dental practitioners have become keen to exploit the advantages of cosmetic dentistry for adults. The demand for ‘cosmetic’ dentistry has escalated largely due to the media and the fact that many smiling celebrities are photographed wearing braces. Short term orthodontics or ‘Six Month Smiles,’ as a method of improving the aesthetics, is being promoted by many general practices and also to a limited extent by specialist practices. However, the teeth are often moved into an unstable position and the results do not always match the patient’s expectations.

Colleagues who undertake medico-legal work are seeing an ever increasing number of complaints from patients about the outcome of treatment, where appliances have been used which are designed to carry out limited aesthetic improvement to the front teeth.

There are two ways of improving the uneven appearance of teeth: orthodontic treatment or the use of crowns and veneers. From the dentist’s point of view, there are benefits in being able to offer cosmetic treatment. For the patient who has been attending regularly and caring for their teeth, the amount of decay has significantly reduced, largely due to fluoridation of the water and inclusion of fluoride in most brands of toothpaste.

The use of crowns to improve the appearance of the front teeth can only be justified if the teeth are decayed or broken. Crowns require invasive, irreversible removal of enamel which is difficult to justify for aesthetic reasons alone. They also require maintenance and replacement at intervals. In addition the vitality of the tooth may be compromised. Sadly, I often see adult patients who have had crowns made for all six front teeth, which have been fitted solely to improve their appearance. A more conservative way of improving the appearance is considered to be the use of veneers which require the removal of a very thin layer of enamel, however healthy



tooth tissue is replaced with porcelain. Again, the veneers require maintenance and replacement.

My professional experience is in orthodontics and this in adults can significantly improve their appearance. In response to this increased demand, the supply companies have been promoting invisible or cosmetic appliances, not only to specialist orthodontists but also to general dental practitioners. Some practitioners have taken advantage of the increase in demand from adult patients by advertising themselves as cosmetic dentists. Some are giving courses on short term orthodontic treatment in conjunction with the supply companies. These courses are not regulated and not part of any formal postgraduate education. What is being promoted is a ‘six month smile’ with the implication that the treatment can be completed in a short period of time.

Comprehensive orthodontic treatment usually takes up to two years and is most commonly provided by specialist practitioners who have undertaken three year full time postgraduate training courses which are run by university hospitals. Treatment of minor irregularities of both the upper and lower front teeth can usually be completed in less than a year. Unfortunately, in so-called six month smile treatment, the position and function of the back teeth is deliberately ignored and appliances are fitted only to alter the front teeth.

There are two main methods of straightening teeth which may be used by those who promote this short term treatment. The first method uses fixed appliances, known by children as 'Traintracks'. These are available in tooth coloured attachments to the teeth and even the wires that are used are tooth coloured. There may be a temptation to apply incorrect forces with these appliances, to achieve alignment within the time specified. This may increase the risk of damage to the roots of the teeth sometimes resulting in loose teeth.

Another way to straighten teeth is to use aligners. These are thin transparent covers which fit tightly over the teeth, a series of which are designed to move teeth progressively into a new position.

Aligners are replaced periodically and move the teeth incrementally, alignment is slower than with conventional appliance treatment and only limited tooth movement can be achieved within six months. There are many aligner brands on the market: they can be expensive and usually have to be paid for before treatment is started. Invariably there is insufficient space to accommodate the changes necessary to get the teeth straight. In a young patient teeth can be extracted to make space. While this may also be done for an adult, it immediately lengthens the treatment time.

How then do practitioners get favourable results in six months? Well – can we be certain that they do? Who is going to stop treatment if they are still wearing appliances when the six months are up, the teeth are not corrected and they have parted with the fees?

Two ways are available to make space to accommodate the teeth. One is to move the teeth forwards, which can give a very wide smile and an artificial appearance. Moving teeth forwards increases the risk of receding gums which again is undesirable, this most commonly occurs with the lower front teeth.

Restricting movement to the front teeth may have undesirable consequences in the way teeth bite together. Front teeth may also be placed onto a wider arc than the shape of the bone of the jaws and as a result the patients will always need to wear retainers to keep their teeth in the new position. Failure to do this will result in the teeth moving back towards their original crowded position.

An alternative method of creating space to straighten the teeth is to remove some of the enamel from between the teeth, making them narrower. Whilst a small amount of enamel can be removed safely, removing excessive amounts can lead to ongoing problems.

Adults offered short term treatment would be wise to seek the opinion of a recognised specialist in orthodontics who will be able to advise the various options available for their condition. There is no "one size fits all". Straightening the front teeth alone and ignoring the way teeth bite together may not be in their best interests.

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Treatments

Testosterone for ageing men?

The normal reduction of testosterone production in men is gradual and the "andropause" does not have an age-related association. Men's levels of testosterone fall with age starting as early as their thirties and are part of normal senescence. Despite no clinical evidence or indications (other than pathological hypoandrogenism) the sales of testosterone have increased 100 fold in the last 3 decades, being promoted under the rubric "low T" with the supposed purpose of slowing men's ageing.¹

Since there is no support for testosterone rejuvenation for any male features or function, a series of placebo controlled studies, known as the TTrial were initiated in the US to investigate the effects of testosterone gel application in men over the age of 65 years. Two of these trials were recently reported in JAMA and are instructive.

The first looked at the effects of testosterone on cognitive function.² After a year of treatment there were no improvements in memory or other cognitive functions compared with the control group.

The second measured coronary artery plaque volume by computed tomographic angiography.³ At the end of 12 months those receiving the active gel had significant increases in their coronary artery plaque volume compared with those using the placebo gel. Although the clinical

sequelae will take further investigation these findings must cast doubt on the safety of testosterone therapy in otherwise healthy men.

Other TTrial results have shown modest but unsustainable improvements in sexual function, increases in haemoglobin in anaemic men and some rise in bone mineral density but none of these findings are indications for the initiation of testosterone therapy.

Testosterone rejuvenation is not evidence-based and carries potential harms.

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1. Handelsman JAMA 2017;317:699-701
2. Resnick et al JAMA 2017;317:717-27
3. Budoff et al JAMA 2017;317:708-16

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Book review

Sex, Lies and Brain Scans: how fMRI reveals what goes on in our minds

By Barbara J Sahakian and Julia Gottwald

Published 19 January 2017 by Oxford University Press. Hardcover: 176 pages, £16.99 (Kindle edition £12.35)



As a university tutor I tell my medical students that the most difficult thing to do as a journalist is to tell “the truth”. It is very easy to report what you are told or to regurgitate a press release, but this may be far from the truth or, just to confuse things, true in part. I was reminded of my “truth talk” when I read this book about a controversial technique for measuring and mapping brain activity. Functional magnetic resonance imaging (fMRI) works by tracking blood flow changes in the brain. Active brain areas derive energy from oxygenated blood: fMRI shows the differences between oxygenated and deoxygenated blood.

Based on the same technology as MRI, it has prompted questions such as: Is mind-reading possible thanks to fMRI? Can a brain scan show if you lie? Can we look into your brain and know what you will buy? Yes, this is whiz bang technology of the kind that that generates colourful images showing how our brains “light up” as we watch a romantic movie or see a terrifying image. fMRI has inspired TED talks viewed by millions and provided supporting evidence in TV shows and self-help books about how to lose weight, succeed in business, be happy and have multiple orgasms.

Critics have as much disdain for fMRI as classical HealthWatchers do for homoeopathy, dismissing it as a modern equivalent of phrenology, the popular 19th century movement which had it that the shape and size of regions of the head corresponded to personality traits. Inquisitive scalp massaging is clearly absurd, but it was an intellectual rage in 19th century America. Edgar Allan Poe, Walt Whitman and Herman Melville all wrote about it, while Ralph Waldo Emerson’s obsessive views deviated between enthusiasm and fear for its deterministic view of the brain and behaviour. Perhaps, in a 100 years’ time, a medicine watcher like me will be similarly dismissing fMRI as a pseudoscience ... or perhaps not.

You may have guessed by now that I was sceptical before reading this book, but it is extremely well written and compelling. Of course, just as a whiz bang technology can have more glitter than substance, so can writing, but I commend this book to you. The authors are Barbara J Sahakian, professor of clinical neuropsychology at the University of Cambridge Department of Psychiatry and at the Behavioural and Clinical Neuroscience Institute; and Cambridge PhD student Julia Gottwald.

They quote dozens of examples showing how fMRI is giving us unprecedented access to and understanding of brain function. For example, in 2005 teams from the University of Cambridge and University of Liège tested a young woman who was in “a vegetative state” five months after a car accident. Areas in her brain involving motor control became active when they asked her to imagine playing tennis. Asking her to imagine visiting all the rooms of her home prompted further brain activity.

The researchers observed the same kind of brain activation in healthy controls, meaning that the injured

woman must have had conscious awareness. This had not been picked up in a classical clinical assessment — it only came to light because of fMRI. A Liège team took the findings further. One out of 54 patients who fulfilled clinical criteria of vegetative state learned how to answer “yes” or “no” questions. When he wanted to answer “yes,” he was instructed to imagine playing tennis. For “no” he imagined navigating through his city or home.

The results were reported to show clearly that the patients were able to communicate with the outside world. Sahakian and Gottwald comment: “Such an exceptional way of communicating could be used to assess if the patient is in pain and if he has any wishes. fMRI might enable us to re-establish communication with a small proportion of patients who were thought to be unaware.”

One of the strengths of this book is that it acknowledges the limitations of fMRI. For example,

- fMRI can only look at blood flow. It cannot measure the activity of single neurons. It breaks the brain down into cubes – so called voxels. A voxel can contain about a million or more neurons. Seeing an fMRI scan is perhaps comparable to flying over a city at night. You may be able to see thousands of lights but you cannot see what people are doing in their homes and how they interact with other people in adjoining neighbourhoods.
- fMRI rarely establishes causality. For example, the authors point out that if they see abnormal activation in a brain scan, and the scanned person behaves abnormally, they can rarely ever tell which one causes the other. The abnormal brain activation may have started earlier, triggering the behaviour, or the abnormal behaviour itself could change brain activation.
- Most neuroimaging studies are based on groups not individuals. Because there are so many differences between people, it is necessary to screen a range of subjects to find out which patterns are generally present. Thus, in a study comparing a control group with a group of patients, it is rarely possible to draw a conclusion about an individual because analysis focuses on the average activation of the group.
- There is major concern about the number of false positive results reported. In a highly controversial paper last year the *Proceedings of the National Academy of*

Science reported that the most common software packages for fMRI could result in false positive rates of up to 70%. In theory, the authors said, they should have found 5% false positives, for a significance threshold of 5%. These results, they said, “question the validity of some 40,000 fMRI studies.” This over-estimate was corrected to read: “question the validity of a number of fMRI studies.” One of the authors is reported to have written in a blog that the actual number of studies implicated was probably closer to 3,500.

This takes me back to my introduction and the elusiveness of truth. Truth seekers, I tell my students, are often like greyhounds chasing an electric hare. No matter how quickly they run, they will never, ever catch the hare. But having read this book, I share the optimism of the authors

that they are onto a winner, but the glittering prizes may still be years away.

John Illman is the author of *Handling the media: communication and presentation skills for healthcare professionals* JIC Books, £14.99. Available from <http://www.jicmedia.org/shop/>

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Book corner

A memoir of principles

In *Unanticipated Outcomes: A Medical Memoir* Jerry Kassirer tells the story of his personal and professional journey as the doctor who became editor of the *New England Journal of Medicine*, then paid the price for standing up for his beliefs. He resigned from the journal in 1999 after an 8-year tenure, following a dispute on marketing policies, and went on to be a vocal critic of financial entanglements between physicians and the pharmaceutical industry. He is now a distinguished professor at Tufts University School of Medicine. Kassirer's new book was published on 7th May and can be ordered direct from: <http://www.jeromekassirer.com>

Stats classic available online

HealthWatch member Alain Brailon recommends a favourite – not new but valuable and now freely available online at PubMed Health: *Know Your Chances: Understanding Health Statistics* by Steven Woloshin, Lisa Schwartz and Gilbert Welch (published in 2008 by University of California Press). HealthWatch readers will especially appreciate Chapter 10: who's behind the numbers:

<https://www.ncbi.nlm.nih.gov/books/NBK126163/> - a readable succinct explanation of how to get exaggerated results in drug research. The full book is at <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0050876/>

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- Consumer protection in regard to all forms of health care
- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

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