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HealthWatch

WHO'S IN CHARGE OF THIS RUNAWAY TRAIN?

FOLLOWING SUSTAINED pressure from HealthWatch and others, information for prospective patients taking part in the ill-conceived Age Extension Trial of Breast Cancer Screening has at long last been updated on Cancer Research UK's website. But our concerns over the many ethical issues raised by the trial are still not being acknowledged by those who should oversee ethics in UK clinical trials, and we have gone public yet again in the *British Medical Journal*¹ to protest that there is still no assurance of informed consent in this screening trial which is the largest human experiment ever undertaken.

First, some good news: Cancer Research UK are now describing the trial more openly.² It is now clearly stated on their website that the policy on screening the extended age ranges will depend on the outcome of this trial, although that won't be known until 2022.

But the issue of screening for breast cancer remains deeply controversial. An example is a recent WHO summary which concluded in favour of screening for women aged 50-74³ but has drawn criticism over its handling of the evidence and the way its experts have been selected. The WHO report, which was summarised in June in the *New England Journal of Medicine*,³ will be published in full at the end of 2015. However, a WHO panel member has told the *BMJ*⁴ that his colleagues did not adequately take into account bias or confounding factors. Cochrane author Karsten Juhl Jørgensen questioned the panel's impartiality: "they look at a selection of research and find that their own is the most reliable", while HealthWatch's Susan Bewley told the *BMJ*, "This is bad science and lazy communication about it. This report has no new evidence, is methodologically unsound, and can safely be consigned to the bin."⁴

Professor Bewley took the opportunity of the news coverage of mammography to highlight once more the lack of proper informed consent in the NHS Age Extension Trial of Breast Cancer Screening. In a 15th June rapid response in the *BMJ*, she wrote "We believe women are put in harm's way as they continue to be deceived about the nature of breast screening, especially whilst staff are not trained nor obliged to discuss and obtain formal, written consent for this unscientific and unethical randomised clinical trial."¹ A response on 4th July from retired doctor JK Anand was headed: "We are Public Health England. Informed consent be blown".

The least welcome news is that our concerns about the Age Extension Trial of Breast Cancer Screening have been dismissed by the National Research Ethics Advisors' Panel (NREAP), the body charged with oversight of decisions of the research ethics committee (REC). They have allowed the study to proceed unconditionally.

Believing that our earlier concerns to the REC had not been taken seriously, we appealed to the Health Research Authority (HRA) in December 2014, itemising 20 valid and carefully evidenced points to be addressed by the REC. The HRA's response, received on 20th March after much prompting, is now publicly available on our website⁵ and raises more questions than it answers.

Details about ethical shortcomings are dismissed. For example, it

is a mandatory requirement of Good Clinical Practice (GCP) that REC members present at a relevant meeting must be documented in the Trial Master File. Yet names are redacted, so there is no way of knowing whether, for example, a competent statistician was present. Referring to the absurdly brief 8-page protocol we are told, "The panel further noted that the length of a protocol is not related to its quality." There is doubt as to whether the matter of proper informed consent was ever fully discussed by the REC, and there is the REC's puzzling insistence on calling this an epidemiological study. It is not, it is a randomised controlled trial.

Two points stand out:

•The REC assert, "The researchers have always been in a position of equipoise—hence the reason for the trial." Yet the original trial summary (at <http://www.isrctn.com/ISRCTN33292440>) reads: "The age extension will proceed regardless of whether this study goes ahead or not, and therefore regardless of whether the phasing-in is randomised or not."

•GCP compliance is not the concern of the REC. So whose is it? For a trial of a drug or a device, it would be the MHRA. Who inspects publicly funded trials? Will there be an audit?

The NREAP has made it clear that this is the end of the road, hence we have not replied, and have been mulling over the implications. HealthWatch is eager to learn what you think. Let us know at newsletter@healthwatch-uk.org

Mandy Payne

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5. Age extension trial of mammography screening—update June 2015 <http://www.healthwatch-uk.org/news/83-age-extension-trial-of-mammography-screening-update-june-2015.html>

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French whistleblower sued for libel by his own hospital

FRENCH NEUROLOGIST Christian Marescaux is being sued for libel by his own hospital after blowing the whistle on equipment shortages which he said endangered patients.

Every second counts when a stroke is suspected, and a delay in accurate diagnosis and treatment can lead to complications with a risk of severe neurological damage. Professor Marescaux heads the neurovascular unit at the Strasbourg University Hospital (HUS), in the north-east of France. For years now his colleagues have reported difficulties and delays in accessing magnetic resonance imaging (MRI) examinations for emergency patients. For example an e-mail to the hospital's director, sent in 2010 by the then chief of neurosurgery, now deceased, reported patients being hospitalized several days while waiting for MRI.

Earlier this year, frustrated by the continuing difficulties and disappointed by the response of the HUS, Professor Marescaux spoke to French media. *Marianne*, *Mediapart* and

Rue89Strasbourg all reported shocking cases of patients who Marescaux believed had been harmed as a result of delay in receiving MRI scans. HUS responded by suing Marescaux for defamation. A hearing scheduled for June 15 in the Criminal Court of Strasbourg was deferred after questions over the admissibility of the hospital's complaint, and will now take place in September. In the meantime, according to an online report in *Rue89Strasbourg*, Professor Christian Marescaux has been relieved of his responsibilities in the department of Neurology and his nameplates removed from the doors.

Rue89Strasbourg, 15 June 2015.

<http://www.rue89strasbourg.com/index.php/2015/06/15/societe/la-nceur-dalerte-le-pr-christian-marescaux-poursuivi-par-lhopital/>
Marianne, 29 June 2015

<http://www.marianne.net/christian-marescaux-lanceur-alerte-strasbourg-ne-veut-pas-se-taire-100234950.html>

FSM concern over CAM chair for Sydney

AUSTRALIA'S Friends of Science in Medicine (FSM) are troubled by the news that the University of Sydney is to create a Chair in "Integrative Medicine" funded by Blackmores, a leading provider of complementary medicines and supplements. The Chair will enable the university to "honour Maurice Blackmore (who was founder of the company), a pioneer of Australian naturopathy".

While welcoming the university's commitment to exploring the evidence base (or lack thereof) for alternative and complementary approaches, they are concerned by the University's announcement: "It is our hope that our support for this Chair will contribute towards a holistic approach in medical practice that combines modern western medicine with established and proven practices in the area of integrative medicine".

We asked Professor John Dwyer, President of FSM, whether there could be a parallel with the history of a similar situation in the UK. When Edzard Ernst was appointed to the Laing chair of complementary medicine at Exeter in 1993, the chair was funded by the estate of a donor who had supported CAM, and yet Ernst went on to do quality independent research. Does Professor Dwyer think

that there is any possibility that the Blackmore chair could ever seat an independent thinker of Ernst's calibre? He doubts this, telling HealthWatch: "This is a donation to the University and Blackmores will have no say in who is appointed and how the research is conducted. However we are concerned that a prestigious university would approach a company that has a poor track record in terms of its commitment to an evidence base to support the claims it makes for its products. The University in "honouring" its founder is providing invaluable credibility to a company that does not deserve such an endorsement."

This news from Sydney University coincided with the issuing in May of a position statement from The Royal Australian College of General Practitioners (RACGP) which said that medical practitioners should not practice homeopathy, refer patients to homeopathic practitioners, or recommend homeopathic products to their patients; and private health insurers should not supply rebates for or otherwise support homeopathic services or products.

Friends of Science in Medicine www.scienceinmedicine.org.au/

NEWS IN BRIEF

A SIX-YEAR-OLD boy is being treated for diphtheria in a Barcelona hospital—Spain's first recorded case of the disease for 29 years. Eight other children who came in contact with the boy have tested positive for the bacteria but have not become ill. The boy's mother and father told reporters last week that they "feel terrible guilt" for not vaccinating their child and said they felt hoodwinked by the anti-vaccination movement that convinced them not to immunize their son.

The Local ES, 5 June 2015

<http://www.thelocal.es/20150608/eight-more-children-infected-with-diphtheria>

BEN GOLDACRE, doctor, author and past HealthWatch Awardwinner, says the chief medical officer is looking for answers on statins and oseltamivir in the wrong places. There was extensive news coverage in June of a leaked letter from the CMO

Dame Sally Davies, to the Academy of Medical Sciences, asking them to undertake an expert review to shore up public confidence in the safety and effectiveness of medicines, in the wake of controversy around statins and Tamiflu. Writing in a *BMJ* editorial Goldacre says, "To restrict a review of these problems to the interpretation of inadequate existing data—as the academy apparently proposes—would be recklessly backward looking."

BMJ 2015;350:h3397

<http://www.bmj.com/content/350/bmj.h3397>

PUBLIC UNDERSTANDING of screening is a long way from what screening actually delivers, so Sense About Science have launched a new edition of their guide "Making Sense of Screening", downloadable free from their website.

<http://www.senseaboutscience.org/pages/making-sense-of-screening.html>

TREATING ADDICTION: SCIENCE vs DOGMA



ADDICTION IS RARELY out of the news but articles about addiction are often notably ill-informed. Partly, that may be because journalists are unsure whether addiction is a disease or a moral defect. After treating addicts for 40 years, I'm not entirely sure myself but it doesn't matter much. What does matter, as in other conditions, is whether particular addiction treatments have more than placebo and non-specific effects.

Some of the best and earliest research in this field was British. In 1977, an insufficiently famous paper¹ described a trial of 'treatment' vs 'advice' in 100 married male alcoholics requesting help for the first time. Their being married meant that the researchers could seek independent progress reports from the often long-suffering wives. The 'treatment' group received conventional interventions (including Alcoholics Anonymous, or AA, meetings) while the 'advice group just had monthly follow-ups for information-gathering, not therapy. Both groups showed equal improvement. In half, the improvement was considerable. When celebrities check in to rehabs, many do well, or use much less. Others abstain for a while and then relapse. Some walk out or relapse quickly after typical 28-day, '12-step', NA (Narcotic Anonymous) or AA-based treatment. This largely mirrors that pioneering British study.

The most important stage in treating addiction is for addicts to accept that they have a problem and need to do something about it. If they do, that's half the battle. If they don't, or if they accept treatment with reluctance and ambivalence, they will probably relapse, though many relapse despite accepting both propositions. To suggest that 'rehab' has largely non-specific effects causes outrage in the US. When I congratulated the author of a critical article in 'Atlantic'² who cited a well-referenced recent book,³ she said it was a rare exception to the torrent of hate-mail.

"You hardly need controlled trials to predict that treatment which blocks opiate effects for up to six months should help heroin addicts stay clean straight after withdrawal, when the risk of relapse is highest, though the trials show precisely that."

AA and the whole 12-step movement (and 'rehabs') are a very American phenomenon. If it were simply a support group like those for many other conditions, it would be unobjectionable but unlike most such groups, AA is (or has become) extremely rigid and doctrinaire about treatment. It started as an evangelical Christian organization based on the largely-forgotten Oxford Group, whose founder, Lutheran pastor Frank Buchmann, delivered one of history's most unfortunate one-liners: 'I thank God for a man like Adolf Hitler'. AA embraced the Puritan habit of public confession of sins that arrived with the Pilgrim Fathers. It involves exhortations to 'let go and let God' and much talk of 'God as we understand him'. Despite claims that AA is not a religious organization, American courts have repeatedly ruled that offenders cannot be compelled to attend AA/NA meetings during parole or probation because that offends against constitutional church-state separation. There are 12-step groups for sex, overeating, gambling, shopping and even for people addicted to ... 12-step groups!

Forget precise definitions. My favourite is: 'In spite of many attempts to delineate the alcoholic personality, the only thing that all alcoholics have in common is that they drink too much'. That 'too much' expresses itself in several ways. It may be daily, consistent drinking (or heroin use, etc.) that may or may not involve physical dependence and withdrawal symptoms. In Britain, weekend binge-drinking is common. The consequences are conveniently summarised as the 'Seven Ds': Disease, Death, Divorce, Dismissal, Disgrace, Debt and Detention. Charles Kennedy, who resigned as Lib-Dem leader and recently died of massive oesophageal bleeding secondary to liver cirrhosis, had at least three of them. Others may

have none despite heavy consumption. Instead of arguing about whether someone is 'alcoholic', 'alcohol-dependent' or a 'high-risk drinker', the important thing is whether the amount regularly causes problems to the drinker or others, or both.

Most physically dependent alcohol addicts recover from alcohol withdrawal in a week or two at most but many opiate addicts suffer prolonged and unpleasant withdrawal symptoms that make it difficult to sleep, relax and work. This can last for months and is a major cause of relapse in otherwise well-motivated heroin addicts. Methadone (or buprenorphine) maintenance prevents withdrawal symptoms and lets them function normally. The principle is exactly the same as nicotine patches or e-cigarettes for people addicted to cigarettes. I treated many people with demanding jobs (including doctors, tree surgeons and divers) who took large doses of methadone daily. They were still addicted to opiates but took them in a way that caused little or no harm, including harm to their organs, and to others. At the very least, maintenance reduces the amount of harmful substance use, as e-cigarettes do with tobacco smoking. This approach is called 'harm reduction' (or 'minimisation') and it is anathema to the 12-step movement because AA/NA accepts only total abstinence as a goal. However, AA groups often reject abstinence-assisting drugs as well, like the heroin-blocker naltrexone (now available as depot-injections and implants) or disulfiram (Antabuse), which deters drinking in the same way that speed cameras deter speeding. German AA and NA groups have a motto that translates as 'no medicines'. No other support group takes that view.

You hardly need controlled trials to predict that naltrexone implants or injections which completely block opiate effects for up to six months should help heroin addicts stay clean straight after withdrawal, when the risk of relapse is highest, though controlled trials confirm it. Yet it took several years before the famous 12-step Betty Ford clinic reluctantly and discreetly 'allowed' depot-naltrexone. Our own National Addiction Centre still hasn't even studied depot-naltrexone for heroin addicts, though its Norwegian counterpart first reported positively on implants a decade ago. Some NA groups, especially in Britain, accept methadone maintenance but many are unhappy about it. We rather expect organisations founded by evangelical Christians to be a bit rigid and anti-science but some other explanation is needed for the British addiction establishment's strong opposition to methadone maintenance for two decades from around 1980, just as the HIV epidemic was starting and the first (and very positive) controlled trials of maintenance were published. Many lives were avoidably ruined before the establishment had its own Betty Ford moment with methadone. In neither case has anyone apologized for their dogmatism.

Colin Brewer

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Colin Brewer is research director of the Stapleford Centre, London, a private clinic that concentrates on evidence-based treatments for addiction, including both methadone and naltrexone.

PROTEIN SUPPLEMENTS FOR BODY BUILDING, ATHLETES AND SLIMMING—WHAT IS THE EVIDENCE?

THERE IS A considerable market for protein supplements, promoted for sportspeople, body building and weight reduction. Most of these supplements are comprised of whey protein. From an environmental point of view, this market is a good thing. Whey is the watery fluid from milk after the casein proteins have been coagulated in cheese making, and contains about 20% of the protein of milk. Historically, it was an unwanted by-product, and was difficult to dispose of, although it can be used for pig feed. It cannot simply be put into rivers, for obvious reasons, and as I recall, at one time some cheese manufacturers poured much of it into disused mines.



There is some rationale and evidence for the use of whey protein drinks as a meal replacement for weight reduction. Indeed, there is evidence to support the use of high-protein low-carbohydrate diets for weight reduction (for example, the Atkins diet, which at its most extreme allows only 20 g of carbohydrate per day). The body has an absolute requirement for carbohydrate (as glucose) to meet most of the energy needs of the brain and nervous system, and all of the requirements of red blood cells. On a very low carbohydrate diet, this glucose has to be made from amino acids derived from protein.

This is an energy-expensive process—each molecule of glucose formed from amino acids costs 6 molecules of ATP, which must be provided by the metabolism of fat (or another metabolic fuel). In addition, there is no storage of amino acids in excess of more or less immediate requirements for formation of tissue proteins; instead, they are oxidised as metabolic fuels. The oxidation of amino acids is relatively inefficient, with a number of steps in which ATP is used, leading to heat production.¹ Finally, in response to a high protein diet there is an increase in the rate of both synthesis and breakdown of tissue proteins—again this is an energy-expensive process, and there is a considerable increase in metabolic rate (and hence in the oxidation of fat and other metabolic fuels) after a high-protein meal.²

Protein World³ tells you to consume 40 g of their “slender blend” whey protein concentrate, in 400 ml of water or milk, two or three times a day, “as a meal replacement shake, or smoothie, alongside one or two healthy, 400–500 calorie meals”. This will certainly lead to weight reduction, since if you follow the instructions you will have a total intake of only 800–1000kcal a day.

One set of advertisements for Protein World³ supplements for weight reduction has been withdrawn, in advance of a final ruling by the Advertising Standards Authority, because of a massive online petition—almost 300 complaints to ASA—and a protest demonstration in Hyde Park. The complaints were against the use of the term “beach body ready”. The complaints are that by using the term “beach body ready”, with a photograph of a bronzed and glamorous model, they are targeting individuals, objectifying women, and aiming to make them feel physically inferior to the unrealistic body image of the model, in order to sell their product.^{4,5}

There is some evidence that some types of exercise increase protein requirements. However, there is little or no evidence that protein supplements are necessary or beneficial.⁶ The average requirement for protein is 0.65g/kg body weight, or 46g per day for a 70kg person. Allowing for individual variation, the recommended daily allowance (RDA) for protein is 0.83g/kg body weight, or 58g per day for a 70kg adult.^{7,8} Average intakes of protein in the UK and other developed countries are considerably higher than this, some 80–100g per day. So, an increased protein requirement as a result of (relatively strenuous) exercise is likely to be met by a normal western diet anyway. Assuming that you consume more of your usual foods to meet the increased energy needs of the exercise, you will

certainly meet any increased protein needs.⁶

Finally we come to the use of protein supplements for body building and increasing muscle mass. It might seem obvious that if you are to increase the total amount of muscle (and therefore protein) in your body, a high protein diet or supplement will help. Again, however, there is no need for a protein supplement or an especially high-protein diet. There is continual breakdown of tissue proteins and replacement synthesis. All that happens in response to an increased protein intake is an increase in the rate of both synthesis and breakdown, with no increase in muscle mass.² The only way to increase muscle mass is by exercise (or the use of anabolic steroids)—and again if you meet the increased energy needs for increased net protein synthesis by eating an increased amount of ordinary foods, you will meet the small increase in protein requirement.

There is a further problem with some of the protein supplements marketed for body building. They may contain a wide variety of other compounds, including either declared or undeclared anabolic steroids. There have been cases of athletes being banned from competitive sport because they have unknowingly consumed banned substances in protein supplements.⁹

Protein World³ do not only sell whey protein supplements for various uses (the “muscle collection”, the “weight loss collection”, the “slender blend”, the “glow collection” (for beauty) the “tone collection”, and the “strength collection”), they also sell vitamin and mineral supplements to go with the

“there is little or no evidence that protein supplements are necessary or beneficial”

whey protein powder. Some of these are at very high doses—for example vitamin B1 at 500% of RDA per capsule, B2 at 450%, B6 400%, B12 2500% with a recommendation to take 3 capsules per day. While none of these would reach a dangerous level of intake, there is no scientific justification for such large amounts. The capsules also contain a variety of other compounds of questionable use, including saw palmetto extract, ginseng, vanadium sulphate, ginkgo biloba extract, digestive enzymes, and royal jelly.

For the “slender blend”, in addition to the whey protein drink and multi-vitamin and mineral capsules, there are Slender Blend Capsules, “designed to reduce the amount of fat you digest [but we are not told how, and none of the ingredients listed on the website as appearing in these capsules would seem to be likely to have such an effect], ignite your metabolism and increase the rate your body burns fat”.³ The capsules each contain 100mg caffeine (equivalent to a cup of strong coffee), green tea extract, guarana extract (which itself is 22% caffeine), yerba maté powder, cayenne powder and 100mg of the amino acid tyrosine (why this is needed in addition to a protein supplement is unclear). You start with one in the morning and one in the afternoon, straight after meals in the first week, increasing to two in the morning and afternoon thereafter. Four additional cups of strong coffee may not sound like much, but on top of a normal intake of tea and coffee (and perhaps “energy drinks” that contain caffeine), it may make some people feel twitchy and unwell. Fortunately, caffeine is metabolised and excreted relatively rapidly, so the adverse

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CPR2: YOUR CHANCE TO SUPPORT HEALTHWATCH, STAND UP FOR FAIR TESTS, AND GET PUBLISHED

UNSCRUPULOUS ADVERTISERS continue to make unsupportable and misleading claims for health products, apparently unhindered. That was the experience of many frustrated HealthWatch members, and so a few years ago we initiated a small research project to see exactly how effective the legal protections really are. In 2012 a team of HealthWatch volunteers published a research paper in the *Medico-Legal Journal*¹ reporting the results of their systematic efforts to engage UK authorities over misleading health claims made for three products. The findings from this small-scale study exposed disappointing responses from Trading Standards departments, and concluded that the European Directive designed to prevent misleading health claims in UK consumer products is “largely ineffective”.

This was just a small study. Now we’re doing a larger-scale follow-up—“Consumer Protection Research 2”—to see how effective UK consumer legislation is at regulating commercial claims about health benefits, and look at the extent to which Trading Standards legislation is actually enforced. If our initial conclusions are justified it will give more clout to the push to reform the system that’s supposed to protect consumers.

Thanks to the HealthWatch Research Fund, the study is up and running, but we need some more good people to step up to join the volunteer team. Anyone can play a part, no qualifications or equipment are needed (other than your computer and internet connection), you can take part from home and it really does take only a few minutes of your time to make a meaningful contribution to the study. You don’t even have to be a member of HealthWatch—students and younger family members, parents and friends, anyone can dip their toes into the research pond to experience taking part in a real study, without any longer term commitment whatsoever.

We have already drawn up a list of 10 health claims that we know have no evidence. You will be sent the full protocol and detailed and easy to follow instructions for collecting the information. The protocol provides templates for all the communications you will have with traders and with the regulators, so you won’t even have to think what to write.

This is all that you’ll need to do:

1. You’ll be randomly assigned five products (of the 10) whose claims are agreed to be unsupported.
2. You’ll be asked to send an “evidence please” e-mail or letter to

each of the traders, explaining that you’re enquiring for research purposes and that a reply within one week is required.

3. If the trader doesn’t respond with evidence, you’ll send a further letter which will ask the trader to stop marketing the product.
4. If evidence supporting their product’s claim is still not forthcoming, you’ll send a complaint to the Citizens’ Advice service (the gateway for Trading Standards).
5. Follow up the progress of the complaint on a monthly basis for six months.
6. Keep records of all your study communications. We have a suite of web-based forms for capturing all data, so you won’t need to organise your own records.

And that’s all there is to it! All data collected, including details of your nominated products, and records of study-related correspondence, will be kept by the project team on a study website which you’ll have access to. The findings will be written up and submitted for publication in a peer reviewed journal. All volunteers who have contributed will be acknowledged in the published paper (unless of course they prefer to remain anonymous).

Interested in making a difference? Don’t wait. Contact study lead Les Rose directly at lesrose@nthworld.com

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Protein supplements for body building, athletes and slimming—what is the evidence?

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effects are unlikely to last for too long.

So, protein supplements are not necessary, but as a meal replacement may help weight reduction. If you are restricting your food intake, then a modest vitamin and mineral supplement may help (but no more than 100% of RDA is needed, since RDA is anyway greater than most peoples’ requirement). For body builders and athletes, the protein supplements are of no value—but they are widely sold, online and on the high street, and also by gyms and trainers.

David A Bender

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NHS PROTOCOL UNDER STUDENT SCRUTINY

EVERY YEAR HealthWatch awards prizes to students of medicine, nursing and allied health professions, for their critical evaluation of trial protocols that HealthWatch experts design—with integral hidden flaws—for our annual competition. At last year's HealthWatch AGM we suggested to the winners that they might like to critique the protocol of a real-life trial in progress—the NHS Age Extension Trial of Breast Cancer Screening. Physiotherapy student Lynette Fox of Nottingham University, last year's winner in professions allied to medicine; and Arthur Woo of Glasgow University, runner up among the medical students, rose to the challenge. Their assessments appear below.

Evaluating the net effects of extending the age range for breast screening in the NHS breast screening programme in England from 50-70 years to 47-73 years—a CASP tool informed critical analysis

This study summarises a proposal to assess the 'risks and benefits' of extending the age range for breast screening, taking into account the 'net effect'.

In the outcomes however, there is no comparison of risk and benefit, making the results somewhat invalid. Outcomes reported to be used will only analyse mortality rates in those aged 47-49 and 71-73 years, during a 10 year follow up. This does not implement any strategy to estimate the 'risks' of extending the age range, in particular measuring the percentage over-diagnosis. In the new age brackets measuring the outcome of 'over-diagnosis' may be a beneficial way of measuring the risk versus 'benefit' of breast screening. Over-diagnosis is already reported to be 1:4 ratio¹ and this has been brought to the attention of appropriate organisations more recently. In consideration of the high over-diagnosis, it would be beneficial to know if the over diagnosis increases in the age brackets 47-49 and/or 72-73 year olds. It is clear that as well as physically affecting women the trauma of being recalled for repeat breast screening and treatment involving benign tumours can cause psychological distress. Included in this is an obvious cost to the NHS, hence the consideration that funding would be better spent on treatment for the disease.²

The protocol mentions using the gold standard of random allocation of screening/no screening to the clusters created by the NHAIS system and random allocation to the two concerned age groups of 47-70 year olds and 50-73 year olds. It is unclear how women can be randomly allocated to the age groups, as this would have to depend on them meeting the age criteria, but may just be

an oversight in the proposal in the description.

The proposal does then clarify how it aims to reduce bias by ensuring that outcomes are only considered for the age groups of interest (47-49 years and 70-73 years). However the study proposes an unfair consideration of mortality rates for varying age ranges between the 2 groups. In the younger group, mortality is considered from age 47-60 followed up for 10 years, meaning that each mortality for the 47-49 year olds is registered as a meaningful statistic. In the older group of 50-80 year olds, mortality rates will only be included in the analysis if they develop terminal cancer and die within 7 years, before they reach 80. Anyone screened at 71, 72 and 73 years of age initially, will not count statistically although followed up for 10 years until the ages of 81, 82 and 83.

This study survives ethical approval with an intention to treat basis and opting/in out of breast screening with informed consent of the method of roll out. Due to the omissions in data collection and analysis, this study cannot claim to calculate a net effect of extending breast screening and does not provide proof of external validity for the general population.

Lynette Fox, University of Nottingham

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1. Breast cancer campaign (2014) Breast Cancer Screening <http://www.breastcancercampaign.org/about-breast-cancer/breast-screening?gclid=CNao8pb698ECFbDLtAodlh8AKA> [Accessed 10th November, 2014].
2. Baum M. Harms from breast cancer screening outweigh benefits if death caused by treatment is included. *BMJ* 2013;346:f385

A less formal, but still thoughtful, point by point critique:

1. **Time scale** Although the time scale of follow up is set as "at least 10 years", it has not specified when they will stop.
2. **Recruitment** It is very confusing trying to understand their recruitment method. Are they recruiting patients every year or are they going to recruit just a set amount of patients (i.e., 200 patients in 2015) and follow them (200 patients) up for 10 years 2035?
3. **Sample size** Although some numbers are mentioned, a clear target is not specified. So, is the target sample size 200 or 1000? Each year? Each centre? England? It will significantly affect the power of the study if the sample size is not very big.
4. **Randomisation** Specific method in order to achieve randomisation is not specified.
5. **Study method** It is not a blinded study (maybe the analysis is blinded but it is not stated in the protocol). The analytical strategy was not specified and the statistical methods that will be employed are not mentioned.
6. A hypothesis was not set.
7. **Data analysis** Why are the patients separated into two groups, then to examine 47-49 and 71-73 within the two groups? Would it be better to compare the 3 groups 47-49 years old group, 50-70

years old (the control) and 71-73 years old group collectively?

8. If the patients are separated into clusters according to the area, are they comparing within their cluster's control group? If not, geographical and ethnicity background should also be considered in the data analysis.

9. When analysing the data, it does not specifically outline the method, i.e., how can they actually assess the risk, benefit and effectiveness of a screening programme? They also have not defined the risks and benefits. However, prognosis and treatment outcome are also subjective to current conservative/surgical treatment. Will these factors be taken into account?

10. **Follow up** During the follow up, how can the research group ensure the compliance of the patients, will there be a large loss to follow up?

11. **Controlling factors** While recruiting the screening centres and following the NHSBP standards, will some screening centres have better equipment? Are they all screening using the same machines, same level of competency in operating the machine, same competency in interpreting the data?

Arthur Woo, University of Glasgow Medical School

NICE recommendations: why no disinvestment recommendations to offset investment decisions?

WHILST THE MAJOR political parties have pledged manifesto commitments to increase investment in the NHS' questions remain over how these are to be funded.² Growing demand, alongside ever increasing drug costs, means that funding for new treatments is a particular area of concern. While the NHS in England and Wales is legally obliged to fund and resource medicines and treatments recommended through the NICE technology appraisal (TA) programme,³ NICE has no budgetary responsibilities over the funding of its recommendations.

The opportunity cost of new interventions requires other activities to be displaced in order to fund them. NICE acknowledges this in its cost-effectiveness threshold and also by setting out the case for investment and disinvestment through its guidance programmes and other advice.³ However, how NICE disinvestment recommendations are delivered in practice remains unclear.

NICE maintains a database of 'Do not do' interventions but these are not linked to positive TA recommendations. NICE determined that a designated disinvestment TA programme was not warranted,⁴ hence the database is primarily based on negative TAs, clinical guidelines, and low-value practices identified by the Cochrane reviews as being primarily due to a lack of randomized evidence of effectiveness, rather than robust evidence of a lack of effectiveness, or evidence of harm.⁵

Consequently, whilst NICE has made a start at providing disinvestment recommendations, this is advisory rather than mandatory, and mainly based on recommendations which generally do not take cost-effectiveness into account. Calls have been made for more research into interventions of uncertain cost-effectiveness and more TAs of existing health care interventions in order to provide evidence-based disinvestment guidance that is appropriately engaged with new commissioning structures.⁶

Published evidence for how disinvestment is carried out is limited. An English study of local disinvestment generally found there to be no formal processes, difficulties in collaboration between commissioners and healthcare providers, reluctance to engage in explicit rationing, and limited central and political support for disinvestment.⁷ NICE 'Do not do' recommendations may be ineffective at improving clinical practice or achieving disinvestment,⁸ perhaps as commissioners are seen to make disinvestment decisions using reductionist criteria that ignore intuitive clinical judgment.⁹

In Wales, a survey of funding decisions for NICE TAs reported that the financial impact was generally anticipated and planned for, but funded through efficiency savings rather than service displacement.¹⁰ Whilst NICE has no mandatory status in Scotland, its outputs are reviewed for implementation as appropriate. However, a similar lack of consistent implementation of cost-saving TAs, clinical guidelines and 'Do not do' recommendations was apparent, although there was more consistency in cancer areas.¹¹ Evidence of disinvestment based on cost-effectiveness in Scotland is limited, with the majority of savings, when required, made through increasing technical efficiency and not through explicit disinvestments or service reductions based on cost per QALY criteria.¹²

Saying 'no' or ceasing to provide a service, is far more difficult to implement than introducing a new healthcare intervention. More transparent public engagement may be the way forward to obtaining public concurrence for disinvestment; however a review of decommissioning tools found that whilst the importance of engaging all relevant stakeholders to build a better understanding of disinvestment related practices and to ensure sufficient 'buy-in' was emphasised, no particular criteria or process of including the public was explicitly made.¹³

In conclusion, whilst disinvestment is acknowledged by NICE as a priority, there is no formal process. The burden of disinvestment is shifted away from NICE/central government to local powers, where decisions are likely to be made covertly rather than overtly. The ad-hoc nature of this approach may result in treatments being displaced

which are more cost-effective than those being introduced¹⁴ and may result in geographical inconsistencies leading to fresh accusations of a 'postcode lottery'.¹⁵ In these times of increasing demands for efficiencies within the NHS, an explicit framework for the disinvestment of less cost-effective interventions is warranted.

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IS GWYNETH PALTROW WRONG ABOUT EVERYTHING?: how the famous sell us elixirs of health, beauty & happiness

By Timothy Caulfield

RRP £16.47 (Hardcover: 272 pages). Published 5 May 2015 by Beacon Press (MA) US ISBN-10: 0807057487
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WHETHER IT BE through modelling, music, movies or sports, award-winning University of Alberta-based academic, Professor of Health Law & Science Policy and a Canada Research Chair, Timothy Caulfield, loves celebrity culture. His book "Is Gwyneth Paltrow wrong about everything?" is a journey unravelling the considerable influence of celebrities on what we think and on our resulting health and life choices.

In the first section of the book, we are introduced to the misconception that becoming a celebrity is achievable. The latter part challenges the myth that all celebrities are happy, healthy, wealthy people leading desirable lives.

Caulfield analyses and debunks a plethora of celebrity messages and promises—from treatment endorsements to career ambitions—which lead us to believe that following their advice would make us happy. In reality, this inevitably fails to do so—sometimes at considerable financial and emotional cost.

The book includes research backed by opinions from relevant academics and clinical experts, intermixed with extensive interviews with celebrities, young hopefuls and older "has-beens". He carefully separates science from pseudoscience, fact from fiction, myth from truth, eventually providing the reader with a summary of well-informed advice that could save them considerable angst, time and money.

As he did in his first book, *The cure for everything*, Caulfield immerses himself in his work, this time putting his own health and wellbeing at risk by trialling the celebrity-endorsed detox, diets and beauty routines.

The final chapter is appropriately titled "The Dream Crusher". Celebrity culture is not just an interest in celebrities, but reflects the

complex interplay between social expectations and socioeconomic realities, while presenting an illusion that we could all be famous. While we should all aspire to achieve happy and fulfilled lives, it might be easier, in fact, to win a lottery than to become a successful celebrity; even then, the chances of remaining one are doubtful.

No matter how young, talented or beautiful you are, the American dream of going from rags to riches is little more than an unachievable illusion. Entertainers and artists, like the successful, beautiful, talented and 40+ year old Gwyneth Paltrow and other celebrities, do have a place in our lives, but in a time when celebrity "wisdom"

often trumps science, when it comes to our health, we should not rely on them for truthful information on anything other than what they do professionally, and even that is distorted through the lenses of the media.

If you want to be a star (or want your child to be one), are thinking about plastic surgery, or you keep trying the latest celebrity-endorsed fad diet—or if you believe that celebrities have ideal lives—this book might change your mind. It is easy to read, both educational and entertaining, and will appeal to a wide audience.

Loretta Marron

*Friends of Science in Medicine
Australia*

"in a time when celebrity "wisdom" often trumps science, when it comes to our health, we should not rely on them for truthful information on anything other than what they do professionally"

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