AWARD FOR LIBEL HERO SIMON SINGH

The 22nd winner of the annual HealthWatch Award is to be Simon Singh, the author, journalist and mathematician. As well as being an accomplished communicator of science, his award recognizes his courage in fighting a libel suit, at considerable personal cost, and in doing so inspiring the movement which has resulted in a new law: the 2013 Defamation Act.

Singh began his career in television, producing award-winning science documentaries, and along the way carved a niche for himself which enabled him to combine his passions for maths, physics and cryptography with his ability to talk science in an entertaining way. His first book, “Fermat’s Last Theorem”, published in 1997, was followed by “Big Bang”, and “The Code Book”. Between them he squeezed in more TV work, and received more awards including an MBE for services to science, technology and engineering in education and science communication.

In 2008 Singh published “Trick or Treatment? Alternative Medicine on Trial” co-authored with Edzard Ernst. This diversion from maths into medical science turned out to be the start of his unexpected and unwelcome new source of fame. That April The Guardian published a column by Singh, “Beware the Spinal Trap” in which he criticized the British Chiropractic Association for claiming that their members can help treat children with colic, sleeping and feeding problems, frequent ear infections, asthma and prolonged crying. The BCA retaliated with a libel suit. This aroused a furious ire amongst the nation’s previously gentle community of sceptical bloggers. Within hours formal complaints of false advertising had rained down upon more than 500 individual chiropractors.

Two years later, and tens of thousands of pounds the poorer, Singh won his court appeal for the right to rely on the defence of fair comment, and on 15 April 2010 the BCA withdrew its lawsuit. By now a libel reform campaign had gained support and on 25 April 2013 the Defamation Act 2013 received Queen Elizabeth II’s Royal Assent and became law. The new law aims to restore the balance between the right to freedom of expression and the protection of reputation, and requires plaintiffs to show they have been harmed; defences of “responsible publication on matters of public interest” and of truth and honest opinion are also included. Undeterred, Singh continues to write and publish. His latest book, “The Simpsons and Their Mathematical Secrets” is unlikely to attract further libel suits.

The 2014 HealthWatch open meeting and Annual General Meeting will take place Thursday 30th October 2014 at The Medical Society of London, Lettsom House, 11 Chandos Street, London W1G 9EB (nearest underground station Oxford Street).

Mandy Payne

An oral history of evidence-based medicine

The term evidence-based medicine (EBM) was first coined over 20 years ago, although the way of thinking it encapsulates can be traced back centuries.

In recent years a number of individuals—many of whom have since been recognized with HealthWatch Awards—have pioneered EBM. Their stories have been captured in a series of video interviews which can all be seen on the website Evidence-Based Medicine: An Oral History, an internet project assembled by the international medical journals *JAMA* and *The BMJ*.

The centerpiece is a 45-minute documentary in which one-to-one interviews are interwoven with a panel discussion featuring some of the giants of EBM and produced by the editors-in-chief of those journals, Howard Bauchner and Fiona Godlee (2013 HW Award). The interviewees are Cochrane co-founder Iain Chalmers; former director of the Oxford Centre for Evidence-Based Medicine, David Sackett; former BMJ editor Richard Smith; Kay Dickersin of the US Cochrane Center; Paul Glasziou who directed Oxford University’s Centre for Evidence-Based Medicine; Muir Gray who has supported EBM in the UK NHS; Gordon Guyatt and Brian Haynes of the Health Information Research Unit, McMaster University; and Drummond Rennie of the Lee Institute for Health Policy Studies, University of California.

The website is at: [http://ebm.jamanetwork.com/](http://ebm.jamanetwork.com/)

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Research fund: apply before end September

APPLICATIONS are invited for another round of grants from the HealthWatch Research Fund, with a closing date of September 30, 2014. The research fund results from a donation of £50,000 which has been made by a private individual who supports our aims and objectives, and who has no connection with any pharmaceutical company, nor any financial interest in any complementary or other therapy or treatment. Applications are now invited for funding to support research projects that meet the aims and objectives of HealthWatch. These applications may be for tranches of up to £10,000 each, but it is anticipated that most will be for lesser amounts. For more information, and an application form, see www.healthwatch-uk.org/research

EBM app now available

TERRY SHANEYFELT, an associate professor at the University of Alabama School of Medicine, has developed a critical appraisal app for Android called “EBM Rater”. It covers all the major study designs including noninferiority studies, along with the criteria to evaluate subgroup analyses, composite endpoints, and surrogate endpoints. It also includes standard EBM calculators. Android users can find it in Google playstore or on Amazon; an iOS version is under development. All of the cost (59 pence) goes to the students who helped code it, to maintain it and update it in the future. If you try it, send Terry feedback at UABEBM@gmail.com

NEWS IN BRIEF

HEALTHY SKEPTICISM UK are inviting all prescribers in the UK to sign up to a promise that they will not allow their prescribing to be influenced by the pharmaceutical industry. At www.prescriberpromise.org they can pledge that they do not accept money, gifts or hospitality from any party whose interests conflict with those of patients; avoid, wherever possible, participating in education, practice and research with conflicts of interest; and avoid information disseminated by industry and its representatives. Prescribers signing up receive a certificate which can be displayed for patients to see. Please consider signing the prescriber promise, and share the information to prescribing colleagues.

www.prescriberpromise.org

A NEW book by Tracey Brown and Michael Hanlon explores the absurd safety rules that blight modern life, and encourages readers to hold the rule makers to account. In the Interests of Safety was published by Sphere on 3 July 2014, RRP £12.99.

BBC STAFF are receiving training to improve the quality of their science coverage—and that includes not giving so much airtime to unqualified sceptics in the name of “balance”. The BBC Trust’s recent (3rd July) progress report into the corporation’s science coverage found that there was still an ‘over-rigid application of editorial guidelines on impartiality’ which sought to give the ‘other side’ of the argument, even if that viewpoint was widely dismissed. According to the Telegraph, some 200 staff have attended seminars and workshops to stop them giving ‘undue attention to marginal opinion.’

http://www.telegraph.co.uk/culture/tvandradio/bbc/10944629/BBC-staff-told-to-stop-inviting-cranks-on-to-science-programmes.html

LAWYERS WHO represented families that believed their child’s autism was caused by the MMR vaccine may now themselves be sued for pursuing “hopeless” claims and profiting from legal aid payments, says a report in The Guardian. More than 1,000 families were involved in a class action suit that was dropped in 2003 when research that claimed the link between autism and the MMR vaccine was discredited. The suit, which had been expected to win billions in compensation, attracted an estimated £15 million in legal aid but not a penny in compensation for the claimants, who suffered raised hopes and expectations, driven by the media frenzy over the health scare. A man in Falkirk, Scotland, who was diagnosed with autism three years after receiving the vaccine, is now reported to be suing the lawyers who represented him in the suit, and seeking damages to “include compensation, distress, expense and inconvenience of engaging in hopeless litigation”.


ALTRIALS goes from strength to strength. At the time of writing 485 organisations have signed up to declare their support for the principle that all clinical trials should be registered and results reported. Bristol-Myers Squibb has just announced that it will be providing access to data from its clinical trials since 2008; and Elsevier, one of the world’s largest scientific and medical publishers, has said it wants to embed clinical trial registration in the peer review process.

THE 2014 JOHN MADDOX Prize for standing up for science is now open for nominations. The annual prize rewards an individual who has promoted sound science and evidence on a matter of public interest, with an emphasis on those who have faced difficulty or hostility in doing so. Nominations of active researchers who have yet to receive recognition for their public-interest work are particularly welcomed. Sense About Science runs the prize, a joint initiative with Nature Publishing Group and the Kohn Foundation. The award is presented in October and an announcement of the winner will be published in Nature. Nominations can be placed up to 20th August 2014. See: http://www.senseaboutscience.org/pages/maddox-prize-2014.html

EVENDOCTORS can find the statistics of tests and screening unfathomable. Risk Savvy by statistician Gerd Gigerenzer (published in April by Penguin; RRP £14.99 or £6.49 Kindle) says this number-blindness means health professionals are not giving patients the information they need to make choices about healthcare. A recent BBC News Magazine article includes a detailed synopsis and makes entertaining and enlightening reading: http://www.bbc.co.uk/news/magazine-28166019
TRIALS IN THE DOCK

The pharmaceutical industry is often painted as the villain in the clinical trials debate, accused of withholding methods or results from trials or, worst still, failing to report trials at all. The charges are well corroborated. Industry bodies like the Association of the British Pharmaceutical Industry publically pronounce themselves transparency advocates but the actions of their members often undermine the rhetoric.

This part of the clinical trials debate, important though it is, has been well-rehearsed in recent years; not least because of Ben Goldacre’s indefatigable journalism and pressure groups like the Alltrials Campaign. But it would be wrong to place the blame for the imperfections of the existing multi-faceted clinical trials system solely on Big Pharma. “Trials on Trial”, a debate held by the Medical Journalists’ Association on 22nd May, sought to examine the role played by another important part of the clinical trials infrastructure: the medical journals.

Dubbed the “gatekeepers of medical evidence” by Goldacre, the medical journals face grave charges eerily similar to that of the drugs industry. The publishing system, some argue, is underpinned by opaque practices often driven by self-interest rather than a desire to benefit patients.

The MJA event saw a series of expert witnesses plead their cases on the subject of whether the current system of publishing clinical trials was fit for purpose. Witnesses faced cross-examination in an amusingly camped up mock court setting, complete with some slightly questionable judicial regalia, before ‘the jury’, an audience of medical journalists, made their final verdict.

The setting may have been light-hearted but the arguments were far less so.

“He rubbished the publishing industry’s professionalism and ethics in a scathing attack in which he called for the journal system to be ditched all together.”

First up was Stephen Senn, a former pharmaceutical statistician at University College, London and Glasgow University. Now a pharmaceutical industry consultant and head of the Competences Center for Methodology and Statistics at CRP-Sante in Luxembourg, Professor Senn was the prosecution’s star witness. He argued the medical journals were in fact more to blame for the lack of trial data which gets published than the drugs companies. He rubbished the publishing industry’s professionalism and ethics in a scathing attack in which he called for the journal system to be ditched all together. Journals’ desire for high impact content meant that they were less likely to report negative studies and a lack of regulation meant they were under qualified to play such a pivotal role in the clinical trials chain, he said.

He added: “I agree that all clinical trials should be published and that includes all pharmaceutical ones.

“You can only guarantee that things be published if the person responsible for writing up the research is the person who is responsible for publishing it… If you divide the responsibility between the scientist and publisher, then there can be no guarantee that the work is published in time.”

Professor Senn called for trials to be self published on a public access portal such as the Clinicaltrials.gov website.

Next on the stand, Trish Groves, head of research and editor in chief of the BMJ Open, sought to set out the defence. She agreed that “reporting bias [was a] huge problem” but rejected Professor Senn’s accusation that her own journal did not publish enough negative trials. While not every journal is perfect, she admitted, publication is just “a tiny part of reporting bias”, she said. Drug companies and academics, “simply not writing up their studies or submitting them to journals in the first place” was a far bigger problem. She cited research which reported “disturbing things” like researchers not publishing their studies because they thought the results were “a bit dull” or “it didn’t really fit with our hypothesis”.

She pointed out that academics as well as commercial organisations were often as much at fault. “Academics rely on grants from the National Institute for Health, so they have a conflict of interest in that their next grant is often based on the fact that there current theory is correct,” she said. Dr Groves added that there were now many journals with high acceptance rates where industry and academics can publish reports where they were not especially pleased by the results. “The raison d’etre of some these journals is to get as much of the literature as possible published,” she said.

Another charge the journals face is that the system of peer review lacks transparency because reviewers do not have to disclose their identity, they are unaccountable and editors need give little reason for their choice of reviewer. Dr Stephanie Harriman, deputy editor of the open access publisher BioMed Central, eloquently presented the case for open peer review, a system in which peers are named. She did however concede there were also draw backs, not least that it was harder for journals to attract reviewers when the cloak of anonymity is unavailable for protection.

So what does the industry have to say about all this? Sadly, the only pharmaceutical company representative who agreed to attend could only take part in the debate on condition that none of what he said was reported, in order to avoid promoting, or being seen to promote, medicines to the public.

Even under such restrictions he deserved credit for turning up, which is more than can be said for his industry’s body, the Association of the British Pharmaceutical Industry (ABPI), who declined to take part at all.

Evan Harris, the director of the Campaign for Evidence-based Policy, was however quick to dismiss the industry arguments as “red herrings”. But sadly, you will never know why. Dr Harris said the main problem was not with the publishing but with the conduct of researchers for the reasons previously outlined by Dr Groves. He added the blame had to be placed on the funders and regulators which allow this “outrage” to take place both in industry and academia.

And so to the final verdict. The jury overwhelmingly but not unanimously voted in favour of the prosecution: the current publishing system is not fit for purpose.

This should not be confused with Professor Senn’s assertion that the journals were more to blame for the lack of trial data which gets published than the drugs companies. But, the verdict does go to show how much improvement is required in the process of carrying out and reporting clinical trials despite considerable improvements in the field over the last two decades.

James Illman
Correspondent for Health Service Journal

For more about the Medical Journalists’ Association go to http://www.mjauk.org/
DOCTORS PROMOTING EVIDENCE-BASED DRUG POLICIES

THE EVIDENCE base for a health-focused approach to drug use, particularly opioid substitution treatment, and needle and syringe programmes, is extensive. Yet access to these and other evidence based interventions is limited all over the world. This is most apparent in countries where health is not really considered as an issue when dealing with drug use.

For people who use drugs, we know that these interventions and access to general healthcare demonstrate successful outcomes, particularly in reducing HIV, hepatitis C and other infections. There is also bountiful evidence that punishing drug users—and particularly those who inject drugs—is detrimental to their health. With the existing stigmatisation and discrimination suffered by people who use drugs, the prospect of punishment only serves as yet another barrier to healthcare and treatment.

Health outcomes for these individuals tend to be far worse in countries where more punitive attitudes and actions are adopted over health focused interventions.

Since the early 1990s, harm reduction strategies have been hugely successful in minimizing the prevalence of HIV among this group of people. This is easily demonstrated by comparing countries that adopted these strategies with those that did not. For example in the UK, Switzerland, Germany and Australia, countries where comprehensive harm reduction strategies for drug users are in place, the prevalence of HIV among drug users is below 5%. However in Russia and Thailand, where the implementation of such strategies has been resisted despite the presence of drug injecting and needle sharing, prevalence is 37% and 42% respectively.1

In Thailand, the heterosexual spread of HIV was dramatically reduced in the mid 1990s through a public health campaign. But the HIV epidemic among those who inject drugs continues to rise where there is a drug policy built on punishing drug users.2

A major worldwide review of coverage in 2012 found that only 86 (45%) of countries provide needle and syringe programmes and only 77 (38.5%) provide opioid substitution treatment. Rates of provision vary widely and often appear to be most lacking where most needed. Considering the success enjoyed by countries that have adopted these evidence-based interventions and made them accessible it appears that millions of lives are being put at unnecessary risk. This situation seems to be driven by political dogma where people who inject drugs are stigmatised and labelled as undeserving of treatment.

Furthermore when we look at the highly effective anti-retroviral treatment of HIV in people who use drugs, we also see this is not consistently applied to those who inject. For example in Russia 83% of HIV infection is in individuals who inject drugs, but they only receive 20-30% of the antiretroviral therapy. Similarly in China the equivalent figures are 60.5% against 10%.3 The situation is particularly bad in Russia where 37% of the 1.8 million people who inject drugs are infected with HIV, needle and syringe programmes are severely limited and opioid substitution treatment is illegal. In Central Asia, Latin America and Sub-Saharan Africa, treatment coverage equates to less than one person for every 100 people who inject drugs.4

There are also drug detention centres, which are described as drug treatment but where there is no right of appeal, no treatment, and there is forced labour. A study by Harm Reduction International found that over 40 states apply some type of judicial corporal punishment for drug and alcohol offences.5

International Doctors for Healthier Drug Policies (IDHDP) is a global network of medical doctors that supports drug policies based on the health of individuals and society. Our goal is for people who use drugs to have equal access to all forms of healthcare, and in doing so to improve the health of the whole community—by reducing death and disease, protecting children and families, improving public safety, and reducing crime.

Effective drug policy stands on four pillars: 1) Prevention, 2) Treatment, 3) Harm reduction and 4) Public safety. Like all good policies it should be subject to regular review and evaluation.

What does this mean for doctors? It is our job to provide the best possible healthcare to people who use drugs just like anyone else. We should challenge bad policies that make this work unnecessarily difficult or sometimes impossible. In order to optimise the healthcare of people who use drugs we need to unite to promote healthier drug policies.

IDHDP aims to have at least 5000 doctors as members by March 2016, when the future direction of drug policy will be debated at the United Nations General Assembly Special Session in New York (UNGASS). Every country in the world will be represented at Ministerial level. We are already involved to ensure the voice of physicians is heard clearly and that health is moved high up on the agenda. IDHDP had a big presence at this year’s United Nation’s High-Level Segment on Drugs, as reported in the Lancet.6

We hope that HealthWatch’s doctor members reading this will join IDHDP and add their voices to a growing number of physicians calling for health based drug policies. Join us at www.idhdp.com

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6. From the Mountaintops: What the world can learn from drug policy change in Switzerland. Joanne Csete, Global Drug Policy Program, October 2010.
TO OPERATE OR NOT: WHEN THE BIAS IS THE BELIEF

The PulMiCC trial (Pulmonary Metastasectomy in Colorectal Cancer) is a controlled trial in which we are seeking to find out if there is a difference in survival in patients who do or do not have lung metastases removed surgically. There are plenty of expert clinicians who believe they already know the answer to this question, or at least have a conviction so strong, that it makes them unable to allow the decision to be a matter of random allocation. They want to carry on as they do at present, guiding patients on an individual basis.

As with nearly every other decision in the surgical management of thoracic malignancy, there is little or no unbiased evidence to provide answers and yet there is a great deal of data. There have now been more than a hundred surgical follow-up studies reporting the survival of patients who have had metastasectomy. Typically 30% to 50% of patients are reported to be alive at five years. Three readily identifiable preoperative factors have been repeatedly found to be associated with shorter survival after pulmonary metastasectomy: more than one metastasis, an interval since resection shorter than three years and elevation of the tumour marker, carcino-embryonic antigen (CEA).

If patients with one or more of these adverse factors are select- ed out, patient subgroups with higher survival rates can be identi- fied. But these are general prognostic factors. Selection of patients on the basis of these features will produce a biased sample of patients destined to survive longer than average, whatever is or is not done to them. This conclusion was reached and published over 30 years ago.

It is in the nature of surgical follow-up studies that the starting point is to retrieve a list of the surgeons’ operations. We do not know from such a list how many patients were excluded from con- sideration before referral, nor those who might have been candi- dates but who were later discounted, nor those in whom the disease was clearly progressing during the period of assessment and investiga- tion. If an operation was performed, but it was evident that not all the metastatic disease was removed, these patients are generally not included in follow-up studies because they did not meet the entry criterion of having had a metastasectomy. Even in a carefully planned prospective registry study, which captured an estimated 60% of all pulmonary metastasectomy operations for colorectal cancer in a two year period, the opportunity was lost to capture the denominator, or to collect data on intention to treat. Many studies further exclude patients post hoc if examination under the microscope did not show clear margins (an R0 resection).

Not only does the tradition of surgical follow-up studies systematically exclude patients who did not have the operation being reported, but it provides multiple opportunities for well-intentioned reports on the outcome following surgery, to be biased by hindsight. These are just some of the traps for the unwary in interpreting surgi- cal follow-up studies.

So far we have paid no attention to what might have happened to these same patients if they had not had a metastasectomy—the con- trol group. The background assumption, implicit and sometimes explicit in the follow-up studies, is that survival at five years would have been nil, or thereabouts, were it not for the operation. Thames Cancer Registry (TCR) data do not bear that out: for patients with metastatic disease there are five year survivors, 10% according to the registry.

This prompted my colleagues in the Clinical Operational Research Unit to model what might have been the outcome for patients in follow-up studies if they had not had pulmonary meta- tasectomy. From TCR data, cancer stage at registration and the interval to death were available. From two of the larger follow-up studies the cancer stage mix and the interval between the primary operation and the metastasectomy were available. Patients for whom the ‘death free interval’ in TCR was shorter than the interop- erative interval were excluded (patients already dead cannot be can- didates for metastasectomy) and a survival curve plotted for patients with the same mix of cancer stages. The observed and modelled five year survival rate were both 40%. The model, like all models, is not perfect but it makes less sustainable the assumption that five year survival would have been nil for these carefully selected patients, if their metastases had not been resected.

The belief in effectiveness of pulmonary metastasectomy in extending survival grew through the 1980s and became accepted as ‘known’ in the 1990s. A citation network analysis showed a pat- tern of information cascades in which those who write up their clinical experience, cite similar practice and thus gain affirmation. ‘It is like rolling a snowball: it gets bigger and bigger—but it is just more snow’.

At the same time there was clinical interest in rescuing patients whose colorectal cancer metastasised to the liver. This too had generated a large mutually citing literature. The possibility of an RCT had been mooted in 1992. If the five year survival in the control group were no more than 5% as was believed, and survival rates being reported (around 30%) were indeed attributable to the grow- ing practice of resection of liver metastases, it was estimated that a trial of as few as 74 patients might prove the point. Powerful rhet- oric won the day; the trial was never done. The surgeons reporting and promoting liver resection declared that the trial was both unnec- essary and unethical.

Also wanting to reduce the death rate from recurrent cancer, sur- geons at The Middlesex Hospital started the CEASL trial in 1982 with funds from the United States’ National Institute of Health. By 1992, 1447 patients who had a potentially curative resection were screened with regular CEA measurements. Patients whose CEA fell to baseline, and subsequently had a sus- tained rise, were eligible to be randomised to a control group in whom the CEA results was concealed from the surgeon, or be in the active arm with the CEA rise disclosed to the surgeon. This was to prompt a second-look laparotomy which included full mobilisation of the liver. 216 patients who had a CEA rise were randomised. The CEA rise detected recurrence on average 11 months sooner than it was diagnosed clinically in the control group. On analysis in 1993, 88/108 had died in the control group and 91/108 had died amongst those who had the CEA disclosed. There was no survival gain. The Data Monitoring Committee considered that it was highly unlikely that any survival advantage would be demonstrated and the trial closed. CEASL data have recently been recovered and published.

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FERTILITY AND THE MEDIA HYPE

Kate Brian, author of “The Complete Guide to Female Fertility” and “The Complete Guide to IVF: An inside view of fertility clinics and treatment” explains why couples experiencing fertility problems are drawn to complementary therapies

FOR FERTILITY PATIENTS, dividing science from snake oil when it comes to treatments is not always easy; the Internet is awash with often conflicting information and working out who and what to trust can be a challenge. It’s not just the vast industry of therapists, coaches and complementary practitioners that has attached itself barnacle-like to the side of conventional medicine which can make it confusing, but also the steady stream of stories in the media about new techniques which are apparently set to double or even triple IVF success rates.

Patients can rarely tell whether these new medical advances have gone much beyond the early stages of research, and limitations on patient suitability are rarely mentioned. A succession of new techniques have been introduced in recent years which have yet to be proven to be effective by randomised controlled trials, but which many patients are already paying for.

It’s not just medical advances that make the news—there is also endless lifestyle advice about what you should or shouldn’t be eating, drinking or doing to improve your fertility. Eat more brussels sprouts or carrots, or was it raspberries, but whatever you do don’t touch bacon. Don’t use a mobile phone, a laptop or get on a bike. What links much of this advice is the suggestion that your fertility is in your own hands, and that you have the power to influence the outcome of your treatment—an idea which is promoted by many of the alternative, complementary or holistic therapists working in the field.

"a fertility patient said: ‘I don’t want to get to 45 and look back and wish I’d spent more on complementary therapies’.”

This kind of advice is particularly attractive to the surprisingly large number of patients who have been told that they have unexplained infertility. When doctors don’t know why you can’t get pregnant, following the advice of those who claim it’s down to your stress levels, your diet or your lifestyle may seem to offer some kind of solution.

People are encouraged to “take control” of their fertility, to rid themselves of negative thoughts that may be preventing them from conceiving and women are urged to “visualise” themselves pregnant in order to ensure success. If a pregnancy ensues, all well and good, but what happens when it doesn’t? Patients are left to conclude that this has little to do with the limits of modern medicine, but is rather their own failure to have taken control of their thoughts and emotions.

There is no doubt that many fertility patients take great comfort from the counselling aspect of alternative or complementary fertility therapies. In a busy clinic, staff rarely have time to sit and chat, to ask patients how they are feeling or whether they are coping. Infertility can be a lonely and isolating business, and the hour of a complementary therapists’ time can be particularly valuable to the patient. Complementary therapies are now so widely used for fertility patients that it has become quite normal to have acupuncture along with your IVF, and it’s not uncommon to find an acupuncturist at hand in a mainstream fertility clinic, ready to deliver a session to patients as they have their treatment. There are fertility clinics offering herbal medicine, reflexology and hypnotherapy along with conventional IVF, which gives patients the impression that clinicians are endorsing the effectiveness of these therapies.

Some may say that this doesn’t really matter if it is helping patients to feel calmer and more relaxed. It is, however, a financial burden, particularly when around 60% of fertility treatment takes place in the private sector. Most fertility patients would do anything to get pregnant, and may worry that not paying for extras on top of conventional IVF could affect their chances of success. As one patient explained, “I don’t want to get to 45 and look back and wish I’d spent more on complementary therapies”. Another reflected on the therapies she’d tried, “At one point, we were taking 21 tablets a day of different vitamins and minerals. We spent so much money, but you get to a stage where you are so desperate that you will try anything. Occasionally I do feel bitter about all the money we spent and all the time we wasted, but at least I can look back and think we tried everything”. 11

With so much at stake, fertility patients are often willing to gamble on unproven treatments and therapies, which may seem worthwhile if a pregnancy follows. With national average IVF success rates of around 25%, it is more likely that an individual cycle of treatment will not work, and this is can be all the harder to cope with when you have been encouraged to believe it might be your own fault.

Kate Brian
Writer and journalist www.katebrian.co.uk/blog

References
He then makes us wonder why we see crime as we do. He looks at our perception of crime, which we see in terms of detection, conviction and punishment of individuals with moral weakness. He contrasts this with our view of health, where protection is enacted on population and individual levels and questions of morality are separated from considerations of prevention and treatment. “Anachronistically we continue to treat crimes as largely discrete episodes,” he says.

He then, helpfully, shows you a rationalist way forward. Efforts to tackle crime should focus on prevention, rather than detection and conviction, and the methods used to prevent crime should be subject to scientific testing, he says. “We all demand such testing when our lives depend on it: the crashworthiness of a car, the purity, the integrity of a high-rise building, the safety of a medicine,” he says. “We ought to demand it for public policy. Yet science has rarely been applied systematically to crime prevention.”

Crime will make you reconsider many assumptions. It will also make you long for a world in which criminal justice and public policy are required to meet the same standards of evidence and rigour already expected of health interventions.

**Tom Moberly**
Medical Journalist
Fully twenty years later the question was asked again in the FACS trial: would intensive monitoring of patients improve survival by allowing a second chance of curative surgery? The findings were essentially the same as in CEASL: no survival benefit was found. The intensive monitoring was with CEA, or CT, or both (as recommended in the 2011 NICE guidance) and the control was clinical follow-up. Despite earlier detection in all three intensively monitored groups, the number of deaths was higher. The difference was not significant but the largest likely survival advantage of intensive monitoring is 2.6% but the detriment could be up to 7.1%. CEASL was stopped when any survival benefit was found to be highly unlikely. The FACS trialists changed the primary outcome to surgery with curative intent and reported it as such despite there being no hint that more cures were achieved.

“All too often the author’s conclusions are a better match for the prior beliefs in the introduction than the findings reported in the results.”

So much for cure at second surgery but what about quality of life? Major surgery always has some detrimental effect: it hurts, you have to be in hospital, and it takes time out of normal life while you recover. Lung metastases considered for resection are asymptomatic; the objectives of monitoring are to detect metastases before symptoms. When the end approaches, as is inevitable for most patients with metastatic cancer, lung metastases rarely contribute substantially to symptoms and not usually to the process of dying. The net effect of metastasectomy on quality of life, unless proven to be otherwise, is likely to be detrimental.

The last gasp at justification is ‘psychological benefit’. None of the many studies I have pored over have included any measure of psychological measurements or any mental health input in the authorship. Hard though it may be to come to terms with it, the anxiety and distress engendered by lung metastases comes with knowledge that metastases are there. Metastases in the lung can be shown easily, white showing starkly against the black radiolucent lung. Once found, and shown, we cannot put that genie back in the bottle. If earlier discovery of recurrence has been shown in two trials to confer no survival benefit, what are we doing it for? To provide surgeons with therapeutic opportunities cannot be a good enough reason.

From the present state of knowledge I would not be able to honestly tell a patient whether or not there is benefit from the widespread and accepted practice of pulmonary metastasectomy. There is strong evidence that for large groups of patients any benefit is improbable: multiple metastases, short interval, rising CEA. And yet in the same paper the authors reporting ‘robust information regarding nearly 3000 patients with colorectal cancer who underwent surgery for (lung metastases) with a curative intent’ later conclude ‘as long as a R0 resection is feasible, it seems currently unfair to deny surgery for those patients with two to four lesions’. All too often the conclusions are a better match for the prior beliefs in the introduction than the findings reported in the results. All too often the careful work of scientists, analysts, and methodologists is over-ridden by clinical zeal. The value laden language of ‘not denying the chance of cure’ and ‘giving the benefit of the doubt’ are often invoked; this paper is an example. If there is doubt, random allocation is a rational and ethical course of action. When actually asked, the majority of 70,000 patients in the Cancer Patient Experience Survey were willing to be in studies. Our commitment has to be to complete PulMiCC and report what we find: no more, no less.

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This article, written for the HealthWatch Newsletter, has been adapted from the original for reasons of space. The full version with complete list of references appears on our website www.healthwatch-uk.org

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