Ethical flaws in AgeX trial exposed, to international support

The largest randomized controlled clinical trial ever undertaken has had its ethical flaws laid bare by HealthWatch authors in an Analysis in the British Medical Journal, and concern is mounting among international scientists.

A dozen rapid responses to the article have been received to date, including from scientists in Australia, Canada, France, and Denmark, and all are supportive. Notably, no response has been received from any of the bodies criticized in the Analysis. The article tracks the murky history of the UK government-sponsored investigation into the effects of extending the breast screening age range, describing its poor design and lack of explicit fully informed consent. Millions of women taking part in the trial, which involves breast screening units throughout England, are being exposed to known risks of unnecessary life-changing treatment – including many thousands of mastectomies – with little hope of either benefit to patients or of achieving results fit for publication. The paper was authored by HealthWatch chair Susan Bewley, writing with award-winning medical author and HealthWatch member Mitzi Blennerhassett, and newsletter editor Mandy Payne. The trio, whose investigations were helped by retired clinical research scientist Les Rose, also revealed how the already massive trial doubled in size, to a target of 6 million participants, without seeking ethics committee approval. The full story, with links to key documents and the full text of the BMJ article, is in our latest blog update.

Outrage over Lancet’s trachea transplant article

Veteran whistleblower Peter Wilmshurst has been challenging ethical standards at one of the most respected international medical journals. He claims The Lancet jeopardized patient safety in order to protect its own interests and reputation.

The role of medical science journals has long been debated, amid concerns that they have income and circulation to protect and so face similar pressures to any other publications, from specialist magazines to tabloid newspapers. Many studies have concluded there is publication bias, favouring the more dramatic research outcomes at the expense of cautious or negative results. But rarely has such a prestigious journal been so forcibly attacked. Peter Wilmshurst, a cardiologist at the Royal Stoke University Hospital, Stoke-on-Trent, is celebrated for his courage in speaking out whenever he sees something wrong, especially where he suspects research misconduct. He has faced down many threats and actual legal action in the past and he won the 2003 HealthWatch (cont. page 2)
Award for his bravery in challenging misconduct in medical research. In this case, Wilmshurst takes issue with the actions of The Lancet over a paper they published in 2008 (1) which reported apparently successful pioneering surgery. He alleges that staff at the journal would, or at least should, have known for several months that the transplanted airway had in reality collapsed three weeks after the operation. The experimental technique went on to be used in other patients and resulted in deaths, including that of a 15-year-old girl in Great Ormond Street Hospital.(2) Some of the surgeons behind the Lancet paper were later found guilty of scientific misconduct by the Karolinska Institute with respect to six subsequent publications (of which two were in the Lancet), and which were then retracted.(3) The journal only made the failure of the original experimental surgery public, says Wilmshurst, when the issue was the subject of a BBC Newsnight report earlier this year. (2) Even then, their response was not to retract, but to solicit a clinical update letter which they published in March 2019.(4) The journal editor has defended the Lancet’s actions, citing guidance from the Committee on Publication Ethics (COPE), in letters to Rt Hon Norman Lamb MP and Dr Sarah Wollaston MP: “We must not assume that evidence of past misconduct always indicates misconduct in other cases.”(5,6) The case is of importance both because science and medical practice both rely on the ethical standards of science journals but also because of the essential freedom to challenge in the public interest whenever there is any suspicion of wrongdoing.

Nick Ross, HealthWatch President, and Mandy Payne, HealthWatch Newsletter Editor

References
2. BBC Newsnight, 26 February 2019.

News in brief

HealthWatch Symposium 2019 on medical devices
As you read this, there may still be time to register for the HealthWatch Symposium 2019: Evidence, Healthcare and Medical Devices & Implants. It takes place on Monday 17 June 17, 2019 from 1pm to 4.30pm at St Luke’s Community Centre in central London. Giving presentations, we have Carl Heneghan, professor of Evidence-Based Medicine and director of the Centre for Evidence-Based Medicine, Oxford University; Deborah Cohen, investigative Journalist, British Medical Journal and BBC, London; and Peter McCulloch, professor of Surgical Science and Practice and chair of the IDEAL Collaboration, Oxford University. The symposium aims to clarify current issues facing evidence-based healthcare in the field of implants and medical devices, and to identify areas where organisations (including HealthWatch) might most productively concentrate their efforts. Attendees will be active participants in the process input to the process, by taking part in the discussion groups and giving feedback.

The programme is on the HealthWatch web site, and registration is via Eventbrite – click on Register then Checkout.

Funding research projects
Some years ago, HealthWatch received a generous donation of £50,000 from an anonymous donor, a private individual who had no connection with any company or any potential conflicting interests, to establish a research fund. To date we have sponsored four research projects (more information is on our website), and we are holding a symposium on “Evidence, healthcare and medical devices and implants” in June, after which we will determine our research priorities for the coming years. Although we have some of the original funding in hand, now is the time to start thinking about fundraising to maintain the research fund for the future. If any members of HealthWatch have experience in fundraising, or know people who have, please email the secretary at david.bender@btinternet.com, so that we can start thinking about serious fundraising.

Questioning health-related charity claims - action for you!
After a five-year campaign by HealthWatch trustee Les Rose, the Charity Commission has issued new guidance for charities that operate in the health sector. Les was concerned that certain charities were misleading donors and beneficiaries by making false claims. Examples are the Maun Homeopathy Project, which provides homeopathy to HIV and AIDS victims in Africa, and the Vaccine Awareness Network which campaigns against vaccination. Working with charity The Good Thinking Society, a legal challenge was raised, stating that the Commission was failing in its statutory duty to enforce The Charities Act 2011. The Act states that charities must operate for the public benefit, and the Commission’s guidance makes clear that claims of benefit must be evidence-based. This was an outcome of a major consultation by the Commission, which reported in December 2017, and it has taken a further year for the new guidance to be issued.

So far, Les has identified about 30 charities which make questionable health-related claims, but these are only the most obvious based on their names. We invite HealthWatch members to advise us of any charities they encounter that may also fall into this category. Now that the guidance is clearer, the Charity Commission must be held to account with regard to enforcement. (cont. page 3)
Please visit Les’ blog which contains several posts on this subject, including a critique of the guidance.

Transparency news
It has never been easier for researchers to find out how to meet high standards for clinical trial transparency. AllTrials has just published useful guidance to help researchers upload their data. And a report from Health Action International and TranspariMED outlines some very simple steps to facilitate trial reporting by universities. It also flags continuing problems with accessing those clinical study reports which should be publicly available. Ben Goldacre’s recent report sheds more light on the issue of trial result misreporting and the reasons given for it: COMPare: Qualitative analysis of researchers’ responses to critical correspondence on a cohort of 58 misreported trials.

Great news is that the House of Lords Science and Technology Committee is to monitor trial reporting by universities and NHS trusts, as a new report shows mixed progress by universities in posting missing trial results. For more detail and data for each university read TranspariMED’s report.

An unidentified payment
HealthWatch’s treasurer is having difficulty identifying the member who has made a regular contribution of £25 to HealthWatch every January for the last three years, via Charities Aid Foundation (CAF). If this sounds like you, please could you contact membership@healthwatch-uk.org so we can update our records and make sure your membership is in order. Many thanks.

Catch-up viewing
Watch presentations from the Symposium about Scientific Freedom, held in Copenhagen on March 9, 2019. Peter Gotzsche, a recent HealthWatch Award winner, was expelled from the Cochrane Collaboration last year. He has now founded a new international Institute for Scientific Freedom with the goal “to preserve honesty and integrity in science”, launched at the symposium. The individual presentations (each lasting around 20-25 minutes) are now available free on YouTube. Peter Gotzsche presents on “Death of a whistleblower: scientific censorship in action”; and fellow HealthWatch award winner Peter Wilmshurst speaks about “Litigation as an instrument for silencing whistleblowers”. Others focus on scientific censorship in psychiatry, fake news in healthcare, and bias in statistics research.

In the US, public funding of drug development could be much greater than previously appreciated. In a recent webinar “Public funding of drug development: contributions of the US NIH”, Dr Ekaterina Cleary, of the Center for Integration of Science and Industry, Bentley University, talked about her research into pharma funding. The webinar, which is now available free to view, took place 25th April, from the Knowledge Network for Innovation and Access to Medicines, Graduate Institute of International and Development Studies, Geneva.

On a lighter note, we’ve been enjoying Medlife Crisis, the 10-minute science and medicine videos by Rohin Francis – cardiologist, internal medicine doctor, university researcher, and purveyor of awful jokes. His YouTube channel is worth a visit for a snatch of evidence-based light relief.

James Lind Initiative has closed
The James Lind Initiative closed at the end of March 2019 with the retirement of its co-founder Iain Chalmers, the giant of evidence-based medicine. For 16 years the initiative has promoted critical thinking among patients and professionals about treatments. Their free teaching and learning resources to help children and adults learn how to recognize untrustworthy claims about the effects of treatments have been translated in more than twenty languages. Their amazing work is chronicled in a recent journal article (Chalmers et al., Research Involvement and Engagement 2019;5:6).

Chiropractic in Australian babies curtailed
After widespread alarm over a disturbing online video in which Melbourne chiropractor Andrew Arnold manipulates a two-week-old baby’s spine, health watchdogs could be a step closer to limiting the scope of practice of chiropractors, in Australia at least.

The Chiropractic Board of Australia has now issued an interim policy that chiropractors cannot manipulate children under two years old, pending the outcome of an independent review, which is now open. The moves follow outrage by paediatric experts from the independent Australian consumer health watchdog Friends of Science in Medicine (FSM) whose statement issued earlier this year said it is inappropriate for any chiropractors to be treating infants without risking significant harm, and challenged the federal government to legislate that no child under 8 years can be treated by chiropractors. The review into “Chiropractic spinal care for children under 12 years” has now been launched. Australian members of the public, and registered Australian health practitioners (which may include chiropractors themselves), are invited to respond before 21st June. The findings will inform the government’s national health policy.

Healthnewsreview.org is back …
… though on a limited scale. The award-winning non-profit, which helps consumers critically analyze claims about health care interventions through its excellent reviews of health news coverage in the press, was forced into a “quiet phase” at the end of 2018 due to a loss of grant support. Now Gary Schwitzer, the veteran US health care journalist behind the initiative, has announced that they will continue to publish occasionally, with the help of individual donations. Visiting healthnewsreview.org is still highly recommended, and there’s a tab for individuals to donate to support this site which is entirely independent of industry influence and funding.

(cont. page 4)
John Maddox Award
Nominations are open for the 2019 John Maddox Prize for Standing up for Science. The award recognises the work of an individual who promotes sound science and evidence on a matter of public interest, facing difficulty or hostility in doing so. Now in its eighth year, the prize is named in honour of Sir John Maddox FRS, editor of Nature for 22 years, and is a joint initiative of Sense about Science and the science journal Nature. Nominations are open until July 19. The winner will be announced in November. Last year’s winners were Professor Terry Hughes, who exposed the extent of coral reef damage caused by rising water temperatures, and Britt Marie Hermes, the former naturopath who has faced legal action for writing about proponents’ questionable claims.

New proposals to fight overdiagnosis
Radical reforms have been proposed that should reduce overdiagnosis and stop defining healthy people as diseased – with strict independence from pharmaceutical companies. Writing in BMJ Evidence-Based Medicine in April an international group of leading doctors and researchers called for changes in the rules for defining disease and setting thresholds for medical diagnoses via a new process to be led by family doctors or GPs, with help from consumer or citizen groups, and entirely free of ties to drug companies or other vested interests.

Lead author, Ray Moynihan, an Assistant Professor at Bond University in Australia, said that the current trend towards expanding disease definitions is “causing too many people to be diagnosed and treated unnecessarily, producing harm and waste, and posing a major threat to human health and the sustainability of health systems.” Examples include a definition of chronic kidney disease, which labels many older people who will never experience related symptoms, that was launched at a meeting sponsored by a drug company; a vastly expanded definition of gestational diabetes, which may now label up to one in five pregnant women, without good evidence of any meaningful benefits that outweigh potential harms; and the creation of “pre-diseases” such as pre-osteoporosis, or pre-diabetes, which classify healthy people who are essentially “at risk of being at risk”. Disease definitions are currently set by panels led by disease specialists – including those with ties to drug companies – hence with a vested interest in labelling people as being in need of treatment. The new reforms would see existing panels replaced by multi-disciplinary panels, led by generalists, with all members free of financial conflicts. The proposal arises from the Preventing Overdiagnosis conference series.

Drug side effects explained
“Things you may not know about drug side effects” is a new free consumer resource co-developed by Sense About Science and the MRC Centre for Drug Safety Science. It explains that all medicines have side effects and some foods can compromise, reverse or amplify the effects of different medications; also, how to go about reporting any drug side effects we experience. It includes a 5-minute animated video “Things you may not know about side effects” along with a companion guide.

Obituary

Michael O’Donnell
Michael O’Donnell was one of the best-liked as well as the best-known doctors in Britain. If he had any enemies, it was among the more smug, pompous, self-important, humourless, unimaginative and hypocritical members of the medical profession, of whom no country has ever experienced a shortage. He was also one of the founders of what eventually became HealthWatch.

Regu lar or promising contributors to World Medicine, which Michael edited for 16 years, would usually be invited to WM’s very conveniently-sited offices near Leicester Square and then to lunch at a nearby eatery. This made it relatively easy for Michael to hear directly the views and concerns of busy London clinicians and academics, as well as visitors spending a working day or two in the metropolis. It helped him to become not only the most voted-for elected member of the General Medical Council but also a very well-informed one and he was responsible for initiating several important reforms.

Michael was rightly proud of quoting the British Medical Journal’s opinion that “not to have read Michael O’Donnell’s World Medicine was to have been incomplete as a doctor”. One of WM’s great strengths was that it was the only non-academic journal (though it did publish occasional academic pieces) that was widely read by both GPs and hospital doctors, but Michael brought to WM apart from a fine sense of humour, a warm and friendly personality and writing skills honed during his student days in the Cambridge Footlights, he was the son of an Irish Catholic GP. That meant not only being steeped in general practice as a child while accompanying his father on his rounds, but also experiencing some of the anti-Catholic prejudices that were then common even among doctors. Perhaps that added to WM’s support for causes like the psychiatrists forcibly confined in Soviet psychiatric hospitals (with uniquely Soviet diagnoses such as ‘reformist delusions’) for criticizing their government.

World Medicine was fortunate to have Geoff Watts as deputy editor; and also Karl Sabbagh as a regular columnist – at least, that is, until WM published a news item inviting readers to attend some medical Olympics that were due to be held in Israel. Karl – whose (cont. Page 5)
Palestinian Christian father helped to set up the BBC’s Arabic service in 1939 – wrote a short response, pointing out that Menachem Begin, the prime minister of the country they would be visiting, had led a notorious massacre in a Palestinian village that was now the site of an Israeli mental hospital. This produced an immediate flood of ‘Disgusted!’ letters and a significant withdrawal of advertising that, as Michael later recounted in the BMJ, was an important factor in WM’s closure a couple of years later. It also forced Karl’s resignation from his other job as director of the MSD Foundation (the charity created by drug company Merck, Sharp and Dohme), to which he had just been reappointed at an increased salary.

After leaving WM, Michael regularly appeared on BBC radio and TV programmes. He also wrote novels with medical themes, including one that involved the last-minute thwarting of an attempt to poison London’s reservoirs with botulinus toxin grown in a yoghurt-maker. He had always supported medical assistance in dying but became an active campaigner with another BMJ article describing his wife’s very unpleasant death after a stroke. With the help of a quadruple coronary by-pass, he remained both mentally and physically active and easily managed four flights of my stairs when he came for lunch last year but his own death, at 90 on April 6, was also not as peaceful as it could – and should – have been. However, his cremation service on April 29 this year was more like a wedding than a funeral and avoided any mention of religion. It featured his son’s jazz quartet and – right at the end – a performance of ‘blaze away’ by a colliery band from Michael’s native Yorkshire, which we were urged to accompany on thoughtfully provided kazoo.

Michael joined My Death, My Decision’s medical group because he felt that the aims of Dignity in Dying and its associated Health Professionals for Assisted Dying group were too narrow and restricted. Despite being educated at Stonyhurst, the Eton of Catholic public schools, he stated firmly on joining the medical group that he remained “grateful to the Jesuits who taught me how to think but less enthusiastic about some of the things they wanted me to learn… in particular ‘truths’ supported not by evidence but by a faith I was told I could acquire by praying for it”. His statement finished with a quotation from the great American secularist Thomas Jefferson. “I never submitted the whole system of my opinions to the creed of any party of men whatever, in religion, in philosophy, in politics or in anything else, where I was capable of thinking for myself… If I could not go to Heaven but with a party, I would not go there at all.” It would make a good epitaph for Michael.

Colin Brewer, Psychiatrist, retired
Convenor of the My Death, My Decision medical group

Change in focus brings results

This year has seen the fruits of HealthWatch’s intentional change in strategic focus from 2016, when we decided to improve communications, focus on specific projects and do student outreach. We’ve aimed to pursue a defined range of ongoing projects, alongside improving our ability to respond quickly to consultations or issues picked up in journals or the media as a formal HealthWatch response.

I was reflecting on my nearly three decades of involvement with this beloved charity that is one of the guardians of the holy grail of evidence-based healthcare, and how I always describe myself as ‘the youth wing’. However, this year I acquired official dinosaur status as I both picked up my free Transport of London bus pass and became the Chair.

Communications

The good news is that HealthWatch has entered the 21st century in terms of communications! Internally, the committee has undergone a number of innovations, mixing two annual face-to-face with four teleconference meetings and that is settling down. The website is greatly improved. Mandy Payne has been indefatigable in continuing to produce excellent online newsletters with such diverse topics as electronic patient records and prostate biopsy. We have reached 1,385 separate threads on the HealthWatch Googlegroup, a place of wonderful information sharing, discussions and networking. Twitter is an increasingly useful way of communicating what we are doing. As of today, HealthWatch has tweeted 1,632 times and has 842 followers. A decision has been made to investigate opening an Instagram account alongside our Facebook account. All this means speedier communications and being part of an influencing network. We keep in touch with many previous HW award winners. Who knows whether their careers were boosted by HealthWatch (it may be association not cause), but we note that Ben Goldacre is now the Health Secretary’s digital ‘tsar’ and just today Peter Wilmshurst was involved in a Daily Telegraph article about alleged research misconduct by stem cell researchers making trachea implants and the possible involvement of University College London and the Lancet (a story previously reported on the front page of both this and our Autumn 2018 newsletters).

Other examples of timely successes with media this year included getting three letters in major newspapers related to the ‘so-called’ scandal of older women missing a last invitation to breast screening, which provoked a lot of discussion about the risks and not just presumed benefits of screening. We were pleased to work with Deb Cohen, our 2017 award winner, on a Daily
**Telegraph** investigative feature about concerns over Public Health England’s Age-X trial of breast screening. You can expect to see more publicity on this in the coming months. Les Rose and Roger Fiskin have been instrumental in keeping up and publishing in a long running dispute with *BMJ* Case Reports about a misleading report on Curcumin that was uncritically discussed on BBC Radio 4. Sadly, our complaints to the BBC about quality scientific reporting have so far gone unheeded.

**Consultations**

We have been more proactive in responding to consultations, and there are at least four consultations to which individuals and HealthWatch responded in 2018. In particular we must thank Roger Fisken and Till Bruckner. In October the Science and Technology Committee of the UK’s House of Commons issued a report calling on the government to launch a “national audit programme of clinical trials transparency” and impose sanctions on institutions and individuals who fail to register trials or report their results. The report cites Healthwatch and TranspariMED (Till Bruckner’s UK-based initiative that develops and promotes policy solutions to the problem of evidence distortion in medical research) and even reproduces the table on “options for auditing clinical trials” that we jointly submitted. It elicited a rapid and positive response from the Health Research Authority about imposing sanctions. So this is very good news and we must keep an eye on further developments. It is good to have participated in a joint submission and further collaborations may be the way to go in the future.

Several consultations are still awaiting final decisions. HealthWatch took part in Improvements to the Research Excellence Framework, undertaken by the four UK research funding bodies (Research England, the Higher Education Funding Council for Wales, the Scottish Funding Council and the Department for the Economy). The weight of our response was placed mainly on trial registration and trial reporting and we await publication of their guidance in the first half of 2019. We also await publication of NHS England’s response to their Consultation on Evidence-Based Interventions which will apparently be used to develop provider contracts for 2019/20 later this financial year. We don’t know when a response will be forthcoming for the Professional Standards Authority’s consultations on refining their measures for overseeing various health regulators, to which we submitted. We note there does not appear to be any involvement of the Human Fertilization and Embryology Authority with the PSA or its processes, despite the obvious connection between the work of fertility clinics and other forms of medical care.

**Specific projects**

We have been more active in policy collaborations, and have used some of our research fund to support Till Bruckner’s project on Clinical trial transparency in the UK: Who gets to see what evidence? We have seen interesting and reassuring preliminary results about the Health Technology Assessment authorities and will be receiving a full report soon. Next year we hope he will be able to explore more about regulatory device processes to inform HealthWatch’s strategy.

Les Rose has continued to pursue the CPR2 (Consumer Protection Regulation) project with trading standards. You’ll recall that the Trading Standards Review journal had a problem seemingly because the results were perceived as critical of Trading Standards but several publications did ensue. Les Rose, Alan Henness and John Kirwan have been working on a conciliatory approach, and met officers at Camden Trading Standards in March, with a view to establishing a working partnership with HealthWatch. At the time Camden Trading Standards provided the legal backstop to the Advertising Standards Authority, for non-compliant advertisers who do not respond to ASA sanctions. They were warm to the idea of HW providing free expert advice on health-related marketing claims. However, this function has now been transferred to Surrey and Buckinghamshire Trading Standards, with whom we are trying to engage. We also wanted to bring the ASA into the discussion, but they have been hostile to having any meeting with us. We are still working on this as we see that the problem lies with regulation working at individual Local Government level, thus failing to deal with national, international and multisite businesses. Other work Les has been doing on reporting several bioresonance machines manufacturers and practitioners to UK and EU regulators can be followed in the newsletter.

An enormous amount of work goes into running the Student Prize and I thank John Kirwan for his continuing commitment to this (see Page 15). Plans to involve students and expand membership have not progressed as well as hoped (see membership report) but we still recognize the vital importance of improving evidence-based teaching in medical and other healthcare schools, so that students have critical thinking skills, and pursuing projects in line with our aims, improve evidence-based teaching, and maintain a long-term commitment to our aims and objectives.

Last, but not least, a particular highlight was the public meeting on Debunking False Health News held earlier in October at King’s College with three excellent speakers; the GP/journalist Faye Kirkland, researchers Jens Koed Madsen and Geoff Walton. We learned how and why false reports travel further, wider and more rapidly than truthful ones due to our emotional responses and personality types – there is hope in teaching and although the audience was select, we must build the insights into future work. I thank Philippa Pigache particularly for her hard work setting up the event largely single handed. We will look to repeating a public event next year, and value any suggestions for future topics for debate and discussion, or for any volunteering to help with workshops.

I am indebted to James May – the latest in series of excellent HealthWatch chairs – for (cont. Page 7)
From GP to MP: How to lose friends but try to influence people

Sarah Wollaston, MP for Totnes, Devon, spoke at the 2018 HealthWatch AGM on Wednesday 31 October 2018. It had already been an eventful week. Our AGM took place the day after the House of Lords Science and Technology Committee had published the results of their inquiry: Research integrity: clinical trials transparency. Earlier that week, the Chancellor of the Exchequer had presented his 2018 Budget to Parliament. The following text is adapted from her presentation and the question and answer session that followed.

There is a real challenge ahead of us about how we present evidence within our politics, and value evidence. Something that I have noticed in my role chairing the Health and Social Care Select Committee, is how within politics you have to find a balance between the idea that everything should be based on popular demand, and presenting the evidence.

Nowhere is this more evident than in public health. When you go out and ask the public where they would like to spend investment within the health service, public health is always at the bottom of the list. Yet the evidence shows that if you really want to tackle health inequalities and make a difference, that’s where the money should be going. But it always tends to get deprioritized. There’s been a bit of smoke and mirrors in the Budget, in that some of the funding for NHS England is actually going to come out of public health, which is a tragedy because it’s through public health that we’re going to really tackle the issues that governments all pay lip service to – burning injustices, and reducing inequalities.

You’ve got to look at the evidence about how you’re going to achieve those aims. To take a headline from this week – we’ve got the Chancellor talking about how he wants to reduce the tragedy of lives lost to suicide. While we would all agree that’s an extraordinarily important objective, you shouldn’t at the same time delay implementing evidence-based policy around reducing gambling addiction because you’re caving into industry lobbying that is fighting against the introduction of a maximum £2 fixed-odds stake for betting terminals. We absolutely need people in Parliament to make the case relentlessly for evidence and how you actually make a difference, rather than what the lobbying industry says makes a difference, or what is popular. And right now we are in the midst of the fight of our lives, against the “Trumpification” of politics, the downgrading of evidence, the ridiculing of expertise, and I think nothing has exemplified that more than the referendum campaign and the way it was conducted.

In summary, it’s been a positive year. Do look at the website, and join the google group. There are financial resources to spend on projects in line with our aims, so do apply and particularly if you have ideas student groups can work on. It cheered me up to realize just how much has been done this year, and how the focus on strategy and systems within HealthWatch has paid dividends in terms of wider impact, though more needs to be done to draw in a rejuvenated membership of students and new doctors who are as passionate about evidence as we are.

Susan Bewley, HealthWatch chair

2018 HealthWatch Award winner

Sarah Wollaston MP speaking at HealthWatch AGM 2018

So, that’s my job in parliament, to be rattling a few cages and to keep doing that! But there’s something you in HealthWatch can do. Never underestimate the effect of going to see your MP in person. Of course, it’s always easy to write an e-mail, send a postcard, or re-tweet, but you’re not actually going to shift the dial. And it doesn’t help for us to be talking to people who already agree with us. What we need to be doing is talking to the people that don’t agree with us, and having somebody actually turn up in your constituency surgery makes an MP
think, “Maybe I have to look into this.” Tomorrow I’m launching our committee’s report into prison health care, and that for me came out of a grandmother coming to talk to me in tears about the death of her grandson in prison, and the authorities’ failure to follow up on reports that had been coming out from inspectors about circumstances that had led to that avoidable tragedy.

So, going to see your MP really has an impact. I hear time and again from colleagues, that it is the person who takes the trouble to actually come and see you that makes the lasting impression. So, encourage your members to get out and talk to their MPs and explain to them about the importance of evidence and science.

Any questions from the audience?

Peter Wilmshurst: The Science & Technology Committee have done two reports on research integrity, but if you read them, nearly all the concerns are about medical research. I gave evidence to that committee, and it’s entirely about medical research. Should the Science and Technology Committee co-ordinate efforts more with other areas of research?

SW: Increasingly committees are doing joint enquiries where something is of mutual interest, for example, the report we recently published on anti-microbial resistance follows up on many of the points from previous committees. So, we do try to consolidate efforts so we can cover as much as possible.

Mandy Payne: At a meeting today at the Royal Society we heard about TARGIT (TARGIT IORT is targeted intraoperative radiotherapy treatment for breast cancer), which is a well-researched innovation that has been reviewed and recommended by NICE, that would save NHS money, and which offers huge benefits to patients, yet has not been adopted by Public Health England. How can we free NICE so that their recommended good practice actually gets implemented?

SW: It’s a huge challenge in many areas of the NHS where there is potential for good evidence-based practice and it’s not being effectively rolled out. I would advise you (1) to go to your MP and try and get them to stand up and talk about it in Parliament; (2) there are all party parliamentary groups within parliament, for example there is one on breast cancer specifically, you could raise it with them; (3) although the Health and Social Care Select Committee tends not to look at single disease issues, we do hold regular accountability session with bodies like NICE, so there’s the possibility we could use a session to raise such an issue and ask whether we could help if their recommendations aren’t being implemented. You are very welcome to write to me, and although we wouldn’t hold a specific enquiry I might be able to raise the issue in correspondence or in response to other issues that people raise with me.

David Colquhoun: Do you have any thoughts on the matter of a People’s Vote?

SW: Look at it this way: who would want to be wheeled into the operating theatre on the basis of a consent form we had signed two years ago, or in the case of younger voters, one their parents signed, if you didn’t even know which operation you were going to have, and the surgeons are still arguing amongst themselves, and there is no majority for anything. The implications of Brexit will last for generations.

John Kirwan: At our recent HealthWatch symposium on debunking false health information, one of the issues was the level of confidence people have in their source of information – how do you and your committee decide whether a group or individual presenting you with evidence is credible or not?

SW: There are some markers for not being credible, for example, people who write to you with a sample size of ten to support their view that something is important and should be implemented straight away. Essentially in an inquiry we publish everything, but we choose the witnesses we then hear from selectively. Unfortunately, there are always more fantastically credible witnesses we’d like to hear from than we have time, so we have to prioritize based on what they write to us in their evidence. And we also try and get out of London and meet as many people from different areas as we can.

Till Bruckner: Concerning the Science and Technology Committee report on clinical trials reported yesterday on Research Integrity; the government now has two months to respond to this report, is there anything we can do to tip the scales towards a favourable response? Secondly, looking at the various NHS foundation trusts that sponsor clinical trials, the reporting rates are bad, and there’s now going to be a lot of inefficiency as each individual trust tries to figure out how to improve their clinical trial reporting. So how can we ensure economies of scale to do this? Who is responsible in each trust and can they nominate someone to do it?

SW: Some people have got considerable expertise already – it is encouraging that Matt Hancock has appointed Ben Goldacre to be chair of his advisory panel, who has done fantastic work in this area and is not afraid to hold Public Health England to account. But it is not easy to identify who exactly is responsible. When asking government to respond to a report, it is worth putting in a specific recommendation to the government to identify who is responsible and who to hold to account.

Peter Wilmshurst: Part of the problem is that the Science and Technology Committee have put this back to UKRIO (the UK Research Integrity Office), the UK universities, who have consistently failed to self-regulate, and who have a concordat that only 30 per cent of them adhere to, and none of the hospitals where human research is conducted are part of that concordat, so the committee has come up with a solution that has failed in the past and doesn’t anyway apply to medicine.

SW: It would be worth speaking to Norman Lamb MP about that. (Peter replied, “I have!”)

Roger Fisken: Would you agree to introducing clear guidelines on minimum staffing levels for the NHS?

SW: I would agree that in an ideal world we would have minimum staffing levels, but the trouble is, there is overall a workforce staffing shortfall. If you were (cont. Page 9)
to impose a minimum staffing level on wards, if there was limited flexibility to move staff around there could be unintended consequences, such as you might not be able to transfer people out of ambulances into the emergency department, and then you end up with people being cared for in corridors and ambulances. The workforce challenge across the NHS and across social care is extraordinary. In my area, for example, there is an 8 per cent vacancy rate in social care, and 7 per cent of the workforce are from the EU, and among the nursing workforce in Devon that figure is nearly 30 per cent. What is going to happen if we make it much more difficult to recruit and people don’t feel welcome here?

Nick Ross: Granted, you can’t say, if you’re understaffed you’ve got to shut the doors and stop. But are there halfway houses? Supposing an acute hospital trust had to be on amber, so that if something goes wrong we can’t blame the person on the coalface?

SW: People make comparisons with airline safety, but healthcare is different in that you can ground an aircraft, but you can’t close a hospital – although there is a precedent even for that in critical areas – or you end up with people being cared for in sub-optimal conditions. I agree with the suggestion of a very clear amber alert where a hospital is understaffed, though if we imposed such measures too rigidly I would have concerns.

Susan Bewley: Why don’t we have proper standards of informed consent in cancer screening? And how can we improve decision-making so that we can stop doing something that doesn’t work? On screening, there are also concerns over vested interests and charities running awareness campaigns that create fear and havoc and end up sending healthy people to add to their GPs workload?

SW: Margaret McCartney has done some amazing work highlighting this, and my congratulations to her for highlighting the losses and harms resulting from the rise of the private screening industry, with the costs falling back to the NHS, and harms to people who are persuaded to have these tests. Just yesterday I asked the Care Quality Commission what they are doing to ensure these clinics are operating in an ethical manner. Certainly, there’s more that can be done. Drop me a line.

Roger Fiskin: Do you feel reassured about the provisions for medicines supply after we leave the EU?

SW: There has been a phenomenal amount of money diverted into contingency planning, which is ultimately going to feed back into the cost of drugs and healthcare. When you look at the amount of time it can sometimes take even now to source medicines – for example, my daughter is a junior doctor in paediatrics at the moment, and she recently spent two hours trying to source an epen for a patient. I can’t begin to imagine what it will be like if these problems occur on an industrial scale after we leave the EU. The public is used to being able to take a prescription to the pharmacy and expect the medicine to be there. What is going to happen when the medicine is not there and no-one can find it for you? When my constituents get cross with me for banging on about Brexit, I say to them, when we are three months on after a hard Brexit, and these issues are still ongoing, I want to be able to look you in the eye and say that I tried my best to present the evidence of what would happen as a result. I hope these problems won’t happen, I hope I’m wrong, but even if I am, it’s been a most tragic waste of resources.

Nick Ross: Has the NHS become a religion? We are spending £150bn a year on the NHS alone, about a quarter of all public spending, yet it’s nothing like enough? Where is this going?

SW: There’s a huge success story we shouldn’t forget – we’re helping people live longer. Yes, we’re living with more years of ill health and multiple morbidity, but it’s a success story not a disaster. Did we adequately plan for it, though? For generations people have failed to take the long view and look at what longer life means for the health workforce, and people’s readiness to put money into supporting the health needs of an ageing population. The trouble is, we promised people they can have all this for free. This week’s budget was an opportunity to say to people honestly: “This extra commitment has to be paid for somehow.” But what we’ve seen is talk about Brexit dividends, and giving people a tax cut a year early, instead of being straight with people and saying that if we value our NHS we’re going to have to pay more. When something is a religion, criticism is not very welcome, and you can be vilified for it. We should guard against treating the NHS like a religion, because we should be able to challenge bad practice.

James May: A lot of what I do as a GP only results in marginal gains, we are given the impression we’re saving lives, but in practice we are throwing money at end of life.

SW: The biggest gains in healthcare have resulted from public health measures. If you were going to start somewhere, start with the first 1000 days of life – it is the subject of our current inquiry. Look at education, housing, dealing with poverty, the things that make the biggest difference to health.

Alan Henness: How do you cope with being an MP in Totnes?

SW: It is a wonderful and interesting place, but let’s take just one issue, that of vaccination. Totnes has the lowest vaccination rate in Devon, and many people in town strongly believe in homeopathic vaccines, and many children there have not been vaccinated against anything at all. Some people can become very cross if I point out that some of the claims made against vaccination are untrue, and say I have no business to represent Totnes when I do not support the alternative community. But my view is that it is absolutely my job, to speak the truth it as it is. The rise of the anti-vaccination movement and the resulting resurgence of measles is deeply worrying.

Fortunately, Totnes is much happier about my stance on Brexit.

Text adapted from Sarah Wollaston’s AGM presentation
Students

Student prize winners come from far and wide

This year students from 28 universities took part in the HealthWatch Student Prize, showing that the competition’s impact is steadily growing. Our talented winners came from Scotland, Northern Ireland, Cambridge and London, but the winning medical student’s entry almost didn’t reach us at all ...

Abdul Badran, winning the £500 first prize in the medical & dental category, was on a summer placement at the National Institutes of Health in the USA when he uploaded his entry, and the time difference resulted in his essay coming in within a hair’s breadth of the window closing. Abdul is a South Londoner studying at Churchill College, University of Cambridge. He appreciates the importance of critical appraisal in evidenced-based practice and research planning, so jumped at the opportunity to test his ability to critically appraise clinical research methods. “I feel honoured to have been awarded the top prize and I would strongly recommend this competition to anybody that will be involved in managing patients. Abdul found his US experience amazing, working in a massive research hospital with patients admitted from across the globe under many different research protocols. “The experience helped develop my understanding of clinical trials and how integrating care with research could be a standard.”

Susan Parker sent an outstanding entry in the nursing, midwifery and professions allied to medicine (NMPAM) category. She is studying midwifery at the Uni of Greenwich, she lives in Kent and is married with a three-year-old daughter. “I chose midwifery after the care I received when having my daughter and absolutely love my course and studies,” she said. “I would love to be a Delivery Suite Coordinator and undertake additional training such as an Advanced Practice Masters.”

One of three runner-up medics, Edward Christopher, is on track to be the first doctor in his family. He is in his 5th year of a six-year course at Edinburgh University. He found the competition challenging, “I had to do lots of background reading – but it has been highly rewarding and I have learnt lots.” Matthew O’Donnell, a final-year medic at Queen’s University in Belfast, would like to become an ophthalmologist, and is excited by opportunities to do research that could prevent blindness and visual impairment. He has a keen interest in academic medicine. “It’s a really unique and challenging competition, it has given me a new perspective and perhaps has made me a tad more sceptical when reading about new research studies.”

Nicholas Heng was disappointed not to be able to make it to the AGM, as he is already a keen reader of the HealthWatch Newsletter. He is a fifth-year medical student at the University of Dundee, Scotland, and appreciates the importance for medics to be able to spot research flaws, especially given the ease of accessing health-related articles today. “I believe that the competition is incredibly relevant to us students, as it provides an invaluable opportunity not only to test oneself, but also to increase exposure to the key principles of critical appraisal.” His summer internships at various labs over the past few years have broadened his outlook to medicine and he looks forward to becoming a clinician-scientist.

For 2018 the entry closing date was changed to 30th April so that students could work on their entries at a time when they would not be over-burdened by exam stress. Students had to scrutinize four mock trial protocols which this year were for acupuncture to prevent tension headache, saffron treating pre-menstrual syndrome, castor oil for baldness, and low-dose sulfasalazine to prevent relapses of Graves’ hyperthyroidism. The entrants were not expected to consider the value of the actual treatments. They must assess the merits of the studies designed to investigate those treatments. It is about showing you understand how to generate quality (cont. Page 11)
evidence to support treatment decisions – the basis of good medicine.

This year 70 per cent of entrants placed the protocols in the correct order of merit and received congratulatory certificates. Each entrant also had to explain their chosen ranking in a 600-word essay, highlighting issues and implications around the study designs. Winners in each of the two categories – medical & dental; and NWPAM – received cheques for £500 each, and each runner-up received £100.

The HealthWatch Student Prize 2018 was devised and administered by HealthWatch committee-members David Bender, Roger Fisken and John Kirwan. We acknowledge with thanks the generosity of this year’s sponsors, the Royal College of Physicians.

Mandy Payne
Editor, HealthWatch Newsletter

Debunking health misinformation – a HealthWatch symposium

The diagnosis had been confirmed: false news flies faster than facts. It was the explosion on social media of misleading and untrue information about treatments, that concerned HealthWatch in mounting this discussion. Confronting mis-or dis-information about health is our raison d'être after all.

“We are here because we care about information” confirmed Susan Bewley, HealthWatch chair, as she introduced our 2018 event on October 4, 2018 at King’s College London. We all agree that misinformation and false news needs to be corrected, but how?

The first speaker, GP and award-winning investigative journalist, Dr Faye Kirkland, was not about to offer comfort to our audience of students and HealthWatch members and followers. The evidence, she said, is that misinformation really does spread faster than the truth. A few months ago US researchers published a striking demonstration of this. Writing in the journal Science, Soroush Vosoughi and colleagues from the Massachusetts Institute of Technology reported the results of their in-depth investigation of the interaction between social media and the news (1). They analyzed 126,000 rumours which circulated around 3 million people on Twitter between 2006 and 2017. They included conspiracy theories around the 2013 Boston Marathon bombing, the Sandy Hook shooting and the Bataclan attack in Paris; the Apple-Samsung patent battle and propaganda for the US election campaign. “The investigators teamed with Twitter and had access to the whole Twitter database.” The tweets were examined by six independent expert fact-checking organizations to establish if they were true or false. The result? “Tweets containing false information spread faster, faster, and more broadly. And the other striking finding was that the spreaders were not bots, the false news was being spread by humans.”

“We find similar results whether we are talking about news around science, technology, politics or terror events.” If the story was false, the MIT team concluded, it was 70 per cent more likely to be tweeted by more than 1000 people. True stories were rarely tweeted by more than 1000 people.

“The more shocking and novel the story, the greater the element of surprise or disgust it contains, the more likely it is that the story will spread.” An artificial intelligence device has now been created that can predict, based on various features associated with veracity, how a story will spread on Twitter – with 75 per cent accuracy. Not surprisingly, social media advertising has found that false stories are a more powerful vehicle for sales than the truth. To turn to health – in 2015 the Guardian, BBC Radio 4 and the British Medical Journal all slammed the then health secretary Jeremy Hunt for misrepresenting data to allege that death rates are higher among patients admitted to hospital at the weekend. Yet the myth persists.

To learn more about why, we turned to Dr Jens Koed Madsen, of the Oxford Martin School, University of Oxford, where he researches the development of formal models of reasoning and decision-making. His PhD was in “the power of persuasion”. He gave us some disturbing facts about what he calls “Wonky beliefs”: 97 per cent of experts agree that climate change is real, yet only 42 per cent of the US population believe there is any consensus among scientists. Similarly, we see people defy scientific consensus to embrace wonky ideas that the earth is flat, that the moon landings were faked and more dangerously, that vaccines cause autism.

Is it enough to just weigh in with the facts? “The evidence suggests not, and trying to correct people may even backfire by making their beliefs even more entrenched and extreme.” There are “gulfs in beliefs” he said, quoting from Turgenev’s classic Fathers and Sons (1861) “Man is capable of understanding everything – the vibration of ether and what’s going on in the sun; but why another person should blow his nose differently from him – that, he’s incapable of understanding”.

To understand why accurate information is just not enough, we need to take into account the beliefs already held by the subject. “New facts must fit into their belief structure in order to be assimilated.” There are other modifying factors: the credibility of the person giving the information, and whether the source is viewed independent or not. “If you can find someone who believes in a concept to the same degree that I believe that Paris can be found in France, you can see how… (cont. Page 12)
parent who is convinced that vaccines cause autism will react with complete mistrust to everything said by a doctor who says they don’t.”

People are drawn to others sharing their beliefs and views, forming echo chambers – for example anti-vaccine groups in California can be like closed circles, in which everyone is engaging with like-minded others. Their exchanges serve to reinforce each other’s beliefs. “We’ve even been able to simulate this effect using artificial intelligence, mimicking the flow of information in complex social networking systems. As time goes on, the false information is repeated and shared with increasing levels of confidence.”

Fact-checking alone is never going to be enough. If you present people with reliable evidence that conflicts with their established beliefs it may increase their adherence to that deep-rooted belief. To modify a belief, you first need to understand how and why people search for information, how their information network is structured and, only then, how it might be restructured. “What we badly need,” he concluded, “is research based on psychologically plausible dynamic models, so that we can try out possible interventions, and combinations of interventions, and track how they play out in real life situations.”

By this point, though entertained, our audience was beginning to feel a little dizzy with the size and complexity of the task of correcting health misinformation. It remained to Dr Geoff Walton, information scientist from Manchester Metropolitan University, to offer hope.

He has been looking at what distinguishes people who have a good and bad levels of what he calls “information discernment” or ID – the ability to take information presented, judge its quality, and use it to make well-calibrated conclusions. Because there are differences.

“High ID people exhibit curiosity about the world, they tend to take their information from more than one source, they consider contradictory information and check the credentials of different authors. Low information discerners are less likely to show that awareness and critically examine information that is put in front of them.”

Walton demonstrated this by showing heat maps which showed how study participants read elements in a complex infographic poster about terrorism. The poster included text, pictures and graphs. Their study found: “High ID people scanned the whole poster, processing all the information that was available, in order to come to a balanced view. Participants with low ID only read some of the text and barely glanced at the graphs and tables.”

To come to the crux of the matter – is it possible to increase an individual’s ID level, to support them to become more critical thinkers and better able to judge whether news is likely to be true or false? “Yes, with the right training. It has to be collaborative, practical and conversational.” Young people especially are open to learning to be more discerning, says Walton. “Teach them that accuracy and veracity really matter. Encourage children to question information but not to dismiss it. The level of discernment is not necessarily correlated with the level of a person’s education. We need to promote questioning without encouraging people to be cynical.”

Our audience left reassured, stimulated and inspired.

HealthWatch offers thanks and appreciation to our invited lecturers, to King’s College London for hosting in their comfortable and well-equipped lecture theatre, and to HealthWatch committee members Philippa Pigache and Debra Bick for all their work organizing the event.

Mandy Payne
Editor, HealthWatch Newsletter

Reference

Postscript to report on debunking symposium

At the symposium I was astounded to learn that a very significant number of people use social media as their main or sole source of news. Perhaps I should not have been surprised – after all, Twitter, Facebook, etc., are the modern equivalent of the village pump, around which news and gossip were traditionally shared.

I was reminded of a survey conducted in 1969, to celebrate the centenary of the invention of margarine, by the Margarine and Shortening Manufacturers’ Association, to determine the public’s knowledge of nutrition. (The bottom line is that it was abysmal.) Unfortunately, I cannot find the original report, although there is a commentary on it in British Food Journal, 71:6, 168, 1969. What sticks in my mind is that, when asked where they would go for information about nutrition, a very significant number of people would ask friends and neighbours, while only a very small number would ask a nutritionist or dietitian. But then presumably very few knew such people existed. Many would ask their doctor (and the commentary noted that at that time there was very little about nutrition in the medical curriculum, something that has improved in the last half century). A significant number said they would use books, magazines, TV and radio, although it is doubtful if they could distinguish between “sound” books and magazines and those more on the fringe that can be found in the “popular nutrition” section of large bookshops.

David A Bender
Secretary, HealthWatch
Breast cancer treatment: Doctor’s Dilemma or Patient’s Choice?


This lively one-day event had big ideas. It covered three areas where women don’t always get the information they need to make a shared decision with their doctors – screening for breast cancer, hormone replacement therapy at menopause, and intra-operative radiotherapy after breast conserving cancer surgery. The day was organized by Pink Ribbon (1), an international network of practitioners, patients and political campaigners; and the Latte Lounge (2), an online support forum for women over 40; with support from Europa Donna: the European Breast Cancer Coalition (3), an independent non-profit that advocates for better education, screening, treatment and research for breast cancer. The meeting’s aim was to help women already diagnosed, or in at-risk groups, to be able to take a more active role in partnership with health care teams. The room was filled with patients, researchers, nurses, radiographers, doctors and – so far – healthy women; it was also streamed online to Latte Lounge members, who took part in the discussions.

Journalist and broadcaster Kirsty Lang, who has herself been treated for breast cancer, was a warm and knowledgeable chair for the panel discussions.

First, to the debate on breast screening. This was the reason HealthWatch was there. We have been opposing mass screening by mammography for over a decade, on grounds that it saves no lives overall and causes excessive harm. So we were interested to hear how Anthony Howell, professor of medical oncology at the Manchester University NHS Foundation Trust, and Research Director for the charity Prevent Breast Cancer, would present the case for screening’s defence.

He showed graphs demonstrating a sharp decline in deaths from breast cancer since the UK breast screening programme began in 1987 (at HealthWatch we believe the evidence points to these lives being saved by improved care, rather than screening). A forest plot showed how meta-analysis of randomized controlled trials of breast screening concluded that it reduced mortality from breast cancer by 20 per cent. In absolute terms, that equaled one breast cancer death prevented for every 200 women screened for 10 years.

Professor Howell then questioned the extent of overdiagnosis – this is finding cancer which, if undetected, would never have made its presence known in the patient’s lifetime but which, having been found, leads to aggressive treatment with all its accompanying risks. Estimates vary widely, he said – anything from 5 per cent to over 50 per cent of screen-detected breast cancers have been said to be over-diagnosed. “Whatever one’s personal opinion on the extent of overdiagnosis, we can find evidence that contradicts it.” It is difficult to get accurate figures because so very many women have to be screened to see any result, and those data are easily contaminated by outcomes resulting from other causes. For example, there may be concurrent improvements in treatment, or deaths from different cancers or other causes; all things that may or may not have been a result of either the screening or the treatments.

Howell’s current research: the “Prediction of cancer screening” PROCAS trial, under way in Greater Manchester, aims to find a way to identify women who are at higher risk of breast cancer and who therefore would be more likely to benefit from being screened. Women in the trial complete a risk factor questionnaire, give saliva test for DNA to detect single nucleotide polymorphisms, and have an assessment of breast density – more dense breasts being linked to higher risk of cancer. This is “risk adapted screening”, which would find a subgroup for whom the screening risk-benefit balance is tipped further towards benefit than for the average woman. This sounds like a useful goal.

Howell then introduced his debate opponent with a graceful tribute: “a visionary and a great man, responsible for the greatest advances in breast cancer treatment.”

Here Michael Baum stepped up. He is professor emeritus of surgery, University College of London and, though an architect of the UK breast screening programme in the 1980’s, he now fiercely opposes it. His own mother had died of breast cancer in uncontrolled pain. Years later, he was tasked with the setting up of the UK’s first screening unit, in 1988. “I have a conflict of interest: I always wanted screening to work.”

The panel discuss breast cancer screening. From left to right: Renee Houndercamp, Michael Baum, Michael Howell
Today, though, Baum objects to what he describes as the coercion of women to be screened in order to maintain NHS targets. He resigned from the National Screening Committee when evidence persuaded him that the benefits of the programme were being exaggerated and harms ignored. “I was told that if we shared that information, and treated women as being able to understand complex issues, we would not meet targets.”

He savaged Howell’s claim that screening 200 women for 10 years saves a life. “It is absurd – that number can be derived only by using the most optimistic estimates.” He countered with the icon array chart produced by the Harding Center for Risk Literacy (4). This chart, based on best evidence, shows the results of mammographic screening on 1000 women over a 10-year period. In the screened group, we see one fewer breast cancer death. But we also see one additional death from a different kind of cancer in that group. So, the small red handful of cancer deaths is the same size whether women are screened or not. But a big square of green dots in the screened group shows the 100 or so women who suffer false alarms, further investigations, biopsies, chemotherapy and radiotherapy; a blue row represents an unnecessary full or partial removal of a breast. “In any group where you start breast screening, you get an increase in mastectomies,” he explained. “And radiotherapy is not benign – there’s a significant risk of ischaemic heart disease, increase in rate of major coronary events; and also higher risk of lung cancer – all increased risk of death.”

“So, if your cancer is not programmed to progress, you are being exposed to these harms for no purpose.” Some screen-detected small cancers stabilize, or get smaller, says Baum, and woman are better never having known they were there. So, what should we do? “We’re doing an amazing job with modern treatments. But there’s more to life than breast cancer and we risk losing sight of other diseases that are a greater threat to women’s health, like dementia and osteoporosis. The answer must surely be better risk assessment and risk management, which is where Professor Howell and I can agree – let’s improve tests that can determine who is at greatest risk. If we can reduce the toxicity of breast cancer treatments then the benefits of screening will start to outweigh the harms. But for now, we have to change our attitude and complacency over screening, which is a political issue.”

Dr Renee HounderCamp is an NHS GP, BBC Radio London’s resident GP, writes for the Daily Express and OK magazine, as well as the Latte Lounge; and is at 51 the mother of an 11-week-old baby girl, who was the most popular member of the audience. So, HounderCamp asked rhetorically, what is the GP’s role in screening? “Sadly, there is none. Breast screening is a standalone service. My patient gets a letter, goes for a mammogram, and the first I know is when she self-presents with a diagnosis.”

Yet counselling should be crucial in the decision whether or not to go for screening. “We have a duty, recognized in law via the Montgomery ruling, to tell the patients every single risk, even very small, as well as the benefits. As a GP I need to be able to arm patients with all the information they need to give an informed consent. As it stands, we are not part of that process. We should be.”

A lively discussion followed. A listener online reported having had two private mammograms, and ending up back at her GP surgery – her worries over clinically meaningless findings of “fatty tissue in the breast” were now another burden on the strained NHS. Then, a mammographic radiographer in the audience described how, in her five-minute appointments, she asks if women have read the leaflet they’d been sent. Mostly they haven’t, so how can that be informed consent?

Next up, all the way from the University of Southern California, was Dr Avrum Bluming, clinical professor of medicine and author of Oestrogen Matters: Why Taking Hormones in Menopause Can Improve Women’s Well-Being and Lengthen Their Lives – Without Raising the Risk of Breast Cancer. His 50-minute talk on the benefits and harms of hormone replacement therapy (HRT) was strongly and convincingly weighted towards the benefits. Post-menopausal oestrogen, he said, can prevent bone fractures and Alzheimer’s, increase well-being and lengthen lives. The fears it could increase the risk of invasive breast cancer, raised by the $1bn US NIH Women’s Health Initiative study in 2002 and which triggered a 75 per cent crash in use of HRT, are now thoroughly debunked, he said. He slated the methodology of the Million Women study that had linked oestrogen use to breast cancer, and pounded us with slide after slide demonstrating that, far from causing breast cancer, oestrogen was more likely to protect against it. “Don’t let fear be the sole determinant of your decision,” he told the women in the audience. “The more you learn the more you know the less you fear.”

The HRT showcase continued with GP Louise Newson who had set up her own private centre (5) in response to inadequate funding for menopause services in UK, low levels of understanding among doctors and poor adherence to NICE guidance on menopause treatments. “Many women end up being given antidepressants inappropriately.” This comment was brought to life by menopause counsellor Diane Danzebrink. She gave her own moving perspective from the point of view of a patient who had suffered severe depression in an early menopause brought on by a medical hysterectomy. It was not until she came close to suicide that she was given HRT, which had restored normal life.

Of the afternoon’s speakers the biggest impression was left by Jayant Vaidya, professor of surgery and oncology at University College, London, who described his team’s development of an extraordinary innovation in the treatment of breast cancer. Following lumpectomy, most women undergo weeks of radiotherapy, which can be painful, stressful, scarring, and costly to the patient in terms of time, lost work and an average

---

“If your cancer is not programmed to progress, you are being exposed to these harms for no purpose”

(cont. Page 15)
30 hours travel per patient. TARGIT Intra-operative radiotherapy (IORT) involves applying that radiotherapy only once: during surgery itself. After removing the tumour, the machine bulb is inserted into the wound, applying radiotherapy directly to the tumour bed, concentrating the dose where needed and sparing the heart, lungs and other nearby tissues from harmful rays. Efficacy in controlling cancer is similar or better than for the whole-breast post-operative radiotherapy courses currently offered. As well has having obvious benefits for patients, implementing TARGIT IORT across the UK would save the NHS almost £10 million a year. Not surprisingly, hundreds of centres across 35 countries globally are rolling out the treatment. But, despite being rubber-stamped by NICE in 2017, NHS patients still cannot access this revolutionary cancer treatment developed in our own country. Why not? One theory is that many careers have been built around fractionated radiation therapy for breast cancer, so, depending on your perspective, IORT could be either a quantum leap forward or a serious threat.

HealthWatch will continue to oppose mass population breast cancer screening and promote quality information so that people can make a properly informed choice on whether to take up screening invitations. We would also strongly urge our readers to learn more about TARGIT (6) and consider visiting their MPs to call for this innovation to be introduced throughout the UK.

Mandy Payne
Editor, HealthWatch Newsletter

Further information
1. Pink Ribbon website: http://pinkribbon.co/
2. The Latte Lounge website: https://www.lattelounge.co/
3. Europadonna website: https://www.europadonna.org/
5. Menopause Doctor website: www.menopasedoctor.co.uk
6. Information on TARGIT IORT: https://www.targit.org.uk/

Consultation

NICE to share decisions with you

Most people will be familiar with NICE (the National Institute for Health and Care Excellence) and what it tries to do when it creates guidelines for the treatment of a particular medical condition: specifically, it seeks to provide evidence-based guidance on how to achieve the best, and most cost-effective, clinical outcomes for that condition.

The criteria for judging what is “best” usually involve hard outcomes (or as near as anyone can get to them) such as survival, freedom from symptoms, ability to live independently, reducing harms from medication, etc. But how do you establish guidelines for shared decision making, where the focus is as much on what patients want (and how they want to get it) as it is on external, “scientific” measures of success?

In early December Susan Bewley and I went along to a meeting in south London at which this problem was tackled: to their credit, NICE had asked a wide range of registered stakeholders, of which HealthWatch UK is one, to come to a meeting to discuss this issue. As one would expect, those attending came from very diverse backgrounds including, in our group, a decision scientist (a cross between a behavioural psychologist and a statistician), a paediatrician, a physician with RCP experience of assessing patient-focused care guidelines, a patient, a patient’s relative (with a mental health connection), a social worker, someone from NHS England and two people from NICE itself, one of whom acted as chair.

We began by considering why the guidelines are necessary. Surveys have shown that 44 per cent of inpatients and over 30 per cent of primary care patients want to be more involved in decisions about their care. Perceived advantages of shared decision-making may include: fewer regrets about decisions; less decision conflict; people being better informed and making decisions aligned with their values; better communication between people and their clinicians; better adherence to treatment; patients reporting a better experience, including more satisfaction with the outcomes, and a reduction in unwarranted variation in clinical practice. There is also a medico-legal view on this: a 2015 decision of the UK Supreme Court includes the statement that consent for medical treatment “should only be gained when patients have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable treatment options.” The court goes on to say that “it is the doctor’s duty to take reasonable care to make sure that patients are aware of any material risks involved in proposed treatment, and of reasonable alternatives”.

The new guidelines on shared decision-making are intended for both providers and commissioners of health and public health services and for people using health services, their families and carers. They will be, it was suggested, applicable to almost all areas of clinical practice apart from those dealing with life-threatening emergencies; this immediately brought up the difficult areas of diminished mental capacity and poor “health literacy”. As regards the first of these, most clinicians know what is meant by assessing mental capacity in people with mental illness, learning disability, dementia, etc. (even if doing so is frequently a challenge!) and the Mental Capacity Act makes it clear that people whose faculties are impaired still have a right (cont. Page 16)
to make decisions about their care in so far as they are able to do so. What is even more contentious is the business of ensuring adequate “health literacy”: how can we provide for shared decision-making in someone who is completely untutored in human biology or who has been brought up, for example, in a Christian Science family which doesn’t believe in medical treatments at all?

We next considered what existing information was relevant to the formulation of the guideline, including a number of existing NICE publications such as “Decision-making and mental capacity” (NICE guideline NG108), “People’s experience in adult social care services” (NICE guideline NG86) and some guidelines which are in development such as “Infant, children and young people’s experience of healthcare”, a NICE quality standard.

Finally, the group discussed some specifics about what to do next and also the question of who should be on the NICE committee which draws up the guidelines.

The various groups which had convened on the day met for a brief plenary session, after which the staff of NICE planned to spend the afternoon reviewing what had come out of the groups’ discussions and then writing a consultation paper to be aimed at all its registered stakeholders. HealthWatch went on to formally contribute during the consultation on this paper, which closed in February this year. The new guidelines are expected to be published in April 2021.

Roger Fisken, HealthWatch committee

Public health

Evidence-free hospital transport policy leaves old people stranded

Yesterday I qualified for ambulance car transport; today, I don’t. A fall and severe head trauma (subdural haematoma, multiple hairline skull fractures) left me unable to drive, so I was grateful to get ambulance car transport for a series of tertiary centre gastrointestinal appointments in the following months. I had to arrange these myself because I was ‘out of area’. Each time they asked the same question, “Do you have a health condition?”

I’ve had two cancers, one of which involved radical treatments and caused midline lymphoedema, long term pelvic radiation disease and allodynia (acute sensitivity to temperature, the slightest pressure, e.g., crossed ankles etc). I have osteoarthritis, with cervical spondylosis; osteoporosis, with spinal fracture at T11; bronchiectasis (breathlessness, prolonged coughing bouts, chest infections); and hip bursitis. Two conditions are progressive and require daily self-management.

Somewhat taken aback, I answered, “No”, because I was not blind or deaf, although I do use a walking stick outside. My list of ailments had often sparked the joking dry response, “I only needed one!” But today no-one asked about medical conditions. “Do you need someone with you when you go outside?” they asked and, “Do you use a stick when you walk about indoors?” I was shocked as the unexpected barrage of questions continued.

As a passenger, the slightest unexpected acceleration or braking causes instant, long-lasting head and neck pain, as do rough car handling and uneven roads; I need to support my head repeatedly, with a hand beneath my chin, while trying to keep my back rigid (a neck brace would cause too much head pain). I really do need to be driven by someone who understands my frailty!

“I feel stressed. Most of my health conditions cause, or exacerbate pain, which cannot be well controlled. “How many metres can you walk outside?” I had no idea – well, none, without pain! To stand for just a few minutes increases head and skeletal pain. Head sensitivity has increased since my fall: the softest pillow feels as if my head is being pressed into concrete. I need to change position regularly. Sleep has reduced to two-hourly slots. Unsurprisingly, massive fatigue and debility are part of daily life.

As a passenger, the slightest unexpected acceleration or braking causes instant, long-lasting head and neck pain, as do rough car handling and uneven roads; I need to support my head repeatedly, with a hand beneath my chin, while trying to keep my back rigid (a neck brace would cause too much head pain). I really do need to be driven by someone who understands my frailty!

Somewhat taken aback, I answered, “No”, because I am not blind or deaf, although I do use a walking stick outside to relieve pain. Later it occurred to me that since the head trauma I have been mostly confined to home. When kind friends arrange outings they carry my belongings because they know how frail I am and what causes pain (they don’t hug me any more!) Perhaps I should have answered, “Yes”.

I felt stressed. Most of my health conditions cause, or exacerbate pain, which cannot be well controlled. “How many metres can you walk outside?” I had no idea – well, none, without pain! To stand for just a few minutes increases head and skeletal pain. Head sensitivity has increased since my fall: the softest pillow feels as if my head is being pressed into concrete. I need to change position regularly. Sleep has reduced to two-hourly slots. Unsurprisingly, massive fatigue and debility are part of daily life.

As a passenger, the slightest unexpected acceleration or braking causes instant, long-lasting head and neck pain, as do rough car handling and uneven roads; I need to support my head repeatedly, with a hand beneath my chin, while trying to keep my back rigid (a neck brace would cause too much head pain). I really do need to be driven by someone who understands my frailty!

But I wasn’t asked about health conditions, or their effects. Suddenly, I was shocked to be told, “You don’t qualify!” Apparently, I had given the wrong answers. Yet I had recently qualified for a Council Disability Grant! My mind was in turmoil; head pain increased.

(“What’s happened to me?”, he thought. It was no dream...” Franz Kafka, The Metamorphosis)

As people age their health problems are liable to increase, but this does not seem to be taken into account. I explained I could no longer drive and was unable to use public transport (health conditions had prevented me from visiting family members for the past year) but was then given contact numbers for a community transport organisation – and taxis.

Locally, trains seats are no longer bookable. The small station has no toilets, and trains have a toilet in only one carriage. Cancellations and extreme overcrowding cause chaos and exacerbate frailty.

Roger Fisken, HealthWatch committee
passengers' health conditions; patients and elderly people cannot compete in the stampede for seats(1), or access the toilet. A six-mile taxi journey from my home to the train station costs £15; the tertiary centre is 42 miles away. The hospital letter pointed out I might need to stay an extra 3 to 4 hours for surgery pre-assessment. But community drivers only wait for two hours. I might also need to arrange a second hospital appointment if necessary, which would double the travel expenses.

Society’s attitude towards the elderly is often to see them as a blot on the landscape, perhaps deny them medical treatments(2) exclude them from medical trials - or include them, without fully informed consent(3). I learned that, apparently, the CCG (Clinical Commissioning Group) and local Ambulance Trust had held a meeting to change transport qualifying criteria. A reliable inside source told me that concerns had been raised by patients in their 80s and 90s who were terrified of having to drive themselves to hospital on the notorious A64 with its “rush-hour motorway madness”(4, 5).

Community transport for my next hospital appointment would cost an £18.00 membership fee, plus £47.50 mileage(6). People who, like me, are eligible for the Healthcare Travel Costs Scheme (HTCS) may be able to claim a refund(7). However, according to NHS Business Services Authority information, hospitals “decide whether you can get a refund based on what they deem to be ‘necessary travel’”; “the rates at which hospitals reimburse travel costs are set entirely at their own discretion”; and if you qualify for a refund, the hospital will pay you directly, but “this can take several weeks”(8). Claiming travel costs ‘on the day’ can entail: bringing proof of benefit; obtaining signed proof of attendance; and walking the entire length of a hospital after an appointment to locate the cashier’s office, only to find it has closed early. The hospital said they could not pay community transport costs and offered me only £15.23 (although a manager later reversed this decision).

Without client consultation, or an evidence base, changed policies are more likely to cause serious difficulties rather than result in improvements: older people are put at risk; medical conditions become exacerbated to the point where they become emergencies, which brings increased burdens on the health system. Will this new policy be rolled out nationally? I am 79 and have attended the tertiary centre five times in the past eight months. In winter, with fuel, food and electricity prices rising, the cost of hospital visits is not affordable for some. I have just cancelled next week’s appointment with the gastroenterologist.

Mitzi Blennerhassett, Medical author, Slingsby, Yorks, and MJA Award Winner for “Nothing Personal, disturbing undercurrents in cancer care” (Radcliffe Pub Ltd, 2008)

Postscript: on March 18, 2019 the author was advised by NHS Scarborough & Ryedale CCG that they would be supporting her appeal to receive patient transport from Yorkshire Ambulance Service.

References
1. BBC1 Inside Out, North East and Cumbria, 10 September 2018.
2. Oliver C. Why did they put her on a geriatric ward? BMJ 2018;362:k3701 [https://www.bmj.com/content/362/bmj.k3701]
3. Margaret McCartney. A trial to extend breast screening may be unethical. BMJ 2014;349:g5105 [https://www.bmj.com/content/349/bmj.g5105]
4. Motorway Database: A64 [http://www.roads.org.uk/motorway/a64]
6. Ryedale Community Transport [https://ryedalect.org/]

Last word

Dealing with misleading claims, Californian style

In this country, if we come across a misleading claim for a product, we can go to the ASA and/or Trading Standards, asking for the misleading claims to be withdrawn. Things appear to be different in California. A company is being sued for $5 million in a class action over a biotin vitamin supplement.

The product concerned provides 5000µg of biotin per tablet (and the recommended dose is two tablets per day), compared with an Adequate Intake of 30 – 50µg. There is little or no evidence on which to set a Dietary Reference Value for biotin, since deficiency is unknown except in people with a rare genetic defect, or consuming very large amounts of raw egg white, and the Adequate Intake figure is based on average intakes of biotin, which are obviously more than adequate to prevent deficiency.

The basis of the legal action is that the company claims on the packaging that the product “provides hair, skin and nails support”. The plaintiff’s case is that this health benefit representation is “false, misleading and reasonably likely to deceive the public”. I agree with the plaintiff. It is true that the rare cases of biotin deficiency involve skin and hair abnormalities, but there is no evidence at all that intakes that are more than adequate to prevent deficiency will have any beneficial effects on skin, hair or nails. At least there is no evidence that such massive intakes of biotin as would be provided by this supplement have any adverse health effects; neither the US Institute of Medicine nor the European Food Safety Authority
(EFSA) found any data on which to base safe upper levels of intake.

The US Food and Drug Administration has lists of permitted health claims, but it is perfectly allowable in USA to make an unsubstantiated claim, provided that the following wording is also included: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” You might wonder what is the point of something that is not intended to do anything useful, but conspiracy theorists will take the view that this is something beneficial and useful that the FDA and US government want to prevent us having.

David A Bender
Emeritus Professor of Nutritional Biochemistry,
University College London

Published by HealthWatch

www.healthwatch-uk.org

President: Nick Ross
Chair: Susan Bewley
Vice-Chair: Keith Isaacson
Secretary: David Bender
Treasurer: Anne Raikes
Newsletter Editor: Mandy Payne

Committee: Roger Fisken, Andrew Fulton, Alan Henness, John Illman, John Kirwan, James May, Tom Moberly, Philippa Pigache, Les Rose, Kenneth Chan, Jolene Galbraith, Sofia Hart and Ruth Lamb are Trainee Doctor Representatives. James Illman is Medical Journalist Representative.

Press enquiries please use contact form at https://www.healthwatch-uk.org/media or e-mail enquiries@healthwatch-uk.org

Opinions expressed in letters and articles published in the HealthWatch Newsletter belong to the authors and do not necessarily reflect the views of HealthWatch. Authors are responsible for the factual accuracy of their own articles; the editor reserves the right to amend text if necessary but will, where possible, consult the author to ensure accuracy is maintained.

Unless otherwise indicated, all web addresses referenced in this issue were accessed on or after 7 February 2019.

Letters and articles for publication are welcomed and should be sent to the editor at: newsletter@healthwatch-uk.org For our requirements please see https://www.healthwatch-uk.org/authors

HealthWatch is the charity that has been promoting science and integrity in healthcare since 1991

We stand for:
• The assessment and testing of all medical and nutritional treatments, products and procedures
• 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

We are against:
• Misleading advertising of health products
• The sale of unproven remedies to the vulnerable and desperate
• Unethical marketing by pharmaceutical companies
• Misconduct in clinical trials
• Media misinformation on health and nutrition
• Government promotion of health and screening programmes unsupported by evidence

Our activities include public debates, symposia, awards, a student competition, and this quarterly newsletter. HealthWatch welcomes membership enquiries from those who share its aims. Join at https://www.healthwatch-uk.org/join

Patrons:
Robin Ince
Professor Steve Jones FRS
Dr Margaret McCartney
Sir Michael Rawlins
Lord Dick Taverne QC

Registered Charity No 1003392