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HealthWatch Newsletter

for Science and Integrity in Healthcare

Issue 117, Winter 2021-22

We will be HealthSense

For over a decade we have dealt with the confusion and daily administrative burden resulting from our charity's (un-registered and un-copyrighted) name being appropriated by the completely unrelated government initiative "Healthwatch England".

At our October AGM members voted for change and, as a result, early in 2022 we will adopt the name HealthSense. A logo is being developed that will look new and modern while retaining enough of the feel of our original branding to limit any confusion.

The Charity's Commission has now accepted our proposal to change our name, but there are some administrative challenges to tackle before it can be fully enacted. One of the most significant and labour-intensive is a new, modern layout that is being created for our website. We will also have to change our social media identity. Our thanks go to our web designer, Alan Henness who, like our other committee members, does this exceptional work as a volunteer.

An announcement will come in the coming weeks with timings and details of our relaunch, but for the time being we would advise members to continue to refer to us as HealthWatch.

News in brief

Consultation success: Professional Standards Authority

We are pleased to report that another of our consultation responses seems to have hit home. The Professional Standards Authority (PSA) is to introduce a 'public interest' test as part of its Standards for registers of health and care roles not subject to statutory regulation. The test will allow the PSA to weigh up whether the evidence about the benefits of treatments covered by a register outweigh any risks.

With the publication of the new standards, the Society of Homeopaths withdrew from the accreditation scheme and can no longer claim accreditation. This development was celebrated in *The Times*, and owes much to the work of the Good Thinking Society.

The response submitted by HealthWatch to the PSA's public consultation had expressed concerns over the potential for the public to be harmed or misled by claims made for unproven treatments provided by members of bodies that are given credibility by being registered with the PSA. The PSA oversees 10 statutory bodies that regulate health and social care professionals in the UK, and these include the General Chiropractic Council and the General Osteopathic Council. More information is here.

BMJ award for Christina Pagel

Christina Pagel, joint winner of the 2021 HealthWatch Award, has also picked up a BMJ special recognition award for public engagement in science during the Covid-19 pandemic. She was praised for her work on how the evidence around coronavirus can be explained to the majority, given the general lack of understanding of science and statistics throughout each wave of the pandemic. Christina Pagel is Director of the Clinical Operational Research Unit at University College London.

Exposing threats to research integrity: this year's John Maddox Prize winners

Dr Elisabeth Bik has exposed data manipulation, plagiarism, image manipulation or methodological concerns in almost 5000 scientific papers, and communicated her findings directly to the public in an effort to improve understanding of the importance of research integrity. The dogged and courageous investigations of this Dutch microbiologist and scientific integrity consultant have now been rewarded with the 2021 John Maddox Prize.

As she commented, "Work on science integrity also is often not considered to be a real part of science, with little to no funding opportunities." We congratulate Dr Bik and

In this issue:

all our fellow volunteers labouring in the pursuit of sound evidence.

An additional early-career prize was awarded to Dr Mohammed Sharif Razai, a clinical fellow at St George's, University of London, for bringing an evidence-based understanding of racial health inequalities to bear in public and policy debates. The John Maddox Prize was presented this year at the Wellcome Institute on 1 December. It is a joint initiative of the charity Sense About Science and the scientific journal Nature.

NEW PUBLICATIONS

How much data does NICE redact?

A key function of the National Institute for Health and Care Excellence (NICE) is to produce guidance on medicines, devices and other interventions for their use in the National Health Service (NHS). While NICE are rightly praised for transparency of their processes, they take a lenient position on redacting data in their publicly available documents. Data on, for example, adverse effects of a new drug, might not be available for scrutiny. A BMJ Open paper by HealthWatch's vice-chair Leeza Osipenko is the first comprehensive audit of data redaction practices in NICE's technology appraisal programme. It finds that over 20 years 82% of NICE's documents pertinent to these assessments have some level of data redaction.

Over the past 5 years the extent of data redaction has increased and today no appraisals are published without blacked-out data in background documentation. Data redaction is never reversed. Even when the data is published in the literature or becomes available on regulatory websites, NICE redactions remain. Policy change is urgently needed to make data available to patients and clinicians.

Osipenko L. Audit of data redaction practices in NICE technology appraisals from 1999 to 2019. BMJ Open 2021;11:e051812 with Leeza's Consilium talk on the subject here (duration 1 hour 20 minutes).

Can drug-induced fetal damage be passed on through the generations?

A short communication published by two HealthWatch activists describes higher than expected rates of malformations in children born to parents who themselves had suffered complications by being exposed to the drug valproate in the womb. Among the 90 families surveyed, 187 children had been born of which 53% had either malformation or neurodevelopmental disorders. The authors, including HealthWatch chair Susan Bewley and member Alain Braillon, call for funding for research into possible transgenerational effects of drugs known to cause malformations or neurodevelopmental disorders. Individuals who had been exposed in utero to valproate must be informed about the possibility of risk to their own children, so they can consider fertility options, antenatal diagnosis, and adequate early surveillance.

Martin M, Hill C, Bewley S, MacLennan AH, Braillon A. Transgenerational adverse effects of valproate? A patient report from 90 affected families. Birth Defects Research 2021:1-4 (subscription required)

WEBINAR CATCH-UPS

Transparency, power and influence in the pharmaceutical industry

The five academics behind the book of the above name took part in a panel discussion to interrogate the successes and failures of transparency, including in the context of COVID-19. Hosted by the MacEachen Institute for Policy and Governance at Canada's Dalhousie University, the one-hour session is viewable online here.

Debating COVID-19 Vaccine Boosters: Public Health Strategy in a Shifting Landscape

In a fact-packed and sometimes heated session, a group of US public health experts presented data on the long-term effectiveness of COVID-19 vaccines before debating the need for vaccine booster shots. As fascinating as the individual presentations were, the discussion that followed was even more compelling – scientists on the panel presenting quite different views on the ethics based on the same evidence. It provided a glimpse into the complexities of public health decision making in the pandemic. Hosted by the University of Minnesota Consortium on Law and Values. Recording lasts 90 minutes.

See Consilium lectures on YouTube

Recordings of the weekly lectures from Consilium Scientific are now freely accessible online on their YouTube channel. Recent topics include "Disclosure of R&D industry payments in Europe", "Is EBM being hijacked in oncology?", and "Reading the literature with a critical eye". Find out about upcoming events on the Consilium Scientific website.

Harnessing the placebo effect without deception

A new series of seminars on the Science of Suggestion & Suggestibility brings together researchers and clinicians studying the science and application of suggestion. The recording is now available for a recent one-hour talk by placebo expert Professor Irving Kirsch of Harvard Medical School, about some fascinating research that has found that dummy treatments can be effective even when presented openly and honestly as such. Watch it here and check out forthcoming seminars on the Science of Suggestion & Suggestibility website.

Free e-learning on shared decision making

NICE have included a free e-learning package on shared decision making to accompany their new guideline. The package, which has a good mix of videos, diagrams and reading, comprises six modules split over 4 hours. Although aimed at health care practitioners, it might be of interest also to students of medicine and health care, patients and interested members of the public. Try it here.

A hidden web of influence

A recent paper looks at how the pharmaceutical industry – and the organisations it funds – works via All Party Parliamentary Groups (APPGs) to interact with Parliament as part of a multi-layered web of influence. APPGs are informal cross-party single-topic groups which facilitate engagement between parliamentarians and external organisations. There have been concerns that some corporate interests exploit the unique opportunities for access offered by APPGs, turning them into a backchannel for lobbying. The study looked at financial reports between 2012-2018 from 146 health-related APPGs, and found that payments from external donors totalled £7.3 million, of which the pharmaceutical industry and industry-funded patient organisations supplied £2.2 million. In: PLOSOne, a paper from 24 June:

Rickard E, Ozieranski P. A hidden web of policy influence: The pharmaceutical industry's engagement with UK's All-Party Parliamentary Groups. PLoS ONE 16(6):e0252551

Automating scientific discovery

This is fun – it's a prototype for an automated science discovery engine built with a piece of code that extracts data from published work and churns out its own analysis. For input, you need to start with a database that applies to your

chosen research field, search the hypothesis space, and formulate a theory for the data to support or disprove. It is all explained in this article, and you can play with a live example which explores the relationship between democracy and growth, here. Just slide the scale from left to right to see how the conclusions change with the regression values.

2021 HealthWatch award winner

COVID-19 Data – what's the story?

The joint winner of the HealthWatch Award 2021 was Christina Pagel, Professor of Operational Research, Clinical Operational Research Unit, University College London and a member of Independent SAGE.

Presenting the award, Nick Ross said, "How politicians reach their views on healthcare is of huge importance, especially at the moment. Christina Pagel has numeracy, literacy; she understands risk, and managing uncertainty. She also has a disarming way of taking things that to many of us are extraordinarily complex, and finding ways to unravel them and make them seem simple as daylight." Professor Pagel shares the 2021 award with David Spiegelhalter.

The following is a lightly edited version of her talk. The full recording of the HealthWatch Annual General Meeting 2021 and awards, including this presentation, can be experienced on the HealthWatch YouTube channel.

Independent SAGE

I was asked to join Independent SAGE when it started back in May 2020, based on my expertise in mathematical modeling and decision making. But it quickly became clear that was not what I was going to be doing. We have some of the world's most brilliant infectious disease modelers already in this country. What I felt I could do, was to talk to the public, to try and communicate the data, and to show them how different contexts, demographics and policy, affect the data.

Since last summer we have been giving weekly briefings to the media. We still get thousands of people tuning in every week and I hope it is making a difference. COVID data has inundated our daily lives, and we are all used to looking at cases, hospital admissions, deaths, and vaccinations. But the numbers don't speak for themselves. So, what do you need to know to interpret that data?

COVID data – what lies beneath

To know what exactly we are measuring, we need to understand how this disease progresses.

With COVID, you are infected on Day 0. You might become infectious to people 3-5 days after that. But it is not until days 5-7 symptoms that may appear, and *that* is when you first appear in the data on numbers of cases – as long as a week after you get infected, and then only if you get a test. If you don't get symptoms, or don't recognize them as COVID, you won't get tested. It also relies on you knowing how to get a test, wanting to get a test, and having time to get tested, and having the agency to act on a positive result. These are all biases that affected data on case numbers.

This has changed since we started doing asymptomatic testing, particularly in schools, although the accuracy does depend on whether the test is being done properly.

The NHS website offers a free PCR test which is the gold standard to check for coronavirus. It is offered to those with symptoms of a high temperature, a new, continuous cough, or loss of sense of taste or smell. *But these are no longer the most common symptoms of COVID*. The ZOE symptom tracker app lists the top five symptoms in children and vaccinated adults as being a runny nose, headache, sneezing, sore throat, and loss of smell. This has not been communicated at all, and is affecting people's likelihood of seeking testing.

Ten to fourteen days after infection, if it gets worse and you are admitted to hospital, that is when you show up in hospital data. The advantage of this data is, it doesn't rely on your testing behaviour. But it does skew to an older, sicker, and now unvaccinated population. So, while hospital data tells you something about the burden of COVID in your community, it misses a lot of cases. Last year, hospital admission data missed the rise in cases among students, and only showed later as their infections spread to the older people.

Finally, maybe three weeks later, someone might die if they get sick enough. It takes time for deaths to be registered, which is when they show up on the dashboard. All countries have good death registries but the data takes a very long time to come through, which makes daily deaths a very poor indicator of the state of a pandemic and, again, it skews to the oldest and sickest and unvaccinated.

Finally, there is long COVID, with symptoms usually 12 or more weeks after the initial infection, and can occur whether you've been asymptomatic, mild disease, or hospitalized. It's common, it is really hard to measure, so we don't measure it routinely. Which means that its burden is not feeding into policy decisions.

Contexts and demographics

Contexts and demographics are important. Take age. Pre-vaccination, hospital admissions and deaths were very much concentrated in older people. It is that relationship that informed the vaccine priority rollout, which had a really great impact in protecting the elderly.

This summer, as the school term ended, the Delta variant was running rampant, with very high case rates among school children, and through the summer among young adults as festivals and nightclubs opened. Currently, we have high case rates among 10 to 14-year-olds, and among the 40 to 50-year-olds – their parents.

We have all been affected by COVID, but we haven't all been affected equally. The most deprived communities have suffered disproportionately, with a combination of workplace exposure, and more having to work outside the home or in public-facing jobs. They are less likely to be able to isolate, living in overcrowded housing and without access to green space. They are more likely to get it, more likely to be hospitalized, more likely to die or get long COVID.

They are also less protected – there is a 20 percent difference in the vaccination rates between the most and least deprived populations. Looking at ethnicity, over 90% of white English over-50's are fully vaccinated, compared with about 65% of black English people.

When we compare ourselves to other countries, here in the UK we have persistently had a much higher level of weekly confirmed cases than the rest of Europe. Our vaccination levels are the same or not much lower than other European countries. Yet some of our most similar neighbours have much lower case rates, and many have not seen a back-to-school spike. That is partly because they have vaccinated their teens over the summer, but it is also because of

"vaccination plus" – they still have mask mandates for indoor spaces, many require COVID passes for entry to crowded venues. We should look around other countries to see what is working.

COVID data – interacting contexts

Look at what is happening around England. The North, the Midlands, and particularly the North East have consistently had higher case rates and hospitalizations than anywhere else. The impact of geography and deprivation on the disease is toxic politically, especially considering the regional restrictions last year.

Care homes represent another really tragic interacting context. Our most vulnerable populations, who bore such disproportionate numbers of deaths are being cared for by people from our most deprived populations – many could not afford to isolate if infected because they got no sick pay. These people might work agency shifts, moving from care home to care home, spreading COVID very effectively. SAGE did not understand this initially when they were modeling it, so could not foresee how to protect care homes during wave one.

The last context I want to talk about is hospital admissions. Although we've had quite a high burden this summer, it is nowhere near as high as last year, and that is entirely down to the power of vaccination.

But hospital admissions for children, are now as high as they have ever been. Cases stayed low until the Delta variant came in during the summer, and mask mandates were removed. We have had over 4,000 under-18s admitted to hospital with COVID since 1 May 2021. So, for children, the risk right now is the worst time of the pandemic. Even though their risk is low compared to adults, I don't feel that we should forget that.

Final thoughts

It has been a strange year and a half, life-changing in some ways. I never expected to be working other than behind the scenes, yet mostly it has been more public.

But the principles I have used in my "day job" have carried over into my role in Independent SAGE. I do a lot of looking at data in hospitals, communicating it to clinicians and also to patients and the public. And I've directly taken the learning from that job into this role, but I've also learned so much about, what are the pitfalls in COVID data? What is important to understand? Where is the story hiding in the data? How much detail do I need to tell people?

A running theme has been combining knowledge, evidence, and expertise from as many different areas to try to make sense of the whole, and then communicate it as honestly as I can, the good news as well as the bad.

Data is not neutral. Understanding is hard, and you have to make decisions in an uncertain situation. For example, on child vaccination, the government's Joint Committee on Vaccination and Immunisation may have wanted to wait for six months for more safety data. But, by that time, most children will have been infected.

It has meant a huge amount of work on top of my day job. It has changed how I interact with people online, I have a lot more twitter followers so if I make a mistake it will be very public.

But it has been a privilege and a responsibility and one I take very seriously.

Edited transcription from Christina Pagel's talk. The full recording is on the HealthWatch YouTube channel.

HealthWatch AGM

Chair's report 2021

Presented by HealthWatch's Chair, Susan Bewley, at the 2021 HealthWatch AGM on 6 October, at the Royal Society of Medicine.

This has been a steady year. HealthWatch holds its first hybrid (mixed in-person and virtual) AGM thanks to the continuing pandemic and mitigation via vaccinations and other precautions and moves to the Royal Society of Medicine as a more accessible venue. Our membership numbers remain constant (see the table on the next page).

Our trustees continue to give their volunteer service with good attendance over Zoom. With inevitable turnover, we are sad to say goodbye and offer many thanks to the irreplaceable Anne Raikes who is stepping down as Treasurer after managing our finances so prudently for so many years.

Committee meetings: we have met together six times with other occasional meetings on specific subjects. The process of writing job roles and tighter governance grinds slowly forward.

Googlegroup: This has grown slightly and continues to have largely respectful but robust internal discussions, especially about the nature of diagnoses, harms of treatments, medically unexplained symptoms, and NICE's stand-off with Royal Colleges.

Website: The newsletter and website remain an excellent source of information going to subscribers, students, media, and medical schools. We have increased the number of Twitter followers to more than 1,300. Many of our members are active in 'Medical Twitter'.

Youtube channel: In the last twelve months we have live-streamed three Award lectures which can be found on the HealthWatch YouTube channel alongside the 2015 Saatchi debate.

Newsletter: Amongst news, book reviews and special articles, highlights of the HealthWatch Newsletter this year included reports on the success of our joint transparency campaign; shocking findings in the private healthcare sector reinforcing the case for a register of doctors' interests; ME and why it is not only drugs and devices that can harm; trouble with nutrition research; historical quackery; Covid-19 and fermented foods; why antidepressants are overprescribed; the dark side of biomedical research; are children's orthodontics really necessary; and alternative medicine and women's healthcare needs.

HealthWatch Student Prize: An enormous amount of work goes into running the unique and successful competition which continues, with prizes for winners and runners up now generously sponsored by the Royal College of Surgeons of England. A student group, working with Andrew Fulton, is producing an education resource, compiling material to help students read and critically analyse research protocols for flaws.

Annual Award: In view of both the pandemic and HealthWatch's 30th birthday, the Committee decided to give two awards this year: (1) 30th Birthday Award to David Spiegelhalter, Winton Professor of the Public Understanding of Risk at the University of Cambridge, who spoke about 'the battle against naughty numbers in the news' and (2) our Annual Award is to another excellent communicator - Christina Pagel who is Professor of Operational Research at

University College London and a member of Independent SAGE.

Public Consultations: Roger Fisken collated, wrote and made submissions to: NICE, on shared decision making; Department of Health, on a proposal for a Patient Safety Commissioner; House of Commons Science & Technology Committee, on Reproducibility in Research (Peter Wilmshurst helped in compiling a compelling argument for better investigation and prosecution of fraud); UK National Screening Committee, on public involvement; NICE: update of guidelines for elective caesarean section; DHSC women's health strategy; the Professional Standards Authority on proposals to reform its Accredited Registers programme and the MHRA on a proposed strategy for patient and public involvement.

Research Fund: Awarded a new grant to Margaret McCartney at the University of Dundee to supervise students on a project investigating the public's access to declarations of interests, and approved a no-cost extension due to Covid to Till Brucker's transparency project.

Charity Commission: Work continues, partnering with the Good Thinking Society, to challenge the perceived lack of action on charities peddling pseudoscience. We were featured in Private Eye (issued dated 26 May 2021). Les Rose has compiled an impressive record of nearly a decade's worth of complaints to the Commission. The CEO rejected our briefing paper. We will next approach the Chair or new Secretary of State at the Dept of Culture, Media & Sport who have oversight of the Charity Commission.

MHRA and devices: We have corresponded with the Medicines and Healthcare products Regulatory Authority about our concerns over the promotion of bioresonance machines, and also sent a letter jointly with the Good Thinking Society about thermal imaging to Matt Hancock. We are keeping a watchful eye on nutraceuticals.

Misleading advertising: A HealthWatch member had success with Lloyds Pharmacy, helping to persuade them to withdraw misleading anti-viral claims.

Open Government Partnership: The Chair and Newsletter editor are contributing to the UK arm of this initiative which aims to use open data and participatory, accountable public decision-making in order to build stronger healthcare systems.

General Medical Council: The Chair and President had a meeting with GMC to discuss (1) sex/ gender markers where changes appear to have been made without legal advice or equality assessments, (2) a register of interests as recommended following the Cumberlege Report "First do no harm", which, especially in the case of medical devices, they appear keen to devolve responsibility to employers.

History reminiscence: Inspired by early founder members (Caroline Richmond & Vincent Marks), a Zoom reminiscence was held to record HealthWatch's origins, discuss archives and an article, which will appear in the next issue. More may follow.

Name change looking forward: As explained at last year's AGM, our problem of appearing fusty and also our brand having been drowned by the government's Healthwatch England has not been resolved. The committee examined favoured terms, but with difficulty in overlap and availability of domain names for a website and social media. With committee assent, the name "HealthSense" is being proffered to be voted on tonight.

Susan Bewley, Chair of HealthWatch

International news

Celebrating ten years of Friends of Science in Medicine

HealthWatch congratulates our sister organization on the other side of the world on their anniversary. Here, founding president John Dwyer talks about the early days of the campaigning Australian health champions, their achievements, and what lies ahead

In the early 80s, many of my patients with acquired immune deficiency syndrome (AIDS) were promised expensive cures by 'alternative practitioners'.

In 2002, the state's Health Minister asked me to chair an inquiry, the New South Wales Healthcare Complaints and Consumer Protection Advisory Committee (HCCPAC), to tighten controls on "wonder drugs" and "miracle cures", and to "combat dodgy cures and health practices". The committee of non-evidenced based practitioners deliberated for a year. Consensus was impossible.

Outbursts on behalf of individuals may generate publicity for 24 hours, but nothing changes. Loretta Marron was an exception. A health scare, which gave her personal experience of exploitation by 'alternative' practitioners, started her on the path to exposing fraud. A skilled media user, the 'Jelly Bean Lady' (as she became called) used jelly beans to test the 'therapeutic' value of magnetised mattress underlays. Loretta substituted jelly beans under one mattress. Participants using a magnetism-detecting meter were not able to tell which contained the magnets.

Table: HealthWatch in numbers, 2017 to 2021

	2020-21 AGM	2019-20 AGM	2018-19 AGM	2017-18 AGM
Membership numbers (total)	229	232	212	231
Googlegroup members (total)	66	60	54	-
Twitter followers	1292	1185	979	842
Healthwatch UK youtube channel (views)	764	-	-	-
Cumulative HW Committee threads	3021	2416	1845	460
Cumulative Tweets (~500/ year)	2886	2648	2169	1630

In 2011, Loretta and some senior academics became concerned that universities were lending credibility to non-evidenced-based practices. She introduced me to Professor Alastair MacLennan, countering false information about cerebral palsy, and Professor Rob Morrison, a persuasive science communicator. Also concerned was Professor Marcello Costa, neuroscientist member of the Australian Academy of Science. Costa had been educating the public, about neuroscience and acupuncture.

Australian Skeptics, a group of volunteers who investigate pseudo-scientific and paranormal claims from a scientific viewpoint, had become alarmed by universities teaching pseudoscience. They produced a list of such courses. For example, the Royal Melbourne Institute of Technology (RMIT) which specialises in art and design courses was promoting a Complementary Medicine course that promised 'Energy Healing', and ran 'Open days' where Traditional Chinese Medicine (TCM) staff gave participants ear-rings which, placed strategically, were claimed to prevent and treat depression.

Southern Cross University in New South Wales and Queensland, employed a foundation Chair of Science practising 'Healing Touch', which was training homeopaths and ran an on-site clinic. Other universities offering Chiropractic courses were teaching 'subluxation theory', which claims that running along our spines is an essential invisible energy, and all illnesses result from bony 'subluxation' interfering with this energy. Although invisible with the latest imaging systems, this energy is supposedly corrected by spinal manipulation. Many practitioners were manipulating infants' cervical vertebrae and offering pregnancy care that included techniques to turn breech babies.

The Central Queensland University was proposing a Bachelor's degree in Chiropractic. They did not have a satisfactory response when we challenged them with our concerns over giving credibility to 'pseudo-sciences'.

The birth of Friends of Science in Medicine

Brought together by Loretta, we recognised that a formal organisation, of medical and scientific leaders promoting "credible scientific evidence underpinning the provision of health care", might be an effective force for good, and in 2011, 'Friends of Science in Medicine' (FSM) was launched, with Loretta as foundation CEO. Within a few months it had attracted 1,000 members. Ten years later, FSM is respected by those we want to respect us and loathed by many who feel threatened.

We approached the two major government agencies supposedly protecting consumers: the Australian Health Practitioner Regulation Agency (AHPRA) and the Therapeutic Goods Administration (TGA).

Australia's Health Practitioner Regulation Agency

AHPRA regulates health care provision through 15 standard-setting Boards. The 'National Law', the legislation that governs such boards, is inadequate. It allows them to determine what registrants may *advertise*, but not what they *do*!

Meeting AHPRA executives (none of whom is a health professional or scientist) and members of the Chiropractic Board, we found that Board included members some of whom were themselves advertising and practising pseudoscience. The issue of Board members apparently flouting the National Law also applied to Osteopathy and Traditional Chinese Medicine (TCM).

Our CEO 'bombarded' AHPRA and the Chiropractic Board with evidence from hundreds of practitioners' websites' false claims. All needed investigation and overburdened the AHPRA staff. In succeeding years, we provided hundreds of instances of fraudulent osteopathic and TCM advertising.

Reform came when AHPRA appointed a senior executive to oversee complaints, compelling registrants to respond within six weeks, stating what remedial action they intended to take. But it could not change what practitioners might actually *do*.

Chiropractic

The Chiropractic Board eventually informed registrants that they were not to offer pregnancy care nor claim to be 'specialists' in any given area of health care. Some states have recently forbidden them from manipulating young childrens' necks. Yet a majority still offers correction of the invisible 'subluxations'.

Acupuncture

When FSM came to review acupuncture – mostly offered by TCM practitioners and some registered doctors and physiotherapists – Marcello Costa's neuroscience expertise became invaluable. These practitioners had acquired credibility by the World Health Organisatio (WHO) recognising acupuncture's use in treatment of some 160 diseases/problems. The underpinning theory is nonsense (I.e., not science). There are no well-performed studies demonstrating that acupuncture can alter any pathology. It is "the perfect theatrical placebo".

The WHO's list of benefits, supplied by TCM practitioners, had been accepted without questions. When FSM approached the WHO, and after considerable wrangling, the recommendations were removed and replaced with plans for further study of the evidence prior to the provision of a new list. FSM met the Chair and members of the TCM Board and AHPRA executives. The latter seemed content with the Board's refusal to challenge their members, with the justification that "research was proceeding".

Osteopathy

Particularly objectionable techniques in osteopathy are what is called 'Osteopathy of the cranial fields' (OCF) and 'Visceral manipulation'. Osteopaths claim to feel, through the skull bones, pulsations of the brain's cerebrospinal fluid. This supposedly alerts them to disease treatable by manipulating the skull bones. The truth is that the fluid does not pulsate and that adult skull bones cannot be moved.

With 'Visceral manipulation', osteopaths palpate the abdomen and claim to send healing vibrations in different directions to treat diseases outside the abdominal cavity.

When we met members of AHPRA's Osteopathy Board, including the Chair, we pointed out that her own website advertised OCF. She promised to consider advising practitioners against this technique. No action resulted. As of today's writing, her website still offers OCF.

Nursing and Midwifery

In 2013, experienced nurse Joanne Benhamu, joined FSM's Board. She was concerned about the anti-vaccination movement and the role of nurses in championing evidence-based care. We complained to the Midwifery Board that midwives could get Continuing Professional Development points for studying reflexology. We got no traction about our complaint that some midwives' were claiming that they could turn a breech baby by placing crystals around a patient's bed!

Australia's Therapeutic Goods Agency

The Therapeutic Goods Agency (TGA) that oversees the safety of medicines and supplements that claim health benefits, and 'therapeutic' equipment – which was ostensibly a natural partner for FSM, turned out to be anything but.

The TGA, funded by the very companies whose products it regulates, is an example of a flagrant conflict of interest. It tells its funders that claims must be supported by credible science. But they do not have to *provide* proof, just have it available for a random audit. Few claims are checked.

When FSM first tackled fraudulent claims in the advertising of alternative medicine or so-called therapeutic instruments the TGA had an independent advertising review committee. This has recently, following pressure from industry, been dissolved.

Ten minutes' study of claims made for 'Bioresonance' devices, which aim to diagnose and treat diseases based on energy wavelengths purportedly measured by electrodes placed on the skin, should have been enough for the TGA to ban these products. It was years before our CEO's persistent badgering saw them de-listed.

Where is Friends of Science in Medicine now?

When FSM was studying problems of consumer protection and the TGA, we learnt much from Professor Ken Harvey, an outstanding Melbourne public health advocate. With unmatched knowledge of all things concerning the TGA, he has been an effective, vocal critic of its deficiencies. In 2014, he resigned from Melbourne's LaTrobe University when it accepted AUS$15 million in research funding from vitamins manufacturer Suisse Wellness. Harvey feared that the funding would constitute a conflict of interest that would taint resulting research.

Our mutual respect paid enormous dividends when, in 2019, Ken Harvey agreed to succeed me as President.

As we reach our ten-year anniversary, FSM is well respected by sister organisations in the US, UK and Canada. Australian media frequently consult us. No other organisation here is organised to champion evidence-based medicine and expose fraud.

The Australian legislative framework protects consumers poorly and needs an urgent overhaul. Hindering this is the powerful, profitable 'alternative' industry which influences political parties and governments' decisions. There is no protection from the myriad of registered self-identifying 'health professionals' offering unscientific, often dangerous, advice. Even the nation's pharmacists, schooled in evidence-based care, have allowed the profits from the sale of non-evidence-based products overrule their professionalism.

As foundation President, I am proud of what FSM has achieved. I don't doubt that the current committed and talented executives will work with our membership to tackle the many continuing issues. If you have taken the time to read this history, I encourage you to join, at no cost, and support our important, continuing struggle. See the Friends of Science in Medicine website for more information.

John M Dwyer, emeritus professor, University of New South Wales, Sydney, Australia

Public health

Assisted Dying: free speech meets the religious cancel culture of the British palliative care establishment

Colin Brewer, of "My Death My Decision" is concerned that open and respectful discussion about a topic that affects us all is being stifled

In April 2019, five senior consultant palliative care physicians (PCPs) wrote to the BMJ in support of assisted dying but explained why despite having "94 years of consultant level experience in palliative medicine" between them, they had to support it anonymously because "all of us have been stifled from talking about this topic".(1)

Every time it comes up in public debate, "the Association of Palliative Medicine emails its members with the clear and unequivocal direction that they are to oppose these developments. There is no concession to the possibility that other doctors practising high quality, ethical specialist palliative medicine may hold a different opinion—or simply want to hear different views". Even worse, the specialty lacks "a climate of open and fair discussion…where doctors do not fear being criticised, ostracised, or—worst of all—having their careers threatened". These are extraordinary claims but, unfortunately, entirely believable. To realise just how extraordinary and unique they are, you only need to remember the abortion debate that occupied many pages of medical journals in the late 1960s and early 1970s. Abortion divided medical opinion then just as much as assisted dying does now but numerous senior consultant gynaecologists and obstetricians publicly supported reform despite the opposition of many senior members of the obstetric establishment.

Depending on charities

Understanding this historical contrast requires an awareness of two features that distinguish British palliative care and the membership of its establishment from most of their counterparts abroad. The first is that for historical reasons and unlike any other part of the NHS, it is very dependent on charities, many of which are religious foundations. The second is that PCPs are "more likely to be Christian, white and report being 'very or extremely religious' than doctors in other specialties".(2) That makes them very different from the majority of their potential

patients, few of whom have strong religious views. British surveys show that around 90% of us now want some form of assisted dying (3) and like My Death, My Decision (MDMD) they also want it for the chronic degenerative conditions (including early Alzheimer dementia) that are resistant to treatment and palliation and make many old people long for death. They do not want it restricted to terminal illness, as Dignity-in-Dying advocates.

Palliative care had been a neglected field

Much of this ideological incompatibility between British PCPs and their patients originated with the devoutly religious Dame Cicely Saunders. In many ways, she was an inspirational campaigner who did much good. She almost single-handedly put palliative care, and British palliative care particularly, on the national and international map. At a time when many doctors were reluctant to inform cancer patients of their prognosis or even their diagnosis, it was a neglected area. For every doctor approving the royal physician Lord Dawson's famous 1936 one-liner that there was no need to legalise assisted dying because 'all good doctors do it anyway', there were others who ignored the problem.

Naturally, Dame Cicely attracted many like-minded Christians to the new specialty and they became its self-replicating establishment. If their concern for the dying were simply the product of traditional Christian compassion for the unfortunate (not, actually, an exclusively Christian tradition) the 'frightened five' PCPs would surely not have concealed their identities, because assisted dying campaigners, including unbelieving ones, are also motivated almost entirely by compassion. In other countries, palliative care is a broad church and particularly in Belgium, PCPs were prominent in campaigning for assisted dying, as others were in opposing it. Where assisted dying is legalized, many PCPs find, sometimes after initial doubt and hesitation, that they can work with assisted dying providers, even if they don't prescribe or administer life-ending drugs themselves.

Unfortunately, when it came to religious doctrine, Dame Cicely was not a broad-church Christian. An uncertain agnostic until her twenties, she experienced a sudden conversion to Evangelical Protestantism. As it happens, Britain's most senior member of the Evangelical wing of the Church of England, former Archbishop of Canterbury Lord Carey, supports MDMD's broader aims (he was 'greatly influenced' by the case of locked-in patient Tony Nicklinson) (4) but most Evangelicals strongly oppose assisted dying in any form.

'Assisted suicide'?

It seems that Dame Cicely's fundamental objection was that assisted dying is a form of suicide, which is fair comment. Indeed, it's often called 'assisted suicide', especially in Switzerland and other countries that prohibit anyone from directly administering lethal medication to a patient. For me and for the 99% of Canadian patients who choose doctor-administered rather than self-administered medication, it's a minor stylistic distinction but for many Evangelicals, suicide is a much worse sin than homicide. In my presence, Dame Cicely certainly called it a sin but not all religious PCPs are as transparent as she was about the religious origin of their opposition to assisted dying. Some even play it down and as UK legislation becomes more likely (in November 2021 the island of Jersey voted for reform) their arguments become more desperate. There are – possibly co-ordinated – efforts to present barbiturates as a very unpleasant way of dying.(5)

I recently spent a week at Pegasos, the latest of the Swiss providers of assisted dying which, like LifeCircle, uses an intravenous pentobarbitone infusion rather than the oral route preferred by Dignitas. Swiss law requires patients to open the valve. It also requires all such organizations to be non-profit but the main point I want to make is that none of the patients I saw had a terminal illness. Three had chronic pain, unresponsive to palliative care; two had Parkinson's disease. All had received (and could afford) the best treatment but it had failed. For the record, unconsciousness occurred at around 20 seconds, respiratory arrest around 30 seconds, and cardiac arrest within a minute or two. The anti-barbiturate campaign is actually an argument for more rather than less medical involvement in the process.

Early Christians, living in a Graeco-Roman culture that positively honoured some suicides, were not particularly concerned about 'self-murder'. None of the several biblical suicides is denounced and some Church Fathers even regarded the crucifixion as a kind of suicide for mankind's benefit. That all changed around 400 AD with St Augustine of Hippo, who pronounced suicide the worst of all sins, beginning 1500 years of atrocious penalties for failed suicides and the ritual desecration of successful ones. Until 1825, they were buried at a crossroads but until 2015, Anglican Canon Law refused them funeral services and burial in consecrated ground and the Synod vote to change that Augustine-inspired law was not unanimous. Vatican doctrine hasn't changed but both churches gradually found some wiggle-room by claiming that suicides must have been too deranged to be responsible for their behaviour. That may be true for many impulsive suicides, especially in the young. It's completely untrue for the mainly retired and professional people who think long and carefully before choosing assisted suicide in Switzerland; or for people like Tony Nicklinson. Yet belief in the inherent wickedness of suicide evidently survives in Britain's PCP establishment.

Majority support

In Britain, there is majority support for assisted dying even among practising mainline Christians. MDMD's patrons include an Anglican canon; Dignity-in-Dying's include a Reform Rabbi. The 26 Anglican bishops who exercise their medieval right to sit in the House of Lords vote *en bloc* against reform (joined by practising Jewish and Muslim peers whose faiths deny the central beliefs of Christianity) but several other bishops are supportive. A cheerful unbeliever myself, I'm currently writing a book about the persisting power and attraction of religions and the similarity of their comforting mental and behavioural rituals to the vastly under-rated placebo and non-specific effects of therapeutic rituals, both conventional and 'alternative'. Several clerical patients appreciated my non-judgemental interest in the way their beliefs might influence their illness behaviour. One invited me to his splendid retirement dinner at Lambeth Palace.

Like most British citizens, I deplore both religious extremism and religious intolerance. Unfortunately, it seems that these characteristics largely explain why too many members of the palliative care establishment bully and 'cancel' those with different views, as powerful doctrinaire religions (and political parties) have done throughout history. This matters enormously in medicine because censorship and cancel culture are completely inconsistent with good medical practice and patient autonomy. As the silenced consultants note, "many of the dying people for whom we care have expressed a wish that assisted dying be an option that they could access".

Colin Brewer. Convener, My Death, My Decision *medical group*

Colin Brewer is also a trustee of the Rationalist Association and the author of "O, let me not get Alzheimer's, sweet heaven! Why many people prefer death or active deliverance to living with dementia".

Palliative Care physicians and nurses who want to support MDMD anonymously can email Colin Brewer directly at colin.brewer@mydeath-mydecision.org.uk and will be assured of anonymity.

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Meeting report

Make It Public: transparency and openness in health and social care research

After decades of talking about the problem of transparency in research, the UK is finally striding forward with important new initiatives that we hope will be copied globally.

Clinical trial transparency is not about adding bureaucracy and hampering innovation, it is about protecting patients and the quality of research. Registering clinical trials publicly, even before they start, helps other scientists discover who is currently researching which treatments, preventing needless duplication of medical research efforts. Wasted research comes at mind-boggling financial and also human costs, as patients in clinical trials may be subjected to unnecessary risk. And by requiring investigators to declare publicly at the outset what their study will be measuring, it is harder to manipulate the resulting data at a later stage, either to distort the evidence or for financial gain or glory.

With this in mind HealthWatch welcomed the announcement on 20 October this year from the NHS's Health Research Authority (HRA), one of the bodies that regulates UK research, of a new system to ensure that every single clinical trial will be listed on a trial registry from the outset (for more on this, see below).

A further welcome announcement came soon after, on 11 November 2021 from the National Institutes for Health Research (NIHR), another UK body that works with the NHS, government and universities to fund, enable and deliver health and social care research. A new Open Access policy will require all peer-reviewed research articles arising from NIHR-funded research studies immediately to be made open access under an open licence – this means that the published results of research funded by UK taxpayers and others will be available to read online for free. This change will apply to all peer-reviewed articles submitted for publication on or after 1 June 2022.

Against the backdrop of these new UK transparency initiatives, the HRA held its first "Make It Public" conference on 3-4 November 2021. This event showcased the impact of transparency on health and social care studies in the UK and featured talks from the regulators, the funders, patient representatives and those responsible for clinical trial registries.

The regulators - HRA

The Health Research Authority (HRA) is one of the bodies responsible for regulation and governance of research in the UK. Naho Yamazaki, Head of Policy and Engagement at the HRA, confirmed that their traditional reluctance to adopt sanctions for not reporting clinical trial results has not changed. While the HRA had made a "commitment" to impose sanctions, it would "proceed carefully" and only after engaging with stakeholders. There is no timeline for when HRA will impose sanctions. HealthWatch has in the past repeatedly called for the adoption of sanctions with teeth – if the HRA is left to its own devices, this seems unlikely to happen in the foreseeable future.

On the positive side, the HRA has made impressive progress with all other elements of the UK's national #MakeItPublic strategy. In a world first, the HRA itself will in future automatically register all clinical trials after they receive ethics approval, thereby ending the problem of unregistered trials. It is already a requirement that all clinical trials are registered with a World Health Organisation (WHO) recognised registry before the first participant is recruited to a study, nevertheless many are not.

From January 2022, in partnership with the London-based globally recognised clinical trial registry ISRCTN, the HRA will automatically register all UK drug trials as part of the study approval process. The process will later be rolled out to cover all interventional trials. The HRA has already developed clear guidance for researchers and set up a system to monitor whether trial results are made public, which should be within one year of study end.

HealthWatch and our partners at TranspariMED have long called for this initiative, and we are delighted that it is at last being set up. By the end of 2022 trial results should also be appearing on the HRA's website. For the key milestones see TranspariMED's report.

The HRA also encourages reporting of results in plain English (lay summaries), but this is not mandatory.

The trial registry - ISRCTN

Claire Veryard from the London-based trial registry ISRCTN (which stands for "International Standard Randomised Controlled Trial Number") announced the registry's formal partnership with the HRA, which will in effect make ISRCTN the UK's national trial registry going forward. ISRCTN launched a new "output table" this year, allowing those running trials to share a wealth of information on the registry, including statistical analysis plans, preprints, funder reports, and links to external platforms. ISRCTN will continue to develop its existing system of using email prompts to remind researchers to update registry data and upload trial results regularly.

The regulators - MHRA

Martin O'Kane from the Medical and Healthcare products Regulatory Agency (MHRA) provided an overview of the agency's current and future efforts to improve clinical trial transparency. The new, post-Brexit, medicines regulator

continues to send reminders to researchers to make the results of older drug trials public on the European trial registry as required by MHRA. Current compliance by UK sponsors is a high 85%, but the MHRA continues to aim for 100%. The Good Clinical Practice (GCP) Inspectorate within MHRA is notified when sponsors fail to upload results.

O'Kane noted that current UK law contains no requirements to register trials or make their results public, but that the recent Medicines and Medical Devices Act has provided a "once in a lifetime opportunity" to mandate these steps. Before the end of 2021, the MHRA would launch a consultation on options for making reporting of trial results within 12 months of trial completion compulsory. The MHRA is also considering introducing sanctions for non-reporting, and making the involvement of patients and the public in the design of clinical trials a legal requirement.

Going forward, the MHRA will work to align trial registration forms with those required by the HRA and the ISRCTN, hopefully making the process easier and less time-consuming for researchers. O'Kane noted that the close collaboration of the MHRA with the HRA, NIHR and NHS really added value during the UK's widely praised Covid-19 clinical research efforts.

Patients in research

On keeping participants informed was explored by Jo Taylor, a secondary breast cancer patient. She said that health professionals were not telling patients that primary breast cancer - even when successfully treated - can often result in metastatic breast cancer. They might not even be told the red flags to look out for because, apparently, "it's too scary for people".

As a result, people who may benefit from new treatments for metastatic breast cancer miss out on opportunities to take part in research on treatments.

Metastatic breast cancer is not a chronic condition – it's incurable and terminal. But there are disease-mitigating treatments, and Taylor claimed that patients affected are not being informed about the opportunities to take part in research, so are excluded from trials until often it's too late, whereas being in a trial of an effective new treatment could have given them more time.

Communicating with research participants

An excellent new communications toolkit developed by Parkinson's UK deserves to be adopted by all research funders in all areas of health research – possibly even as a condition of receiving funding. In this panel session Lynn Laidlaw, the only patient participant, made a deep impression. Having started as a research participant herself, she is now co-producing research where she will be holding celebration events with the participants along with informing them of the results of the study.

When she was asked why researchers should go to these lengths, Laidlaw replied that it was extremely rude not to! To assume people will ask for the results if they want to know them, and that if they don't ask, they don't want to know, was an attitude instantly recognised by our reporter Caroline Struthers from her experience as a "healthy control" in observational studies.

It comes down to the current research culture. Researchers are incentivised to publish in the Lancet, but not to share their results with participants. Yet, without them the research could not happen. Laidlaw advocated using the small amount of power you have as a research participant to refuse to take part unless the results are going to be shared. She now does this every time.

In the conference's closing remarks, HRA's CEO, Professor Matt Westmore, observed: "Seventy-five per cent of UK trials publish their results. This is not perfect, but against a global figure of 50 per cent this is momentous and world leading."

HealthWatch and TranspariMED are keeping an eye on the new developments as they are implemented in 2022.

For more about the HRA transparency initiatives, read their full strategy report.

Reported by Till Bruckner, TranspariMED; Caroline Struthers, UK EQUATOR Centre; Mandy Payne, HealthWatch Newsletter editor

Book review

Patients' Emancipation: Towards Equality by Charlotte Williamson

This remarkable book had an immediate impact on me.

As a patient activist aiming to improve health services, I had often found useful information too difficult to obtain. I had felt like a lone voice pushing against brick walls, as controlled and disenfranchised as women from an earlier age who sought voting rights. Sometimes there seemed to be a deliberate 'Them and Us' policy which kept patients in their place to prevent upsetting the status quo. Genuine patient centred care seemed an unobtainable goal.

Over many years, although official policy had encouraged healthcare providers to be patient-centred, and doctor-patient groups brought joint working, even small improvements emerged slowly and often melted away as personnel changed roles.

Increasingly, patient representatives began working alongside health professionals at a national level which fostered understanding, mutual respect and trust. Sadly, however, this was not the case countrywide. Despite the apparent acknowledgement of the need for change, there were plenty of words, but no deeds. Often tantalising improvements dissipated like scorched summer mist, while patients' poor experiences of healthcare illustrated that patient harm, even if inadvertent, continued to occur. Why?

Charlotte Williamson attempts to answer this question. She is a patient activist who was appointed to a health authority (forerunner of today's trusts) who exercised her patient activism there. It caused dismay among some health professionals, admiration in others. After successes and failures in raising standards of care there, and being awarded an OBE, she moved onto the national scene. She was appointed first a member, then chair, of the patient liaison group of the Royal College of General Practitioners. She then became a founder member of a similar patient activist/doctor group at the Royal College of Pathologists (where she was awarded the College Medal). She was then invited to start and chair a similar group at the Royal College of Anaesthetists, where she was awarded the Humphry Davy medal.

This extensive experience of co-ordinating patient activists and health professionals working together locally and nationally, plus academic reading, inform her book.

As I turned the pages, I realised why it felt like the final missing piece of a jigsaw puzzle. It was precisely what had been needed for so long, and the key to achieving patient-centred healthcare modernisation.

This brave book not only discusses how unintentional patient harm can be caused by doctors, and even managers, but dares to suggest how improvement and change can be achieved.

The well-structured, rich content explains the author's theory of the need for patients' emancipation, while clarity of thought and reasoned argument backed by a wealth of examples and detailed information all lead in planned sequence to the final chapter, Chapter 7. Here she acknowledges the stress that doctors experience, as well as steps that 'interest holders' such as patients, doctors and managers can take to help patients' emancipation.

We are all potential patients, so this remarkable book could be useful for everyone. It is not an overstatement to say this superb work not only deserves to be an essential part of medical education, but also recognised as an important foundation for modernising patient-centred care.

Mitzi Blennerhassett, Medical Author and patient advocate, Yorkshire

Mitzi Blennerhassett is author of the award-winning "Nothing Personal: disturbing undercurrents in cancer care".

"Patients' Emancipation: Towards Equality" by Charlotte Williamson was published 2021 by Quacks Books, York. RRP £15.00 + p&p, 170 pages, soft-cover. It **is available for purchase direct from the publisher: Quacks Books, 7 Grape Lane, Petergate, York YO1 7HU. Email: design@quacks.info Telephone: 01904 635967 or visit the website.**

Last word

Reading for sanity

The flood of thought-provoking books continues unabated: Prisoners of Geography, The Chimp Paradox, Wilful Blindness, Thinking Fast and Slow, There is No Planet B, and Gladwell's books.

But among them all I would, for the sake of our sanity, especially recommend the simple wisdom of Richard Holloway's Stories We Tell Ourselves: Making Meaning in Meaningless Universe; and the realistic positiveness of Factfulness by Hans Rosling. In a world where bad news sells, it is so good for us as HealthWatchers to be reminded of the too-often invisible progress towards a healthier world.

Rupert Fawdry, Retired Gynaecologist

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- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

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