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HealthWatch Newsletter

for Science and Integrity in Healthcare

Issue 114, Winter 2020-21

News

"Make it public": transparency campaign success

The UK is to become the first country worldwide to ensure that all clinical trials are registered and their results reported, with clinical trials registered centrally and a government agency checking whether their results have been made public. A new national strategy was published on 1 October by the UK's Health Research Authority in response to sustained campaigning by patient, transparency and health groups including TranspariMED – with whom HealthWatch partnered on this issue – and Cochrane, Universities Allied for Essential Medicines and AllTrials, as well as a 2018-19 parliamentary enquiry into unreported clinical trials that highlighted research waste at UK universities and in the NHS.

In future, the Health Research Authority (HRA) will itself directly register clinical trials based on data submitted during ethics approval. All clinical trials will be expected to report their results within 12 months and include 'lay summaries' for non-expert readers. Publicly available monitoring data will keep the pressure on trial sponsors, as will sanctions – ethics approval may be refused for further studies.

This new long-term strategy covers all interventional clinical trials, including not only medicines but medical devices, surgical techniques, public health measures, and behavioural therapies. Till Bruckner, founder of TranspariMED and a member of HealthWatch, said: "In future, decision-makers in other countries, notably in continental Europe, can no longer argue that it is impossible to prevent research waste in clinical trials."

New sponsor for HealthWatch Student Prize

We are delighted to be able to announce our new sponsor for the 2021 HealthWatch Student Prize. The Royal College of Surgeons of England (RCS) works to enable surgeons to achieve and maintain the highest standards of surgical practice and patient care, so they are solid match for our competition which encourages students to appreciate evidence in health care. The RCS have generously agreed to support our next competition, which was launched on 10 December. Deadline for entries to the competition is 23:59 on Friday 30 April, so don't leave it too late - find out more here.

Charities Commission is challenged to meet its statutory duty

Charities whose activities could harm those who turn to them for help, continue to escape sanctions despite pressure on their regulator to act. Les Rose, HealthWatch committee member, writes in his latest blog about his attempts to press the Charity Commission to meet its statutory duty to ensure that all charities provide a public benefit. Since July 2019 Les has raised official complaints about eight UK charities, supplying evidence that they promote practices that could endanger or exploit the sick, vulnerable and/or desperate.

While Charity Commission management have assured complainants that they are giving high priority to the problem of charities failing in their public duty, the glacial speed of action – if indeed there is any being taken, as there is no transparency in the process and no outcomes to be seen – means the public continue to be misled and harmed unnecessarily. Of particular concern is that the Commission's responses to complaints refer to discourse with legal advisors but fail to acknowledge the need for any scientific input. There will be more from HealthWatch on this subject in 2021.

Advance in treatment following breast cancer surgery

There was good news from breast cancer researchers in August, who published their finding that a single shot of radiotherapy given during surgery is just as effective as the conventional series of whole breast radiotherapy (WBRT) sessions that women traditionally have to endure after tumour removal in early breast cancer. The new technique is called targeted intraoperative radiotherapy during lumpectomy (TARGIT-IORT), and is an attractive alternative to the uncomfortable, costly and inconvenient post-operative WBRT courses currently offered.

And there is more. A course of WBRT increases a woman's risk of dying from cardiac events and lung cancer. But the new study found that TARGIT-IORT was linked with far fewer such deaths than was the traditional WBRT programme.

Surgeon and co-researcher Michael Baum notes that these data also have profound relevance for the practice of population screening for breast cancer, because they shed new light on a rarely-publicised result of routine

In this issue:

mammographic screening. “Sixty per cent of the cases recruited for this study had been screen-detected, and we know about half of screen-detected cancers are over-diagnosed,” says Baum. This means that a sizeable proportion of women receiving potentially hazardous treatments for breast cancer have tumours that might never have harmed them, had they not been found by screening. “Over-diagnosed women have been bearing the brunt of the lethal toxicity of treatment for a disease that if left alone would never have progressed,” he explains. “This excess mortality is now revealed for those patients who have been subjected to WBRT not only in this study but ever since population screening was introduced.”

“Pseudoscience kills”, warns international collaboration of 2,750 doctors and scientists from 44 countries

More than two and a half thousand scientists and medical experts from 44 countries have come together to warn of the dangers of pseudoscience, and to urge lawmakers to close the legal loopholes that allow quack medicine to flourish. Their ‘Manifesto Against Pseudo-Therapies‘, published internationally on 19 October, highlights cases in which patients have died as a result of taking unproven or disproven medicines. The current Covid-19 pandemic has contributed to the problem by cultivating an “infodemic” of pseudoscientific health claims that could threaten more lives.

The manifesto is an international collaboration of ten scientific associations across Europe, including HealthWatch. One focus is the European directive 2001/83/CE, which allows the sale of homeopathic products as if they were medicines. The manifesto calls on the EU Parliament to repeal this directive in the interests of protecting consumers, and to introduce laws preventing the sale of ineffective treatments.

My love-hate relationship with HealthWatch

In an online seminar, HealthWatch chair Susan Bewley reflects on the charity’s history and future. Thirty years ago the quackbusting group “Campaign Against Health Fraud (CAHF)” was formed to tackle the problem of charlatans who mislead, defraud and offer false hope to cancer patients. Following complaints that the name was provocative, a name change and charity registration followed, and HealthWatch was born. Since then our scope has widened to fight bad science in all areas of health care. Where are we now? On 19 November Dr Bewley, an emeritus professor of obstetrics, presented and led a discussion in a 1hr free online seminar, arranged and hosted by the non-profit Consilium Scientific. To watch the recording of this and other events in the series go to this link and log in using seminars2020 as both username and password.

First Do No Harm – next steps

An All Party Parliamentary Group was launched on 16 December to build support to implement the recommendations made in First Do No Harm, the report of the Independent Medicines and Medical Devices Safety (IMMDS) Review published this summer (known as The Cumberlege Report). The report’s recommendations concerned support for those who have suffered grievous harm as a result of medical interventions and devices, and actions to reduce the risk of avoidable harm in future. They include the appointment of a Patient Safety Commissioner for England, and it seems that positive discussions have been had with the Government on this point. For more, see FirstDoNoHarmAPPG.org.uk

Online guide for journalists investigating health and medicine

A new online resource aims to equip journalists with the tools and knowledge to independently assess the evidence, critically appraise the risk-benefit ratio of any given product or policy, and expose corruption and malpractice. “Investigating Health and Medicine”, has been written by medical investigative journalists Serena Tinari and Catherine Riva for the Global Investigative Journalism Network (GIJN). The manual explains evidence-based medicine, how to assess evidence, drug development and regulation, safety reporting, and corporate influence. Find the Guide online here. Also downloadable as a 92-page pdf.

John Maddox Prize 2020

When communicating sound science gets difficult, it takes courage to walk towards the public. The John Maddox Prize is awarded to people who have done just that. Anthony Fauci, Director of the US National Institute of Allergy and Infectious Diseases (NIAID), and Salim S Abdool Karim, an infectious diseases epidemiologist and Director of the Centre for the AIDS Programme of Research in South Africa, impressed prize sponsors *Nature* and Sense About Science by going above and beyond the line of duty as advisors, talking the public through the uncertain science behind Covid-19. A worthy winner in the Early Career Scientist category was Anne Abbott, a neurologist from Monash, Australia. She took on a multi-million-dollar industry when she determinedly challenged established treatment for carotid stenosis with her research showing that, for symptom-free patients, lifestyle changes were more effective at reducing stroke than the costly surgical procedures traditionally used. The full one-hour event from 14 December is on Youtube.

New paper from Declaration to Improve Biomedical and Health Research

The international group of academics behind the Declaration to Improve Biomedical and Health Research – to which HealthWatch is a signatory – has published a new review paper spelling out practical measures. “Reducing bias and improving transparency in medical research: a critical overview of the problems, progress and suggested next steps”, in the Journal of the Royal Society of Medicine, proposes three actions to improve transparency and mitigate against bias: (1) mandatory registration of interests by those involved in research; (2) that journals support the ‘registered reports’ publication format; and (3) that comprehensive study documentation for all publicly funded research be made available on a World Health Organization research repository. The authors invite feedback on the proposed actions and invite others to join in calling for their implementation.

Positive impact from call for EMA transparency

Last summer HealthWatch joined 27 organizations and academics in a letter calling on the European Medicines Agency remove a key barrier to citizen’s requests for information that should be publicly available. The campaign was organised by the transparency non-profits Access Info Europe and TranspariMED. It has finally begun to bear fruit – Access Info Europe have informed us that they had a call with EMA’s representatives on 14 September which is expected to be the start of an ongoing open conversation about how to advance the public’s right to transparent information, in an appropriate balance with protection of privacy and commercial interests. Read more here.

2020's best reads: writing that made us think

Pandemic Science Out of Control, by Jeanne Lenzer and Shannon Brownlee, Issues in Science and Technology, 28 April 2020. How scientific integrity became another casualty of the pandemic – wise words that still stand months later.

Against pandemic research exceptionalism, by Alex John London and Jonathan Kimmelman, Science 01 May 2020. London and Kimmelman spell out five critical conditions to make research informative and of value to society.

Covid-19's known unknowns, editorial in the BMJ, 19 October 2020. Why "The more certain someone is about covid-19, the less you should trust them".

Five rules for evidence communication by Michael Blastland and colleagues, in Nature, 18 November 2020. The stats experts advise: "Avoid unwarranted certainty, neat narratives and partisan presentation; strive to inform, not persuade".

Investigation

Conflicts of interest (COI): The case for a register of doctors' interests – a perspective from the private healthcare sector

I should probably start by introducing myself as I have followed a most unusual career path. I started my medical career working in anaesthetics but for two decades have worked in the insurance industry, where I have developed a specialist expertise in countering healthcare fraud waste and abuse.

Along the way I trained as an investigator, initially informally with NEFF (North East Fraud Forum), which is a public-private partnership set up by Northumbria Police, and later taking a formal qualification accredited by the Centre for Counter Fraud Studies at Portsmouth University.

In 2011, quite by chance, I went to see a group of doctors because their billing had escalated precipitously. During the conversation I made a casual remark about the state-of-the-art consulting room and brand new equipment, and the senior partner informed me that he now sent all his patients to a new hospital who had paid for everything – his staff had been taken onto the payroll, the equipment was free and the hospital were even funding an agency to do his billing. I asked him to explain a little more and he immediately started to be evasive. I got no further, so I left and searched the land registry and confirmed that what I had thought to be an independent consulting room was in fact owned by a private hospital chain.

I tasked my investigators to search the land registry and give me a list of every building the hospital chain owned. Then at 5am the following Saturday, I sent a team of people out with cameras to visit, catalogue and photograph every building on the list with a specific instruction to photograph business signs and any name plates - anything to identify the purpose of the building. To my surprise I was presented with a list of clinics I had previously considered to be independent.

I then identified occupants I felt might speak to me, with appropriate promises of confidentiality. It was not long before I had persuaded a doctor to part with a photocopy of his lease agreement, which clearly showed he had been given the use of the building rent free in return for making 'reasonable endeavours to refer patients to the hospital'.

Over the next 12 months or so, my team visited doctors and hospitals all over the UK and discovered that the payment of 'incentives' was widespread and almost all private hospital groups operated some schemes, usually targeted at big earners.

Included in the schemes we found were:

1. Free services, secretarial support, administrative services, billing services and equipment.
2. Profit shares where a percentage of hospital bills was paid to the doctor in return for increasing the bills over an agreed target.
3. Commissions on pathology tests.
4. The most concerning scheme I discovered was where a hospital set up a joint venture with doctors to buy equipment, and made a loan to the joint venture. The doctors then referred patients to the service and billed insurers. The charges were at a level which would repay the loan after a time, making the doctors and hospital joint owners of a new clinic or equipment. Even more worrying, we found some multi-disciplinary teams (MDT) which were gatekeepers for a new technology, where many or all of the MDT had financial interests.

Deeply concerned by what I had seen, I visited the General Medical Council (GMC) – the public body that controls registration of medical practitioners – with a catalogue of evidence. I was astonished to be told that they would not investigate the matter. My evidence was submitted to the Competition and Markets Authority (CMA) who performed their own investigation, agreed with most of our findings and acted to ban the majority of these schemes.(1,2) They also mandated disclosure of COI on hospital websites. The entire report and all the evidence can be accessed on the CMA website. It should be noted clearly however that the ban was because the CMA believed that the schemes were distorting the operation of a free market. The CMA has no remit to consider medical or ethical issues.

Disturbed by the GMC's refusal to investigate, I also passed a file of evidence to the *British Medical Journal*, who covered the issue in detail: *The truth about cash for referrals.*(3) I asked to remain anonymous, however one night, in a low moment at a health conference in Tel Aviv, I also emailed a file of evidence to Grahame Morris MP for Easington who helped me get it in front of the Health Select Committee. Unfortunately, whilst the following hearing was undoubtedly uncomfortable for the GMC, no meaningful change was forthcoming.(4)

Five years on, little has changed. Large sums of money are still paid to doctors. The banned schemes have gone but new transaction types whose effect is transferring money from hospitals to doctors and which are perfectly legal have emerged. For example, advisory contracts which may be worth over £100,000 are awarded. Transparency is rare and disclosures are partial and exceptionally hard to find.

In 2018 *The Sunday Times* reported that significant fees for psychiatric patient referrals were still being paid.(5)

In 2019, the Centre for Health and the Public Interest (CHPI) released an excellent and well-researched analysis of the situation entitled *Pounds for Patients*, which documented again the ways in which hospitals find ways to pay doctors and the ongoing lack of transparency. The CHPI noted that the majority of these schemes involve high-value cardiology and oncology services, something which accords with my own experience. I commend this report to anyone interested in this matter.(6)

So does this matter? There is ample evidence that these schemes corrupt judgement at the population level, not just at the margins. In 2011 *JAMA* published research from the USA showing that the propensity to order cardiac imaging was dramatically increased where a fee could be claimed and further increased where the doctor had an equity stake in the facility.(7) A review of this subject is far too complex for a short article but every study I have seen tells a similar story.

The GMC continues to turn a blind eye to the issue of doctors' conflict of interests. In 2018, the CEO Charlie Massey wrote to the Health Select Committee setting out the reasons why the GMC does not wish to set up a register of interests.(8)

This situation cannot continue. The case for a register of interests is overwhelming. I do not believe this is the ultimate goal but it is an essential stepping stone, as until a light is shone on these payments we cannot even know the scale of the problem. In my view it is inappropriate for doctors to covertly accept money from hospitals to whom they refer patients, from drug manufacturers whose products they prescribe or from manufacturers of equipment they recommend to patients. Whilst these payments are invariably 'justified' or sanitised, the true purpose must be obvious to all and if there were any doubt on this matter the ongoing culture of secrecy, defensiveness and silence around these payments speaks volumes.

Ultimately if we do not act, the final casualty will be the reputation of the medical profession itself.

Simon Peck is a doctor who is also an accredited counter-fraud specialist. He works part-time in the insurance industry advising a team specialising in investigation of healthcare fraud waste and abuse. All views here are his own.

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AGM 2020

HealthWatch Chair's report

The 2020 Chair's report was delivered by Susan Bewley at HealthWatch's first virtual AGM.

Last year I started with a reminder of the history of the charity that was rooted in the Campaign against Health Fraud. We consciously moved from being 'against' things, to being 'for' fair testing, and 'for' science and integrity in healthcare. We have always been particularly concerned about people being deceived about illusions of cures from those posing as healers when people are at their most vulnerable - when ill or depressed.

Just as you thought bias, dishonesty, corruption and fraud couldn't get worse the pandemic (or syndemic) hit. This year's events with Covid-19 and its aftershocks undoubtedly play into all our deepest fears, uncertainties and hope in science, and yet also into the hands of those who are fools at best, and greedy liars at worst. It has shown, more than ever, how hungry people are for trustworthy, reliable, scientific information. Yet more than ever, misleading information flows around the internet faster, further and deeper than truth.

So, how is HealthWatch doing, in terms of its activities and effectiveness, as we take the cool, calm long view? Although conceived two years earlier in 1989, we were born or formally constituted in 1991, so next year will be our 30th birthday.

Let's remind ourselves that HealthWatch, with its entire reliance on unpaid volunteer Trustees, has been foresightful, a kind of crucible or 'think tank', set up before all of the following and yet with many overlapping aims and personnel: the Cochrane Collaboration (started in 1993), Transparency International's global coalition against corruption (1993), NICE (1999), Sense about Science (2003), James Lind Initiative (2004), Harding Centre for Risk Literacy (2009), Friends of Science in Medicine (Australia, 2011), AllTrials (2015). These and so many others have changed the landscape since the 1980s. Did HW spawn all this? No, but we spotted and celebrated many of the individuals, and we've been part of the fabric or glue between initiatives and institutions. Sometimes we're the 'awkward squad' raising concerns about the culture of institutional 'pass the parcel' of responsibility.

The problems haven't gone. Our work remains as vital as ever, notwithstanding limited manpower and resources, so we have to be targeted if we are to continue to 'punch above our weight', and to offer something different – our 'unique selling point' or USP, which is more than simply a lack of financial indebtedness to corporations.

THE WORK

We've continued with the three areas of strategic focus, trying to be professional and proactive, but concentrating limited resources to where there is a special HW contribution.

1. Communications

Trustees: We are reliant and indebted to the Trustees who continue to give their volunteer service. Clearly it's been harder for those who do still have full time jobs, let alone small children in a year dominated by the pandemic, lockdown and homeschooling on top of the usual pressures, but I particularly want to thank David Bender who is stepping down after many 'tours of duty' as a Trustee, Chair and Secretary. He's been a fabulous support, holding us all to come up with action points, while acting as a 'corporate memory'. I do hope we get a vaccine soon so he can enjoy many more years cruising.

Meetings: The committee has taken to Zoom like a duck to water, and met remotely four times this year. We've embedded the role of responding to consultations, and a new role of parliamentary liaison. Although we've looked and invited a couple of observers, we've not yet appointed a Trustee with a patient-user background, and we have retained and had useful input from our students. We've started a process of writing job roles and tighter governance, but not lost the informal and enjoyable familiarity of meetings.

Googlegroup: The googlegroup continues to be a great source of information and ideas without being too onerous,

averaging just over one email a day, though often in bursts of discussion. Anyone who wants action can make suggestions to the committee, or better still offer to help – let's say drafting a letter that might then go in HealthWatch's name about your particular 'bee in the bonnet'.

Newsletters: We rely as our main benefit to members on the news items and our seasonal newsletters. Tremendous thanks to Mandy Payne for this. Articles are now to be published first online as the paper version starts to be gradually phased out. Highlights of articles this year have covered: unreported medical device trials; the Cumberlege Review; ethical concerns over student research activities; dental implants, the Caster Semenya case, and the pelvic mesh scandal. We've had book reviews of Sex Robots & Vegan Meat, Pharma's Funding Trap, and Why we need to talk about Alzheimer's. It would be very good if more members joined in the tasks of reading/reviewing books, and spotting new talent to write and work with us. Please could everyone commit to identifying and praising an up-and-coming young person, draw their work to Mandy's attention and invite them to join HealthWatch?

Twitter: we have increased our followers by another 200 to 1185 (if not our hardcore membership), and benefit from some of the conversations.

Website: in Alan Henness's capable hands this has been undergoing a refresh to modernise and make more attractive thanks to the feedback from committee observers and new trustees.

	2019-20 AGM	2018-19 AGM	2017-18 AGM
Membership numbers (total)	232	212	231
Googlegroup members (total)	60	54	-
Twitter followers	1185	979	842
Cumulative HW Committee threads	2416	1845	460
Cumulative Tweets (~500/ year)	2648	2169	1630

2. Projects

Background briefing papers These can be found on the website (from the menu go to Publications > Background Briefings). I thank Roger Fisken and James May for their excellent new briefing paper on Statins.

Consultations Roger Fisken has continued with his work of anticipating relevant Public Consultations (largely with government bodies), eliciting comments from the membership and writing our formal responses. This year has included the Parliamentary Select Committee on Health & Social Care: delivering core NHS and care services during the pandemic and beyond; The Competition and Markets Authority consultation on advice to be given to private-sector IVF clinics on consumer law; and the Department of Health and Social Care consultation on extending the storage periods for embryos, eggs and sperm. He has also looked at the final reports to judge HealthWatch's impact and we'll be reviewing this role and a handover to another Trustee during the next year when he takes over as Secretary.

Research: In March the HealthWatch funded study by Till Bruckner led to publication of a report comparing Health Technology Assessment agencies in UK, France and Germany. Overall, this found that the UK's NICE does a very good job, but we must keep an eye on transparency and redactions, and influence especially with new leadership. Although the study did find transparency gaps, it helped us to decide not go further in that direction, but to concentrate on devices.

Devices: In November 2019 HW wrote to Baroness Cumberlege to ask the Independent Medicines & Medical Devices Safety Review to demand that those who implant a device must know (and be able to explain to the patient): what it is and what its constituents are, how it is identified and tracked, how the evidence shows that it works, what risks are involved, and what to do if things go wrong. In March we published our five demands to keep patients safe from medical device harms, well in advance of the delayed Independent Medicines & Medical Devices Safety Review (Cumberlege report, 'First do no Harm'), that had been set up to examine historical harms to pregnant women from Primodos, the decades of valproate-damaged babies, and women with health complications resulting from vaginal mesh and breast implants. HealthWatch's submission led to my being invited, as HealthWatch chair, onto the Today Programme and to the report's launch press conference (sadly our contribution hit the cutting room floor on both occasions). We must make more links with patient organisations and keep the pressure on the government to enact its recommendations in full. The key problem is how to put patients before profits.

Breast screening: In April NHS breast cancer screening was paused. And the BMJ published my blog explaining why that's a good thing. Then we noticed in August that the vast AgeX breast screening trial had been ended, ever so quietly. This is tremendously good news. HealthWatch requested that Jeremy Hunt (as Chair of the House of Commons Health Select Committee) ask his successor as Secretary of State to reveal what the Age X trial cost and who approved the spend. We received no answer and were fobbed off, but will continue to investigate, ask questions and ensure that the results are not buried, and examined independently as we cannot trust the team in charge.

Trading Standards/Charity Commission and the regulation of uncharitable charities: Our indefatigable committee member Les Rose, continues to collate fantastic information about the most egregious of some alternative medicine-promoting charities, and has been chasing six complaints that have languished in the Commission's pending trays for far too long. We've been working on strategy with the Good Thinking Society, and were pleased to be able to ask a difficult question about their criteria of 'public interest' at the Charity Commission's recent rather 'stage-managed' AGM thanks to HealthWatch member David Colquhoun's place becoming available. We are not achieving much rapidly, but continue on doggedly.

Puberty blockers for gender dysphoria: Questions about the quality of evidence, particularly for puberty blockers in gender dysphoric children and young people, continue and the Chair has written to Hilary Cass and NHSE about the processes of the two Independent Reviews (initially just about drugs, now extending to the services). Our previous HealthWatch award winner Deborah Cohen continues to do features on this for the BBC.

Students: An enormous amount of work goes into running the annual Student Prize and I thank everyone for their

continuing contributions to setting and marking this. We have had more input from students on the committee than before and know from them that teaching and training on critical analysis and evidence based healthcare remains improvable. I hope that we will identify tasks and work for them that are fulfilling, maybe within a separate workstream or subcommittee.

Annual Award: As usual we had a plethora of good candidates to choose between, and we look forward to hearing from our latest Annual Award winner, Jennifer Rogers.

3. External outreach and Partnerships

Centre for Evidence-Based Medicine, Oxford: HealthWatch volunteer Mandy Payne has been helping communicate best evidence about COVID-19 by working with Oxford CEBM to produce lay summaries of the Oxford COVID-19 Evidence Service reviews on important questions about the science of the pandemic.

Royal College of Surgeons: Since our Vice-Chair, Keith Isaacson, and I met with Derek Alderson (the previous president of the RCS) regarding surgical devices, we have noted a much better, more fulsome response from the RCS. We are delighted that they have taken up funding our annual Student Prize, maybe more educational links or joint activity will follow (especially on teaching and training in appraising evidence at student and early academic career level).

French advocates for good science: HealthWatch has been at the forefront of raising concerns about breast screening programmes. We joined a cross-European challenge to an EU-funded clinical trial to publicly share concerns about inevitable and avoidable harms to women from MyPeBS, a flawed randomised controlled trial of breast screening. Through this, we formed links with three other groups who share concerns about women's health and human rights in research: Belgium's Group de Recherche et d'Action pour la Sante (GRAS), the Italian epidemiologists and scientists of NoGrazie, and the French group Cancer Rose.

European Manifesto against Pseudoscience Launched the day before the AGM, HealthWatch is an official organising supporter as well as having many individual members sign the manifesto.

Access Info Europe In 2019, along with 27 other consumer and health related agencies, we signed a letter asking for better transparency from the European Medicines Agency. Although of course, this is moot once we leave the EU next year, because the EMA will not be under any obligation to respond to requests that come from outside the EU. Nevertheless it resulted in more conversations about transparency within the EU that we will still want to support.

THE FUTURE

This is something we hope that Healthwatch can do more of in the future – working with other like-minded organisations to 'get more bang for the bucks', whether supporting one another's initiatives or even getting grants for funded projects, as we've seen the value of using our Research Fund to generate ideas and evidence. Our president, Nick Ross is very well connected, and our applicant for Vice-Chair is also a keen 'networker' so again, next year, we hope to capitalize further on these links.

Susan Bewley
Chair, HealthWatch

HealthWatch Award winner 2020

Can't see the wood for the trees? Making sense of data during a global pandemic

The HealthWatch Award 2020 was presented at our AGM on 20 October to Professor Jennifer Rogers. Professor Rogers is Head of Statistical Research and Consultancy, PHASTAR and Vice President (External Affairs) at the Royal Statistical Society. It was a happy coincidence that her presentation was on World Statistics Day. A recording of her 50-minute presentation in full including the slide show and the questions and answers that followed can be seen online here. An adapted transcript of her talk follows.

News headlines are telling us what we should do, how we should live our lives, but headlines can be misleading and our own personal experiences can skew our understanding. Would it not be better to give people the tools they need to ask the right questions?

Let's take for example the humble bacon sandwich, and warnings from news stories that eating bacon boosts your risk of cancer. Headlines like this in recent years caused bacon sales to plummet. But when we see headlines like this, we are looking at something called "relative risk". It is not answering the real question, which what is our own individual "absolute risk".

What is the chance of getting pancreatic cancer? The charity Cancer Research UK says that one person in 80 might develop it in their lifetime. If eating bacon is supposed to boost your risk of developing pancreatic cancer by 20%, that is actually increasing the absolute risk from 5 in 400 to 6 in 400 individuals. So, although 20% sounds scary, it's 20% of what was quite a small number to start with.

2020 has been a really interesting year for medical statistics. Daily government briefings presenting data are being updated on a daily basis. There are all sorts of important questions about the virus that causes Covid-19 – how it is spread, where is the risk, what treatments are most effective. Amidst the flood of data, there has never been a more important time to use this data to inform decisions.

So now we're going to look at some of the challenges behind even some of the easiest questions.

How many Covid-19 cases are there in the UK?

We have become used to seeing daily reported number of cases, and terms like 7-day moving averages, but how can we know how prevalent the disease is in the general population? Are cases going up or down? Are we any worse off now than we were in March?

The number of reported cases can only ever be a proxy, to help estimate what is going on in the general population. Because the way we test people has changed so much over the last 10 months, we can't easily compare case numbers detected now with what was detected in March. Prevalence is defined as the proportion of the population who are positive. But we don't have the capacity to test everyone, so we have to make estimates based on assumptions. Let's assume the test is 100% accurate, and we detect 100 positive cases amongst 1000 tests. That gives us 10% prevalence, which suggests that 10% of people might have the disease. But we can't know that for certain. In reality the test will sometimes

give us false positives, and false negatives. Also, we are assuming the sample of the population being tested is picked at random. But we're not doing that. We are mainly only testing people who have symptoms or who have been in contact with others who have symptoms.

What effect does this have? Reported numbers of cases in the UK did not seem to come down as fast as they did in other countries. But if we look at the same period there was an increase in the number of tests. So, prevalence of the disease is likely to be lower now than it was in March, even though numbers of positive tests are higher.

Who we are testing has been changing. Firstly it was mainly people hospitalized with bad symptoms. Lots of the general population had the disease but were not tested. Then we started testing the general public, using drive in centres, and national surveillance data was being generated by random sampling of people. The test and trace system came in, with contacts of cases being invited for tests. Schools started, there are plenty of anecdotal stories of youngsters being sent home with a bit of a cold or fresher's flu and not allowed to go back without a positive test, so the system has been inundated with people who were probably negative. This surge in demand for tests had such an impact on testing capacity, that many people who were positive had difficulty getting tested. So, figures on test results alone make it difficult to infer anything about the actual prevalence of Covid-19.

Can we use actual deaths as a proxy for case numbers?

It is certainly a hard end point. Data from the Office for National Statistics uses information from actual death certificates. Look at graph of deaths over time, there is a reduction after the peak in April, then growth.

But the demographic has changed in that time. There are different risks associated with different demographics. In April, most cases of Covid-19 were being recorded in the older populations, who were turning up in hospital with severe symptoms, and who were at highest risk of dying from the disease. But at the end of September, much younger people were testing positive with the disease. The spread of the virus is changing, so we can't use the death data to estimate the prevalence.

Data – on the one hand, it is great that the government is being transparent about the figures, but the number theatre of showing daily reported cases on the news, is it the most useful way to explain what is really going on? There have been instances of good communication at government press conferences, but I've also spotted some things in the narrative that I take issue with, and here are my biggest bugbears:

"Rising rates among school-age children"

On 30th September Chris Whitty, when talking about figures on weekly individual test positivity, showed a graph that he said showed that rates among school age children are not going up. I am not sure I entirely agree! The graph showed test positivity by different age groups, and it is true that the positivity rates among the younger groups don't seem to be changing based on the information in that graph. That isn't necessarily true. Assume that we are testing children and the test positivity rate is 10%. Test more children and positivity remains 10%, but the number of cases will be going up. From beginning to end September shown the graph, what was testing over that period? If we look at actual number of tests we find that over this period they increased by a factor of 2 or 3. So just because the positivity rates stayed the same throughout, that doesn't mean that the number of cases that were positive also stayed the same. It seemed a slightly sneaky interpretation of the data that told a narrative that I think was quite convenient at the time.

"Exponential growth"

This is a phrase we hear quite a lot. On 21st September we saw a plot that showed what would happen if cases would double every 7 days, and said that by the middle of October we could reach 50,000 new cases. On the 30th September when Patrick Vallance was questioned about this he said, "Doubling means things get very big quickly". But really, "exponential growth" doesn't necessarily mean "fast". It is more concerned with the way speed is changing. The speed of growth is proportional to the size of the population. Think of it in terms of doubling times. If the doubling time is a day, that gets big really quickly. But with a doubling time of 10 years, that gets big a lot more slowly. In the month before lockdown on 23rd March, it is possible to calculate that cases were doubling every 2-3 days. Now, I don't want to say that cases will not increase rapidly again. But exponential growth should not be a blanket term used to scare people. Different surveillance studies looking at growth rates give us different values. The REACT-1 study at Imperial College London is doing random population sampling of volunteers to learn about community transmission, and is using this to estimate rates of prevalence, and what growth and doubling time might look like. In the latest publication it estimated that between the 18th September and 5th October it was doubling every 29 days.

Now, the government figures given to us then projected doubling of the number of cases every 7 days. But if you make it every 29 days, the curve is much flatter, which gives us 6,200 cases daily. The government presented the 7-day doubling time data with no idea of measures of uncertainty. Look at what we actually ended up with in the middle of October: although there was a surge early on, there were lockdowns in place in some areas, and now it does seem like the doubling time is coming down.

There are attempts to get better estimates of the figures. The strategy of the REACT study is to invite people randomly to take part. The ONS survey is inviting households who have taking part in other surveys, doing home visits and offering reimbursement. This is not as random a sample as in the REACT study, and the estimated prevalence figures are different: REACT puts it at 45,000 new cases a day, while ONS estimates 17,200 a day. These differences may be due to the different sampling strategies that they have. But the findings for both will be interesting.

Covid-19 has been a unique opportunity, with lots of challenges around messy data. We are in a pandemic that is brand new, and the knowledge landscape is changing constantly. There are many issues I've not been able to touch on here. One is the quality of the data, because there is always a balance between data that is available quickly but may be less accurate or harder to interpret meaningfully, and the data that we have to wait for but is more reliable. I've not mentioned risk data, but David Spiegelhalter has done some interesting work comparing risks of dying from coronavirus with annual general mortality rates at different ages. He has found that the risk of death from Covid-19 mirrors the way the risk of death generally increases with age.

This winter I'm going to be working with ITV as their Covid-19 statistician. I've been looking at how cases are distributed within cities, and finding that increases in cases in cities are being driven by increased numbers of students. It is also interesting that we are still seeing excess deaths at home but fewer deaths in hospital. There may be a conversation to be had not just about numbers of deaths but also quality of

death. Test accuracy is another topic – new tests on the way may be more rapid, but will they be accurate? And of course, clinical trials for vaccines and for treatments, to be sure that anything we get on the market will be safe and effective.

Good data alone doesn't help us make important decisions, we need that narrative and statisticians will continue to be essential in the fight against Covid. At the end of this we will have a new appreciation of the value of numbers, and we will be leaning on statisticians to lead the way through this.

Jennifer Rogers' talk was transcribed and adapted by Mandy Payne. A recording of her 50-minute presentation in full including the slide show and the questions and answers that followed can be seen online here.

Psychological treatments

It is not only drugs and devices that can harm

"First Do No Harm", the Independent Medicines and Medical Devices Safety Review focusing on three drug/devices aimed at women (aka the Cumberlege report) was published on 8 July 2020.(1) It should have welcome implications for much-needed change in the way patients are treated.

Two of the review's proposals are that there be a new Patient Safety Commissioner and Redress Agency established. However, they would only look at harms from "medicines and medical devices". The review did not consider potential harms to patients from psychosocial and behavioural interventions which are still widely recommended within the NHS for the ever-expanding range of patients who find themselves in the "medically unexplained symptoms" (MUS) swamp. Currently, patients with a range of unexplained conditions such as chronic fatigue syndrome (also known as myalgic encephalomyelitis) and irritable bowel syndrome would fall under the UK Government funded IAPT (Improving Access to Psychological Therapies) remit.(2) The inclusion of MUS patients under IAPT signifies a massive expansion of its coverage, far beyond the patients with common mental health complaints where it originated. The benefit of this expansion to MUS patients is doubtful.(3)

There is currently no UK mechanism for recording or monitoring harms from these types of interventions, or for challenging the assumption that they are appropriate first-line treatment options for long-term conditions where either the cause or the perpetuating factors are unclear. It is vital that the safety and effectiveness (or lack of effectiveness) of psychological and behavioural interventions is also covered by a future Patient Safety Commissioner and Redress Agency.

This agency must also be prepared to look hard at the potential for conflicts of interest in those conducting any such research. When people have a financial or other vested interest in an intervention of any kind, they have already convinced themselves and their peers, and maybe also regulators, government policy makers, and insurance companies, that it has merit. There is no incentive to genuinely try and prove it doesn't work. But that is what scientists are trained to do; to try and prove their hypotheses are wrong. If an investigator designs an experiment to try and prove that an intervention *doesn't* work any better than placebo or an alternative treatment, and they can't prove that 'null hypothesis', then it's likely there is a genuine benefit. But this is not what happens in practice.

There is, quite rightly, a huge fuss made about the fact that pharmaceutical companies are allowed to test their own products, and how this corrupts academia and harms patients.(4) Yet no one questions that developers of behavioural and psychological therapies can lead large publicly funded trials of therapies they have developed themselves, have been offering for years, and built their career and reputation upon. Why not? There is also no incentive for others "invested" in these treatments further down the line, including health service providers like the NHS, to carry out the same kind of post-marketing surveillance which could reveal the lack of long-term benefit, or evidence of harm which would not be picked up in a trial.

For example, myalgic encephalomyelitis (ME), sometimes known as chronic fatigue syndrome (CFS) is a debilitating illness which was been recognised as a disease of the central nervous system (ICD-10 G93.31) by the WHO since 1969.(5) Its hallmark symptom is post-exertional malaise (PEM) which is extreme debilitating fatigue even after a minor degree of physical or cognitive effort. Other symptoms include muscle pain, headaches, palpitations, sickness and orthostatic intolerance. There are no reliable biomarkers yet, and biomedical research to investigate the causes and potential treatments has been chronically underfunded.(6)

In 2011 the Lancet published results of the PACE Trial, a randomised trial designed to compare a number of different behavioural strategies to treat ME/CFS – including cognitive behaviour therapy (CBT) and graded exercise therapy (GET) – with standard medical care (SMC).(7) It concluded that CBT and GET can safely be added to SMC to moderately improve outcomes for patients.

But was PACE effectively a "show trial"? Certainly it seemed to confirm the value of treatments that the triallists told the participants were evidence-based*. The UK government would have hoped the treatments would save them money in disability payments. It is the only trial ever to have been partly funded by the Department of Work and Pensions.(8)

However, PACE and the trials which came before it which claimed to provide evidence of benefit, relied on subjective outcome measures when the interventions could not be blinded. This is a well-known cause of significant bias.(9) Objective measures such as activity monitoring, school or employment records, or healthcare resource use were either not measured or null results were published separately and downplayed. The trial had numerous other methodological shortcomings, such as reducing one of the recovery criteria from what was specified in the protocol to a level low enough to be eligible to take part in the trial. In other words, a participant could get worse on that measure during the trial, and still be classed as recovered at the end. PACE has been widely criticized by the scientific research community, as well as by patients and clinicians.(10)

In the case of GET, a Cochrane review was published four years after PACE,(11) acknowledging "advice" from the lead PACE investigator. This 2015 review was the second update and the review is now in its 8th version.(12) Despite extensive comments on the review (13) and a formal complaint,(14) the latest amendment still attracts criticism.(15)

If post-marketing surveillance were ever done properly for psychosocial and behavioural interventions, it might reveal lack of long-term benefit. In some cases, such as for people with ME, it might have revealed evidence of harm (16,17) a lot sooner. The lack of adequate follow up is discussed in McPhee et al.'s 2019 paper.(18)

The assumption that any intervention that isn't a drug or device probably won't do any harm, even if it doesn't work, is preposterous. Behavioural and psychological treatments, like drugs and devices, cost money to deliver. They also require a huge amount of time and emotional investment from patients, and from the professionals trained to deliver them.

If these treatment approaches don't work, or cause harm, and continue to be offered anyway, the money, time and emotional investment of both therapist and patient continues to be wasted. This is time and resources that could be spent on research to find treatments that do 'work', and on finding out what causes and perpetuates conditions like ME in the first place. It is cruel to patients to give reassurances and recommend treatment based on questionable untested and unproven theories about what is causing and perpetuating their symptoms.

In the case of people with ME in the UK and elsewhere, patients are still being prescribed GET and/or CBT by doctors who are following the current national treatment guidelines (19) in good faith. Patients have a well-founded fear that if they don't do as advised by the professionals caring for them, they may risk forfeiting further medical help or benefits if the treatments don't work or even make things worse.

The irreparable damage done over decades in plain sight by the financially and professionally conflicted promoters of pelvic mesh, valproate, Primodos and other drug/device interventions is horrific. There are many cases, however, where the conflicts of interest are less obvious, such as in the case of behavioural and psychological treatments for applications in which their value is in question.

The interventions may be so well established and accepted by the medical establishment, that there is now no interest in conducting further trials, such as withdrawal trials or surveillance studies. There is not even a Yellow Card reporting system to raise the alarm.

Any commitment to listen to patients and protect them from harm must extend to behavioural and psychological treatments. The merit and safety of these interventions is often backed up by poor science which escapes the greater scrutiny given to research on drugs and medical devices. Patients who are treated with psychological or behavioural interventions are often blamed if they don't get better and disbelieved if they report they have been harmed. They are also labelled anti-science if they point out obvious methodological flaws in the studies which rely on an embedded assumption that the interventions are both effective and safe when they are neither.

The Cumberledge review highlights the failings of regulators and drug and device makers, but huge failings in academic institutions and the medical establishment enabled and compounded these, and it is no different for behavioural and psychological interventions. It must stop.

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* From trial participant information sheets.

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Students

Matthew leads the field in 2020 student prize

One clear stand-out winner was approved by all four judges of this year's HealthWatch Student Prize: Matthew Choy, final year student at the University of Cambridge School of Clinical Medicine, took the £500 first prize.

Matthew, who is from South London, popped up at our virtual AGM on 20th October to receive his prize and have a chat with Nick Ross, before excusing himself to revise for an exam the next day. Matthew says he came early to sceptical thinking: "It was reading 'Trick or Treatment'* back in high school that tipped the balance for me to choose medicine instead of law, as I realized I could combine both my interests in healthcare and debating that way." He is a keen and competitive debater with a side interest in medico-legal matters, and hopes to pursue a career in academic surgery, ideally neurosciences.

A unique competition

Like past winners, Matthew expressed surprise that there is nothing else like the HealthWatch Student Prize competition. "A firm grasp of critiquing clinical trials and research is essential for any evidence-based doctor keeping up with recent developments – that's all doctors!" Responding to Nick's question on how much trial methodology featured in his curriculum, Matthew replied, "We do have extremely good public health teaching, a very good epidemiology course and quite advanced statistics, but on analysis of clinical trials there is not so much."

The annual HealthWatch Student Prize competition, which has categories for students of medicine, dentistry, nursing and allied healthcare professions, awards cash prizes to students who can prove their research skills. Entrants must evaluate four hypothetical research protocols and rank them in order of quality, with a short essay explaining their rationale. The winning students of 2020 were chosen from 80 entries overall. This year only 24 achieved the correct order, and all but two were from medical and dental students. Matthew was a clear stand-out winner, and three runners-up were very much ahead of the field.

Praise for runners-up and highly commended entries

One was Rahul Penumaka, a 5th year medic from Imperial College London, who is deeply interested in research and critiquing it for scientific rigour. He told Nick, "Imperial College has changed its curriculum, focuses more on critically appraising research, and what is done well and what poorly. It's a step in the right direction." The other runners-up were David Hewitt who graduated this year from Glasgow University and is now an academic FY1 doctor; and Edward Christopher, just graduated from Edinburgh University, who was last year's winner! Edward, celebrating qualifying as the first doctor in his family, has taken a HealthWatch Student Prize for the last three years. "I really enjoy it that much! I always discover and learn something new each time I participate. I thought this year the competition was particularly challenging and I definitely had to carefully consider my responses to each trial protocol. I am so glad and grateful to have been chosen as one of the winners this year!

There was also praise for three highly commended entries. Emily Lancastle (4th year, Edinburgh University Medical School) and Shafeer Rishad (5th year, University of Glasgow Medical School), both told us they had entered the competition to practice critical appraisal skills after being inspired by their experience of clinical research during their intercalated degrees. Matthew Kingham, a 2nd year medic at Kings College London, was intrigued to understand more about how research protocols work. "I will definitely be looking to enter again next year!" he told us.

The full list of 2020 and previous year's winners is here. We are grateful for the generosity of our sponsors, the Royal College of Physicians.

Mandy Payne
Editor, HealthWatch Newsletter

*by past HealthWatch Award winners, Edzard Ernst and Simon Singh

Nutrition

The trouble with nutrition research

Most of the "easy" questions in nutrition research were answered in the last century: how many calories do we need to maintain body weight and carry out exercise and work?; how much of the vitamins and minerals do we need to prevent deficiency disease?; how much protein do we need? (although this is still controversial).

Over the last 50 years, the emphasis has been on achieving "optimum nutrition" to promote the best possible state of health, rather than preventing deficiency diseases. Optimum health is a more difficult goal. We cannot really define it; it is certainly more than just the absence of disease. If our aim is to devise diets to promote healthy longevity then we are probably looking at studies lasting 70 or more years to test whether they work or not.

There are in fact a number of such long-term cohort studies, in which individuals are followed for many years. The oldest of these is the 1946 birth cohort study in the UK, in which everyone born in the second week of March 1946 has been, and still is being, followed. The Framingham study in USA has followed every resident of the town of Framingham, Massachussetts, since 1948.

It is difficult to draw any conclusions about how the diet in early life in the 1940s and 1950s may give us any information that is relevant to people born in the 21st century. Food was still rationed; the variety of fruits and vegetables available was minute compared with today; yogurt was known only to a few "food cranks", while nowadays there is a 5m long aisle of fermented milk products in every supermarket.

There has been a great deal of information from the Nurses' Health Study in USA, which is following some 85,000 nurses and their diet and health records. This is an observational study, so all we can say is that people who eat more of this, or less of that, are more or less at risk of developing whatever disease we are interested in. It won't tell us whether the food causes it, only that there's an association.

For example, people who eat relatively large amounts of processed and preserved meat products are more likely to develop gastric and colorectal cancer. But these people may also eat less fruit and vegetables, less whole grain cereal products, less oily fish, etc. They may also have other

behaviours that are, or may be, conducive to ill health, such as smoking, taking little exercise, being obese, etc.

At one time there was a list of some 600 factors associated with the development of atherosclerosis and coronary heart disease, one of which was religious observance! The presence of so many variables in normal life confounds our interpretation of the data. It muddies the water and makes it difficult to draw clear conclusions about what it is about a diet that makes it healthy, or not.

News editors love stories about the discovery of a single potentially harmful (or lifesaving or cancer-fighting) ingredient. (So, also, do the bodies who award grants for expensive long-term observational studies or intervention trials). Unfortunately, "Eat sensibly to live longer" or "a little of what you fancy does you good" will never make a news headline and will struggle for research funding.

Observational studies can lead to very misleading results. Here's an example. The generally accepted guidelines for a healthy diet are that fat should provide no more than 30% of calories, with saturated fat only 1/3 of total fat, and sugar no more than 10% of calories. The Seneca study, published in 1991, was a Europe-wide study of healthy elderly people aged 70 – 75, living in their own homes. The data from the town of Roskilde in Denmark showed that 5% received more than 50% of calories from fat, and 22% received more than half of their fat as saturated fats. 90% received more than 10% of calories from sugar, and 46% of the men were smokers. The problem here, of course, is that we know nothing at all about what was being eaten by those people who did not reach the age of 70.

In medical research, the randomised controlled trial (RCT) is the gold standard of proof. In nutrition research, RCTs are not feasible if we are interested in long-term health outcomes. No-one can be expected to follow a dietary intervention for many years, just to see the outcome, and we cannot control a group of people to receive a "placebo" diet. In any case, the pattern of foods available will change over the years.

So, the focus of much nutrition research is on relatively short-term interventions in which we measure the experimental diet's effect on levels of a biochemical or other biomarker that we believe to reflect the likelihood of developing the disease of interest. If we are interested in cancer, then we can measure how eating the food in question affects blood levels of biochemical markers indicating damage to DNA; if we are interested in heart disease then we can measure effects on blood cholesterol in plasma or arterial stiffness. These are indirect signs. Not proofs, just indications of an effect on the likelihood of developing disease.

Furthermore, because these trials are short-term, we cannot know whether or not the changes we see will persist, or whether the body will simply adapt to the changed diet in the longer term. The problem of how much protein we need to eat is a good example here. Relatively short-term experiments suggest a higher protein requirement than studies that continue for several weeks, because the body adapts its protein metabolism according to changes in intake. Protein turnover slows if we eat less protein, so we can get by on less.

There is one nutritional intervention for which there is excellent evidence of efficacy: folic acid supplements taken before conception are effective in preventing neural tube defects in the baby. Of course, this is a short-term experiment (9 – 10 months), with a clear outcome at term.

David Bender
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Last word

Secret remedies analysed – the BMA's war against quackery a century ago

In 1909 and 1912 the British Medical Association published two books, *Secret Remedies and What They Contain*, and *More Secret Remedies*. They were a response to the thousands of ads for medicines, mostly worthless but some harmful, that assailed the public from billboards, newspapers, magazines, buses, trams and railway stations.

The remedies covered almost everything conceivable — cure-alls like Burgess's ointment, nostrums for coughs and colds, consumption, headache, 'blood purifiers', kidney medicines, obesity, diabetes, skin disease, baldness, cancer, and epilepsy. There were remedies for teething in babies, ear disease, deafness, piles, rupture and inebriety. Most cost between 1s and 1s 1½d (*s* being shilling and *d* being pence) for the basic size. Some came in a range of sixes. The average weekly wage for a 55-hour week at the time was £1/10s for men and 12s for women, so they were not cheap. The books cost 1s each, cheaper than almost all the nostrums, and were crammed with information — each had 250 pages of small type. They clearly sold in huge quantities: my copy of the first volume was one of the seventy-second thousand. A tax, stamp duty, was chargeable on patent medicines, bringing the government of the day £50,000 in 1908. Advertisers had to print the stamp on the label and many used this to imply official endorsement.

Surprisingly, the books contain no treatments to boost, ahem, virility. Volume two has remedies for female problems couched in such vague terms that the reader can't know whether they were intended for painful periods, absence of periods, or were supposed abortifacients — which of course didn't work. These were expensive, Miss Lydia E Pinkham's ("Lily the Pink's") famous vegetable compound cost 4s 6d, a third of a week's wage. It consisted of 19.3% alcohol with a trace of bitter vegetable matter. Vin Urane Pesqui, old Bordeaux wine laced with uranium, was 8s a bottle and was claimed to cure diabetes.

The pills and liquids mostly contained everyday chemicals such as table salt, borax, bicarbonate, tartaric acid and sugar, with the addition of some colour and bitter flavouring. Ointments were mainly lard and olive oil.

A typical cure-all was Burgess's lion ointment. Priced at 1s 1½ pence for an ounce, it also came in five larger sizes. A circular wrapped round the box was headed, "Amputation avoided — the knife superseded." It continued, "E Burgess's Lion ointment and pills have deservedly become the popular remedies for curing all diseases of the Skin, Old Wounds, Ulcers, Abscesses (including tuberculosis, Tumours, Polypuses, Piles, Fistulas, Shingles, Venereal Sores, Whitlows, Broken Breasts, Bad Legs, Boils, Scurvy …" and so on. It ends, untruthfully, "they are vegetable preparations, and the ointment can be applied to the most tender skin." The vender claimed that all the advertised cures had been independently verified and references (testimonials) checked.

Mr Edward F Harrison, then a pharmaceutical and analytical chemist in private practice but who conducted analyses for the BMA, found he could make a similar ointment from 13% lead plaster (an obsolete medication consisting of lead oxide in lard), 20% beeswax, 11% resin,

12% olive oil and 40% pure lard. Estimated cost of ingredients about 10d per pound, five eighths of a penny a pot.

In contrast, Munyon's catarrh tablets and special catarrh cure, manufactured by a US homeopathic company with a London office, cost 1s 1d by post for 17 tablets. Customers were assured that they would cleanse and heal the afflicted part and should be used along with Munyon's catarrh cure, which would eradicate the disease from the system. The tablets varied in size ranging 6 grains (a grain was about 65 mg) of sodium bicarbonate, table salt, borax, phenol (carbolic acid) and a trace of gum. Estimated cost of making 460 pillules would have been one tenth of a penny.

In all, Harrison analysed some five hundred nostrums for the first volume and the same again for More Secret Remedies. They represented only a small proportion of what was on the market.

Most manufacturers are long forgotten but some have lasted till modern times, perhaps with different formulae: Owbridge's lung tonic, Veno's lightning cough cure, Beecham's cough pills (which claimed not to contain opium but did), and their ordinary pills, which contained a farthing's worth of aloes, ginger and powdered soap), Doan's kidney pills, Cuticura, and Zam-Buk.

Years later, while reading a biography of the forensic pathologist Bernard Spilsbury, I learned that the notorious murderer Dr Hawley Harvey Crippen had run the London branch of Munyon's homeopathic remedies. He had been sacked in 1899 for spending too much time managing his wife's stage career, and became manager of Drouet's Institution for the Deaf. Here he hired Ethel, a young typist, in 1900 and they were having an affair by 1905. He disposed of his wife, an aspiring music hall artist, and buried her body under the cellar floor, where the police missed it at first but found it on a later search. He attempted to flee to Canada with his mistress Ethel Le Neve disguised — not very successfully — as a young man.

They were spotted on board ship by the captain, who used new-fangled wireless telegraphy to notify the British authorities. He was arrested by a detective who sailed to Quebec on a faster boat. Dr Crippen was returned to Britain and hanged in 1910. Ethel was acquitted.

In 1946, Hugh Linstead, Labour MP for Putney, published a booklet, *Patent medicines*. It was two years on from the government White Paper proposing a national health service at an estimated annual cost of £170,000, substantially less that the nostrum makers were spending on press advertising. Linstead revealed that the anonymous *Secret Remedies* and *More Secret Remedies* had in fact been written by the analyst Edward Harrison. Harrison later became the first director of chemical warfare at the War Office.

Declaration of interest: the author's mother, 1909–67, swore by Elliman's embrocation and its bible, the *Elliman's REP (rubbing eases pain) book*. Being a good housewife she bought the horse formulation, which cost the same as the human version but was stronger. It was readily available from chemists. An internet search made during the 2020 lockdown showed that it was still listed by Amazon, who were out of stock. A 100ml bottle contains acetic acid and turpentine oil, is sold for the relief of muscular and rheumatic pain, and has had the same formula since 1847.

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Published by HealthWatch

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