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HealthWatch Newsletter

for Science and Integrity in Healthcare

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News

We are 30! Celebrating with live "Naughty Numbers" event with David Spiegelhalter

At HealthWatch's 30th birthday event, one of the world's leading statisticians explained the figures that will help, for good or ill, to shape our destiny. David Spiegelhalter, Chair of the Winton Centre for Risk and Evidence Communication, Centre for Mathematical Sciences, University of Cambridge, England, spoke on "Trustworthy communication of risk and evidence: the battle against naughty numbers in the news" at a celebratory in-person event at the Medical Society of London on Tuesday July 27th 2021.

The 80 tickets for the free in-person event were snapped up within days, but the event was also live-streamed for remote viewing—a further 40 registered to watch Professor Spiegelhalter's 25-minute talk. For those who missed it, a recording has been uploaded to the HealthWatch YouTube channel (subscribe now and check out our past events), or read a lightly edited transcript on our website.

For this special year in HealthWatch's history we have awarded two HealthWatch Awards. Professor Spiegelhalter is recognised for a lifetime achievement of clearly communicating facts about health risks to the public. At our AGM in October we will make a further presentation to his joint award winner, Christina Pagel, mathematician and professor of operational research at University College London, for her contribution to public understanding of issues during the Covid-19 pandemic.

HealthWatch investigation hits the pages of Private Eye

"Quack Team" was the title of a Private Eye report published 26th May, featuring HealthWatch trustee Les Rose's investigations into the Charity Commission's inaction over the questionable and possibly dangerous practices of some registered health charities. An earlier issue of the satirical news magazine had reported on a heavy-handed nine-month Charity Commission investigation into a small charity that exposes neglect and abuse in care homes. So the Private Eye reporter was particularly keen to note that the Commission has, by contrast, "for years batted away complaints about charities promoting lucrative unproven 'remedies' for health conditions, including cancer."

The Eye reports that HealthWatch has identified dozens of alternative medicine charities making misleading health claims, and that detailed complaints have been filed on 16 of them. Finally, we have an outcome on one: the Charity Commission says that it has at last decided to remove the Gerson Support Group—whose "cancer treatment" includes an extreme diet and massive doses of vitamins plus coffee enemas—from its register of charities, 21 months after Les Rose's complaint. "Strangely, in October 2019 the Commission's CEO and legal head both stated in public that they did not have the power to remove charities. Confused? So am I," commented Les. STOP PRESS: At the time of writing, despite their assurances, the Charity Commission has still not removed the Gerson Support Group's charity registration. The Gerson Support Group still runs a private Facebook group and private website.

HealthWatch Student Prize

The 2021 HealthWatch Student Prize for assessment of clinical trial protocols has closed for another year with some excellent entries. You can read about this year's winners now on the website, and we are delighted to have had a good spread of awards across students of nursing and midwifery as well as medicine.

Successful contribution to report on private fertility treatments

In the spring of 2020 HealthWatch contributed to a public consultation by the Competition and Markets Authority (CMA) on private fertility clinics. In June 2021 the CMA published its report, and the Advertising Standards Authority, in consultation with the CMA, has issued an Enforcement Notice to clinics, here. Dr Roger Fisken, who co-ordinates HealthWatch's consultation responses, was pleased to report that both documents contain comments and advice that are in line with what HealthWatch had contributed.

The CMA has also produced a written report for patients, entitled: "Fertility treatment: A guide to your consumer rights" and produced a two-minute YouTube video with brief advice for prospective parents considering private fertility treatments. "On the whole I think the CMA has taken a useful step with these reports,

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though a lot remains to be done. I think that our contribution to this issue has definitely been worthwhile," said Dr Fisken.

Forthcoming consultation: Research Reproducibility and Integrity

Next on the consultation agenda—the science and technology select committee is having an enquiry on research reproducibility and integrity: https://committees.parliament.uk/work/1433/reproducibility-and-research-integrity/. Deadline for submission 30th September. HealthWatch's response is in preparation, if you would like to contribute please write with your suggestions to enquiries@healthwatch-uk.org.

Honour for Nick Ross, HealthWatch's president

Nick Ross, president and founder of HealthWatch has been awarded a CBE in this year's Queen's Birthday Honours in recognition of his lifetime's work in broadcasting, charity and crime prevention. The former CrimeWatch presenter dedicated the honour to the crime science institute founded in memory of his late co-presenter Jill Dando, who was murdered in 1999. Ross co-founded HealthWatch in 1988 with a small group of journalists and health professionals, including the breast cancer surgeon Michael Baum. As well as being a household name for his broadcasting, Nick Ross is closely involved with a range of initiatives in medical ethics, and has played a leading role in social action campaigns, most notably crime prevention, road safety and fire safety.

Lasting allure of "phoney medicine"

A Financial Times article by a past HealthWatch Award winner is now free online and will interest our readers. In "Why phoney medicine has such lasting allure", our 2012 winner, Tim Harford of BBC Radio 4's "More or Less", talks about treatments ranging from the speculative to "pure quackery". He explores the regulator's tightrope between safety and over-caution, and asks why demand continues to be so strong for products that fail to deliver.

Health research—fraudulent until proven otherwise?

How much is public health impacted by fake research and the perverse incentives to produce it? Significantly it seems, and the evidence was laid out in a recent webinar by experts at the London School of Hygiene and Tropical Medicine. The one-hour 15 minute recording of this shocking exposé about invented data and "zombie trials" is now on the Cochrane YouTube channel, but if you haven't time to watch there is a detailed report in a recent BMJ Opinion penned by our 2004 HealthWatch Award winner, Richard Smith. Read and despair.

Step up, Jack Lawrence, London medical student's investigation triggers retraction

Concerns raised by an evidence-spotting medical student have played a part in the retraction of a major study into a drug being controversially promoted for treating Covid-19. Jack Lawrence, doing a masters degree, found his university assignment turned into a comprehensive investigation into an apparent scientific fraud. The study in question suggested that the anti-parasitic drug Ivermectin is effective against the virus, but Jack suspected some of the study text might have been plagiarized, and had concerns over the data. His letters to the study's lead author went unanswered, and now the study has been withdrawn due to "ethical concerns", says The Guardian.

Expressions of concern campaign

A new international campaign encourages evidence enthusiasts to flag examples of poor science for a $1000 prize. Restoring Invisible or Abandoned Trials (RIAT) is an initiative of the University of Baltimore, Maryland, USA to tackle bias in the health research literature resulting from misreporting or nonreporting of clinical trials. They want volunteers to write "Expressions of concern" letters to publicly register any serious concerns about clinical trials—and the RIAT experts are happy to lend their support. It is an ideal exercise for students, post-docs and trainee researchers, and the results of the letters will be tracked on the RIAT website. Check out the details here and get writing!

Covid conspiracy theories—a new guide

The charity Sense About Science has developed a short guide, Talking about Covid Conspiracy. It results from a project led by Peter Knight at the University of Manchester, under UK Research and Innovation Covid-19 funding, which included workshops with people who were either inclined to believe conspiracy theories or had been involved in difficult discussions about them. The new guide delves into how people prefer to be engaged during these conversations and offers suggestions at how to have better, more constructive conversations on the topic. The seven-page pdf is free to download.

WEBINAR CATCHUPS

Defamation: how-to and how-not-to

This issue's prize for the most worthwhile hour spent webinar-watching must go to the Good Law Project who ran a compelling session on how to speak truth to power without putting your life savings on the line. Their 11th May panel "Defamation: a guide for activists" covered how to protect yourself when publishing articles or social media posts that might leave you vulnerable to the threat of libel proceedings, and untangled the complexity of defences to defamation—in particular the "public interest defence"—and how to make them work in your favour. The full recording is available on YouTube and is accompanied by a free seven-page downloadable pdf guide "Defamation: the basics".

Exposing a scientific scandal

In this YouTube recording, Glasgow psychiatrist Anthony Pelosi describes his battle to expose a historical science scandal: the psychologist Hans Eysenck famously purported to show that certain personality types were linked with a higher risk of cancer and heart disease, but scholars later identified errors and suspected data manipulation in his work, and subsequent research has not been able to replicate the results. The one hour and 40 minute recording of "Personality and fatal diseases; exposing a scientific scandal of Hans Eysenck" has been made available by the early-career researcher-led RIOT Science Club.

Ethics

Medicine neglects women's needs, but alternative medicine is not the answer

By Arianne Shahvisi

In 2008, Hollywood actor Gwyneth Paltrow launched her lifestyle company, Goop, claiming she "wanted it to be a word that means nothing and could mean anything." Over the last decade, the claims and recommendations made by the company have been widely criticized. Goop claimed that underwire bras cause breast cancer, suggested that women ought to be increasing their sexual energy using vagina eggs and vaginal steaming, and recommended the use of coffee enemas. Experts have shown these recommendations to be spurious and sometimes dangerous.

Around the same time that I heard about *Goop*, I was becoming more interested in feminism as an area of research. In speaking to other women about their experiences of gender inequality, an issue that came up time and again is the way in which medicine neglects women's needs. I met several women who were dabbling in alternative remedies only marginally less ridiculous than those espoused by Paltrow's site. These women were not unintelligent or uncritical. Their serious long-term health issues were not being addressed by mainstream medicine, and they were desperately casting around for other solutions.

It occurred to me that medicine's poor treatment of women might be pushing them towards alternative remedies that are often expensive or dangerous, and generally just don't work. I started a research project to investigate women's relationship to conventional medicine and alternative medicine.

Women and conventional medicine

One major reason that medicine often doesn't work well for women is that female participants have long been excluded within clinical trials. While things are gradually improving, we still have poor knowledge of the way diseases present and progress in females, even though we know that there are sex differences in how certain conditions appear clinically, e.g., anaemia, osteoporosis, and cardiovascular disease. This means that women are being given "standard" medical diagnostic tests and treatments which were designed with men in mind, and which are sometimes sub-optimal or unsafe for women.

Other factors relate to the way that women are treated by clinicians. One of the most important experiences that women report is not being believed when they describe their ailments. Studies show that women's pain reports are often discredited, or attributed to mental health issues. Women are 13-25% less likely to receive painkillers for abdominal pain even when they have the same pain scores as men, and typically wait longer to receive pain medication. Further, women who are admitted to hospital with irritable bowel syndrome are more likely to be offered sedatives and lifestyle advice while male patients with the same symptoms are offered X-ray imaging of the digestive system.

Women are also less likely to receive appropriate treatment for heart attacks, which means that they are more likely to die once a heart attack is underway. They're also more likely to die in hospital from septic shock, and critically-ill older women are less likely than men to be admitted to intensive care units and receive life-saving treatments, again leading to an increased risk of death. Almost all of these worrying trends are also observed for people of colour, and women of colour fare worst of all.

Given these shortcomings, it's fairly unsurprising that "medically unexplained disorders" are more common in women, who may be further harmed by the side effects of endless tests and investigations while doctors try, and invariably fail, to figure out what is going on.

Women and alternative medicine

"Alternative medicine" means all therapies that don't have any proven benefits beyond the placebo effect, and generally do not have any *plausible* explanation for how they're supposed to work. Some examples include homeopathy, chiropractic, energy medicine, naturopathic medicine, and faith healing. Studies across populations in high-income settings show that the typical user of alternative medicine is a woman, who is more highly educated, relatively affluent, and often suffering from a long-term health condition.

Those who use alternative medicine say they value it because it is "natural," has few or no side effects, and it offers a feeling of greater control over their health. Patients are usually much happier with their alternative medicine practitioners than with their GP, and describe their appointments as feeling friendlier, more personal, less rushed, and less authoritative. It is easy to see why alternative medicine can be an attractive possibility for women whose health needs are not being met within conventional medicine.

Yet alternative medicine raises ethical issues. In order for any kind of medicine to be ethically acceptable, practitioners must make sure they seek informed consent from patients. This means explaining the proposed treatment to the patient to make sure they understand how it works and why it's been chosen, and then asking them to agree to the treatment. My first worry about alternative medicine is that there are *no* acceptable explanations that can be offered to patients, so *informed* consent becomes impossible. Patients must therefore trust alternative medicine practitioners, even though they are not able to offer evidence or explanations. That kind of trust can be easily exploited. My other worry is that, beyond the placebo effect, alternative medicine doesn't work!

What should happen going forward?

The bottom line then is that alternative medicine is, like Paltrow's *Goop*, something "that means nothing and could mean anything"—it doesn't work, and can easily exploit people. It's the wrong answer to a very important question: what should we do when medicine lets certain groups down? I think the clue can be found in the reasons people give for using alternative medicine—they get more time with a practitioner, and they feel listened to. We need to make more time in medicine, and everyone will save time in the long run. It's been shown that longer consultations lead to: a greater likelihood of taking a thorough medical history and providing the right clinical examinations, a lower prescribing rate, a greater likelihood of offering advice about preventative healthcare, and fewer follow-up consultations.

But we also need to think more broadly about the way in which we as a society fail to listen to and believe women, which is a problem that also comes up in another context, that of sexual harassment and assault. Women deserve better, and it is up to clinicians and medical researchers to step up, while it's up to the rest of us to start normalizing the practice of believing women when they say they're hurting.

Arianne Shahvisi, senior lecturer in ethics at the Brighton and Sussex Medical School

Arianne Shahvisi is a philosopher whose work explores gender, race, and migration. She is writing a book on the philosophy of social justice, which will be published by Penguin in 2022. She tweets at: @ArianneShahvisi

This essay was first published in the Brighton and Sussex Medical School Magazine Pulse https://www.bsms.ac.uk/_pdf/about/news/pulse/bsms-mag-spring-2019-final-v2-update.pdf and is based on: Shahvisi A. Medicine is patriarchal, but alternative medicine is not the answer. Journal of bioethical inquiry 2018:1-14. https://link.springer.com/article/10.1007/s11673-018-9890-5

Consumer protection

Bioresonance Q&A: the MHRA answers our questions

By Les Rose and Mandy Payne

At HealthWatch we have for some time been concerned that the marketers of so-called "bioresonance devices" persist in making therapeutic and diagnostic claims in the absence of any robust evidence. A recent ruling by the Advertising Standards Authority reported a device marketed as "the Resonator" claiming to cure infections including Covid-19, treat long Covid, and even replace vaccines. The ASA quoted text from its website including: "viruses are not alive, so they cannot be killed. They have to be destroyed, and the only safe way to destroy a virus is to shake it to pieces, which is what the Resonator does … Yes, it can replace vaccines as it will—if used, destroys any virus, parasite, or bad bacteria that invade the body."

Les Rose, HealthWatch trustee who has worked doggedly to highlight and fight misleading claims by marketers of such devices, was surprised to see that one of the complaints had been brought by the Medicines & Healthcare products Regulatory Authority (MHRA). In fact, the MHRA is itself the statutory regulator for medical devices, so why was matter referred to the ASA, an independent body whose code is voluntary, instead of using its own regulatory powers? In this case, the ASA upheld the complaints and asked for the claims to be removed. But at the time of writing, six weeks after the ruling, they remain on the company's website.

So, what is going on, when a government regulator's action is to refer to an independent regulator which has no enforcement powers? HealthWatch asked the MHRA directly. In the following text we adapt their written answers in the form of a Q&A.

HealthWatch asked: Can you provide a statement please, answering these questions?

1. Why was the ASA asked to deal with this matter?
2. What constrains the MHRA from taking regulatory action?
3. The ASA says that medical claims are not permitted for devices which are unregistered or not CE marked. Can you explain please why the MHRA did not take action on this basis?
4. What is the regulatory status of so-called `bioresonance' devices, of which there are many on the UK market? To our knowledge all make unsubstantiated claims.
5. Does the MHRA propose to take any further action on this case, in view of the advertiser's refusal to comply?

MHRA replied:

"There is not a defined regulatory status of bio resonance products. The regulatory status is defined by the intended purpose and usage claims assigned to the product by its legal manufacturer when first placed onto the market. If a bio resonance machine placed on the market is making specific medical claims that bring it within the definition of a medical device (as defined in the Medical Device Regulations 2002), that device would fall under the remit of the MHRA for our review and investigation. Each product is reviewed on a case by case basis.

"The MHRA does not directly regulate the advertising of medical devices, as there are no specific provisions in the Medical Device Regulations 2002 (as amended) in relation to the advertising or promotion of medical devices. As such, referrals received by MHRA which specifically relate to advertising are passed to the ASA, as the body responsible for regulating advertising in the UK.
We are not able to comment on individual cases due to confidentiality restrictions however we continue to monitor allegations of non-compliance."

We were grateful for the MHRA's prompt response to our questions, but their statement raised new ones. So we pressed for clarification, and the answers are reported below.

HealthWatch's request for clarification

1. You say: "There is not a defined regulatory status of bio resonance products. The regulatory status is defined by the intended purpose and usage claims assigned to the product by its legal manufacturer when first placed onto the market." So, if a manufacturer placed a product on the market with non-medical intended purpose, and then started promoting it and selling it using medical claims that bring it within the definition of a medical device (as per MDR2002), they could thereby escape coming within MHRA regulation. Is that a correct interpretation? If so, does MHRA agree that this presents a danger to the public? How might it be addressed? Note that provision 2(1) of the MDRs 2002 state that intended purpose includes labelling, the instructions for use and/or the promotional materials. It is not confined to when the product was first placed on the market. We also pointed out that the Medical Device Regulations (MDRs) state that the intended purpose is defined by what the manufacturer says about the product. If the purpose is medical diagnosis and/or treatment, the product is therefore a medical device. The MDRs then say that a medical device must have a CE marking. What action can the MHRA take against devices that make medical claims but do not have a CE marking?
2. You say: "If a bioresonance machine placed on the market is making specific medical claims that bring it within the definition of a medical device (as defined in the Medical Device Regulations 2002), that device would fall under the remit of the MHRA for our review and investigation. Each product is reviewed on a case by case basis." What are the possible outcomes of "review and investigation"? If the device is found to be unlawful, how is non-compliance penalised? Is there a publicly available online source that lists findings of these investigations and whether a penalty was enforced (as there is for the ASA—which acts as a deterrent for

the non-compliant behaviour)? If there is no such source, what is the reason for this?

3. You say: "We are not able to comment on individual cases due to confidentiality restrictions however we continue to monitor allegations of non-compliance." Please could you expand on the nature of the confidentiality restrictions—what information does this apply to, and why are they not lifted on conclusion of investigation (as they would be for ASA or a legal case)? We understand that confidentiality might apply during an investigation, but once concluded there is a clear public interest to know the outcome. What does "continue to monitor allegations of non-compliance" mean? What are the possible outcomes from such monitoring?

MHRA's response

"It would not be correct to state that a manufacturer could avoid regulation by making medical claims only once they've placed their product on the market. If a manufacturer subsequently makes medical claims for a product which has already been placed on the market and those claims bring the product within the definition of a medical device then it will be regulated as such. If the manufacturer wishes to continue making such claims, they will have to undergo the relevant conformity assessment.

"Unless exempt, medical devices which do not display the appropriate conformity marking (CE / UKCA / CE UKNI) may be subject to enforcement action. For example, we may issue a Compliance Notice under the Medicines and Medical Devices Act 2021 requiring a manufacturer to cease sale and supply until such time that they have undergone the relevant conformity assessment and their device meets the requirements of the Medical Device Regulations.

"Every allegation of non-compliance is reviewed by the Devices Compliance team and is subject to a risk assessment. This helps us identify and prioritise referrals, ensuring any enforcement action is proportionate to the level of risk posed by the non-compliance and balanced by the resources we have available. Where referrals are prioritised, they are assigned to a member of the team for further investigation and enforcement action, where necessary.

"We have a range of enforcement powers at our disposal which are set out in the Medicines and Medical Devices Act 2021. A person commits an offence if they breach an enforcement notice and may be liable to imprisonment, to a fine or to both.

"We also work with a range of stakeholders including Border Force, Trading Standards, online trading platforms such as eBay and Amazon and other UK and international regulators to help us monitor the market and to take the necessary enforcement action to ensure medical devices in the UK are safe and perform as intended. As well as the enforcement notices referred to above, we can take other action such as seizing consignments of non-compliant devices and removing websites or product listings.

"The confidentiality restrictions refer to Section 237 of the Enterprise Act 2002 which prevents the disclosure of information about the affairs of an individual or business if that information comes to the MHRA in connection with the exercise of any function it has or by virtue of the Devices Regulations. We do not currently publish the outcomes of Compliance investigations, however, this is something we are looking to do in the future.

"We continue to monitor allegations of non-compliance by regularly reviewing the information we receive to help us identify any trends or emerging issues. This might lead to wider market surveillance work or targeted action within a particular sector or device-type. We can re-visit risk assessments and consider whether there has been any change to the risk profile that might warrant further investigation."

HealthWatch's verdict

Given that the confidentiality restrictions deny us access to decisions made on individual devices or even device categories, and that the devices continue their non-compliant activities unabated, we speculate that the outcome of risk assessments of bioresonance machines place them at a low priority for enforcement given budgetary limitations. Should these risk assessments be re-visited? We also have concerns that there is no transparency in a process that is publicly funded and run in the public interest.

Any members who wish to report non-CE marked devices to the MHRA should write to Devices.Compliance@mhra.gov.uk. Readers of the HealthWatch Newsletter can share their views with us via the newsletter editor's contact form, or by tweeting a link to this article (you can tag @healthwatchuk and @MHRAgovuk).

Les Rose, HealthWatch trustee and Clinical Science Consultant (retired)
Mandy Payne, HealthWatch Newsletter Editor

Research Integrity

The Declaration to Improve Health Research—2 years on

by Stephen Bradley

The work of patient activists, campaigning clinicians and researchers in the field of meta-research ('research on research'), has been crucial in exposing the crises in medical research. Achievements like mandatory registration of clinical trials and the increasing popularity of open science practices show that change is possible, but we still have a long way to go in making research more transparent and rewarding academics for genuine discovery rather than obtaining 'positive' or newsworthy results.

Without promoting clear and achievable remedies to these problems our mediocre status quo will persist. Although many fantastic initiatives are having a real impact on improving research culture we cannot rely on these efforts alone. We should not tolerate a situation in which the basic documentation that is necessary to scrutinise publically funded research is frequently unavailable and there is still no straightforward way to find out about researchers' conflicts of interest. Whilst there are basic measures that could improve this situation we must surely demand their implementation.

The Declaration

Just over two years ago some of the participants at the Evidence Based Medicine Live Conference came together to advocate for this change. We believe that the systemic nature of the problems in research along with the scale of the resulting harms represents a challenge which the entire public, not just motivated researchers, have a stake in resolving.

Through our Declaration we proposed three actions that warrant immediate implementation:

- Mandatory registration of interests for all health researchers;
- That journals allow researchers to publish using *Registered Reports*, whereby peer reviewers make decisions based on study methods rather than the results;
- That all publicly funded research is pre-registered and published on a research registry along with basic documentation such as protocols.

These measures are not intended to be a 'gold standard', but represent basic minimum standards patients and taxpayers are entitled to expect, right now, from research.

Achievements

HealthWatch was one of our first signatories, an important early milestone for the campaign and we remain extremely grateful for the support and suggestions we have received from many HealthWatch members. Over 100 other individuals and organisations worldwide have since also signed the Declaration. Maintaining an international perspective is important to us and signatories have translated the Declaration into Arabic, German and Portuguese. We are grateful for support from organisations including the German EBM Network and the Oxford-Brazil EBM Alliance along with collaboration with the US Based Centre for Open Science.

We have authored several articles, including in BMJ and The Conversation. Our review paper, which was conceived both as a primer on the principal problems in research and to explain how the aims of the Declaration could help address these, has been accessed over 2,000 times and has been cited by other important work in the area.

Signatories have presented the Declaration at the REWARD | EQUATOR Conference in Berlin and the Wellcome Trust's Reproducibility, Replicability and Trust in Science conference. Our twitter account @ImproveHealthR has almost 600 followers and our website ImproveHealthResearch.com went live last October. In April this year we collaborated with the Centre for Open Science for our first 'hack-a-thon', in which participants emailed the editors of dozens of the major medical journals and asked them to consider adopting the registered reports format.

A mountain to climb

Our vision for a basic charter that succeeds in uniting patients, researchers and clinicians in a high-profile campaign remains unachieved. Few academics and even fewer members of the public will even have heard of the Declaration. The unprecedented public engagement with science during the pandemic has helped us to explain the problems and the need for change, but the polarisation of the past 18 months has also prompted reflection on the challenge of pressing for urgently needed reform without engendering further division. We have also not yet managed to get our voice heard in the mainstream media.

Where next?

In the next two years I think our strategy should prioritise:

- Reaching more of the public and patients, including through the mainstream press;
- Engaging directly with policy makers and funders;
- Establishing new collaborations with other campaigning organisations, and developing existing collaborations such as those we have with HealthWatch and the Centre for Open Science.

Critics

The responses we have received to the Declaration have been overwhelmingly positive, but we are very grateful to those who have taken the time to explain why they disagree with us. The following are condensed summaries of many responses received and are inspired by no specific individuals. The nuance of the many discussions that we have had cannot be conveyed in a concise way and these composites are necessarily somewhat caricatured.

"What's the problem?"

Surprisingly many academics seem largely unware of the problems, or feel that talk of a 'replication crisis' is over-dramatic. Sometimes we hear that "all those problems have been fixed now", invoking for example, clinical trial registration, although this does little to prevent abuses like 'outcome switching' and neglects the fact that clinical trials are only one type of health research. We sometimes receive comments that misunderstand our position, for example, that that we seek to prohibit exploratory research or that we are calling for data to be shared that would lead to violation of patient confidentiality.

"It's too little, too much, or not what I would have chosen"

It is certainly true that even if our demands were implemented in full, many problems would remain. For example, researchers could still commit outright fraud. However, some have commented that what we propose would be too disruptive, while others have argued that what we propose is both asking for too much *and* that our proposals would not improve matters enough. Our focus on just three demands required difficult decisions and a few have been disappointed that we did not include other objectives. In responding to these concerns we have tried to express our goal of raising basic standards across the research system. This necessitates embracing 'better', even though it is a long way short of 'ideal'. When considering whether to support us the most pertinent question is not "*are these three measures what I would have chosen?*" but "*could these measures improve the matters, compared to what we have now?"*

"It's not fair to change how we do things because of a few bad apples"

This perspective sometimes comes from institutions and tends to emphasise the responsibility for (other) individuals to improve standards. This is informed by a sense that problems in science are predominantly down to wilfully dishonest and negligent practices. Poor research practices are clearly an important problem and warrant a maintained focus on improving education and culture. But if we ignore systemic problems that drive such failings, such as the career imperatives for academics to obtain publishable (i.e., 'positive') results, these dysfunctional incentives will continue to shape behaviours in insidious ways.

A related concern is that our proposals would burden honest researchers with 'red tape'. Actually, declaring interests and submitting documentation through centralised portals should reduce reporting burdens, while the experience from registered reports suggests this format can be readily incorporated into journals' workflows.

"These are not new ideas"

We couldn't agree more! This objection seems to reflect academia's pre-occupation with proprietary innovation and novelty. The problems in research have been discussed for decades. It seems a better bet to focus on implementing well-understood solutions, rather than holding out for the hope that

some ingenuous and painless solution to all these problems is just around the corner.

"I don't want to look foolish by putting my name to a campaign that might not succeed"

Given just how entrenched our problems are, idealism about trying to change things for the better can easily look like naivety, particularly in the cynical world of academia. Many of us in research are by nature contemplative and relish nuance. Calling for specific change can feel unseemly or a kind of activism. I share this discomfort, but also believe that any negligible reputational embarrassment is easily justified by even a remote possibility of helping to improve our deeply flawed research system.

We need your help

If you would like to find out more about the declaration visit www.improvehealthresearch.com. If you think that adopting the measures outlined in the declaration could improve research then please:

- consider signing the declaration
- tell your friends and tweet @ImproveHealthR
- to get more involved, please get in touch
- Or, If you disagree, we would still love to hear from you

Stephen Bradley is a GP and PhD student at the University of Leeds. Email: medsbra@leeds.ac.uk

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Conflicting Interests: I am on the steering group for the declaration to Improve Health Research, I receive funding for my PhD research from Cancer Research UK. I am a member of the executive committee of the Fabian Society which is a think tank linked to the UK Labour Party. A full disclosure of interests is available via the University of Leeds website

Book review

Transparency, Power and Influence in the Pharmaceutical Industry: Policy Gain or Confidence Game?

by Till Bruckner

"Transparency, Power and Influence in the Pharmaceutical Industry: Policy Gain or Confidence Game?", edited by By Katherine Fierlbeck, Janice Graham and Matthew Herder, was published 4 July 2021 by University of Toronto Press. RRP £23.59, paperback, 304 pages.

Public and academic discussions around transparency tend to take on Manichean overtones. Transparency, like democracy or participation, is often conceived as an intrinsic good worth pursuing for its own sake, and more transparency, more democracy, and more participation are always better. The edited volume "Transparency, Power and the Influence of the Pharmaceutical Industry" provides a welcome departure from this simplistic framing.

Katherine Fierlbeck throws down the gauntlet in the first chapter. After providing a detailed overview of the different kinds of transparency applicable to pharmaceuticals, including a typology of clinical trial data, she warns that transparency does not always translate into real-life benefits. For example, making data accessible does not automatically result in more data being accessed, and "too much transparency" can drive decision-making processes underground.

The following chapters describe the evolution over time of transparency policies of the European Medicines Agency, the US Food and Drug Administration, and Health Canada. The key takeaway is that transparency victories are not won in one-off epic battles. Instead, past transparency gains have been achieved by diverse coalitions of actors persistently pushing for more access to data and information, which often required deploying a broad variety of tactics and engaging with arcane policy making processes over many years.

Better patient care?

But does more and better information automatically lead to better patient care? Nav Persaud persuasively argues that this is not always the case, citing Tamiflu and three other examples in which shifts in the evidence base failed to produce shifts in public procurement and clinical practice. "Producers of clinical practice guidelines seem largely unmoved by new information," he concludes.

Three subsequent chapters explore the interplay between the pharma industry and regulators in greater detail. Joel Lexchin warns that in Canada, the state has in some instances "voluntarily turned over de facto regulatory power to industry," while Marc-Andre Gagnon provides a detailed examination of how pharma influences not only regulators, but the framing of public and expert discussions about medicine and medicines. Kanksha Mahadevia Ghimire and Trudo Lemmens tackle the thorny issue of striking the right balance between data transparency and patient confidentiality in rare diseases, concluding that "the fear of privacy breach is often overstated" and should be balanced against the potential benefits to patients of greater transparency.

Tom Jefferson's chapter on the European registration of the flu vaccine Pandemrix raises issues that, with the benefit of Covid hindsight, many in the field probably wish they had paid greater attention to years ago. These include the assumption by European governments of all legal and financial liabilities for problems with pandemic vaccines, and concerns about the different safety profiles of vaccine batches produced at different manufacturing sites.

A more politically savvy approach

Rounding off the volume on a positive note, Rita Banzi discusses opportunities for increasing data sharing, based on her experience with the Mario Negri Institute, and the editors draw on all contributions to plead for a more politically savvy approach to advocating for greater transparency in the pharmaceutical sector.

Taken as a whole, the volume has two major limitations. First, it does not unpack the concept of the "public interest," by default equating it with patients' interests. This narrow public health perspective obscures the fact that policy makers typically pursue a broader conception of the public interest, occasionally trading off patient interests against maximising domestic pharma companies' contributions to employment, tax revenue, and strategically important economic sectors.

Second, the book focuses exclusively on Europe and North America (a sin of which this reviewer has also been guilty). As the recent development, production and export of Covid

vaccines by Russia, India and China have shown, the quality and transparency of regulation in these countries is now a key factor shaping global health outcomes. Arguably, raising regulatory and industry standards in the Global South has become a more urgent priority than pursuing ever greater transparency within OECD countries.

Despite these caveats, this volume is very refreshing in its rejection of simplistic framings and its deliberate embrace of a political economy analysis approach. Detailed accounts of protracted legal, technical and bureaucratic struggles with, and within, regulatory agencies are hardly airport bestseller material. However, the accounts contained within the book provide an extremely valuable resource for advocates by highlighting possible pathways, opportunities and limitations for changing medical regulation—and hopefully medical practice—for the better.

Till Bruckner, TranspariMED

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